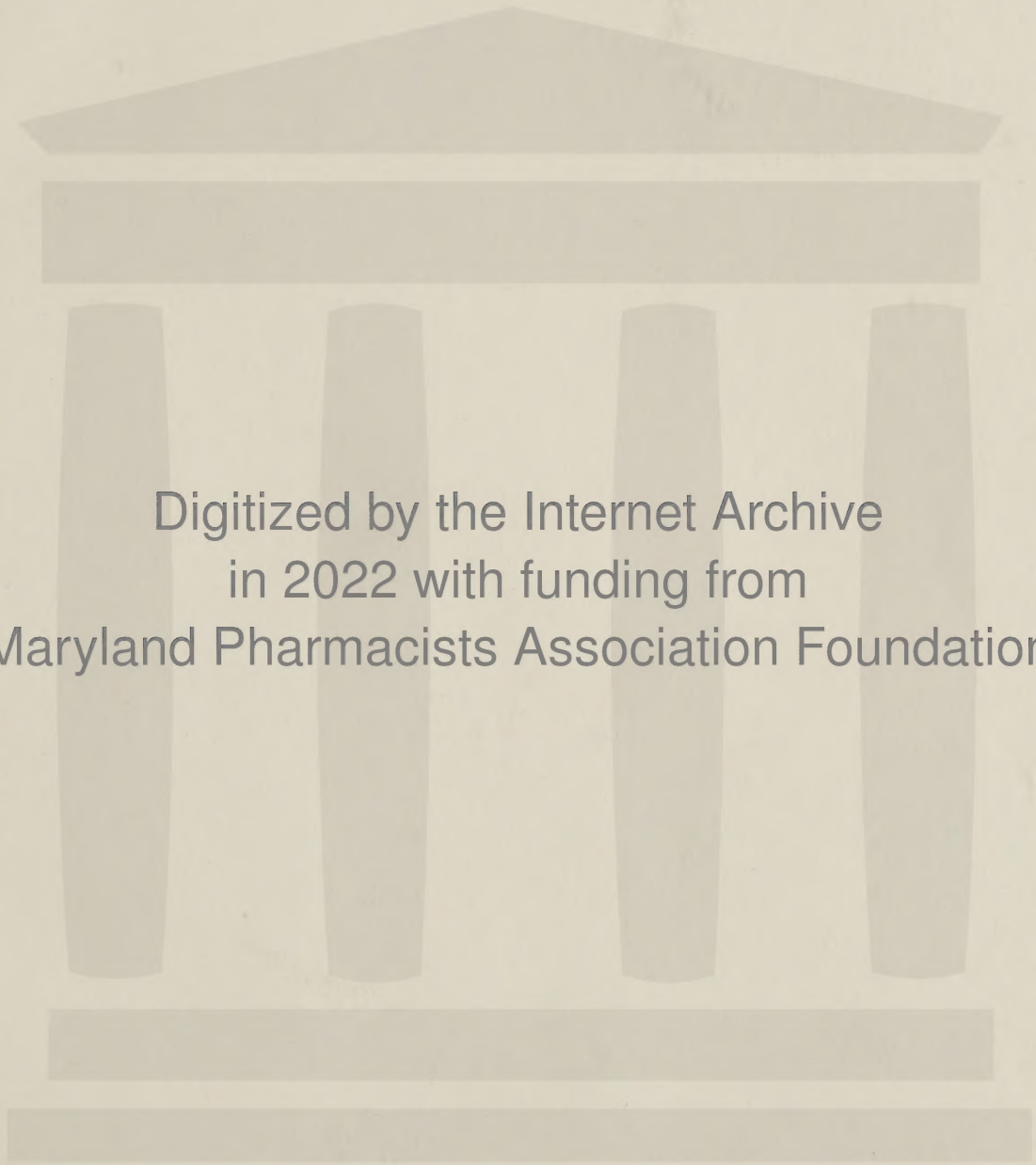

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January, 1984
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NO. 1

MPhA Comprehensive Attitude Survey
— Dean Leavitt, Stuart Speedie, Alex Yung

Counseling Consumers on Dry Skin
— Thomas Gossel, Richard Wuest

1984 Tax Dates

THE MARYLAND PHARMACIST

650 WEST LOMBARD STREET
BALTIMORE MARYLAND 21201
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JANUARY, 1984 VOL. 60 NO. 1

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On a recent T.V. news program, I listened as the commentator described the Marine Corps motto, *Semper Fidelis,* as *always there.* It was obvious he was not an ex-Marine or a pharmacist. The term *Semper Fidelis* means *always faithful.* This made me think back over more years than I care to count about another term used to describe the Marines—*Spirit de Corps,* the Spirit which lives in all Marines and brings them together in times of turmoil and trouble.

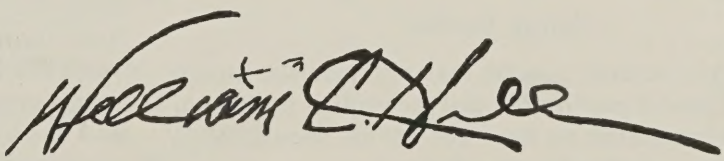
As pharmacists we must always be faithful to the grand old profession of Pharmacy. We must have that Spirit de Corps to move our profession ever onward, ever forward, making it ever better and everlasting. Any profession to succeed needs a professional organization; any professional organization to succeed needs the support of all its professionals.

As Pharmacists we will not see fancy posters asking for a "few good men and women" to join our ranks. It is up to us to urge the new young pharmacy professionals to march with us, to share with us their ideas, their thoughts and their expertise to help strengthen the profession of Pharmacy.

I know many of you are busy; I know many of you cannot always attend meetings. However, you can write to us and give us your thoughts. We need to know how you feel about a wide range of pharmacy problems.

Become a vital part of Pharmacy in Maryland. Become a member of the Maryland Pharmaceutical Association. Today.

Remember, our strength can become your strength and your strength is our way to move forward in pharmacy in our great State of Maryland.



William C. Hill, P.D.

PRESIDENT

The MPhA Comprehensive Pharmacist Attitude Survey of 1981

by Leavitt, D. E., Speedie, S. and Yung, Alex

In 1981, the Maryland Pharmaceutical Association sent out to the state's pharmacists a comprehensive attitude survey. The school was asked to compile the results. The compilation was supervised by Dr. Stuart Speedie and a lot of the tabulation work was completed by Alex Yung, a second year student in the B.S. program.

A couple of days before leaving on a sabbatical leave, Dr. Speedie dropped the surveys and compilation in my office with the intimation that there ought to be a couple of publications in reporting the survey. Dave Banta has asked that I concentrate on the Professional Issues portion of the survey and if deemed appropriate, at a later date, discuss the results of the other portions of the survey.

Seven hundred thirty-seven (737) surveys were returned and although between 50 and 57 percent of the respondents did not answer questions in the Professional Issues section, the 320+ respondents that did, should give an adequate indication of the professional feeling toward some of today's issues. Please note that the numbers indicated are percentages of those responding to the question (350+) and does not include those who did not answer the question. A more complete compilation of the answers is included in the appendix.

Patient Profiles

Seventy percent agreed that pharmacists should maintain patient profiles but that the profiles should not (60%) be mandated by law. The MPhA should (65%) support the use of patient profiles.

Continuing Education

Pharmacists should (76%) attend continuing education programs but it should not (48%) be mandated by law. The MPhA should (87%) encourage continuing education and 52% of the respondents felt that the association is in favor of mandatory continuing education. Eighty-two percent of the respondents feel that continuing education is necessary to maintain professional growth but only 58% attended a program during the past year.

Periodic Examination for Relicensure

Seventy-two percent felt that pharmacists should not have periodic examinations for relicensure and 79% were against mandating it by law. The respondents were not sure (49%) whether or not MPhA favored the periodic reexamination nor should (76%) MPhA support such a test.

The School of Pharmacy

Forty-nine percent felt that the current five year program should award a M.S. degree. Fifty-nine percent were against converting to a six year program only, but 62% felt that if it did happen the school should award only a Pharm.D. degree. The MPhA should not (53%) support a move requiring a six year Pharm.D. and the school should (59%) continue to award both the B.S. and Pharm.D.

The present programs properly prepare students for community practice (62%), institutional practice (63%), clinical practice (40%) and the Pharm.D.'s properly (49%) prepared for clinical practice.

Part Time Advanced Degree at the School

Forty-nine percent of the respondents indicated an interest in obtaining an advanced degree on a part time basis through the School of Pharmacy. One evening a week (48%) was the most popular amount of time for such a program, followed by two evenings a week (40%) and one weekend a month (12%).

The major difficulty with pursuing an advanced degree was time away from practice or family (63%), while 52% felt that an advanced degree would not offer opportunities for professional or economic advancement.

Pharmacology was the most popular subject for such a program selected by 98 respondents, followed by clinical pharmacy—56, therapeutics—46, business management—43 and drug interactions—34.

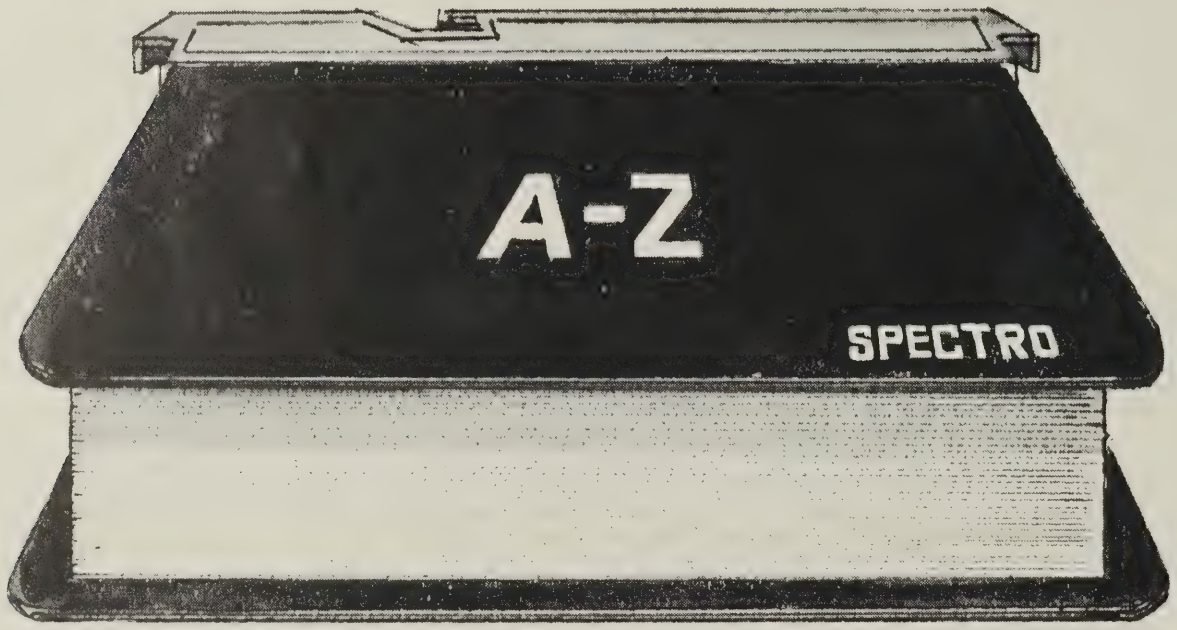
Nurse Practicioners (NP)

Eighty-four percent felt that if a nurse practicioner has some prescribing duties, both the nurse practicioner

Comprehensive Pharmacist Attitude Survey

Professional Issues	Percent Responding		
	Agree or Yes	Disagree or No	Uncertain
1. Pharmacists should maintain patient profiles.	70	16	14
2. Patient profiles should be mandated by law.	29	60	12
3. MPhA should support the use of patient profiles.	65	23	12
4. Pharmacists should attend continuing education programs.	76	10	14
5. Continuing education for pharmacists should be mandated by law.	37	48	15
6. MPhA should encourage continuing education for pharmacists.	87	7	6
7. Do you think that MPhA is in favor of mandatory continuing education for pharmacists?	52	16	32
8. Continuing education is necessary to maintain professional growth.	83	11	7
9. Have you attended a continuing education seminar in the past year?	58	38	4
10. Pharmacists should have periodic examinations for relicensure.	14	72	14
11. Periodic licensure examinations for pharmacists should be mandated by law.	10	79	12
12. MPhA should support periodic relicensure examinations.	10	76	14
13. Do you think MPhA is in favor of periodic relicensure examinations?	10	41	49
14. The current five year program in pharmacy should confer a M.S. degree.	49	34	17
15. The University of Maryland School of Pharmacy should convert to a six year program only.	19	59	21
16. If a six year program is adopted for all pharmacy students, it should award only a Pharm.D. degree.	62	19	18
17. MPhA should support the move to require future graduating pharmacists to have a six year Pharm.D. degree.	23	53	24
18. The University of Maryland School of Pharmacy should continue to award both the B.S.Pharmacy and Pharm.D. degrees.	69	24	17
19. Would you be interested in obtaining an advanced degree on a part time basis through the University of Maryland School of Pharmacy?	49	33	18
20. Would an advanced degree in pharmacy offer you opportunities for advancement professionally or economically?	29	52	19
21. Time away from my practice or family is the main difficulty in pursuing an advanced degree.	63	27	10
The present University of Maryland School of Pharmacy B.S. program properly prepares students for:			
22. community pharmacy practice	62	15	24
23. institutional pharmacy practice	63	9	28
24. clinical pharmacy practice	40	23	37
25. The University of Maryland School of Pharmacy Pharm.D. program properly prepares students for clinical pharmacy practice.	49	5	45
26. If a N.P. has some prescribing duties, do you think the N.P. should also sign the prescription in addition to the required physician's signature? (So the pharmacist will know where the prescription originated.)	84	12	3
27. Do you think prescribing is an appropriate function for N.P.'s?	18	65	17
28. Assuming the N.P.'s will be prescribing, do you think that they should have a standard formulary as to which drugs they can prescribe?	74	16	10
29. Do you think a computer would be of value in your current prescription operation?	66	16	18
30. Community and outpatient pharmacists should provide patient counseling on medications.	94	3	3
31. Chain store pharmacies provide pharmacy services that are comparable to independent pharmacies.	33	56	11
32. Chain store pharmacies allow for pharmacist interaction with the patient.	30	53	17
33. Would you as a pharmacist prefer to have more time to interact with patients?	84	7	8
34. Pharmacy technicians free the pharmacist for more patient interaction.	78	9	12
Which of the following do you think represents good use of pharmacy technicians?			
35. typing labels	88	9	4
36. counting medications	96	3	1
37. talking to patients about medications	6	90	4
38. operating cash register	83	13	3
39. Are you optimistic about the future of pharmacy?	53	25	22
40. There is an oversupply of pharmacists in Maryland.	37	30	34

22,000 Items. Now that's healthy!



You'll find in this book the most comprehensive listing of items available to your pharmacy. You'll also find we can deliver everything we list and do it within 24 hours.

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and the physician should sign the prescription, although 65% felt that prescribing is not an appropriate function for this group. If the nurse practicioner will be prescribing, 74% indicated they should have a standard formulary as to which drugs they can prescribe.

Patient Counseling

Ninety-four percent indicated that community and outpatient pharmacists should provide patient counseling on medications. Fifty-six percent indicated that they felt chain pharmacies did not provide services comparable to independent pharmacies.

While 84% indicated a preference to have more time to interact with patients, 53% indicated that chain pharmacies did not allow for pharmacist interaction with patients.

General Professional Issues

Yes, a computer would be of value in current prescription operation—66%.

The technician can free up the pharmacist for more patient interaction—37% Good use of technician represented by:

typing labels	yes—88%
counting	yes—96%
talk to patient about medication	no—90%
operating cash register	yes—83%

Other mentions included: pulling Rx/profile, inventory control, call M.D. for refills, paper work, filling out third-party forms, ordering.

Are you optomistic about the future of pharmacy?

Yes—53%
No—25%
Uncertain—22%

There is an oversupply of pharmacists in Maryland.

Yes—37%
No—30%
Uncertain—34%

Nothing startling in the above data but certainly interesting as an indication of where Maryland pharmacists are right now and could be compared with similar surveys in other states or similar surveys conducted at some future time here in Maryland.

A number of questions were asked about organizations in general and the MPhA specifically, these will be addressed at a future date after review.

LETTERS

Mr. Jim Vincent
President
NARD

Dear Jim:

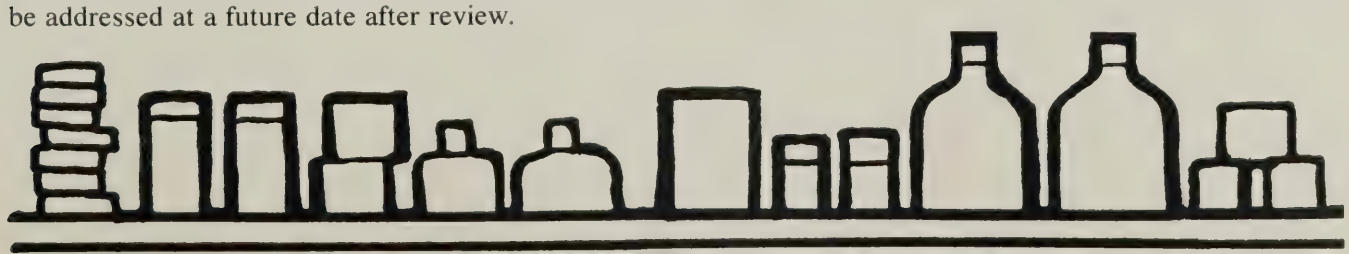
Congratulations on your election to the office of President of the National Association of Retail Druggists. We need a man with courage, experience, and pharmaceutical "know-how" to keep your organization at its present level of excellence. I can think of no one in retail pharmacy today better qualified to assume these responsibilities.

In your recent letter you asked me to identify two areas of concern that I consider critical to pharmacy. My first area of concern is the apparent lack of cooperation between our two national associations of pharmacy, the National Association of Retail Druggist and the American Pharmaceutical Association. Many thousands in our own ranks feel this lack of cooperation between these two organizations. No one is suggesting in any way that either group lose its individuality; however, someone has to extend the hand of cooperation in the name of pharmacy. We must not let interprofessional competition overshadow the larger goal of protecting and improving our wonderful profession.

Another area of concern is third party programs. I feel the survival of pharmacy as we have known it depends on how we deal with this problem. Recently, I read about the M.A.C. program discussions and fixed fees. This is an example of a critical area where communication with all the leaders of pharmacy should constantly be available.

In closing, I would like to extend a personal invitation to you. Whenever visiting our mutual friend, Bill Woods, on our fine Eastern Shore, feel free to spend time in my duck blind or take advantage of our famous shoreline for crabbing or fishing.

Sincerely yours,
William (Bill) C. Hill
President of the Maryland Pharmaceutical Association



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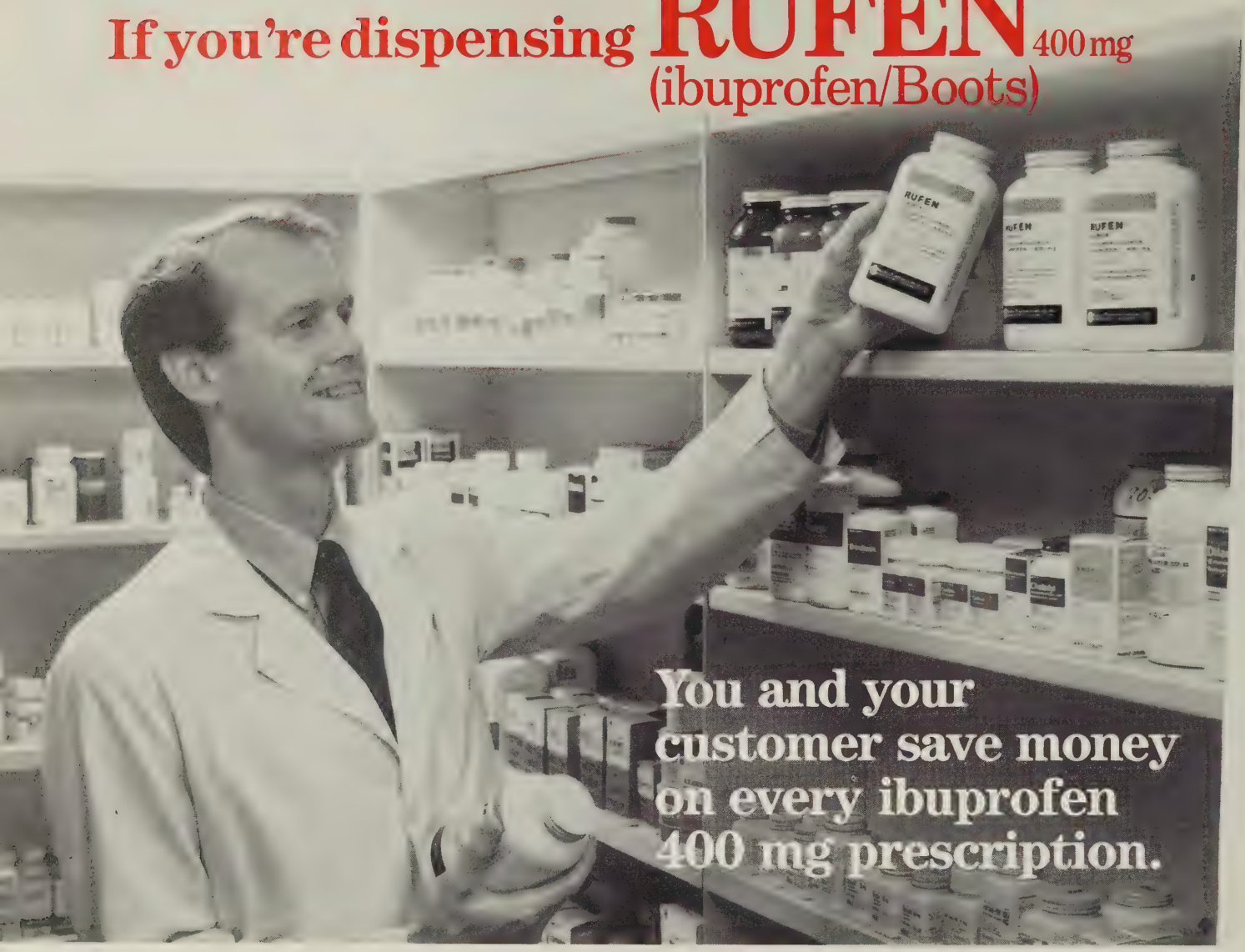

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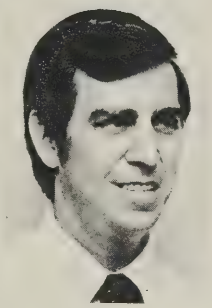
The Era of Self-Medication

Gossel



Wuest

By Thomas A. Gossel, R.Ph., Ph.D.

and J. Richard Wuest, R.Ph., Pharm.D.

University Consultants, Inc.

The 1980's, more so than any other decade in recent years, will come to be known as the era of self-care. Over-the-counter (OTC) products are evolving into a highly sophisticated form of therapy. It is no longer true that OTC medications provide palliative support to relieve symptoms of a disease while prescription (Rx) drugs treat the disorder. Today, an OTC product must be proven to be effective to be marketed. True, there are still some proprietary products which have outlived their therapeutic usefulness, but these are being replaced by newer, more exciting, and much more effective products. There will soon be a day when any item a consumer requests can be recommended with complete confidence that it has met or exceeded very rigid standards established for safety and effectiveness.

Americans currently spend in excess of six billion dollars annually on OTC products. By next year this figure is expected to top eight billion dollars, although the recent Tylenol® Extra Strength capsule scare may dampen this estimate.

The desirability of the self-medication trend is obvious when some other figures are examined. If only two percent of all Americans who currently self-medicate with OTC products were to seek a doctor's assistance, the annual increase in physician office visits would probably approximate 300 million dollars. This added financial burden would be unmanageable by today's standards, and it is estimated that the number of primary care practitioners would need to be increased from the present 91,000 to 147,000.

Furthermore, the physician-patient contact time would have to be shortened. This reduction in time could well lead to less time for observation, less information communicated, perhaps incorrect or incomplete diagnosis, and inappropriate prescription drug usage along with increased costs.

The Pharmacist's Role in Patient Self-Care. The first logical question to ask is, 'Just what role does the pharmacist play in today's era of self-care?" To answer this question we need only look at the results of recent nationwide studies. In one such study surveying over 2,100 adult consumers, 95 percent indicated that they would accept the advice given them by pharmacists. Of this group, 92 percent indicated they were completely satisfied with previous advice from their pharmacists.

An equally interesting report showed that consumers place pharmacists in high professional esteem. This study demonstrated that 1,443 consumers ranked the pharmacist second only to physicians as being **the** authoritative person to counsel them on OTC items. These respondents were also satisfied with the advice received because 62 percent of them were "extremely satisfied" and 35 percent more were "somewhat" satisfied, compared to the physicians' statistics of 67 percent and 32 percent. With recent switching of dozens of previously prescription-only products to OTC status, the pharmacist's role will become even more important as the challenge of counseling on correct usage is apparent.

The time is ripe for pharmacists to become more personally and professionally involved in their customers' health care needs. We have heard so many pharmacists criticize manufacturers of OTC products for placing these goods in grocery stores, automotive centers, and hotel lobbies. They complain that purchasers cannot get professional advice about the products' correct uses or safety because no pharmacist is on duty. Still, many of these same professionals hide themselves behind massive prescription counter displays or make themselves unavailable to those who come for advice. Or, they casually allow a clerk to provide the very ad-

in the service of pharmacy

This continuing education for Pharmacy article is provided through a grant from MERRELL DOW PHARMACEUTICALS INC.

vice that they suggest only a pharmacist should give.

We would like to challenge each pharmacist to become more aware of the current trend towards consumer self-care. With this awareness, then, a commitment to aid consumers in their quest should follow. Consumers do want their pharmacists to aid them in selecting self medication needs and the current health care economics of America point to the necessity for this service. We are now in a much better position than ever before to exert a very significant influence on a major portion of the health care needs of Americans.

Look around. Times are changing! Over the past few years many OTC products have undergone changes in formulation or label information. Have you been keeping up? A vast array of consumer-oriented publications is being sold to a health-conscious nation. Will you allow yourself to be underrated by these books and articles? Studies have illustrated that consumers want more personalized service and informative consultation on the (OTC) drugs they take. Are you willing to supply this need? The market is a multi-billion dollar annual expenditure. Don't you want your share?

The U.S. Department of Commerce has emphasized the worth of self-care with OTC items. It recently stated, ". . . . escalating costs of health care creates a greater need for low cost self-medication than ever before. Seventy-five percent of all illness and injuries are initially treated through self-care and OTC medications. If only a small percentage of self-treatment were shifted to medical practitioners, the patient load would disrupt the U.S. health care system."*

This and subsequent pharmacy education lessons are geared toward providing useful information on a variety of OTC products. We welcome your comments.

*U.S. Department of Commerce: 1978 U.S. Industrial Outlook, Government Printing Office, Washington, D.C., 1978, p131.

Counseling Consumers On Dry Skin

By Thomas A. Gossel, R.Ph., Ph.D.

and J. Richard Wuest, R.Ph., Pharm. D.

University Consultants, Inc.

Goals

The goals of this lesson are to:
1. Discuss the etiology and treatment of dry skin.
2. Review the pharmacology and therapeutics of drugs used to treat dry skin.

Objectives

At the completion of the lesson, the successful participant will be able to:
1. Choose the appropriate OTC agents to treat dry skin.
2. Explain the proper technique for applying these OTC agents.
3. Decide when self-treatment is not appropriate and the consumer should be referred to a specialist.

The Skin

Skin disease is an expensive disorder, both personally and to the nation as a whole. It impairs physical functioning and limits occupational activity to a much greater extent than is generally recognized. Almost one in every twenty Americans has some type of skin disorder. It has been reported that during World War II there were more U.S. evacuations from the South Pacific for skin diseases than for battle casualties. Even relatively minor afflictions (e.g., itching, rash, acne, etc.) can exert an enormous impact on a person's occupation or professional activities. For example, fissured, thickened dry skin on the hand can disable a skilled craftsman, machinist or surgeon. At the present, acute and chronic disorders of the skin account for over half of all workman's compensation cases in some states, and constitute the most common of all occupational diseases.

Other important factors involved in consumers seeking advice on dermatological conditions are the ease by which they are detected, and the psychological impact they have.

Treatment of skin disease is achieved with both OTC and prescription medications. However, the pharmacist is still the first person seen by many persons with such disorders. Since most individuals consider the majority of skin conditions to be relatively minor (albeit irritating), the pharmacist's advice is frequently followed first. Staying with the theme of this year's continuing education topic, this article will discuss those medications which can be purchased without a prescription to treat dry or itching skin.

Profile Of The Skin

The skin is a remarkable organ; it is the largest and most versatile of the body. It affords an efficient barrier to physical, chemical, and biological attack from our environment. It helps maintain the body's integrity by preventing fluid loss outward and access inward by foreign substances and microorganisms. It filters the sun's ultraviolet rays. It helps maintain the body's temperature by cooling it during warm weather and retarding heat loss in cold weather. It helps regulate blood pressure and directs the flow of blood. It plays a major role in electrolyte balance and systemic pH. We often think of the kidney as the primary organ for these functions and, it is. But at any given point in time, there is a far greater blood supply in the skin than in the kidneys. Because of its rich nerve supply, the skin plays a major role in providing the body with sensations of stimulation; it is, of course, the major organ of sexual attraction and activity.

The skin is comprised of two primary layers. The outer layer, **epider-**

mis (epi = upon), is the surface layer that, in turn, consists of several sublayers of cells tightly packed together. The lower level, **dermis,** is much thicker and actually serves as the "business end" of the skin since this is where the blood vessels, glands and nerve fibers are found.

The outer covering of the epidermis is comprised of dead cells that have lost most of their moisture. Because they are hard and scaly, they are referred to as the "horny layer". This layer is also called **keratin,** and the **stratum corneum.** This hardened covering is necessary for the skin's well being, as long as it is not too thick. For example, as the skin constantly regenerates itself by cellular division, new cells are formed that push upward toward the surface. During this process, cells are moved through the area of the dermis where a rich blood (and hence, nutrition) supply is available, and the cells are fully viable. However, as they enter into the epidermal layer and continue their migration upward, there is less available nutrition and they die.

By the time the cells reach the surface to form the horny layer, they have been almost completely dehydrated. The presence of this horny layer provides protection for the underlying levels of skin tissue. Normally, substances trying to cross body cell membranes can only penetrate through cells that are alive. Once dead, the mechanisms responsible for transmitting chemicals across cellular membranes are no longer operative and the dead cells serve as effective barriers.

Excessively thickened keratin also contributes an important pathologic role when the normal physiological properties of sweat glands and sebaceous glands are considered. For example, sweat is one of the body's excretory products. It consists of numerous waste products of the skin's cellular metabolic reactions. Sweat is excreted from the body through tiny ducts that open to the skin's surface. Here, the sweat evaporates into the air. However, when the keratin layer is too thick, sweat cannot reach the outermost skin as readily. This is especially true during periods of excessive sweating when sweat may accumulate under the horny layer where it can cause intense stimulation of nerve fibers leading to persistent and severe itching.

Lichenification. This is a term that describes a process due to an "itch-scratch" cycle. The process is stimulated through repeated irritation (e.g., by scratching) of the keratin layer.

To illustrate, consider an individual whose skin is dry, or for some other reason itches profusely. The individual scratches the area to relieve the itching. The scratching may relieve the itching and nothing else is noticed. However, in some instances, especially when the skin is excessively dry, scratching initiates a phenomenon known as the "itch-scratch" cycle. Once the scratching stimulation is started, the itch is only temporarily relieved and returns momentarily. This causes more scratching which induces even more itching, and so forth. If scratching persists only a day or two, there is no longterm damage. However, if the individual continues to scratch, even so slightly, or rub the area over a prolonged period, such as several weeks to months, lichenification (skin becomes smooth, hard and almost "shellac-like" in appearance) occurs. The process occurs because of chronic irritation of the horny layer which, in essence, destroys more and more cells. As they accumulate one on top of the other, the horny layer's depth is greatly increased. Because moisture cannot penetrate into the thickened horny layer and partly because sweat cannot be extruded as readily from the sweat gland ducts, itching is the usual outcome.

Dry Skin

Dry skin (xeroderma) is one of the least understood but most common afflictions suffered by millions of Americans. It can occur at any age, but it is most common in people over 70. It is also most generally experienced on the legs, although a great many post-menopausal women have dry skin of the face. While certainly not life threatening, dry skin does cause a wide variety of physical discomforts and can predispose the skin to invasion by infective organisms.

Dry skin is not well understood by the medical community or by consumers. Since it is usually secondary to some other abnormality (e.g., lack of adequate production of endogenous estrogens), it is rarely taught in medical school or discussed in textbooks, as a disease state of its own.

Commercial advertising and its puffery have not helped the situation, and its outlandish claims for a "cure" have confused the public. A case in point is the estrogen-containing cosmetics. The word "cosmetics" is used because, labeled "drugs", they fail FDA's tests for safety and effectiveness. While undoubtedly safe, there is no evidence that applying estrogens to the surface of the skin will correct a situation (i.e., dry skin) which is caused by an inadequate supply of endogenous hormones.

Dry skin is a condition in which there is insufficient moisture present in the outermost layers of the skin. The most important factor for adding moisture to the skin is the relative humidity. There is a direct proportion between the quantity of moisture that keratin will absorb, and the relative humidity. At 60 percent relative humidity, the moisture content of keratin will be 10 percent or greater and it remains soft. At this point, skin is fully elastic and smooth and its physiologic functions are maximized. However, when keratin is no longer moist, skin is brittle and relatively defenseless. A 10 to 15 percent keratin hydration level is normal for most climates. Once the relative humidity of air decreases, such as during the winter months when households are heated with furnace air that has not been humidified, keratin's moisture content drops below the critical 10 percent minimum. It then dries, cracks and loses its integrity as a physical barrier. Furthermore, all of the symptoms of dry skin previously described may be experienced. Realize of course that moisture can be added to the upper layers of skin by diffusion from the deeper levels. However, moisture moving upward through the skin is a slow process and, for all practical purposes, this provision is not an efficient means for maintaining a softened keratin layer.

Actually, dry skin is a problem during all seasons, not just the winter. However, the cold, dry winter

months do affect the skin the most. This is partly due to household heating systems that warm the inside air without replacing moisture, but also to strong arctic winds with their lower relative humidity that pull moisture off exposed skin. During the summer months, people who spend a lot of time in air conditioned buildings may also experience dryer-than-normal skin. Excessive exposure to sunlight and artificial ultraviolet light also burns, and therefore, dries out the skin. This concept will be explained in more detail in a future lesson.

During any season of the year, the chronic use of strong soaps and detergents, or strong solvents and cleaners may remove lipid (from the skin's surface) that normally aids in preserving moisture. This lipid material, composed largely of sebum, is important because throughout life it helps trap and hold moisture on the skin. With aging, there is a decrease in the quantity of lipid produced by the body. This allows moisture to evaporate from the skin more readily, so dry skin is also a problem that worsens as we grow older.

Appearance. In the early stages of a dry skin condition, the skin does not appear different. However, with time, small cracks (chaps) or fissures that may cause scaling appear. The affected skin may appear reddened (erythema) due to the underlying blood vessels dilating in an attempt to provide more moisture to the area. The skin then feels dry and itching is common. As the dryness continues, itching increases. The skin begins to flake off in large patches that frequently leave diamond-shaped lesions. If dryness is severe enough, itching may become so intense as to cause almost constant scratching or rubbing and, thus, dermatitis and/or infection occurs.

Treatment Of Dry Skin

There are numerous treatments for dry skin conditions, and a few points about them are worth mentioning.

(1) The best way to treat dry skin conditions, and to prevent drying in the first place, is through increasing the amount of moisture in the environment. This is best achieved by adding a central humidifying unit to the furnace, or by minimally running the air conditioner's dehumidifying element during the summer. One less expensive alternative to these is using a cool mist vaporizer whenever the air is dry.

Relative humidity is the ratio of the amount of water the atmosphere can hold in relation to that quantity actually present. When the relative humidity is 65 percent, for example, the air in the area contains 65 percent of its maximum capacity (i.e., when it is raining the relative humidity approaches 100%). Warm air that has 50 percent relative humidity contains far more actual moisture than air at 10°F with the same relative humidity reading because warm air can hold more moisture than cold air.

When cold air is brought into a home warmed by a furnace that does not humidify air as it is heated, the relative humidity within the home will drop significantly. This happens because there is no reservoir of water to replace that removed when we breathe, or to contribute the extra moisture needed to maintain the in-house relative humidity.

(2) Avoid excessively long baths, very hot water, and strong detergents/soaps. Avoid any chemical irritant or rough clothing that constantly rubs against the skin. Elderly people should bathe infrequently and blot the skin dry rather than rub it.

(3) Apply a skin emollient/protective to rehydrate or prevent further dehydration of the stratum corneum.

Occlusives. The primary goal in treating dry skin is to increase the water content of the stratum corneum to at least 10 percent. Simply placing water onto the skin, however, is not an effective means to rehydrate keratin, because the skin cannot retain it unless it is physically held there. In fact, frequent or prolonged bathing or soaking without occlusion can actually remove moisture and dry the skin even more than it was previously.

The most effective means for rehydrating the stratum corneum of patients with dry skin without complicating dermatitis or secondary dermal infections is to first soak it for about ten minutes, then cover the area with an occlusive dressing. This permits keratin to soften, and then if a hydrophobic (occlusive) agent is applied, the moisture will be retained within the keratin and maintain the softness. These occlusive preparations include any water in oil (w/o) emulsion-based product such as lanolin, or, petroleum jelly (e.g., Vaseline®). These products also fill in tiny fissures on the skin and help smooth it. However, these same items may not be acceptable to many patients because they leave a greasy film, readily stain clothing, and in general, are messy and hard to work with.

It may help to bathe in water to which one of the proprietary products such as Aveeno Oilated® or Alpha Keri Bath Oil® has been added. Because these products render the bathtub quite slippery, persons using them should take special precautions to avoid injury, and elderly or weak patients should not use them unless they are aided getting into and out of the tub. More efficient hydration is usually achieved, however, by soaking in plain water no more than once a day, followed by application of the occlusive emollient.

If the product's greasy film on the skin is unacceptable, an oil in water (o/w) emulsion product may be chosen as a second alternative. Once applied, water evaporates from these products and provides a sensation of cooling which also may aid in itch control. They do leave a thin layer of oil which at first feels greasy, but overall, they provide minimal occlusiveness. They are, therefore, less effective than w/o emulsion-based products.

Simply applying an occlusive agent without first soaking the area in water, or just patting water on the area, is not usually sufficient to correct a dry skin condition especially during the winter months. Occlusive emollients used alone can block evaporation of water from the skin, but researchers have shown that this barrier action is not sufficient to maintain normal hydration. As stated above, moisture movement from deeper structures to the keratin layer is a slow process.

A great variety of products containing high concentrations of animal and vegetable oils have appeared on the market in recent years. Such "natural" products that contain oils of turtle, mink, sesame,

jojoba, or avocado, or other exotic substances of natural origin may possess a certain psychological appeal. But their occlusive properties are less effective than petrolatum and their cost is frequently inflated.

Likewise, fad products containing vitamins A, D, or E, elastin, collagen, or the so called "natural moisturizing factor" (NMF) which are promoted for dry skin conditions offer no significant benefits over using their emollient base alone. Because of this, as well as their high price, they should not generally be recommended. Products that contain more than 15 percent propylene glycol should be avoided since they may actually worsen the dry skin condition.

Moisturizers (Humectants). Glycerin and products that use glycerin as their base have long been employed as skin moisturizers and generally are effective for this purpose. Glycerin probably acts by attracting moisture from the air and holding it on the skin where it can then penetrate into the keratin layer. There is also some evidence that it may work in another yet unknown manner. A 50 percent solution of glycerin (e.g., glycerin and rose water) provides adequate hydration of the skin in most persons. Glycerin-based products are mainly effective when the environmental relative humidity is high (e.g., during the summer months). To be maximally effective during the winter, a humidifier or vaporizer must be used concurrently to raise relative humidity in the home. Despite this drawback, when a thin layer is gently applied several times a day, glycerin can provide an effective, yet economical means to treat even the driest of otherwise uncomplicated skin conditions.

Urea is another moisturizing agent to consider. Urea is a component of urine and, for centuries, people have applied animal and human urine to dry skin with apparently successful results. Needless to say, applying urine to the skin is no longer an acceptable form of therapy in today's society. Urea increases water uptake into the keratin layer. There are numerous products available that contain 2 to 30 percent urea (Table 1) and it can be added *secundem artem* to most pharmaceutical bases. One possible exception is 50/50 Aquaphor® and water in which the urea will sometimes take up the water and leave a gooey mess. This can generally be overcome by using Eucerin® instead of Aquaphor® and water. Urea products are safe and effective for treating dry skin, except for an occasional person who may show some tissue sensitivity.

TABLE 1
Commercially Available Products Promoted For Relieving Dry Skin

Urea — Containing Products
Aquacare
Carmol
Lowila
Neutragenic Body
Neutraplus
Vitamin A&D — Containing Products
'A&D'
Balmex
Caldesine
Clocream
Comfortine
Desitin
Emollients
Acid Mantle
Allercreme
Corn Huskers
Dermassage
Jergins
Keri
Lanolor
Lubriderm
Neutragenic
Nivea
Oil of Olay
Purpose
Shepards
Vaseline Intensive Care
Wibi

Choosing a product. Frequently, a patient is faced with choosing between a cream, gel and ointment form of the same product and the pharmacist is asked to assist. These pharmaceutical bases do offer distinct advantages and disadvantages over each other when used for certain purposes. Choosing the correct base may mean the difference between the product working or not. Thus, a few words about them are in order.

Creams are easily rubbed into the skin to leave an invisible film layer, but they are also water-washable and non-occlusive. They have a distinct disadvantage in not occluding the skin well. Therefore, creams do not provide moisture to the skin or retain it there. Unless specifically indicated (e.g., when an oozing dermatitis is present, or as discussed below) a cream-based product should not be used to treat a dry skin condition.

Products with **ointment** bases are not miscible with water and thus are not readily removed by washing. They provide excellent occlusive properties and hold moisture onto the skin where it can penetrate into keratin. An ointment base should be recommended for most patients with dry skin unless otherwise contraindicated (e.g., when seeping lesions or pus-producing infection is present, on hairy areas, or on large areas of the face). Many specialists believe that for severely uncomfortable and large dry skin areas on the face, the patient will not comply fully with proper administration of medication because of the unsightly appearance caused by greasy ointments. For this reason, a cream, even though it doesn't provide as much occlusion, may be better than an ointment when lack of compliance will result in little benefit to the condition.

Gels have a high alcohol content. When applied to the skin, they "break down" into their water and alcoholic components. These then evaporate to produce a cooling sensation. While gels have a significant place in dermatological therapy (i.e., acne), they reduce the moisture content even more. This is especially true with repeated usage of gels.

Itching

A major symptom of dry skin is a lowered threshold to pruritic stimuli. Pruritus (itching) is the most common symptom encountered in dermatology, being especially bothersome in people with dry skin, and people with eczema. To most people, itching is even more aggravating and uncomfortable than pain. Dry skin itches and as the victim attempts to relieve it, the "itch-scratch" response may initiate development of severely inflammed skin as explained earlier.

Rehydrating dry skin is frequently all that is needed to terminate itching. However, on occasion, itching persists long after moisture has been added. When this occurs, a topically-applied antipruritic remedy with a moisturizer or occlusive

preparation will often be useful.

A variety of preparations that contain a local anesthetic or antihistamine in an ointment base is available and effective. They will be discussed in a future lesson. For otherwise "intolerable" itching caused by dry skin, the patient should follow the recommendations presented earlier for soaking, then applying one of these products. Their benefit is twofold: they occlude moisture, and provide a mild numbing sensation. However, these preparations should not be used regularly, or by people whose skin in easily irritated by soaps or other chemicals. Such persons may have an underlying eczema that is best treated by other means. Antihistamines and local anesthetic products may cause sensitization of the skin to increase pruritus and dermatitis in susceptible persons, if they are used over long periods.

Products that have a high alcohol content should also be avoided as these will dry the skin ever further. Likewise, "shake lotions" (e.g., calamine lotion) that dry to form a paste should not be used. Their drying ("drawing") action will actually exacerbate the itching and discomfort.

Consumer Advice

The pharmacist can aid a patient's self treatment for dry skin with OTC products by explaining why a petrolatum-type product is better than a non-greasy one. Explain that a little goes a long way, use it sparingly, and rub off any excess. These points should help maximize compliance. Without proper compliance, whether it be following the manufacturer's instructions on OTC's or the physician's directions on prescription dry skin remedies, there is little hope that the condition will be corrected. Since this type of skin condition is tenacious and hard to treat, even with compliance, often the best hope is for alleviating the itching and preventing a worsening of the condition.

If a person is self-medicating for months, and the itching is not relieved or the condition has worsened, it is time to consider obtaining the advice of a dermatological specialist.

Lilly Digest Results for South Atlantic States

(Delaware) (South Carolina) (District of Columbia) (*Maryland*) (West Virginia) Averages per pharmacy	1982 South Atlantic States (204 Pharmacies)	1981 South Atlantic States (195 Pharmacies)	1982 United States Average (1,528 Pharmacies)
SALES			
Prescription	$ 271,516— 59.6%	57.4%	54.7%
Other	183,970— 40.4%	42.6%	45.3%
TOTAL SALES	$ 455,486—100.0%	$ 399,831—100.0%	$ 498,021—100.0%
COST OF GOODS SOLD	293,179— 64.4%	64.8%	66.4$
GROSS MARGIN	$ 162,307— 35.6%	35.2%	33.6%
EXPENSES			
Proprietor's or Manager's Salary	$ 28,806— 6.3%	7.1%	6.0%
Employees' Wages	56,115— 12.3%	11.7%	11.3%
Rent	10,293— 2.3%	2.2%	2.4%
Miscellaneous Operating Expenses	50,673— 11.1%	10.7%	11.0%
TOTAL EXPENSES	$ 145,887— 32.0%	31.7%	30.7%
NET PROFIT (before taxes)	$ 16,420— 3.6%	3.5%	2.9%
TOTAL INCOME OF SELF-EMPLOYED PROPRIETOR (before taxes on income and profit)	$ 45,226— 9.9%	10.6%	8.9%
VALUE OF INVENTORY AS A PERCENT OF SALES			
Prescription	$ 29,682— 10.9%	10.8%	10.9%
Other	38,652— 21.0%	— 21.0%	20.7%
TOTAL	$ 68,334— 15.0%	$ 60,358— 15.1%	$ 76,216— 15.3%
ANNUAL RATE OF TURNOVER OF INVENTORY	4.4 times	4.4 times	4.5 times
NUMBER OF PRESCRIPTIONS DISPENSED			
New	13,518— 46.9%	46.7%	48.8%
Renewed	15,282— 53.1%	53.3%	51.2%
TOTAL	28,800—100.0%	27,145—100.0%	27,501—100.0%
PRESCRIPTION CHARGE	$ 9.43	$ 8.46	$ 9.91
NUMBER OF HOURS PER WEEK			
Pharmacy was open	61 hours	61 hours	62 hours
Worked by proprietor	47 hours	47 hours	48 hours
Worked by employed pharmacist(s)	37 hours	37 hours	38 hours

* Source: 1983 *Lilly Digest*

1984 Tax Dates

The following are due dates for federal and state taxes that most affect you. Taxes that are due four or more times during the year are identified by abbreviations explained below the chart. Note that if a tax is due on a weekend or holiday, the due date is advanced to the next business day, causing some taxes due the last of the month to be payable early the next month.

January, 1984

Thursday, January 5	FD(a)
Monday, January 16	FI
Monday, January 23	ST
Tuesday, January 31	FQ, FU, SQ, SU, FD(c)

February, 1984

Friday, February 3	FD(a)
Wednesday, February 15	FD(b), SD
Tuesday, February 21	ST

March, 1984

Monday, March 5	FD(a)
Thursday, March 15	FD(b), SD Calendar Year corporations must file income tax return or pay 50% of unpaid taxes and file for 3 months automatic extension. Accrual basis corporations declare accrued expenses by this date (2 1/2 months after end of taxable year).
Wednesday, March 21	ST

April, 1984

Wednesday, April 4	FD(a)
Monday, April 16	FC/P, FI, SC Federal and state income tax due or you must pay estimated amount due and file for 60 day extension. Interest will be due on amount paid after April 15. Sate corporation tax due. 60 day extension may be requested. State personal income tax due.
Monday, April 30	FQ, FU, FD(c), SQ, SU

May, 1984

Thursday, May 3	FD(a)
Tuesday, May 15	FD(b), SD
Monday, May 21	ST

June, 1983

Tuesday, June 5	FD(a)
Friday, June 15	FD(b), FC/P, SC, SD, FI
Thursday, June 21	ST, Annual State and Federal Tax if extensions were received

July, 1984

Thursday, July 5	FD(a)
Monday, July 23	ST
Tuesday, July 31	FQ, FU, FD(c), SQ, SU

August, 1984

Friday, August 3	FD(a)
Wednesday, August 15	FD(b), SD
Tuesday, August 21	ST

September, 1984

Thursday, September 6	FD(a)
Monday, September 17	FD(b), FC/P, FI, SD, SC
Friday, September 21	ST

October, 1984

Wednesday, October 3	FD(a)
Monday, October 22	ST
Wednesday, October 31	FQ, FU FD(c), SQ, SU

November, 1984

Monday, November 5	FD(a)
Thursday, November 15	FD(b), SD
Wednesday, November 21	ST

December, 1984

Wednesday, December 5	FD(a)
Monday, December 17	FD(b), SD, SC, FC/P
Friday, December 21	ST

FD(a)	Last payment due on Federal income and social security taxes withheld during the previous month if over $3000 was withheld. You are required to deposit the amount withheld within 3 banking days after you reach $3000 at the end of any eighth-monthly period (these periods end on the 3rd, 7th, 11th, 15th, 19th, 22nd, 25th, and last day of the month)
FD(b)	Federal income and social security taxes withheld must be deposited by this date if between $500 and $3000 was withheld during the previous month. Earlier deposit is required when $3,000 is reached prior to this date.
FQ	Federal Quarterly income and social security taxes withheld must be paid.
FU	Federal Unemployment tax must be paid.
FC/P	Federal estimated corporation and partnership taxes must be paid if on calendar basis (note—fiscal year corporations pay this tax on 15th day of 4th, 6th, 9th, and 12th month of their year)
FI	Federal estimated individual tax for previous quarter due.
FD(c)	Federal social security and withholding tax if any due domestic workers.
ST	Maryland State Sales Tax due.
SQ	Maryland State income tax withheld due for previous quarter.
SU	Maryland State Unemployment taxes due.
SD	Maryland State estimate of income tax withheld the preceeding month must be deposited.
SC	Maryland State Estimate of corporation tax due.

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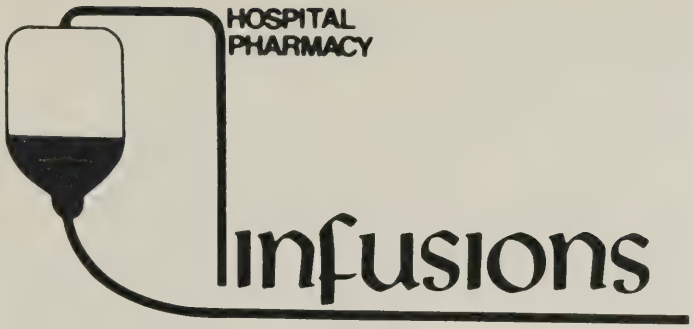

Information contributed by the Maryland Society of Hospital Pharmacists.

Contributors: Paul J. Vitale
Barbara L. McHenry
The Anne Arundel General Hospital

How many times has your hospital pharmacy been asked for a recommendation of an equipotent dosage of parenteral propranolol when converting from an oral dose? What about an equipotent conversion dose of intravenous propranolol for a patient taking oral atenolol or nadolol? At first glance these questions appear easy enough to answer. However, when you consider the potential complications which may arise because of underdosing or overdosing a beta blocker, or have searched the medical literature only to find that no hard and fast recommendations relative to this problem have been documented, the answers to these questions become more difficult. This short paper is designed to point out some of the variables to consider when converting from an oral beta blocker to parenteral propranolol, and to present some guidelines for dosage conversions. No attempt will be made to list all the different properties of the various beta blockers available nor to compare them. We will only mention the equipotent doses of each relative to propranolol. Propranolol is used as the standard because at the present time it is the only beta blocker which is commercially available in the United States as an injection.

Recommendations in the literature for oral to parenteral propranolol dosage conversions range from 1/4 to 1/40 the oral dose. Some clinicians suggest using a "fraction" of the oral dose, while others advocate using an intravenous propranolol dose of 1 to 3 mg per dose irrespective of the oral dose[2,3]. *Medical Letter*[4] consultants recommend against the abrupt withdrawal of propranolol in patients undergoing surgery, and suggest that patients who cannot take oral doses be given parenteral propranolol. However, these same consultants point out that an equivalent parenteral dose is not known[4]. In a study using resting heart rate and exercise induced tachycardia as measures of drug potency, Sutton, et. al.[5] have demonstrated, on the average, that the approximate ratio for oral to intravenous propranolol is between 13:1 and 20:1. As a general rule, in converting a patient's propranolol dose from the oral to parenteral route we adhere to the study of Sutton, et. al.[5] and use an approximate ratio of 15:1 as a starting point. With these guidelines in mind, a total daily oral propranolol dose of 240mg would be equivalent to a total daily intravenous propranolol dose of 16mg. This total daily dose of 16mg is administered in 4–6 equally divided doses. Each dose may be admixed with 50–100ml of 5% dextrose or normal saline, and may be infused over a 15 minute interval or at a rate not to exceed 1mg/minute[6]. This dose is used as a starting point and alterations in dose and/or dosing intervals may be necessary.

When the patient who needs intravenous propranolol is taking a different oral beta blocker, such as metoprolol, nadolol, atenolol, timolol, or pindolol, an equipotent oral dose of propranolol must first be determined for these beta blockers in order to calculate an equipotent intravenous propranolol dose. Reports in the literature often list the beta blockade potency ratio comparing to propranolol, but fail to give examples of equivalent daily doses[1]. Such factors as pharmacologic and biologic half lives play a role in determining equipotent daily dosages. Johansson, et. al.[7], using resting pulse and exercise induced tachycardia as a measure of drug potency, evaluated the effects of several beta blockers. Their dosage recommendations for an equipotent oral total daily dose of propranolol of 160mg are as follows[7]: metoprolol—20mg daily; atenolol—100mg daily; pindolol—10mg daily; and timolol—20mg daily. According to the manufacturer (Squibb) and reports by Frishmen[8,9], the equipotent oral dose of nadolol is approximately 75% of an oral dose of propranolol.

Let us now consider two important patient related variables, renal function and liver function. Beta blockers eliminated by the kidney will require smaller doses to attain a given effect when used in a patient with decreased renal function. The same is true of hepaticly eliminated drugs in a patient with decreased liver function.

Using the data from Sutton et. al.[5] and Johansson et. al.[7], the following table was compiled. The table assumes normal renal and hepatic function and also assumes an oral to parenteral propranolol ratio of 15 to 1.

A challenge

To Maryland's Professional Pharmacists

from the University of Maryland School of Pharmacy

The MPhA will be participating in a special Scholarship project. Shown here in a planning meeting are: Marvin Oed, Coordinator of the School of Pharmacy's PEP program; Patricia Ensor, President of the Maryland Society of Hospital Pharmacists; Harry Bass, President of the Alumni Association and Grady Dale, Assistant to the Dean for Academic Services.

On the following two pages is a two-part application form for the School's First Annual Pharmacy Achievement Scholarship. It represents a brand new and exciting challenge to *you* as a practitioner concerned with the future of our profession. By sponsoring a qualified high school or college student (Maryland Resident) for this tuition-free one-year scholarship, you will:

1) stimulate general community interest in the profession;
2) encourage one outstanding young person of your acquaintance to choose pharmacy as a career;
3) demonstrate to your colleagues an awareness of the need for *more* and *better* pharmacy students.

The guidelines are simple. The student you sponsor must have a record of achievement in high school or college, an interest in pharmacy as a career, a cumulative grade point average of 2.75 or equivalent, and PSAT/SAT scores ready for submission. He or she completes the Student Section of the form opposite, while you complete the Pharmacist's Section. You then mail both forms, to be received no later than midnight March 30, 1984, to:

The Pharmacy Achievement Scholarship Committee
University of Maryland School of Pharmacy
20 North Pine Street
Baltimore, Maryland 21201

That's all there is to it.

The recipient will be selected by representatives of the School of Pharmacy, the Maryland Pharmaceutical Association, the Alumni Association, the Maryland Pharmaceutical Society and the Maryland Society of Hospital Pharmacists. The award (one year's tuition) will be announced at a formal ceremony for all nominees and sponsors at the School of Pharmacy during the spring term, 1984. The recipient will be required to meet established admission requirements for the School of Pharmacy at the time of entry.

For additional forms or further information, call Dr. Grady Dale, Assistant to the Dean for Academic Services, 528-6586.

Join with us to heighten the image
and brighten the future of pharmacy!

University of Maryland
Pharmacy Achievement Scholarship

APPLICATION

(Please type or print)

PHARMACIST'S SECTION

I nominate _____ for the School of Pharmacy First Annual Pharmacy Achievement Scholarship

Pharmacist's Name: _____

Address: _____

Name of Pharmacy: _____

College of Pharmacy: _____ Degree _____ Year _____

Telephone # _____

Indicate below why you feel this student is deserving of this scholarship. Include how you came to know the student and his/her qualities and attributes. Also include your knowledge of his/her extracurricular activities and how the student has demonstrated an interest in pharmacy as a career.

** Note: All writing must be kept within the space provided. No additional information may be attached. To do so may void the application.

Please make sure the student you have nominated has completed all the information on the other side of this application before sending to the Scholarship Committee.

_____
Sponsoring Pharmacist's signature

_____
Date

Send completed form to:
Pharmacy Achievement Scholarship Committee
University of Maryland
School of Pharmacy
20 North Pine Street
Baltimore, Maryland 21201

(Over for Student Section)

DETACH HERE

STUDENT SECTION

Date of Application _____

Name: _____ Telephone # _____

Address: _____

Permanent Address (if different from above) _____

_____

List your most recent place(s) of employment (if any):

	Employer	Dates of Employment	Brief Description of Duties
1.			
2.			

Indicate any extracurricular (social or service) activities.**

Briefly, how did you become interested in pharmacy as a career?**

Describe how you came to know the pharmacist nominating you for this scholarship.**

Include transcript of high school grades (college transcript if beyond first year of college). PSAT, SAT and/or ACT scores must be submitted if not included on transcript. *NOTE:* The awarding of the scholarship does not constitute admission to the School of Pharmacy. The recipient must be a bona fide full-time student at the University of Maryland School of Pharmacy in order for the scholarship to be activated.

_____
Student's Signature

** Note: DO NOT WRITE OUTSIDE of the box or attach additional information. To do so may void the application. THIS APPLICATION MUST BE RECEIVED NO LATER THAN MARCH 30, 1984.

DETACH HERE

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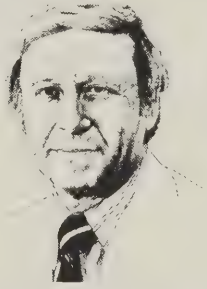
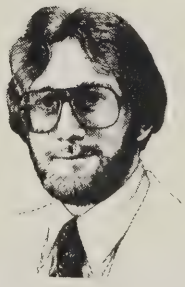
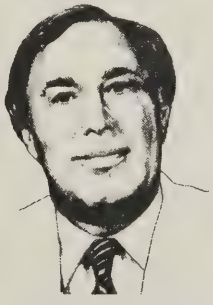


Stuart J. Renbaum



Steven H. Steinberg



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1984 Edition of USP DI Published

A newly revised and expanded edition of *USP DI* is now available from USP. *USP DI* is a comprehensive, continuously updated reference of drug-use information for the health professional and the patient. Published in a convenient two-volume format, the 1984 edition is 20% larger than the 1983 edition because of the increase in the number of drugs covered, and an expansion of the information in each monograph. *USP DI* now contains information on practically all drugs available in the United States, including such newly approved drugs as ranitidine, diltiazem, and guanadrel.

As is expected from USP, the 1984 *USP DI* is the result of an elaborate drug information system designed to provide a common data base of unbiased and current drug-use information for those who prescribe, dispense, administer, or use drugs. When first released in 1980, *USP DI* gained widespread attention as a landmark in drug information—a source book containing both a practitioner and a lay-language patient section—representing the consensus of hundreds of experts.

The 1984 *USP DI* soft cover, two-volume set covers most prescription and non-prescription medications. Volume I, *Drug Information for the Health Care Provider,* is specifically written for the health professional. Volume II, *Advice for the Patient,* presents corresponding information in lay language for the consumer. Each volume contains over 500 individual monographs contained in each volume, nearly 80 of which are family groupings covering an additional 500 agents or combinations. Over 4500 drug dosage forms and brands (including Canadian) are represented.

New in 1984

Changes that have been incorporated into the 1984 edition of *USP DI* include:

—placement of brand names in both Volume I and Volume II monographs, as well as in the indexes;
—complete revision of category-of-use terminology;
—special identification of unlabeled uses in the category and indications sections;
—inclusion of an expanded indications section;
—addition of specific precautions sections on carcinogenicity, mutagenicity, and/or tumorigenicity;
—addition of precautions relating to pediatric and geriatric use;
—expansion of pregnancy and breast-feeding precautions sections;
—inclusion of signs and treatment of overdose;

—inclusion of a dosage form preparation section; and
—addition of an incompatibilities section.

Extensive Use of USP DI Data Base

USP DI has been selected as the data base for the patient education leaflet program of the American Medical Association, the National Association of Retail Druggists, the Canadian Pharmaceutical Association, and the state pharmacy associations in Louisiana, Missouri, Montana, Pennsylvania, and Washington. *USP DI* is also the basis of the Drug Use Education Tips (DUET) program of the American Academy of Family Physicians.

The USP DI System

The USP DI System provides a coordinated approach to patient drug-use information. Elements of the System include *About Your Medicines,* a consumer-oriented home reference book of the most widely used prescription and non prescription drugs covered in *Advice for the Patient;* English and Spanish brochures about specific drug families and general drug use; English and Spanish patient drug education leaflets; English and Spanish patient education posters; and a bimonthly, consumer-oriented newsletter.

The 1984 *USP DI* is available from USP for $44.95 per two-volume set. Copies of each volume are also available separately (Volume I, *Drug Information For The Health Care Provider,* $29.95; Volume II, *Advice For The Patient,* $21.95). Subscriptions to the bimonthly *USP DI Update,* which supplements both volumes, are $9.00 for one year.

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Lubbock, Texas

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Executive Director
Michigan Pharmacists Association
Lansing, Michigan

Marilyn Slotfeldt, Pharm.D.
Clinical Services
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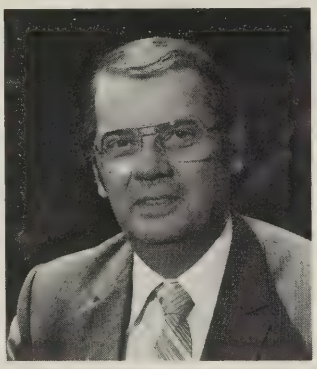
Portland, Oregon



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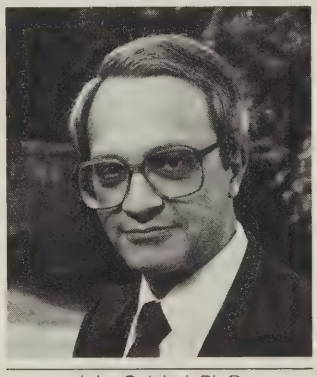

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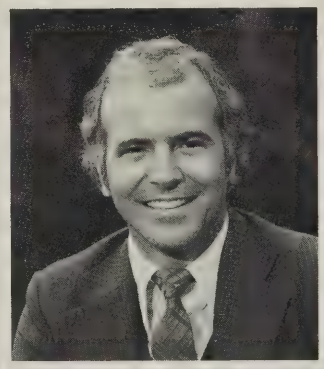

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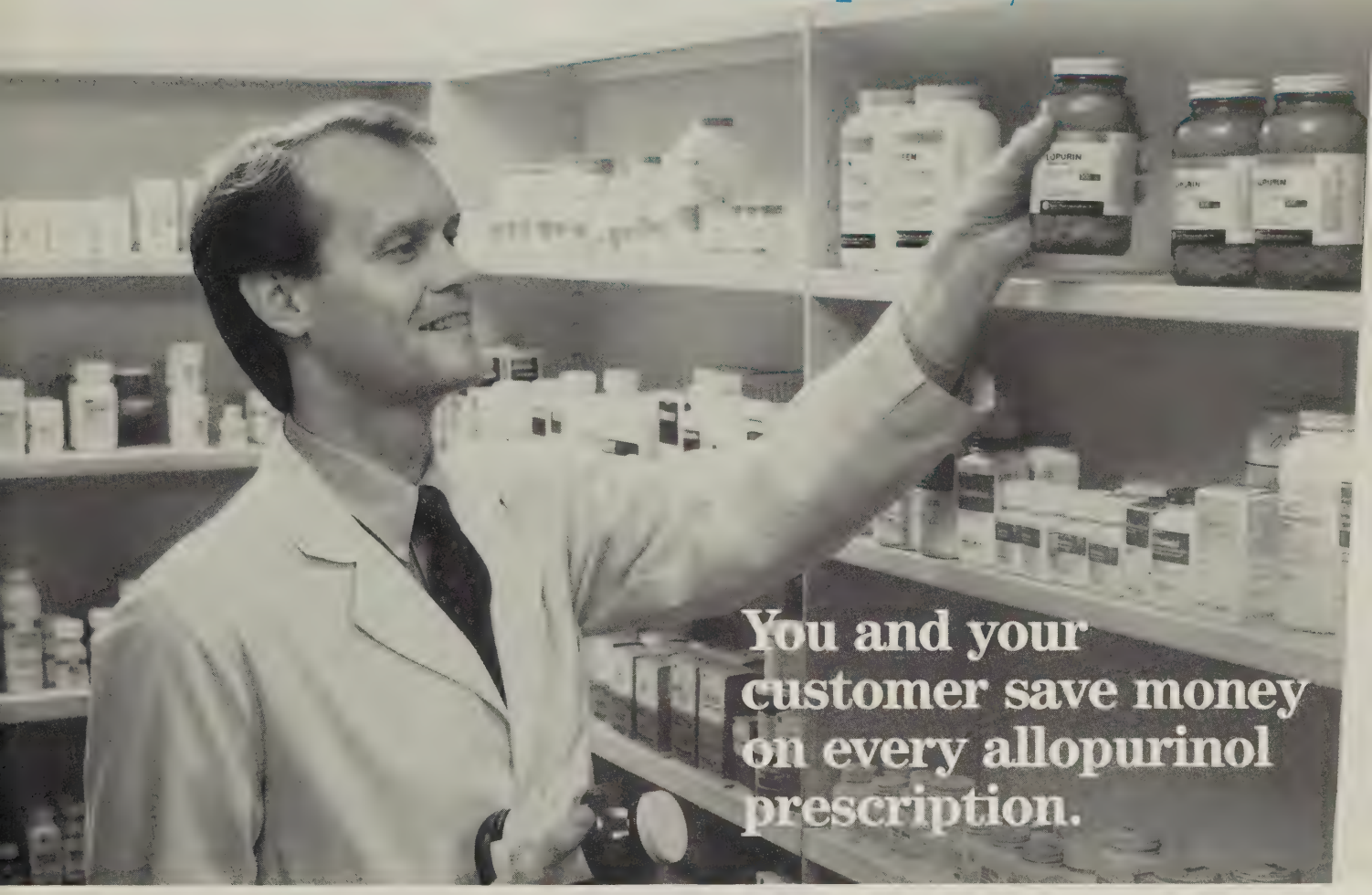

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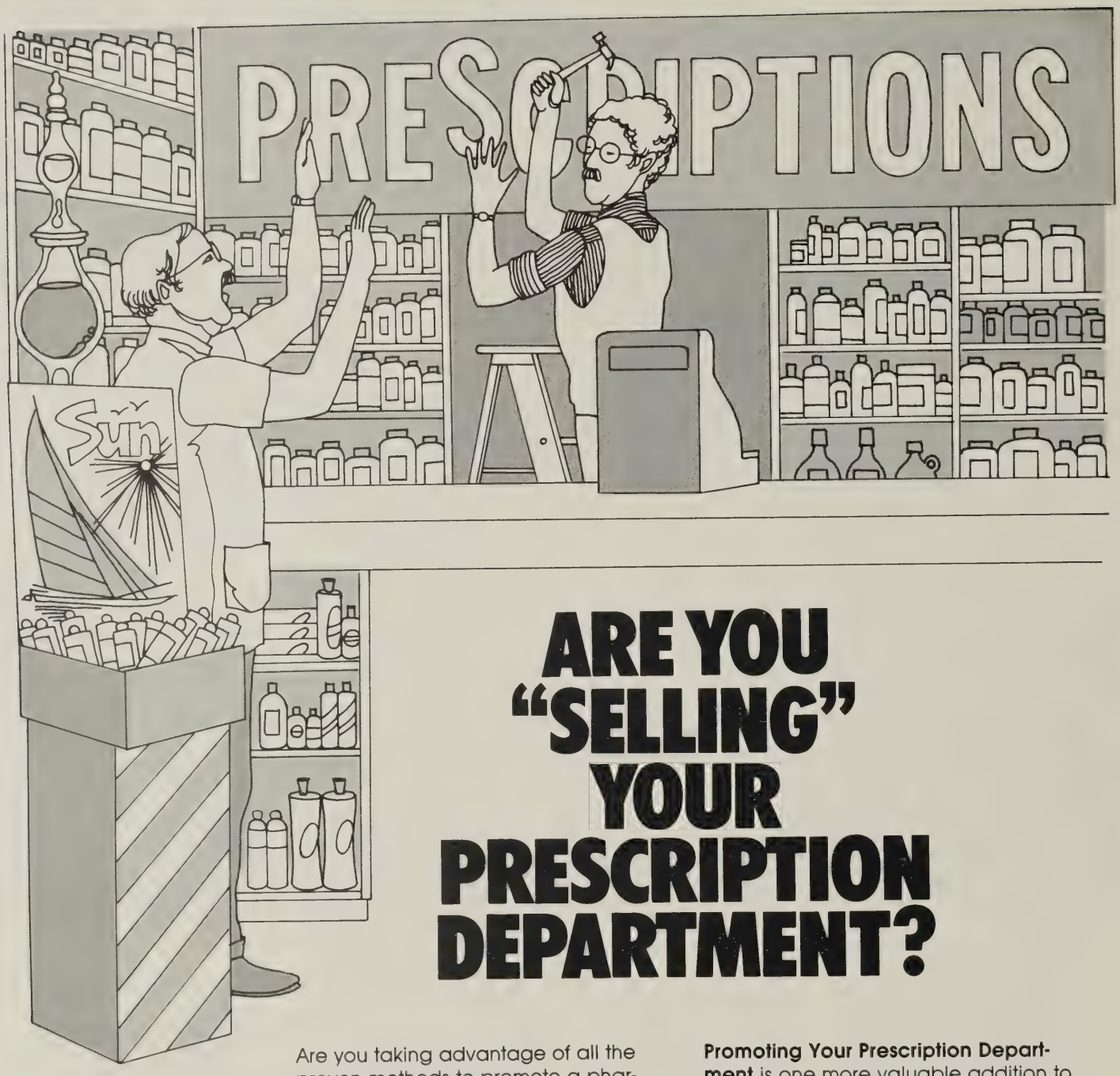

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The Annual Alumni Association Dinner was held Sunday, November 20th. Alumni Association President Harry Bass (left) introduced the Father Francis Quinn who discussed the subject of Ethics in Pharmacy.

The recipient of the Alumni Association's Annual Honorary President's Award was Dr. Peter P. Lamy.

Dean William J. Kinnard, Jr. introduced Dr. Lamy for his remarks and presentation of the Award.

Kevin T. Quinn has been assigned to the Baltimore territory for the Upjohn Company. He recently completed four weeks of training at the Upjohn Company learning center in Kalamazoo, Michigan.

ABSTRACTS

Excerpted from PHARMACEUTICAL TRENDS, published by the St. Louis College of Pharmacy; Byron A. Barnes, Ph.D., Editor and Leonard L. Naeger, Ph.D., Associate Editor

HALOPERIDOL DECANOATE:

Another long acting neuroleptic agent has been prepared in an injectable form. Haloperidol decanoate is dissolved in vegetable oil and is used via intramuscular injection. Levels are maintained within the therapeutic range for four weeks after administration of the drug. Steady state plasma levels are reached after the third monthly injection. *Drug Ther Bull,* Vol. 21, #10, p. 37, 1983.

KIDNEY STONES:

Two new non-surgical procedures have been developed to aid in the removal of kidney stones. One technique, called percutaneous ultrasound lithotripsy, uses ultra sound to disintegrate the stones. The other non-invasive procedure focuses shock waves on the stone causing it to disintegrate. The procedures are new and some questions still remain, but it seems as if they may represent a safer and more convenient way to remove renal stones. *JAMA,* Vol. 249, #18, p. 2435, 1983.

CANCER PATIENTS AND MEDICATIONS:

Cancer patients are facing a dilemma as they try to obtain medication to allay their pain. Many pharmacies are no longer stocking narcotics because of the growing threat of armed robbery. Patients requiring such medication should make themselves known to pharmacists so a better understanding can be reached. *Am Med News,* Vol. 26, #24, p. 9, 1983.

HEMOPHILIA:

Hemophiliac patients lack certain clotting factors which make hemorrhage a serious problem. Patients with this condition were given danazol (Danacrine) in doses of 600 mg daily for 14 days. Data collected suggest danazol therapy may decrease the likelihood of hemorrhage in hemophiliac patients by increasing the concentration of factors which are characteristically absent in this condition. Danazol also has been said to be effective treatment for patients with idiopathic thrombocytopenic purpura. *N Engl J Med,* Vol. 308, #23, p. 1393, 1983.

CAFFEINE:

Although caffeine is said to be the most commonly used drug in the world, until recently little was known of its metabolic disposition in the body. Studies show people handle the drug in a variety of ways, dependent upon both genetic and environmental influences. Studies of caffeine metabolism may be useful in determining acetylator status in man. *Clin Pharmacol Ther,* Vol. 33, #5, p. 591, 1983.

DIURETIC-BETA BLOCKER THERAPY:

High doses of thiazide diuretics seldom increase the hypotensive response seen at lower doses and only serve to increase toxicity. Investigators have added a beta adrenergic blocker to a thiazide diuretic regimen and it appears that the dose of the diuretic can be lowered without loss of the antihypertensive effect. Doses of hydrochlorothiazide of 12.5 mg, when combined with a beta-adrenergic blocking agent, seem to be adequate in producing the desired antihypertensive response while significantly reducing the metabolic consequences of high dose thiazide therapy. *Br Med J,* Vol. 286, #6377, p. 1535, 1983.

BACTERIAL MENINGITIS:

Ceftriaxone was compared to ampicillin/chloramphenicol therapy in the treatment of bacterial meningitis in children. Within 12 hours after starting therapy, a higher precentage of sterile cerebrospinal fluid samples were seen with the cephalosporin derivative than with standard regimen. Bacteriocidal activity remained higher with the single agent even at the termination of the study. There were no differences in the clinical response or in frequency of complications between the two regimens. Cost comparisons were not made. *Lancet,* Vol. I, #8336, p. 1241, 1983.

KATACALCIN:

Calcitonin is a potent calcium-lowering peptide which plays a major role in regulation of plasma and skeletal calcium concentrations. Another hormone has been identified which is excreted when calcium levels increase. Named katacalcin, the newly-discovered hormone seems to augment calcitonin activity and thus may be useful in the treatment of various types of bone disorders. *Lancet,* Vol. I, #8329, p. 846, 1983.

CIMETIDINE INTERACTION:

Cimetidine (Tagamet) has been implicated in several drug interactions, generally potentiating the effects of other drugs. An interaction has been reported between imipramine (Tofranil) and this H-2 antagonist. The elimination half-life of the antidepressant was doubled in the presence of the antihistamine. The same phenomenon has been found to occur between cimetidine and phenytoin. *Drug Ther,* Vol. 13, #5, p. 157, 1983.

ALPHA-2-RECEPTORS:

Clonidine, an alpha-2 stimulant, was found to control pharmacologically induced diarrhea in animal models. The activity is thought to be due to the presence of alpha-2 receptors in the GI tract and is inde-

pendent of other mechanisms governing gastrointestinal motility. It has been only a short time since the alpha-2 receptors have been identified, but already significant roles for these receptors have been postulated. *J Pharmacol Exp Ther,* Vol. 225, #2, p. 269, 1983.

NAPA:

The metabolite of procainamide (Pronestyl) is N-acetylprocainamide, a substance which has been used for almost a decade as an antiarrhythmic agent itself. The metabolite is less likely to produce lupus, and lacks the negative inotropic effect of procainamide. It is effective when used three times daily. Gastrointestinal side-effects are similar for both drugs. N-acetylprocainamide (NAPA) has been found to be safe and effective for long term treatment of ventricular arrhythmias. *Clin Pharmacol Ther,* Vol. 33, #5, p. 565, 1983.

NADOLOL ELIMINATION:

The elimination of nadolol (Corgard) has been studied to determine if it participates in the enterohepatic circulation. Administration of activated charcoal decreased the bioavailability of nadolol while pretreatment with erythromycin and neomycin increased the peak plasma concentration. It is concluded that nadolol does participate in the enterohepatic circulation. *Clin Pharmacol Ther,* Vol. 33, #5, p. 585, 1983.

PROSTAGLANDIN SYNTHESIS:

In a healthy person, there exists a balance between the vessel wall production of prostaglindin I-2 and thromboxane A-2 which is released by the platelets. A disturbance in this balance may lead to disease of both the vessel and the platelet. Nicotine, as obtained from cigarette smoke, was found to inhibit prostaglandin I-2 formation in the vascular wall and thus may be a factor in the development of accelerated cardiovascular disease seen in smokers. *Lancet,* Vol. I, #8336, p. 1248, 1983.

NIFEDIPINE:

Patients were placed on placebo medication and then on various doses of nifedipine (Procardia) to determine the relative effectiveness of various doses on exercise tolerance. Ten patients with stable angina participated in the study which showed that in some patients higher doses of the calcium channel blocker actually produced less benefit than lower doses. One should be careful to titrate the dose of this drug to obtain maximal benefit. This type of effect is sometimes described as a "therapeutic window". *Br Med J,* Vol. 286, #6376, p. 1476, 1983.

METOPROTERENOL:

Metoproterenol is a more specific beta-2 adrenergic agonist which has been used successfully to treat asthmatic patients. The drug has been reviewed by the FDA and they have proposed it be marketed as an OTC product. The drug is superior to epinephrine for patients with certain types of airway obstructions. *FDC Rep,* Vol. 45, #24, p. 14, 1983.

ASTHMA:

Two agents generally used because of their ability to relax vascular smooth muscle were administered to patients with exercise-induced asthma. Isosorbide dinitrate and isoxsuprine were found to be effective in preventing the attacks associated with treadmill exercise. The drugs were administered via aerosol inhalation. *Br Med J,* Vol. 286, #6382, p. 1935, 1983.

ORAL INSECT REPELLANTS:

The FDA has classified as ineffective preparations containing thiamine hydrochloride for use as insect repellants. The claims made for the products were found to be misleading and there seems to be no evidence to show that vitamin B-1 works in any way to repell insects and/or mosquitos. *FDC Rep,* Vol. 45, #24, p. T&G 9, 1983.

PYRIDOXINE TOXICITY:

Toxicity produced by administration of water soluble vitamins is seen infrequently. However, recent reports have appeared in which seven patients were found to have pyridoxine (Vitamin B-6) toxicity due to excessive ingestion of the vitamin. Patients developed sensory or neuropathic syndromes. *N Engl J Med,* Vol. 309, #8, p. 445, 1983.

DAZOXIBEN:

A new class of prostaglandin inhibitors has been introduced with the experimental use of dazoxiben. The new agent does not affect cyclooxygenase as does aspirin and the NSAID drugs, but it selectively inhibits thromboxane synthetase thus preventing platelets from synthesizing thromboxane A-2, a potent aggregator. Prostacyclin levels are not affected. *Hosp Formul,* Vol. 18, #7, p. 683, 1983.

OXYGEN CONCENTRATORS:

Oxygen concentrators are devised about the size of a small refrigerator which separate nitrogen from the air on a "molecular sieve" thus producing oxygen in concentrations approximating 90%. Patients who formerly used oxygen cylinders for oxygen sources found the new device to be more acceptable for home use. The oxygen concentrators may also be less expensive to the patient with a chronic need for oxygen. (A firm in St. Louis is manufacturing these units). *Br Med J,* Vol. 287, #6390, p. 459, 1983.

ZINC

More evidence has accumulated which suggests that the zinc ion may play an important role in the functioning of special senses. Zinc is said to be necessary for maintenance of vision, taste, saliva production and smell. *Ann Intern Med,* Vol. 99, #2, p. 227, 1983.

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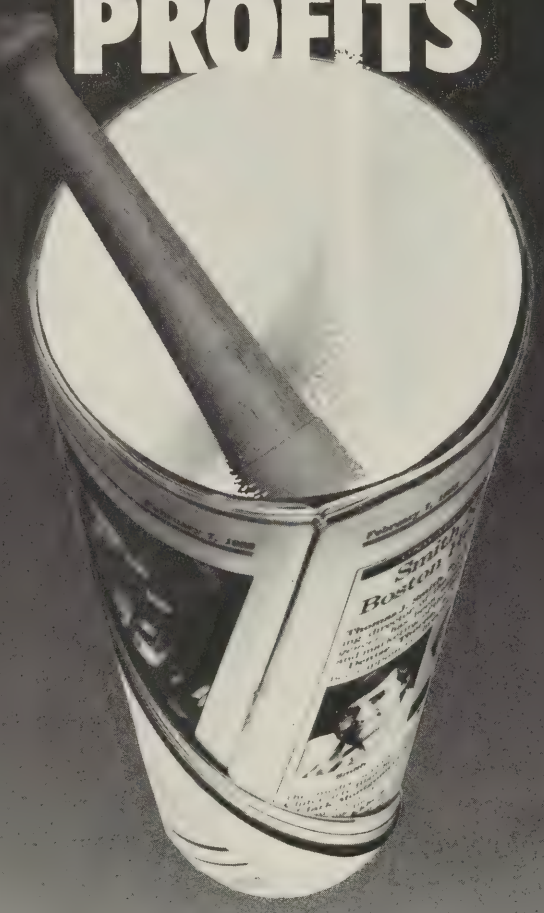

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Jan. 29—MPhA MID YEAR MEETING, ANNAPOLIS HILTON
March 11—BMPA Annual Banquet, Bluecrest, Pikesville
March 16–18—AZO Fraternity Regional Convention—Hyatt Hotel, Baltimore
March 18—CE Seminar—Fritz Berman Seminar—Hyatt Hotel, Baltimore
April 1—CECC Seminar—Critical Care—Timonium Holiday Inn
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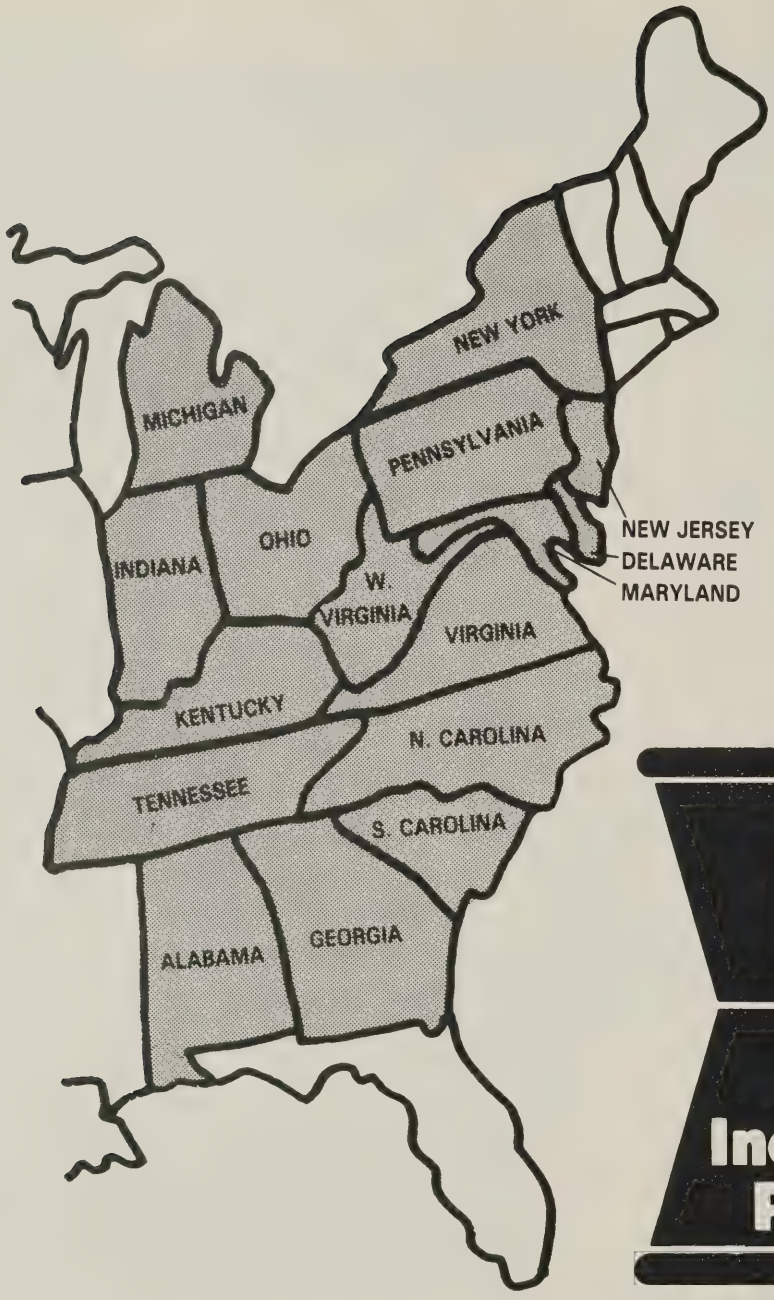

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February, 1984
VOL. 60
NO. 2

Counseling Patients on Dermatitis and its Treatment

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A SIGN OF THE TIMES

The other day Mr. James Cope approached me in our pharmacy and directed my attention to the old neon sign, suspended high above our store. "Bill, the rest of your store looks fine, but why don't you fix up your old sign. It surely needs a paint job."

I explained to Mr. Cope that the historical society had requested me not to turn on the neon sign some ten years ago, and that I had not given it much thought in recent years. Taking another look, I had to agree, the old sign did need attention!

My memory began to light up with vivid images of the past. It was the Winter of 1933 and snowing as my father and I rounded the corner and approached the store, his new sign was sending forth a spectrum of brilliant colors dancing on the snowflakes. Through the eyes of an eight-year-old, this was truly the most beautiful site in the world.

The country was just beginning to recover from The Great Depression—the good news was prices were low; the bad news, no one had any money so it didn't make any difference. It was truly a time that tried men's souls.

Pharmacists during The Great Depression worked long, tiring hours for little gain. They were an important part of a great family of Americans trying desperately to survive.

Through their efforts, pharmacy has endured not only The Great Depression, but is today one of the most respected professions of this country.

As pharmacy moves into the computer age and high technology takes over many of the manual chores, let's not forget that we are truly our brother's keeper.

In truth, the old drug store building has changed some through these years; the once red brick now holds white paint, colonial window panes now add a touch of Williamsburg, but the old neon sign, even though unlighted, still remains for me, a sign of the times!

William C. Hill, P.D.

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Counseling Patients on Dermatitis And Its Treatment

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Goals

The goals of this lesson are to:
1. Discuss the etiology and treatment of dermatitis.
2. Review the pharmacology and therapeutics of drugs used to treat dermatitis

Objectives

At the completion of this lesson, the successful participant will be able to:
1. Choose the appropriate OTC agent for treating minor dermatitis.
2. Explain the proper technique for applying these OTC agents.
3. Decide when the consumer should be referred to a specialist.

in the service of pharmacy

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Allergic conditions involving the skin are among the most common of all afflictions suffered by Americans. Basically, the typical dermal reactions occur in a manner similar to allergic reactions elsewhere in the body. Unfortunately, they are not only discomforting because of their symptoms such as itching, which may be severe and unrelenting, but they also may impair physical functioning and limit personal and occupational activity. For example, thickened fissures caused by repeated dryness or allergic reactions on the hands of musicians can greatly limit their performance; a weeping rash on the face of a public official may cause great consternation. Likewise, a person with atopic dermatitis experiences the constant fear that he or she will trigger the condition which produces severe symptoms lasting many months. This in turn can and has led to the onset of adverse behavioral tendencies.

Many of these persons can receive relief through the use of OTC products, so it is important for the pharmacist to be aware of basic information regarding the causes and treatment of allergic skin disorders. There should also be an awareness of the over-all care the patient with skin allergies may require.

This month's lesson focuses on two specific dermatologic conditions of allergic origin: contact dermatitis and atopic dermatitis. **Dermatitis** may best be defined in its generic sense as any inflammatory condition of the skin. The term **eczema**, while frequently used interchangeably with dermatitis, refers to inflammed skin that is also characterized by lesions varying greatly in their appearance, amount of vesiculation (blistering), presence of weeping, and the development of scales and crusts.

Atopic dermatitis is a specific form of dermatitis characterized by its intense symptoms of dry skin and itching, and its association with asthma and hay fever.

Last month's lesson reviewed the skin's structure and function, and the importance of maintaining a normal hydrated state. Many of the symptoms associated with dermatitis (e.g., rash, itching) are the same as those caused by dry skin, and their management is similar.

The term **contact dermatitis** actually refers to any rash that results when a substance touches the skin. The resulting reaction may be either allergic or nonallergic in nature. **Allergic contact dermatitis** is caused by the body's immune system responding in a typical allergic manner and is also referred to simply as **contact dermatitis. Nonallergic dermatitis,** on the other hand, produces irritation and inflammation through non-immunologic mechanisms and is generally referred to as **irritant dermatitis**. Irritant-induced skin damage may result from a single contact with a strong acid or alkali (e.g., battery acid, toilet bowl cleaner), or from repeated exposures to milder irritating agents (e.g., laundry detergents, bleaches). Since irritant dermatoses are not allergic in nature, they are not discussed further in this lesson. However, it should be remembered that any irritant can cause dermatitis by both allergic and nonallergic mechanisms.

Contact Dermatitis

Contact dermatitis is widespread, but its incidence varies greatly among countries. Part of this differ-

ence is due to its allergic (and hence, at least partially, genetic) nature. The other consideration relates to the geographical location of the specific allergen. For example, Europeans who do not leave the continent do not get poison ivy or oak because these plants do not grow in Europe. Americans, on the other hand, are exposed to these plant allergens in many outdoor areas during most seasons of the year.

Contact dermatitis due to nickel-based jewelry (e.g., earrings, watch bands, rings) and to dishwashing soaps and detergents is more common in women, although males are generally more easily sensitized to chemicals. Persons with chronic skin disorders are also more reactive to drug-induced contact dermatitis, probably because they use topically applied medicaments more frequently. The very young and the elderly are less easily sensitized than middle-aged adults.

The incidence of contact dermatitis in Americans due to allergenic substances normally found as components of numerous products around the home is shown in Table 1. Poison ivy-oak contact allergy will be discussed in a future lesson as a separate topic. Plants, including poison ivy and oak, are the most common cause of contact dermatitis in America.

Common Causes. Following plants, topical medicaments are the next most common cause of allergic skin inflammation. Actually, quite a large percentage of people may be involved (Table 1). The type of medicament-induced dermatitis varies with what's in vogue at the moment. Whereas dermatoses to sulfadiazine and scarlet red were fairly common during the 1940's, they are no longer seen. Rather, neomycin, in common use in topical products today, is among the leading sensitizers. Not only may the active ingredient induce an allergic reaction, but the various preservatives (e.g., parabens, thimerosal, etc.) found in medicaments can be sensitizers as well. Furthermore, systemic medications may cause contact dermatitis. Health professionals who have come into frequent contact with injectable chlorpromazine or streptomycin in hospitals or nursing homes have become sensitized to them. There is some indication that pharmacists who open pressure-sealed bottles of penicillin or other antibiotic powders that are to be reconstituted may be sensitized to that substance.

TABLE 1

Incidence of Contact Dermatitis Due to a Variety of Common Allergenic Substances*

Substance	Percent of Positive Respondents
Medicaments	
Neomycin sulfate	6
Ethylenediamine hydrochloride	7
Thimerosal	8
Benzocaine	5
Wool alcohols	3
Parabens	3
Metals	
Nickel sulfate	11
Potassium dichromate	8
Rubber Chemicals	
Mercaptobenzothiazole	5
Tetramethylthiuram	4
Other	
Formalin	4
p-Phenylenediamine	8

*Rudner, EJ *et al*: Epidemiology of contact dermatitis in North America, 1972. *Arch Dermatol*, 108:537, 1973

Additionally, sensitizing antimicrobial agents may be applied to the skin either directly during treatment of an infection, or indirectly as a common preservative ingredient in a large variety of household products. Thus, soaps, toothpastes, skin creams, etc. may contain sensitizing agents and cause contact dermatitis reactions.

Another frequent cause of contact dermal allergy is exposure to jewelry containing nickel. This can occur during ear piercing and the subsequent wearing of earrings. Cosmetics such as perfumes, deodorants and hair care products are sensitizers in both men and women. With the perfume fragrances, while any component may be sensitizing, the preservatives and stabilizers are mainly at fault.

Mechanism of Sensitization. Sensitization is the result of chemical reactions within the body. The chemical (hapten) combines with a skin protein to form an antigen. These hapten/protein antigens are transported to lymph nodes where they cause the cells (lymphocytes) to become altered. These, then, are transported throughout the body to produce skin sensitivity. Once sensitization has occurred, exposure to the offending chemical on subsequent occasions may produce a reaction within seconds or be delayed for days. While some sensitivities remain throughout life, others decrease with time becoming less severe. The patient may eventually become tolerant (desensitized).

Contact dermatitis is often difficult to properly diagnose since its cause may be very elusive. Occasionally the sensitizing substance may be an airborne pollutant. In this instance, the resulting dermatitis may appear at any site on the body, and the actual cause is not readily identified. When confronted with an otherwise unexplained rash or area of itching, the physician may consult a chart similar to that in Table 2, containing information on common causes. Once a "probable" allergic cause is suspected, it can then be confirmed by patch testing. For this, the specific substance is injected under the skin on an uninvolved portion of the body and the skin is carefully observed for the appearance of inflammation.

Accurate diagnosis is also often hampered because the contact dermatitis is superimposed over another skin disorder. Thus, a minor topical infection causing a rash and itching may be treated with an antibacterial chemical product which is sensitizing in its own right. This agent then induces further skin irritation and inflammation leading to even more itching. While the infection may be healing, the rash (contact dermatitis) worsens, and the patient's normal response is to apply more of the medication. An endless but worsening cycle insues whereby the patient continues to further incite the inflammatory condition. Pharmacists should advise patients that when the condition does not clear up, but instead worsens in spite of drug therapy, the chance for a contact dermatitis is great. Physician intervention and withdrawal of the medication may be in order.

Treatment. A **topical steroid** prod-

TABLE 2

Regional Areas for Contact Dermatitis and Common Causes

Armpits — Deodorants, depilatories, garments, dress shields
Anal area — Hemorrhoid products
Body — Garments (dyes, formalin, rubber in elastic)
Face — Cosmetics (including aftershave lotions), plants, topical medicaments
(a) **Ear** — Nickel earrings, perfume, earplugs, earphones, telephone receiver
(b) **Eyelids** (more common in women) — Eye cosmetics, face creams, and lubricants are major causes; hair spray, nail polish
(c) **Forehead** — Hatbands, hair lotions, etc.
(d) **Lips** — Lipstick, lip protectants, toothpastes, gargles
Feet — Shoes, shower sandals, stockings, slippers, athlete's feet remedies
Genital — Contraceptives (creams, rubber diaphragms, condoms), douches, tampons, "Jock itch" remedies
Hands — Topical medicaments, hand lotions and lubricants, soaps and detergents, rubber gloves and rubber bands, plants
Neck — Perfume, jewelry, clothing
Scalp — Hair products and cosmetics. The scalp is relatively resistant to contact dermatitis, so most symptoms occur on forehead and scalp edges.

uct is the treatment of choice for most mild cases of contact dermatitis, as well as for the latter stages of severe disease. They are best applied in a thin layer, immediately after bathing or using a wet dressing, usually four to six times daily. Fluorinated creams or lotions (all require a prescription) are frequently prescribed for initial treatment of areas anywhere on the body except the skinfold areas (groin, armpits) where there is occlusion. Hydrocortisone products may be more appropriate on affected areas in these locations because there is less systemic absorption. It should also be pointed out that numerous authorities still recommend a hydrocortisone product for use on all affected areas regardless of their location. A product containing one-percent hydrocortisone (Rx-only) may be employed initially to treat the acute phase, followed by a product of one-half percent concentration (OTC) once the acute phase has passed. In this instance, the pharmacist can be a valuable source of counsel to assist the patient in choosing the most appropriate and economical product.

Systemic corticosteroids are frequently prescribed to help manage blistering, swelling and oozing associated with the acute stage of severe contact dermatitis. Their use is generally limited to short periods of time. Except for extremely severe reactions, topical products are preferred because they can be applied directly to the affected area. There is far less chance for systemic steroid toxicity.

OTC Hydrocortisone Products. The switch of 0.5 percent hydrocortisone from perscription-only to OTC status has created one of the more unique chapters in medical history. The FDA Advisory Panel on Miscellaneous External Preparations determined in 1978 that, based on evidence it had reviewed over a several year period, the use of 0.5 percent topical hydrocortisone products by American consumers without direct physician supervision was a safe and effective means of treating minor inflammatory and itching conditions.

While FDA has not yet "officially" acted on the panel's recommendation to switch such products from prescription-only to OTC status, the agency is allowing manufacturers to market hydrocortisone products while it is reviewing the data and formulating its official position. All indications point to final approval.

In the meantime, sales of OTC hydrocortisone products have exceeded $50,000,000 yearly. Further, one spokesman for the pharmaceutical industry has claimed that their availability has saved consumers almost $650 million during 1980-81, based on time that would have been lost waiting in the physicians' offices, physicians' fees and prescription costs.

On the other hand, the fear of side effects due to improper and excessive use of OTC hydrocortisone products has not yet materialized. So, in spite of the initial controversy, it appears that the benefit-to-risk ratio for consumers self-medicating with hydrocortisone products is in favor of the benefits of relief of their minor inflammatory ailments.

Nonetheless, several items should be kept in mind to maximize these benefits and minimize the chances of adverse effects. The patient should be advised to apply a thin film and massage it into the skin thoroughly, three or four times a day.

Before using an OTC hydrocortisone product, the patient should make sure there is no infection in the area because steroids inhibit the body's ability to protect itself against microbial invasion. Telltale signs of a bacterial or fungal infection include redness, crusting, scaling, pus, and a great deal of localized heat.

The product should not be overapplied. The manufacturers must warn on the label against continued use for a period longer than seven days. This is good advice for two reasons. First, if the condition does not clear by then, it is undoubtedly something more complex than simple dermatitis and may require specialist intervention. Second, although it is estimated that one percent or less of a given amount of hydrocortisone applied to the skin is absorbed, the potential for systemic side effects warrants this limitation.

This is especially true in children. The labeling of hydrocortisone products states that they should not be used in children under the age of two. Since children are at a period of rapid development and skin growth, they are much more susceptible to absorption of all steroids including hydrocortisone. Growth retardation has occurred with topical steroids (not with hydrocortisone), but the products have never before been available for unsupervised self medication. These products should **not** be used for treating diaper rash without the approval of the baby's physician. While it may be "cheaper" to use them than to seek medical advice, the moisture and occlusion of the area greatly enhances the chance of absorption. Petroleum jelly or other non-medicated skin protectants should work just as well for minor diaper rash.

The point of occlusion is important for persons of all ages. Occluding the area of topical application of nearly all drugs, including hydrocortisone, leads to its movement in only one direction —downward through the skin to be systemically absorbed. Occlusion increases absorption and the potential for side effects. Its use should be reserved for physician su-

pervision situations.

Placing these points in proper perspective, however, leads to the conclusion that, properly used, OTC topical hydrocortisone products are safe and effective for temporary relief of minor skin irritations including dermatitis. They do prevent further inflammation in most instances allowing the body to correct the problem on its own.

For those persons requesting advice on which type of product to select, creams are the most commonly used vehicles because of patient acceptance. They are non-greasy, rub in easily, and do not leave much of a residue on the skin. They are appropriate for nearly all types of dermatitis conditions and can be applied to any area of the body. The lotions are best for chafed areas, and for the scalp or other hairy areas because they spread easily. The ointments are preferred for dry, scaly lesions since they hold some moisture to the skin, and are more emollient.

Other Therapies. Oral antihistamines such as trimeprazine and diphenhydramine may have some value in treating contact dermatitis. Several days of therapy are often required before relief from itching will be experienced. The reason for this is that histamine, which is causing the itching, is already stimulating its receptor sites in nerve endings. Antihistamines must displace histamine from these receptors and, in normal therapeutic doses, this may require several days. The pharmacist should point this out to a patient receiving antihistamines for the first time and recommend compliance. The pharmacist should also inform the patient of the drugs' potential for causing drowsiness.

Topical antihistamine cream and ointment use is not justified in treatment of contact dermatitis. They may induce a slight antipruritic response, but they do not suppress contact-type allergy. They are also sensitizers and may exaccerbate the patient's existing condition. Topical local anesthetic products have a similar sensitizing potential. Thick "shake lotions" such as calamine lotion should be avoided since they dry to a firm crust that may increase discomfort and itching. The crust may also strip off granulation tissue needed for healing and cause bleeding when it is removed. Both of these will worsen the condition.

In the early stages of severe inflammation (acute dermatitis), especially when there is extensive blistering, topical steroids may not be adequate because they cannot readily penetrate into the skin. Thus, soaks or baths can be used until blistering and swelling are brought under control with systemic steroids.

Antipruritic Baths immediately help relieve itching and leave a cooling sensation which often lessens the itching for many hours afterwards. Patients using them should be advised to closely follow the manufacturer's directions and take extreme care when getting into or out of the bathtub, as it may be extremely slippery. The water temperature is also important and should not exceed lukewarm.

Wet dressings relieve itching and rehydrate dry skin and can be employed almost anytime during the day without having to subject the entire body to the bathing process. Several agents are available (Table 3) which may bring almost instantaneous relief from itching, and help manage weeping lesions if present. Again the solution should be cold or lukewarm, never hot.

TABLE 3
Wet Dressing Solutions

Preparation	Concentration
Boric acid*	1-2%
Burow's (aluminum acetate)**	1:40 to 1:20
Potassium permanganate*	1:10,000 to 1:5,000
Silver nitrate*	1:1000 to 1:800
Sodium chloride	0.9%

*Should only be used on recommendation of a physician.
**1 tablet/packet to 500 ml = 1:20
1 tablet/packet to 1000 ml = 1:40

Any nonirritating cloth (e.g., towel, strips of bed sheet, gauze, etc.) can be used as a wet dressing. The cloth is dipped into the solution and lightly wrung out. It is normally applied to the affected area and left in place for 15 to 20 minutes, then removed. Applications longer than 20 minutes should be avoided since the skin may become irritated from the solution itself (e.g., the aluminum salts in Burow's solution may become concentrated on the skin to cause irritation as the solution evaporates). Wet dressings can be applied four to six times a day, or more frequently if the physician advises.

Another remedy that can effectively relieve itching, especially during the latter stages of an inflammatory response, is the application of very cold tap water or ice packs.

Atopic Dermatitis

The term **atopy** was coined in 1925 to describe "a strange disease", although the disorder had been recognized as a clinical entity since the late 1800's. In its basic form, **atopic dermatitis** is a chronic, hereditary, distinguishable form of eczema that produces severe itching, and is usually associated with **asthma** and **allergic rhinitis** (hay fever). These three symptoms are classic for the disorder, and their presence provides for a probable diagnosis. In addition, dry skin and increased vasoconstriction of the skin may be seen. Persons with atopic dermatitis can also produce antibodies to a wide variety of common irritants. The condition is definitely genetically controlled since 40 to 45 percent of family members of atopic dermatitis patients exhibit at least one of its classic manifestations (severe itching, asthma, or hay fever).

Clinical Manifestations. Atopic dermatitis is most prevalent during childhood and early adulthood, but it may occur in any age group and it is generally categorized into three phases: infantile, childhood and adult.

The infantile phase appears during the fourth to sixth month of life. The scalp first begins to scale heavily. An erythematous weeping, pruritic rash appears on the infant's cheeks, then spreads to the forehead and the arms and legs. This type of dermatitis generally disappears by five years of age.

The childhood phase frequently begins between ages 2 and 4, extending from the infantile phase, or beginning from scratch with no prior symptoms. This form is characterized by a rash with flaking skin appearing on the extremities as well as on the face. Lichenification (discussed below) can occur especially on the legs and ankles. This phase often disappears by age 10, though it

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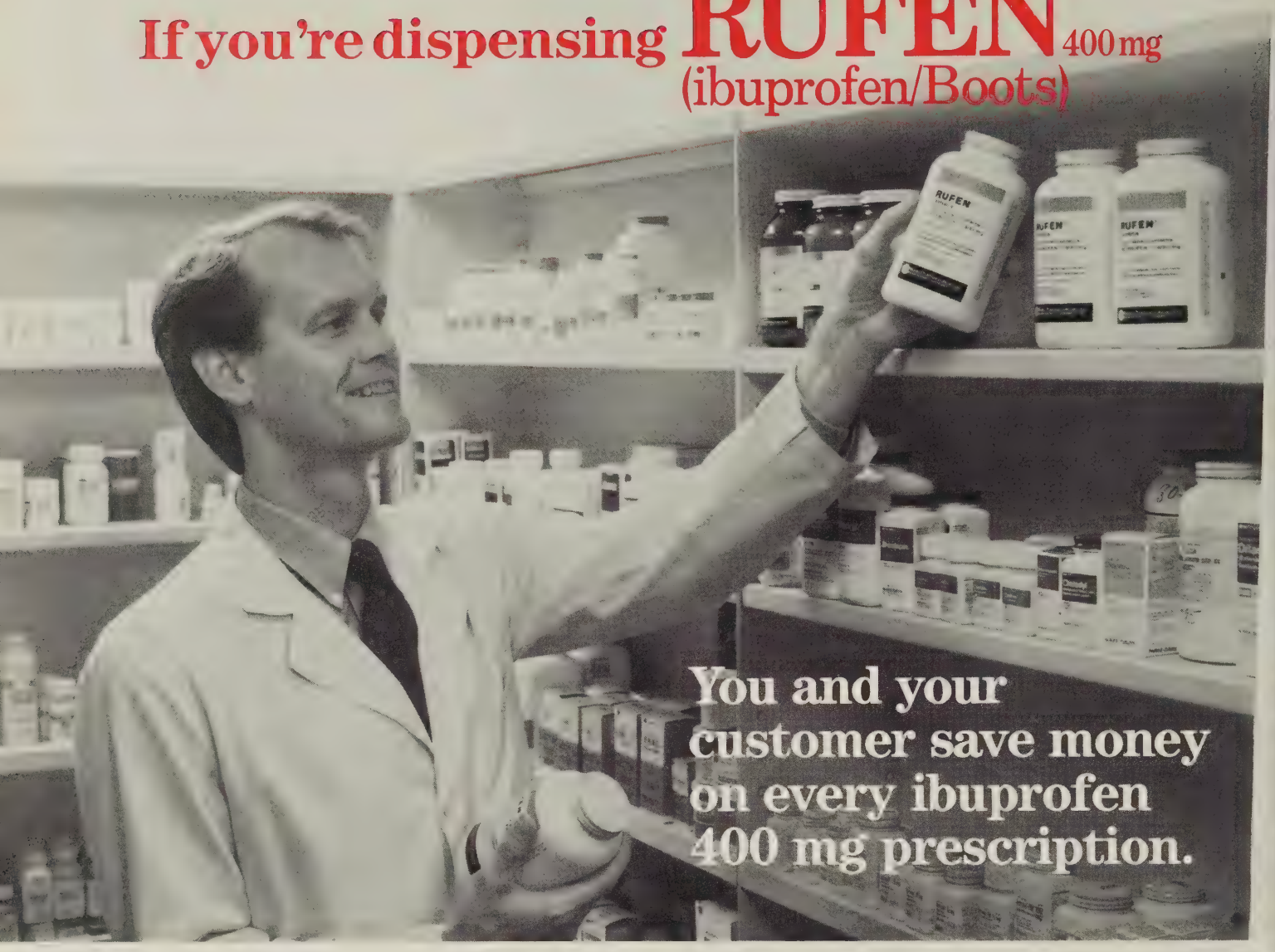

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may continue into adulthood.

Adult atopic dermatitis is best described as widespread, highly pruritic, confluent papules (elevated solid patches) and extensive lichenification that affects the wrists, feet, neck and forehead.

The major symptom of atopic dermatitis is intense and prolonged itching that occurs at a stimulation threshold far less than that normally required to induce it in a normal individual. Because the natural response is to scratch an itch, a series of events known as the "itch-scratch" cycle is set into motion. Once the scratching stimulation is started, the itch is only temporarily relieved and returns momentarily. This then causes more scratching which induces even more itching, and the cycle continues. If scratching persists for only a day or so, the skin experiences no long-term damage. However, if the individual continues to scratch or rub the area even slightly, for a prolonged period, **lichenification** develops. This condition was described in last month's lesson, but it is important enough to review once again. Lichenified skin is dry, smooth, hard and almost "shellac-like" or leathery in appearance and texture. It receives its name from a similarity to the fungus *lichen planus* that grows on the bark of trees. It is caused by the constant dermal irritation which induces cellular atrophy. As more and more of the skin's cells are destroyed and accumulate one on top of the other, the keratin layer ("horny covering") becomes hardened and thickened. Since moisture cannot penetrate into the thickened horny layer, the skin becomes dryer and itching persists. Sweat cannot be secreted readily through its duct work system as it should; so it accumulates beneath the skin for prolonged periods to cause further irritation to the nerve endings and more itching. The skin condition is usually worse in the winter (when the relative humidity is lower) and improves during the summer when humidity is higher. Unfortunately, accumulation of sweat during the summer months can cause **miliaria** (acute, inflammed sweat glands which lead to a prickling or tingling sensation).

Atopic patients also have increased fine creases and lines on the palms and fingers. They are most likely due to the dry skin. Fingernails appear buffed and shiny, probably as a result of constant scratching.

Complications. Patients with atopic dermatitis have an increased incidence of cutaneous bacterial and viral infections. *Staphylococcus aureus* is the most frequently encountered bacterial pathogen leading to impetigo, folliculitis (inflammed hair follicles), and abscesses.

A wide variety of viral infections occur in these patients. One of the more important such infections is **eczema herpeticum** caused by *herpes simplex*. The disorder varies in severity from mild, transient illness to fatal involvement of the brain, liver, lungs, gastrointestinal tract and adrenals.

Treatment. It is estimated that between 1 and 3 percent of Americans are afflicted by atopic dermatitis. Its symptoms are sufficiently severe that most will seek physician advice and care. Since it is such a morbid, long-term disease, most of the therapeutic regimens will be via prescription drugs. However, the use of OTC topical hydrocortisone products (discussed earlier) and general measures for alleviating dry skin may be involved.

Another extremely important factor for these patients is psychological support since each flare-up of the disorder may cause symptoms lasting several months.

Preventative measures are very important, especially avoiding as many of the common triggering factors listed in Table 4 as possible. Correct humidification of environmental air is important since both high and low relative humidity can elicit an attack. This is one of the reasons why some individuals with extreme atopic conditions move to warmer environs, where the humidity does not fluctuate as much as in northern climates.

Clothing, bed coverings, and other items which come in contact with the skin should be nonirritating, washed with mild soaps, and thoroughly rinsed. Other environmental factors such as pollen sources which incite respiratory or dermal allergies should likewise be avoided.

TABLE 4
Triggering Factors for Atopic Dermatitis

Allergens
Detergents
Exercise with sweating
Hot water
Heat and humidity
Infections
Rough clothing
Soaps (e.g., antibacterial, highly perfumed, etc.)
Sudden temperature changes
Stress

During the acute phase, since there is a great deal of weeping from the lesion, application of a wet dressing (e.g., Burow's solution) can be effective in controlling itching. Proper use of wet dressings was discussed earlier.

While it is recommended that systemic steroids be avoided in these patients (because of the long-term symptoms), after controlling acute manifestations, the application of topical steroids with occlusion is indicated for the subacute phase.

Some physicians utilize coal tar derivatives in combination with steroids. This form of therapy has declined in popularity amidst a great deal of controversy since coal tar derivatives, by themselves, are sensitizers and may worsen the condition. If they are prescribed, the patient should be advised that they can permanently stain whatever clothing they come in contact with.

An alternative treatment used by some dermatologists involves avoiding water, soaps, and all creams and ointments. Corticosteroids are applied in a propylene glycol vehicle and a lipid-free lotion (e.g., Cetaphil®) is used to cleanse the skin. While this regimen may work for some patients, it is no doubt resented by others because of its rigid nature. Excessive dryness of the skin is a common outcome of this therapy.

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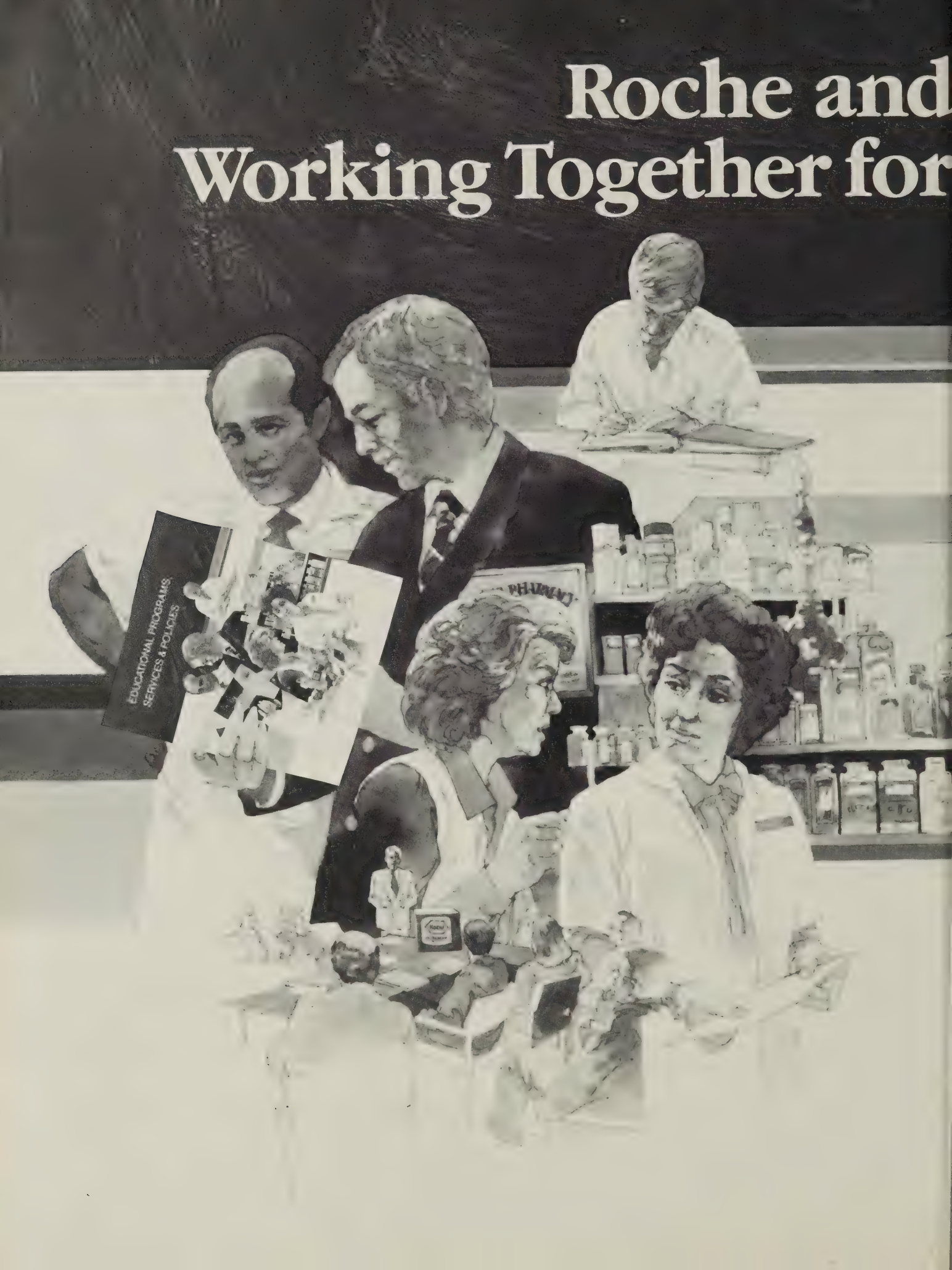

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Alcohol, Medicine and Aging

by Philip P. Gerbino, Pharm. D.

Pharmacists must act aggressively to prevent the complications of combining alcohol and medication in the aging. Even moderate or intermittent alcohol use can be harmful, if the patient is taking potentially interacting drugs.

Interactions

Central Nervous System Depressants

Certain classes of drugs interact consistently with alcohol. The most potentially dangerous reactions occur with those drugs affecting the central nervous system (CNS). Alcohol, itself a significant CNS depressant, produces additive or synergistic effects when combined with narcotics, barbiturates, tranquilizers, antihistamines or other psychotropic agents.

Codeine is commonly used in combination with mild analgestics, to alleviate moderate or severe pain, or as a cough suppressant in prescription and nonprescription cough syrups. The pharmacist should alert patients to the contents of these syrups. Narcotic analgesics produce varying degrees of CNS and respiratory depression and sedation. The combination of alcohol and codeine can be expected to potentiate CNS impairments. Alcohol ingestion with these drugs could be hazardous.

The aging process alters CNS depressant drug pharmacology and the depressant effects of alcohol and other drugs may be enhanced and prolonged in the older patient. As an example, the aging process may change the pharmacokinetics of tranquilizers, such as benzodiazepines. Concomitant alcohol use causes substantial impairment of psychomotor skills, which is especially evident in driving proficiency. Similarly, alcohol and meprobamate, barbiturates or chloral hydrate will compete for metabolizing enzymes, resulting in slower drug clearance and extended drug action.

Although studies have shown increased effects of some CNS depressants in older patients, it is not known whether this group is more sensitive to antihistamine depression than younger individuals. Alcohol will augments the CNS depressive activity of most antihistamines when blood alcohol levels exceed 50 mg/dl. As a comparison, intoxication is associated with levels over 150 mg/dl.

Two or more drinks can be sufficient to induce drug-alcohol interactions. It is not known how much alcohol is required to induce metabolic drug interactions. Since older patients experience varied effects with combined alcohol-psychotropic drug administration, pharmacists should counsel patients to avoid liquor entirely or to use it with extreme caution.

Other Medications

The availability of OTC drugs, their efficacy and low cost compared to prescription drugs have made their use common among older people. For instance, analgesics like aspirin and acetaminophen are taken by millions of older patients routinely for a variety of minor complaints. This trend to self-medicate has placed the pharmacist in the pivotal role of advising patients on alcohol interactions with drugs that are otherwise "generally considered safe."

Aspirin is the active ingredient in many OTC arthritis, headache and cold remedies. Ethanol, which produces gastritis, can potentiate aspirin's well-known negative effects, gastric inflammation, gastrointestinal erosion and gastrointestinal bleeding. Although the magnitude of the interaction is not known, the consensus is the older patient with a history of ulcer or bleeding should avoid chronic aspirin and alcohol use.

To date, no studies demonstrate acetaminophen-alcohol interactions. There have been suggestions that patients with chronic or severe liver disease should not take acetaminophen, but recommended doses of the medication have not worsened underlying disease. The same was true for those patients who are chronic alcoholics. Four grams or less daily failed to produce hepatoxicity.

Alcohol should be avoided by individuals taking warfarin and other anticoagulant therapies because of its association with GI bleeding, red blood cell and platelet abnormalities, anemias, vitamin malabsorption and other coagulation disorders. Since alcohol can change a patient's behavior and cause confusion, if a patient receiving anticoagulants, confuses or miscalculates drug dosage, the result can be either subtherapeutic and ineffective drug concentrations or excessive

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serum levels leading to major bleeding.

The prevention of alcohol-medication interactions is often not possible, since there is little control over the patient's self-prescribing habits. But pharmacists can help by establishing communication with patients, alerting them to the dangers of mixing drugs and alcohol and advising them on the proper use of OTC medications.

Milton S. Moskowitz, 1983 Recipient of ASCP's Berman Award

The American Society of Consultant Pharmacists has selected Milton S. Moskowitz, FASCP as the 1983 recipient of the Society's Richard S. Berman Service Award. This award was established in 1979 in order to recognize the contributions made by dedicated individuals to foster the goals of ASCP and the consultant pharmacy profession.

Moskowitz was presented with the award as well as a donation of $500 to the School of Pharmacy of his choice, at the Annual Awards and Installation Banquet during ASCP's 14th Annual Meeting in Las Vegas, Nevada. These awards are made possible through the support of ASCP Allied Member The Purdue Frederick Company.

Moskowitz is President of Accredited Surgical Company in Silver Spring, Maryland, a pharmacy and surgical supply business which provides pharmaceutical and consulting services to 22 nursing homes and 3,000 long term care patients. He has served in many positions on the Society's Board of Directors including Secretary/Treasurer and President. He is an active spokesman for consultant pharmacy and the Society and is always available to represent ASCP on task forces and committees affecting the profession.

Moskowitz is the fifth recipient of the Richard S. Berman Service Award. Previous recipients are Edward J. Monroe (1982), Phyllis Wilson (1981), Rolf K. Schrader (1980) and Arnold B. Cammeyer (1979).

The Drug House Home Health Care

In this era of increasing hospital and nursing home costs, and the growing preference of convalescing patients for the home environment, THE DRUG HOUSE, INC., an ALCO HEALTH SERVICES company, is offering "TOTAL HOME HEALTH CARE" (THHC) through the Community Pharmacist.

(THHC) provides an unlimited resource of durable medical equipment, software, and consumables used by the home convalescent. Through THE DRUG HOUSE, marketing and distribution services are available on a daily basis to those Pharmacists who become affiliates of (THHC). Home delivery, installation, nursing consultation, direct Medicare billing, and computer service are all part of the (THHC) package. Pharmacy, the oldest of the health professions, has been traditionally the best suited among the health providers to supply the information and material needs of the health consumer, while offering the greatest ease of access to those in need.

(THHC) eliminates the massive space requirements that a Pharmacy would ordinarily need to display and warehouse medical equipment. A modest sized Pharmacy will require minimal space to house a (THHC) facility, but it will nonetheless offer a comprehensive inventory of medical equipment and supplies to the health consumer.

Initially, The Drug House will be testing (THHC) in the Greater Baltimore area, using the Calvert Division of The Drug House as a center of operations. Future expansions of (THHC) are contemplated in all the other Drug House locations, including Pittsburgh, where The Drug House, Inc., now has a 5th Major Distribution Point with the recent acquisition of the Allegheny Wholesale Drug Company.

calendar

March 11—BMPA Annual Banquet, Bluecrest, Pikesville
March 16–18—AZO Fraternity Regional Convention—Hyatt Hotel, Baltimore
March 18—CE Seminar—Fritz Berman Seminar—Hyatt Hotel, Baltimore
April 1—CECC Seminar—Critical Care—Timonium Holiday Inn
April 6–8—NARD Home Health Care Conference, Dallas
May 5–10—APhA Convention, Montreal
June 22–24—MSHP Seminar, Ocean City
June 24–28—MPhA Convention, Ocean City

Every Sunday Morning at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the Pharmacy Public Relations Program "Your Best Neighbor," the oldest continuous public service show in Baltimore.

APhA President Apple Dead at Age 65

William S. Apple, 65, president of the American Pharmaceutical Association (APhA) and prominent pharmacy leader, died of cardiac arrest on Saturday, December 17 at RFK Stadium in Washington, D.C., immediately following the Redskins-Giants football game.

Born in Spokane, Washington, July 28, 1918, and reared in Duluth, Minnesota, Dr. Apple grew up in, was educated in, and spent his working life in the profession of pharmacy. He had been serving as the chief executive officer of the American Pharmaceutical Association, the national professional society of pharmacists in the United States, since 1959, and was scheduled to retire December 31, 1985.

Dr. Apple attended Wayne State University and then transferred to the University of Wisconsin where he received his Bachelor of Science in Pharmacy (magna cum laude) in 1949, his Masters in Business Administration in 1951, and his Doctor of Philosophy—Pharmacy in 1954. He was licensed as a Registered Pharmacist in Wisconsin on July 15, 1950.

Prior to his university education, Dr. Apple enlisted as a private in the U.S. Army and rose to the rank of lieutenant colonel after his graduation in 1944 from the Command and General Staff School of Fort Leavenworth, Kansas. He served almost four years in the Pacific Theater during World War II, including assignment on the staff of Fleet Admiral Nimitz.

Dr. Apple joined the faculty of the University of Wisconsin in 1950 as an instructor, then as assistant professor, and finally as associate professor where he served as the first head of the Department of Pharmacy Administration. During this period he also served as president and chairman of the Board of the Wisconsin Pharmaceutical Association.

Early in 1958 Dr. Apple was elected the executive secretary of the Wisconsin Pharmaceutical Association, but before he assumed that position, he was selected as the secretary-nominate of the American Pharmaceutical Association, a position he held from July 1, 1958, to August 23, 1959, when be became APhA's chief executive officer.

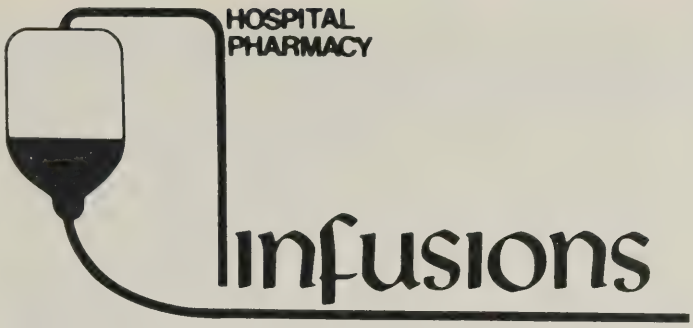
During his tenure of service, Dr. Apple received every major award in the field of professional pharmacy, held numerous offices in the health services area, and was awarded Honorary Doctor of Science degrees from both Long Island University in 1966 and from Union University in 1969. He served as president of the American Council on Pharmaceutical Education from 1964 to 1969; member of the Board of Directors and vice-president of the National Health Council from 1961 to 1968; and secretary, vice-president and president of the National Drug Trade Conference from 1967 to 1970.

Dr. Apple received worldwide recognition for his contributions to pharmacy. He served as a member of the Council from 1959 to 1977 and as vice-president from 1974–1978 of the International Pharmaceutical Federation; as a member of the Board of Directors and vice-president of the American Association for World Health from 1970 to 1978; and was made an Honorary Member of various foreign pharmaceutical associations, including those of Chile in 1961, Japan in 1971, Canada in 1975, and Great Britain in 1976.

His professional and honorary memberships include Phi Lambda Upsilon, Rho Chi, and Phi Kappa Phi. His awards include *American Druggist* Man of the Year (1961 and 1967—the only recipient to be twice selected), and J. Leon Lascoff Memorial Award (1961), Rho Pi Phi Man of the Year (1961), the Wayne State University Distinguished Service Award (1962), the University of Wisconsin Citation (1965), the Hugo H. Schaefer Medal (1966), and the Remington Honor Medal (1967).

Dr. Apple testified more than 50 times before congressional committees; served as a consultant to the U.S. Department of Health, Education and Welfare (now Department of Health and Human Services) as well as to many foreign government officials; and published more than a hundred articles and presented hundreds of lectures around the world.

Survivors include his wife, the former Lucille Josephs of Phillips, Wisconsin; a brother, Sam Apple of St. Paul, Minnesota; a sister, Vivian Libby of Detroit, Michigan; a daughter, Chandra Eden Apple (age 16), and a son, Hugh Charles Apple (age 15), who reside with their mother at 6423 Crosswoods Drive, Falls Church, Virginia 22044. The American Pharmaceutical Association office is located at 2215 Constitution Avenue, N.W., Washington, D.C.



Information contributed by the Maryland Society of Hospital Pharmacists.

Lawrence Green
Clinical Pharmacist
Johns Hopkins Hospital

A Rational Choice of Antiemetics for Chemotherapy-Induced Emesis

Nausea and vomiting are dose-limiting toxicities in many cancer chemotherapy regimens. These side effects of cancer treatment have become an increasing problem as a result of more aggressive therapeutic modalities. Standard anti-emetics have not provided satisfactory control of nausea and vomiting in all patients. However this may be due, in some circumstances, to a misunderstanding and the inappropriate use of currently available anti-emetics.

Vomiting is initiated after the vomiting center (VC) is stimulated from the chemoreceptor trigger zone (CTZ), a specialized chemosensor, the vestibular center or from other chemosensory inputs. Anti-emetic therapy, therefore, should be directed at blocking input to the vomiting center. However, because of the multifactorial nature of chemotherapy-induced emesis, no single antiemetic regimen designed to block one set of inputs can be expected to provide total relief.

The antihistamines, anticholinergics and antidopaminergics are the three major drug classes which are used as antiemetics. The ability of these agents to relieve emesis presumably relates to the high density of dopamine, histamine, and cholinergic receptors in the CTZ, VC and vestibular center[1]. It follows that pharmacologic blocade of one or more of these receptors may provide antiemetic efficacy. Unfortunately, no known single drug can simultaneously and adequately block dopamine, histamine and cholinergic receptors. For example, scopolamine has a high affinity for muscarinic cholinergic receptors but practically no affinity at dopamine and histamine sites. Haloperidol and droperidol are relatively specific dopamine antagonists. Other antiemetics, such as promethazine may be active at two of the three receptors. Simultaneous blockade of all three receptors is only accomplished by using a drug combination. Drug combinations such as prochlorperazine and diphenhydramine or fluphenazine and nortriptyline can accomplish such a blocade and have reportedly been effective in limited clinical studies[2]. It appears logical to use combinations such as these to maximize antiemetic actions in the central emetic pathway. Using two drugs from the same class or with the same receptors blocking profile however would be inappropriate.

There are some problems with the hypothesis of multireceptor blockade which must be considered. First, gut stimulation can also participate in chemotherapy-induced emesis. Specific neurotransmittors have not been identified in these pathways. Second, there are at least thirty substances that are potential factors found in the brain stem which may play a role in nausea and vomiting[3]. The exact mechanism of synaptic transmission in the central nervous system is far from being well understood. Obviously there is still much to be learned about the physiology of emesis.

Other antiemetic agents such as THC and glucocorticoids are also effective in some patients. It is not clear how these agents exert their antiemetic effect but it is probably not mediated by cholinergic, histamine or dopamine receptor blockade. A combination regimen using a glucocorticoid with other antiemetics is quite effective in reducing cisplatinum induced emesis and may also be effective against other chemotherapy induced nausea and vomiting[4].

Chemotherapy induced nausea and vomiting can be the most unpleasant symptoms a cancer patient must endure. Until studies elucidate the exact mechanism of chemotherapy-induced emesis, the conscientious application of rational combinations of antiemetic agents may be a reasonable approach.

The following table can be used as a guide to using antiemetic combinations. An appropriate antiemetic combination would be one that had adequate activity at all three receptor sites. Different combinations may be more useful than others in different patients.

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1. Peroutka SJ, Snyder SH. Antiemetics: Neurotransmitter receptor binding predicts therapeutic actions: *Lancet* 1:685–9, 1982.
2. Peroutka SJ. Combination antiemetics *Cancer Treat Rep* 66:1449, 1982.
3. Borison HL, McCarthy LE. Neuropharmacology of chemotherapy-induced emesis. *Drugs* 25:8–17, 1983.
4. Aapro MS, Alberts DS. High-dose dexamethasone for prevention of CIS- in Platinum- duced vomiting. *Cancer Chemother Pharmacol* 7:11–14, 1981.

Anti-Emetic Drug Potencies at Neurotransmitter receptor sites (Adapted from Peroutka)

Drug Group	Dopamine	Cholinergic	Histamine (H_1)
Anticholinergic			
Scopolamine	–	++	–
Antihistamines			
Diphenhydramine	–	+	++
Promethazine	–	++	+++
Neuroleptics			
Fluphenazine	++	–	–
Prochlorperazine	++	–	–
Chlorpromazine	++	+	++
Metoclopramide	+	–	–
Haloperidol	++	–	–
Tricyclic Antidepressants			
Amitriptyline	+	++	+++

– little or no activity
+ increasing activity

Editor's Note: The following table was omitted from the January *Infusions* on page 17. We regret the error.

Drug (elimination)	Approximate Equivalent Dose	Approx. Equivalent *Parenteral* Propranolol Dose
Propranolol (hepatic)	160 mg	10 mg
Nadolol (renal)	120 mg	10 mg
Metoprolol (hepatic)	200 mg	10 mg
Atenolol (renal)	100 mg	10 mg
Timolol (renal, hepatic)	20 mg	10 mg
Pindolol (renal)	10 mg	10 mg

NOTE: The total daily parenteral dose of propranolol should be administered in 4–6 equally divided doses as previously mentioned.

This table should only be used as a general guideline, and as a starting point when treating those patients who need to be converted to intravenous propranolol. By no means should these recommendations be perceived as a "cookbook recipe" applicable to each patient. Further titration of the dose may be necessary depending upon the clinical status of each individual patient.

1. NEJM 1981; *305:*500–6.
2. CMA 1976; *144:*188.
3. U.S. Pharmacist 1982; *Aug:*47–60.
4. The Medical Letter 1976; *18:*41–2.
5. Clin Pharm and Therap 1977; *21:*700–5.
6. Handbook on Injectable Drugs. 1983; *3rd ed.:*421.
7. Clin Pharm and Therap 1980; *27:*593–601.
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9. NEJM 1982; *306:*1456–62.

MSHP MEETING DATES FOR 1983–1984

February 9	Mercy Hospital
March 8	Greater Baltimore Medical Center
April 12	Howard County General Hospital
May 10	Baltimore County General Hospital

We welcome everyone and encourage anyone interested to come and join us at our monthly meetings.

Lisa Welch
Secretary MSHP
3003 Lindell Street
Wheaton, Maryland 20902

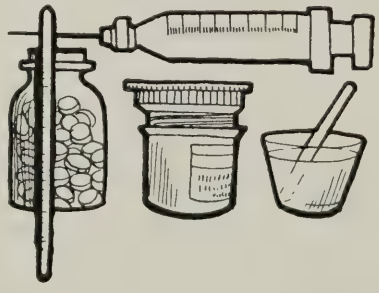
Peter P. Lamy, 1983 Recipient of ASCP's Archambault Award

The American Society of Consultant Pharmacists has selected Peter P. Lamy, Ph.D. of Baltimore, Maryland as the 1983 recipient of the Society's George F. Archambault Award. Named for Dr. George F. Archambault, the "father of consultant pharmacy," the award is conferred in recognition of outstanding and meritorious contributions to the specialty practice of long term care pharmacy. The award was presented during the Society's Awards and Installation Banquet at the ASCP 14th Annual Meeting in Las Vegas, Nevada.

Dr. Lamy wears many hats at the University of Maryland School of Pharmacy. He is Professor and Director of the Center for the Study of Pharmacy and Therapeutics for the Elderly and Director of the Institutional Pharmacy Programs and also Chairman of the Department of Pharmacy Practice and Administrative Science. His expertise in drug use in the elderly is frequently called upon as he has served as consultant to a host of committees, projects, and task forces all relating to the subject.

Dr. Lamy is editor of one journal, *Contemporary Pharmacy Practice,* one column on geriatrics and gerontology in *Drug Intelligence and Clinical Pharmacy,* and on the editorial board of two other publications on geriatrics. He has no less than 111 publications, 159 presentations and 30 radio and TV appearances to his credit. Dr. Lamy has been very active promoting positive drug use in geriatric patients and is the author of the important text, *Prescribing for the Elderly.*

Dr. Lamy is the twelfth recipient of the George F. Archambault Award. Previous recipients were James Cooper (1982), Mark Abrams (1981), Denis Portaro (1980), John Rawlings (1979), Donald Baker (1978), Samuel Kidder (1977), Herman Kessler (1976), George Freedman (1975), Jack Machbitz (1974), Richard Berman (1973) and George Archambault (1972).



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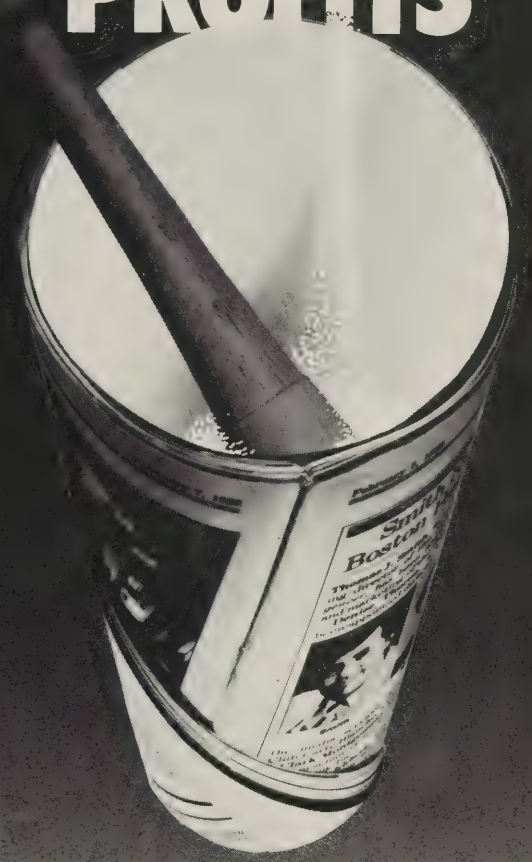

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Hidden Costs

The direct costs of health care actually account for only 40 percent of the total cost of illness. The remaining 60 percent are indirect costs, such as absenteeism and loss of productivity caused by illness. These are as real economically as the health care expenditures usually associated with illness.

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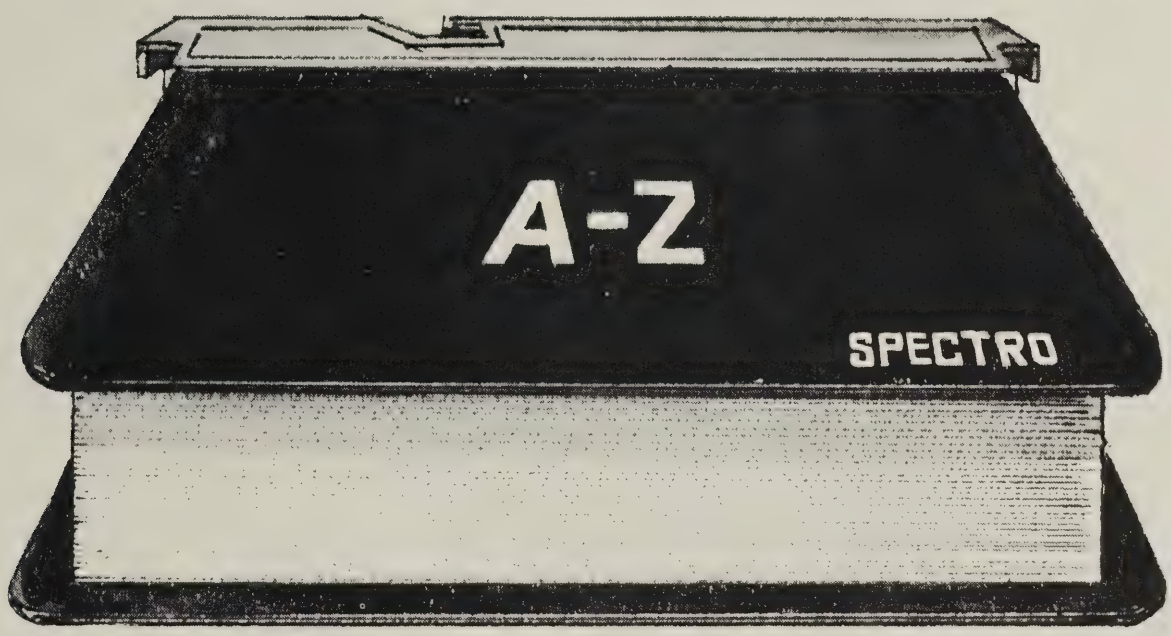

You'll find in this book the most comprehensive listing of items available to your pharmacy. You'll also find we can deliver everything we list and do it within 24 hours.

This book is only Volume One in our library. Sales ideas, pricing, services, and time saving procedures, are all contained in the table of contents. Please call us.

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The Industry Relations Committee Says:

Make February

The Month

You Clean Out

Dated

Merchandise

The Industry Relations Committee of the Maryland Pharmaceutical Association formed a subcommittee to study the issue of a Model Return Goods Policy. It was the feeling of the Committee, which is made up of manufacturing representatives and practicing pharmacists, that the policy should be fairly comprehensive and yet, provide some guidance and consistency in this area. The goal of the Committee was to develop a policy which could be endorsed by the Association in an attempt to establish a standard and which would be acceptable to both manufacturers and retailers.

The Committee recommends that members retain this page from the journal and refer to the following MPhA adopted policy whenever a question concerning returning merchandise arises. In addition, the Industry Relations Committee serves as an ombudsman whenever members refer a problem concerning this subject in writing to it.

MODEL RETURN GOODS POLICY

1. **New prescription drug products shipped to the pharmacy automatically by the manufacturer or wholesaler may be returned at any time for credit or exchange.**
2. **Regardless of expiration dates products may be returned for credit or exchange at any time, providing they are sealed, intact, original packages.**
3. **For patient protection, open packages of prescription drug products which are outdated may be returned for at least partial credit.**
4. **Authority for returns may be required by the pharmaceutical manufacturer or wholesaler—a form should be provided to the pharmacy.**

SAMPLE FORM to Return Merchandise

TO: (Name of Manufacturer)
Address — including the name of Town, County, State and Zip Code

(Note — the above as well as the policy for making returns may be located in the NWDA list of Mfgs. in January 1977 edition of the American Druggist Blue Book).

Please grant us authorization to return the following pharmaceuticals of your manufacture as per your policy:

It is best to list the items — listing complete packages as well as open containers. If a return of a schedule 2 is requested, be sure to give exact count and hold these aside as they usually will send a narcotic form. (Because of mail rates, it may be less expensive to have the drug inspectors destroy them.)

Note — If in their reply, they say they do not accept open containers — or — partially filled ones, call their attention to the fact that for the protection of the patient, as well as the pharmacist and the manufacturer, you believe it best they change their policy to permit them to accept them for credit.

Convention Awards

The Awards Committee of the Maryland Pharmaceutical Association is soliciting nominations from the membership for two prestigious awards which are presented to pharmacists at the Annual Banquet. The Committee decided that more membership input into the Awards process would be appropriate. The two Awards are:

BOWL OF HYGEIA This award is presented annually through the cooperation of the A. H. Robins Co. to a pharmacist who has compiled an impressive record in the area of community service.

MPhA ACHIEVEMENT AWARD This recently instituted award is given to a pharmacist who is distinguished in the area of contributions to the profession of Pharmacy.

Nominations for either of these two awards may be sent to the Awards Committee for consideration. Nominations must be in writing and should outline the qualifications of the individual for the award being considered. Nominations are kept on file each year and may be considered by the Awards Committee in future years. Nominations or inquiries about the nominating process should be sent to the M.Ph.A., 650 W. Lombard Street, Baltimore, Maryland 21201.

Convention Resolutions

The Vice Speaker of the House of Delegates, Martin Mintz, also serves as Chairman of the Association's Resolutions Committee. The Committee will be meeting soon to consider issues and resolutions for the Annual Convention of the Association, June 24–28, 1984 in Ocean City, Maryland. In order to allow for greater membership participation in the resolution process which forms the basic policy making structure of the Association, the Committee is soliciting input from the membership in the form of suggested resolutions or resolution topics. Resolutions may be sent to the Association at this time with any background or supporting information necessary. They should be sent to the M.Ph.A. Resolutions committee, 650 West Lombard St., Baltimore, Md. 21201.

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OTC Drug Use by Older Patients Requires Careful Monitoring

by Peter P. Lamy, Ph.D.

Older people frequently take over-the-counter (OTC) medications in addition to, or in lieu of, prescription drugs without consulting a physician or pharmacist. The misuse of otherwise therapeutic nonprescription drugs may harm the patient. Hence the pharmacist's role has expanded from formulating and dispensing drugs to actively alerting patients to the risk of uniformed self-medication.

All segments of the population use OTC medications liberally, but older people form the single largest consumer group for such products, particularly internal analgesics and antacids. OTC drug use should be recommended by the pharmacist with the same consideration and precautions given to prescription drugs.

Aspirin is the most commonly used OTC analgesic. Aspirin can reduce the increasing aches and pains commonly associated with aging, but chronic overuse can lead to toxicity characterized by confusion, irritability, tinnitus, vision disturbances, sweating, nausea, vomiting and diarrhea. Diagnosis of salicylate toxicity is frequently difficult because the physician, pharmacist and patient may blame the symptoms on old age.

In conjunction with certain prescription drugs, aspirin can have a negative effect. For example, the interaction of aspirin and anticoagulants can impair primary hemostasis or blood clotting, cause gastrointestinal bleeding and enhance the hypoprothrombinemic effect. Salicylate interactions with methotrexate can decrease both clearance of the drug and plasma protein binding, increasing the risk of methotrexate toxicity.

Greater awareness of aspirin's potential adverse effects has led to an increase in the use of acetaminophen. Available in a liquid dosage form, the drug may be more convenient for older persons. Acetaminophen has analgesic and antipyretic properties equal to aspirin and is a suitable replacement.

Chronic antacid use can lead to various adverse effects, including altered bowel habits, disturbance of acid-base balance and absorption of individual ions, such as aluminum or magnesium. Concurrent use of an antacid with another drug may impair the absorption of the second medication. The interaction is in some, but not all cases, clinically important. Most OTC antacids contain a large amount of sugar per dose, often unbeknownst to the consumer, and this may lead to serious consequences in those patients with diabetes.

Optimum drug therapy can only be obtained with necessary communication between pharmacist, physician and patient. This necessity extends beyond the use of prescription to nonprescriptive drugs.

Peter P. Lamy, Ph.D. is Professor and Chairman of the Department of Pharmacy Practices and Administration Services, Center for the Study of Pharmacy and Therapeutics for the Elderly at the University of Maryland School of Pharmacy, Baltimore.

LETTERS

Dear Sir:
There is a nationwide movement in the Pharmacy profession in the area of drug abuse prevention. McNeil Pharmaceutical and Johnson & Johnson are announcing a program of Pharmacists Against Drug Abuse and some major chains are publishing "fact sheets" for distribution to consumers. This effort appears to be in harmony with a general national awareness of the costs of drug and alcohol abuse and the promise held by prevention programs. Witness the current flurry of community activities around the "Chemical People" television broadcasts.

It has been about 15 years since the origin of the Student Committee on Drug Abuse Education. Some readers of this letter will recall undergraduate experiences in SCODAE during their pharmacy education at the University of Maryland. I am writing this letter to remind pharmacists here in Maryland, that SCODAE is available to support community drug education programs and to serve as their personal drug abuse information center. We invite them to utilize this service by calling 528-7513 or by visiting us in the new pharmacy school building at 20 North Pine Street in downtown Baltimore.

Over the years drug abuse and alcoholism prevention programming has waxed and wanned. It is my belief that pharmacists must maintain a steady concern in this area. The consciousness of drug abuse prevention extends from community involvement in drug education efforts to close scrutiny of questionable prescriptions and active participation in the referral of people suffering from chemical dependence. These are important areas and pharmacists can assume leadership roles. Let SCODAE support your efforts.

Sincerely;
Tony Tommasello; Pharmacist, M.S.
Instructor, UMAB

MSHP Schedules Robert Henry

"Robert" and "Henry" are two of the most common names in America today.

Put them together, however and you get Robert Henry—the name of a very uncommon man from Auburn, Alabama.

Robert Henry is one of the most sought-after platform speakers in America today and he will be in Ocean City, Maryland June 22, 1984. He will be speaking at The Carousel Hotel Friday evening. His appearance is being sponsored by the Maryland Society of Hospital Pharmacists at their Annual Seminar, June 22, 23 and 24, 1984.

Henry averages 12 to 15 speeches each month all over the United States. He has been called a comedian, joke teller, student of humor and "true Son of the South!" A prominent newspaper editor accused him of ". . . relieving the pain and healing broken hearts."

Henry has spoken in 49 states, Canada, Puerto Rico, the Bahamas, Denmark, Norway and Sweden. He is a funny man who uses clean humor to take a penetrating look at contemporary problems. His "down home" stories have audiences laughing uproariously. Yet, he skillfully conveys a message that will be long remembered.

He is President of the National Speakers Association, and additionally serves as a Director of this 2,000 member organization. He is also a member and current President of the prestigious "Platform Professionals" speakers group.

The C.P.A.E. award, presented by the National Speakers Association, recognizes the highest levels of excellence achieved in professional speaking. The recipients of this most-coveted award were Ronald Reagan, President of the United States and Robert H. Henry.

For a man who is in such great demand, Robert Henry's speaking career got started in an unusual way.

It began when he was called on to speak on behalf of the United States Pharmacopeia, the book of official drug standards in the United States. This book is about as exciting as an automobile parts manual so Henry began making points about it by using stories and anecdotes from his native land . . . the "Heart of Dixie." His reputation as an entertaining, humorous and motivational speaker quickly spread nationwide.

He still maintains a home in Auburn with his wife, Merrilyn, and their two boys, Brent and Patrick. A Southerner by birth, nature, inclination, upbringing, inspiration and choice, Henry is at a complete loss to explain why he lived in Washington, D.C. for five years, but his audiences love to hear him tell about it.

For more information about his appearance in Ocean City, Maryland, contact David Chason, Mercy Hospital Pharmacy Dept.

Metro Crime Alert

Citizens Make the Difference

Witnesses to hundreds of crimes each year never come forward because they fear for personal safety and/or anonymity.

Yet, an organization called Metro Crime Alert (MCA) solves scores of felony cases every year through tips from anonymous witnesses. In addition to guaranteeing callers anonymity, MCA also pays rewards of up to $1,000 to witnesses whose tips lead to arrest and indictment of a felony-crime offender, or recovery of a sizeable amount of property.

Each Monday at 6:00 p.m. and Tuesday at 6:30 a.m. and 12 noon, WJZ-TV features a reenactment of MCA's Crime of the Week. This program has encouraged many more calls than would normally be received because it serves as a constant public reminder of the crimes, the awards, and the guarantee of anonymity.

MCA was originally conceived to represent the Baltimore City area. But, because crime respects no boundaries, the program also serves to solve felonies committed in Anne Arundel, Baltimore, and Howard Counties.

The types of crimes for which rewards are paid are: homicide, rape, aggravated battery, armed robbery, auto theft, larceny, forgery, fraud, embezzlement, arson, narcotics, vice, fugitives, and theft from autos, residences, and/or businesses.

If you witness any of these crimes, or view a reenactment and think you might have information leading to the arrest of a suspect, these are the steps you should take:

- Call the 24 hour, seven day MCA hot line at 276-8888. You do not need to give your name. The person taking your call will write down the information you give, and issue you an identification number. Arrests, of course, are not made based solely on called-in information. Your and every caller's claim is carefully checked out by the police.
- To determine the status of the case and whether an award will be made, call MCA at 244-8888 two weeks after your initial call, Tuesday through Friday, from 9 a.m. to 4 p.m. It will be necessary to use your identification number before information is given to you.
- To safeguard anonymity, rewards are paid in cash, and you as a caller are not required to testify in court, unless, of course, you choose to.

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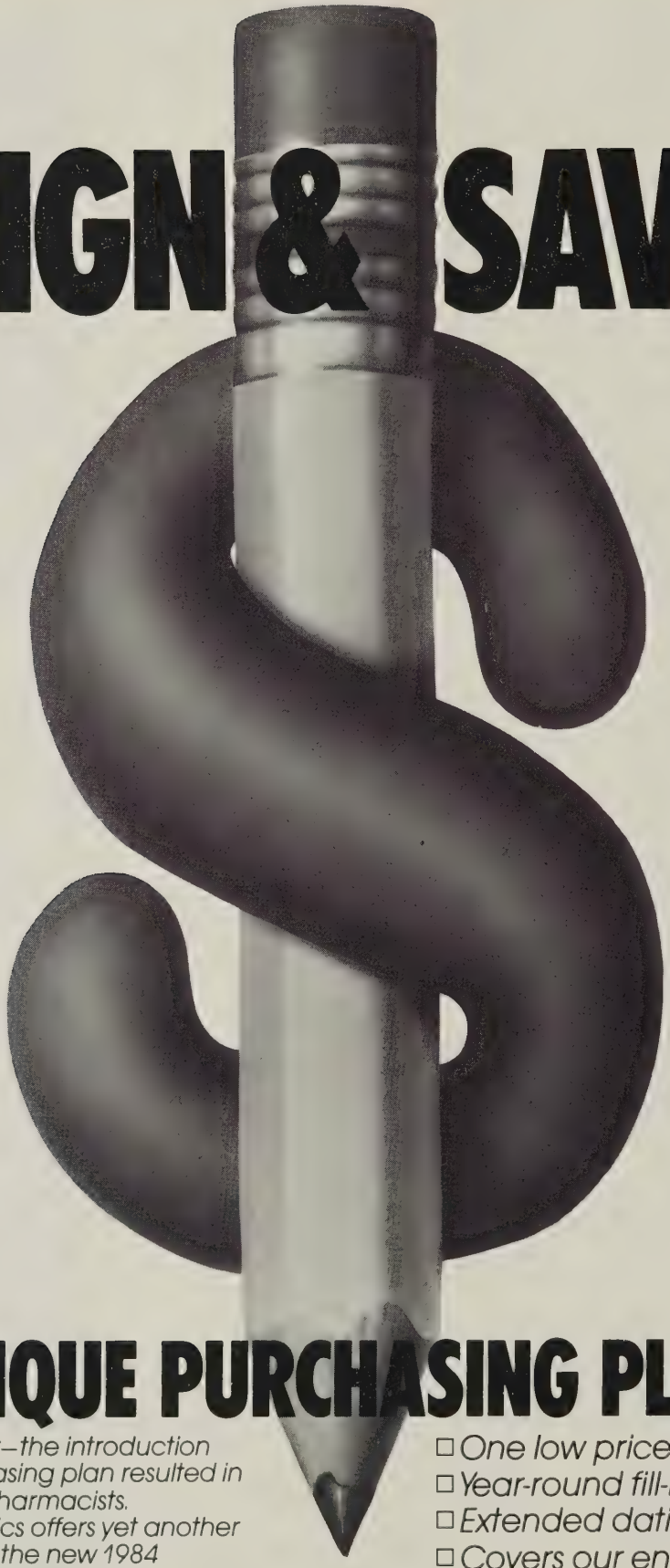

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On November 19th the Prince George/Montgomery County Pharmaceutical Association held a dinner honoring S. Ben Friedman, their Pharmacist of the Year and winner of the AZO Ephriam G. Sless Award. Paul Reznek (right) presents the Award to Ben.

Milton Moscowitz (left) was the recipient of the American Society of Consultant PHarmacist's Berman Award (see article on page 13) and presented a check for $500 at Dean William J. Kinnard.

Linda C. Mapp has been assigned to the Hagerstown territory for the Upjohn Company. She is a graduate of Western Maryland College.

S. Ben Friedman is shown with his family and relatives at the Dinner held in his honor.

ABSTRACTS

Excerpted from PHARMACEUTICAL TRENDS, published by the St. Louis College of Pharmacy; Byron A. Barnes, Ph.D., Editor and Leonard L. Naeger, Ph.D., Associate Editor

FASTING AND UTERINE ACTIVITY:

It has been noted that women who strictly adhere to the religious customs of Judiasm tend to deliver premature infants if they undertake a vigorous fast during the Yom Kippur observances. Islamic women, who are not obliged to fast during pregnancy but who make up those days after delivery, did not show an increased tendency to deliver prematurely. Although clinical implications are still unclear, there may be a special risk for those mothers with a tendency to early delivery should they undertake a vigorous fast. *JAMA*, Vol. 250, #10, p. 1317, 1983.

AIDS:

Several homosexual males were evaluated to determine if any indicator of AIDS susceptibility could be identified. Subsequent work indicates that the presence of an acid labile alpha interferon from leukocytes may serve as a marker for those at high risk of contracting this disease. Similar abnormalities in interferon were found in hemophilic males treated with lyophilized clotting-factor concentrates. This group is also associated with a high risk to develop AIDS. *N Engl J Med*, Vol. 309, #10, p. 583, 1983.

PENTOBARBITAL:

Barbiturate-induced respiratory depression was studied in animal models. Investigators have concluded that the respiratory depression produced by pentobarbital (Nembutal) is due to activation of the gabaergic system. Topical application of bicuculline, a GABA antagonist, reverse the depression. *J Pharmacol Exp Ther*, Vol. 226, #2, p. 349, 1983.

GASTRIC BICARBONATE SECRETION:

Evidence has been gathered which suggests that the stomach secretes bicarbonate as well as acid. Intravenous administration of pentagastrin increased acid secretion but had no effect on bicarbonate secretion. If bethanechol (Urecholine) was administered during the infusion, both acid and bicarbonate secretion increased. On the other hand, administration of PGE_2 during pentagastrin infusion decreased acid production while increasing the release of bicarbonate. *J Clin Invest*, Vol. 72, #1, p. 295, 1983.

ANTITUSSIVE ACTION:

Antitussive activity of codeine was studied in cats to determine the receptor subtype associated with this action Codeine seems to exert its antitussive effect through action involving the mu and the kappa receptors. The activity is not readily reversed with narcotic antagonists such as naloxone (Narcan). *J Pharmacol Exp Ther*, Vol. 226, #1, p. 108, 1983.

THERMOGENIC EFFECTS:

Obesity is a complex condition complicated by hyperphagia and inactivity. Some obese patients restrict intake and perform exercises without achieving the weight reduction seen in other participants in like programs. Investigators feel this may be due to a defect in the thermogenic regulatory system of the body thus allowing the patient to experience a reduced need for calories. Foods ingested are then used to produce fatty tissue and obesity ensues. The activation of beta-1 receptors may be implicated in increasing caloric requirements and thus correcting the thermogenic defect. More work in this area is being planned. *Lancet*, Vol. II, #8346, p. 386, 1983.

ORABRONZE:

A naturally occurring orange carotenoid devoid of vitamin A activity has been found to improve the color of farmed salmon, and is thus classified as a food additive. The substance called canthaxanthine (Orabronze) is available for oral use to alter the color of the skin. Patients receiving the medication do not get any sunburn protection from the regimen, but their skin develops an orange-bronze color due to deposition of the chemical in the subcutaneous fat. The dye is used in Great Britain without a prescription because the dose of 30 mg is well below the acceptable limit set by the World Health Organization as a food additive. Side effects are essentially absent and only discoloration of the feces has been reported. The "tan" lasts approximately 10 days. *Drug Ther Bull*, Vol. 21, #15, p. 57, 1983.

PROPRANOLOL:

Propranolol (Inderal) is said to exert its antiadrenergic effect by non-specific blockade of beta adrenergic receptors. Evidence accumulated from work done in animal models suggests that in addition to the competitive blockade, propranolol may be taken up by the nerve terminus and released from these presynaptic sites during activation of the adrenergic neuron. This would dilute the effectiveness of the endogenous transmittor and decrease receptor response. *J Pharmacol Exp Ther*, Vol. 226, p. 324 1983.

LEUKOTRIENES:

Leukotrienes are derived from the action of lipoxygenase on arachidonic acid and had formerly been known as SRS-A (Slow reacting substances of anaphylaxis). These substances were found to have accumulated in infants experiencing hypoxemia and pulmonary hypertension. Leukotrienes C-4 and D-4 are known to produce pulmonary vasoconstriction, bronchoconstriction, decreased lung compliance and pulmonary edema.

If a drug can be designed to inhibit the formation of these leukotrienes, it may prove lifesaving in neonates born with pulmonary hypertension. *N Engl J Med,* Vol. 309, #2, p. 77, 1983.

NITROUS OXIDE:

Five patients with disseminated cancer experienced pain unresponsive to conventional analgesic therapy. They were fitted with a mask for inhalation of nitrous oxide and the drug was delivered via the conventional method. Analgesia was achieved in these patients and they demonstrated a reduction in anxiety and agitation. It was also noted that the patients appetite improved and their ability to communicate was better. No side-effects were noted and the only discomfort they experienced was that associated with the wearing of the mask. Nitrous oxide represents a safe, easily administered, non-invasive and effective method of producing analgesia in cancer patients refractory to conventional analgesic therapy. *JAMA,* Vol. 250, #4, p. 511, 1983.

ANTIEMETIC:

Metoclopramide (Reglan) has been used as an antiemetic as well as for other purposes. Another agent, domperidone, seems to exert a similar effect via central depression of the chemoreceptor trigger zone in the brain and via a peripheral action on gastrointestinal motility. It has been suggested that domperidone does not penetrate the basal ganglia and thus does not antagonize dopaminergic receptors in this area of the brain thus producing fewer dystonic reactions than does metoclopramide. The drug has been used in patients receiving antineoplastic therapy. *Drug Ther Bull,* Vol. 21, #12, p. 47, 1983.

GONORRHEA THERAPY:

Uncomplicated gonorrhea in men was treated with either spectinomycin or ceftriaxone, an experimental third generation cephalosporin derivative. Neither drug caused toxicity in this study but patient acceptance for ceftriaxone was greater than it was for spectinomycin. Ceftriaxone in a single dose of 125 mg administered via intramuscular injection may become the treatment of choice for uncomplicated urethral or anorectal gonorrhea in men. *Lancet,* Vol. II, #8341, p. 67, 1983.

TARDIVE DYSKINESIA:

Patients who receive long-term phenothiazine therapy have a risk of developing tardive dyskinesia, a condition which is difficult to treat. Studies indicate that symptoms are probably caused by both an increased sensitivity to dopamine and a decreased cholinergic sensitivity. More basic pathological research is needed before the cause and subsequent cure for this condition can be documented. *J Pharmacol Exp Ther,* Vol. 226, #1, p. 7, 1983.

METHADONE:

Many drugs produce pharmacological activity which cannot be monitored by measuring the concentration of the drug in the plasma. This is especially true of drugs which act within the central nervous system because there may not be a constant equilibrium set up between the drug in the plasma and within the brain. Methadone was studied in animals to see if analgesic activity could be correlated with plasma level of the drug. Investigators feel that plasma levels of methadone produce an accurate index of analgesic effectiveness and thus suggest that other preparations be studied to see which drugs might be monitored via this technique. *Drug Metab Dispos,* Vol. II, #4, p. 335, 1983.

SYNCOPE IN ELDERLY:

Elderly patients experience potentially dangerous fainting episodes which are unexplained in the majority of the instances. Patients with and without histories of syncope were studied intensively to determine if a cause of the syncope would be found. It was noted that elderly patients experienced a significant reduction in blood pressure (25mmHg) approximately 35 minutes after ingesting a meal. The drop occurred in those with and without histories of syncope but did not occur in young volunteers or in the elderly not ingesting a meal. *N Engl J Med,* Vol. 309, #2, p. 81, 1983.

BUMETANIDE:

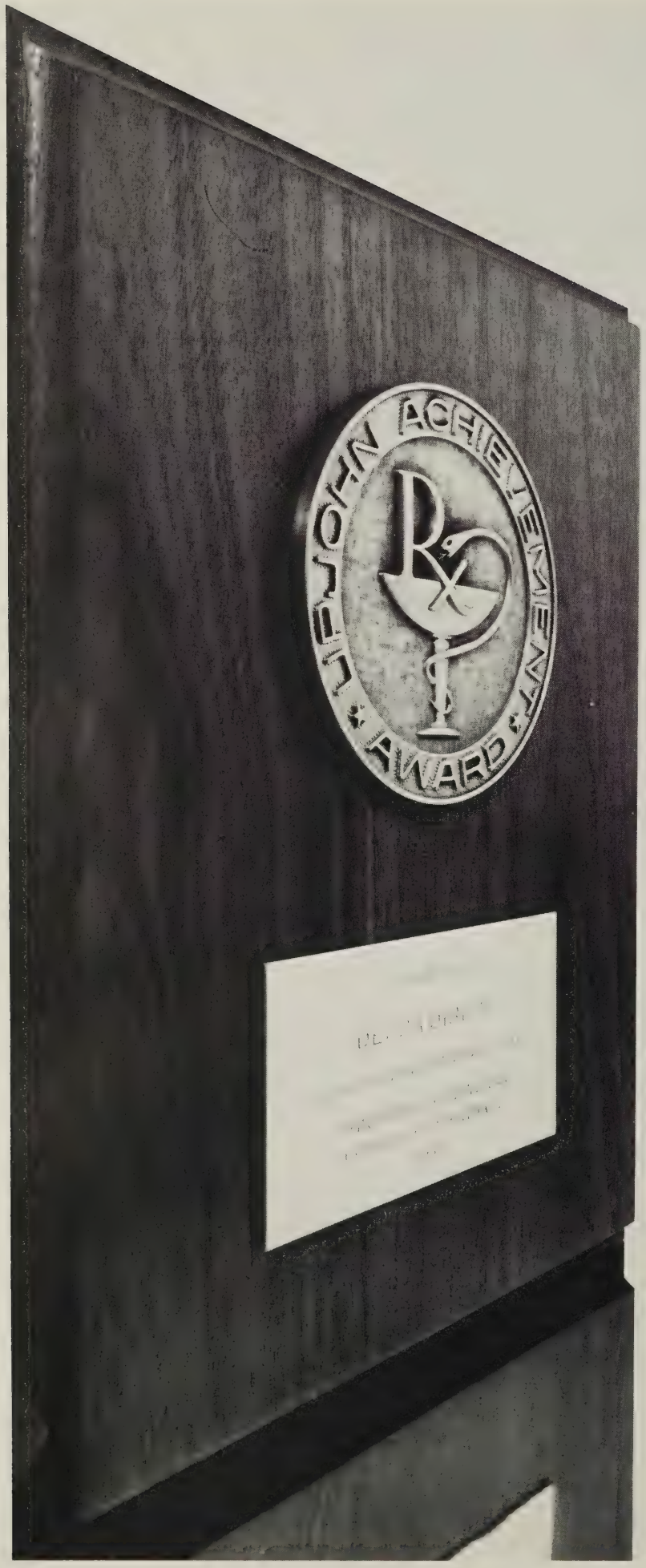
Bumetanide (Bumex) is a newly marketed loop diuretic which is similar in its action to furosemide (Lasix). Bumetanide is twice as bioavailable (80% of the oral dose is absorbed) and it has a greater intrinsic activity. The clinical significance of these findings is unclear. *Clin Pharmacol Ther,* Vol. 34, #2, p. 207, 1983.

RAYNAUD'S PHENOMENON:

In 1862, Raynaud's phenomenon was described for the first time. Today it is hypothesized that this reversible type of vasospasm is due to a "local fault" in the histaminergic vasodilating system in peripheral vessels. Many possible causes have been suggested as to its etiology, but the histamine-related defect seems most plausible. *Lancet,* Vol. II, #8345, p. 313, 1983.

ETHANOL:

Patients who regularly consume large quantities of ethanol experience an elevated mortality rate due to ischemic heart disease. This is thought to be due to the ability of ethanol to increase the plasma concentration of high density lipoproteins and reduce the beneficial low-density lipoproteins. The opposite effects are said to occur in patients who ingest small daily amounts of ethanol. High doses of ethanol also seem to decrease the ability of platelets to aggregate and it can lower the fibrinogen level while increasing fibrinolytic activity in the plasma by enhancing plasminogen activator secretion by the endothelial cells. *JAMA,* Vol. 250, #6, p. 772, 1983.



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by

William Arthur Ward

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I will do more than dream — I will **work.**
I will do more than teach — I will **inspire.**
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I will do more than give — I will **serve.**
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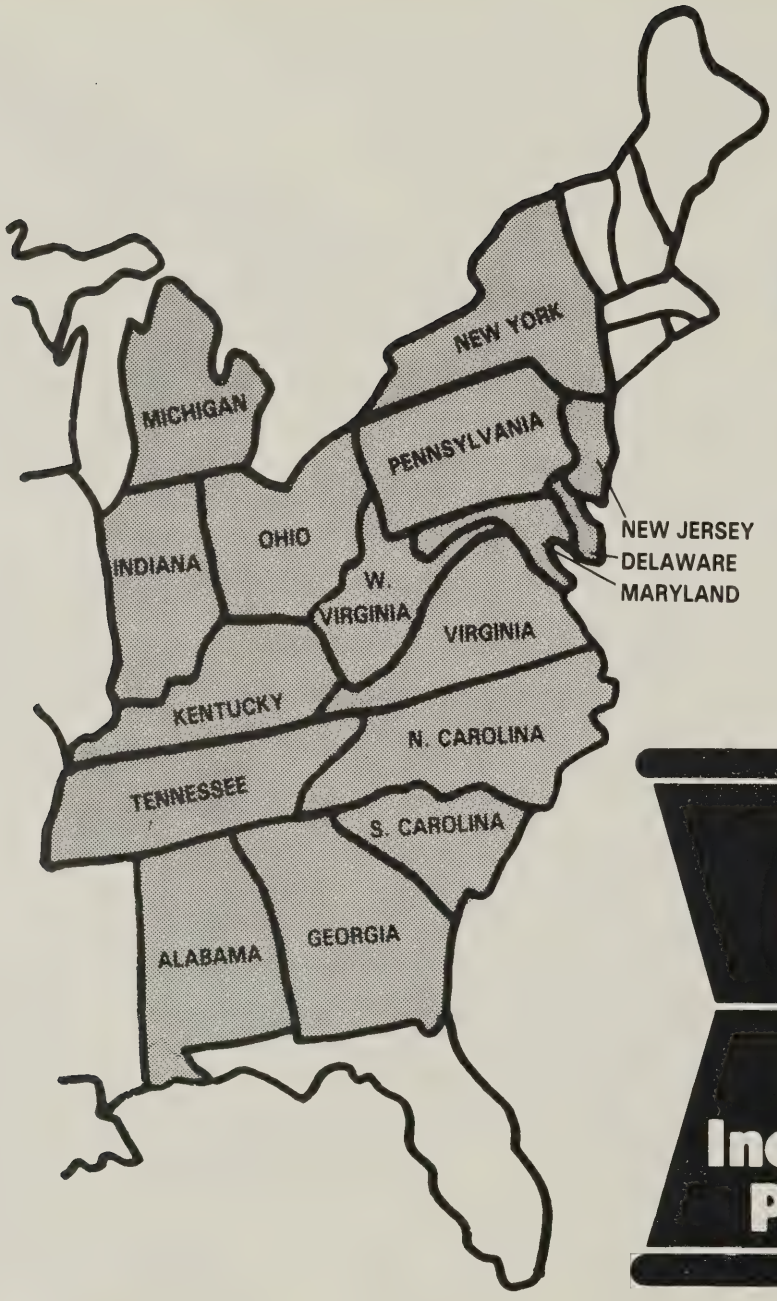

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Official Journal of
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March, 1984
VOL. 60
NO. 3

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MARCH, 1984 VOL. 60 NO. 3

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DAVID A. BANTA, *Editor*
BEVERLY LITSINGER, *Assistant Editor*
ABRIAN BLOOM, *Photographer*

What it Takes

Many years ago an English gentlemen said the three qualities for success were being capable, available, and affable. You must have a measure of each quality to truly make it in the world whether you are a pharmacist, doctor, or indian chief.

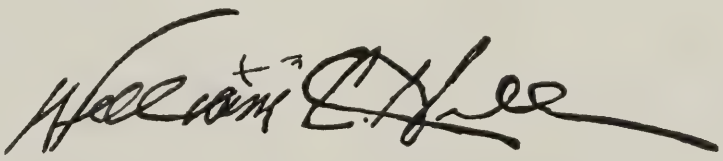
When you take a second look at this statement, it becomes obvious that we all must fit somewhere in this formula. How we measure up in this hypothesis is probably directly responsible not only to our success as a pharmacist, but also to our success as a human being.

It is true you can be the brightest pharmacist on the block. You may also be friendly, have a warm personal approach to your job and customers, however, if you do not make yourself available to your clientele, these qualities are lost.

You can arrange this formula, subtracting any one of the other two qualities and still it comes out the same. You cannot really be a success unless you uphold all three qualities.

No matter how sophisticated our profession may get, the golden qualities of humanity still dictate our success. Hard work, a sense of humor, a true love and respect for our neighbor, a good attitude towards our work, profession, and people we work with will help us be successful in the pursuit of our profession.

As pharmacists, we must not measure our success with our material gains alone. Our profession presents us with a wonderful opportunity to help our neighbors on a daily basis. Let us remember the most important gift we will ever receive is the gift of life and hope; pass it on by deed and word!



William C. Hill, P.D.

PRESIDENT

SCOPE

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION • VOL. I, NO. 3

OTC Pediculicide (Anti-Louse) Products

By Thomas A. Gossel, R.Ph., Ph.D.
Ohio Northern University
Ada, OH

and J. Richard Wuest, R.Ph., Pharm.D.
University of Cincinnati
Cincinnati, OH

Goals

The goals of this lesson are to:
1. Discuss the etiology and treatment of lice infestations.
2. Review the pharmacology of drugs used to treat lice infestations.

Objectives

At the completion of this lesson, the successful participant will be able to:
1. Properly advise consumers on the selection and technique for applying OTC agents for treating lice infestations.
2. Decide when the consumer should be referred to a physician when self-treatment is not appropriate.

in the service of pharmacy

This continuing education for Pharmacy article is provided through a grant from MERRELL DOW PHARMACEUTICALS INC.

Throughout the ages, historians have related that entire armies were devastated by the ravages of typhus and other diseases transmitted by the body louse. Napoleon was threatened by defeat, for example, more so than by Wellington's armies, because, at one time, several thousand French troops were infected by typhus carried by the body louse. It's interesting to speculate on how our lives might be changed today, if many of these early societies would have had effective antimicrobial agents to treat these once dreaded diseases. Thus, lice infestations, or more correctly, pediculosis, is a disorder that has bothered people of all classes, probably at all periods of history.

The term **pediculosis** describes a skin infestation of blood-sucking lice. Three varieties may infest humans: *Pediculus humanus capitat* (head louse), *Pediculus humanus corporis* (body louse, "cooties"), and *Phthirus pubis* (pubic or crab louse). A **pediculicide,** then, is a substance that kills lice, and replaces the older term, **parasiticide,** which is less descriptive of the target insects it is intended to kill. Body lice infestations are now under control in this country, so outbreaks are rarely seen. Consequently, this month's lesson will concentrate on head and pubic lice, both of which are still rampant.

Incidence

There have been countless cases of head and pubic lice in the U.S. reported during recent years. Crab lice is the more common condition. However, when epidemics are reported, they are usually caused by head lice. Most outbreaks have appeared in the public schools at all grade levels, in institutions, and in places of close communal living. There are no accurate figures which describe the exact number of cases since pediculosis outbreaks do not have to be reported to any epidemiologic data collection center. Some data sources report that an excess of three million cases of lice appear in this country each year, but a more realistic estimate was given by a spokesperson for an OTC manufacturer of pediculicide products who recently stated that, based on sales of OTC pediculicide products, the number more closely approaches 6 to 7 million cases per year. One point that nearly everyone agrees with is that the number of cases is increasing each year.

Head lice occurs more often in females, although length of hair doesn't seem to be an important criterion. Boys with short hair are also affected. Blacks are infested much less frequently than whites. The occurrence of crab lice, on the other hand, shows no sexual preference, and blacks are affected as commonly as whites.

There appears to be no significant difference in incidence of pediculosis among the various socioeconomic groups. However, lice infestations do occur more frequently where unsanitary conditions prevail or there is a lack of correct personal hygiene.

The Medical Problem

Both the adult insect and nymph (stage of development immediately prior to adult) are **hematophagous** (blood sucking). During feeding, they introduce small quantities of saliva into their dinner area on the infested host. This causes an erythematous

papule (small, reddened, raised and hard area) that appears within hours. These papules itch and as a result of vigorous, nearly constant scratching, secondary bacterial infections such as impetigo and boils may follow. Neither head nor crab lice transmit infections *per se*, although some reports occasionally state (erroneously!) that they do. (*Body* lice are transmitters of typhus, relapsing fever and trench fever, as stated earlier). However, there does seem to be a correlation between repeated attacks of crab lice and venereal disease (probably due to the person's enhanced sexual activity, rather than from the insect). This is why it is often recommended that persons with frequent bouts of crab lice be examined by a physician—to confirm or deny that this secondary condition exists.

After prolonged periods of scratching, microscopic examination of the affected area reveals infiltration with lymphocytes (white blood cells), and discharge of erythrocytes (red blood cells). The skin at these sites may eventually become pigmented because of deposition of iron, biliverdin or other blood components. The affected hair shaft becomes dry and lusterless. Later, a pustular eczema (dermatitis) may appear.

Crab lice may cause an added condition known as **macules caeruleae.** These bluish-gray elevations in the skin do not itch, are not necessarily uncomfortable, and do not disappear when pressure is applied. They are believed to result from interaction of the insect's saliva with bilirubin from the host's blood, changing it to biliverdin.

Head and crab lice have **operculate** legs, which means the legs are capable of folding over as a lid to close around a hair shaft. This enables the insect to hold on. Once a person is infested, head lice usually attach themselves to hair on the head and crab lice to hair on the pubic or perianal area. Head lice are most easily found on the nape of the neck or behind the ears. Crab lice are not always confined to pubic areas, and may actually establish residence on any hairy area of the body. All lice depend primarily on scratching and rubbing to transmit them from one part of the body to another, as they do not have the ability to move great distances by themselves. Contrary to popular belief, lice do not jump from one person to another.

Both forms attach themselves to hair shafts, about one-fourth inch from the skin. When hungry, they bite into the skin and feed on the victim's blood. Lice may remain attached by their mouth parts to the same site for several days, continually feeding. Crab lice seldom become engorged with blood; head lice do.

Pediculosis is a true parasitic disease, as lice depend on their human host for housing, feeding and reproduction. They cannot remain off their host for periods longer then 12 to 24 hours, although eggs can hatch anywhere, as long as the temperature is above 72° F. However, once hatched, the nymphs must have access to a human host within this 12 to 24-hour period if they are to survive.

An initial infestation is mild in most cases, reported at 8 to 10 lice per encounter. However, each female insect lays eggs (nits) at the rate of 3 to 10 per day, and lives 30 to 40 days. Thus, within several days of infestation, the initial number of lice has increased manyfold and the population will continue this upward climb unless the insect's life cycle is quickly interrupted.

Eggs are held in place on the hair shaft by a sticky cement-like secretion from the female louse. This bonding of an egg to the hair shaft is strong enough so that ordinary washing of the hair will not dislodge them. Nor will OTC pediculicide products dissolve the "cement". However, they will kill the nits.

Methods for Contamination. Head lice are most commonly spread by head to head contact with an infested person through contact between hats, scarves or clothing hung close together in school coat rooms, or by using communal combs and brushes. Bed linen or head rests of chairs and couches are another source of contact.

Crab lice are most frequently spread by sexual contact, by bedding, shared clothing and towels, and yes, even by toilet seats!

Is It Head or Crab Lice?

The first step in distinguishing between head and crab lice is to note the site of infestation. However, as stated above, crab lice are not always confined to the pubic or perianal areas. Since crab lice are usually contacted through sexual activity, it is especially important to identify the source and treat all sexual partners.

Both head and crab lice appear on the hair as tiny brownish-dark gray spots, approximately 1 to 2 mm long. If engorged with blood, head lice may appear reddish in color. Nits appear as yellowish or white spots.

Lice are undistinguishable by the naked eye, but can be differentiated by viewing under a strong magnifying glass. Head lice are elongated, flat insects. Their legs are short and have claws that can grasp skin, hair and fibers. Crab lice are shorter, broader and more rounded. Unlike head lice, they have lateral hairy processes (Figure 1).

Many pharmacists can relate stories about patients bringing in plastic vials with "something" inside that they think is lice. If the insects' features can be distinguished by the unaided eye, they are not lice. If they are reported to "jump" from area to area, they are also not lice, and in fact, more likely are fleas.

If a lice infestation is suspected, either through questioning the patient, or by identification of the insect, an OTC pediculicide product can be safely and assuredly recommended. Both head and crab lice infestations are effectively treated with the same OTC products.

Treatment

Treatment of pediculosis is directed toward two goals: killing the lice and nits, and controlling symptoms. The most bothersome symptom is itching, which may be unrelenting. Secondary infection, when it occurs, constitutes the other symptom of concern.

Itching. Patients should be advised that even after the causative organisms and their nits have been killed, itching may persist for several days to a week or longer. This occurs because the insect's salivary secre-

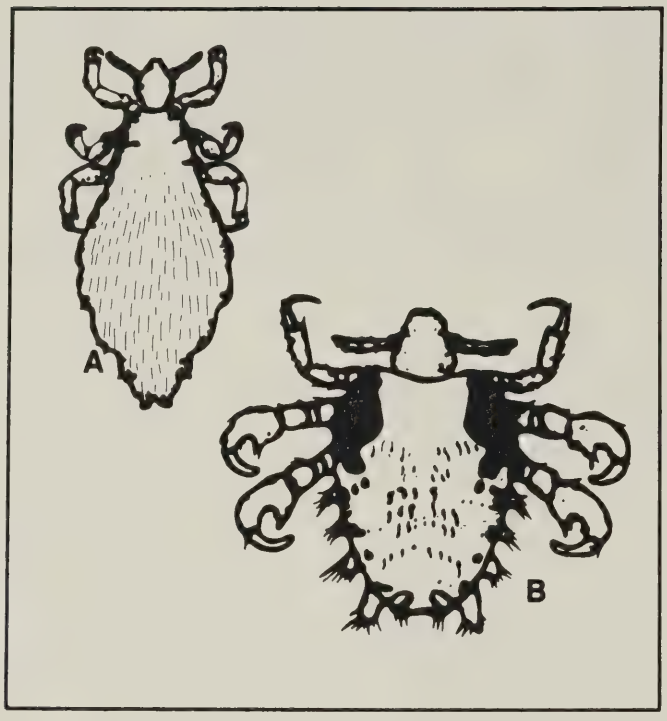


Figure 1. Head (A) and crab (B) lice. These insects can be readily recognized by their shapes; head lice have an elongated abdomen and crab lice have a shorter, rounded abdomen. Head lice have legs of the same length, crab lice have two front legs that are smaller than the second and third pairs. Crab lice have hairy lateral processes.

tion, which is deposited under the host's skin, incites release of histamine and perhaps other inflammatory substances. After the insect's death, time is required for the saliva droplets to be absorbed and destroyed by the host, and for localized inflammation to subside.

Such advice is necessary because a normal patient's response to continued itching would be to repeatedly apply a pediculicide product, thinking the former application was ineffective. Excessive use of these products subjects the patient to increased risk of needless side effects, including excessive drying of skin which may cause further itching. Any of the medications or procedures for controlling itching that were discussed in the previous two lessons are appropriate measures for itching caused by lice. Secondary bacterial infections may be treated by use of an appropriate topical antibiotic remedy (discussed in next month's lesson). Such infections occur rarely. When they fail to heal within seven days or worsen with continued therapy, a physician should be consulted.

Home Remedies. Because of the social stigma attached to lice infestations, a number of home remedies and self-treatment regimens have originated. For example, the head and/or pubic areas can be shaved to eliminate lice, but this is not necessary. The area can be heated with a hair dryer until the skin tingles. Or the head can be soaked in hot water for 3 minutes to kill head lice and their nits. These measures can be uncomfortable to the human and are unlikely to be effective for all insects and eggs. Because of the rapid rate of louse reproduction, after a day or so, the patient is back to square one.

One older procedure is to soak the scalp or affected area with kerosene or gasoline. This is a potentially lethal procedure and must not be advocated. Sufficient petroleum distillate may be absorbed to cause fatal poisoning. At the very least, these substances will dry the skin to greatly intensify the itching.

Current Status of OTC Pediculicide Products

The FDA - OTC Advisory Review Panel on Miscellaneous External Drug Products has finalized its study of pediculicidal products and published its report. It still remains as an "Advance Notice of Proposed Rulemaking" as FDA has not yet ruled on the panel's findings. If accepted, some OTC pediculicide products will have to undergo change because they do not contain acceptable medications. Most others on the market already meet the standards. More importantly, pharmacists will then be assured that the OTC products they recommend are both safe and effective for eradicating head and pubic lice infestations.

Products containing pyrethrins in combination with piperonyl butoxide (pyrethrins 0.17 to 0.33%; piperonyl butoxide 2 to 4% in a non-aerosol dosage formulation) were listed by the advisory panel as safe and effective for OTC use in controlling head and pubic lice. The panel reviewed available data on a variety of other ingredients (Table 1), but dismissed all but one of them from further consideration because they had insufficient evidence to demonstrate their safety and effectiveness. The panel did not consider lindane since it believed (and most experts concur) that lindane (gamma benzene hexachloride - Kwell®) should only be used with proper medical supervision. Malathion (Prioderm®) is another pediculicide in the prescription-only, (i.e., effective but not safe for self medication) category.

Pyrethrins with Piperonyl Butoxide. Piperonyl butoxide is one of a few true pharmacological synergists. It potentiates the insecticidal activity of pyrethrins (as well as many other environmental insecticides). A synergist is defined as a substance which potentiates the effect of another agent, by acting through a different biological mechanism, to bring about an effect that is greater than merely additive. The former enhances pyrethrins' pediculicide effect by suppressing the insect's oxidative degradation mechanisms which inhibit its ability to metabolize and, hence, destroy pyrethrins.

TABLE 1

Ingredients Reviewed by FDA's OTC Advisory Panel

1. *Active Ingredients*
   - Piperonyl butoxide*
   - Pyrethrins*
   - Isobornyl thiocyanoacetate**

2. *Inactive Ingredients*
   - Deodorized kerosene
   - Petroleum distillate

3. *Other Ingredients*
   - Alkaloids of sabadilla
   - Aqueous coconut oil soap
   - Benzocaine
   - Benzyl alcohol
   - Benzyl benzoate
   - Copper oleate
   - Dichlorodiphenyl trichloroethane (DDT)
   - Dioctyl sodium sulfosuccinate (Docusate®)
   - Picrotoxin
   - Propylene glycol
   - Sublimed sulfur
   - Thiocyanoacetate

*Safe and effective for use as a pediculicide.
**Insufficient data available demonstrating safety and effectiveness when used as OTC pediculicides. Thus, the panel classed these as Category II for this use.

Thus, the contact time (and consequently, the kill rate) of pyrethrins on the insect is increased. Pyrethrins kill the insects by disrupting their ion transport mechanisms at nerve membranes, in a manner perhaps best clinically correlated to a massive systemic overdose of local anesthetic with its toxic consequences. The insects die of convulsions and paralysis.

Pyrethrins are rapidly acting insecticides. Commercial preparations consist of a mixture of substances obtained from the flowers of a chrysanthemum plant. Hence, the term "pyrethrins" actually refers to several substances, identified chemically as esters of two acids (chrysanthemic acid and pyrethric acid) and three alcohols (pyrethrolone, cinerolone, and jasmolone). Much of the commercial pyrethrins are obtained from plants grown in Tanzania and Kenya.

Numerous *in vitro* studies have repeatedly shown that pyrethrin products are effective pediculicides when used in concentrations up to 0.33% (in combination with piperonyl butoxide up to 4%). An insect kill rate of 97 to 100% at 10 minutes exposure can be demonstrated. The questions that many pharmacists raise are, "Will this combination stand up to clinical trials and treat human infestations," and if so, "How effective is it compared to lindane?"

To answer these questions, several studies were designed to compare pyrethrins, 0.3%, in combination with piperonyl butoxide, 3.0%, to lindane lotion or shampoo. In these studies, lice-infested patients were treated either with pyrethrins plus piperonyl butoxide, or a lotion or shampoo product containing lindane. Patients with head lice who were treated with the pyrethrins plus piperonyl butoxide combination or lindane shampoo, received two additional treatments at weekly intervals. When examined immediately after the third application, all individuals in the pyrethrin group were free of lice and viable nits, while one individual in the lindane group still remained infested.

Subjects with crab lice received a single application of pyrethrins with piperonyl butoxide, lindane lotion, or lindane shampoo. One week after treatment, all were carefully examined for lice. No lice or viable nits were found on any patient, regardless of his treatment.

The advisory panel recommended to FDA that a second application of the product after one week was appropriate. It pointed out that while pyrethrins with piperonyl butoxide is an effective pediculicide combination, there is little evidence that the combination is completely effective in eradicating all viable forms of lice (adults, nymphs and eggs) with a single application. Since unaffected eggs normally hatch into their nymph stage within 7 to 10 days, reapplying the product 7 to 10 days after the initial treatment should increase its effectiveness.

The safety of any OTC product should be a primary concern to the pharmacist and patient. Neither pyrethrins nor piperonyl butoxide are extensively absorbed following cutaneous application. What is absorbed is rapidly metabolized, and the estimated human lethal doses are (pyrethrins) 0.7 gm/kg and (piperonyl butoxide) 11.5 gm/kg. Most clinical reports describing toxicity with OTC pediculicidal products containing pyrethrins and piperonyl butoxide refer to the problems due to other ingredients such as petroleum solvents in the preparation. One or more teaspoonfuls of such a product could be a potentially fatal dose for a child. When the products are used as intended (externally), their toxicity is minimal.

Side effects to either agent are uncommon. Contact dermatitis is the most frequently reported condition. Since pyrethrins are obtained from natural plant origin, allergic rhinitis and asthma attacks may be precipitated in susceptible individuals. When pyrethrins are inhaled, some persons may develop nausea and vomiting, which on rare occasion, can lead to muscle paralysis and even death. In most instances, cutaneous irritation and itching usually disappear within minutes.

The current literature contains conflicting reports regarding the potential of pyrethrins to cause allergic responses. The advisory panel stated that there is no standardized procedure for extracting pyrethrins from their natural sources. Therefore, the allergenic component(s) may be present in one batch but not in another. Nevertheless, the chance for an allergic reaction in a susceptible person is great enough that the panel recommended placing the warning: "Use with caution on persons allergic to ragweed" on all pyrethrin preparations. Pharmacists should make sure that all purchasers of these products heed this statement.

Manufacturers may indicate that their products are for treatment of head, pubic (crab), and body lice. The panel cited two other claims that cannot be made. In the first instance, no inference should be made that the product is ovicidal (capable of killing the eggs). The ovicidal effectiveness of these products is variously reported in the literature at 20 to 34% of nits killed, even though the panel recognized that the products, in actual clinical use, do have a high nit kill rate. In its opinion, current data do not support clinical claims that the products are ovicidal. Should such studies be undertaken

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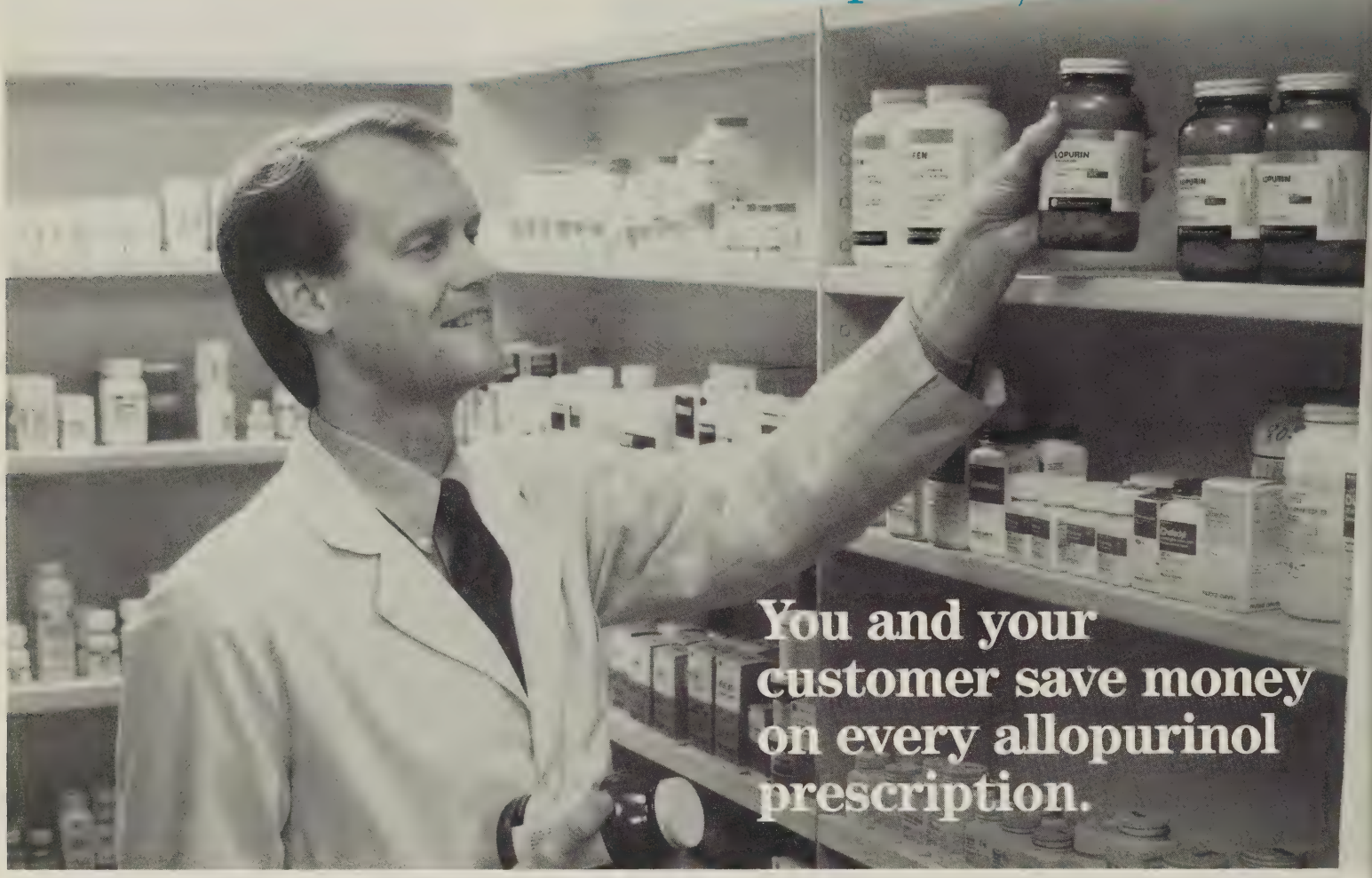

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and their results show a more positive ovicidal action, this indication could become permissible.

Secondly, no claim can currently be made that the product should be reapplied sooner than seven days. The reasoning behind this notice is that unaffected eggs usually hatch in 7 to 10 days, so any re-application prior to 7 days will not have maximum value.

Isobornyl Thiocyanoacetate. This ingredient has long been used as an OTC pediculicide for head, crab and body lice. However, the panel placed it in Category II (ineffective and/or unsafe) because of insufficient data demonstrating either safety or effectiveness. Until FDA rules on this recommendation, products containing isobornyl thiocyanoacetate (e.g., Thanite®) may continue to be sold.

Conclusions. At this time, there is no guarantee that the advisory panel's recommendations will be accepted by FDA, exactly as they are written. As is always the case, FDA's final rule will be published after public comment on the panel's report has been reviewed. If the panel's recommendations are accepted, then only those products containing a pyrethrin-piperonyl butoxide combination at concentrations of 0.17 to 0.33% pyrethrins and 2 to 4% piperonyl butoxide will be permitted to be sold as OTC pediculicides. One can expect to see a proliferation of new products, and nearly all of the previously non-complying ones have been reformulated to conform to the new standards. An interesting example of this is the product Barc® (this is "crab" spelled backwards). When the panel's report was published, its manufacturer reformulated it from isobornyl thiocyanoacetate to pyrethrins plus piperonyl butoxide. Table 2 lists the currently marketed products that meet the review panel's recommendations.

Adjunctive Therapy

OTC pediculicide products definitely kill the insects and probably kill their eggs. However, they do not dissolve the cement which holds the nits onto hair shafts, nor dislodge nits from their point of attachment. This point should be told to all consumers purchasing an OTC pediculicide. Like the residual itching that persists after the product has worked, the presence of remaining nits (albeit dead) may signal the consumer to needlessly re-apply the medication.

TABLE 2

OTC Pediculicides containing Pyrethrins and Piperonyl Butoxide Which Meet the FDA Advisory Panel's Standards of Safety and Efficacy

Liquids:	A-200 Pyrinate®
	Barc®
	Pyrinyl®
	Rid®
	Tisit®
Gels:	A-200 Pyrinate®
	Blue Gel®
	Tisit Blue®
Shampoos:	R & C®
	Rid®
	Triple X®

Therefore, nits must be manually removed by combing with a fine-tooth comb. Alternatively, white vinegar diluted in half with water, or rubbing alcohol used full strength or diluted, may be applied and left in place for several minutes to dissolve the cement; then may be removed by thorough shampooing. As a last resort, the patient can play "professor" and "nit-pick" them off, one-by-one! Patients should be advised to not confuse hair spray globules, hair casts, dandruff, or other extraneous debris with nits.

Equally important to killing all insects and eggs on the host, is eliminating them from clothing and other items that the infested person has come into contact with. The advice listed in Table 3 should be heeded.

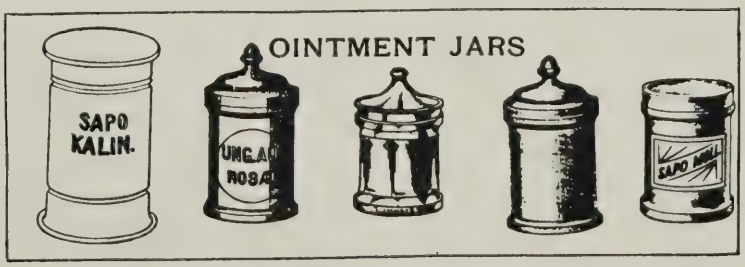
TABLE 3

Adjunctive Methods for Controlling Lice Infestations

1. *Washable material items:* machine wash in hot water (130°F) and dry; use hot cycle of dryer for at least 20 minutes.
2. *Nonwashable material goods:* dry clean or seal in plastic bag for 2 to 3 weeks.
3. *Personal items* (comb, brushes, etc.): soak in hot water (130°F) for 5 to 10 minutes.
4. *Carpets, chairs, couches, etc.:* Vacuum thoroughly. OTC spray products are no more effective in removing the risk of reinfestation than thorough vacuuming.

Summary

The pharmacist should actively counsel each consumer purchasing an OTC pediculicide product. The products will only work if used correctly; and when used properly, they are not only effective, but also safe. When lice are discovered on one individual in a family, the other family members should also receive treatment unless it is absolutely sure that they have not been exposed. All personal items and areas of the home which may have been contaminated must be de-contaminated (i.e., Table 3) if treatment is to be completely effective.



Improving Personal Selling in Small Retail Stores

By Bert Rosenbloom
Associate Professor of Marketing
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Summary

Good personal selling in retail stores is hard to find today. The small retailer who works at building a good personal selling effort will develop a valuable competitive edge over larger competitors.

The basic elements for developing a program to improve personal selling in your store(s) are discussed in this paper. If you are willing to develop your own program based on the framework and examples presented, your personal selling program will be a more effective and rewarding one.

Good personal selling in retail stores is getting harder and harder to find today. This is particularly true in the large multi-unit retail establishments that have increasingly stressed self service at the expense of good personal selling.

The deemphasis of personal selling by large scale retailers leaves a gap in customer service that the small retailer is in a good position to fill. By emphasizing good personal selling, the small retailer can gain a competitive edge not easily matched by the bigger stores. It is much easier for your larger competitors to dominate in such areas as merchandise assortments, pricing, and advertising, than to provide a well developed personal selling effort.

Good personal selling, however, does not automatically occur simply because the retail store is small. Nor does high quality personal selling result merely by paying sales people more money. Rather, good personal selling results from a carefully developed program which accounts for the major elements necessary in all successful personal selling programs.

This **Aid** discusses a basic framework for such a program as it applies to personal selling in small retail stores. By patterning your own program for improving personal selling along the lines suggested in this **Aid**, you are likely to improve the quality of personal selling in your store.

Good Personal Selling

Before discussing the framework for improving personal selling, lets define good personal selling at the retail level.

Personal selling in retailing is essentially a matching of the customer's needs with the retailer's merchandise and services. In general, the more skillfully this match is made the better the personal selling. If salespeople make a good match not only is a sale made but a satisfied customer is created (or maintained). Thus, a long term, profitable relationship can be established.

Figure 1 helps to illustrate this process. The salesperson is pictured as an individual attempting to match the needs of customers to the retailer's merchandise and services. If the match is made effectively, the salesperson is more likely to make the sale and satisfy the customer who will continue to patronize the retailer. Figure 1 suggests that there are three basic skills needed by salespeople to make this match effectively:

1. Salespeople must be skilled at learning the needs of the customer.
2. They must have a thorough knowledge of the merchandise and service offered by the retailer.
3. They must have the ability to convince the customers that the merchandise and service offered by their store can satisfy the customer's needs better than that of their competitors.

A Program for Improving Personal Selling

Developing a program for improving these three basic selling skills in your salespeople is the essence of building a better personal selling effort for your store. The framework for the program consists of three basic elements: (1) selecting people who are suitable for particular sales positions, (2) providing training, and (3) devising an appropriate compensation plan.

Selection. Finding good salespeople is a problem for both large and small retailers. Both are frequently heard talking about how hard it is to find "good" people. What they fail to realize, however, is that much of the problem is of their own making because they do not define clearly what they mean by good sales people. In short, these retailers do not specify what qualities they want in the salespeople they are seeking. It is no wonder then that they are not satisified with many of the people whom they hire.

An effective way to help avoid this problem is to use job specifications. This device has been used successfully for many years by large industrial firms. And, it can be used with equal effectiveness by small retailers. A job specification is basically a written statement, typically no longer than one or two paragraphs, delineating the requirements for a particular job For example, a job specification for a retail sales position in a sporting goods store might appear as follows:

An Example of a Job Specification
for a Sales Position in a Retail
Sporting Goods Store

Type of Job
Retail Sales of Sporting Goods

Requirements of the Job
This job involves mainly in-store sales of full line of sporting goods ranging from items of low unit value (such as golf balls) up to higher priced merchandise (such as complete sets of golf clubs and skiing equipment). The emphasis is on big ticket items. Telephone follow up selling is expected and there is occasional stock work.

The value of the job specifications is that it forces the retailer to be more explicit about what the job requires and thereby provides a guide for appraising the capabilities of prospective employees. For example, since the job discussed above emphasizes the big ticket items, the retailer should look for people who have this kind of experience. There are many instances of salespeople who can do an excellent selling job on low unit value merchandise but have trouble closing sales on the big ticket items. Job specifications help to avoid such problems.

Training. When the word training in mentioned, the small retailer typically associates this with the formalized programs conducted by some large department stores and national chains. However, sales training by the small retailers does not have to be, nor should it be, a formal and structured program. Actually, any conscious effort the retailer makes aimed at improving the three basic skills needed for effective retail selling is a form of sales training.

To get you on the road to thinking about the kinds of approaches you might use, here are several examples of sales training methods used by some small retailers.

An excellent method for developing a salesperson's skills at learning customer needs is through role playing. Role playing consists of acting out the customer-salesperson relationship by the salespeople. One person plays the part of the customers, and the other plays the part of the salesperson. Next time around, they reverse the roles. Role playing enables salespeople to see various sales situations from the customers' point of view. The skill necessary to quickly "size up" customers (learn about their needs) is rapidly sharpened through role playing. A particularly good time for you to try out this method is during slow period when your salespeople are just "standing around" anyway.

A good approach for improving the second skill—knowledge of the merchandise and service—is to make use of regularly scheduled sales meetings. Such meetings offer an excellent opportunity to discuss the features of new product, changes in store policies, new merchandising strategies, or other matters relating to the store's merchandise and services. These sales meetings do not have to be formal and precisely scheduled events. Instead, you can conduct them right on the sales floor during slack periods or shortly before the store opens for business.

What is important is that you hold these sales meetings regularly and frequently (once per week at a minimum) and that each meeting has a speific theme or focus. For example, at one meeting you might want to discuss the features of a new line of products which the store is now carrying and how to introduce these to the customer. The next meeting might focus on changes in the store's merchandise returns policy. The meeting after that you might talk about the sales strategies for the upcoming inventory clearance sale. If you hold these meetings regularly, you will be pleasantly surprised at how much better informed your salespeople will be about the store's merchandise and service offerings.

Training aimed at improving the third skill—the ability to convince customers that a store's merchandise and service offering is superior—is perhaps the most difficult. Some people believe that an individual either has this skill naturally or does not, and hence training makes little difference. While there may be some degree of truth in this position to the extent that people do differ in their natural communication abilities, training

can still make a difference. Such training can range from encouraging your salespeople to take a formal course in salesmanship to informales sales seminars which you can organize at your store. These seminars may be nothing more elaborate than sitting down with your salespeople for a half hour over a cup of coffee to discuss ways by which your store's merchandise and service offering can be better communicated to customers. These sessions if conducted informally (but regularly), will foster a constructive interchange of ideas about selling. For example, one salesperson might have developed a good argument which he or she used to successfully close a sale when it looked like the customer was ready to walk out. Good salespeople do like to talk about and share their success stories and can contribute to a sales development program.

Compensation. Unfortunately there is no one best way of compensating retail salespeople. Compensation plans depend upon the type and size of store, the number of employees, and the policies of the firm. There is however, a general principle that should be observed in any type of compensation plan. This is that compensation should be closely linked to performance.

The key to gaining a real understanding of the principle and being able to apply if to your compensation plan is in how you define performance. Performance does not mean simply sales volume. While the importance of sales volume cannot be overemphasized, other factors such as providing information to customers (which can lead to future sales), creating goodwill for the store through friendly and courteous service, and a willingness to help out in non-selling tasks are also important and should be rewarded. Failure to recognize these other aspects of performance is a mistake made by to many retailers. Hence, they tend to reward only the salespeople who make the most sales and neglect others who have acceptable sales volumes but do a better job in the other aspects of performance. Of course, if a salesperson does well in nonselling work and not in sales, this weakness must be dealt with through increased sales training.

Thus, if you feel that your salespeople are doing a good job, regardless of the volume they produce, let them know it. See if you can devise a way of reflecting your appreciation in their compensation. One retailer developed a rather ingenious approach using repeat business as a reflection of customer goodwill. This retailer developed an increasing schedule of commissions for sales to the same customer. This encourages the salespeople to treat customers right so that they would come back and ask for them by name. With some careful thought you can develop your own plan to more effectively reward good personal selling performance.

Poison Prevention Week Activities

Dear Pharmacist:

This is a special year for the Maryland Poison Center—it marks our 30th anniversary. Thirty years ago when Maryland's first poison centers were established at the University of Maryland and the Johns Hopkins Hospitals, poison control centers were a revolutionary concept in medical care. Today, the Maryland Poison Center is a mainstay in Maryland's emergency medical care system and is recognized both regionally and nationally for its expertise.

This year during Poison Prevention Week in Maryland (March 18–24, 1984), the Maryland Poison Center is using the national sub-theme, "Distractions can be disastrous," to emphasize that even a brief interruption—a phone call, a doorbell, a visitor—can be long enough for a child to be poisoned. This ties in with our educational focus which stresses poison proofing the home. If household products and drugs have been properly closed and stored out of reach, a child will not have access to a potential poison.

Your support in promoting Poison Prevention Week is always appreciated. Won't you complete the bottom portion of this form and return it to the Maryland Poison Center at 20 N. Pine St., Baltimore, MD 21201 so that we can publicize your contribution to our campaign?

Sincerely,
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State Coordinator, PPW-84

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Your name (optional): _____

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___ give a community/school presentation (where? _____)

___ have a display. PLEASE SEND ME FREE MATERIALS.

___ promote syrup of ipecac

___ sell syrup of ipecac at cost

___ give ipecac syrup away free

OTHER: _____

_____

DRUG-NUTRIENT INTERACTIONS

Therapeutic Class	DRUG NAME		Recommended Daily Vitamin/Mineral Supplement or Restriction During Drug Therapy*
	Proprietary Examples	Generic/ Active Compound	
Dermatological preparation	Accutane®	isotretinoin	Avoid vitamin A supplement
Antibiotics	Panmycin® Achromycin® Other Aureomycin®	tetracycline chlortetracycline	Riboflavin (B_2), 5 mg Ascorbic acid, 100-200 mg Calcium, 0.8-1.5 gm**
Anticonvulsants	Dilantin®	phenytoin	Vitamin D, 400-800 IU† Vitamin K, 1-5 mg Folic acid, 0.4-1.0 mg (not > 2.0 mg/day)
	Mysoline®	primidone	Vitamin K, 1-5 mg†
Anti-inflammatory	Azulfidine®	sulfasalazine	Folic acid, 0.4-1.0 mg
	Bayer aspirin® Bufferin® Other aspirin	aspirin	Ascorbic acid, 50-100 mg Folic acid, 0.4-1.0 mg Iron, 20-50 mg
	Indocin®	indomethacin	Iron, 20-50 mg
Antilipemic	Questran® Colestid®	cholestyramine colestipol	Vitamin A, 2000-5000 IU Vitamin D, 200-800 IU Vitamin K, 2-25 mg‡ Folic acid, 0.4-1.0 mg
Antituberculous	INH Rifamate®	isoniazid rifampin-isoniazid	Vitamin B_6, 25-50 mg Niacin, 15-25 mg Vitamin D, 400-800 IU
Anticoagulant	Coumadin®	coumarin anticoagulants	Avoid vitamin K
Diuretic	Dyrenium® Dyazide®	triamterene	Folic acid, 0.4-1.0 mg
Gastrointestinal	Agoral®	mineral oil	Vitamin A, 5000-10,000[11] IU Vitamin D, 400-800 IU
	Soda mint	antacids	Folic acid, 0.4-0.8 mg
Hypotensive	Apresoline®	hydralazine	Vitamin B_6, 25-100 mg
Oral contraceptives	Norinyl® Demulen® Ovral® Ortho-Novum® Modicon® and others	estrogen/progestin	Vitamin B_6, 1.5-5 mg Folic acid, 0.4-1.0 mg Avoid high doses of vitamin C (i.e. ≥ 1000 mg)
Tranquilizer	Thorazine® Mellaril®	chlorpromazine thioridazine other phenothiazines	Riboflavin, 2-5 mg
Other	Larodopa®	levodopa	Vitamin B_6, restrict supplement < 5 mg
	Depen®	penicillamine	Vitamin B_6, 25-100 mg

Pregnant or lactating women should consult their physicians for specific micronutrient recommendations.

*Short-term drug therapy may or may not necessitate specific vitamin/mineral supplementation.

**Calcium-containing foods and supplements should be given ≥ 2 hours away from drug dose.

†If Dilantin (phenytoin)-induced demineralization is identified, give vitamin D 2000 IU/day. Pregnant women on Dilantin or Mysoline should receive vitamin K_1 5 mg/day for 3 days prior to delivery and neonate should receive 1 mg.

‡Routine use of vitamin K_1 not required with Questran (cholestyramine) or Colestid (colestipol). Give vitamin K_1 I.M. in stated dosage range if hypoprothrombinemia exists.

[11]When daily dose of mineral oil preparation equals or exceeds 30 ml/day, a vitamin supplement is required. Recommended supplement, vitamin A, 5000-10,000 IU/day plus vitamin D, 400-800 IU/day. Mineral oil should be taken at bedtime and never within 2 hours of a meal. Toxic signs of hypervitaminosis A may occur with chronic intake of vitamin A (retinol), ≥ 50,000 IU/day in the adult and ≥ 20,000 IU/day in the infant or child. Hypervitaminosis D may occur with chronic intake of vitamin D ≥ 4000 IU/day or ≥ 1000 IU/day in the infant or child.

Prepared by Daphne Roe, M.D., Professor of Nutrition, Cornell University, Ithaca, New York, as a service to the health profession by Hoffmann-La Roche Inc.

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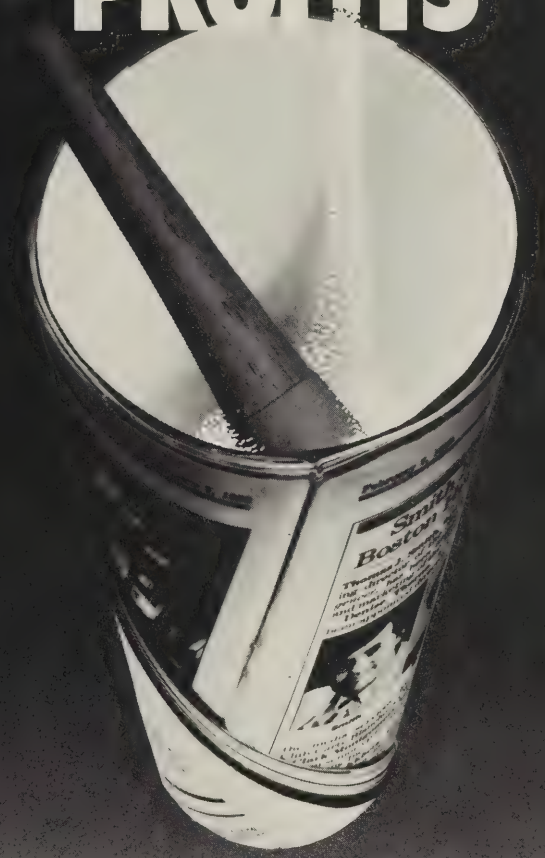

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Clam extract, anticancer goat serum, chaparral tea, krebiozen, D.M.S.O., laetrile, and approximately 75 other substances have been promoted for the unproven treatment, prevention or diagnosis of cancer by individuals preying on the emotions, fears and misconceptions of cancer patients and their families. Because of the unique role played by the community pharmacist in our health care delivery system, it is possible, perhaps even likely, that from time to time pharmacists may be asked to obtain such a substance for an unsuspecting patient. What should the pharmacist's response be? How does the pharmacist determine the validity of the request?

To help answer these types of questions, the American Cancer Society has prepared a pamphlet entitled "Unproven Methods of Cancer Management", Code No. 3014. Because of the recognized role of community pharmacists and the potential for them to interact on behalf of a misdirected patient, the Journal has requested and received permission from the Maryland Division of the American Cancer Society to reprint, in its entirety, this pamphlet. Original copies may be obtained by contacting the local community unit of the ACS. Individual evaluations of each unproven substance are also available. The individual monographs provide information regarding the proponents, the background of the "remedy", the scientific basis for the claims, and relevant references.

The pamphlet, reprinted on pages 16 to 20, provides an excellent statement of the problem, how it adversely affects patient care and some suggestions for appropriate responses by health professionals.

William R. Grove, M.S.
Professional Education Committee
Maryland Division
American Cancer Society

Unproven methods of cancer management are as much a part of the cancer problem as is the capacity of the disease to kill. Fear of cancer is nearly universal and becomes increasingly more acute the closer one comes to the disease, either as a patient or as a member of the family of the patient. Standard management with surgery, radiotherapy and/or chemotherapy, unfortunately, may be so fearsome in itself that many people are strongly tempted to seek unproven methods of treatment. The stakes are high. This year about 835,000 people will be diagnosed as having cancer. About 58 million Americans now living will eventually have cancer. When normal life expectancy is taken into consideration (factors such as dying of heart disease, accidents and diseases of old age), 41% of cancer patients will survive at least five years.

Fear and Unproven Cancer Remedies

Due to our inability to totally prevent and cure cancer, it is not surprising that the public is afraid of cancer and that enthusiastic claims for unproven remedies have appeared in increasing numbers to exploit these fears.

For more than any other reason, people go to proponents of unproven methods because they are afraid. What are their specific fears? (1) They fear that all cancers are incurable. Many people do not know that localized and even some moderately advanced cancer *is* curable. (2) They fear the expense. Many think it is less expensive to procure and use unproven methods than to place themselves under the care of a reputable physician. (3) They fear surgery, radiation or chemotherapy. Many prefer the illusion of painless, prompt medical "miracles." (4) They fear that their own doctor has given up hope and they are ready to clutch at any

Definition

Those diagnostic tests or therapeutic modalities which are promoted for cancer prevention, diagnosis or treatment and which are, on the basis of careful review by scientists and/or clinicians, not deemed proven nor recommended for current use.

Board of Directors
American Cancer Society, Inc.
June, 1981

straw. (5) They fear mental or physical disability. (6) They fear damage to the family through their illness.

The Problem is Old and Varied

Unproven remedies for the treatment of cancer are as old as the disease itself. In the 19th and 20th centuries, literally thousands of unproven cancer "remedies" were promoted and sold in this country. These remedies cover a wide range of materials, methodology and rationale.

Among the simpler ones are phony salves and escharotics (substances producing a scab) used to treat external cancer; natural products such as cobwebs saturated with arsenic powder; liquid applied as a poultice, or clover blossom tea; and raw diets such as the grape diet which requires the patient to live exclusively on grapes or grape juice for a period of one to two weeks. Other complicated or special types of diet such as the "metabolic diet" are often proposed, either as the principal treatment or in combination with drugs and compounds, which are purported to cure cancer.

Biological products, prepared from the patient's own blood and/or urine, or from animal blood and/or urine, have been promoted.

Numerous machines and devices for the diagnosis and/or treatment of cancer have been used, such as a zinc-lined pine box in which the patients sat to absorb the "orgone energy," or the more portable "coloronics" hand-held box.

Others claim that cancer is caused by an imbalance in the body and that it may be cured by rectifying this imbalance. Special "vitamin" preparations, which do not conform to the necessary criteria to identify a substance as a vitamin, are widely sold as cancer "controls" or "preventatives."

The extent of the unproven methods problem is a measure of our inability to cure cancer totally and our failure to offer complete support to the patient and his family.

Proponents of Unproven Methods of Cancer Management

Proponents of unproven methods are encouraged by the nature of the disease itself. Statistics indicate that cancer is on the increase; the disease is often fatal; it is expensive; and has a psychological impact on the family that is difficult to bear.

Such proponents are the beneficiaries of the overworked, the incompetent, the disinterested, the brusque professional and orthodoxy's misuse and overuse of drugs, the "no time to listen or explain" syndrome, therapy that is often prolonged and unpleasant, the fear of mental or physical incapacity, and the "what have I got to lose" attitude.

Proponents of unproven methods of cancer management range from ignorant, uneducated, misguided persons to highly educated scientists with advanced degrees who are out of their area of competency. Some proponents hold Ph.D. or M.D. degrees. Their false promises and exaggerated claims lead patients and their families to believe that cure can be achieved or at least that marked improvement is possible. The hope they offer is sometimes considered worth the large sums of money that the "treatment" may cost. Unfortunately, many patients with curable cancer leave the care of competent physicians to be treated with a worthless, unproven remedy until a cure by accepted methods becomes impossible; thus, they have in effect been killed instead of cured. Proponents of unorthodox methods often seek out cancer patients and their families as the prime targets of their propaganda, playing not only on fear and ignorance, but on the natural desire to make suffering loved ones as comfortable as possible.

Certain common features are noted among those with some scientific background or degrees:

- They tend to be isolated from established scientific facilities or associates.
- They do not use regular channels of communication (current, reputable, scientific journals) for reporting scientific information. Physicians of this type tend to publish articles in journals which are not read by cancer specialists.
- They claim that prejudice of organized medicine hinders their efforts.
- They are prone to challenge established theories and attack prominent scientists with bitter criticism.
- They are quick to cite examples of physicians and scientists of the past who were forced to fight the rigid dogma of their day.
- They are often inclined to use complex jargon and unusual phraseology to embellish their writing.
- Their records are scanty or nonexistent.
- They often discourage, or even refuse, consultation with reputable physicians. If a scientific evaluation of their methods is made, they generally decline to accept the results, claiming that the "medical trust" is against them.
- Their method of treatment is often secret and is available only from them. Or, the mode of administration depends on special judgment which can be learned only from them.
- They discount biopsy verification in cancer diagnosis, sometimes by saying that it "spreads" the cancer. They may accept patients who have already been cured of cancer by orthodox means but fear they have not.
- They may use proven drugs or other methods of treatment as adjuvants to the unproven therapy, and if a favorable effect on cancer is shown, claim that it is the result the their unproven remedy.
- They may have multiple unusual degrees such as N.D. (Doctor of Naturopathy), Ph.N. (Philosopher of Naturopathy), or Ms.D. (Doctor of Metaphysics). These degrees may have been received from correspondence schools.

- Their chief supporters tend to be prominent statesmen, actors, writers, lawyers, even members of state or national legislatures—persons not trained or experienced in the natural history of cancer, the care of patients with cancer, or in scientific methodology.

A common pattern is that of the proponent who has tried a remedy in several people with what seem to be good results. These are often based entirely on the subjective response of the patient, which may result from the false hope instilled in him. The proponent claims the results as "research," which in turn provides the basis for testimonials—the earmark of this type of treatment.

Some proponents do not claim to have a cancer cure, and treat only advanced cases for palliation, charging only the cost of the materials used. On investigation, it is usually discovered that there is no documentation to support their claimed results. Careful objective records are not available. Diagnoses are not confirmed by biopsy. Treatment used is not made freely available to other investigators for independent trial under controlled conditions.

How Cancer Patients Become Involved With Unproven Methods

Personal Contact

Proponents of unorthodox methods seek out cancer patients and their families as the prime targets of their propaganda. In some areas, the traffic in unorthodox medicine is so well organized that proponents of unproven methods have been able to infiltrate hospitals in order to tout their remedies in waiting rooms; patients have been persuaded to forego conventional treatment by apparently "chance" acquaintances who have "inside" information about the alleged success of an unorthodox treatment. Their typical arguments include: "This is nontoxic and therefore harmless; the patient has nothing to lose and everything to gain." "Nobody claims that this will cure cancer, but it *controls* cancer and relieves the patient's pain." "The patient has a right to the treatment of his choice, and it's evil to deprive him of that choice."

Many cancer patients who seek treatment with unproven methods do so because they have heard about someone who was supposedly cured or greatly improved by using the treatment. Information distributed by proponents of unproven cancer remedies is largely made up of testimonials from patients who allegedly have cancer who have been treated by a particular method, and from families of such patients.

Books—Magazines—Advertisements

An important factor in the promotion of unproven methods of cancer management is our free press, making it possible for books, magazines, newspapers and the mass media to present seemingly favorable information on unproven methods. Books on medical science, especially if they are on so-called controversial medical problems, are quite appealing to the reading public. This type of book is often so skillfully written that the average reader concludes that he himself can make a valid judgment on the merits of the treatment in question, usually in favor of its use. By distributing pro and con information throughout the book, the author may give the reader the impression that he is impartial and therefore factual, although the argument is heavily weighted in favor of the method. The reader, once convinced, then becomes a promoter of the treatment, recommending it to his associates and friends.

Unproven cancer remedies get additional support from sensational mass circulation magazines which are anxious to publish the latest "pseudo-scientific" theories and "advances," especially if they are controversial.

In addition to sporadic articles in mass circulation magazines, there are a variety of "health" magazines which are especially interested in unproven treatment regimens. Most are issued monthly and reflect an opposition to the "medical monopoly" and accepted forms of treatment. Such magazines are the forum for proponents of unproven remedies and non-medical approaches to health in this country, and many individuals get information on these unproven methods from them. A favorite ploy is to send a gift subscription to the family of someone under treatment for cancer.

One of the most popular "health" magazines is *Prevention,* published by Rodale Press. This magazine carries articles on unproven methods and developments in the health field. Articles are generally well written and often include features on worthless methods of cancer management, sometimes by the chief proponent of the method. *Prevention* magazine also publishes advertisements of unproven methods of cancer treatment and/or books which describe them.

Radio and Television

With the interest in cancer so general and the desire to find an effective treatment for cancer so widespread, any unproven remedy which becomes well known and controversial is likely to be discussed on television and radio. Personalities and issues associated with unorthodoxy often appeal to the "show business" instincts of broadcasters. Attempts are made to set up pro and con confrontations in the hope of starting lively debates. If the representatives of conventional treatment refuse to participate, pointed references to their refusal are made on the air. When only the proponents are interviewed, some moderators attempt to even things up by playing the devil's advocate, but the proponents almost always get the last word. Stations may attempt to compromise by interviewing representatives of each side separately and blending the results on the air. This solution is equally satisfying to quackery proponents because even after every statement supporting an unorthodox remedy has been completely repudiated, many in the audience

will still choose to accept the unorthodox point of view. Their reasons often have an emotional base. Since among the media, television tends to most easily stimulate emotional response, its relative impact is usually greatest in those viewers who are involved in personal cancer crises and are searching for any source of hope. By being on the air, the proponents have been given an opportunity to disseminate information to a widespread audience that would otherwise not have been reached. It is ironic that in the name of "public service," many cancer victims have been lured away from beneficial treatment and have fallen into the hands of proponents of unproven methods of cancer management.

"Health" Organizations

As mentioned previously, much information on unproven methods reaches the public through meetings and other activities of "health" organizations which are in opposition to the "medical monopoly," or "establishment." Such organizations adopt high-sounding purposes and purport to be concerned about freedom of choice for the patient, the costs of medical therapy and the protection of the public; they play on fear and rely on testimonials and personal experience. These organizations have strong fund-raising campaigns through sales, dues and fees. They hold revivalist-type meetings and feature highly emotional appeals. Laetrile, Krebiozen, Hoxsey and Gerson dietary method are some of their widely promoted unproven remedies.

One such organization is the International Association of Cancer Victims and Friends (I.A.C.V.F.), founded in 1963 by Cecile Hoffman, a cancer patient who believed her life had been saved by the use of Laetrile. Mrs. Hoffman died in 1969 of metastatic cancer.

Another organization is The Committee for Freedom of Choice in Cancer Therapy, Inc., founded in California in 1972.

The Committee for Freedom of Choice in Cancer Therapy is supported by donations from its members. It holds seminars symposia, doctors' conferences and workshops, and distributes books, pamphlets, cassette tapes and other information on unproven methods of cancer management. The Committee maintains an educational and advocacy group working for the vindication and legalization of laetrile as well as the concept of freedom of choice in cancer therapy.

The Committee for Freedom of Choice published a quarterly magazine, "The Choice," that promotes the use of unproven methods of cancer management such as laetrile, chelation therapy, Jason Winters' Herbal Tea, some forms of holistic medicine and metabolic therapy.

These and similar organizations attack generally accepted medical services and agencies such as the American Medical Association, voluntary health agencies such as the American Cancer Society, and Federal agencies—usually the Food and Drug Administration and the National Cancer Institute—for their orthodox approach to the management of cancer.

Sponsorship by Prominent Individuals

In addition to support or promotion by organized "health" groups and various types of publications, unproven remedies are often championed by prominent citizens.

Entertainers, socially prominent persons, celebrities and others in the public eye may be persuaded to promote various unproven methods of cancer management. These individuals, while they are often sincere, do not have the scientific training or background to judge the merit of the method they are promoting, and are unaware of the strict criteria for scientific investigation necessary before a drug or method of diagnosis or treatment is acceptable for medical use. They are uninformed of the proven effective medical treatments available and the danger of delay in not using them.

Standards of Scientific Investigation of Unproven Methods

If the investigation is to be conclusive, scientific standards must be established. These should be the normal scientific criteria required to substantiate any claim for a product and must be capable of confirmation by others.

Standards of investigation in cancer should include at least the following criteria: complete evaluation of all clinical and laboratory data presented by the proponent including cases histories, X-rays, and microscopic slides; reproducible analysis of the drug and laboratory results; observations on the effects of the therapy under study in a sufficient number of patients with biopsy-proven cancer; assessment of treatment results for each case compared to other previous or concomitant therapy; examination of autopsy data; and consultation with other investigating groups.

Problems Connected With Investigation of Unproven Methods

The history of medicine reveals numerous instances in which important advances came from rather humble beginnings. Leads must be followed if there is the slightest possibility of gain. Numerous letters are received by various government and private agencies from people deeply anxious to help provide a cure. So in many instances, some preliminary investigation by a qualified agency is required. However, it would be physically impossible and scientifically absurd to investigate every suggestion, no matter how well-meaning, that is offered by the lay public.

With most unproven methods of cancer management it is difficult if not impossible to secure the cooperation of the involved proponents. Difficulties may develop in several ways:

- The amount of supporting evidence is extremely scant.
- Frequently, biopsy proof is lacking; when available, it is sometimes found that the entire tumor has been removed surgically or destroyed radiologically prior to the initiation of the treatment in question.
- Patient interviews are hard to obtain.
- Case histories are incomplete.
- No patient follow-up information is available.
- Autopsy data is usually not provided.

In addition to the difficulty of initiating and carrying out such a scientific evaluation of unproven cancer remedies, an unfavorable result is seldom accepted by the proponent or causes any reduction in his efforts and promotions.

Because of the medical profession's insistence on reliable standards of proof of efficacy and safety, the proponents of unproven remedies are prone to charge that they are being persecuted by the "medical trust" or "organized medicine."

This article will be continued in the April, 1984 issue of the Maryland Pharmacist.

This and That about Pharmacy

by Leon Weiner, P.D.

Charles Myers will be honored as the "Man of the Year" by the Beth El Men's Club. The affair will be held Wednesday April 11, 1984 at Beth El 8101 Park Heights Avenue, Baltimore, Maryland 21208. Starting at 6:00 P.M. Myers has worked for Read's Drug Company and Baltimore City Hospital as a pharmacist. Call 484-0411 for information on affair.

The University of Maryland Pharmacy Class of 1955 had a bad month of January 1984 in losing two of their outstanding members. On January 14, 1984 Jean Chow Wong passed away in the Rockville area. Four days later on January 18, 1984, Alan Lee Settler passed away in Coral Springs, Florida.

It appears that owning a pharmacy has some strong appeal for some people. For example, Iving J. Heneson has recently acquired Wilkins Pharmacy, 1625 Wilkens Ave, Baltimore, Maryland 21223. In the past, Heneson has owned Heneson's Pharmacy and Manheimer Pharmacy. Another case is Gerald N. Freedenberg who recently acquired Irvins's Pharmacy, 4001 Annapolis Road, Baltimore, Md. 21227. Freedenberg had been part owner of Caplan's Drug Store.

Harry Bass, President of the Alumni Association is very proud these days. No wonder! His daughter, Debby, will be graduating from University of Maryland School of Pharmacy this May.

Pharmacists will be seeing different faces from the Division of Drug Control. Two new staff members are Raymond Lichter and William Hahn. In the past, Hahn has worked for Eli Lilly and Giant Drug Company. Raymond and his brother, George Lichter, owned Joe Weiner and Company for many years.

The following are new Pharmacies which opened up about December 1983.

1. Syncor Corporation
   10033 M. George Palmer Highway
   Lanham, Maryland
2. Revco # 2724
   4400 Park Heights Ave
   Baltimore, Maryland
3. Bethany Pharmacy
   10176 Baltimore National Pike
   Suite 111
   Ellicott City, Md.
4. Fort Washington Prescription Shop
   11701 Livingston Road
   Fort Washington, Maryland
5. Dennis Professional Pharmacy
   10313 Georgia Ave
   Silver Spring, Maryland
6. Antietam Pharmacy
   1595 Oppossumtown
   Antietam Village Center
   Frederick, Md.

The following are new pharmacies which opened up about January 1984.

1. Big B. Pharmacy
   2401 Belair Road
   Baltimore, Md.
2. Glen Vilah Community Pharmacy
   12962 Travilah Road
   Potomac, Md.

The following are pharmacies which closed in the Month of January 1984.

1. Arcade Pharmacy
   500 Race Street
   Cambridge, Md.
2. West Street Liquor and Pharmacy
   1100 West Street
   Annapolis, Md.
3. Great Oaks Center Pharmacy
   12001 Cherry Hill Road
   Silver Spring, Md.

Pharmacy changes Name.

1. Leader Drug (was Sav-A-Lot Pharmacy)
   609 Taylor Ave
   Annapolis, Md.
   12001 Cherry Hill Road
   Silver Spring, Md.

Imminent Hazard? The Case of Phenylbutazone and Oxyphenbutazone

by Peter P. Lamy, Ph.D., F.A.G.S.

Responding to a request from The Public Citizen Health Research Group, an organization founded by Ralph Nader, the secretary of health and human services, Margaret M. Heckler, agreed to a review of two widely used anti-arthritic and anti-inflammatory drugs, i.e. phenylbutazone and oxyphenbutazone. On December 29, 1983, the FDA announced that a full review of the two drugs will be undertaken and that the benefit-risk of these drugs will be re-examined.

What happened?

Well, the chronology of events seems to go something like this: In February 1983, CIBA-GEIGY in Basel, Switzerland, finished two internal memoranda regarding these two drugs. Apparently, these memoranda were part of an effort of CIBA-GEIGY to update the labeling of these two drugs, based on an internal review. The review turned up reports of overall usage of these two products (50 to 100 million people who have taken phenylbutazone and 40 to 80 million people who have taken oxyphenbutazone in the last 20 to 30 years). The memoranda also cited company statistics on 1, 182 deaths world-wide, mainly due to aplastic anemia, which depresses bone-marrow production mainly of red blood cells; agranulocytosis, which depresses production of white blood cells leading to heightened susceptibility to infection; leukemia; and gastrointestinal bleeding, peptic ulceration, or both.

A swedish physician, Dr. Olle Hansson, who apparently has been active in the past regarding the publication of adverse drug effects, seems to have been able to obtain copies of these memoranda and published their content in a swedish newspaper. Apparently, he also sent copies to Ralph Nader's group.

Early in December, representatives of CIBA-GEIGY met with the Deutschen Bundesgesundheitsamt (their FDA). The two sides reached an agreement that open hearings would be held on March 15, 1984. However, near the end of December, the Germans requested from CIBA-GEIGY some immediate action. As of January 1, 1984, these two drugs may be prescribed only for chronic inflammation of joints, particularly of the spine, and in acute attacks of gout, with a limitation of seven days on usage. The open hearing will be held as scheduled.

The Norwegian Ministry of Health ordered that, as of April 1, 1984, the two drugs would be available only on a case-by-case basis, and that they could be dispensed only by application to the Ministry of Health.

Physicians and pharmacists in Switzerland received a letter from CIBA-GEIGY early in December, 1983. The letter suggested that the two drugs be used only for acute attacks for a maximum of one week (the dangerous adverse effects apparently appear only after several weeks of use in 80% of the reports, although, according to newspaper reports, Dr. John L. Decker, an arthritis specialist at the National Institutes of Health, is quoted to have said that the risks from the two drugs do not appear to increase with extended use, indicating that users who have not had adverse reactions probably will not have them).

The Schweizerische Kontrollbehoerde IKS (their FDA) will review the problem in January 1984 to determine a course of action.

In the meantime, Dr. Sidney Wolfe of the Health Research Group, calculated the data somewhat differently. First of all, the assumption is made (and not incorrectly at all) that many adverse drug effects are neither recognized nor reported by physicians (as an editorial comment, it might be added that just this statement alone ought to serve to underscore the need for pharmacist participation in long-term, home health care). In any case, based on these considerations and other calculation, the Health Research Group calculated that in the United States, probably 3,000 people died from the adverse effects of these two drugs and set a world-wide figure of 10,000 fatalities.

The FDA countered with the statement that their files showed only 311 fatalities as of the middle of 1982 and that "the drug's known side effects, clearly emphasized in the current labeling have, properly, led to a declining use".

CIBA-GEIGY has declared that it "strongly believes that [both drugs] are safe and effective as currently labeled and that they are useful alternatives to be available in the physician's armamentarium [and that it] will vigorously contest any effort to remove these products from the market".

Stay tuned.

Dr. Lamy is Professor and Director, the Center for the Study of Pharmacy and Therapeutics for the Elderly and Chairman, Dept. of Pharmacy Practice and Administrative Science, School of Pharmacy, University of Maryland at Baltimore.

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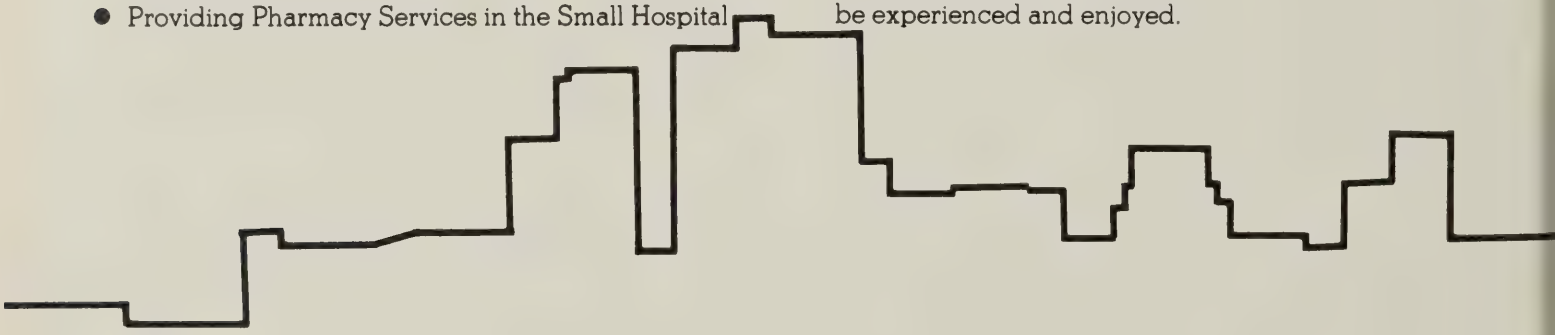

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MPhA Introduces A New Member Service and Journal Feature

The patient education aid on the right is the second in a series presented by the MPhA Public Affairs Committee. It is intended to assist the pharmacist in providing useful health information to his or her patients. If this sort of material is valuable, the committee hopes to prepare such aids on a continuing basis. Since the effort at right represents a "pilot test" it would be most helpful if members would let us know whether they are able to utilize such material, suggest future topics, or suggest improvements in content or format. Please address your comments to MPhA, 650 W. Lombard St., Baltimore, Md. 21201.

The aid is designed for distribution to patients as a "package stuffer" or for mailing as an enclosure with monthly statements. Where possible, and for best results, review the material with your patients, emphasizing items of individualized importance.

To remove the patient aid, simply cut along the dotted line. The aid may be reproduced in quantity by photocopier or inexpensive offset printing. If you want to add your name, address, or other information, place such information so that it covers the artwork in the upper right hand corner.

How CPR training helps business.

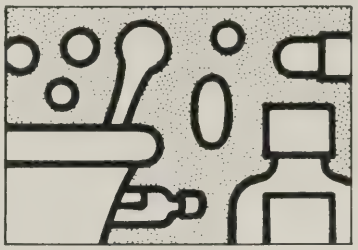
CPR—cardiopulmonary resuscitation training is one of the valuable assets an employee can have.

If even one employee has this training, (which is available from Red Cross), every other co-worker benefits. Everybody can breathe easier knowing that in the event of a cardiac arrest, help is immediately available.

Why not set up a goal for your company... so many employees with CPR training per floor—or area?

It's easy to do. Call your Red Cross Chapter... they'll be glad to help you do it.

Things You Should Know FOR YOUR GOOD HEALTH



Earache and Ear Drops

An ear ache is such a common affliction that few of us go through life without experiencing this malady. During the winter months ear aches are especially common in young children and babies. The ear, being a vulnerable and complicated organ, may have a number of things affecting it, all of which can cause ear ache of one kind or another.

Wax in the ear, if it becomes hard and caked, can cause trouble. Children often place foreign bodies in their ears, and sometimes foreign bodies, such as insects, fly into ears by accident.

Never try to dig anything out of an ear; you may only push it in further and may actually perforate the delicate eardrum. Drop some warm, sweet oil (olive oil), mineral oil, or baby oil in the ear while the head is turned to the opposite side, and let it remain there for a few minutes.

While instilling drops into the ear, pull backward a little on the lobe of the ear; this will straighten the canal, (the tube between the outside of the ear and the eardrum) and let it fill more easily. Then let the oil run out and the foreign body may come out with it. Gently wipe the canal with a tissue. For a specific demonstration talk to your pharmacist.

External otitis is an infection of the tissues of the external ear canal and is another cause of earache. This condition is not limited to children and may occur at any age. It is common during the summer swimming season and is often referred to as swimmer's ear. This infection may be extremely painful, and is accompanied by redness and swelling of the tissues of the canal.

Non-prescription products, including ear drops, are often effective in treating external otitis. An acidified aluminum acetate solution may decrease swelling within the ear and eliminate crusting of the ear canal lining. Consult your pharmacist when selecting a specific non-prescription product.

Ear drops are of very questionable value in otitis media. This is a more serious infection of the deeper or middle portions of the ear behind the ear drum. It is common in young children, particularly from age three months to three years. This condition is present to some degree in almost every acute upper respiratory infection. The reason for this is that in young children the eustachian tube, leading from the ear into the throat, is relatively short and straight and easily allows infection to ascend from the nose and throat into the middle ear. With this painful ear infection, fever may rise to as high as 105 degrees F

Pressure inside the ear may increase to the point where the eardrum breaks and bloody pus leaks into the ear canal and then from the ear itself. If the child cannot talk, he will be crying because of the pain, which is usually worse at night or may come on suddenly in the middle of the night. He may be brushing and pulling at the affected ear as if he were trying to get rid of it. Treatment of otitis media usually requires a physician's care and the use of antibiotics given by mouth and/or injection.

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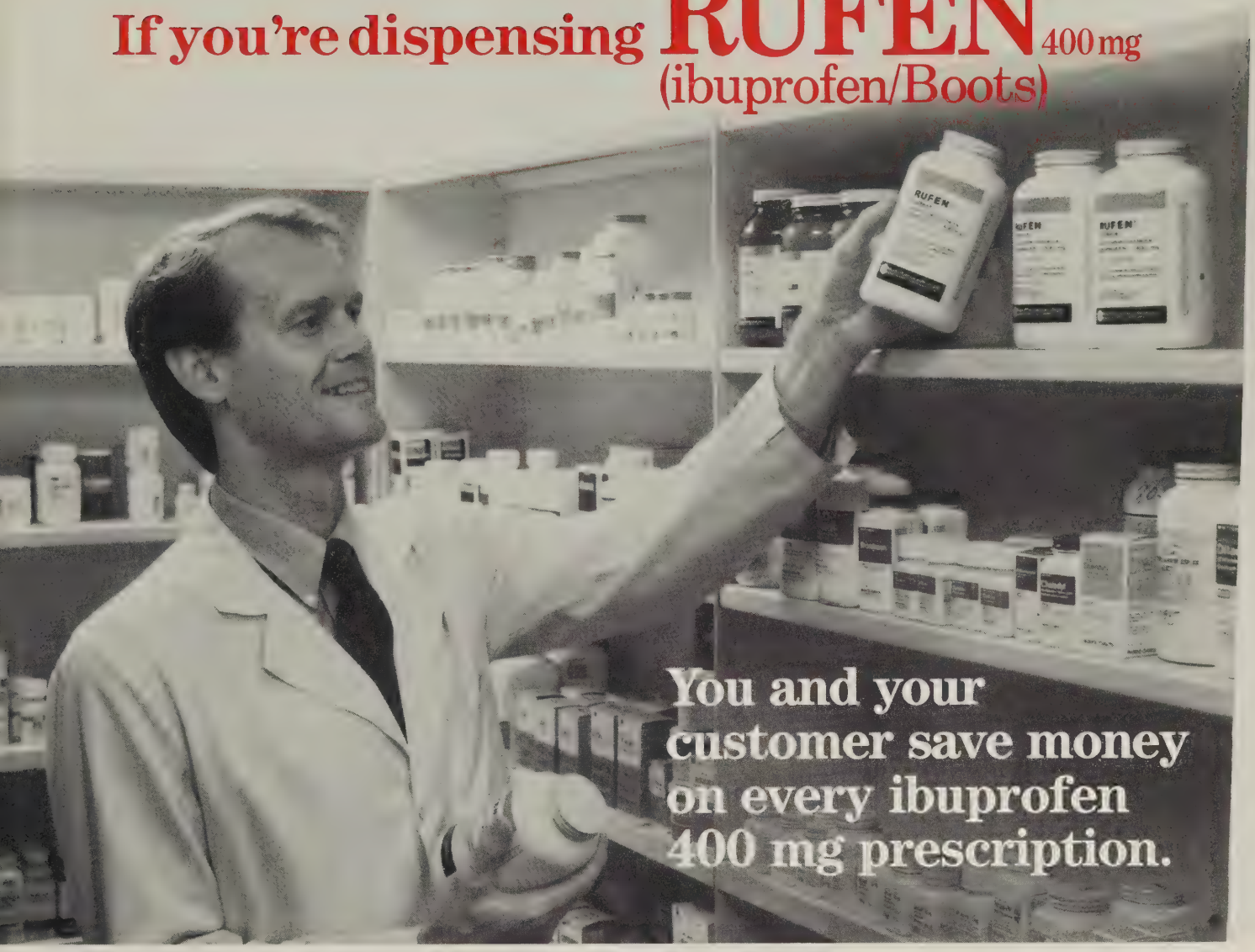

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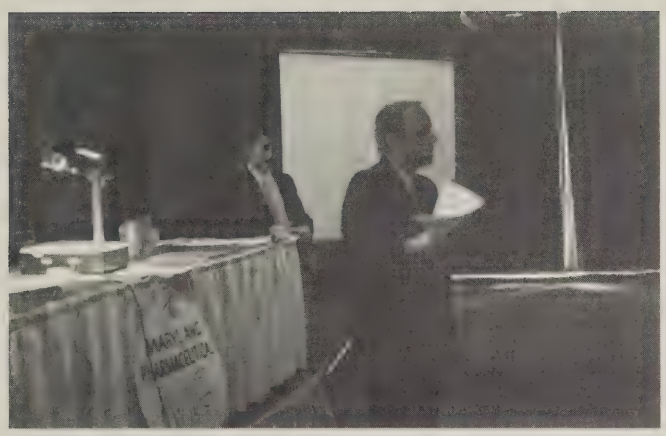
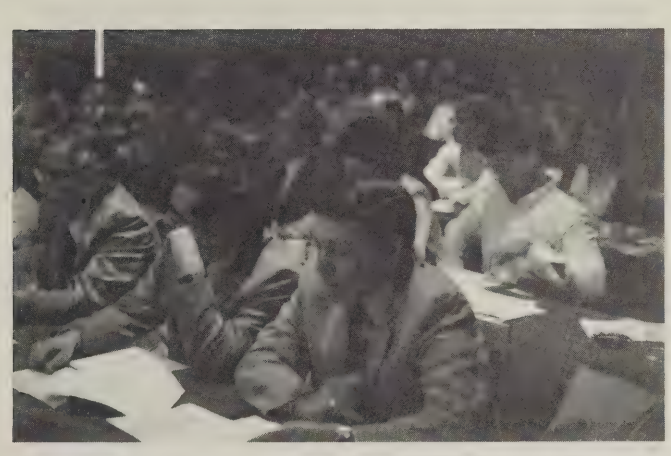


Thomas Gossel (right) and Richard Wuest (left) presented a continuing education program on the "Rx to OTC Switch, Obituary or Opportunity" at the First Annual Mid Year Meeting held January 28th in Annapolis, Maryland. They are also authoring a series of articles in the *Maryland Pharmacist,* (See page 4).

Recently, (left to right) Andy Mirabole, American Lung Association of Maryland; Robert Whitney, Commerce and Industry Combined Health Appeal; Elza Davis, Medical Society; and Carol Shaner, The Joseph E. Shaner Co. met in the Kelly Building to begin studying for the American Society of Association Executive's Certified Association Executive Examination.



An overflow crowd at the Annapolis Hilton also saw the House of Delegates approve the Nominating Committee Report for the election of Officers and Trustees for the Association which will take place soon.

Director of Medicaid Compliance Administration, Larry Payne (left) and Medicaid Pharmacy Operations Specialist Joseph Fine (right) were speakers on the Mid Year Meeting's Pharmacy Law Review Panel.

ABSTRACTS

Excerpted from PHARMACEUTICAL TRENDS, published by the St. Louis College of Pharmacy; Byron A. Barnes, Ph.D., Editor and Leonard L. Naeger, Ph.D., Associate Editor

PAIN SENSITIVITY:

Pain is perceived differently by different people and by the same person in different circumstances. Investigators found that the same patient placed in a laboratory setting will be able to tolerate pain much better than if they were in a clinical setting. Anticipation of harm, and anxiety seem to enhance the sensitivity to pain. *JAMA,* Vol. 250, #6, p. 718, 1983.

LEGIONNAIRE'S DISEASE:

Since 1976, there have been isolated at least 23 different organisms in the Legionella subgroup and 10 serogroups of Legionella pneumophilia, the organism responsible for the outbreak of Legionnaire's disease in 1976. Clinical diagnosis depends on laboratory tests to detect antibodies using the indirect fluorescent method. The organisms are found in water including that in the hot springs in Yellowstone Park, the rain forests of Puerto Rico, irrigation sprinklers in Israel, and in commercial and domestic cooling systems employing water as an agent to transfer heat. The organisms do not always seem to be associated with infection and thus studies are continuing to determine which species are more virulent in man. Good engineering practices are thought to help reduce the contamination of the water systems which serve as reservoirs for these bacteria. *Br Med J,* Vol. 287, #6390, p. 443, 1983.

CADMIUM:

Cadmium has been shown to inhibit the agonist-induced contraction of cardiac, vascular, myometrial, and intestinal muscle. In-vitro studies show that although it is possible that cadmium affects the contractile system of these muscles directly, there is strong evidence to support a calcium channel blocking action of this ion. *J Pharm Pharmacol,* Vol. 35, #8, p. 505, 1983.

PREMATURE LABOR:

Ethanol had been used to prevent premature delivery, but its use was virtually eliminated when it was discovered that the beta-2 adrenergic agonists would produce better results with less toxicity. Agents such as terbutaline (Brethine) and riodrine (Yutopar) have been used successfully but careful monitoring of both mother and fetus is required. In situations where these agents are refractory or not tolerated, substances such as magnesium sulfate, postaglandin synthesis inhibitors, diazoxide, or calcium antagonists may be used. *Drugs,* Vol. 26, #3, p. 243, 1983.

PRESCRIPTION ERRORS:

A study conducted in a large hospital outpatient department has been used to establish guidelines for pharmacists employed in these facilities. Over a 12 day period of time, six full-time pharmacists made dispensing errors in approximately 12% of the prescriptions filled. Most of these errors were made during times of high volume filling and increased as the day went on. Most errors were not of a serious nature, but it was estimated that 1.5% of them were potentially serious. Under circumstances such as those in this institution, a pharmacist should be expected to fill 16 prescriptions/hour without error. Errors in any profession are difficult to discuss but only through identification of high risk areas will practitioners be able to reduce the number of errors. *Drug Intell Clin Pharm,* Vol. 17, p. 742, 1983.

FENFLURAMINE AND AUTISM:

Approximately 40% of autistic children have been found to have elevated levels of serotonin in their plasma. Since fenfluramine may have an effect on serotonin, it was administered to a small group of autistic children to determine if improvement might be gained by using the drug. Initial reports are encouraging and larger studies are now being conducted to determine the role fenfluramine (Pondamin) may have in treating this generally refractory condition. *JAMA,* Vol. 250, #11, p. 1369, 1983.

PASSIVE SMOKING AND LUNG CANCER:

Non-smokers have an increased risk of lung cancer if they are married to heavy smokers. Likewise, family members have an increased risk of neoplastic disease if there is maternal smoking. No association between paternal smoking habits and cancer in the family was noted as was the case if both parents were non-smokers. It has not yet been determined if genetic and/or environmental factors play a greater role in this disease. *Lancet,* Vol. II, #8350, p. 595, 1983.

ALPHA-1 RECEPTORS:

The post synaptic alpha-1 adrenergic receptor was studied in animal tissue to determine the ionic events which may be altered by binding of an agonist to these receptors. It appears that alpha-1 agonists are capable of increasing the contraction of the smooth muscle by allowing for additional influx of extracellular calcium. The calcium ion is necessary for smooth muscles to contract and all of the calcium responsible for contraction comes from the outside of the cell. Other work shows that alpha-1 receptor blocking agents will inhibit the uptake of calcium ions by the reperfused animal myocardium, thus reducing contractility. *J Pharmacol Exp Ther,* Vol. 226, #3, p. 668, 1983 and *J Clin Invest,* Vol. 72, #3, p. 802, 1983.

BENDECTIN:

A jury award for $750,000 to the family of a woman who gave birth to a child with deformed hands has been reversed by a Superior Court Judge. The woman had taken Bendectin during the pregnancy and claimed the drug was responsible for the malformation. The judge stated that there was insufficient evidence to support the jury's finding. Bendectin has been withdrawn from the market because of the litigation against it. Merrel-Dow maintains the drug is not responsible for these effects. *Am Med News,* Vol. 26, #37, p. 25, 1983.

ANTINEOPLASTIC AGENTS:

Lederle Laboratories is working to market three new antineoplastic agents. Mitoxantrone (Novantrone) is used in combination with other agents to treat breast cancer and by itself as therapy for leukemias and lymphomas. Bisantrene is also useful in treating malignancies of the breast while decapeptyl has shown promise in arresting growth of cells in the prostate gland. *FDC Rep,* Vol. 45, #35, p. 11, 1983.

ALCOHOL:

Increased plasma concentrations of high density lipoproteins (HDL) are generally associated with a reduction in cardiovascular disease. Another study has helped confirm this earlier hypothesis and shows that a moderate alcohol intake does increase the concentration of plasma HDL thus decreasing the incidence of cardiovascular disease while at the same time reducing the formation of cholesterol gallstones. *Lancet,* Vol. II, #8354, p. 819, 1983.

PIPERACILLIN:

Piperacillin is a ureidopenicillin related to both azlocillin and mezlocillin. It is active against many carbenicillin-resistant organisms, but it is destroyed by organisms which produce beta lactamase enzymes. Metronidazole and moxalactam seem superior to piperacillin in treating Bacteriodes infections. In serious infections such as those caused by Pseudomonas aeruginosa organisms, piperacillin is most effective when combined with an aminoglycoside. *Drug Ther Bull,* Vol. 21, #18, p. 71, 1983.

PHENCYCLIDINE AND THE HEART:

The abusable drug phencyclidine has been found to decrease heart rate while at the same time increasing the force of contraction. Studies conducted with myocardial tissue suggest that muscarinic activation is not involved with the reduction in chronotropic effects but phencyclidine does seem to facilitate calcium entry into the muscle thus suggesting a mechanism to account for its ability to increase the inotropic effect of the heart. *J Pharmacol Exp Ther,* Vol. 226, #3, p. 885, 1983.

BLOOD ALCOHOL DETERMINATIONS:

The analysis of blood alcohol is an involved procedure which prompted investigators in Canada to devise a "dipstick" test for the detection of the intoxicant. Although currently made by hand, plans for mass production of the strips are being formulated. Different strips can be used to detect alcohol levels in various ranges in blood, urine and other biological fluids within 60 seconds. *JAMA,* Vol. 250, #13, p. 1658, 1983.

VITAMIN A:

Children with mild vitamin A deficiencies were found to have greater risk of death than those with sufficient amounts of the vitamin. Signs of mild vitamin A deficiencies include mild xerophthalmia, night blindness and Bitot's spots. These are important anthropometric indices for screening children to assess their need for supplemental vitamin A therapy. *Lancet,* Vol. II, #8350, p. 585, 1983.

HISTAMINE:

Histamine has been shown to increase renal flow via dilation of the renal arterioles. Studies conducted in animals suggest that both H-1 and H-2 receptors are involved in this response. The presence of histamine seems to reduce the output of norepinephrine from adrenergic nerve endings after neuronal stimulation thus reducing the vascular response of the sympathetic nervous system. This leads to increased renal perfusion. *J Pharmacol Exp Ther,* Vol. 226, #3, p. 712, 1983.

SENTRALINE:

A new drug, sentraline, has been shown to inhibit the reuptake of serotonin by neuronal endings in the central nervous system. Since this effect is associated with the administration of the tricyclic antidepressants, it has been suggested that sentraline be used in depressed patients because it seems to produce the desired effect without producing the anticholinergic and cardiac toxicities generally associated with tricyclic use. *J Pharmacol Exp Ther,* Vol. 226, #3, p. 686, 1983.

ZINC:

Zinc is a trace metal which has been found to be important for normal growth and maintenance of health. Zinc deficiencies have been noted to occur during pregnancy, especially in women taking iron supplements. This cross-over study indicates that iron competes with zinc for uptake from the GI tract and that zinc deficiencies may result from long-term ingestion of iron supplements. *Br Med J,* Vol. 287, #6398, p. 1013, 1983.

AMINOGLYCOSIDE TOXICITY:

Aminoglycosides produce serious renal toxicity which seems to be dose dependent. These drugs apparently bind to phosphoinositides in the cell membrane and interfere with their activity. This reaction reduces the substrate availability of the renal membrane phosphoinositide and thus may represent the mechanism by which the aminoglycosides produce their renal toxicity. *J Pharmacol Exp Ther,* Vol. 227, #2, p. 415, 1983.

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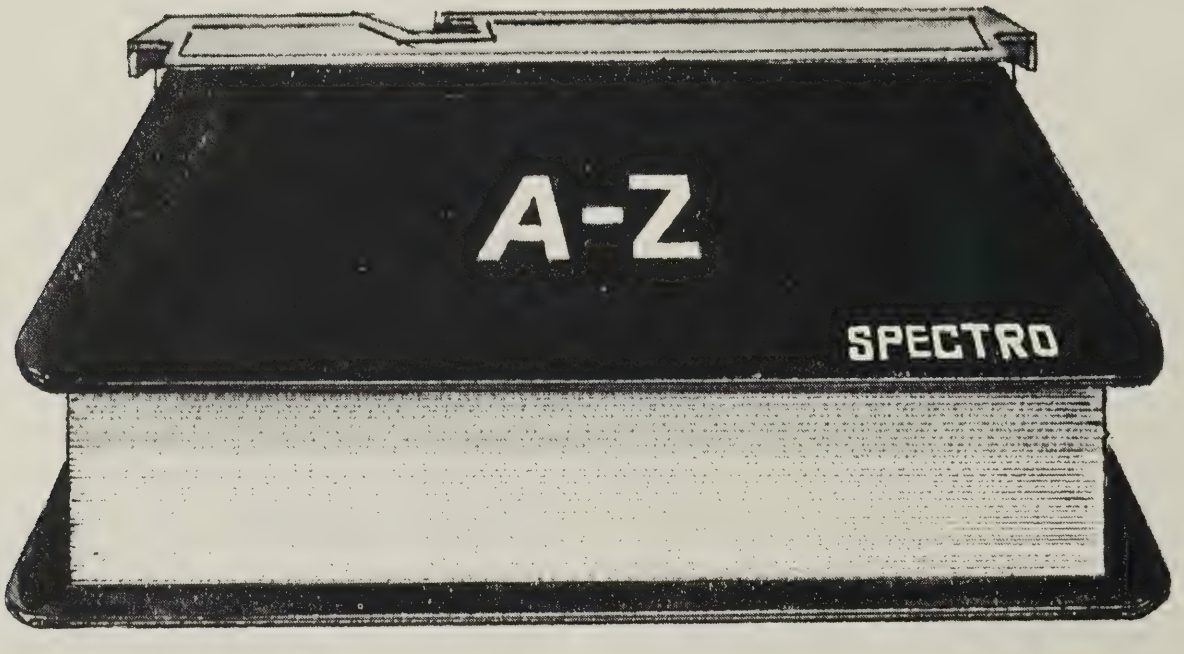

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Cocaine Information Center

A national telephone information and referral center called "**800 Cocaine**" has opened at Fair Oaks Hospital, a psychiatric hospital in Summit, New Jersey. A toll-free telephone number, "800 Cocaine" (**800-262-2463**), connects a caller—a cocaine user, family, or friend—from anywhere in the United States to a staff of cocaine rehabilitation experts at Fair Oaks. The hospital is linked to treatment centers, hospitals, and physicians in every state. The caller may have questions answered or be referred to the nearest treatment facility or physician without fear of losing anonymity.

"800 Cocaine" is a voluntary, nonprofit endeavor. The staffing hours are 9:00 a.m. to 2:00 a.m.; during the off-hours, messages may be left on an answering machine.

LETTERS

Dear Mr. Banta:

In the upcoming weeks, the Baltimore City Health Department in cooperation with the Baltimore City Foundation, Mayor's Office and community organizations is sponsoring the *Give A Seat . . . Save A Life* campaign. The event is an effort to help needy families comply with the Maryland law requiring that infants two years old and younger be secured in a car seat; children three to four years in car safety seats or safety belts.

I would like your support in helping me to secure car seats for parents who otherwise cannot afford them. Please notify your members and encourage them to bring to your location their car seats which are no longer being used. We will provide you with receipts for income tax purposes. Arrangements will be made to have the seats picked up from your site.

In addition, nine locations have been identified around the City as *Collection Sites* where persons with car seats can leave their donation. Each center will have a person designated to give receipts so that contributions can be used as an income tax deduction.

Someone from the campaign office will be in touch with you regarding your decision to participate. If you have any questions, please contact Sheryl Taylor at 396-4442, Baltimore City Health Department.

Thank you for your cooperation.
Sincerely,
William Donald Schaefer
Mayor

calendar

March 11—BMPA Annual Banquet, Bluecrest, Pikesville
March 16–18—AZO Fraternity Regional Convention—Hyatt Hotel, Baltimore
March 18—CE Seminar—Fritz Berman Seminar—Hyatt Hotel, Baltimore
April 1—CECC Seminar—Critical Care—Timonium Holiday Inn
April 6–8—NARD Home Health Care Conference, Dallas
May 5–10—APhA Convention, Montreal
June 22–24—MSHP Seminar, Ocean City
June 24–28—MPhA Convention, Ocean City

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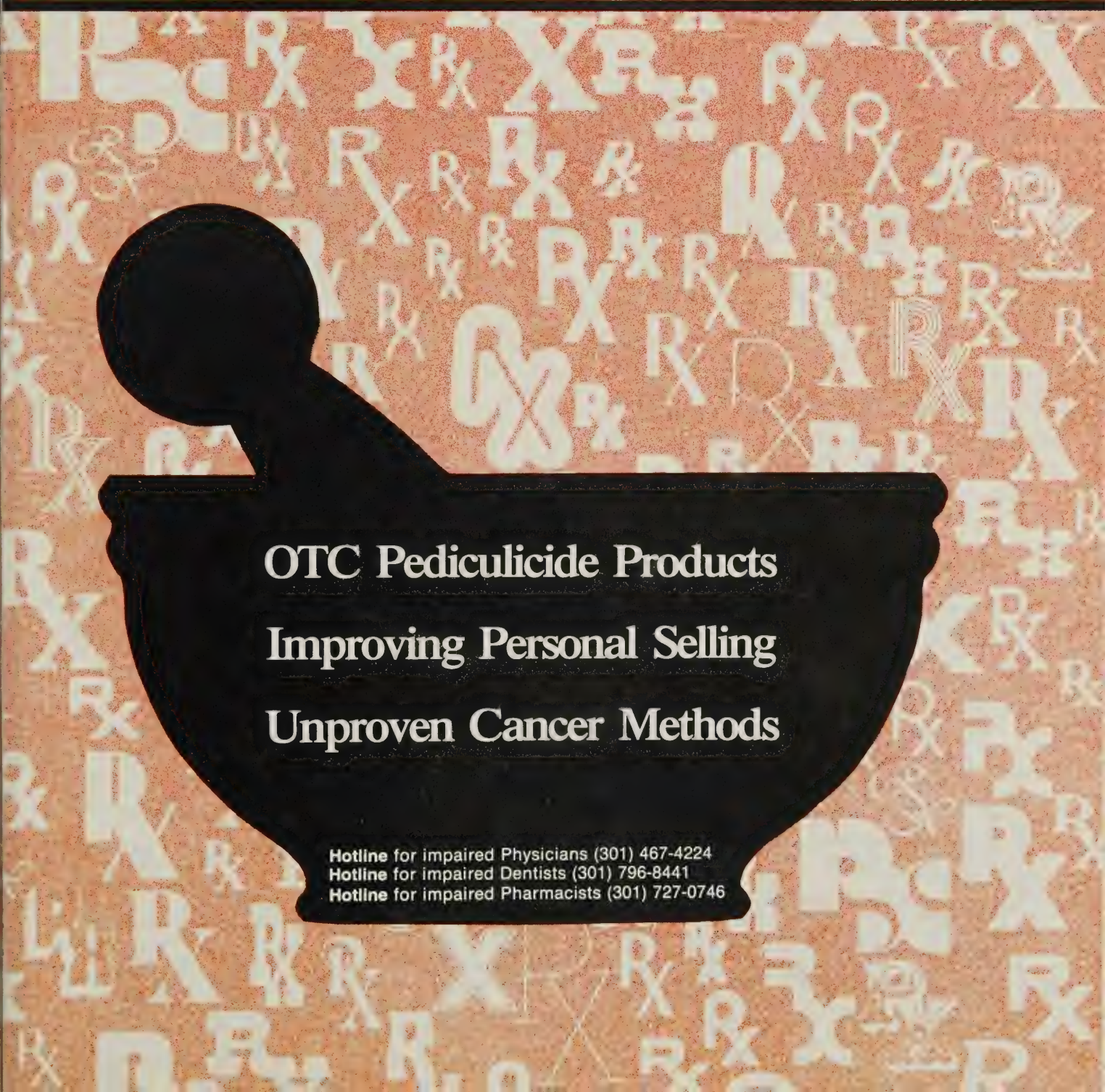

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APRIL, 1984 VOL. 60 NO. 4

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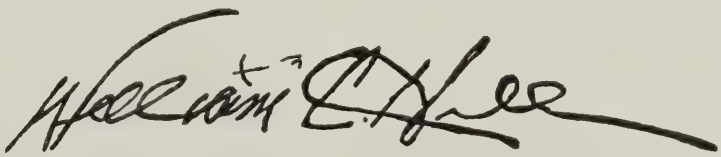
DAVID A. BANTA, *Editor*
BEVERLY LITSINGER, *Assistant Editor*
ABRIAN BLOOM, *Photographer*

There is the old joke—"What did one frog say to the other? Time's fun when you're having flys."

My term as your President has seemed to pass in a hurry. The Association has accomplished a great deal in these past months. We are having another successful year in the legislature which will be reported in the newsletter. We are involved in a number of negotiations with various regulatory agencies. Our membership statistics are on the increase. I can report to you that the organization is vital and actively working on a number of important issues. For example, home health care may be the hottest topic in pharmacy right now. State government is currently considering regulations for this expanding field. The situation is very fluid and the role of the pharmacist in home health care has not been fully defined. Recognizing the need for rapid and decisive action, the Board of Trustees authorized a Task Force on Home Health Care to be Chaired by Madeline Feinberg. The Task Force has been extremely active and this issue of the *Maryland Pharmacist* carries information generated from their work. I believe that this Task Force will have an important impact upon this developing health care delivery system. Home health care is much more than the sale of prescription drugs and durable medical equipment. Home health care agencies must recognize the pharmacist as a community based health professional with a role in drug monitoring in the home setting.

While the year has passed at great speed for me personally, the progress of the Association has been steady and remarkable.



William C. Hill, P.D.

PRESIDENT

SCOPE
STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION • VOL. I, NO. 4

Self Medication of Topical Bacterial Infections

By J. Richard Wuest, R.Ph., Pharm. D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, OH

and Thomas A. Gossel, R. Ph., Ph.D.
Professor of Pharmacology
Ohio Northern University
Ada, OH

Goals

The goals of this lesson are to:

1. Discuss the self-treatment of topical bacterial infections.
2. Review the pharmacology and therapeutics of drugs used to treat topical bacterial infections.

Objectives

At the completion of this lesson, the successful participant will be able to:

1. Choose the appropriate OTC agent for treating topical bacterial infections.
2. Properly advise consumers on the selection and use of OTC dermatological agents.
3. Decide when the consumer should be referred to a specialist.

in the service of pharmacy

This continuing education for Pharmacy article is provided through a grant from MERRELL DOW PHARMACEUTICALS INC.

Each of us lives in an environment where we are surrounded by countless microorganisms. Some are pathogenic while others are benign. Some cause life-threatening diseases, and others are needed for life to properly continue. This latter group serves numerous useful purposes including production of some vitamins and foods; ecological destruction of substances that would otherwise not be biodegradable; proper digestion and putrefication of the food we eat (e.g., lactobacilli); production of biologicals, insulin and other life-saving drugs; and possibly, in the near future, production of prostaglandins and energy.

Protection against pathogenic bacteria, that cause disease should they gain access to the systemic blood supply and internal organs, is provided to a large degree by the epithelial tissue (i.e., the mucous membranes of the alimentary canal and the skin).

A number of organisms can, should conditions be right for them, infect the skin. If allowed to multiply unheeded, they can gain access to the internal organs. Paramount among these are staphylococci, streptococci, and pseudomonae. Normally, the skin is an adequate barrier to these organisms due to its physical nature, its slightly acidic pH, and the normal flora of nonpathogenic organisms that reside there.

The many layers of "dead" keratin cells (stratum corneum) not only help hold the body together and prevent leakage of its contents, but also prevent outside materials from gaining entrance. The stratum corneum is not conducive to bacterial growth since it usually contains less than ten percent water. However, if the skin is macerated with large and continuous amounts of water, if it is occluded so that water accumulates, or, if it is injured in such a way that bacteria can invade, infection is quite likely.

The acid "mantle" of the skin is also thought to impede bacterial infection. In the normal person, the skin's surface is slightly acidic, normally between pH 4.5 and 5.5. This is due to sweat and secretions from the sebaceous glands that deposit fatty acids on the skin's surface. Since most microbes optimally grow at a higher (more alkaline) pH, their growth is inhibited. Herein lies another example of nonpathogenic microorganisms being useful for prevention of invasion by those that are pathogenic. Propionbacteria (formerly called corynebacteria), which are normal inhabitants of the skin and environment, thrive on sebum. They convert this lipid material into the fatty acids that are both bactericidal and fungicidal. They, and other bacteria, help remove waste products from the skin by metabolizing them and breaking them down, thus converting these body by-products into smaller particles that can be washed away. It should also be pointed out, however, (and it will be discussed in detail in a later lesson) that these normally nonpathogenic organisms can be contributory to severe acne if sebum production becomes excessive and the pilosebaceous ducts (pores) become plugged up.

The propionbacteria and other nonpathogenic organisms that reside on the skin also prevent the overgrowth of pathogenic bacteria there

by successfully competing with them for nutrition and space. One point to keep in mind is that these helpful organisms can be removed by excessive washing with strong detergents or with "antibacterial" soaps, thus leaving the skin open to infection by more serious pathogenic bacteria. This will be discussed further.

Bacterial Infections Of The Skin

The bacterial infections that have traditionally been considered to be self-treatable without medical supervision are those that result from minor skin cuts, abrasions, and burns. Another group that lies on the borderline between being safe for self treatment and requiring medical supervision are the mild pyodermas.

A **pyoderma** is a bacterial infection that leads to formation of pus in the skin. It is of some interest to note that **pus** is not a bacterial colony. Instead, it consists of white blood cells (leukocytes) and debris of dead cells and tissue elements which have been liquified by proteolytic enzymes during the normal inflammatory response. The most common of these pyodermas are impetigo, folliculitis, furuncles, and carbuncles.

Impetigo is generally subdivided into two groups depending on whether the major infective organism is streptococcal or staphylococcal. The streptococcal variety is referred to as nonbullous (**impetigo contagiosa**). As the name implies, this variety is extremely contagious but is usually benign and self limiting. It can, however, in approximately one percent of all individuals who contract it, lead to a systemic infection resulting in severe kidney damage. Poor hygiene, over-crowding, and warm, moist climates increase the occurrence and spread of impetigo.

Traumatic damage to the skin usually gets it started because streptococci do not easily penetrate intact skin. The trauma that allows entry of these bacteria includes insect bites, poison ivy and oak, small cuts, or intense scratching of the skin's surface. It should be pointed out that the streptococcal strain which causes impetigo is totally different than the one that causes "strep" throat.

Impetigo contagiosa begins as a small red spot which rapidly develops into blisters. These then fill with yellow fluid and rupture. Some will dry and form a crust. The infection spreads with the fluid that contaminates other parts of the body or other persons. This condition is referred to as a pyoderma because pus will often form in the blister and, upon rupturing, will add to the crusty material that forms.

The other type of impetigo that is caused by staphylococci is referred to as **bullous impetigo.** It does not occur as frequently as does the impetigo contagiosa, and it does not spread as easily. This form looks pretty much like the streptococcal type, except that the blisters are much larger and not as much pus is formed. The crusty material is also more varnish-life in appearance than granular. We will discuss treatment of impetigo contagiosa shortly, but would like to point out at this time that since the bullous variety is caused by staphylococci, penicillin VK is not effective in its eradication. This form requires treatment with a penicillinase-resistant penicillin (e.g., Tegopen®, Prostaphlin®, etc.) or erythromycin.

Folliculitis is a pyoderma infection that occurs around the hair follicles. It is caused by staphylococci that have entered that area, and, due to conditions being right, are able to rapidly grow and multiply. The condition looks similar to severe pustular acne.

Furuncles, more commonly referred to as boils, are also caused by staphylococci. They occur most frequently on hairy skin that is subject to friction or maceration. The affected area becomes softened due to occlusion and sweating. The neck area is a common site of boil formation. Boils are differentiated from carbuncles in that a boil has a central core from which the exudate is discharged.

Carbuncles, on the other hand, are much larger and deeper than boils. They develop in thick, nonelastic skin — most commonly the neck, back and thighs. Carbuncles drain at multiple sites rather than through a central core. They are also caused by staphylococci organisms.

Treatment of Pyodermas

Since **impetigo contagiosa** is the most commonly encountered form of pyoderma, we will discuss it in more detail than the others. Medical science considers topical antibiotics to be ineffective in the treatment of impetigo contagiosa and suggests early referral of the individual to a physician. The opinion is held that this will reduce the duration of infection and the chance of spread to others. While impetigo is a mild disease, it may take six to eight weeks to clear on its own and frequent reinfection or spread to other persons is likely.

The treatment of choice of impetigo contagiosa is penicillin VK for a ten-day course of therapy. Erythromycin, cephalosporins, and clindamycin are alternatives to penicillin VK. If the condition is severe, widespread, or if there is a problem with compliance, benzathine penicillin (Bi-Cillin®) is the treatment of choice. Procaine penicillin does not give high enough blood levels for a long enough period of time. The contemporary conservative view is that topical antibiotics are not only no more effective than placebo, but may actually result in a slower healing rate and continued development of new lesions.

The other more liberal opinion is that while topical antibiotics are not the treatment of choice for impetigo, a considerable number of the persons most likely to be infected, the indigent, are unable or unwilling to see a physician and obtain a prescription. Many of these people are even less likely to take their children to the doctor. This group also has the highest incidence of kidney damage due to untreated impetigo. It is interesting to note that the OTC Advisory Panel on Topical Antibiotics agreed with the "liberal" view and felt that the potential risk is serious enough to consider and evaluate impetigo as an OTC indication for topical antibiotics even though their effectiveness has not yet been proven.

In any case, it is important to assure that parents understand that the impetigo lesions must be carefully cleaned. This is best accomplished by gently washing off the crusty material with nonirritating soap. The more advanced lesions would require soaking in warm water, saline

or soap solution for fifteen to twenty minutes, three to four times a day for their removal. Fluid from the blisters and under the crusts must be absorbed onto some material such as facial tissue or toilet paper and discarded carefully. As stated earlier, the infective organisms will be present in these fluids and the impetigo can spread to others. Some physicians advise applying a bland ointment to the cleaned lesion after the crust has been removed to prevent entry of foreign materials and additional bacteria. When the condition is extensive or does not clear after seven to fourteen days, the parent should be urged to take the child to a physician because of possible systemic complications.

Topical Antibiotics Available Over The Counter

These agents are listed in Table 1. Those that are currently considered to be safe and effective for OTC use by the FDA include bacitracin, neomycin, polymyxin, and the tetracyclines. Its advisory panel has ruled that gramacidin requires further study before it can be so designated.

TABLE 1
Currently Marketed OTC Topical Antibiotics

Bacitracin*
Chlortetracycline
Gramacidin*#
Neomycin*
Oxytetracycline
Polymyxin B*
Tetracycline

*Also available in combination products
#Evidence of effectiveness lacking

Bacitracin is a bactericidal antibiotic that acts by preventing proper synthesis of bacterial cell membranes. Its spectrum of activity is quite similar to penicillin (i.e. mainly gram-positive with a few gram-negative bacteria sensitive to it), but it has never shown the degree of hypersensitivity that the penicillins have. It is recommended that bacitracin be used with polymxyin, neomycin or both for optimal range of activity.

Neomycin is a relatively broad-spectrum antibiotic and a member of the aminoglycoside group. These agents act by a number of mechanisms including interference with cell wall development, bacterial enzyme activity, and intracellular respiration. Since some normally susceptible organisms (including the staphylococci) may develop resistance to neomycin, it is generally used in combination with either polymyxin, bacitracin, or both, to prevent this occurrence.

Polymyxin B is an antibiotic that is effective mainly against gram-negative organisms. It acts by a detergent mechanism—on entry into the membrane of susceptible organisms, it breaks down the linkage between the lipid-protein-lipid structure and causes the organism to burst. Its spectrum is limited to gram-negative organisms. Since gram-positive organisms are so prevalent in dermatological infections, polymyxin is not considered to be an adequate antibacterial agent when used by itself. Most commonly it is combined with bacitracin which broadens the spectrum of the combination significantly.

The **tetracyclines** are broad-spectrum antibiotics effective against both gram-positive and gram-negative organisms. They act by interfering with enzymatic activity within susceptible organisms and preventing their growth and reproduction. Because the tetracyclines are bacteristatic rather than bactericidal, and because of the development of a high degree of resistance by gram-positive strains, their topical usage has dropped off considerably in recent years.

Gramacidin was placed in the "needs more study category" by the FDA advisory panel because of questions on its safety. Gramacidin is a polypeptide antibiotic with a mechanism and spectrum of activity quite similar to bacitracin. There is no doubt that it is effective. The problem is that it has never been studied adequately for use by itself. All studies of gramacidin have been with products in which it is included as an ingredient of a combination (e.g. Mycolog®). While there is no overt evidence of toxicity when used topically, gramacidin is a potent hemolytic agent that can cause destruction of red blood cells. The FDA review panel has suggested that toxicity studies be conducted before approving it as a Category I (safe and effective) OTC antibiotic.

Findings of the FDA Advisory Panel on OTC Topical Antibiotics

This panel reported that OTC topical antibiotics should be used only as part of first aid treatment of small superficial wounds such as cuts, abrasions and burns. It made a major issue of the fact that, before any self medication of a minor wound begins, gentle, thorough cleansing of that wound is the important first step to remove any debris or bacteria that may be present. The panel found that application of antibiotic ointments to small wounds acts as a protective barrier against further contamination and helps prevent microbial proliferation. However, it found that there was insufficient data to prove that topical antibiotics are effective in treating infections of small cut wounds or abrasions and that such use requires more study before a final ruling can be made. Since this report, FDA has ruled that **treatment** of infections is not an OTC indication and it will not allow manufacturers to make such claims. It should be kept in mind that FDA's authority only extends to the manufacturer and its labeling. It does not affect physicians and pharmacists.

Therefore, the previous discussion of whether topical antibiotics are proper for impetigo requires some explanation. While manufacturers may not indicate their products for impetigo, physicians can certainly prescribe, and, pharmacists can recommend their use—within the limits of good professional judgment.

It is beyond the scope of this lesson to delve too deeply into the legal-medical aspects of professional judgment. However, it is the opinion of the authors that pharmacists are acting reasonably and prudently if they contact several pediatricians in their area and ask for opinions on recommending the use of topical antibiotics for mild, uncomplicated impetigo. Part of the discussion should include the understanding that, when a case of obvious prolific infection is seen, the patient will be referred to the physician. The results of this consultation will direct the

pharmacists in dealing with persons requesting advice on impetigo.

The FDA's advisory panel reported that chronic OTC application of topical antibiotics, especially to areas where systemic absorption is probable, should be avoided. The panel specifically pointed out that antibiotic use on diaper rash, extensive heat rash, large burns, and open ulcers should be discouraged. The FDA has agreed with this and will require that the following warning be placed on all OTC topical antibiotic products: "Do not use in the eyes or apply over large areas of the body. In case of deep or puncture wounds, animal bites or serious burns, consult a doctor." The same advice is necessary for redness, irritation, swelling or pain. If they persist or increase, the consumer should discontinue use and consult a doctor. One final warning is "Do not use longer than one week unless directed by a doctor". Certainly, if the condition has not cleared up by then, medical supervision is needed.

Another point of interest is that the FDA OTC advisory panel that reviewed boil remedies concluded that self treatment is not desirable because improper treatment or delay in receiving proper treatment may cause the infection to spread. The panel stated that "drawing salves" have no merit in treatment of boils, and, that moist heat is an effective means of bringing the boil to a head. Sometimes the boil will then drain spontaneously. Recurrent boils require systemic treatment with the appropriate antibiotic (since *Staphylococcus aureus* is the most common infective organism, a penicillin-resistant antibiotic is indicated). The panel suggested that the currently used agents listed in Table 2 should be considered mislabeled if they are labeled, represented, or promoted for external use as boil remedies until their manufacturers conduct studies to prove them safe and effective. Since FDA has not made its final ruling on this recommendation, these products can remain on the market in the interim.

Other OTC Antimicrobials

Numerous other antimicrobial agents have been used for years (phenol was used as a germicide by Lister over a century ago). This group includes the quaternary ammonium compounds (QAC), iodine and the iodophors, phenol and its derivatives, the mercury-containing compounds, alcohol, and several chemically synthesized agents. The categories of these agents in current use are listed in Table 3.

TABLE 2
Active Ingredients In Currently Marketed Boil Remedies

Benzocaine
Camphor
Ichthammol
Juniper tar
Magnesuim sulfate
Phenol
Rosin
Thymol

Quaternary Ammonium Compounds (QAC)

These agents have been in common use as antiseptics and disinfectants since the mid-1930's. They are referred to as surface active agents, but a more appropriate term would be "membrane" active. They enter susceptible organisms and affect membrane permeability leading to the loss or leakage of cell contents. Gram-positive microorganisms are considerably more susceptible to the effect of QAC's than gram-negative ones. Their most serious drawback is that they may leave the area open to invasion by non-susceptible pseudomonas organisms. At very high concentrations, the QAC's can inhibit or kill pseudomonas but the concentrations required are so high that they are very irritating and therefore not desirable for use on the skin.

It is generally held that the microbial spectrum of QAC's does not vary significantly from compound to compound. Benzethonium (e.g., Phemerol®) and cetylpyridinium (e.g., Ceepryn®) are members of the group, but benzalkonium (Zephiran®) has become the most commonly used agent. In its deliberations, the OTC advisory panel did find convincing evidence that these agents are safe and effective as skin wound cleansers. However, there was insufficient evidence to convince the panel that QAC's are effective as antiseptics or any of the other categories listed in Table 3.

TABLE 3
OTC Antimicrobial Product Categories*

Skin Antiseptic: A non-irritating, antimicrobial-containing preparation which prevents overt skin infection.

Patient Pre-Operative Skin Preparation: A fast acting, broadspectrum antimicrobial-containing preparation that significantly reduces the number of microorganisms on intact skin.

Surgical Hand Scrub: A non-irritating antimicrobial-containing preparation that significantly reduces the number of microorganisms on the intact skin. A surgical hand scrub should be broad-spectrum, fast-acting and persistent.

Health-Care Personnel Handwash: A non-irritating preparation designed for frequent use, which reduces the number of transient microorganisms on intact skin to an initial baseline level after adequate washing, rinsing and drying. If the preparation contains an antimicrobial agent, it should be broad-spectrum, fast-acting, and if possible, persistent.

Skin Wound Cleanser: A non-irritating liquid preparation (or product to be used with water) that assists in the removal of foreign material from small superficial wounds; does not delay wound healing; may contain an antimicrobial ingredient.

First Aid Antibiotics: A non-irritating preparation applied to small cleansed wounds. It provides a protective physical barrier and a chemical (antimicrobial) barrier that neither delays healing nor favors the growth of microorganisms.

Antimicrobial Soap: A soap containing an active ingredient with *in vitro* and *in vivo* activity against skin microorganisms.

*defined by FDA

Iodine and the Iodophors

Iodine has nearly a century and a half of history of use as an antimicrobial agent. Iodine works by entering susceptible organisms and overloading their ability to handle it. Thus, it becomes lethal to these cells. Elemental iodine is a powerful oxidizing agent and kills the microorganisms due to this action. It is recognized as a broad-spectrum

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antimicrobial with activity against both gram-positive and gram-negative bacteria as well as fungi and some viruses. The relatively new iodophors contain elemental iodine complexed with carrier molecules that reduce the amount of free iodine, and instead, release it over a period of time. This is claimed to reduce the degree of skin irritation and to provide a longer duration of activity. The antimicrobial activity of all these agents is dependent upon release of elemental iodine.

In the judgment of the OTC advisory panel members, elemental iodine in a hydroalcoholic solution is safe and effective when properly used on unbroken skin as a pre-operative skin preparation. But, they expressed concern about its irritating properties and that it may actually delay wound healing when placed on broken skin. The panel was also concerned that the supposed advantages of complexed iodine in the iodophors may be their most serious disadvantages. The panel pointed out that the advantage of iodophors over elemental iodine is that the area can be treated and bandaged. However, a serious disadvantage is that there may actually be less free iodine available to act as an antimicrobial. The panel reported that the basic questions which have yet to be answered and require more study are, "What is the rate of iodine released from the complex molecule; does it then bind to other materials on the skin; is it thereby inactivated; and, what is the influence of the release rate on the effectiveness of the product?"

Phenol

The germicidal activity of phenol is due to its action as a protein denaturant. Its mechanism of action on susceptible microbes is likely due to its disruption of the cell wall and precipitation of cellular proteins. It has been determined by the FDA OTC advisory panel that phenol, in a concentration greater than 1.5 percent, is toxic to the skin and should be banned from future use. At this strength, phenol penetrates into deeper layers of the skin and can produce severe burns. It might possibly be absorbed systemically with a deleterious effect on the central nervous system. Localized gangrene has also been seen following application of phenol to the skin in higher strengths.

The panel ruled that adequate double blind studies for determining the safety and effectiveness of phenol in aqueous and alcoholic formulations have not been conducted. These studies will be needed before a final ruling can be made and the product made available for OTC use. A similar but less toxic substance, hexylresorcinol, was placed in the safe and effective category (along with the QAC's) as a skin wound cleanser, but in the "needs more study" category for all other topical uses.

Mercury-Containing OTC Topical Products

Mercury has been known to mankind since time immemorial. Many feel that the early days of chemical science developed due to efforts to convert mercury into gold and silver. Down through the ages, mercury compounds have been used in numerous ways for treating illnesses. Because of its potential for toxicity, the systemic use of mercury compounds is no longer considered to be safe or rational. The use of these agents has continued, however, for minor cuts and scrapes. Most particularly thimerosal (Merthiolate®) and merbromin (Mercurochrome®) have been popular home remedies.

The antimicrobial activity of mercuric ions is due to their combining with free sulfhydryl groups in susceptible bacterial cells and thus depriving these cells of proper metabolism and growth. Mercuric ions inhibit growth of bacteria but do not act swiftly to kill them.

In spite of the widespread popular use of these first aid agents, the FDA advisory panel suggested that FDA ban all mercury compounds from future sale. Among the compounds specifically placed in Category II (i.e., neither safe nor effective) were ammoniated mercury, merbromin, red mercuric sulfide, thimerosal, and yellow mercuric oxide. The basic reasoning behind this finding was that the bacteristatic action of mercury can be reversed by many types of sulfur-containing compounds including those present in serum, pus, and other body fluids. The panel found that, if the mercury-containing compounds are first allowed to combine with the sulfhydryl groups and bacterial cells, growth is inhibited. But the introduction of additional sulfhydryl groups to the cell-mercury complex neutralizes the action and growth again takes place. One interesting study showed that 800 times more merbromin and 14,000 times more thimerosal were required to inactivate half of the *Salmonella typhosa* cells suspended in 10 cc of an eighty percent serum solution, than was required to achieve comparable results when these cells were suspended in saline solution. The panel ruled that a bacteristatic action that is capable of being reversed by contact with body fluids and other organic matter does not constitute an effective topical antimicrobial action. The panel also found evidence that thimerosal is highly allergenic and has a potential for cell damage if it is applied to broken skin. Although placing a red solution on the skin has a psychological effect, a solution that stains the skin a deep red is not desirable as an antimicrobial agent because it may mask inflammation. Inflammation is an important warning sign of infection.

Alcohol Drug Products For Topical OTC Antimicrobial Use

Both ethyl and isopropyl alcohol are effective topical antimicrobial agents. They are astringents and precipitate protein. Both act by denaturing bacterial protein, in the presence of water, and thus killing the organisms. Because bacteria in a dry environment are more resistant to their bactericidal action than in a moist environment, one hundred percent absolute alcohol is not as effective as alcohol-water mixtures.

The ideal concentration of ethyl alcohol is 65 to 95 percent, and it really doesn't matter which of the intervening strengths are used. The ideal bactericidal strengths of isopropyl alcohol range from 50 to 91 percent.

Neither of these agents is recommended for use on mucous membranes or extensive open skin wounds because they are extremely

William M. Heller to Receive Remington Medal at APhA Annual Meeting

William M. Heller, executive director of the United States Pharmacopeial Convention, Inc., and a member of the MPhA has been named the 1984 recipient of the American Pharmaceutical Association's (APhA) Remington Honor Medal.

Dr. Heller becomes the 55th Remington Medalist since the pharmacy profession's most prestigious award was established in 1918. The award was named in honor of Joseph P. Remington (1847–1918), one of America's most influential pharmacists who was instrumental in the development of both APhA and the United States Pharmacopeia.

The 1984 Remington Medalist will accept the award at the opening session of the APhA Annual Meeting in Montreal, Canada, on Sunday, May 6, 1984.

A native of Orrville, Ohio, Dr. Heller received his B.S. degree in Pharmacy from the University of Toledo in 1949; his M.S. degree in Pharmacy in 1951; and his Ph.D. in Pharmacy in 1955—the latter two both from the University of Maryland. After service in the U.S. Army during which time he attended the University of Indiana (1943–1944) and Biarritz American University in France (1945), Dr. Heller interned in hospital pharmacy at the Johns Hopkins Hospital (1949–1951) and practiced as a relief community pharmacist in Baltimore (1949–1954).

Dr. Heller joined the faculty of the University of Arkansas School of Pharmacy in 1954 during which time he served as the first editor of the *American Hospital Formulary Service*, a publication of the American Society of Hospital Pharmacists (ASHP), and he pioneered in research on unit dose dispensing systems—both of which had a significant impact on the quality of patient care in American hospitals.

Dr. Heller joined the headquarters staff of ASHP in 1966 serving as director of the Department of Scientific Services; editor of the *American Hospital Formulary Service;* and as editor of *International Pharmaceutical Abstracts*. Two years later (1968), he was named executive director of the United States Pharmacopeial Convention, Inc. (USPC) at a time when FDA was considering absorbing drug standards-setting functions. As its executive director, Dr. Heller redefined the purpose and functions of USPC; relocated the headquarters to its own building; negotiated the acquisition of the *National Formulary* and the National Drug Standards and Testing Laboratory thereby consolidating all drug standards-setting organizations; and broadened the basis of support for USPC with the introduction of both the *Pharmacopeial Forum* and *U.S.P. Dispensing Information*. As one nominator put it: "By his efforts Bill Heller has preserved for the profession the authority for setting drug standards from government encroachment—and then went on to regain some of the authority (USP) previously lost."

LETTERS

Dear Dave:

Syntex Laboratories, Inc., in response to the needs of the retail pharmacist, has implemented a new return goods policy. We are quite proud of this new policy, which will make it much easier for the pharmacist to receive compensation for the return of Syntex products.

The policy will be one of direct exchange of new product for the old product; and, requires the authorization of a Syntex Professional Medical Representative. The pharmacist will also be compensated for mailing charges incurred.

Since this has quite an effect on the retail pharmacists in the state, many of whom are members of the Association, I would ask that you publish a short mention of the new Syntex policy in your next monthly journal or newsletter. Below is a model you may wish to follow.

Thank you for your cooperation.

Effective January 1984, Syntex Laboratories has implemented a new retail pharmacy return goods exchange program that will authorize retailers to return product directly to Syntex to exchange for other Syntex products with written authorization from a Syntex Professional Medical Representative. Retailers will continue to have the option to return product to the wholesaler for credit. The pharmacist should consult with the local Syntex Representative for full details of the program.

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irritating and may be more harmful than beneficial. Because of the resistance of spores to alcohol, these agents are no longer recommended for use in cold sterilization of surgical equipment or needles and syringes for hypodermic injections.

The panel that reviewed them concluded that both ethyl and isopropyl alcohol, properly applied in the strengths listed, are safe and effective antimicrobials when used for the following indications:

(1) for first-aid use to decrease germs in minor cuts and scrapes;
(2) to decrease germs on the skin prior to removing a splinter or other foreign object; and
(3) for preparation of the skin prior to an injection.

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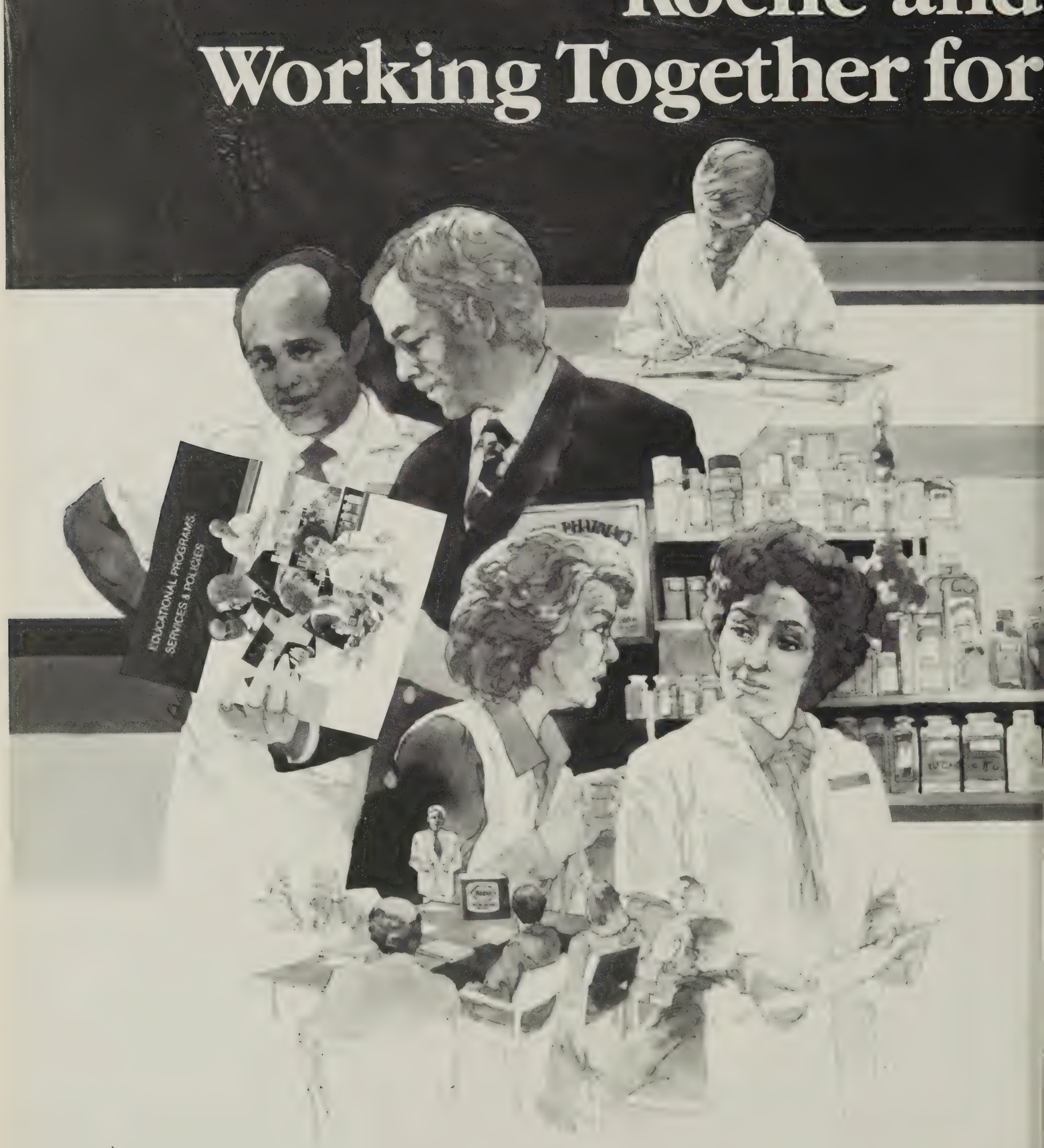

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"Unproven Methods of Cancer Management"

Continued from the March issue

courtesy of the American Cancer Society

MAJOR SOURCES OF INFORMATION ON UNPROVEN METHODS OF CANCER MANAGEMENT

Various agencies and organizations participate in reporting and investigating claims made for new methods of cancer management. They include: The American Cancer Society, American Medical Association, U.S. Food and Drug Administration, National Cancer Institute, U.S. Postal Service, and other Federal, state and local government agencies, State Cancer Commissions and Advisory Councils. In addition, many reliable cancer research centers and independent, scientifically trained cancer investigators are willing to cooperate.

The American Medical Association

The American Medical Association directs much effort toward the education of the public and the profession on health care frauds and quackery. This service has been augmented by resource files on questionable medical procedures, products and devices. Information on unproven methods of cancer management is available through the Division of Archival and Library Services. In addition, verification of a physician's professional credentials is furnished upon written request.

The Food and Drug Administration

The Food and Drug Administration, under the mandate of the Food, Drug and Cosmetic Act, has regulatory control of foods, drugs and devices in interstate commerce.

Under the 1962 Amendments (revised 1980) to the FD&C Act, "New Drug" sections of the law, proof of efficacy and safety of drugs (including cancer remedies) are the responsibility of the sponsor of the drug. Devices and drugs are subject to other sections of the Act pertaining to labeling, misbranding, hazards to health and advertising of prescription products. Advertising of over-the-counter products is under the legal control of the Federal Trade Commission.

Field districts of the F.D.A. are located throughout the country. Each division has its own chemists, inspectors and testing laboratories. When necessary, reports are made to the Department of Justice with recommendations for seizure, criminal prosecution or injunction actions in the Federal Courts.

National Cancer Institute

The National Cancer Institute conducts comprehensive drug development programs which encompass preclinical testing in animal tumors and other screening systems, toxicologic study, dose formulation and clinical trials. Well-characterized materials provided by proponents will be tested in accordance with NCI policy.

The U.S. Customs Service

The U.S. Customs Service is actively engaged in anti-smuggling activity to suppress unproven methods of cancer management.

The U.S. Postal Service

The Fraud Division of the U.S. Postal Service actively engages in the investigation of worthless cancer tests and remedies promoted through the mails. These investigations have resulted in the conviction and sentencing of individuals who use the mails to defraud the public.

Control of Unproven Methods of Cancer Management

There are two other approaches to the control of unproven methods of cancer management: legislation and education.

LEGISLATION

Federal Legislation

The most important of all legislative approaches to controlling unproven remedies comes under the jurisdiction of the Food and Drug Administration.

State Legislation

California, in 1959, was the first state to pass legislation to control cancer quackery. The California cancer quackery law stipulates that diagnostic and therapeutic means of managing cancer be scientifically sound and subject to scrutiny. Through the Food and Drug Fraud Section of the State Department of Health, evidence can be assembled, testing and investigation conducted, and recommendations for legal action reported to the Cancer Advisory Council, a 15-man body of competent

medical experts, educators and laymen who evaluate the data and submit recommendations to the State Director of Public Health. The Council may recommend the issuance of cease and desist orders to those practitioners who have used or are curently using drugs or devices banned by regulation.

The Council reviews extensive evidence before taking action. This may involve testimony of expert witnesses; testing procedures such as animal studies; chemical analysis; clinical tests; court action; opinions of medical school deans and other medical experts; and interviews with relatives of cancer victims treated by the agent in question. Testimony which has been introduced in the departmental hearings is also evaluated. California's Cancer Advisory Council has assumed national leadership in the control of cancer quackery.

The California cancer law places the burden of proof of efficacy and safety of a cancer agent on the proponent. It also makes approval of an application under the Food, Drug and Cosmetic Act, or a similar application approved by the California State Board of Health Services, a requirement for selling, prescribing or administering a drug or device to be used in diagnosing to treating cancer. In 1969, a bill with all the above provision was enacted as permanent legislation. In September 1974, the State of California enacted new legislation which makes a first conviction of a "quackery" charge of felony rather than a misdemeanor, with jail terms of up to five years and fines as high as $10,000.

A number of states have passed legislation to exempt unproven methods of cancer management such as laetrile, dimethyl sulfoxide (D.M.S.O.), immunoaugmentative therapy and Liliverum from meeting the standard requirements of safety and efficacy as established by Federal or state statutes.

EDUCATION

A. The American Cancer Society's Program on Unproven Methods of Cancer Management

The American Cancer Society, in its efforts to control unproven remedies, has adopted the following objectives:

- To develop more effective means of dealing with claims made for the diagnosis and/or treatment of cancer that are advanced without objective evidence acceptable to the scientific community.
- To encourage investigation through scientific or other qualified organizations of unestablished claims for cancer diagnosis and treatment.
- To develop and encourage educational programs, providing the public with information on specific cases as well as a better understanding of the criteria for assessing the merits of claims made for cancer tests and remedies.
- To encourage physicians to provide adequate care of patients with far advanced cancer because it is, in the main, these individuals who unwittingly fall prey to "cures" which have no proven merit.
- To encourage physicians to maintain well-documented case histories, including data on subjective and/or objective improvement or progression of disease while under treatment.

In carrying out these objectives, an information center has been developed for the collection and distribution of material on unproven methods of cancer diagnosis and treatment. This unique collection, containing voluminous file material, is one of the principal repositories for such information in the world.

The Society has a Committee on Unproven Methods of Cancer Management which serves as a central coordinating force in this field. The Committee is concerned with legal matters, professional and public education, public information and public issues, in addition to its primary interest in unproven cancer diagnosis and therapy; its membership includes experts in these fields. Under the Committee's guidance many reports on individual unproven cancer remedies and tests have been issued. Pertinent material has been classified into an Index of American Cancer Society File Material on Unproven Methods of Cancer Management (now being revised) for use by the 58 Divisions of the Society and other interested professional groups.

One of the fundamental concepts of the American Cancer Society's approach to the overall cancer problem is its emphasis on action at the local level. This tactic is especially important because it is in the local community that the cancer patient and his family first come into contact with cancer nostrums. At this crucial time, most lives are either lost or saved from cancer.

One of the difficulties in alerting physicians to various unproven methods of cancer diagnoses and treatment has been the lack of easily available information ordinarily published in medical journals. The American Cancer Society if filling this gap by publishing articles of interest on unproven methods in *Ca-A Cancer Journal for Clinicians,* which is distributed bi-monthly to more than 470,000 physicians, medical students, dentists and medical libraries throughout the nation.

The National office of the American Cancer Society stands ready to assist reporters, editors, science writers, program directors and others in checking the validity of claims made for cancer tests and remedies from information contained in its files on unproven methods of cancer management. Early diagnosis and prompt, proper treatment is a life and death matter. An informed press and public are the best safeguards against the hazards of cancer quackery.

Material concerning unproven methods of cancer management, which is obtainable on request to the National office, is listed in the Appendix.

B. Public Education

The layman's best protection against being misled by unproven drugs and gadgets is a basic understanding of what cancer is and how it spreads. When an indi-

vidual realizes that 2,000,000 living Americans are cured of cancer today because of early diagnosis and prompt, proven treatment with surgery, radiation and/or chemotherapy, he is less likely to take a chance with a questionable practitioner or an unproven method.

The public must also be made aware that for many years there has been a sound and effective way by which claims for new treatments of disease are examined, and that this "due process" of science has served mankind well throughout history. It involves presenting evidence in an orderly fashion, according to accepted forms, to one's medical or scientific colleagues. Hundreds of medical meetings are held in the United States every year, and medical and scientific journals are published regularly—all for one purpose—to provide a forum for those with something worth reporting to the scientific world.

C. Professional Education

Professional education is equally as important as offering laymen knowledge. Professionals must accept the burden of discussing this subject with their patients. Unproven methods of cancer management do exist, and patients will hear about them. An honest, forthright discussion of their disease, treatment and expectation might prevent a patient from falling into the hands of a quack.

In short, education, though indirect, is even more important than legislation to control worthless cancer remedies. Laws are difficult to pass and enforce. Knowledge is man's most powerful defense, both in knowing what is good and what is not.

Conclusion

Unproven methods of cancer management cannot be completely eliminated until all cancer is brought under control. As long as some forms of cancer remain incurable, promotion of unproven methods will continue.

Control of unproven methods of cancer management lies on three fronts:

Investigation . . . Legislation . . . Education

In an attempt to combat unproven methods, the following measures are recommended: Development of more effective means of dealing with exaggerated and unfounded claims for cancer diagnosis and treatment by encouraging investigation by scientific or other qualified organizations; promotion of state anti-quackery legislation; formation of state cancer commissions and other state and Federal programs to prevent exploitable treatment of the public; and lastly, encouragement of educational programs. The public must be provided with information regarding specific cases, and offered a better understanding of the standards of investigation which must be met before any new drug or device is approved for use by the medical profession. Education also alerts the patient to this responsibility in seeking treatment from a qualified specialist in cancer. In addition, professional education programs are necessary to provide better and more concerned understanding of the patient's needs and his family's fears, thus dispelling the tendency to seek unproven methods of cancer management. There must be credibility established between physician, health team and patient. If the patient knows that the health team is offering the very best in medicine and support the tendency to seek unproven cures can be reduced. Though cancer may not always be curable, it is always treatable. The professions must offer all possible support to patients and families throughout the course of the illness.

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ADDITIONAL READING

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Herbert, V., M.D.: Nutrition Cultism. George F. Stickley Company, Philadelphia, Pennsylvania. 1980.

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Facts on Quacks: What You Should Know About Health Quackery. Chicago: American Medical Association, 1967.

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Schmidt, A. M., M.D.: Drug Approval Process and FDA. New York State Journal of Medicine, Nov., 1976. Pp. 2039–2042.

Schultz, T. and Lindman, B.: The pain exploiters—the victimizing of desperate cancer patients. Today's Health 51:28–33, 59–60 (Nov.) 1973.

Young, J. H.: The persistence of medical quackery in America. American Scientist 60:318–326, (May–June) 1972.

Young, J. H.: The Agile Role of Food: Some Historical Reflections. Nutrition and Drug Interrelations, 1978.

APPENDIX

Following is the list of materials on Unproven Methods of Cancer Management available on request to the National office of the American Cancer Society, Inc., 777 Third Avenue, New York, N.Y. 10017.

This list will periodically be updated and any change in the status of the items listed will be reflected in the revision.

Individual Statements:

Agpaoa, Antonio, "The Psychic Surgeon"
Anti-Cancer Factor in Clams (Mercenene)
Anticancergen Z-50 and Zuccala Lytic Test
Antineol
Antineoplastons
Bamfolin
H.H. Beard Methods
Bio-Medical Detoxification Therapy
Bonifacio Anticancer Goat Serum
Cancer Lipid Concentrate and the Malignancy Index
Carcin and Neo-carcin
Carzodelan
CH-23
Chaparral Tea
Chase Dietary Method
Clinica El Buen Samaritano
C.N.T.
Collodaurum and Bichloracetic Acid Kahlenburg
Contreras Methods
Cresson Method
Crofton Immunization Method
Cytec System
Diamond Carbon Compound
Dimethyl Sulfoxide (D.M.S.O.)
Dotto Electronic Reactor
Electronic Devices
Ferguson Plant Products
Fonti Methods
Francis Diet
Fresh Cell Therapy
Frost Method
Ganner Petroleum or "Petroleum Pal"
Gerson Method
Gibson Method
Glover Method
Grape Diet
H.11
Hadley Vaccine and Blood and Skin Test
Haematoxylon Dissolved in D.M.S.O.
Hemacytology Index (HCl)
Hett "Cancer Serum" and Gruner Blood Smear Test
Hoxsey Method or Hoxsey Chemotherapy
Iscador
Issels Combination Therapy
Kanfer Neuromuscular or Handwriting Test
KC-555
Kelley Malignancy Index and Ecology Therapy
Koch Antitoxins
Krebiozen and Carcalon
Laetrile
Laetrile: Background Information
Lewis Methods
Livingston Vaccine
M-P Virus
Makari Intradermal Cancer Test
Mininberg System
Mucorhicin
Multiple Enzyme Therapy
Naessens Serum or Anablast
Nichols Escharotic Method
Orgone Energy Devices
Pap-Chek, Female Laboratory Testing
Polonine
Rand Coupled Fortified Antigen (RCFA) and Delayed Double Diffusion
Revici Cancer Control
Samuels Causal or "Endogenous Endocrinotherapy"
Simonton, O. Carl, M.D.
Spears Hygienic System
Ultraviolet Blood Irradiation Intravenous Treatment
Zen Macrobiotic Diet

Information is Available on the Following:

A.I.D. Test (Arthur Immunostatus Differential)
Brych, Vlastimil (Milan)
Committee for Freedom of Choice in Cancer Therapy, Inc. (C.F.C.C.T.) (This Committee distributes a 1-hour documentary filmstrip "World Without Cancer," produced by the I.A.C.V.F.)
Greek Cancer Cure, Inc.
Immunology Researching Centre, Ltd.
International Association of Cancer Victims & Friends, Inc. (I.A.C.V.F.)
Manner, Harold, Ph.D.
National Health Federation (N.H.F.)
Reams, Cary
United Cancer Institute, Robert Cotti-Vixon, M.D., President
American Cancer Society Policy Statement on Chiropractic
American Cancer Society Policy Statement on 5-Fluorouracil
Concerning Patent Rights
"Questions Most Frequently Asked Concerning Unproven Methods of Cancer Management"

The following is a list of some organizations, health centers, books, magazines and newsletters actively involved in promotion of unproven methods of cancer management. The American Cancer Society does not have formal policy statements or summaries of information on these items. They are being brought to your attention for information only.

Organizations:

Cancer Control Society (C.C.S.)
Foundation for Alternative Cancer Therapy, Ltd. (F.A.C.T)
Americans for Medical Freedom

Health Centers:

Degenerative Disease Medical Center (Las Vegas, Nevada)
Health and Wellness Center (Bloomington, Minnesota)
Fairfield Medical Center (Montego Bay, Jamaica)
Evers Health Center (Cottonwood, Alabama)
Immunology Researching Centre, Ltd. (Grand Bahama Island)

Books:

Cancer Cures Crucified by Suzanne Caum, 1968.
Happy People Rarely Get Cancer by J. I. Rodale, 1972.
Has Doctor Max Gerson a True Cancer Cure? by S. J. Haught, 1962.
The Incredible Story of Krebiozen: A Matter of Life or Death, by Herbert Bailey, with introduction by Senator Paul H. Douglas, 1962.
Laetrile: Control For Cancer by Glenn D. Kittler, 1963
Vitamin B-17: Forbidden Weapon Against Cancer by Michael L. Culbert, 1974.
World Without Cancer by Edward Griffen, 1974.
The Curse Causeless Shall Not Come by Nord Davis, Jr., 1976.
Laetrile Case Histories by John A. Richardson, M.D., 1977.
The Little Cyanide Cookbook by June de Spain, 1976.
A Little Dab Will Do Ya! DMSO: The Drug of the 80's by Mildred Miller, 1981.

Magazines & Newsletters:

The Cancer Control Journal (C.C.S.)
The Cancer News Journal (I.A.C.V.F.)
Herald of Health (Paragon Publications, Inc., Mount Ayr, Iowa)
Public Scrutiny (The Journal of the National Health Federation)
Choice (C.F.C.C.T.)
Healthview Newsletter
F.A.C.T. Newsletter (F.A.C.T)
Preventive Health News
The Voice of Medical Freedom (Health World News)

Compute-Rx. The computer system that thinks like a pharmacist.

Lots of companies can sell you a computer. And have probably already tried.

But the important thing to keep in mind is that a computer isn't really what you're buying.

What you should be looking for is a system that meets your specific needs as a pharmacist.

And you should also be looking for a company that is concerned about your problems and gives you the support and back-up services you need.

That's why more and more pharmacists are turning to one of the most respected names in the business. Compute-Rx.

The Compute-Rx Pharmacy Management System was developed by pharmacists, for pharmacists.

It's been programmed to think about things you don't have time to.

Like constantly updating drug prices, so that your prices reflect your current costs.

And making sure patients are billed accurately and on time.

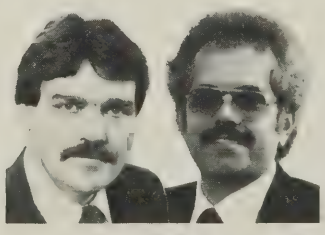
It also types prescription labels and receipts with ease. While it alerts you of patient allergies or potentially harmful drug interactions.

In short, the Compute-Rx system helps you become more professional and more profitable all at once.

Best of all, since it thinks like a pharmacist, it gives you more time to be a pharmacist.

So whether or not you're presently considering putting in your own computer, think what the Compute-Rx system can do for you.

It's the one designed with your needs in mind.



The Compute-Rx system was developed by Preston Hale and Wayne Hague over a four-year period in their own pharmacies. The system has become so popular that it's now used in a growing number of community pharmacies, chain drug stores, and schools of pharmacy.

COMPUTE-Rx
An HVC Company
8235 Hermitage Road, Richmond, VA 23228

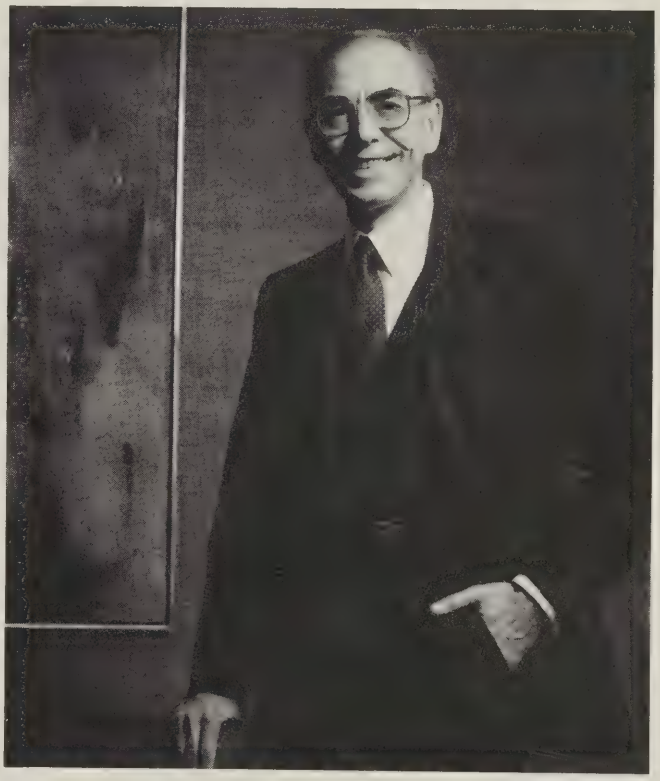
"THERE NEVER WAS A PROUDER TIME TO BE A PHARMACIST."

"We are fast approaching a new century—one which offers the promise of great research achievements in the field of human health. And pharmacists will have an important role in this coming adventure. It is instructive to pause for a moment and consider how far we have come in the past century. My grandfather was a pharmacist in the 1890's and the medicines he compounded and dispensed, and the outcomes, had not changed significantly since the time of George Washington. Little could he anticipate the advances in drug development and changes in pharmacy practice.

"A new era began with the start of the twentieth century. Basic scientific discoveries were made in understanding diseases. The first steps toward the design of specific chemotherapeutic agents took place in the Thirties and helped set the stage for a treasure trove of drug products. Pharmacists played a major role in the discovery and development of most of the products we have today. The commitment to research has resulted in marvelous benefits for mankind.

"Today, we are surrounded by all manner of new breakthroughs in our understanding of genetics and molecular biology. Upon this base of knowledge will be built the new therapies of the future... and pharmacists will play a vital role in their development. This is indeed an exciting prospect.

"There has never been a prouder time to be a pharmacist."



Louis C. Schroeter, Ph.D., R.Ph.
Vice President and General Manager,
Domestic Pharmaceutical Division, The Upjohn Company

Upjohn

Kalamazoo, Michigan 49001

A century of caring.

A Task Force on Home Health Care has been established by the Maryland Pharmaceutical Association's Board of Trustees. This Task Force has been charged to define the issues involved in the home health care industry and delivery of services from the aspects of the practice of pharmacy. It will serve as a forum to explore possible and existing opportunities for the expansion of pharmacy services and will act to educate pharmacists, other health professionals, members of the legislature and the public about the unique services that pharmacists can provide to the home care client. The Task Force is currently developing two surveys to assess current involvement of practicing pharmacists in the delivery of home care services. One survey will be mailed to home health care agencies to determine what existing pharmacy services are being utilized and to explore what areas of services the agencies would like pharmacists to offer. The second survey will be mailed to the MPhA membership and will be used to determine to what extent pharmacists in our state are already involved in delivering home care, how are they receiving reimbursement for service, what unique practice developments have been initiated as a result of their involvement in this "non-traditional" role, and finally, what type of assistance can this Association provide to its membership to encourage those who would get involved in this emerging practice setting.

The following article represents our attempt to define terms and explore issues of regulation and state policies.

A Beginner's Guide to Home Health Care in Maryland

Some Definitions, Policies, Trends/Issues, State Criteria and Standards, Recommendations

Madeline Feinberg, Task Force Chairman

(Adopted from the Home Health Section of the proposed State Health Plan. This document is a draft and is therefore subject to change. From Maryland Health Resources Planning Commission Public Hearing Draft, Vol. II.)

Definitions

Home health agency is a health related institution or part of an institution that: (1) is owned or operated by 1 or more persons, whether or not for profit and whether as a public or private enterprise; and (2) directly or through a contractual arrangement, provides to a sick or disabled individual in the residence of that individual home health care that is administered centrally.

Home health care means any of the following services that are provided under the general direction of a licensed health professional practicing within the scope of their practice act: (1) audiology and speech pathology, (2) dietary and nutritional services, (3) drug services, (4) home health aide, (5) laboratory, (6) medical social services, (7) nursing, (8) occupational therapy, (9) physical therapy and/or (10) provision of medically necessary sick room equipment and supplies. (From Annotated Code of Maryland, Health General Article Section 19-401 [Supp.].)

Policies

1. All providers (as defined by Health General Article 19-1-01) offering home health care programs should be subject to the same regulatory process. The health planning law should be amended to require Certificate of Need review of proposals to start home health programs by hospitals and nursing homes.

Current statute allows existing health care facilities to begin to provide home health services without a Certificate of Need as long as the new service does not generate more than $250,000 or incur a capital expenditure of more than $600,000. Thus, existing hospitals or nursing homes can begin to provide home health services without obtaining a Certificate of Need. On the other hand, new providers or any organization wishing to operate a freestanding home health service must currently obtain a Certificate of Need regardless of cost. It is recommended that this inequity be corrected.

2. A home health agency should offer an array of services and not be a single service provider.

A home health care client should not have to make arrangements with a variety of providers to obtain the services he/she requires.

3. Providers of single medical services that are furnished to clients in their own residences under the general direction of licensed health professionals should operate under contract with a home health agency. Entities that provide only medical supplies and equipment to clients are exempt from this provision.

Medical services delivered to a client in their own residence must be coordinated as part of the total care plan. Home health agencies are responsible for the coordination and quality of all services delivered by one of their contractors.

4. Hospitals and nursing homes are encouraged to contract with existing home health agencies for the provision of home health services to their clients rather than starting institution based programs.

Duplication of existing resources should be discouraged.

5. The number of home health agencies needed will be determined by applying the modified Florida Methodology on a jurisdiction (county and Baltimore City) basis. (For discussion of this methodology, see Ref. 7. Modification described in the draft proposal, p. HH-15.)

The amount of service will be determined by population needs rather than geographical region.

Trends/Issues

1. Proliferation of home health agencies: Statutory change will be required to correct inequities existing in granting Certificate of Need to operate for home health care agencies. Change in the regulatory process should assure the orderly and efficient use of resources.

2. "High Tech" Home Care: This generally refers to the provision of intravenous therapies (parenteral nutrition, antibiotic and chemotherapy) and enteral nutrition in the home setting. This term also refers to the techniques and equipment used to provide therapy to coronary care and post surgical patients as well as to the provision of some types of nuclear medicine therapy in the home. It is recommended by the MHRPC, in conjunction with other agencies within the DMH, that policies be developed to guide the regulation of this new aspect of home care.

3. Single Service Providers: Providers of medical equipment and supplies are permitted to market their merchandise to clients directly, but providers of medical services must work under the supervision of a home health agency when they are performing services in a client's home. Thus, providers of a single medical service must operate under contract with a home health agency who will be responsible for the quality and coordination of all services delivered by a contractor.

Criteria and Standards

1. *Need for Agencies*

The need for additional home health agencies will be determined by using the modified Floridal methodology.

2. *Range of Services*

Every home health agency should provide, at a minimum, the following services: (a) skilled nursing, (b) home health aide, and (c) at least one of the following: 1. audiology/speech pathology, 2. dietary and nutritional services, 3. drug services, 4. laboratory services 5. medical social services, 6. occupational therapy, 7. physical therapy, 8. provision of medically necessary sickroom equipment and supplies.

3. *Certification*

Every home health agency must be Medicare and Medicaid certified.

4. *Operating Policy—*

Home health agencies should establish the capability to provide clients with information and emergency medical services on a 24 hour, 7 day a week basis, what type of information will be provided, and the circumstances under which emergency medical care will be dispatched.

5. *Financial Accessibility*

Agencies must establish payment mechanism for clients unable to make lump sum payments. In addition, agencies must provide mechanisms for assisting low-income clients obtain equal access to health services when full payment cannot be anticipated.

6. *Charges*

Projected costs and charges of a home health agency must be comparable to those of other agencies in the same health systems area. Eligibility for home health care under Medicare (Parts A & B), Medicaid and other third party payors are clearly defined by insurer and must be established before reimbursement can be anticipated.

7. *Continuity of Client Care*

Home health agencies must establish effective linkages with nursing home, domiciliary care facilities, geriatric evaluation services, Gateway programs, day care programs, local department of social services, and home delivered meal programs located within the agency's proposed service area. Formal admission & discharge planning is needed to facilitate the delivery of other community based services to the client after discharge.

In addition, this draft proposal on Home Care recommends the establishment of an accurate data base for home health agencies on a jurisdictional basis which includes data regarding agency services, referral sources, utilization, and reimbursement. It is also recommended that standards for home health care services which address the quality of patient care delivered by home health agencies be developed and used to evaluate care given.

An updated list of licensed home health agency by jurisdiction of office location and type of services offered to clients is currently being prepared by the Maryland Health Resources Commision as of January 1984. The list of these agencies is available to the public upon request from the Division of Licensing and Certification, State Department of Health.

REFERENCES

1. Traxler, Herb. "A Methodology for Estimating the 'Need' for Home Health Care". Presented at the 105th Annual Meeting of the American Public Health Association in Washington, D.C. (October 31, 1977).
2. Policies and Methodology for applying modified Florida Methodology to determine need for home health agencies in Maryland, pp. HH-14 HH-15 of Home Health section of proposed State Health Plan.

The Pharmacist and Home Health Care

A Proposed Position Paper

by

The Pharmacy Task Force on Home Health Care

Overview

The future of the traditional health care delivery system will soon be transformed by one irresistible and transcending factor. The fit-elderly population will increase to such an extent that it will strain society's resources and abilities to provide care for chronic illnesses to these individuals. In addition, the non-elderly population that require certain kinds of chronic care will be increasing to such extent that long term care facilities will not be able to handle their medical needs. There is growing realization that in many instances health care for this population will be delivered in the home. Systems are being developed now to identify and treat the elderly on a pre-institutional basis. Cost containment strategies are emphasizing out-patient treatment modes. It is recognized that, where possible, treatment of chronic diseases in the home setting is not only more cost-effective, but is also highly conducive to patient recovery in familiar surroundings. Federal and state governments are studying block grants for funding and examining methods for expanding existing home health care systems.

There is nothing new about the concept of home health care. Care givers within the immediate or extended family are a long established social custom. Medical care models involving physicians, visiting nurses, social work services and nutritional support are emerging. Even large pharmaceutical companies have recently petitioned the Board of Pharmacy for Pharmacy permits to enter into the home Total Parenteral Nutrition (TPN) market, which represents only a very small part of the home health care market. It appears then that we are on the verge of a rapidly changing and rapidly expanding system of care. Clearly there is a need for a community based network of health care practitioners to address this altered patient environment.

The Pharmacist and Home Health Care

There can be no question that pharmaceutical services are the most cost effective portion of the health care delivery system. Drugs are responsible for the prevention, cure and management of serious illness. Yet we know that the number of drugs taken by the elderly and the frequency of drug related decisions which the elderly must make in order to remain compliant with treatment represents a serious problem even in a institutional and controlled environment. This situation is exacerbated in the home setting. Drug interactions, side effects, drug/food reactions, over utilization and under utilization of prescription drugs and non-prescription drugs are serious concerns. The safety of the patient may well be at stake.

Working from a unique knowledge base, the Pharmacist has been trained and educated to not only provide the prescription drug product, but to advise and consult with the patient. Patient education and drug monitoring are vital components to the prescription dispensing process. When patients purchase prescription drug products, they are paying for more than the product itself.

Pharmacists have a legal basis for this professional activity. The Maryland Pharmacy Practices Act states in Section 12-101(j) under the definition of "Practice Pharmacy":

> "Practice Pharmacy" means to engage in any of the following activities:
>
> (1) Selecting preparing and dispensing drugs, medicines or devices;
>
> (2) Providing information and explanation to patients and health care practitioners about the safe and effective use of drugs, medicines or devices or;
>
> (3) Identifying and appraising problems concerning the use or monitoring of drug therapy.

The provision of information to the patient is a strongly held professional responsibility and represents an important "clinical" portion of current pharmacy practice. In fact, another section of the Pharmacy Practices Act in Section 12-502(a) states:

> In the operation of a pharmacy, only a licensed pharmacist or an individual engaging in a clinical pharmacy training program and acting under the direct supervision of a licensed pharmacist may provide information to the public concerning

drugs, medicines, and devices, including information as to their therapeutic values, potential side effects, and use in the treatment and prevention of diseases.

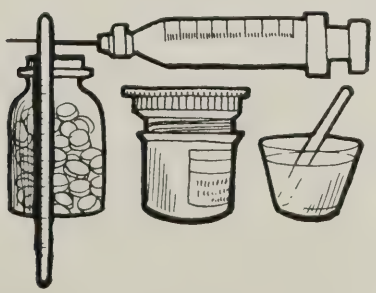
Most community pharmacies maintain patient profile records as an aid to monitoring drug therapy. Such profiles are also useful in recognizing duplications or conflicts in therapy due to multiple prescribers, drug interactions and particular patient allergies. Pharmacy consultant services and drug monitoring are mandated by the Federal government in all skilled nursing facilities. The value of such monitoring by the pharmacist has been repetitively demonstrated to be of significant value in the management of these patients. This monitoring and consulting facet of the practice of pharmacy must now be rapidly incorporated into the developing community based chronic care network.

Conclusions

It is clear that the pharmacist has the education, training, experience, professional responsibility and legal basis for providing consulting and monitoring services to patients. Pharmacists are the most accessible of all community based health care practitioners. Pharmacists do not have a manpower mal distribution profile as exhibited by other professions. Pharmacists are not only available as a health care resource, a recent George Gallup Poll reported that the public considers the Pharmacist to be the most trustworthy of all professionals. Pharmacy as a profession has great credibility and a tradition of community health involvement.

As we experience the dramatic increase in the elderly population and the development of systems to manage their health care, there can be no question that prescription drug usage will also proliferate. We believe that a vital component of developing home health care systems must be drug monitoring and patient consultation by the Pharmacist. Further, reimbursement mechanisms must be implemented which fairly cover not only the provision of the pharmaceutical product, but the provision of clinical consulting services.

The Maryland Pharmaceutical Association's Task Force on Home Health Care actively solicits comments or suggestions regarding our views on the role of the Pharmacist in home health care. We would be pleased to elaborate or discuss any of the issues mentioned in this paper.



David A. Knapp to Receive Award in Economic, Social and Administrative Sciences

David A. Knapp, professor of pharmacy practice and administrative science at the School of Pharmacy, University of Maryland at Baltimore, and a member of MPhA, had been selected to receive the 1984 American Pharmaceutical Association (APhA) Foundation/ Academy of Pharmaceutical Sciences (APS) Research Achievement Award in Economic, Social and Administrative Sciences.

The award is presented every two years and is intended to recognize and encourage outstanding and meritorious achievement in the broad areas of administrative and social sciences. Included within the scope of the award are contributions to the administrative, sociological, behavioral, economic, and marketing aspects of drugs and their use in health care. The award is sponsored by Hoffmann-LaRoche, Inc.

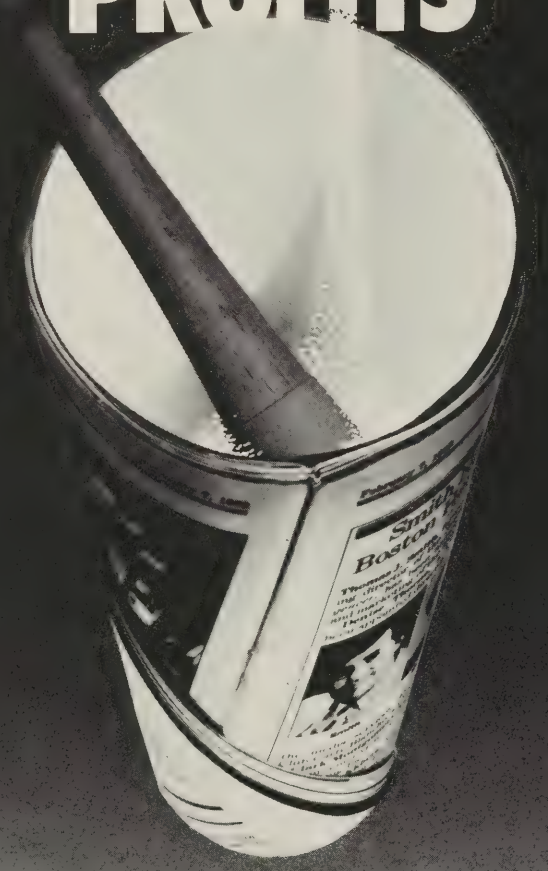
Knapp, a native of Cleveland, Ohio, received his B.S. in pharmacy from Purdue University in 1960, and earned an M.S. (1962) and Ph.D. (1965) in pharmacy administration at the same university. He joined the faculty of the Ohio State University College of Pharmacy in 1964, where he and his wife, Deanne, established one of the first graduate programs in social sciences in pharmacy while doing research on the role of the pharmacist and the process of self-medication.

After a postdoctoral year at the University of Michigan School of Public Health in 1971–72, Knapp joined the faculty at Maryland, where he has served as chairman of the Department of Pharmacy Administration, director of graduate studies and research, and, most recently, associate dean for graduate education and research. He relinquished the latter post last fall to direct a newly established doctoral program in pharmacy practice and administrative science.

During his career, Knapp has spent a summer in Australia as a World Health Organization Fellow and a year at the National Center for Health Services Research on an Intergovernmental Personnel Act appointment. He has served as chairman of APhA's Policy Committee on Scientific Affairs, chairman of the Council of Faculties of the American Association of Colleges of Pharmacy, and chairman of the Pharmaceutical Sciences Section of the American Association for the Advancement of Science (AAAS). He is a member of Rho Chi and Sigma Chi and is a Fellow of the American Public Health Association and AAAS.

The award will be presented to Dr. Knapp at the APS Awards Ceremony on Monday, May 7, during the 1984 APhA Annual Meeting in Montreal, Canada, May 5–10.

PERIODICALS COMPOUND YOUR PROFITS



Reading is the perfect medicine for everyone. SELLING magazines, paperbacks, and comics is our specialty. And it should be yours because turnover is the name of your game and nothing you sell turns over faster or more profitably than periodicals. If you're not now offering periodicals to your customers, you should be. Just ask us how profitable it can be. And if you do have a magazine department, chances are your operation has outgrown it and it should be expanded. Call Jim Trosch or Pete Van Poppel today at (301) 233-4545.

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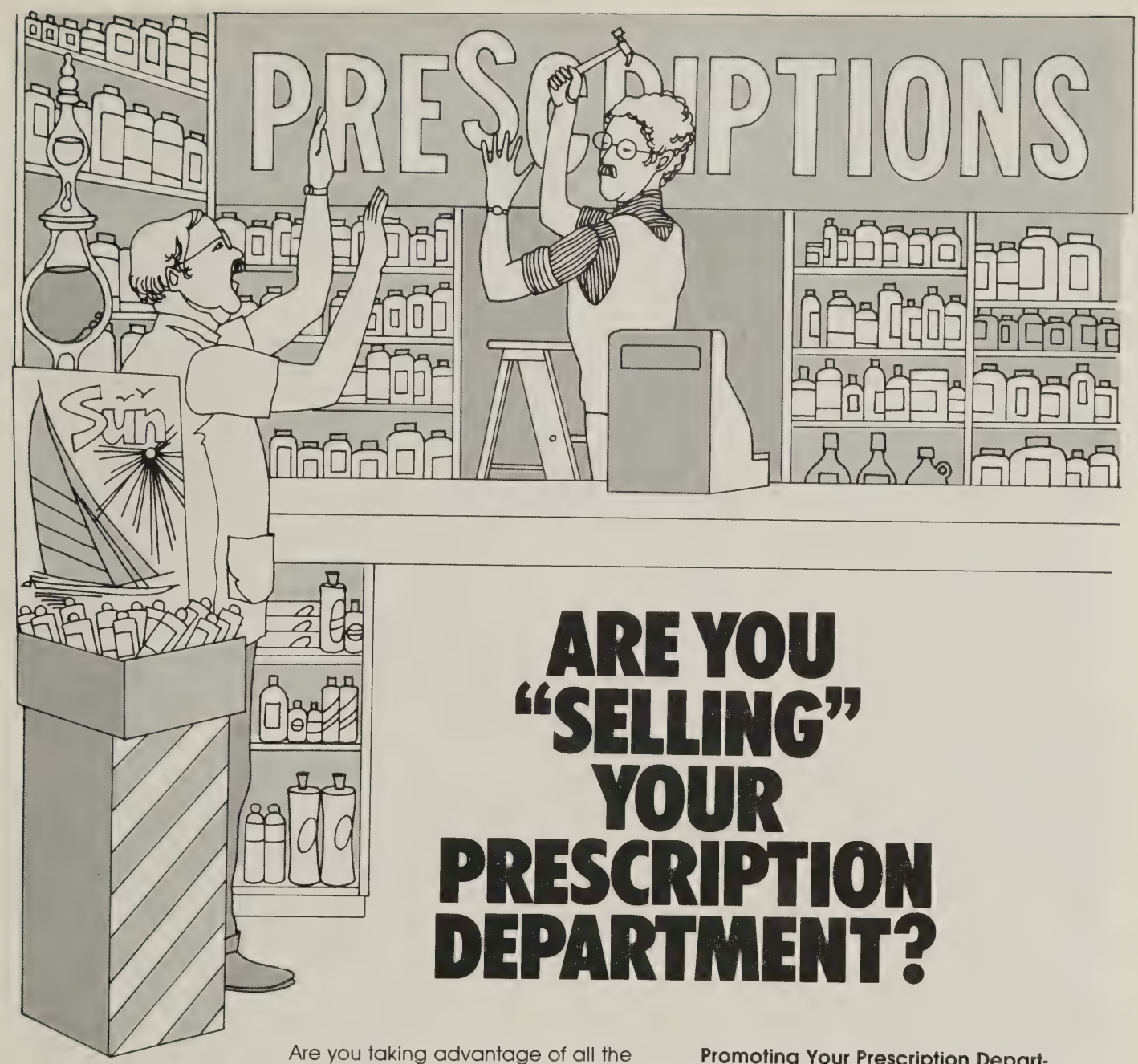

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Are you taking advantage of all the proven methods to promote a pharmacy's prescription department?

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Our management program is called **Promoting Your Prescription Department**—and it's designed as a seminar for interested groups of community pharmacists.

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Promoting Your Prescription Department is one more valuable addition to the pharmacy management series now available from SK&F.

Ask your SK&F Representative how you can obtain this videotape program for your next meeting.

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Hidden Costs

The direct costs of health care actually account for only 40 percent of the total cost of illness. The remaining 60 percent are indirect costs, such as absenteeism and loss of productivity caused by illness. These are as real economically as the health care expenditures usually associated with illness.

Surprising? Yes. But it should come as no surprise that when the patient gets well faster, both the direct and indirect costs can be reduced.

Lilly

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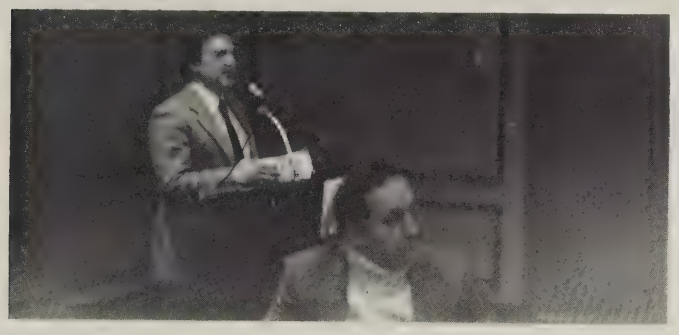
300534

Maryland Governor Harry Hughes proclaimed the week of March 18-24, 1984 as Poison Prevention Week in Maryland. Receiving the proclamation are: David Banta, MPhA; Dr. Thomas Reichelderfer, Md. Chapter of the American Academy of Pediatrics; Dr. Gary Oderda, Director, Md. Poison Center; Governor Hughes; Dr. Richard Gorman, Medical Director, Md. Poison Center; Dr. Gregory Wedin, Clinical Toxicology Fellow, Md. Poison Center; Dr. William Kinnard Jr., Dean, School of Pharmacy.

Frank Radigan (Left), District Manager for Merck, Sharp & Dohme, presents a $500.00 check to Dave Banta, MPhA Executive Director, in support of the Association's June Convention.



BMPA President Martin Mintz presided over the Membership meeting held March 1st. Joe Fine (right), Pharmacy Specialist with the Maryland Medicaid Program discussed the telephone eligibility verification system that is being developed.

Arnold Blaustein, BMPA Board member, rises to ask a question at the BMPA meeting on the Medicaid telephone eligibility verification system. Nearly 100 area pharmacists attended the meeting.

The Student APhA Chapter recently installed its new officers. Shown at the ceremony are: (left to right) Dean William J. Kinnard, Jr.; Rich Benchoff, Vice President; Anne Hom, President; Sara Donegan, Secretary; Jay Shear, Treasurer; Donald Fedder, Faculty Adviser; Harry Finke, Guest Speaker; and Marvin Oed, Faculty member.

Harry Finke was the guest speaker at the Student APhA Chapter installation. He described how he became an independent community pharmacy owner shortly after graduating from Pharmacy College and encouraged others to consider a similar career.

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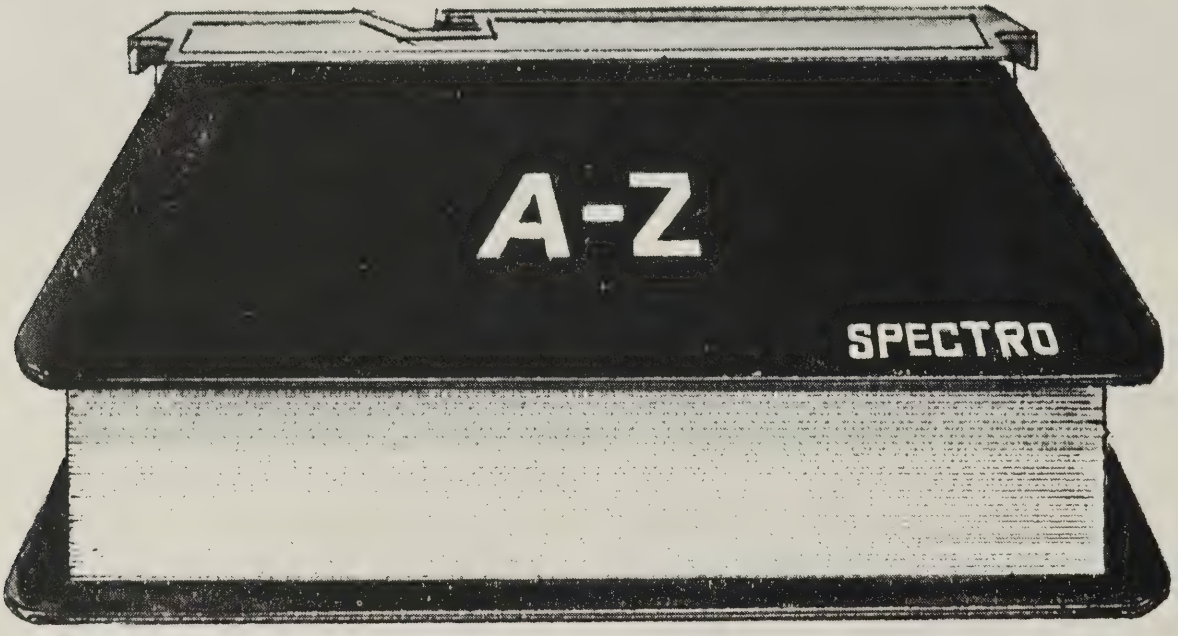

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calendar

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Self Medication of Topical Fungal Infections

— J. Richard Wuest
Thomas A. Gossel

You are Well Prepared to Fail the Formula for Success

— Marvin Oed

This and That about Pharmacy

— Leon Weiner

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June 24–28th Carousel Hotel
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May, 1984 VOL. 60 NO. 5

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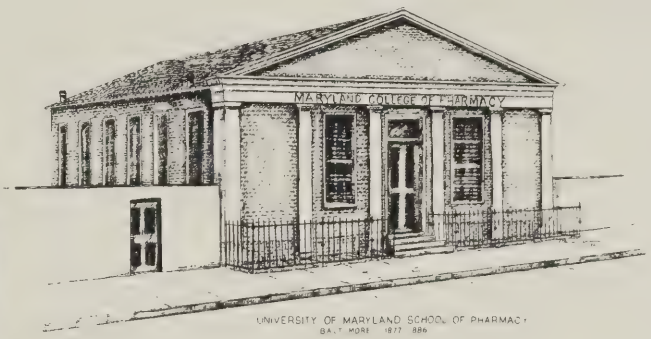

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SCOPE
STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION • VOL. I, NO. 5

Self-Medication Of Topical Fungal Infections

By J. Richard Wuest, R.Ph., Pharm.D.
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Cincinnati, OH

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Professor of Pharmacology
Ohio Northern University
Ada, OH

Goals

The goals of this lesson are to:
1. discuss the self-treatment of topical fungal infections;
2. review the pharmacology and therapeutics of drugs used to treat topical fungal infections.

Objectives

At the completion of this lesson, the successful participant will be able to:
1. choose the appropriate OTC agent for treating the specific topical fungal infection;
2. properly advise consumers on the selection and use of OTC fungal agents;
3. decide when the consumer should be referred to a specialist.

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This continuing education for Pharmacy article is provided through a grant from MERRELL DOW PHARMACEUTICALS INC.

There are two major types of fungal diseases: the **mycotic,** or deep-seated systemic infections; and the **dermatophytic,** or superficial, topical infections. Only the latter, however, are considered to be self-diagnosable and self-treatable. These are the **tinea** infections and are commonly referred to as **ringworm.** The one prevalent organism that can cause both systemic and superficial disease, **candida,** remains in the "intermediate zone." While a number of experts feel that some forms of candidal infections can be safely self-medicated with topical preparations, others (including FDA) are not convinced that the previously available prescription agents (nystatin, haloprogin, miconazole, clotrimazole) should be switched to OTC status and indicated for candidal infections as was recommended by its advisory panel. More will be said on this later.

Self-Treatable Ringworm Infections

These infections are actually caused by one or more organisms of a group of fungi. Since it is difficult to determine the specific organism causing each infection, the diseases are grouped together and referred to as **tinea** infections. They are then characterized as to the area of the body affected rather than to the causative organism (e.g., *Tinea corporis*, body; *Tinea pedis*, feet; *Tinea cruris*, groin; *Tinea unguium*, nails; *Tinea capitis*, scalp; and *Tinea barbae*, beard). These organisms only affect dead, keratinized cells of the body (e.g., skin, hair, nails). They do not cause systemic infections.

Common dermatophytic infections that are considered to be self-treatable include athlete's foot, jock itch, and ringworm of the body. Infections of the hair and nails require systemic therapy with the oral agents available only on prescription (e.g., griseofulvin, Nizoral). We will discuss the superficial self-diagnosable, self-treatable infections in this lesson.

Symptoms produced by fungi that cause athlete's foot, jock itch, and ringworm result from their metabolic products. Fungi colonizing in the keratinized structures release enzymes into the skin which hydrolyze fats, carbohydrates, and proteins. These hydrolytic products then diffuse back into the fungi to be used as nutrients for further growth. As these substances are broken down by enzymes, they irritate the skin and produce the typical inflammatory reactions. Additionally, metabolic products of fungi may produce hypersensitivity (allergic) reactions adding to the inflammatory condition and perpetuating itching.

Athlete's Foot (*Tinea pedis*—ringworm of the foot)

This is the most commonly encountered of all tinea infections. Numerous surveys among persons in confined areas, (e.g., students, inmates of institutions, armed forces members), have shown that the incidence of athlete's foot approaches 65 percent. The disease most frequently occurs in hot, moist weather. Adult men are more commonly affected than women; prepubertal children are rarely affected.

The cause of athlete's foot is not known. Suspicions that shower room floors are the most common source of infection have not been

proven. Several studies have shown that one to three percent of the human population are carriers of fungus pathogens but have no signs of clinical infection.

The term athlete's foot is "generic" in that it is often ascribed to any foot condition involving a rash. When it is a fungal infection, sores or blisters surrounded by narrow zones of peeling, dead, white epidermis, that usually begin between the great and second toe are present. Moisture due to excessive sweating adds to the inflammation, blistering, and spreading. The lesion does not spread symmetrically to form the "ringworm" appearance as do other forms of tinea infection of the body. Untreated, chronic athlete's foot infection can affect the toe webs and soles of the feet. Severe cases can spread to the toenails, invading and ultimately destroying the nail plate.

Itching and burning are prevalent with athlete's foot. The infection can also spread to other parts of the body if proper hygiene is not followed. Secondary infections with bacteria and candida may follow tinea infection of the feet and groin. Both require medical diagnosis, but telltale signs that these secondary invading organisms are present include a bright red coloration to the tissue inside the "sores" and the presence of pus-like exudate within the blisters. The fluid from the blisters of a tineal infection is generally colorless and odorless. Presence of a pungent odor could mean that the gram-negative bacteria pseudomonas is also present.

There are several prophylactic measures which prevent athlete's foot from occurring. These include wearing shower clogs when using public showers, carefully drying the feet after bathing, frequently changing socks and shoes, and dusting shoes with medication between wearings and toes with each sock change. The feet should be kept dry and well ventilated.

In acute flareups, aluminum acetate may be helpful if there is a great deal of blistering, although it is not an antifungal agent. If the blisters are large, the fluid may be removed by draining and absorbing it immediately and carefully with cotton or tissue. Infection spreads with the blister fluid. Care should be taken that the fluid is drained from the margin of the blister where it meets unaffected skin. If the top of the blister is destroyed, healing will take longer and the drainage from the open sore may spread the infection to other parts of the foot or body.

Ringworm Of The Body (*Tinea corporis*)

In days gone by, this infection was actually thought to be caused by a "worm" that was located under the skin and expanded peripherally. In actuality, the ringed lesions are caused by an inflammatory response to the advancing fungi as explained earlier. The lesions often vary from simple scaling to degranulation of the skin's surface tissue. They are generally circular. The center may appear scaly and then heal as the wound spreads outward. Again, this gives rise to the phrase "ringworm". However, several lesions may be present which eventually coalesce to form single, large infected areas, each having a healed central core. The lesions itch intensely, especially in warm weather.

Unlike other self-treatable tineal infections, children are much more susceptible to ringworm of the body than adults. Also unlike the others, the infection is carried and spread by animals, most commonly dogs and cats.

Jock Itch (*Tinea cruris*—ringworm of the groin)

This is a condition in which the fungal microorganisms cause a lesion which extends from the crural fold (the area of the crease between the inner thigh and the pelvis), over the adjacent upper inner thigh, and possibly into the anal area. The lesion will usually appear as a semicircle rather than a ring, but the expanding margin will be slightly raised, rash-like, and scaly. The appearance of blisters is rare. As with athlete's foot, jock itch is uncommon in prepubertal children. The most prevalent group that is affected is males aged eighteen to forty. Also like athlete's foot, the term "jock itch" is generic and may refer to seborrheic dermatitis, psoriasis, or candidiasis, all of which are secondary to *Tinea cruris*.

OTC Agents That Have Proven Effectiveness For Ringworm

A list of these substances is present in Table 1. It includes medications which have been available for years, i.e., the long-chained fatty acids (Desenex®, etc.), tolnaftate (Tinactin®, Aftate®), and iodochlorhydroxyquin (Vioform®). Also listed are two other agents known to be effective against tineal organisms—miconazole (Monistat®) and haloprogin (Halotex®) which have only been available by prescription. The FDA Advisory Panel on OTC Antifungals recommended they be switched to OTC status. FDA is reviewing this recommendation and has stated (as it did with hydrocortisone) that no final ruling will be made until all evidence has been evaluated. In the meantime, manufacturers (again as they did with hydrocortisone) may market these antifungals OTC with the knowledge that the FDA may later disagree with the recommendation. While the volume of sales of these two agents is nowhere near that anticipated for hydrocortisone, nearly one hundred million dollars worth of OTC hydrocortisone-containing products have been sold with FDA still not reporting its final ruling. It is also of some importance that several new antifungals will be coming onto the market (e.g., ciclopirox—Loporox®; econazol—Spectazole®; ticonazole—Trosyd®).

TABLE 1
Antifungals Considered Safe and Effective by FDA's OTC Advisory Panel

Haloprogin*	-Halotex®
Iodochlorhydroxyquin	-Vioform®
Miconazole*	-Monistat®
Nystatin**	-Mycostatin®, Nilstat®
Tolnaftate	-Aftate®, Tinactin®
Undecylenic acid	-Desenex®, Cruex®, etc.

*Not available OTC at time of Panel's review

**FDA will not allow OTC marketing of nystatin at this time

The long-chained fatty acids (undecylenic acid, propionic acid, caprylic acid and their salts) had been used to treat fungal infections since 1939 when it was discovered they were components of human sweat and had anti-fungal activity. The exact mechanism of activity of these substances has not been determined, but it appears as though they interfere with the normal metabolism of susceptible fungi.

The FDA OTC advisory panel that reviewed them found that all three substances were safe for topical use, but it ruled that only **undecylenic acid** and its calcium, copper, and zinc salts have been studied thoroughly enough to prove their effectiveness. The panel therefore recommended that these latter drugs continue to be available as safe and effective antifungal agents. There are some who believe that a 1:4 combination of undecylenic acid with its zinc salt (the USP form) is the most effective form because the zinc salt also provides an astringent activity which may be beneficial.

For **caprylic** and **propionic** acids (actually the sodium and zinc salts), the panel concluded that no well designed, controlled, clinical trials had ever been conducted. At least one such study will be required for each drug before a final ruling is made on its effectiveness.

Tolnaftate is another agent known to be safe and effective. It is thought to act by destroying the filaments that make up the substance of susceptible fungi and, therefore, stunting micelle growth. To review, the micelle of fungi are the complexes of protoplasmic units or tube-like structures (filaments) that constitute the "body" of the fungus.

Iodochlorhydroxyquin is both antifungal and antibacterial. When it enters susceptible organisms, it chemically interferes with metabolic reactions and inhibits their growth. It is effective against tinea and candida organisms and several gram-positive bacteria (e.g., staphylococci, enterococci) as well. One item to keep in mind when counseling consumers is that iodochlorhydroxyquin can stain clothing, skin, hair and nails. The stain in the latter three instances will eventually slough off, but it is difficult to remove from clothing.

As the name implies, iodochlorhydroxyquin contains iodine. Persons allergic to iodine or iodine-containing products should select some other preparation. It also can be absorbed sufficiently to affect thyroid function tests; patients undergoing such tests should not use it.

Ticonazole (Trosyd®) is an antifungal by Leeming (Pfizer) that has an action similar to miconazole. It was approved and released as a nonprescription product in early 1983 under the guidelines proposed by the FDA advisory panel.

Effective Agents Recommended For Switch From Prescription-Only To OTC Status

As stated earlier, **haloprogin** and **miconazole** have been evaluated by an OTC advisory panel. For reasons unknown to the authors, the panel did not review the data on **clotrimazole** and did not publish comments on it. With haloprogin and miconazole, however, the panel recommended that FDA change their status to OTC. The panel was convinced by evidence presented to it that both these agents were safe for nonprescription use and, in fact, pointed out that haloprogin has been available OTC in Japan since 1962, and in Canada since 1976. The panel also recommended that these two agents be indicated for self-treatment of external feminine itching associated with vaginal and superficial skin infection caused by candida.

Haloprogin, miconazole, and clotrimazole are definitely effective against tinea and candida. They appear to act by altering the cell wall's permeability and causing it to lose its ability to act as a selective barrier. The organism then loses its osmotic integrity, its contents escape, and it dies.

The panel also recommended that **nystatin** be changed to OTC status for superficial candidal infections of the external vagina and superficial skin, athlete's foot, jock itch and ringworm of the body. However, FDA disagreed with this recommendation and will **not** allow the transfer of nystatin from prescription-only to OTC status at this time. FDA will also not approve the indication of any OTC product for the treatment of candidal infections.

The panel found that vaginal discharge is the most common pelvic complaint encountered in private medical practice and that it is usually associated with vaginal itching. The two most prevalent causative organisms are *Trichomonas vaginalis* and *Candida albicans* with the latter considered more prevalent (estimated at 1:7 in nonpregnant women and 1:15 during pregnancy). It reported that most women are familiar with this condition (intense itching, erythema, or redness of the vulva, and a white vaginal discharge), especially if they have been previously treated for it.

The panel members felt, however, that the affected woman is bothered mostly by the itching and the raw red eruptions that occur on the vulva. The availability of nystatin (or haloprogin/miconazole) OTC will allow rapid relief of the discomfort until more definitive treatment with oral and intravaginal anti-candidal medications can be obtained from a physician. The panel concluded that the use of topical nystatin is rational and well accepted in the treatment of *Candida vulvovaginitis*.

After reviewing the panel's report, FDA disagreed with the recommendation. FDA felt that candidal infections are not self-diagnosable and that self-treatment of vaginal itching could be hazardous without knowing the underlying cause. Itching around the vagina could be a symptom of a more serious condition such as trichomoniasis, gonorrhea, or a systemic disease. Since nystatin is not effective in treating ringworm infection, FDA will not allow its transfer to OTC status at this time.

FDA requested comments on the issue particularly from gynecologists, and did not approve halopro gin or miconazole for treatment of infections. While FDA did not expressly forbid OTC marketing of these latter two agents for athlete's foot, jock itch, and ringworm, the agency stated that manufacturers who opted to do so did it at their own risk.

Patient Advice

There are some general guidelines that should be followed in treating (and preventing the recurrence of) tinea infections. The involved area should be thoroughly cleansed with soap and water and dried well. Most agents are effective when administered twice a day (morning and night), but a third application during the day might be helpful if it is convenient. Proper care and aeration of the feet is important for that condition as well.

Compliance with this regimen is imperative. If the agent is effective, the condition should clear in approximately two to four weeks. If it does not clear, the patient should contact the physician for advice. The condition could be caused by a nonsusceptible organism or bacteria, or be a more serious disease such as seborrheic eczema or psoriasis.

As far as assisting in the selection of a product, there are no clear-cut, definitive, scientifically documented data on the effectiveness of these agents. The practical approach would be to stay with the agent that worked initially. If an agent has not been effective, the person could switch to another product since the action of undecylenic acid differs from tolnaftate, both of these differ from iodochlorhydroxyquin, and all three differ from haloprogin/miconazole. Again, the patient should anticipate two to four weeks of full compliance before the condition clears.

Product Form

Selection of the proper vehicle is an important factor when choosing an antifungal agent because it must gain access to the fungal colony to exert its action. Any topical agent must be capable of moving freely through its vehicle and being available at the point of contact with the skin. However, the site of application must also be kept in mind. For example, liquids such as tolnaftate solution allow complete movement of the antifungal agent and provide no barrier to its release at the site of infection. It would be an excellent vehicle for ringworm of the body, and small patches of athlete's foot and jock itch that are oozing serum. On the other hand, it might not be the best form for large areas of these latter two conditions because it might run off the area and not remain in contact with the fungi long enough to be effective.

Water immiscible ointments would have a longer "staying" power, but they may not adhere to oozing, moist, or sweaty areas of the skin (prevalent with athlete's foot and jock itch). Ointments may retard the release of active ingredients onto the skin. Water soluble (polyethylene glycol based) vehicles, commonly called creams, reportedly have more advantages over the greasier ointments (petroleum based). They deliver the drug to the site of action more easily and hold it there longer than the aqueous solutions. A slightly viscous, yet water soluble cream is considered to be an excellent vehicle for most conditions where skin rubs against skin, i.e., between the toes and in the groin area. Patients should be aware that they need only apply a thin layer of the medication and rub it in until it dissipates.

The powder forms are recommended for adjunctive use in moist areas where skin rubs against skin because drying will enhance the antifungal activity. Fungi do not survive well in a dry environment. Powders are especially good for prophylactic prevention of recurrent athlete's foot, and should be sprinkled on the toes once or twice a day for this purpose.

The aerosol powders and solutions are designed to deposit the antifungal agent on the skin after the propellants and solvents evaporate. Sweat and moisture present on the skin help dissolve the antifungal agent. Patients preferring these dosage forms should be advised to hold the cannister six to ten inches from the affected area and spray the medication evenly, especially between and under the toes. The powder should be sprayed into the socks and shoes as well. The groin area might be too sensitive for the organic solvents in the solution type of product. The precautions necessary for any aerosol dosage form packaged under pressure should be followed. Do not inhale the vapors, keep it away from the eyes, and be cautious near heat or flame.

One final point on patient advice is that the infective organism is carried with blister fluid and shedded skin. All clothing, washcloths, towels and bedding should, therefore, be laundered after each use.

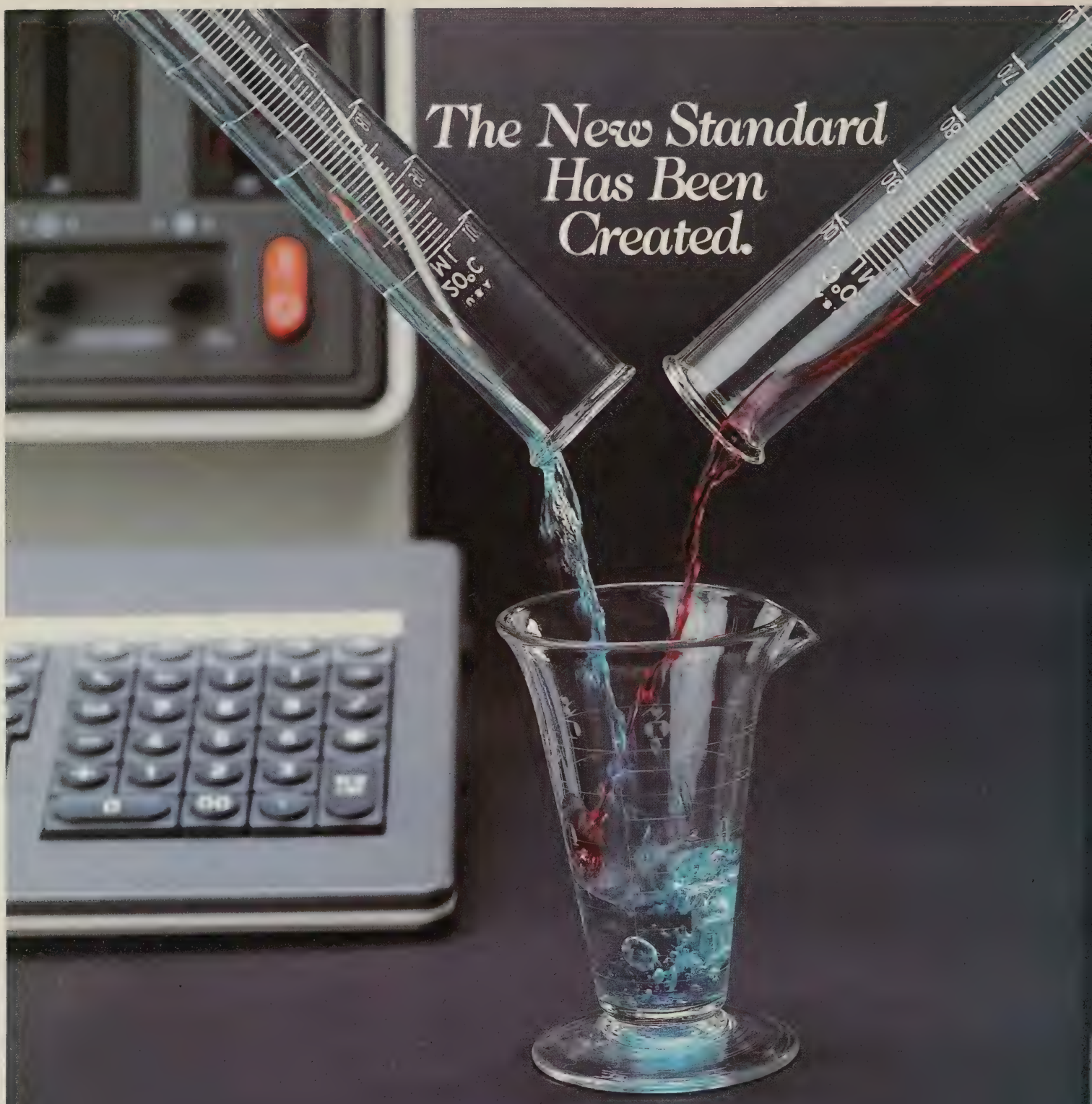
Antifungals Of Questionable Efficacy

For many years treatment of fungal infections has included astringents such as aluminum chloride and aluminum acetate, keratolytics such as salicylic acid and sulfur, and antiinfective agents such as boric acid and potassium permanganate. This latter agent was not submitted to the OTC advisory panel and, therefore, was not reviewed for effectiveness.

A concept paramount in the panel's conclusions was that, unlike most other OTC's, symptomatic relief of discomfort is not good enough when using antifungal agents. While many consumers will be satisfied when the itching and redness cease, a truly effective antifungal agent must actually kill the organisms and remove the underlying cause. When evaluating a variety of traditional "antifungals" (Table 2), the OTC panel found that these substances lacked definitive proof of effectiveness. In most instances, the panel requested at least one, well designed, controlled, clinical trial to establish the effectiveness of these substances before they be classified in the proven safe and effective category.

TABLE 2
Antifungals Requiring More Evidence of Proof of Effectiveness

Aluminum salts	Phenyl salicylate
Basic fuchsin	Povidone-iodine
Benzethonium chloride	Propionic acid
	Salicylic acid
Benzoic acid	Sodium borate
Boric acid	Sodium caprylate
Chloroxylenol	Sodium propionate
Chlorothymol	Sulfur
Cresols	Triacetin
Dichlorophen	Zinc caprylate
Oxyquinolines	Zinc propionate
Parabens	



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The aluminum salts have been shown to be effective in inhibiting growth of both bacteria and fungi, but no such studies have been conducted specifically for athlete's foot, jock itch, or ringworm. Castellani's paint (carbol-fuchsin solution) has been used since the early 1900's to treat bacterial and fungal infections. It contains basic fuchsin, acetone, boric acid, phenol and resorcinol and is not an OTC item. No studies have been conducted on basic fuchsin alone. Therefore, it too was placed in the "needs more study" category. Benzalkonium chloride is a well established antibacterial agent, but there is a lack of evidence to substantiate its antifungal activity. Benzoic acid is an excellent and widely used preservative, but it has not been adequately studied as a therapeutic agent to the satisfaction of the advisory panel.

Boric acid and its salts, in a concentration greater than five percent, have been ruled to be unsafe for any use due to potential poisonous effects. The panel felt that lower concentrations are not a toxicity hazard when used on intact skin. However, it recommended that boric acid not be used on inflammed or broken skin. Even though it is a common ingredient in OTC antifungal agents, it was found to lack sufficient evidence of effectiveness.

There is no doubt that salicylic acid possesses keratolytic activity, i.e., it destroys the bonds that hold keratin cells together. It has been used through the years (e.g., with benzoic acid as Whitfield's ointment) as a mild keratolytic both for its antiseptic and antiparasitic effects, and, to "enhance the penetration of other active ingredients" into the skin. Sulfur has been used for the same reason. In neither instance, however, could the panel find documentation of their effectiveness in treating fungal infections.

This was the case for all of the other agents listed in Table 2, but a special point should be made about triacetin. Its mechanism of action is reportedly due to its hydrolysis to the active principle—acetic acid. Unlike most other antifungals, it works better in the presence of body serum (i.e., the blister fluid). Its manufacturer has conducted experiments to prove effectiveness, but the FDA panel found that these experiments were not adequate. The panel concluded that, when it is proven to be effective, triacetin should only be indicated for "soggy" athlete's foot, and not for the dry forms of ringworm disease.

Agents Ruled To Be Unsafe And/Or Ineffective

These agents are listed in Table 3. If FDA accepts this recommendation of the OTC advisory panel, these agents will be banned from future non-prescription sale.

First among them is carbol-fuchsin solution. The panel concluded that the percentages of phenol (4.5%) and resorcinol (10%) exceed the maximal safe concentrations for self-medication. It recognized that the solution has been used for over half a century with no documented toxicity being reported, but it felt that such use is appropriate for physician supervision, not OTC sale. Phenol and resorcinol alone were placed in this category as well.

TABLE 3
Agents Proposed to be Banned From OTC Sale as Antifungals

Camphor
Candicidin
Coal tar
Menthol
Phenol
Phenolates
Resorcinol
Tannic acid
Thymol
Tolindate

The panel ruled that camphor and menthol were slightly antiseptic but weak antifungals. While they may produce a feeling of coolness and provide a mild anesthetic effect to reduce itching, they do not kill fungi. The panel did, however, suggest that in concentrations of less than two percent, either or both of these agents may be present as inactive ingredients for product identification, (i.e., the medicinal smell).

Thymol lacked evidence of safety and effectiveness. It has also been used for years and was originally touted as being the replacement for phenol because it smelled better and was less toxic to tissue. Its action, however, is reduced in the presence of organic matter and protein. While it may be a good antiseptic for inanimate objects, the panel did not feel thymol could be proven safe and effective for fungal infections on human skin.

Coal tar derivatives were ruled to be unsafe because they are known carcinogenic agents, and can cause phototoxicity reactions, acne-like skin lesions, and generalized pustular psoriasis (authors' note: even though coal tar derivatives are useful in treating some patients with psoriasis).

Tannic acid is a proven astringent. It has little action on intact skin, but on abraded skin, it precipitates protein to form a protective film. It has been used as an astringent and styptic for years. After reviewing all the data, the panel concluded that tannic acid in antifungal medication is of historical interest only. It does not have proven beneficial effects.

Candicidin has been rejected for OTC use by the FDA. Even though it has been shown to be effective for intravaginal use in candidal infections (on a prescription-only basis), it has never been studied for extravaginal use. There was no evidence of its effectiveness or safety for self-treatment (in the panel's opinion) of superficial candidal infections. Tolindate, a compound similar to tolnaftate, was turned down for OTC use by the panel because it is currently in the IND (Investigational New Drug) stage and all data are classified.

Combination Antifungals

The panel recommended that the combination antifungals listed in Table 4 be permitted for OTC sale. FDA, however, disagreed with many of them. While it will permit the marketing of up to three Category I antifungals mixed together as long as each is already available OTC, an additional provision is that each ingredient must broaden the spectrum of

activity of the combination. FDA will not allow marketing of any combination containing a previously prescription-only ingredient at this time. The agency will allow continued OTC sale of antifungal/antiperspirant combinations that are already on the market, but stated that the panel's theory of these combinations' benefits was not supported by the data in the report. FDA also pointed out that the panel's placing of antifungal/antiperspirant combinations in Category I for athlete's foot conflicts with another panel (OTC Antiperspirant Drugs) that relegated antiperspirants to the "needs more study" category when used on the foot. FDA requested comments so that this matter can be resolved.

TABLE 4
Antifungal Combinations Considered Safe and Effective by FDA's OTC Advisory Panel on Antifungals

Up to three antifungal agents*
Antifungals with antiperspirants*
Antifungals with keratolytics*
Antifungals with hydrocortisone**

*FDA will not allow these combinations if they include an antifungal not available OTC as of March, 1982.
**FDA will not allow this combination on the OTC market at this time.

One final point concerns the antifungal panel's recommendation that antifungal/hydrocortisone combinations be available for OTC use. In this instance, FDA again disagreed, for two reasons. First, the only two such products available are iodochlorhydroxyquin with hydrocortisone (Vioform HC®, Domeform HC®, Racet®, etc.), and calcium undecylenate with hydrocortisone (Caldecort®). They are under the DESI review meaning they have not yet been proven to be safe and effective.

Second, another OTC panel that reviewed hydrocortisone (and recommended its switch to OTC status) specifically concluded that it should be a single entity product only and not be available in any combination.

As stated earlier, FDA has requested comments on these matters and will make its final decision after reviewing them. In the meantime, from the pragmatic side, the FDA has authority over manufacturers, not practitioners, or private citizens. If physicians choose to prescribe and consumers wish to mix antifungals and hydrocortisone together, they are free to do so.

In conclusion, there are safe and effective OTC antifungals: undecylenic acid and its salts, iodochlorhydroxyquin and tolnaftate. When haloprogin and miconazole are shifted to OTC status, they will add to the self-medication armamentarium of agents effective against these highly infective and contagious microorganisms.

APhA and NARD Create New Subdivisions

The American Pharmaceutical Association (APhA) is establishing a new membership subdivision, the Academy of Pharmaceutical Management (APM), it was announced today by Herbert S. Carlin, Chairman of the APhA Board of Trustees.

The Academy of Pharmaceutical Management will provide management oriented programs and activities that will benefit all pharmacists in administrative and management positions, irrespective of the nature and location of practice. APM's objective will be to address overall management activities and skills and then demonstrate to members how those basic skills can be applied in their specific management situations.

APhA members who would benefit from the services and programs the new subdivision will provide include independent community pharmacy managers and owners; academicians in research and teaching; pharmacy school deans and administrators; managers in industry; hospital pharmacy managers and administrators; chain pharmacy managers; association officers and executives; government administrators; and independent management consultants.

Chairman Carlin has appointed an Interim Development Committee to oversee the establishment of APM and to provide leadership until officers pro tem can be appointed and installed. The first election of officers by the AMP membership will be held in the summer of 1985.

—The National Association of Retail Druggists has created a new National Center for Independent Retail Pharmacy to be housed in the NARD Building in Alexandria, VA. The National Center will encompass some existing programs already sponsored by NARD as well as develop new ones that will strengthen the profession of community pharmacy. Guiding the direction the new National Center will take will be a distinguished Executive Advisory Council composed of chief executive officers of major companies providing goods and services to the independent retail pharmacist as well as independent practitioners, pharmacy academicians, and members of the NARD leadership.

The objectives of the National Center are centered around the following three areas:

- Education—providing financial, management and merchandising information that will enhance the viability of the independent pharmacist;
- Resource—providing information about independent retail pharmacy to NARD members and other interested parties; and
- Research—investigating aspects of the profession where practical applications of such information will assist NARD members in their businesses.

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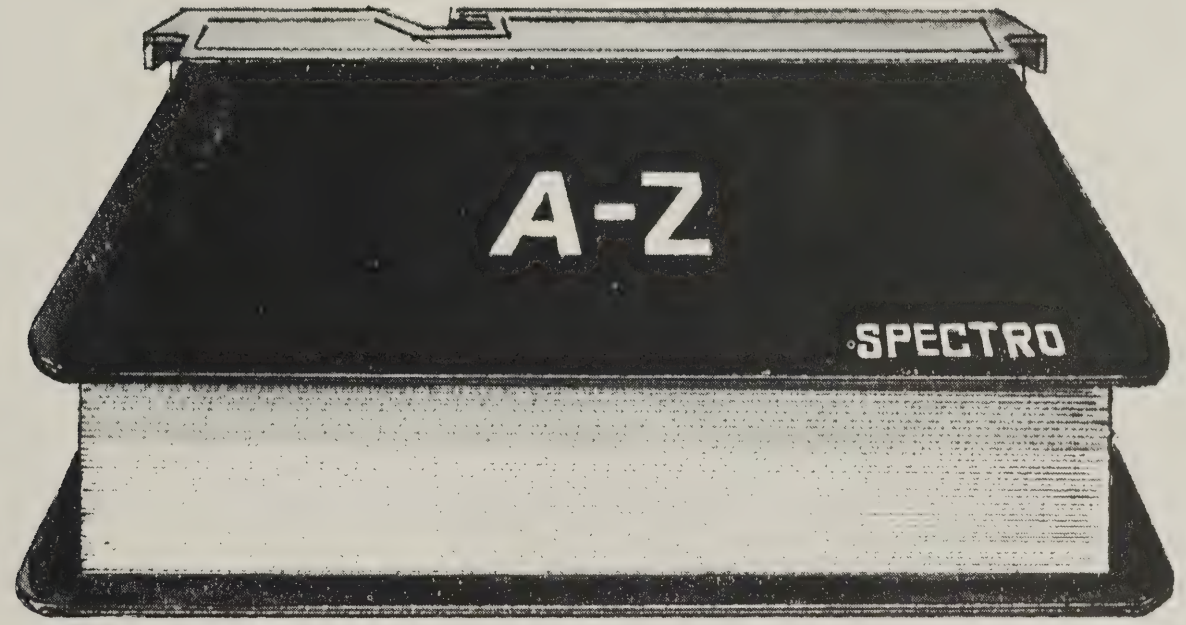

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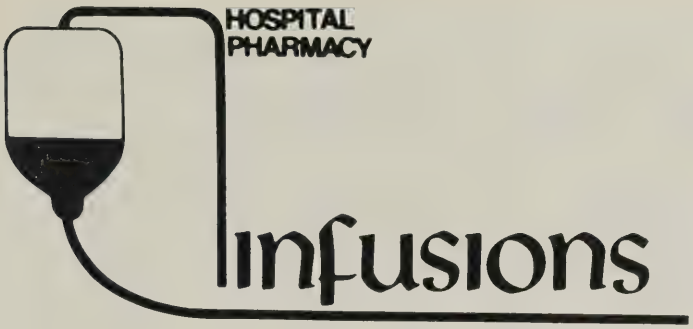

Ranitidine Versus Cimetidine for Treatment of Duodenal Ulcers

Information contributed by the Maryland Society of Hospital Pharmacists.

Contributor: Lisa Welch
Pharmacist
Johns Hopkins Hospital

For the short-term treatment of active duodenal ulcer (DU), there are currently two competitive H_2-receptor antagonists available: cimetidine and ranitidine. While these drugs differ markedly in structure, they are each potent antagonists of basal and meal-stimulated acid secretion, as well as gastric acid secretion in response to a number of chemical stimuli (1–7).

Randomized double-blind placebo-controlled studies in endoscopically-proven DU patients show that cimetidine and ranitidine are both significantly better than placebo for rate of ulcer healing (8–16). Cimetidine 800mg to 1 gram per day showed a four week healing rate of 71–74% compared with a rate of 37% for placebo. Rantidine's four week healing rate at a dose of 150mg po BID was 79–83%, compared with 16–32% for the placebo group.

Randomized double-blind comparisons of cimetidine and ranitidine in equipotent acid-inhibitory doses in DU patients fail to demonstrate differences in efficacy between the two drugs for rate of healing (17–19). Upon cessation of therapy with either drug, relapse is frequent. Although ranitidine is not currently indicated for maintenance therapy of DU, patients receiving doses of 100mg po HS for one year after healing showed a 29% relapse rate, a rate similar to that reported with cimetidine (13, 16, 20).

Clinical experience with ranitidine is limited, relative to over five years of experience with cimetidine, but trials indicate that ranitidine may not be associated with many of the adverse reactions reported with cimetidine. Ranitidine appears to lack the antiandrogenic effects that seem to be responsible for cimetidine's causing gynecomastia and/or impotence in some patients, usually those receiving higher doses for Zollinger-Ellison Syndrome (21, 22).

Mental status changes manifested by confusion are frequently reported in elderly cimetidine-treated patients, and they are postulated to result from increased CNS cimetidine levels due to renal or hepatic dysfunction (23). While ranitidine is able to cross the blood brain barrier, there has been only one case report of its causing mental confusion (24), while yet another report claims that ranitidine reversed cimetidine-induced mental confusion (25).

Cimetidine is widely known for its ability to inhibit the cytochrome P450 oxidase system and thus interfere with the metabolism of drugs which depend on this phase I pathway. In doses that produce ulcer healing, ranitidine does not decrease metabolism of drugs that rely on this metabolic pathway to the extent that cimetidine does. This may be attributable to the fact that ranitidine lacks two of the nitrogen groups found in cimetidine that are known to bind to the cytochrome P450 oxidase enzyme (26). Recently, however, there has been one report of slightly decreased theophylline clearance in volunteers (28) and another report of decreased warfarin clearance (27). Ranitidine at a dose of 150mg effectively suppresses gastric acid secretion for up to 10 hours and can be dosed on a BID schedule. In patients with renal dysfunction (CCr $<$ 50ml/min), it is recommended that the dosing interval be lengthened to q24 hours, while keeping the dose at 150mg. No dosing alterations are recommended when ranitidine is used in the setting of mild hepatic failure (29).

Because ranitidine and cimetidine appear to be equally effective for treating DU, the choice of H_2-receptor antagonist will most likely be based on parameters such as age, treatment duration, concurrent drug therapy, renal and hepatic function, compliance, side effects and cost.

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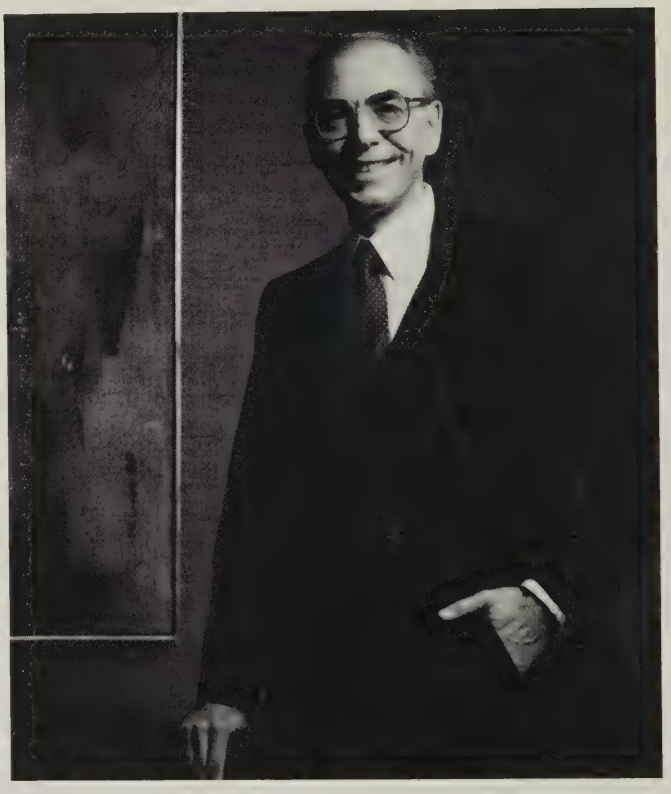

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Things You Should Know FOR YOUR GOOD HEALTH

Take it Without a Grain of Salt

Hypertension is the medical term for high blood pressure. It is not nervous tension. High blood pressure is not caused by nervousness or anxiety, although too much emotional upset can aggravate the condition. Blood pressure is the pressure exerted on the walls of the blood vessels as the heart pumps blood through them. In some people when the blood pressure elevates higher than it should and stays up – they are said to have hypertension. Most individuals do not have any symptoms of high blood pressure. The only way to know is by having a pharmacist or physician measure your blood pressure.

With many patients blood pressure can be lowered by decreasing dietary salt intake. Salt, or sodium chloride, is an important chemical compound and is necessary for proper body function. However, it has been shown that Americans eat entirely too much salt.

The relationship between high blood pressure and sodium intake has been known for many years. When sodium is taken into the body and not fully removed by the kidneys, water tends to accumulate in the body's tissues. Ultimately the heart may have to work much harder to pump blood through the body.

All sodium does not come from the salt shaker. Salt is part of most of the foods you eat and many of the medicines you take. The demand for low sodium foods has increased greatly during recent years. It is now possible to determine the sodium content of many foods by simply reading the label.

The following general restrictions will guide you to developing better "low-sodium habits."
Avoid:

1. *Salt and salt seasonings,* including: MSG, garlic and onion salt, chili sauce, catsup, barbecue sauce, soy sauce, Worcestershire sauce.
2. *Salty meats and fish,* including: bacon, ham, sausage, lunch meats, hot dogs, smoked, salted or dried fish.
3. *Cereal products made with salt,* including: bread, rolls, crackers, pastas, and salted snacks, such as popcorn and potato chips.
4. *Vegatables with high sodium content,* including: pickles, sauerkraut, vegetable juices, spinach, artichokes, beets, carrots.
5. *High sodium dairy products,* including: salted butter or margarine, commercially made salad dressings or mayonnaise, condensed milk, dried milk, milk shakes, ice cream and cheeses.
6. *Other:* Coffee (unless decaffeinated), baking soda, baking powder and peanut butter.

The drug industry has also begun to make known the sodium contents of many medicines. Antacids, for example, were at one time a source of much sodium. Many antacids now have reduced sodium content. Consult your pharmacist for this information. The sodium content of most prescription medicines is still not available. However, with time, this information will be made available for the majority of medicines.

For the New Graduates

You Are Well Prepared to Fail the Formula for Success

by Marvin L. Oed, PharmBS

We generally view failures as a negative factor in our lives. In reality only those who never do anything never fail. Recently, I heard of a basketball coach being extolled in retirement as having "never lost any of his last 500 games". Rather than being a noteworthy athletic accomplishment, he was just in the wrong league. Any bully can beat up all the little kids on the block. There is no satisfaction in that.

Money and position are often seen as indicators of success. In reality, true success is related to satisfaction and happiness and has little to do with the size of your salary or the title of your position. To be successful you need to do that which you want to do and do it to the best of your ability. The rewards are in the attempt, not in the achievement. To continue the sports analogy, a runner may set a personal goal of a 4 minute mile and begins training. There is only a moment of success as that 4 minute mile is attained and before a new goal must be established. The real rewards come from seeing the improvement as a result of the efforts of training and competition. The 4 minute mile was merely a ruler to gauge progress.

Your choice of a career, within pharmacy or elsewhere, is not important to your achieving success. You are capable of doing or learning to do anything you want. What is critical is to strive for excellence in whatever you do. The world's strangest secret, someone once said, is that "You become what you think about most of the time". I didn't believe that the first time I heard it, but now I know that not only is it true, it is unavoidable. You cannot help but become what you think about as long as thinking is defined as a dynamic process. Daydreaming is not thinking. This is the reason those who regularly set goals and pursue them are successful (happy, satisfied) and those who do not, are not.

Defining your goal(s) in specific terms is the first step. You may do it mentally, but it is much more effective if written down. Most people spend more time selecting the type of new car they will drive than determining how they will spend the rest of their lives. Once you have decided what you want to do, the second step is to determine what you are willing to give up in order to obtain it. There is a "cost" involved in every decision. It may include money but almost always includes a commitment of time and effort. As long as you are willing to pay the price the rest is easy. In fact, the rest is inevitable. You need only get on with your life doing all those things that lead you toward your goal and avoiding those things that do not. I said it earlier but it bears repeating, "You become what you think about most of the time".

A goal is a road map with the objective your destination. If you don't have a map, you won't know how to get there. If you have a map but no destination, any road will get you there. Without a destination how will you know when or if you arrive?

You have all spent a number of years obtaining an education. Most of you are now anxious to get on to another facet of your life. As you embark on this new aspect of your life, I want to remind you that there are four elements necessary for success.

Responsibility

Regardless of the position you assume you need to understand exactly what is expected of you. As employers, we usually do a reasonably good job of this even if the definitions are rather vague. The important thing is that both you and your employer know what is expected.

Authority

To carry out your responsibilities, you must have the authority to require what is necessary. Without this authority you are impotent in your job. If you are expected to supervise, you must be able to discipline, etc. As employers, we are reluctant to do this. We like to delegate responsibilities but withhold the authority in order that we remain in control. The employee put in this position cannot be a good practitioner or a good manager. Employers need to be convinced that it is in their own best interest to delegate authority with responsibility.

Accountability

Everyone is, as it should be, held responsible for their own actions, both good and bad. This is the way you balance the checkbook of life. Everyone that wants

Marvin Oed is a clinical Assistant Professor in the Department of Pharmacy Practice and Administrative Science and is Director of the Professional Experience Program at the University of Maryland School of Pharmacy. He is also involved in community practice as the owner of pharmacy and medical equipment businesses.

can have a positive balance (satisfaction). As you make decisions (authority) to carry out your responsibilities, you make deposits in your account. Without authority the best you can expect is a zero balance (neither satisfaction or dissatisfaction).

If you are given neither responsibility or authority, there will be a negative balance (dissatisfaction). There is no reason for anyone to remain in a position that does not bring satisfaction. You have control over your life if you choose to exercise it.

Pride

Pride is the ingredient that makes everything else work. You must strive toward perfection. This means doing your job well, not because the law or the boss says so or because you are getting paid but because you want it done right. There are the carrot and stick theories for getting things done. Pride requires neither.

I wish each and everyone of the Class of 1984 success. But I caution you that salary is the worst measure of satisfaction. Some take many years to learn this and many never learn it at all. Although you need an income that meets basic needs, no amount of money alone will make you happy. Ironically, those who choose a career to their liking and do their best while placing income secondary end up with the greater financial rewards.

You can do or be whatever you want. School is not the end of your education—it is the beginning. Your diploma is just the key that opens the door to any number of opportunities. Graduation is a pause in the learning process that continues indefinitely.

It may sound trite but, "tomorrow is the first day of the rest of your life". Set your goals, determine what you will give up to reach them and then go about your work.

Good Luck!

This and That About Pharmacy

by Leon Weiner

When most people think of the "Candy Man", it is usually Sammy Davis, Jr. However, many pharmacists in the Maryland area have their own "Candy Man" in Joseph Greenberg, who works for the Mary Sue Candy Company. Greenberg (1940 University of Maryland School of Pharmacy) is a former Read Drug and Chemical employee.

This summer, Charles H. Tregoe, Chief, Division of Drug Control, will be moving from far north Baltimore County southward to the Baltimore City area. Hopefully, we will be seeing more of Tregoe (1959 University of Maryland School of Pharmacy) during the non-work, fun hours of the day and night.

Morton B. Scherr, the likeable Essex pharmacist, is looking forward to this summer when he will leave his two green trailers and move his pharmacy into a new medical building at Marlyn and Eastern Avenues. His old Marlyn Pharmacy was destroyed to make way for reconstruction of the intersection. Scherr (1953 University of Maryland School of Pharmacy) also had the misfortune last year of being held hostage for many hours by an armed robber.

Melvin Rubin (1955 University of Maryland School of Pharmacy) will be installed as President of the Pharmacy Alumni Association on Thursday May 24, 1984. According to close sources, "Mr. Allround Pharmacist" spends most days working his drug stores and then attends seven to eight pharmacy meetings etc. per week in the evenings. This constant activity keeps him always thinking young.

Reminder: Federal and state regulations require all schedule two-three-four and five prescriptions to have prescriber's name, address, D.E.A. number; patient's name, address in addition to all else necessary for legal prescriptions. The fact that your computer has this information in its system does not excuse it from being absent from the actual prescription. Also, Red C's are required on all schedule three-four and five prescriptions when using the two file system.

At the May, 1984 business meeting of the Alumni Association, the following deceased alumni, who passed away in the last year, will be called out and a minute of silence will be observed in their honor. This list was prepared by Margaret Beatty, Administrative Aide, School of Pharmacy. If you have any additions, please contact the School of Pharmacy.

Alfred R. Carey—1924
S. Charles Cole—1926
Richard M. Dubin—1934
Julius W. Feret—1935
George Gibbons, Jr.—1908
Louis L. Glaser—1939
Daniel Greif—1929
Karl H. Holtgreve—1931
Harry Jacobs—1936
John C. Krantz, Jr.—1919
Theodore Levin—1929
William Lewis—1972
George T. Lyon—1917
Anton C. Marek—1931
Sherman Pritzker—1942
Stephen W. Ruth—1930
Jacob Sapperstein—1929
Alan L. Settler—1955
Harold W. Siegel—1941
Andrew W. Silbert—1928
Sylvan Siverman—1929
Walter J. Skruch—1934
Richard H. Waterman—1925
Mark D. Werner—1983
Jean Chow Wong—1955
Simon Zvares—1927

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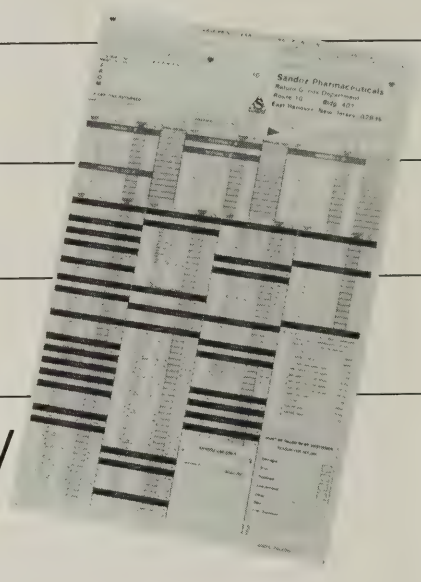

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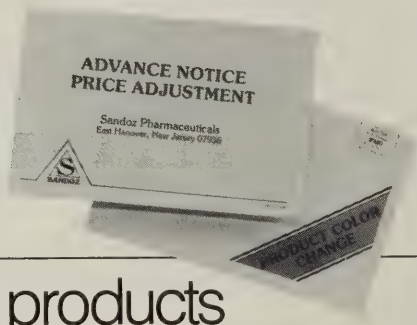

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BMPA President Martin Mintz (right) presents Ben Mulitz (left) with the Honorary President's Award at the BMPA annual Banquet held on March 11th. Nathaniel Futeral (far right) is the President-Elect and served as Toastmaster. Judy Mintz is shown at the far left.

William Hill (right) President of the MPhA, presents Martin Mintz (left) with the NARD Leadership Award. The annual affair was held at Blue Crest North in Baltimore.

Maryland Pharmacists and spouses are shown on the two-week MPhA Sponsored trip in scenic Europe which ran from October 10–25th.

Maryland Pharmacists Wanda Wolfe (left) of Havre De Grace and Ron and Carla Showacre of Pasadena stayed at the Intercontinental Hotel during the 1984 Hawaii Pharmacy Seminar, January 14–28th, co-sponsored the MPhA.

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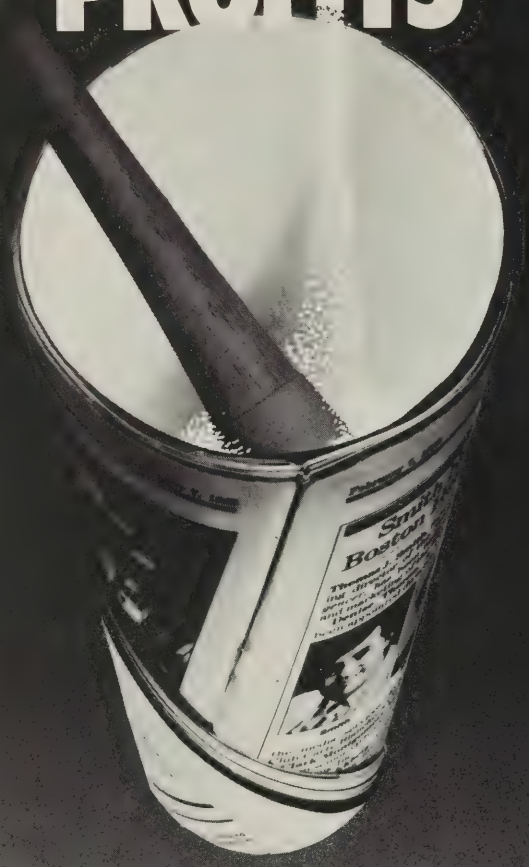

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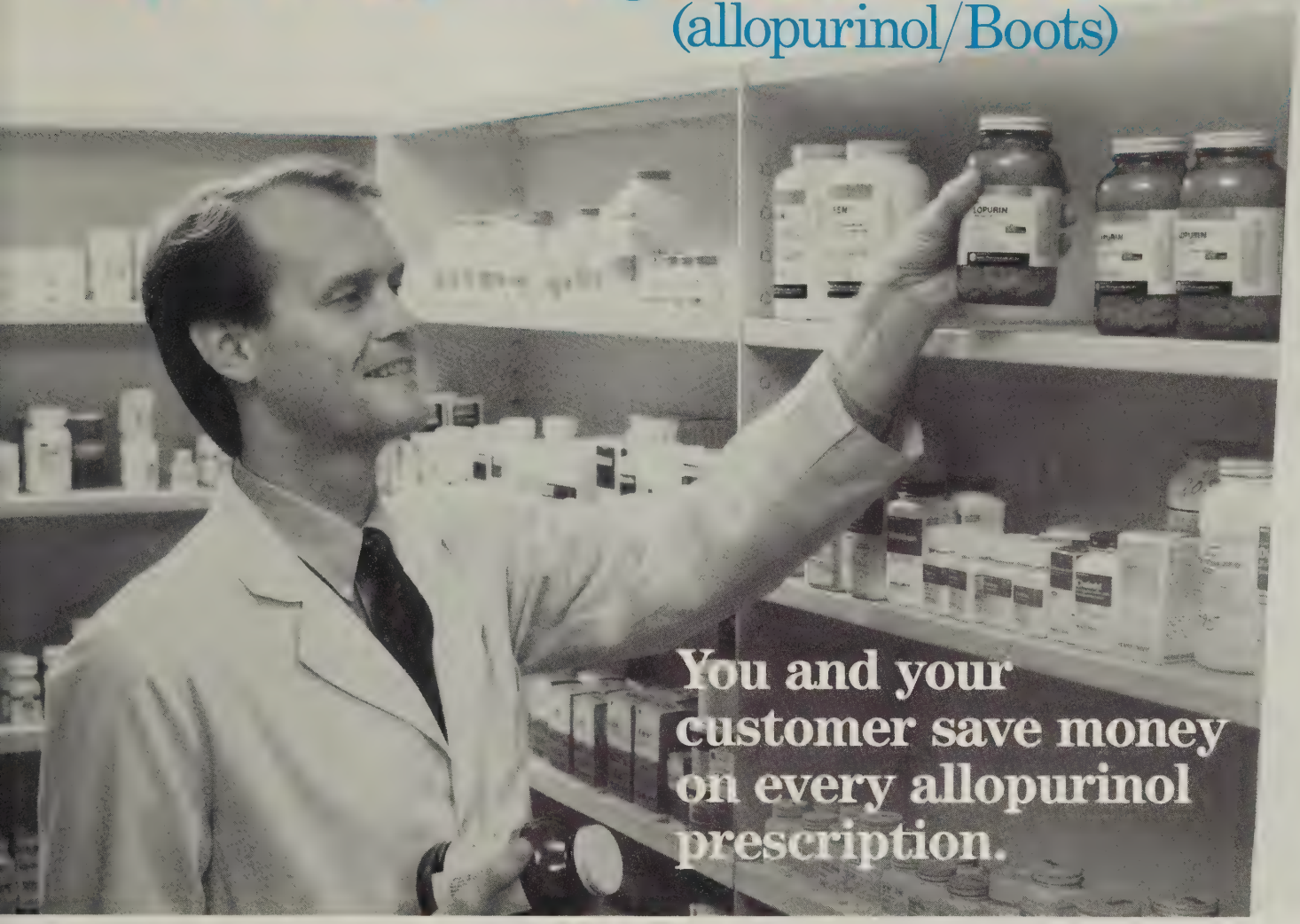

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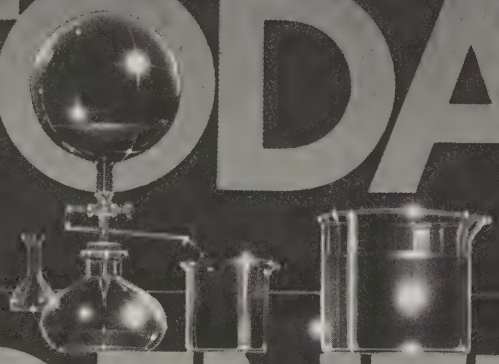

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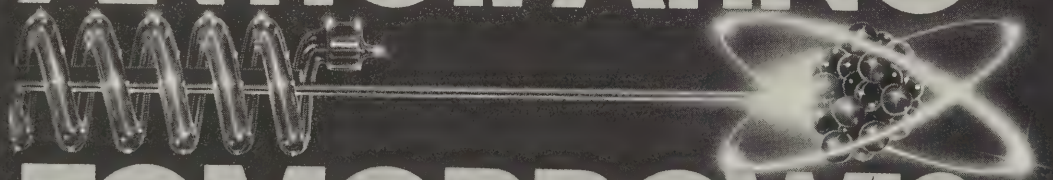

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Sunday June 24	Registration open at 12:00 (rooms available at 3:00 p.m.). Tennis, Golf, Swimming and Ice Skating. Special Gifts.
	9:00 p.m. **Welcoming Cocktail Party** Sponsored by the Drug House—Ice Skating Show
Monday June 25	9:00 a.m. **Opening General Session** House of Delegates, First Session, Officer's Reports. LAMPA Brunch and Fashion Show. Grand Opening of Exhibit Hall featuring over **20 exhibitors**
	6:30 p.m. **Crabfeast and Chicken** at Berlin Fire Hall—Square Dance
Tuesday June 26	9:00 a.m. **Home Health Care—Beyond Durable Medical Equipment.** Special C.E. briefing by Task Force on Home Health Care. LAMPA Board meeting and program.
	8:00 p.m. **Cocktail Party** Sponsored by Loewy Drug Company
Wednesday June 27	9:00 a.m. **Second Business Session** House of Delegates, Resolutions, Installation of Officers, Committee Reports.
	6:00 p.m. **Cocktail Party** Sponsored by Youngs Drug Products
	7:00 p.m. **Annual MPhA Banquet** Awards and Prizes
Thursday	9:30 a.m. Special C.E. program—Simon Solomon Seminar

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ABSTRACTS

Excerpted from PHARMACEUTICAL TRENDS, published by the St. Louis College of Pharmacy; Byron A. Barnes, Ph.D., Editor and Leonard L. Naeger, Ph.D., Associate Editor

DIET AND SLEEP:

Newborn infants were fed various solutions prior to bedtime and their sleep patterns were then monitored. Serotonin is thought to play a role in the production of sleep so its precursor, tryptophan, was administered in glucose solutions as was the amino acid valine. Valine competes with tryptophan for non-specific aminoacid uptake sites in the gastro-intestinal tract as well as for entry into the brain. Information obtained after administration of these solutions was compared to that obtained after Similac was used. Infants fed the tryptophan formula fell asleep more rapidly than did those who received the Similac while infants fed valine solutions took the longest to fall asleep. *N Engl J Med,* Vol. 309, #19, p. 1147, 1983.

AMPHETAMINE OBESITY:

Amphetamine in high doses was injected intraperitoneally into animals for five days and during that period the animals lost weight. However, after that initial period, injections of the drug caused the animals to eat excessively and become obese. Amphetamine injected directly into the lateral hypothalamus caused a supression of feeding but when high doses were used the effect was reversed, apparently due to a local neurotoxic effect of the drug. *J Pharmacol Exp Ther,* Vol. 227, #2, p. 524, 1983.

PSEUDOMEMBRANEOUS COLITIS:

Pseudomembraneous colitis is thought to be caused by Clostridia difficili, an anaerobic organism not susceptible to many of the commonly used antibiotics. Vancomycin has been used successfully to treat this condition, but the therapy is expensive. Since metronidazole (Flagyl) had demonstrated activity against these organisms, it was used to treat this condition and the results obtained were compared to those obtained with vancomycin. Results were similar with both drugs but therapy with metronidazole was significantly less expensive. *Lancet,* Vol. II, #8358, p. 1043, 1983.

AMOXAPINE:

Several newer antidepressants have been used because of a reported reduction in toxicity and a more rapid onset of action. Amoxapine is one of these second generation antidepressants said to possess these characteristics, but recent reports indicate that tolerance may build to its effect after initial favorable pharmacological responses are obtained. Clinicians should be aware of this possibility and watch for tolerance in patients receiving amoxapine (Asendin). *Clin Ther,* Vol. 5, #6, p. 638, 1983.

ACETAMINOPHEN:

Some years ago it was shown that phenacetin metabolism could be enhanced in patients who regularly consumed charcoal broiled steaks. Since phenacetin has been replaced with acetaminophen, and since acetaminophen is a metabolite of phenacetin, it was of some interest to determine if ingestion of charcoal broiled beef would alter the enzyme systems responsible for acetaminophen metabolism. Studies show the dietary intake does not alter the metabolic disposition of acetaminophen. *Clin Pharmacol Ther,* Vol. 34, #3, p. 368, 1983.

ACETAMINOPHEN-CAFFEINE INTERACTION:

A patient consumed 100 tablets of an over-the-counter preparation containing aspirin, caffeine and acetaminophen. Central nervous system stimulation generally seen when caffeine is ingested in this quantity was absent. Since aspirin may enhance the likelihood of stimulation, it was postulated that acetaminophen acted to reduce the likelihood of this effect. No mechanism for the interaction has been postulated. *Clin Toxicol,* Vol. 19, #10, p. 1031, 1983.

THEOPHYLLINE:

During the past several years, there has been a noticeable increase in the use of theophylline in asthmatic patients. Part of this resurgence in interest is due to the development of a radioimmunoassay technique capable of allowing the clinician to closely monitor the plasma concentration of the drug. Theophylline has a narrow therapeutic range and its clearance will vary depending on the patients age as well as infection, vaccinations, drug therapy, liver function, cardiac failure, and cigarette smoking habits. It has been suggested that closer attention be given patients receiving the drug because it may be responsible for considerable hidden mortality. *Lancet,* Vol. II, #8350, p. 610, 1983.

HYPERTENSION:

A digitalis-like substance has been found to occur naturally in the plasma. Hypertensive patients and those normotensive individuals with a family history of hypertension were found to have elevated levels of this substance. In untreated hypertensive patients, the potency of the compound was correlated with urinary sodium output. Digitalis is known to interfere with the sodium-potassium pump mechanism on cell surfaces and thus this discovery may help in diagnosing and understanding the pathology of certain forms of hypertension. *Br Med J,* Vol. 287, #6393, p. 631, 1983.

ALCOHOL WITHDRAWAL:

It has been found that the concentration of gamma aminobutyric acid (GABA) in the spinal cord fluid of alcoholics who do not seize and of normal controls is greater than that found in alcoholics who exhibit seizure activity when experiencing withdrawal. Benzodiazepine derivatives and barbiturates have been used to help reduce symptoms of withdrawal and their activity is apparently due to their ability to increase the binding of GABA to the receptor sites within the central nervous system. The authors have concluded that GABA receptor activation is useful in reducing the incidence of audiogenic seizure activity in withdrawing alcoholics without having much effect on forelimb tremors. *J Pharmacol Exp Ther,* Vol. 226, #3, p. 720, 1983.

CHEMICAL STRUCTURES:

Many drugs which exert effects within the central nervous system have been found to contain an aromatic ring and a strategically placed nitrogen atom. Various classes of centrally active drugs, represented by chlorpromazine, imipramine, amphetamine, LSD, diazepam, phenobarbital, phenytoin and morphine, were found to have definite similarities when their structures were superimposed one on another. It has been postulated that this specific configuration is a requirement for penetration of the blood-brain barrier. These types of observations will be a tremendous help for those studying structure-activity relationships and drug design. *J Pharm Pharmacol,* Vol. 35, #8, p. 516, 1983.

PREMENSTRUAL SYNDROME:

Premenstrual syndrome (PMS) is associated with a large variety of both symptoms and treatments. A recent study conducted in Farmington, Connecticut showed an 80% beneficial response in patients administered spironolactone (Aldactone), an aldosterone antagonist. If the theory that PMS is caused by elevations in the activity of renin-angiotensin-aldosterone system, the choice of spironolactone would be more logical therapy than some of the other agents used to treat this condition. *JAMA,* Vol. 250, #11, p. 1375, 1983.

THEO-24:

A new once-a-day theophylline preparation has been tested and is said to produce bioavailability comparable to the twice daily use of Theo-Dur. Searle will market the new dosage form in capsules containing 100 mg, 200 mg and 300 mg of the phosphodiesterase inhibitor. (Some pharmacokineticists are skeptical and feel nothing can be released evenly over a 24-hour period.) *FDC Rep,* Vol. 45, #35, p. 3, 1983.

VIDEOGAME EPILEPSY:

Some people have convulsive disorders which can be triggered by photic stimulation. Use of videogames in arcades has precipitated such attacks and it has been suggested that patients with this predisposition use only videogames where the light intensity and distance from the screen can be controlled. *JAMA,* Vol. 250, #10, p. 1273, 1983.

FUROSEMIDE:

Furosemide (Lasix) increases renal flow by increasing the synthesis of renal prostaglandins. These substances cause vasodilation which increases the naturetic and diuretic responses associated with this drug. Prostaglandin synthesis inhibitors, e.g., indomethacin (Indocin) may reduce the effectiveness of the diuretic therapy. *J Pharmacol Exp Ther,* Vol. 226, #1, p. 27, 1983.

ZINC:

Wilson's disease is a genetic condition characterized by a deficiency in the plasma protein which carries copper throughout the body. When a deficiency exists, free copper concentrations increase and the ion is deposited in the brain and neuronal tissue. This causes the symptoms associated with Wilson's disease. Penicillamine (Cuprimine) has been the mainstay of therapy for this condition, but some patients cannot tolerate the drug because of its toxicity. Patients with Wilson's disease were given zinc acetate every four hours during the day and were asked not to eat for one hour before or after the ingestion. The zinc acetate regimen produced a neutral or a negative copper balance and thus helped treat a condition which might otherwise be considered fatal. *Ann Intern Med,* Vol. 99, #3, p. 314, 1983.

ASPIRIN METABOLISM:

Aspirin is rapidly hydrolyzed by esterase enzymes to form acetic acid and salicylic acid. There are at least two different types of aspirin esterases and they seem to be distinct from other enzymes. These enzymes are found in various parts of the body including the serum, intestine and liver. *J Pharmacol Exp Ther,* Vol. 226, #2, p. 589, 1983.

PRAZIQUANTEL:

Although helminthic infections are not common in this country, they do cause considerable discomfort and mortality in other areas of the world. Schistosomiasis, flukes, and tapeworms represent infections which may require extensive and toxic drug regimens to control. A new agent named praziquantel has been found to provide excellent therapeutic activity against these infections without causing overt toxicity. The drug is used in a single dose and will be marketed by Miles Labs. *Ann Intern Med,* Vol. 99, #2, p. 195, 1983.

INDOMETHACIN—LITHIUM INTERACTION:

Lithium is a drug which has a low therapeutic index and thus various agents can increase its toxicity. Concomitant administration of indomethacin (Indocin) to patients stabilized on lithium caused development of lithium toxicity. The toxic reactions, which can be fatal, are thought to be due to reduced renal perfusion and subsequent accumulation of the lithium ions. Prostaglandins are apparently required for maintenance of normal renal perfusion and since indomethacin is a potent prostaglandin synthetase inhibitor it can reduce renal perfusion and lead to accumulation of lithium. *Am Fam Physician,* Vol. 28, #2, p. 155, 1983.

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More than a dozen leading pharmacy administration faculty members contributed to the book, which discusses the following: cash flow; business records; advertising; tax considerations; accounts receivable management; inventory; break-even analysis; and nonprescription merchandising and planograms.

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calendar

May 5–10—APhA Convention, Montreal
May 6—CECC Seminar—Pharmacist and Nutrition
May 21–23—NARD Legislative Conference
May 24 (Thurs)—Alumni Association Graduation Banquet
June 7 (Thurs)—CE Seminar—Home Health Care & The Elderly
June 22–24—MSHP Seminar, Ocean City
June 24–28—MPhA CONVENTION, OCEAN CITY
July 29–Aug. 6—AACP Annual Meeting, Baltimore
Aug. 30–Sept. 2—Southeastern Pharmacy Education Gathering
Oct. 12–20—MPhA Trip to Paris
Nov. 11 (Sun)—Alumni Association Dinner

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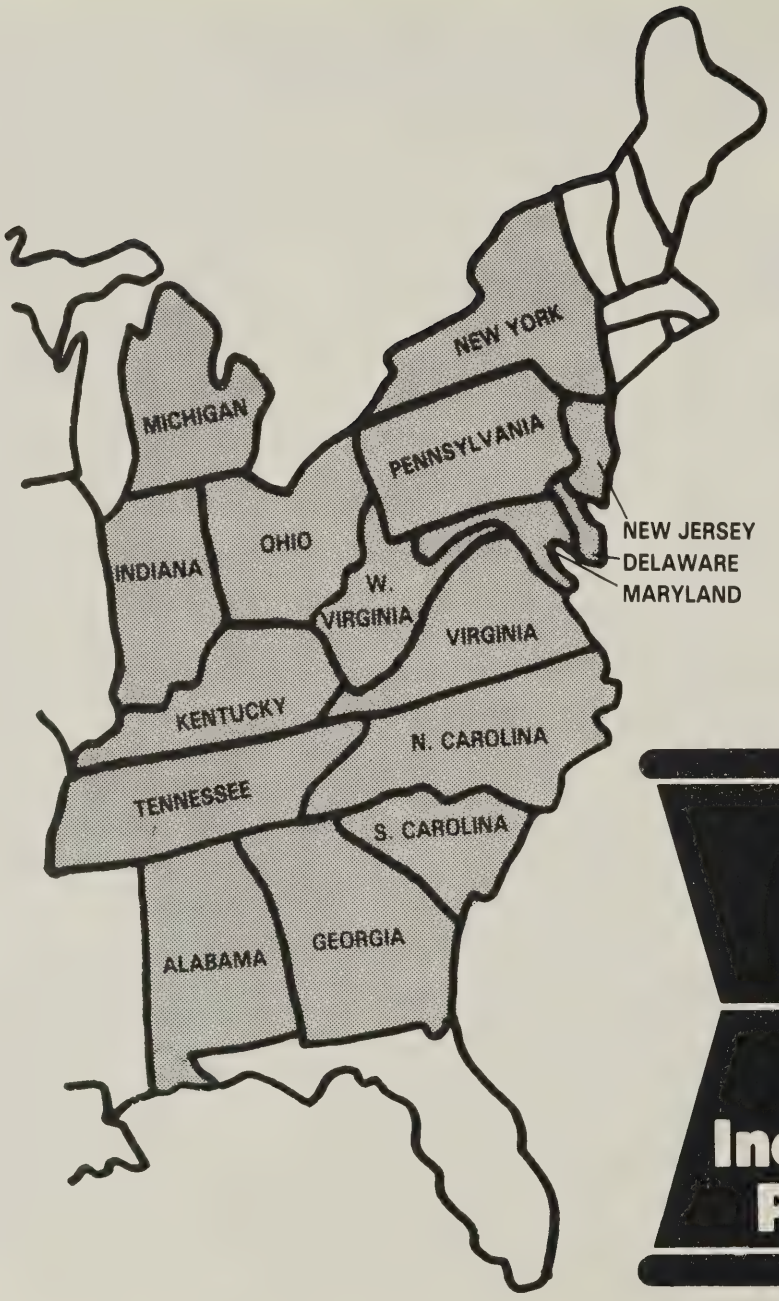

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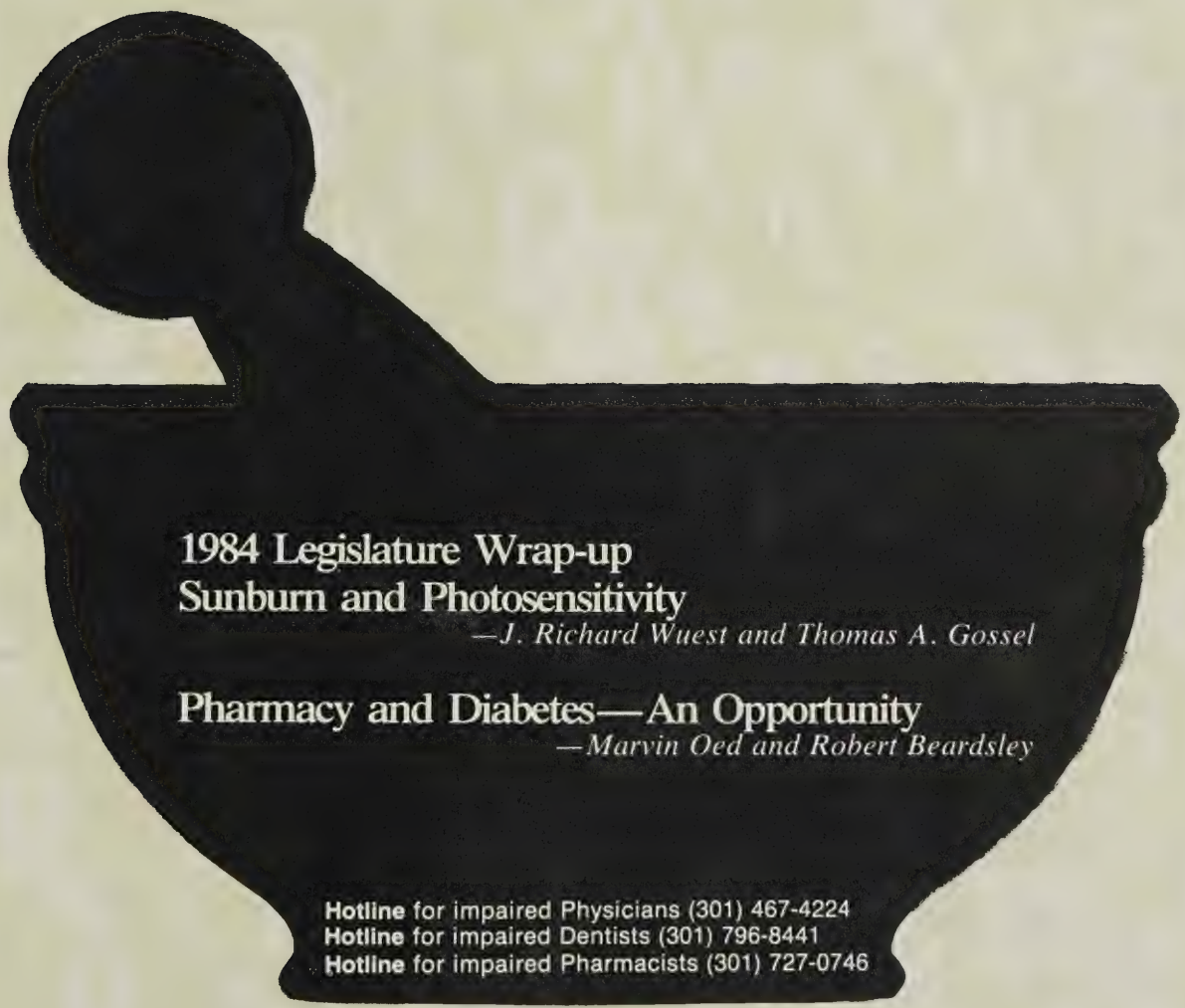

1984 Legislature Wrap-up

Sunburn and Photosensitivity

—J. Richard Wuest and Thomas A. Gossel

Pharmacy and Diabetes—An Opportunity

—Marvin Oed and Robert Beardsley

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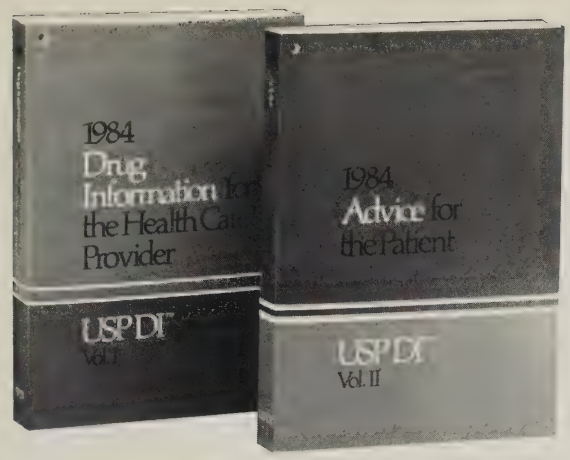

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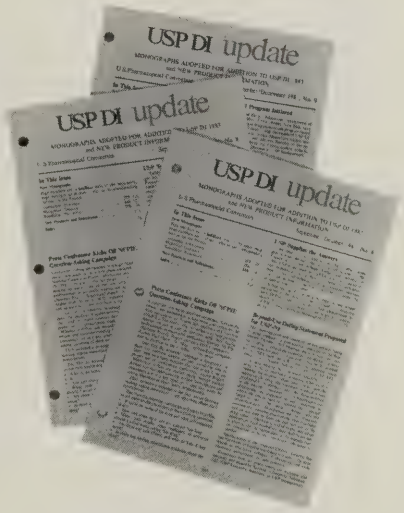

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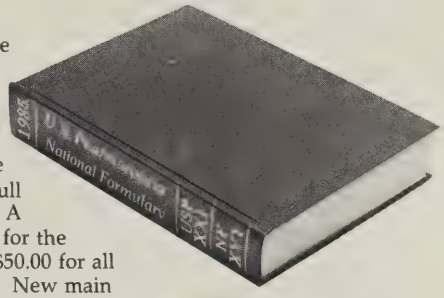

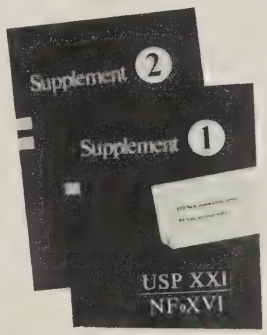

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1984 Legislature Wrap-up

The work of the Maryland Pharmaceutical Association in the area of government relations is perhaps the most vital function of the Association on behalf of all pharmacists; whether they are members or not. It is true, unfortunately, that even non-members of the Association benefit whenever the Association is successful in its lobbying efforts to the extent that the practice of pharmacy is enhanced for all pharmacists. The Association in effect represents all pharmacists when testimony is presented before legislative committees, when interviews are conducted with the news media, and when position papers are provided to important government agencies.

The Association works in cooperation with a number of other lobbying groups such as the Medical Society, the Dental Association, the Nurses Association and several other allied health care professions. The MPhA also works with manufacturing interests, the Association of Chain Drug Stores, insurance companies, proprietary and business interests and others. As the Association begins to formulate a position on specific legislative issues, it coordinates its views and testimony with several other groups within the profession of pharmacy such as the Board of Pharmacy, the School of Pharmacy, the Maryland Society of Hospital Pharmacists, the Maryland Chapter of the American Society of Consulting Pharmacists, the Pharmacy Guild and others to ensure that the voice of Pharmacy can be presented in as unified fashion as possible.

The responsibility for legislative activity is conducted by the Legislative Committee, under the Chair of George Voxakis. Working with the Executive Director, David Banta, who is also the Association's registered lobbyist, the Committee gets its general policy direction from appropriate resolutions from the House of Delegates. Early each Fall, the Committee suggests a legislative platform of positions on issues and proposed bills which is then subsequently ratified by the Board of Trustees. The Committee monitors the legislative process while the General Assembly is in session and makes decisions regarding revised policy as the need develops and situations change. Banta monitors the activity of the legislature on a daily basis during the session. He develops, coordinates and presents testimony on the bills that are heard before legislative committees, including the presentation of position papers when necessary. Occasionally, pharmacists, usually from the Legislative Committee, are called upon to provide expert testimony on certain bills of a technical nature. Certain larger issues will call for a major showing of pharmacy support or opposition in the form of multiple witnesses or an organized telephone and letter campaign. These activities are coordinated by the Legislative Committee.

The results of the work of the Legislative Committee is reported back to the membership in the Newsletter during the session and as a Committee report at the Annual Convention. Over the past several years, the Association has been very successful in full-filling its legislative goals while utilizing a maximum efficiency in expenditure of Association resources. This past year was very productive for the Committee. Of course the Governor must sign into law each of the bills which passed the legislative process and they will not take effect until July 1, 1984 in most cases. Below is a summary of the major bills which were worked on and followed by the Association this year.

Bills that Passed which MPhA Supported

The Budget Bill A $.20 increase in the Medicaid Dispensing fee was included in the Budget bill. This would increase it to $3.45 per prescription. The Association worked to keep the increase intact even though the Medicaid program had projected a $35 Million deficit. The Committee considered this to be especially significant since so many other third parties rely upon the Medicaid figure to calculate their own dispensing fees.

HB 128 This bill changes the state Controlled Substances licenses from an annual renewal to renewal every other year. The Association supported this bill because it reduces paperwork for pharmacists.

HB 231 The Association supported this Board of Pharmacy proposed bill which allows the Board to charge new pharmacist applicants the cost of the Board examination.

HB 455 This Bill placed all exempt narcotic, Schedule five drugs on prescription status state-wide. Previously, these drugs were on prescription status in Baltimore County and Baltimore City only.

HB 604 This bill was strongly supported by the Association and repeals the requirement that pharmacists maintain a "Poison Register." It was a long-standing objective of the Committee.

HB 606 Certain old sections of the Pharmacy Practices Act dealing with Barbiturates had been duplicated when the state controlled substances act was passed several years ago. This bill repealed those obsolete sections in the Practices Act.

SB 317 This Bill allows the Board of Pharmacy to name one of its Staff members as an Executive Director. By placing this provision in State Law, the Association helped to protect the Board of Pharmacy's budget from cut-backs and elevated the status of the chief executive officer of the Board.

SB 231 A coalition of health care professions succeeded in passing this bill which places the following language in the Insurance Code:

"Notwithstanding any provisions of a group or individual policy or contract issued by a nonprofit health service plan, or any certificate issued thereunder, of health, sickness, accident or disability insurance, delivered or issued for delivery within the State, whenever such policy, contract or certificate provides for reimbursement for any service which is within the lawful scope of practice of a duly licensed health care provider, the insured, or any other person covered by the policy, contract or certificate, shall be entitled to reimbursement for such service. The provisions of this section apply to all such policies, contracts, or certificates issued, renewed, modified, altered, or reissued on or after July 1, 1984."

The Legislative Committee believes this bill is significant for expanding roles in pharmacy practice.

SB 672 This bill generally increases the surplus reserves which a Health Maintenance Organization (HMO) is required by the Insurance Commissioner to maintain.

SB 782 Perhaps the most important professional issue which the Committee worked on this year, this bill was known as the Emergency Prescription refill bill. It would allow the Pharmacist to dispense emergency medications when the prescriber is unavailable under certain conditions. This bill specifically legalizes the exercise of the Pharmacists professional judgment for the benefit of the patient. The bill reads in part:

"A Pharmacist may refill a prescription for a drug for which the refill has not been authorized if the Pharmacist attempts to obtain an authorization from the authorized prescriber and is not able readily to obtain the authorization. The refill of the prescription is not for a controlled dangerous substance, the drug is essential to the continuation of therapy in chronic conditions or maintenance of life and in the pharmacist's professional judgment, the interruption of the therapy reasonably might produce an undesirable health consequence, be detrimental to the patient's welfare, or cause physical or mental discomfort. The Pharmacist shall enter on the back of the prescription or on another appropriate uniformly maintained, readily retrievable record, such as medication records, the date and the quantity of the drug dispensed; and signs or initials the record and the pharmacist notifies the authorized prescriber of the refill of the prescription within 72 hours of dispensing the drug. If a Pharmacist refills a prescription under this section, the pharmacist may provide only one refill of the prescription and the refill quantity dispensed shall be in conformity with the prescribers directions for use and shall not exceed a 72 hour period of time."

The Committee was very pleased that there was no opposition to this legislation and the Medical Society supported the bill.

Bills defeated which MPhA supported

While it was an excellent year for the Association's lobbying effort, not every bill supported by the Committee passed.

HB 232 This bill would have reduced the number of years pharmacists are required to retain prescription files from five years to two years. It was defeated when a member of the House of Delegates pointed out that the statute of limitations on Medical malpractice claims is five years.

HB 280 This bill was the work of a coalition of health care providers; primarily the Dental, Psychology and Pharmacy Associations. Its purpose was to require third parties to report certain information to the office of the

Insurance Commissioner and generally extend his authority over them. This has been a long-standing goal of the Association. The bill was opposed by labor organizations and was finally lost on the final reading in the second house only hours before the end of the session on its final night. The Committee anticipates that this will be a high priority for the 1985 session.

Bills opposed by MPhA that were defeated

SB 349 This bill was supported by a large drug chain and would have allowed any employer that deals with controlled dangerous substances to use the results of a lie detector test as the basis for denying or terminating employment. The Association opposed the bill and it was killed in committee.

HB 756 This bill would have required that the pharmacist give elaborate notification to the patient before performing drug product selection. This would have included notification of the price differential and the right of the patient to refuse. While the bill was withdrawn by the sponsor before the hearing, it was apparently introduced because some pharmacists have not been complying with existing law which requires that the patient be notified in writing that a generic has been dispensed. The Board of Pharmacy is urging pharmacists to use an appropriate auxiliary label to accomplish this.

HB 1200 This bill would have restricted the sale of durable medical equipment to prescription only. It would have placed licensed physical therapists under the definition of "authorized prescriber" in the pharmacy practices act. The bill was subject to a number of different interpretations. It was withdrawn by the sponsor before the hearing.

Wrap up

Lobbying is probably the single most important function which the Association performs for its members. Events in Annapolis change daily when the legislature is in session and the results can be dramatic. Often successful passage of favorable legislation can take years of sustained effort. Constant vigilance is required to protect the interest of pharmacists.

Fortunately, the Association has a built-in, community based network of pharmacists who volunteer to contact state legislators when the need arises.

If you are interested in learning more about the Association's Legislative Committee and the process through which legislation is influenced; or if you wish to volunteer to serve on the Committee, contact the Association office.

Business Use of Your Car Gives Several Business Benefits

by Jo An Zito, CPA

The business use of your car allows you to deduct the ordinary costs of operating your vehicle and depreciation against your income.

You are entitled to deduct the business portion of your actual expenses for insurance, gas, repairs, maintenance and depreciation. Under the new system of cost recovery, an automobile is depreciated over three years using an accelerated method incorporated in the law, or straightline if you so elect. The first year's depreciation is 25% of cost, regardless of when during the year the auto was acquired. In the second year, the depreciation is 38% of cost. In the third year, the depreciation is 37% of cost.

In lieu of using the actual cost method, you can elect to use the optional flat deduction which is 20.5¢ a mile for the first 15,000 business miles per year and 11¢ for business miles in excess of 15,000.

Under either method, you are entitled to take a 6% investment credit on the cost of your automobile used in your business. The credit is allowed in the year of purchase no matter when the car was purchased during the year. The investment credit is a direct reduction of your taxes and is available providing that the automobile has a useful life of at least three years. The investment credit for an automobile is 6% of the cost. The cost of the automobile must be reduced by 50% of the investment credit for purpose of depreciation. Thus if the automobile cost $10,000 and it is used 60% of the time for business, the investment credit will be $360. The cost of the automobile for depreciation will be $6,000 less $180, or $5,820. Alternatively, you can elect to reduce the credit by two percentage points, from 6% to 4%, in lieu of the basic reduction.

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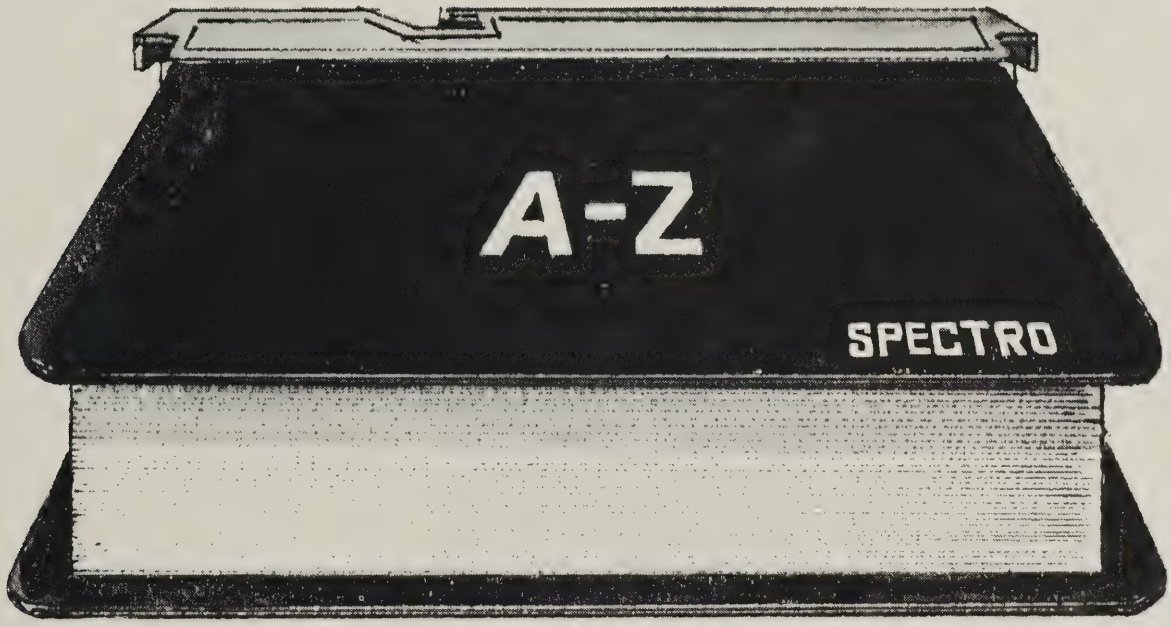

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STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION • VOL. I, NO. 6

By J. Richard Wuest,
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Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, OH

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Ohio Northern University
Ada, OH

Goals

The goals of this lesson are to:

1. discuss the etiology and treatment of sunburn and photosensitivity reactions;
2. discuss the pharmacology and therapeutics of drugs used to treat sunburn and photosensitivity reactions.

Objectives

At the completion of this lesson, the successful participant will be able to:

1. demonstrate an understanding of how sunburn affects the skin;
2. choose the appropriate agents for treating minor burns and sunburn;
3. decide when the consumer should be referred to a specialist.

in the service of pharmacy

This continuing education for Pharmacy article is provided through a grant from MERRELL DOW PHARMACEUTICALS INC.

One part of the body that is often taken for granted and not thought of in the same terms as the heart, liver, kidney, and other vital organs is the skin. The skin is the largest organ of the human body comprising one-sixth of the body's weight. At any given time, the blood vessels transversing through the skin contain one third of the body's blood. The skin serves many important functions for the body including acting as a barrier to invasion of microorganisms, and controlling fluid and electrolyte loss through perspiration. It also assists in regulating body temperature; it is an important sensory organ that responds to touch, pressure, temperature change, and pain; and it helps hold us together in our shape. Few other injuries to the skin destroy its ability to function as do burns.

Introduction to Burns

In excess of two million serious burns occur in this country each year. Approximately one hundred thousand of these burns require hospitalization and about ten thousand people die of burn injury in a given year. While burns result from many causes (i.e., contact of the skin with heat, electricity, infrared and ultraviolet light rays, ionizing radiation, and chemical agents), most mild burns are caused by overexposure to the ultraviolet rays of the sun. Most severe burns are caused by heat from flames, hot liquids, or direct contact with hot objects.

The direct outcome of a burn injury is coagulation of protein within the cells resulting in tissue necrosis. This destroys the skin's ability to serve its many purposes.

Traditionally, burns have been categorized as first, second, or third degree with the differentiation based mainly on the size of the area affected and the depth of the wound. It should be pointed out that many thermal burn wounds have more than one classification.

First degree burns are treatable on an ambulatory basis. As stated above, the most common cause of first degree burns is overexposure to the sun's ultraviolet rays. There is generally only superficial epithelial cell damage exhibited by localized areas of redness which blanch to white on pressure, due mainly to the body's normal inflammatory response to injury. Scarring does not occur in first degree burns and they generally heal themselves within three to four days.

Second degree burns can be caused by excessive sun exposure, contact with excessively hot objects for a short period of time, short blasts of intense heat, and boiling water. Second degree burns destroy the entire epidermal layer and may destroy the upper level of the dermis. They are characterized as weeping, blistering, beefy red wounds. The pain receptors and nerve fibers are generally intact and there is pain on touching second degree burns. If the skinned appendages such as hair shafts, sweat and sebaceous glands remain intact and infection is prevented, regeneration and spontaneous healing is possible. With proper care of second degree burns, the healing process usually takes about a month.

Third degree burns result from prolonged exposure to intense heat, flames, electricity, chemicals, or emersion in scalding liquids. The entire epidermis and dermis are destroyed as are all skinned appendages with varying amounts of subcutaneous fat and muscle. Since the sensory nerves are destroyed, third

TABLE 1
Classification of Burns

	First	Second	Third
Depth of skin injured	Partial; superficial cells of epidermis	Partial; upper level of dermis	Entire depth
Cause	Sun, mild steam, scald, hot water	Excessive sun, boiling water, short blast of intense heat, contact with very hot objects for short period	Prolonged exposure to intense heat, immersion in scalding liquids, chemicals, direct contact with flame, electricity
Pathology	Vasodilation and hyperemia, no loss of dermal continuity	Coagulation of skin protein and necrosis of epidermis, may involve upper dermis, intact skin appendages	Coagulation of skin protein and necrosis of epidermis and dermis, including skin appendages
Appearance	Warm, tingling redness which blanches on pressure	Painful, weeping, blistering. Responds to touch. Skin appendages intact	Brown-to-black or white surface, exposed deep tissues. No response to touch. Skin appendages destroyed
Outcome	Heals in 3 days	Usually heals in 1 month, without scarring, may scar	Total & irreversible damage, skin graft required

Adapted from *Health Practitioner*, 5/77

degree burns cause no pain and do not respond to touch. Because the skinned appendages have been destroyed, regeneration of epithelium and spontaneous wound healing is rare; skin grafting is often necessary to completely heal the wound.

Although it is a matter of opinion, it is generally considered that first degree burns are self-treatable. Second degree burns of less than fifteen percent of the body or third degree burns of less than two percent of the body (depending on the area involved) can be treated on an ambulatory basis with medical supervision. Second degree burns of greater than fifteen percent or third degree burns of greater than two percent require hospitalization and rigorous treatment. The classification and pathology of burns are listed in Table 1.

Therapy For Mild First Degree Burns

The immediate goal of treating first degree burns is to control pain and prevent infection if the skin is broken. Whether or not the skin is broken, pain can be controlled by application of cold as soon as possible. This can be done either by soaking the affected area in cold water, applying wet towels soaked in ice water, or applying ice itself. The application of cold is effective because burned skin retains enough heat to extend the coagulation of protein to surrounding tissues. Cold is a local anesthetic in that it "deadens" pain receptors and, through its vasoconstrictor activity, reduces local edema and the reactive hyperemia that the body's inflammatory response will produce. The individual should keep the cold applications on the area until it is free of pain, both with or without such applications. This may take from a few minutes to an hour.

After the emergency situation has been alleviated, the wound should be kept clean. For mild burns, it is generally agreed that neither dressings nor medications are necessary. However, for the patient's psychological state, an emollient type cream may be soothing. Whenever there is doubt about the severity or extent of a burn, the patient should be referred to an emergency care facility. It is generally agreed that if there is any chance that the wound will require physician treatment, greasy ointments should not be applied because they will make it more difficult for the physician to remove the applied substance and treat the wound.

As stated earlier, minor burns usually repair themselves with or without treatment. If the epidermal area has been damaged and the underlying tissue is exposed, the wound can be covered with a nonadherent burn dressing. This should be changed approximately every forty-eight hours. It is important that a nonadherent type dressing be used and that the individual does not pull off the regenerating skin when removing it. If the bandage sticks to the wound, the dressing should be soaked in warm water or saline solution and removed slowly. This is necessary because skin regenerates itself from the inside out, and from one edge of the wound to the other. Lack of care in removing any kind of wound dressing can result in pulling off the granulation tissue that is responsible for healing.

Burn Therapy

The two major types of therapeutic agents used in treating a wound are the antimicrobial agents and the local anesthetics. Since burn injuries that break the skin remove the body's barrier to microorganisms, infection can be a problem. Immediately after a thermal injury, the wound will be sterile because the organisms have been killed in the process. However, within hours, microorganisms can contaminate the wound surface and invade the hair follicles and sweat glands. The microorganisms rapidly proliferate due to the excellent nutrition provided by the necrotic burned tissue and serum. Staphylococci are always present in the environment both on the skin of the burned individual and on whoever is trying to treat it. Thus, staphylococcus is the most common organism found in the first several days following a burn injury. Other bacteria found in burn wounds are the beta-hemolytic streptococci, *Proteus vulgaris*, *Clostridium tetani*, *E. coli*, and klebsiella. The most dangerous invasive

organism is another gram-negative bacterium, pseudomonas. It can enter the wound within hours to days after the injury occurs, and can lead to systemic complications.

Topical antimicrobial agents were discussed in detail in an earlier article. To quickly review, non-antibiotic antimicrobials are generally considered to be ineffective for actually **treating** a skin infection. The quaternary ammonium compounds such as benzalkonium chloride and hexylresorcinol have shown some evidence of effectiveness as skin wound cleansers that assist in removing foreign material from superficial wounds. The mercurial derivatives such as merbromin (Mercurochrome®) and thimerosal (Merthiolate®) have not been proven effective on open skin wounds. The old standby, tincture of iodine, is considered to be too irritating on broken skin and can actually delay wound healing.

The tetracycline derivatives, bacitracin, polymyxin, and neomycin are all considered to be safe and effective antibiotics for OTC topical use. Since both gram-positive and gram-negative organisms can be involved in a burn wound, it is recommended that a combination of polymyxin-bacitracin, or polymyxin-bacitracin-neomycin be used. These combinations will provide a wider spectrum of activity.

There is also some controversy as to whether water soluble creams or occlusive ointments should be used in treating burn wounds. Most authorities prefer the occlusive ointments, after whatever other necessary treatment is complete. The petrolatum-based products can provide their own protective barrier against invasion of additional organisms, and may actually help the movement of granulation cells in their regeneration and healing functions.

Local anesthetics are considered to be safe and effective for treatment of pain associated with burn wounds on both unbroken and broken skin. Their effectiveness depends on the physical form of the local anesthetic and the condition of the skin itself. After penetrating the outer epidermal layer, they interrupt the conduction of nerve impulses through that area of the skin. The mechanism is thought to be due to their preventing the entrance of sodium ions into the nerve axons thus interfering with the transmission of impulses. Toxicity from the local anesthetics may be a problem. The FDA panel found this is rare from topical use for minor burns because the short term use limits the probability of systemic build-up of these agents.

There is a lack of evidence that any one agent listed in Table 2 is safer or more effective than any other. There is no doubt that local anesthetics are effective in relieving pain on broken skin and mucous membranes. Therefore, the lower strength products are preferred for that type of injury. There is less evidence that the local anesthetics are effective on burns of unbroken skin. The panel, therefore, suggested that the higher strength commercially available products be recommended for those types of burns. Table 2 lists the local anesthetics the FDA panel reviewed and ruled to be safe and effective for OTC use, along with their recommended strengths.

TABLE 2
Representative Commercially Available Safe and Effective OTC Topical Local Anesthetics

Agent	Recommended Strength	Examples
Benzocaine	5 to 20%	Americaine Dermoplast Foille Rhulicaine Solarcaine Unguentine
Butamben	1 to 10%	Butesin
Dibucaine	0.25% to 2%	Nupercainal
Dimethisoquin	0.5%	Quotane
Lidocaine	1 to 5%	Unguentine Plus Xylocaine
Pramoxine	1%	Tronothane
Tetracaine	0.5% to 1%	Pontocaine

Since one of the primary goals of burn therapy is to control pain, aspirin or acetaminophen may be used. While the peripheral pain response to the burn can be successfully treated with local anesthetics, aspirin or acetaminophen can effectively relieve the systemic or central pain response.

Sunburn

Even though a large percentage of the Caucasian American public believes that a dark tan is both healthy and beautiful, it is generally held that overexposure to sunlight damages the skin and can lead to skin lesions. In fact, there is evidence that cumulative sunburn can eventually lead to skin cancer.

The majority of sunburns are of the mild, first degree variety. The cause is the ultraviolet radiation emitted by the sun. The basic measurement of sunlight is the nanometer (nm) which is equal to 10^{-9} meter. Sunlight radiation includes wavelengths from 200 to 1850 nm, but only the lower levels (ultraviolet light) burn or tan the skin. Basically, ultraviolet light is in the range of 200 to 400 nm and represents the wavelengths which are not visible up to the violet end of the color spectrum.

Ultraviolet Light

Ultraviolet light is further subdivided into UV-A, UV-B and UV-C. **UV-A** consists of the wavelengths between 320 and 400 nm. It is also called black light. It penetrates the epidermis to the greatest extent and tans more than it burns. However, it is more likely to cause burning if the individual has applied or taken a photosensitivity-producing drug or chemical.

The wavelengths of 290 to 320 nm are called **UV-B**. They are also called the sunburn radiation because, even though they both tan and burn, they are the worst for causing sunburn. Most of the UV-B emitted from the sun is filtered out by the atmosphere with only approximately 0.2% of the sun's rays reaching the skin's surface. However, 95% of that can be absorbed by the skin.

Ultraviolet C makes up the wavelengths of 200 to 290 nm. This is also called germicidal radiation because it can kill bacteria. Nearly all of the ultraviolet C emitted by the sun is filtered out by the ozone layer of the atmosphere and the skin's dead cell layer of the stratum corneum. UV-C is the type that is produced by artificial lighting used in food processing, drug manufacturing, and similar in-

dustries to maintain a "sterile" atmosphere. UV-C does not tan, but it can burn.

How Does Sunburn Occur?

When ultraviolet light penetrates the skin, it bleaches and oxidizes melanin (skin pigment). This leads to an immediate erythema (redness) within twenty minutes, which can barely be seen and rapidly disappears. True sunburn erythema begins two to eight hours later. The more melanin contained in the skin, the less sunburn erythema that occurs. Skin tanning occurs because the melanin producing cells (melanocytes) in the germinating layer produce more melanin, and the UV light oxidizes the melanin already present. Therefore, tanning is a normal reaction by the skin to protect itself against further damage. The ability to obtain a "good" tan and the "deepness" of tan are controlled, to the greatest degree, by the amount of melanin the person produces. This is determined genetically, not by a commercial "tanning" agent.

If the individual is overexposed and has insufficient melanin-producing capability, extreme redness, blistering, and pain can occur. It is estimated that the delayed erythema appears in 2 to 8 hours after exposure, peaks in 14 to 20 hours, and lasts for 24 to 72 hours.

Sunburn-sensitive individuals should avoid excessive exposure to the sun from 10 A.M. to 12 noon when its burning potential is greatest. Also the danger of sunburn increases the closer one is to the equator. Therefore, individuals living in the sunbelt area of the United States are more susceptible to severe sunburn than those living in the north.

Most sunburn is caused by UV-B, but it can also result from excessive UV-C generated from sunlamps or by UV-A in the presence of a photosensitizing agent. Another interesting point is that UV-B is not screened out by a thin cloud layer, but is partially absorbed by smoke and smog. It is totally blocked out by glass. Infrared light causes the warmth and heat from the sun, so UV-B can cause sunburn in the winter just as it can in the summer.

Treatment of Sunburn

Treatment of mild sunburn is more a matter of opinion than fact. Since the burn is self-healing, therapy should certainly be less noxious than the condition. Most experts agree that applying cool water or Burow's solution for 15 to 20 minutes three to six times a day is considered good therapy. There is a growing feeling that administration of prostaglandin inhibitors such as aspirin may be beneficial. There is evidence that prostaglandins are involved in the immediate redness that leads to the delayed erythema. Prostaglandin inhibitors may prevent this early redness and thus lessen the overall severity of the burn. One study showed that indomethacin (Indocin®) solution, applied to the skin, lightened the color of the redness and lessened the overall severity of the burn. Since steroid application did not protect the skin, prostaglandin inhibition is felt to be the responsible mechanism. Many individuals subscribe to the use of two to three aspirin tablets orally before being exposed to sunlight and every 6 hours afterwards.

The use of an emollient cream or lotion following exposure to soothe and relieve the dryness of the sunburn may be helpful. A local anesthetic will be effective in any form, but sprays might be better since they are cooling due to both the propellant and the evaporation of the solution. On the other hand, the emollient vehicle in creams, lotions and ointments may also be beneficial.

For severe sunburn, physician treatment is necessary. It is far easier to abort severe inflammation than it is to treat a reaction after it occurs. One form of therapy is corticosteroid dose packs or 40 to 60 mg of prednisone daily for three days. Both of these are often effective in aborting the complications of severe sunburn. The other treatments of extensive sunburn are the same as those mentioned for the mild forms. However, more potent analgesics may be needed.

The Dangers of Excessive Sunburn

The scientific community believes that there are two major dangers resulting from excessive, prolonged exposure to ultraviolet light. The first is a premature aging of the skin in susceptible individuals. This is caused by the dissolution of the skin's elastic fibers by ultraviolet light and it is a totally different type of tissue aging than that resulting from growing old. Persons susceptible to this type of skin damage will suffer from excessive drying, thinning, and wrinkling of the skin.

The second and more morbid problem is skin cancer, again in susceptible individuals. The FDA estimates that approximately one out of every two hundred and fifty Americans (1 million per year) will contract cancer. More than half of these patients will suffer from skin cancer associated with excessive exposure to ultraviolet light. Actually, recreational sunbathing contributes very little to this incidence. The major cause is occupational. Farmers, construction workers, sailors, and other individuals who are constantly exposed to sunlight have a far greater incidence of skin cancer than others. Those living or working in southern latitudes of the United States have a greater risk for skin cancer than those living in the north.

Another contributory factor for skin cancer is age. It is rare for a person under 45 to contract skin cancer with the highest percentage of those affected being 65 and older.

Males are more susceptible to skin cancer than females, but this is considered to be due to their occupational roles rather than any innate difference between the two sexes.

Race and ancestry is another significant factor determining whether or not one is susceptible to skin cancer. It rarely occurs in Blacks. Those naturally darker skinned Caucasians who have more melanin (i.e., those of Mediterranean, Middle East descent) are rarely affected. Those of Scandinavian, Northern European, and Celtic ancestry with lighter skin, blue-green eyes, and blond hair are most highly susceptible to the condition.

Like all cancers, those which affect the skin are marked by uncontrolled cell growth that can spread (metasta-

size) to other body tissues or organs . Fortunately, only a small percentage of skin cancer metastasize (i.e., malignant melanoma). But when this does occur, it is invariably fatal.

Skin cancers can be treated by removing the lesion surgically, by freezing the tissue, or treating it with x-rays. There are several active chemotherapeutic agents (e.g., fluorouracil) that can be applied directly to the tumor. Most often a combination of methods is used. Fortunately, the skin is constantly replacing itself. If the individual with nonmetastasizing skin cancer avoids excessive exposure to sunlight, after several months, or possibly longer, the diseased tissue will slough off and healthy epidermal cells will replace it.

Sunscreen Agents

The scientific community feels that the liberal use of sunscreens will reduce the severity of burns and protect susceptible individuals from premature aging and/or skin cancer. Sunscreens are chemicals that either physically or chemically block the entrance of UV-A and UV-B into the dermis. There are also some physical barrier sunscreens such as titanium dioxide and zinc oxide. Those that reflect or scatter UV light between wavelengths of 290 and 777 nm are officially called sunscreens. While the manufacturers control the formulation of sunscreens, knowledge of the active ingredients and their concentrations is helpful in differentiating products.

The most widely used chemical sunscreens are aminobenzoic acid (PABA) and its esters, the benzophenones, cinnamates, salicylates, and anthranilates. They are listed in Table 3.

Two factors to keep in mind when recommending sunscreens are the SPF (sun protection factor) and substantivity. SPF is the ratio of the amount of energy required to produce minimum sunburn through the product after application versus the amount needed to produce the same level of sunburn with no treatment. It is presented by the numbers that the manufacturers place on their products. For example, a sunscreen labeled with an SPF value of 2 indicates that most people can stay in the sun twice as long after applying that product before they will receive the same level of sunburn as if they had applied no product. Those with an SPF value of 2 to 4 are referred to as having minimal sun protection, 4 to 6 are moderate, 6 to 8 are extra, and those with an SPF value of 8 to 15 provide maximal sun protection. Those with an SPF value of greater than 15 provide ultra sun protection. This means that individuals applying these products can stay in the sun at least 15 times longer and be protected from sunburn than if they had applied no product at all. Table 4 lists recommended sunscreens depending on the patient's skin type and need. Once the commercially available product with the appropriate sun protective factor is selected, one can be reasonably assured that each manufacturer's product will be equally effective. The basic differences between the various agents include cosmetic scent, the vehicle used, and marketing techniques. There is some evidence that the vehicle will be the controlling factor in the product's substantivity.

TABLE 3
Safe and Effective Sunscreen Agents

*Aminobenzoic acid
Cinoxate
Diethanolamine p-methoxycinnamate
Digalloyl trioleate
Dioxybenzone
*Ethyl 4-bis (hydroxypropyl) aminobenzoate
2-Ethylhexyl 2-cyano-3, 3-diphenylacrylate
Ethylhexyl p-methoxycinnamate
2-Ethylhexyl salicylate
*Glyceryl aminobenzoate
Homosalate
Lawsone with dihydroxyacetone
*Methyl anthranilate
Oxybenzone
*Padimate A
*Padimate O
2-Phenylbenzimidazole-5-sulfonic acid
**Red petrolatum
Sulisobenzone
**Titanium dioxide
Triethanolamine salicylate

*PABA and its derivatives
**These and zinc oxide totally block out all UV light

Substantivity reflects the ability of the product to remain effective under the stress of prolonged exercise, sweating and swimming. It appears to be a function of both the sunscreen agent and the vehicle. Earlier studies showed that PABA in alcohol was the most substantive of all products, but more recent studies suggest PABA esters may be more substantive than the parent PABA and that cream-based vehicles may be more resistant to removal than those with an alcohol base. Combination products are likely to be more substantive than single ingredient products. Regardless of the claim for substantivity, individuals using sunscreens should be advised to apply them liberally before they become exposed to the sun, and then re-apply them after excessive sweating or coming out of the swimming pool.

TABLE 4
Recommended Sunscreens

If the Individual	Recommended Protection	SPF Value
Rarely burns but tans profusely, or, burns minimally but always tans	Minimal	2 to 4
Burns moderately but tans gradually	Moderate	4 to 6
Burns easily but tans minimally	Extra	6 to 8
Burns easily but rarely tans	Maximal	8 to 15
Has history of skin cancer or photosensitivity reactions	Extra	greater than 15

Photosensitivity

Sunlight and ultraviolet radiation play useful roles in some forms of therapy. For example, methoxsalan (a psoralen agent) plus ultraviolet radiation (PUVA therapy) can clear psoriasis in the majority of persons who can tolerate it. Sunlight and artificial ultraviolet light have been

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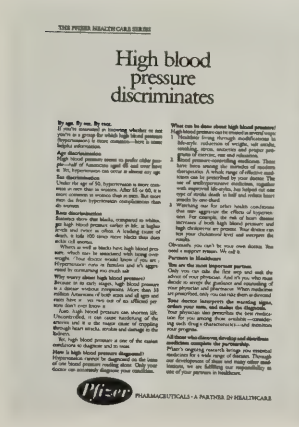
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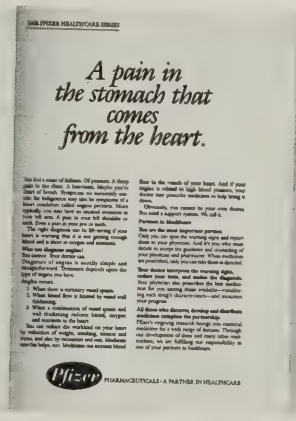
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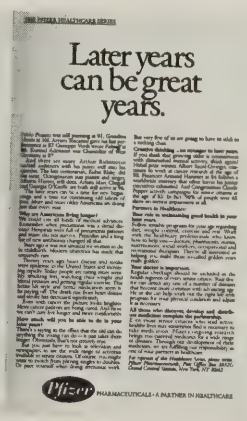
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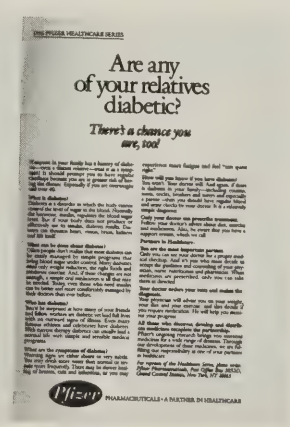
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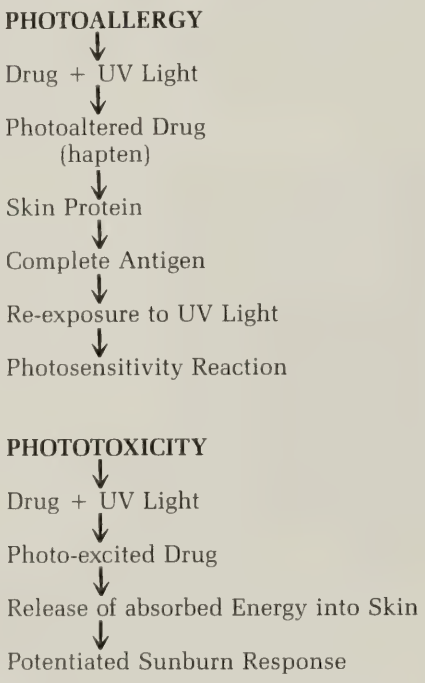
thought to be beneficial in many patients with acne. Ultraviolet light applied to newborns can prevent hyperbilirubinemia that will lead to kernicterus and brain damage if not treated.

However, ultraviolet light can cause problems in some individuals. Paramount among them are two types of photosensitivity: photoallergy and phototoxicity. While there are some similarities between them, there are also some major differences. The proposed mechanisms for each are presented in Figure 1.

FIGURE 1.
Proposed Mechanisms For Photosensitivity Reactions



Photoallergy, like any other allergic reaction, requires prior sensitization to the causative drug and ultraviolet light before a severe reaction occurs. Each time it recurs, however, the reaction is worse. Photoallergy is far less frequent than phototoxicity and looks more like a skin rash than sunburn. Additionally, it extends to unexposed parts of the skin. If it is caused by a drug, it can be especially severe because any subsequent exposure to it or a chemically similar agent results in a flareup.

Phototoxicity takes on the appearance of exaggerated sunburn rather than a rash. It generally has distinct boundaries confined to the skin area that has been exposed to the ultraviolet light. This also differentiates it from contact dermatitis. The same drug can cause both photoallergic and phototoxic reactions. The lay public generally refers to this condition as sun "poisoning." If a patient has this type of reaction but insists that he has not been in the sun, it could be the artificial UV light from fluorescent bulbs.

The use of sunlamps in "tanning" booths can be dangerous. As stated earlier, a considerable amount of burning and photosensitizing rays are absorbed by the atmosphere surrounding the earth, but it is a totally different matter when a person is standing 6 to 12 inches from the source of the ultraviolet radiation.

Tanning booths have become one of the latest fads in America with thousands now operating across the country. Those that are constructed properly with an automatic timer are reasonably safe if the individual follows directions and wears protective goggles. However, FDA reports that over 7,000 patients were treated in emergency rooms for sunlamp injuries in 1979, long before the proliferation of tanning booths. The agency is now considering regulation of such enterprises. Those individuals with a history of excessive sunburn or photosensitivity reactions should certainly not be using tanning booths.

There is a considerable number of agents that cause photosensitivity reactions with antibacterial agents contained in soaps, cosmetics, psoralen- containing plants, and coal tar derivatives. There is a considerable number of drugs that are also photosensitizing. The increase in these reactions is of enough concern that FDA published a warning in its July, 1980 *FDA Drug Bulletin*. Drugs from that list are shown in Table 5.

TABLE 5
Selected Photosensitizing Drugs

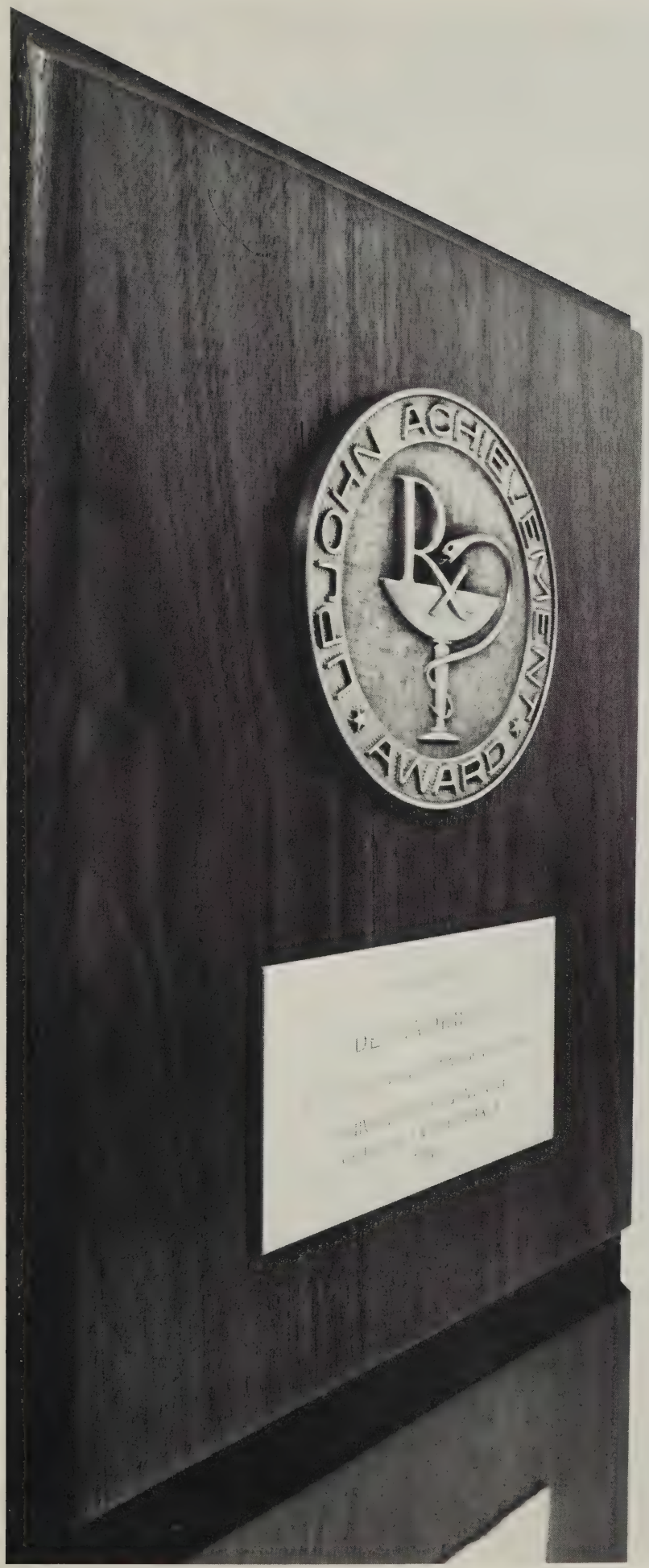
Antihistamines (Benadryl®, Periactin®, etc.)
Estrogens (including oral contraceptives)
Griseofulvin (Fulvicin®, Grisactin®, etc.)
Haloperidol (Haldol®)
Nalidixic acid (NegGram®)
Phenothiazines (Mellaril®, Thorazine®, Trilafon®, etc.)
Sulfonamides (Gantrisin®, Gantanol®, Septra®/Bactrim® etc.)
Sulfonylureas (Diabinese®, Orinase®, Tolinase®, etc.)
Tetracyclines (Declomycin®, Sumycin®, Vibramycin®, etc.)
Thiazide-like diuretics (HydroDIURIL®, Lasix®, etc.)
Tretinoin (Retin-A®), Isotretinoin (Accutane®)
Tricyclic antidepressants (Elavil®, Sinequan® Tofranil®, etc.)

Advice to Patients With Known Photosensitivity

Needless to say, most individuals can sunbathe for moderate or even excessive periods without any undue long-term ill effects. Those individuals who have a history of photosensitivity reactions to excessive exposure to sunlight should be advised to: 1) discontinue use of all cosmetics, 2) use a bland soap such as Ivory™ or Dove™ rather than the highly perfumed "antibacterial" soaps, 3) discontinue use of OTC drugs and discuss their use with a physician, 4) wear protective clothing, 5) avoid prolonged exposure to direct sunlight and artificial ultraviolet light, 6) use a sunscreen agent, and 7) consider taking aspirin 1 to 2 hours prior to going out in the sun and every six hours after exposure. If excessive sunburn does occur, Burow's solution, soaps, and emollient creams may be helpful in alleviating dryness. Systemic antihistamines can be used for itching, and topical steroids for mild inflammation. The severity of the condition should be the determinate factor in whether medical care is necessary.

Sulfonamides, the thiazide diuretics, and the sulfonylureas are chemically similar to PABA. Individuals sensitive to these drugs should not use a sunscreen containing PABA or its derivatives because of the chance for cross sensitivity. In these instances, sunscreens containing dioxybenzone, oxybenzone, or sulisobenzone should be considered. A sunscreen opaque sunblocking agent that reflects or scatters all ultraviolet light and prevents both sunburn and suntan is a better alternative. However, it is often not cosmetically acceptable.

Common sense should be used in giving patients advice to assure that they do not misunderstand or overreact and fear going outdoors. Very few individuals will experience photosensitivity reactions. When these do occur, however, such reactions are both physically painful and psychologically traumatic.



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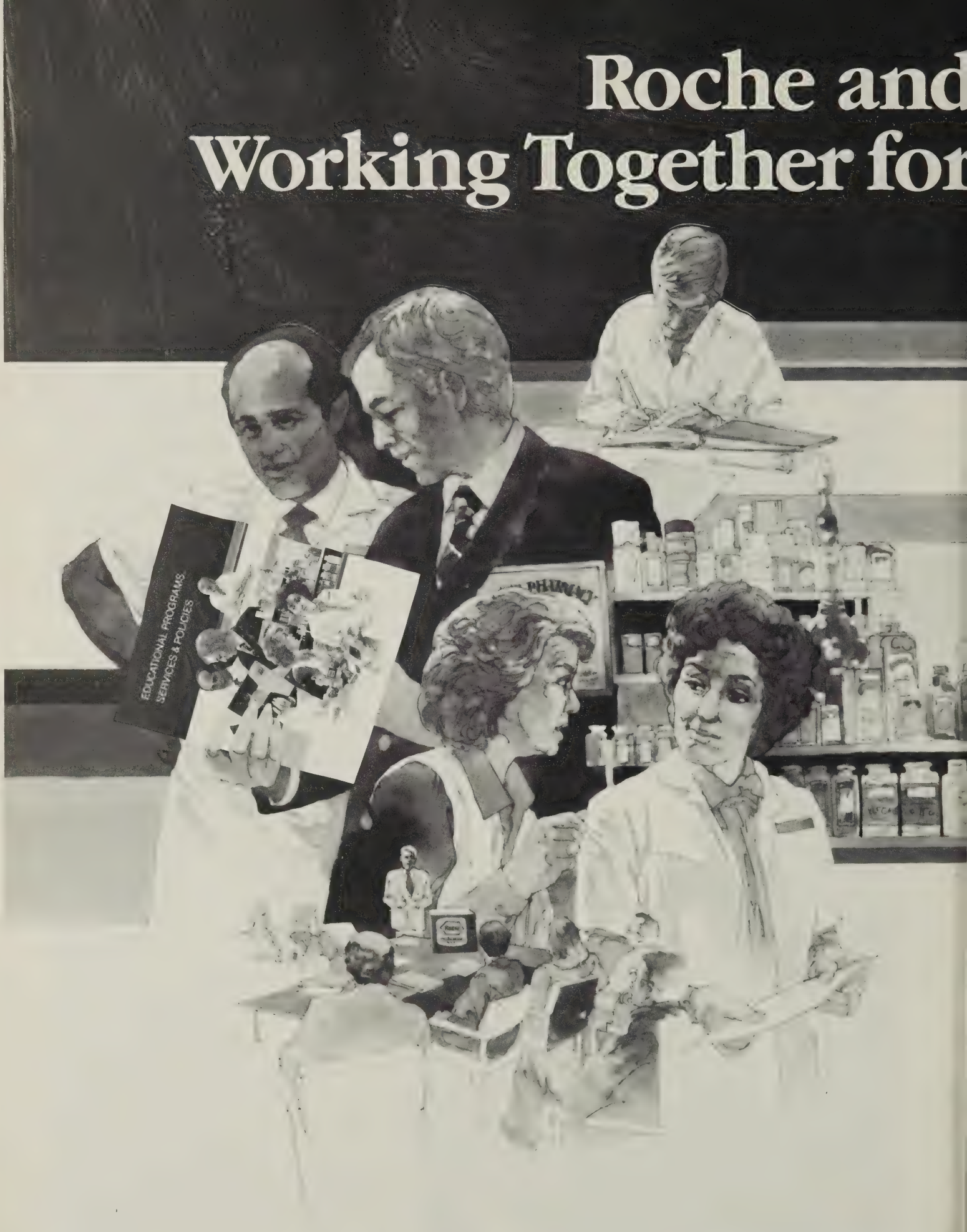
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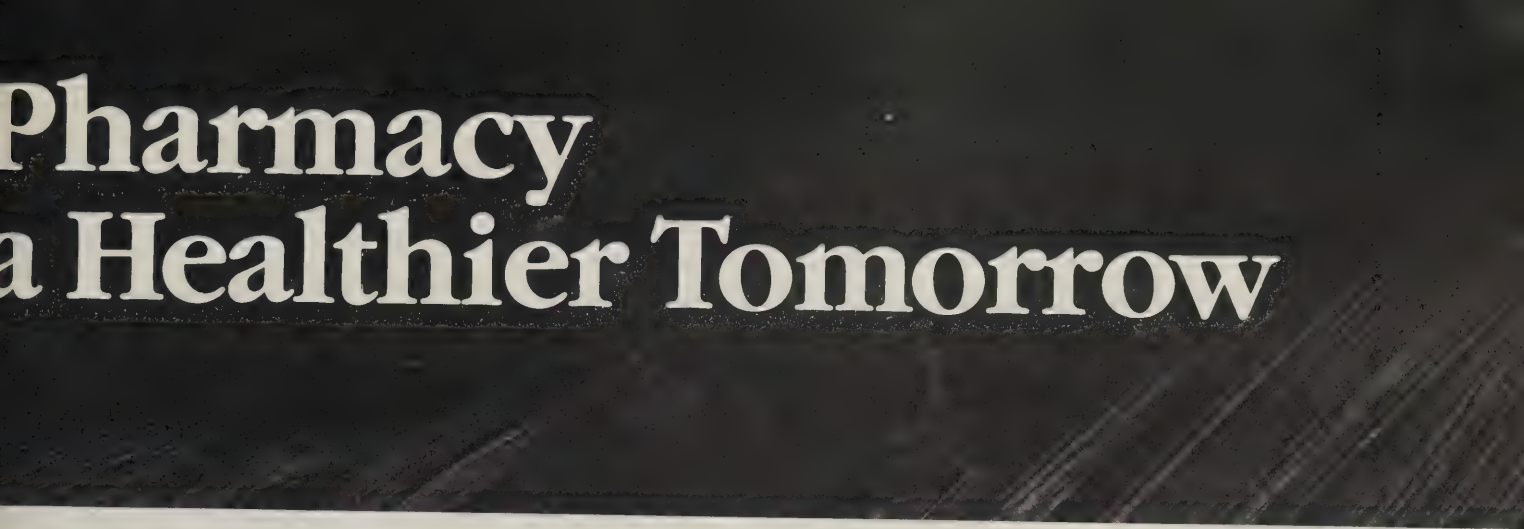

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Pharmacy and Diabetes, The Challenge—The Opportunity

by Marvin L. Oed, Pharm.B.S., Robert S. Beardsley, Ph.D.

The future of community pharmacy lies in community practice becoming more patient care oriented. Schools of pharmacy teach it, professional associations encourage it and the public is asking for it. There is a desire among a large number of pharmacists to become patient oriented. Based upon our experience in the School's Professional Experience Program, one of the main reasons that the level of activity is not as high as it possibly should be is a lack of practical know how. There is a great deal of information regarding what the practitioner should do. There is very little information on how he/she should do it within the constraints (real or imagined) of time, money and professionalism.

There are barriers, real and imagined, to increased patient interactions that must be overcome. For example, there is a fear that the medical community will misinterpret the pharmacists' intentions of offering new services and perceive it as overstepping their professional boundaries. Some pharmacists feel that the responsibility of providing such services should be the physician's. Others cite liability, time and cost factors. Some of these barriers can be overcome by educating the pharmacist. Other barriers, such as available time are more difficult to remove. Some means must be developed to minimize these barriers to permit the practical implementation of the desired intervention(s). Some community practitioners have overcome these barriers and are performing patient care services so there are solutions. We must build on what is already being done.

The Department of Pharmacy Practice and Administrative Science (PPAS) of the University of Maryland School of Pharmacy is largely responsible for teaching a large part of the practice related curriculum. This joint project, ADA, MPhA and School of Pharmacy was developed because of this department's desire to encourage increased patient care activities. Practical mechanisms for implementing patient care activities without disrupting current procedures or involving undue costs of time and/or money must be developed.

The objective is to develop a program that could be instituted, in whole or in part, in any community pharmacy practice. To achieve the widespread acceptance, two concepts were deemed essential for the program to succeed:

1. the design must originate with practitioners, and
2. the format must be simple.

Practitioner input from the very beginning of the project and continuing to the end will assure that the interventions are realistic in practice settings. Our desire is to produce a "user friendly" practitioner's program rather than an educator's program.

Preliminary discussions led to the conclusion that the best way to proceed was to develop a program for a specific disease or condition that could then serve as a prototype for similar programs for other conditions.

Ideally, the condition to be selected would:

(1) have ample opportunities for pharmacist/patient interaction (chronic).
(2) have measurable end points that the patient/pharmacist could measure.
(3) require a significant amount of patient participation as a part of the therapy.
(4) present frequent patient failures and an opportunity for prevention/correction.
(5) have (potentially) serious consequences if not treated appropriately.

Diabetes was selected for several reasons. First, because it met all the above criteria and second because the American Diabetes Association Maryland Affiliate, although underutilized by pharmacists, has been very supportive of pharmacist's efforts with diabetics.

There is no question that diabetes is chronic. Diabetics will undergo therapy for the rest of their lives. The observable endpoints of urine and more recently blood glucose levels are readily available. There are multiple variables, all are the responsibility of the patient rather than the physician. Diet, exercise, weight control and testing are left to the diabetic as are the accuracy of the timing, frequency and dose of hypoglycemic drugs. The physician may direct the patient periodically, but the number of decisions made and actions taken/not taken in adhering to a treatment regimen becomes almost astronomical between such visits. Each decision and action point is a potential error, either of omission or commission. The diabetic is at a significantly increased risk for a number of very serious complications. It is the third leading cause of blindness in persons aged 45 to 65. Diabetics are 17 times more prone to kidney disease, twice as prone to heart disease

and stroke and five times more prone to gangrene than non-diabetics.[1]

Are there patient failures? According to R. Keith Campbell, Professor of Clinical Pharmacy at Washington State University, fewer than 10% of diabetics care following a minimally adequate treatment regimen and fully 35% of diabetic patients haven't had any formal diabetes management training.[2]

Assuming that the community pharmacist can have a positive effect the question then becomes, "is there a patient benefit?" The patient benefit is due to the link between the control of blood glucose levels, and the development of retinopathy, neuropathy, nephropathy, microangiopathy and growth inhibition. Other recent data seem to suggest that strict control vs. loose control may reduce the degree of risk of diabetic complications.[3,4,5]

This condition then is an excellent opportunity for patients to benefit from a pharmacist's knowledge of the disease and the interrelationships of diet, exercise, weight control, monitoring, drugs and insulin. Pharmacists are well grounded in diabetes during their education at the University of Maryland School of Pharmacy. Each receives a minimum of 16-1/2 hours of didactic/laboratory training in the physiology, pathophysiology, pharmacology and therapeutics of diabetes. There are frequent pharmacy journal articles, several diabetes journals, numerous manufacturer's publications and a variety of Continuing Education (CE) programs that enable practitioners to attain and maintain competency. The American Diabetes Association Maryland Affiliate is an excellent source of information through ADA publications and their own CE programs.

If an intervention is to gain wide acceptance among community pharmacist practitioners, it must be perceived as cost effective by the community practitioners. The cost of patient care activities, both in time and in "real dollars" is frequently ignored by those encouraging an increased level of patient care activities. Others are not expected to perform their job without appropriate compensation for the knowledge, skill, effort, time and responsibility involved. It is unrealistic, although frequently expected, to ask pharmacist to do so.

Those involved in this joint project understand the need for some form of remuneration for the services performed. Ideally, this would be a fee for the service. Whether it is realistic at this moment in time is another question. Historically, reimbursement has been for products rather than services. Unfortunately, pharmacists have provided valuable services free for many years with little public recognition. Pharmacy and pharmacists rather than the public must accept the blame for these circumstances. We rarely extole the value or benefits of our services (except to each other) and never ask to be paid for them. It is hoped that this project will document the value of patient care services and be the initial step toward reimbursement for professional services.

Even though direct reimbursement may not be a practical alternative immediately, there are economic incentives to cultivate the diabetic as a regular patron in a community pharmacy. Approximately 5% (over 200,000 Marylanders) of the population is diabetic, many of whom are unaware that they have the disease. The additional sales generated by identifying unknown diabetics can increase total pharmacy sales significantly. The blood glucose monitors currently available require little training and make a screening relatively easy and inexpensive to conduct.

Recent American Diabetes Association information (Table 1) suggest that from $68,000,000 to $144,000,000 is being spent by diabetics in Maryland for the treatment and monitoring of their condition. This does not include the amount spent for prescription drugs unrelated to diabetes, over-the-counter medication, and sugar substitutes. Diabetics visit a pharmacy about 1/3 more often and spend approximately twice as much when compared to non-diabetic pharmacy customers. Cultivating the diabetic who may spend $1200.00 annually on supplies as a regular patron of your community pharmacy is a wise business decision.

The American Diabetes Association Maryland Affiliate was asked to participate in such a project because of their history of cooperation with pharmacists and the need for a comprehensive program.* It was agreed that a multiphase approach using the resources of the School of Pharmacy, the ADA and the MPhA was more likely to result in the development of a successful program.

Phase I

A needs survey would be sent to a random sample of Maryland pharmacies. The threefold purpose of this survey is to determine what:

Table I
Typical Yearly Patient Costs—Diabetes*

A. Type I Diabetic	
Insulin	97.00
Disposable Syringes	146.00
Alcohol/Swabs	24.00
Chem Strip	438.00
Keto-Diastix	15.00
Total	720.00
B. Type II Diabetic	
Oral Hypoglycemics	100.00
Test Strips	219.00
Diastix	21.00
Total	340.00

* April 1983—American Diabetes Association Communication

* The initial meeting included: Marvin L. Oed, and Robert S. Beardsley, faculty of the University of Maryland School of Pharmacy; Louis J. Bandell, Executive Director of the American Diabetes Association Maryland Affiliate and David A. Banta, Executive Director of the Maryland Pharmaceutical Association.

(1) was already being done in diabetic education.
(2) pharmacists could/would do.
(3) assistance pharmacists feel they needed to implement such programs.

Phase II

Appropriate pharmacist-directed interventions will be developed and mechanisms for implementation designed using the combined efforts of the three groups.

Phase III

The interventions developed in phase II will be tested, evaluated, redesigned and retested.

Phave IV

The final step is to combine the effective interventions into a program that can be implemented in community practices and made available in a useable format.

Phase I Results

Thus far, Phase I has been completed. A needs survey was sent to about 100 Maryland pharmacies of which approximately 40 were returned.

The majority of the pharmacists responding indicated they offered some degree of patient education. Most often this was patient initiated rather than pharmacist initiated.

For those pharmacists not offering these services, the reason most frequently cited for not performing diabetic screenings and urine/blood glucose monitoring was a lack of time. On the other hand, many "busy" pharmacists said they were currently doing these activities. Thus, it appears that this is one barrier that can be overcome.

The respondent's most pressing need, according to the survey, was for educational material about diabetes or information on how to set up a program. Fortunately, this information is available, but the need seems to be how to collect it and make it available in a concise useable format. It is interesting to note that only three of the respondents indicated that they obtained information from the American Diabetes Association even though that organization is very cooperative. Two of the three are currently involved in diabetes screening/testing. This indicates that increased awareness of the help available could possibly increase activity.

There were two general comments received that summed up the typical pharmacist's dilemma.

"More and more, society is expecting pharmacy to

Table II
Summary of Responses to Selected Questions

	Do You Offer Diabetic Screening?		
Question 1	Yes	No	Total
Independent	3	27	30
Franchise	2	0	2
Chain	0	7	7
Other	0	1	1
	5	35	40

	Reason for Not Offering Screening				
Question 1A	Not My Responsibility	Insufficient Time	Cost Too Much	Tried & it didn't work	Total
Independent	5	11	2	1	19
Franchise	0	0	0	0	0
Chain	0	5	0	0	5
Other	0	0	0	0	0
	5	16	2	1	24

* All respondents to question 1 did not respond to 1A.

	Initiation of Patient Education		
Question 5	Pharmacist Initiated	Response to Patient Question	Total
Independent	7	23	30
Franchise	2	0	2
Chain	0	7	7
Other	1	0	1
	10	30	40

assume the role of medicine, and they expect it free." "It is difficult to practice patient education the way it is taught in school."

These are valid concerns in addition to the constraints of time, adequate knowledge and cost. It appears that community pharmacy is at a crossroad and must choose one of two alternatives. One may say:

(1) "My job is to fill prescriptions, it's the physician's job to take care of the patient," or
(2) "There is a population that can benefit from my expertise and I will attempt to provide it."

Number one requires no effort and will be chosen for us if we do nothing. Number two will require some effort, but may be a pivotal point in community pharmacy practice. Too often pharmacy has chosen to react rather than act. This is an opportunity for pharmacists to help determine their destiny and that of the profession of pharmacy.

However, the community pharmacy practitioner cannot "go it alone". Pharmacists need to be encouraged to increase their patient care activities. Mechanisms for implementing effective procedures must be developed. These procedures must be efficient so there is little or no interruption to current operations. A fee for these services would be ideal but current economic conditions may dictate that something less may have to be accepted. At the very least the pharmacist should be able to anticipate that the profit from increased sales would offset the expense.

Community practitioner input will be needed to develop the other phases of the project and to help us meet our objective to develop a program for practitioners. You can help us in three ways, if you are currently providing a service or have a concept for providing a service for diabetics. First, please let us know the specifics of the program. Secondly, if you would like to help design and/or test proposed interventions, we would like to hear from you. And finally, just your thoughts and comments regarding this project would be appreciated. This is a project of practitioners, by practitioners and for practitioners so let us hear from you.

Any communications should be directed to: Marvin L. Oed, PharmBS, Clinical Assistant Professor, Department of Pharmacy Practice and Administrative Science, University of Maryland School of Pharmacy, 20 N. Pine Street, Baltimore, MD 21201.

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4. Skyler, S. Complications of Diabetes Mellitus-Relationship of Metabolic Dysfunction. Diabetes Care, 1979, 499–509.
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MSHP Convention Plans June 22–24, Ocean City

The upcoming MSHP Seminar Program is just about set. The following will be the format:

Robert Henry—Friday night—Topic: "The Reindeer Don't Fly."
Dave Schmidt (Upjohn)—Saturday morning—Topic: Communications and Interpersonal Relationships.
Jack McCue, M.D. (Roerig)—Sunday morning—Topic: Antibiotics followed by a maryland pharmacy showcase consisting of local speakers:
Paul Vitalae, Pharm.D.—Home Clinical Program
Buzz Stromberger, M.B.A.—Computerized Controlled Substances
Andrew Hvizdos, Pharm.D.—A revitalization of Pharmacy Practice in Maryland State Mental Health Institutions
Karen Fairchild, Pharm.D. & Carol Baker, Pharm.D.—I.V. Antibiotics Control
Patrick Birmingham & Patricia Ensor, M.B.A.—Advancements in IV Therapy Program

calendar

June 7 (Thurs)—C.E. Seminar—Home Health Care and the Elderly—Pikesville
June 22–24—MSHP Seminar, Ocean City
June 24–28—MPhA CONVENTION OCEAN CITY—OUR BIGGEST AND BEST
Aug. 30–Sept 2—AACP Annual Meeting—Hyatt Hotel, Baltimore
Oct. 12–20—MPhA TRIP FIRST TO PARIS—SOLD OUT
Oct. 19–27—MPhA SECOND TRIP TO PARIS—LIMITED SEATS AVAILABLE. CALL TODAY.
Oct. 29 (Sun)—MPhA DINNER THEATER AT OREGON RIDGE (PIMLICO CATERERS).
Nov. 11 (Sun)—ALUMNI ASSOCIATION ANNUAL DINNER

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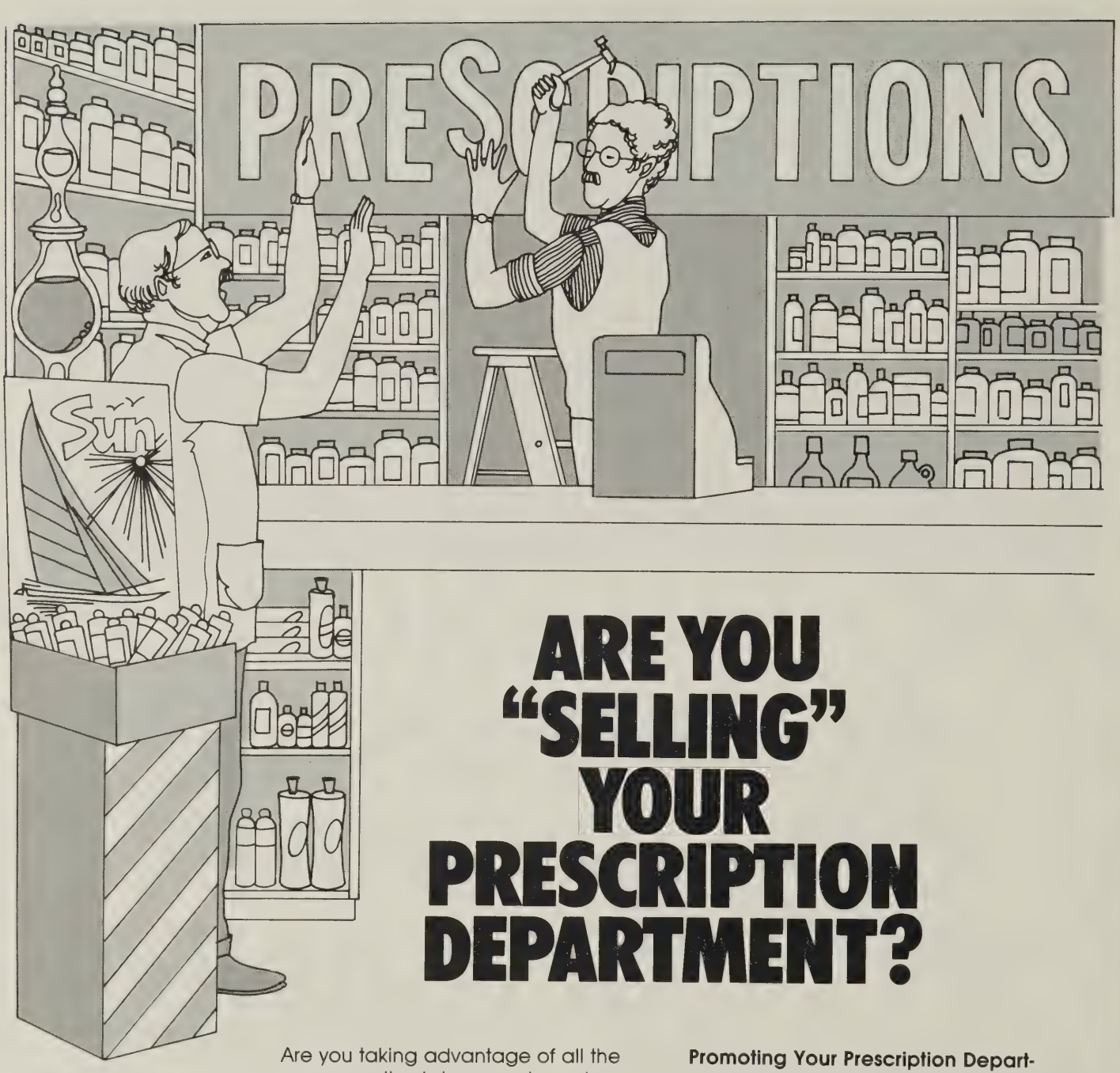

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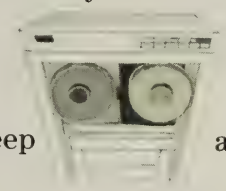

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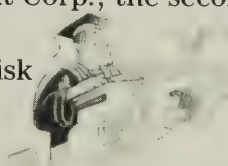

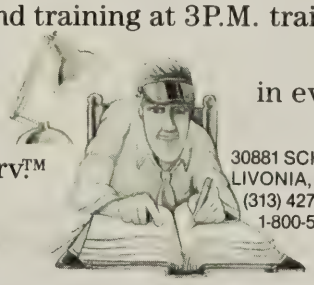

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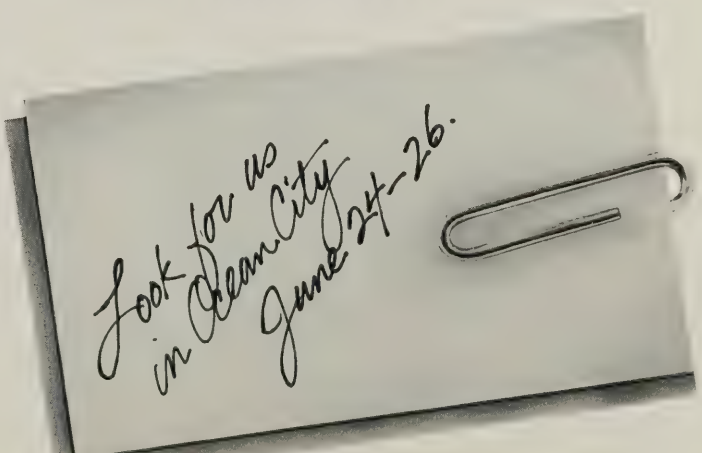

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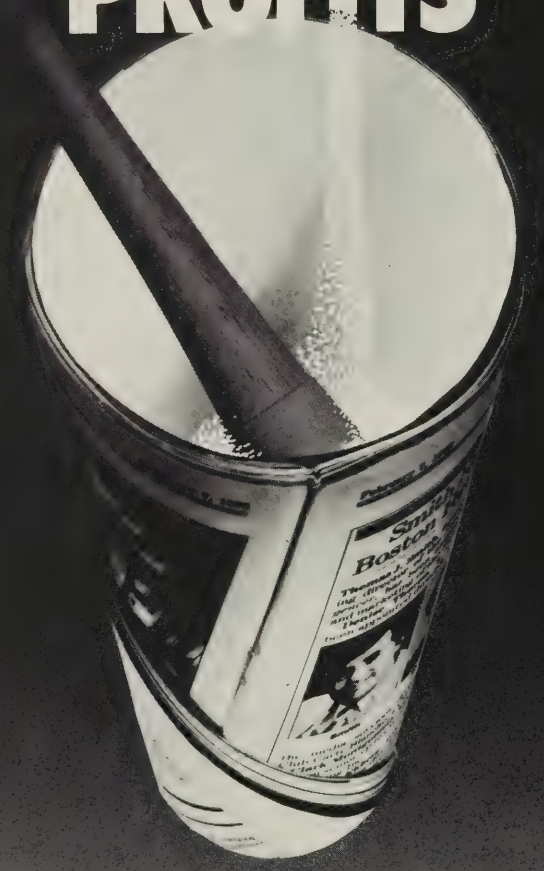

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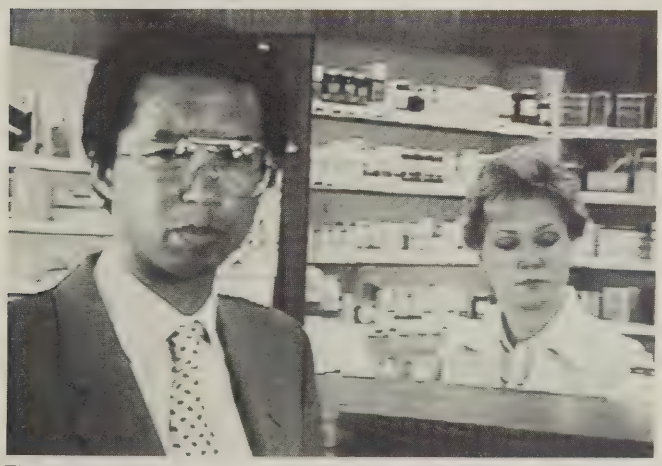
Dr. T. Albert Farmer, Chancellor of the University of Maryland at Baltimore since 1981, died at his home at the age of 52. As Chancellor, Dr. Farmer was the chief executive officer responsible for the six professional schools on campus, including the School of Pharmacy.

The fine art of Pharmacy window decorating is shown here from the Boyd and Fulford Pharmacy in Belair, Maryland. Pharmacists with other window decorations should send a picture to *The Maryland Pharmacist* for publication.



The National Pharmaceutical Council has distributed to television stations nationwide a public service announcement stressing the role of the pharmacist in ensuring patient compliance. The spot features tennis star Arthur Ashe (left) and NPC's Dorthy Wade (right).

G. Joseph Redding has been assigned to the Washington D.C. area for the Syntex company. Redding is a graduate of Mount St. Mary's College in Emmitsburg, Maryland.

ABSTRACTS

Excerpted from PHARMACEUTICAL TRENDS, published by the St. Louis College of Pharmacy; Byron A. Barnes, Ph.D., Editor and Leonard L. Naeger, Ph.D., Associate Editor

TOOTH DECAY:

Competitive swimmers were found to have a higher incidence of tooth decay than did a group of matched controls. The swimmers were found to have been practicing in a pool with water at a pH of 2.7. This reading was not confirmed as the pool was drained soon after the sample was taken. Regardless, it appears that acid water will increase the likelihood of erosion of dental enamel. *JAMA,* Vol. 250, #6, p. 716, 1983.

PARVOVIRUS-LIKE VIRUSES:

A serum parvovirus-like virus (SPLV) has been isolated from patients with hemophilia. The substance is apparently present in clotting-factor concentrates, but was not found to be present in patients who received only whole blood transfusions. The effect of this transmission is unknown at this time. *Lancet,* Vol. II, #8348, p. 482, 1983.

KETANSERIN:

Ketanserin is an experimental antihyertensive agent which has been used to treat various types of hypertension. Its exact mechanism of action was unknown so investigators designed experiments to determine how it did work. It appears that the hypotensive response of ketanserin is due to the blockade of peripheral alpha-1 receptors. *Br Med J,* Vol. 287, #6389, p. 381, 1983.

ETHANOL AND CATECHOLAMINE LEVELS:

Moderate to high doses of ethanol have been associated with an increase in the plasma concentration of catecholamines. Studies conducted in volunteers indicate that the increased levels are due to a reduction in catecholamine clearance rather than by an increase in synthesis. *Clin Pharmacol Ther,* Vol. 34, #2, p. 143, 1983.

STEROIDS AND OSTEOPOROSIS:

Patients with asthma are often treated with long-term steroid therapy. A group of people so treated was followed to determine the effect this therapy might have on bone. It was again determined that the steroid therapy is associated with decreased trabecular bone density and an increase in prevalence of rib and vertebral fractures. *N Engl J Med,* Vol. 309, #5, p. 265, 1983.

KETOCONAZOLE:

The antifungal drug ketoconazole (Nizoral) has been found to inhibit the synthesis of adrenal steroids. Recent findings suggest that ketoconazole also has the ability to block the effect of glucocorticoids by occupying the receptor sites in target organs. *J Clin Invest,* Vol. 72, #1, p. 404, 1983.

ESTROGENS:

Long-term administration of low dose estrogen (Mestranol) in animals suggests that this type of therapy may be responsible for producing hypertension in some women. Investigators feel that this side-effect is due to a reduction in the rate at which norepinephrine is inactivated; thus causing a prolonged alpha-adrenergic response. *J Pharmacol Exp Ther,* Vol. 226, #2, p. 362, 1983.

AMOXAPINE OVERDOSE:

Five of 33 patients who overdosed on the antidepressant amoxapine succumbed to the toxic side-effects of the drug. Most of these patients developed signs of tremors and/or seizures prior to death. Generally most antidepressants do not produce these type of toxicities. Amoxapine had been suggested by some as a drug of choice in depressed patients because it does not have the cardiotoxicity associated with other agents used for the same purpose. However, it seems that concern for other side-effects must be considered. *JAMA,* Vol. 250, #8, p. 1069, 1983.

CHRONIC MENINGITIS:

Twenty-one patients with persistent or progressive chronic meningitis developed a moderate, predominantly mononuclear pleocytosis, a sharp rise in cerebrospinal protein, and intrathecal synthesis of considerable quantities of oligoclonal immunoglobulin G. The condition generally appeared in summer or autumn, and some patients had reported to have been bitten by ticks prior to the onset of symptoms. Clinical symptoms include fatigue, malaise, weight loss and fever. Patients were found to improve dramatically with the use of intravenous penicillin G. Therapy was continued for approximately two weeks. *Lancet,* Vol. II, #8341, p. 75, 1983.

DIAZEPAM:

Women about to experience childbirth are often nervous and anxious. Some clinicians have used diazepam (Valium) to help control these symptoms. Diazepam is a fat soluble drug thus it penetrates the placental barrier and can produce generalized depression in the new born child. Studies conducted in West Germany have concluded that the drug is more tightly bound to plasma proteins in fetal blood than in maternal blood, thus making the drug exert a longer pharmacological effect. This may help explain the "floppy infant syndrome" sometimes seen in infants born to women taking diazepam. *Clin Pharmacol Ther,* Vol. 34, #2, p. 220, 1983.

INTERLEUKIN-2:

Patients with acquired immune deficiency syndrome (AIDS) are very susceptible to viral infections. Studies show that the cytotoxic T lymphocytes in patients with AIDS are markedly depressed in their ability to respond to viral infections. Additionally, the natural killer (NK) cells are also less active as compared to those obtained from non-AIDS volunteers. The activation of a fully active cytotoxic T-cell lymphocytes is at least partially dependent on interleuken-2 activity. Investigators are now checking the possibility that exogenous administration of this lymphokine may be able to restore normal lymphocyte activity in AIDS patients and thus afford them protection against viral infection. *JAMA,* Vol. 250, #9, p. 1125, 1983.

BENZODIAZEPINE TOLERANCE:

Benzodiazepine derivatives are among the most commonly used drugs on the market today. They also possess the ability to produce tolerance and physical dependence. Death has been associated with withdrawal from these drugs, but little has been developed in the way of therapy because of lack of a suitable model for testing experimental protocol. Investigators in Massachusetts have developed an animal model for studying tolerance and dependence to benzodiazepine derivatives. They feel that this system will allow researchers to evaluate various withdrawal regimens without exposing humans to experimental procedures. *J Pharmacol Exp Ther,* Vol. 226, #1, p. 100, 1983.

DESFERRIOXAMINE TOXICITY:

Desferrioxamine (Desferal) is used to treat symptoms produced by excessive ingestion of iron. When used in high doses, it can produce retinal abnormalities including night blindness and field defects. The toxicity is reversible. *Lancet,* Vol. II, #8343, p. 181, 1983.

OBESITY:

Over 200 children with short stature and/or delayed puberty were studied to determine if a common cause could be found to explain the delay in maturation. Approximately 7% of these children were generally normal but ingested only 32% to 91% of their recommended daily caloric intake. Questionnaires discovered that this was prompted by fear of obesity. After nutritional and psychiatric counseling, growth rates and sexual development returned to normal. *N Engl J Med,* Vol. 309, #9, p. 513, 1983.

SALICYLATE HYPOPROTHROMBINEMIA:

Salicylate inhibition of the formation of vitamin K-induced clotting factors, including prothrombin, was studied to determine the exact mechanism of this toxicity. Information accumulated indicates that vitamin K eposide (the inactive form of the vitamin) increases during aspirin therapy. It has been postulated that salicylates inhibit the enzymatic reactivation of the inactive form of vitamin K, thus reducing vitamin K-induced prothrombin synthesis and allowing for the observed accumulation of the inactive vitamin form. *J Pharm Pharmacol,* Vol. 35, #7, p. 421, 1983.

TOOTH DISCOLORATION:

Tetracycline and its derivatives have been associated with discoloration of dental enamal. A non-published study indicates that improvement may be obtained in a majority of patients by using 35% s/w or 130 volume (industrial strength) hydrogen peroxide together with a heat source. More work should be undertaken before one can recommend this therapy as being both safe and effective. *Drugs,* Vol. 26, #3, p. 269, 1983.

ANTIDEPRESSANT THERAPY:

Animals were treated with desipramine and then subjected to various examinations. It seemed apparent to these investigators that long-term administration of the antidepressants increased the concentration of norepinephrine at the synapse by blocking the reuptake of the transmittor by the nerve ending. This apparently results in both a decrease in beta-adrenergic receptor density and an alteration in the effectiveness of gamma amino butyric acid. *J Pharmacol Exp Ther,* Vol. 226, #1, p. 126, 1983.

Hidden Costs

The direct costs of health care actually account for only 40 percent of the total cost of illness. The remaining 60 percent are indirect costs, such as absenteeism and loss of productivity caused by illness. These are as real economically as the health care expenditures usually associated with illness.

Surprising? Yes. But it should come as no surprise that when the patient gets well faster, both the direct and indirect costs can be reduced.

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LETTERS

Dear Dave

Spending a month at the A. H. Robbins Company of Richmond, Virginia was one of the most enlightening and enjoyable experiences of my pharmacy education. It helped me to see just how versatile we pharmacists can be.

While at A. H. Robbins, I participated in a program planned and coordinated by Jacob Miller, professional relations, and Mr. Robert Wampler, research and development personnel.

My first week and a half was spent in the sales and marketing area. I was able to spend time actually participating in their sales training program for newly hired salesmen. A day was also spent gaining first hand experience, as I traveled with a detailman. Time was also spent discussing and participating in daily activities and meetings of a product manager.

The next week was spent in the research and development department. Here I was able to get my hands dirty, so to speak, as I made batches of different tablet formulations and also worked on flavors to possibly be used.

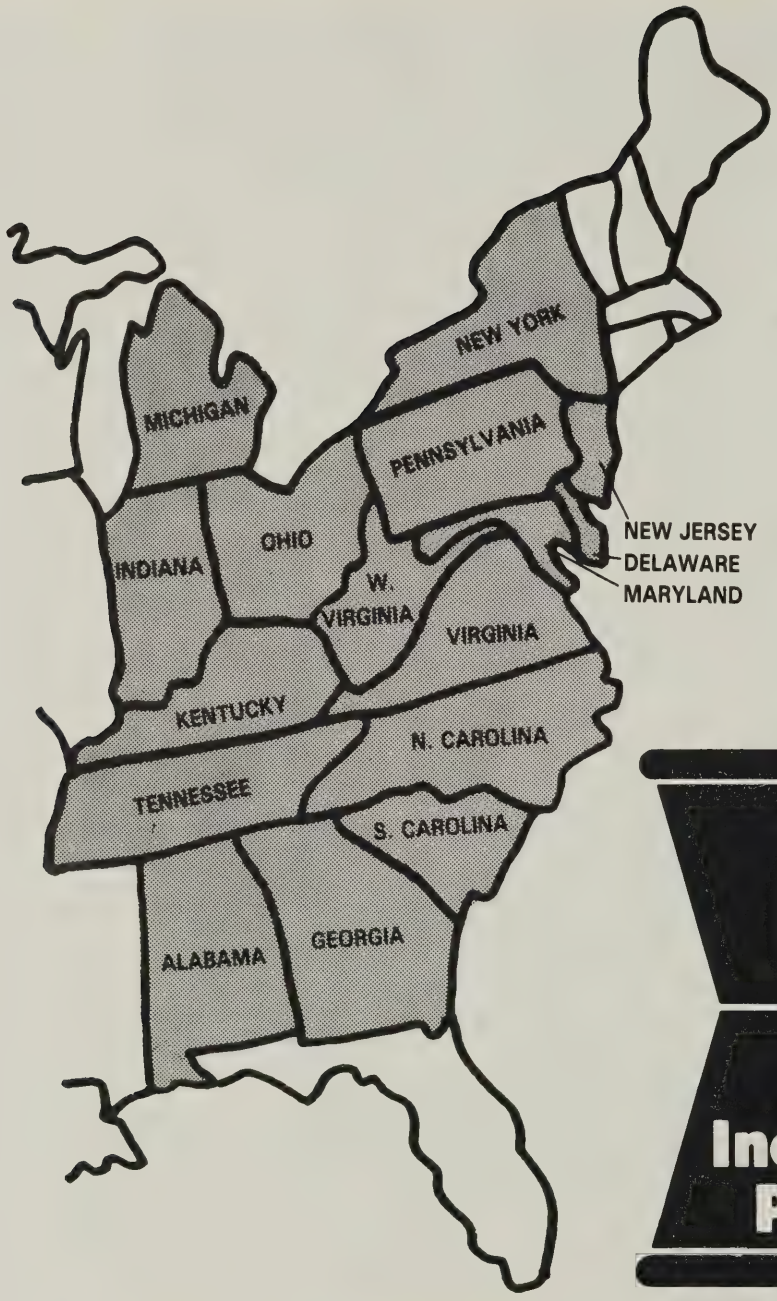
Week three was spent with the manufacturing group in both tablet and capsule manufacturing and also at the new Darbytown packaging and liquid manufacturing facilities. The new plant and its liquid manufacturing and packaging left a lasting impression and a feeling of awe.

I winded up my enjoyable stay at A. H. Robbins by spending a couple of days in the quality assurance department and seeing what a vital part they play in the process that goes on. By the end of my stay I was beginning to see just how the pieces fit together to form the whole.

I wish that more of my fellow students and future pharmacy students could have the chance to participate in such an enlightening and well coordinated externship.

All along the way I saw pharmacists in every area. Pharmacists as salesman, pharmacists in marketing, research, manufacturing, regulatory affairs, Q-A, professional relations, and personnel. The most exciting thing I took away with me from A. H. Robbins was an increased pride in the profession known as pharmacy. So again I want to thank Mr. Jacob Miller and Mr. Robert Wampler for such a well organized and enjoyable externship at A. H. Robbins.

Sincerely,
Christopher Conway
Pharmacy student



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THE
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PHARMACIST
Official Journal of
The Maryland
Pharmaceutical
Association

July, 1984
VOL. 60
NO. 7

Drugs and Oral Health

— Margaret L. Lamy

This and That About Pharmacy

— Leon Weiner

Mail Order Editorial

— Brian Sanderoff

THE MARYLAND PHARMACIST

650 WEST LOMBARD STREET
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TELEPHONE 301/727-0746

July, 1984 VOL. 60 NO. 7

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PRESIDENT MESSAGE

Modern technology has brought pharmacy to the very edge of scientific wonderment. Modern electric calculators, sophisticated computers, electronic order entry systems, microfiche, etc. All of these marvelous machines are changing the way we practice our profession and the way we do business.

The familiar staccato sounds of the typewriter and the friendly old ring of the mechanical cash register has been replaced by sounds directly from the soundtrack of "Star Wars."

What do all of these things mean to us? Can older pharmacists adjust to these new methods? How about our young pharmacists?

I feel very confident about the future of pharmacy in our great state. You can feel the enthusiasm among old as well as young pharmacists. Our new college of pharmacy is already exposing the student to all sorts of technological equipment. We are all proud of our new Pharmacy building. Dean Kinnard and his staff have brought our college to a leading position in pharmacy education in this country.

I am confident that after a few test runs, all of our pharmacists will be able to operate the new computers. The software is getting better and more pharmacy oriented.

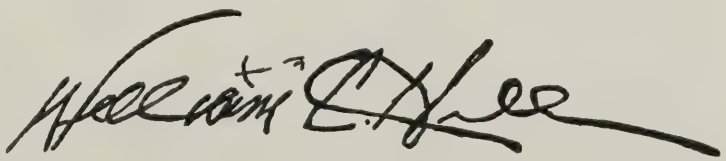
Another real plus for pharmacists in Maryland is our State Association. I can think of no other pharmacy association where retail pharmacy, independents and chains, hospital, educators, all meet together to solve the problems confronting our great profession of pharmacy.

Dave Banta is the fellow who orchestrates and leads our Association. He is always working, on our behalf. He is that spark that makes our team work!

I would like to say to all pharmacists "Support your State Association." Don't sit on the sidelines, represent your profession by membership. What a sad wasteful thing to be a pharmacist and not support your profession.

I would particularly like to say this to all the young pharmacy Graduates. You have just graduated from one of the finest Pharmacy Schools in the World, probably the very best. Your future is limited only to your dreams and imagination, the application of your skills, ambition and courage will lead you to great success in your chosen field of Pharmacy.

(Delivered at the 102nd Annual Convention)



William C. Hill, P.D.

PRESIDENT

Drugs and Oral Health

by Margaret L. Lamy, D.D.S.

Abstract

Drug-induced oral lesions are not infrequent, particularly among the elderly. It is suspected that the incidence of these disorders is likely to increase in direct relation to the increased use of drugs required for the management of chronic diseases.

Lesions may occur due to direct adverse action of a drug or indirectly, because of drug-induced vitamin deficiencies.

Since almost all lesions closely resemble various naturally-occurring diseases, the differential diagnosis is often difficult.

Whenever possible, the offending drug should be withdrawn after close consultation between dental and medical practitioners. If this proves to be impossible, individualized supportive treatment should be devised.

Introduction

Soft and Hard Tissue Damage

Dentists have been familiar with the possible adverse effect of numerous agents and materials on the oral mucosa for some time. It is well-known that strongly acid or alkaline chemicals, astringents and other materials can cause various clinical lesions, ranging from ulceration to superficial desquamation of the mucosa.

Among the chemicals that have in the past been identified as hazardous to the oral mucosa are phenol, silver nitrate, eugenol, and gentian violet. The latter is associated with the so-called "gentian violet burn," particularly if used in an alcoholic preparation in the treatment of oral candidosis (1). Similarly, sublingual administration of isoproterenol may lead to ulceration of the buccal mucosa or the tongue (2,3).

While soft tissue damage due to chemicals has been a major focus, one should not forget that hard tissue damage has also been documented. In the past, when administration of hydrochloric acid to treat hypochlorhydria or anacidity was not unusual, smooth decalcification of the teeth, particularly the incisors, could be seen. This occurred as a direct action of transient chemical contact with teeth over time. Similar effects can be produced when more modern drugs are misused. For example, chewable tablets of vitamin C, used each day in megadoses for three years, caused severe erosion which required restoration by full crowns on at least 12 teeth of a female patient (4). Another type of erosion, frequently seen, is also caused by the acidity of a drug. Many people, mistakenly believing that aspirin placed into the oral cavity has an analgesic effect, present with at times serious oral lesions due to close and continued contact of aspirin tablets with the oral mucosa.

Clearly, soft and hard tissue damage has been documented due to drugs and chemicals, used episodically. There is now concern that, with a major shift in prescribing taking place, dentists may be confronted with more problems related to drugs and oral health.

Changing Prescribing Patterns

Increased Prescribing of Maintenance Drugs

The emphasis in the health care system is changing from one of acute care to long-term, chronic care. Drugs play a major role in the management of chronic diseases, and it is important to anticipate possible adverse effects.

The Elderly at Risk

In 1967, the average number of prescriptions filled for persons receiving supplementary medical insurance (SMI) was 13.4. In 1977, this average was 17.9, an increase of almost 34 percent. Not only did the number of prescriptions (new and refill) per user increase, but also the size of each prescription. The use of maintenance drugs for the management of chronic diseases such as arthritis and cardiovascular conditions has been an important part in that increase. Prescriptions for chronic diseases accounted for 90 percent of all prescriptions filled for aged beneficiaries (5). At particular risk to the possible adverse effects of these drugs, many of which have been identified (Table I) are, of course, the elderly, who constitute the fastest-growing segment of the U.S. population.

While surveys show and suggestions have been made that there are indications that problems exist in prescribing drugs for older adults and that some may even receive drugs when there is no indication for use of drugs (6–8), the disproportionate use of prescription drugs for seniors (as many as 92 percent may receive

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TABLE I
Some of the More Frequently Used Chronic Care Drugs that May Affect the Oral Health Status

Antibiotics (as used in UTIs)
Anticholinergics
Anticoagulants
Anticonvulsants
Antihypertensives
Antituberculars
Diuretics
Hypoglycemics, oral
Mood-altering drugs

drugs to enable them to pursue the activities of daily living) (9,10) may, indeed, lead to more drug-related problems associated with the oral cavity. It is, therefore, important for those who care for the dental health, particularly of older people, to become intimately familiar with the possible hazard of drugs to oral health.

Drug-Induced Oral Disease

Clearly, clinicians should be aware that oral mucous membrane lesions and hard tissue lesions can be caused by drugs, and that the incidence of these problems is likely to increase as more drugs are prescribed for therapeutic, particularly chronic care purposes. Unwanted drug-induced oral disease (Tables II-VIII) may be induced directly by drugs or indirectly, by the effect of drugs, administered chronically, on the nutritional status of a patient (Table IX) (11–32).

Unwanted and undesirable drug effects can present in several different ways. They can be part of a general systemic response, they can present as a specific oral adverse response to the systemic use of a drug or therapeutic agent, or they can present as a local effect, when drugs are placed in the mouth. Treatment of these effects involves first the recognition of the adverse effect and secondly removal of the cause. Often, supportive therapy with hypotonic saline mouthwashes or specific therapy is indicated.

Xerostomia and Drugs Causing Xerostomia

Relative xerostomia is probably one of the most frequent undesirable effects to oral health, particularly among the elderly. It can be caused by anticholinergics, antihypertensives, antihistamines, antipsychotics, anorectics, narcotic analgesics, anticonvulsants, anti-neoplastics, sympathomimetics, antidepressants, and diuretics (or any volume-depleting agent, such as lithium). Although specific data are not available, it is reasonable to assume that antidepressants are most often involved.

Prolonged use of antidepressant medication can lead to the development of caries via the inhibition of salivary flow. Two major factors contribute to the development of dental caries, i.e. the rate of acid formation from residual food in the mouth and the rate of dilution or destruction of that acid. Saliva secreted by the parotid, submaxillary, and sublingual glands and the numerous smaller minor glands found in the oral cavity dilutes, buffers and neutralizes the acid formed in the decay process. It also washes or enzymatically debrides the plaque that binds these acids to the tooth structure.

Viscosity of the saliva is directly related to salivary flow. As salivary flow decreases, the saliva becomes more viscous, reducing its bathing and cleansing ability. Concurrently, the number of dental caries increases significantly.

The antidepressants cause dry mouth by peripheral cholinergic blockade. Zimelidine and nomifensine decrease salivary flow in humans only slightly at recommended therapeutic doses, but an increase in dose may reduce salivary flow further. Imipramine and mianserin affect salivary flow moderately, while maprotiline, nortriptyline, clomipramine, imipramine and amitriptyline have a pronounced effect. Some of the newer antidepressants, not yet introduced in the U.S. market, are claimed to have no effect on salivary secretion.

Treatment of antidepressant-induced xerostomia includes administration of sugar-less hard candy or lozenges which serve to stimulate salivary flow in patients whose glands are still functional. Some clinicians may choose to alter the original prescription and either reduce the dose or change to an antidepressant with less anticholinergic properties (for example trazodone or nomifensine), although questions have been raised about their lack of anticholinergic effect when they are used in high doses. In severe cases, oral pilocarpine 2.5–5 mg three times daily before meals has been effective.

There is now an alternative approach possible, which is helpful in many cases. An artificial saliva substitute is now available which has been claimed to be an improvement over conventional rinses or lozenges because of longer duration of action and convenience of use. Contrary to the older oral rinses, which were mainly based on glycerine, the newer preparations contain methyl cellulose and are buffered with sodium or potassium chloride. However, some patients still complain that these preparations do not have an acceptable taste and some are expensive. However, unless the drug responsible for xerostomia can be replaced, symptomatic treatment is best achieved with these artificial saliva preparations.

It needs to be emphasized that drug-induced xerostomia may not only be responsible for dental caries, but also for difficulty in mastication and swallowing (which may lead to reduced food intake, subclinical malnutrition, and less resistance to disease and stress, particularly among the elderly), and talking. Other clinical consequences may involve ascending infections of the major salivary glands and traumatic injury to the dry oral mucous membrane. In view of the serious medical consequences which may be caused by xerostomia, Table II lists drugs which may induce that condition.

Drugs Increasing Salivary Secretion

Drugs may also cause an increased salivary secretion. All drugs that have a cholinergic effect may be

TABLE II
Drug-Induced Xerostomia

Antihistamines
Antihypertensives
Anti-Parkinson drugs
Antispasmodics
Atropine
Barbiturates
Bronchodilators
Clonidine
Cough and Cold preparations
Cytotoxic agents
Lithium
Phenylbutazone
Psychotropics
Scopolamine
Tri-iodothyronine

involved. Salivary secretion-increasing drugs (sialogogues) act either directly on parasympathetic receptors (e.g. pilocarpine), or inhibit the action of cholinesterase (e.g. neostigmine), thus preventing the normal removal of acetylcholine.

It is well to remember that some of the older agents, such as mercurial salts, iodides, and bromides may also cause ptyalism (sialism, "spitting"), a well-known phenomenon since the iodides are also used as expectorants.

TABLE III
Drugs Affecting Salivary Glands

Adrenergic blocking agents
Clonidine
Cytotoxic agents
Guanethidine
Lithium carbonate
Methyldopa
Nitrofurantoin
Oxyphenbutazone
Phenylbutazone
Sulfisoxazole
Trimipramine
Warfarin sodium

Drugs Causing Parotid Pain

Clonidine, guanethidine, and methyldopa are some of the antihypertensive drugs that can cause parotid pain. The mechanism of action has not yet been elucidated and remains uncertain. It has been suggested, though, that the pain may be caused by the central action or the adrenergic blocking activity of the drug involved, which would cause excessive hyperemia, i.e. it would bring an excessive amount of blood to the area and cause congestion in the gland which is deprived of normal vasoconstrictor action by the drug.

A Condition Resembling Mumps

A condition resembling mumps has been associated with the administration of phenylbutazone, oxyphenbutazone, iodides, insulin, isoproterenol, methyldopa, warfarin, phenothiazines, thiouracil, thiocyanate, potassium chloride and sulfonamides. At times, the disorder is accompanied by signs and symptoms of acute sialadenitis (inflammation of the salivary gland) and xerostomia. Withdrawal of the offending drug usually resolves the problem.

Dysgeusia, Hypogeusia, Ageusia

A number of drugs can give rise to altered taste sensation (dysgeusia), diminished taste perception (hypogeusia), or complete loss of taste (ageusia). Indeed, the National Institute of Aging recently reported that 30 percent of elderly patients receiving drugs complain of these problems. Those reporting the problems are usually women.

D-penicillamine, griseofulvin, phenindione, metronidazole and the oral hypoglycemic agent phenformin are most often mentioned among the more commonly prescribed drugs causing these problems. Here, too, the mechanism of action is not yet clear. However, the effects of drugs on taste may be mediated by their actions on trace metals such as copper, zinc, and nickel. Most often, the problem mandates withdrawal of the drug, although the hypogeusia induced by D-penicillamine often resolves when the drug is continued.

Drugs and Candida Albicans

The normal oral microflora may be disturbed either by a direct action of drugs in the oral cavity or indirectly by systemically administered drugs which render the patient more susceptible to other primary infections.

Corticosterosis, administered via inhalers, may permit Candida albicans to become established in the oral cavity presumably because of drug-induced suppression of local immunological mechanisms. Among the psychotropics, chlorpromazine, other phenothiazines, and imipramine have also been associated with an increased incidence of Candida albicans of the mouth.

Antibiotics and Oral Disease

Theoretically, all antibiotics are able to eliminate bacteria that normally compete with yeasts for nutrients. Such alterations in the microflora would then lead to yeast overgrowth and subsequent infection. If an antibiotic is desired as a mouthwash, one should take into consideration that it could cause acute oral candidosis. To prevent this from happening, the antibiotic should be combined with an antifungal agent.

Black hairy tongue is an overgrowth of chromogenic

TABLE IV
Drug-Induced Discoloration, Erythema, Fixed Eruptions, Glossitis, Stomatitis, Ulceration*

Ampicillin	Gold compounds
Anticoagulants	Indomethacin
Aspirin	Meprobamate
Barbiturates	Phenolphthalein
Captopril	Phenylbutazone
Chloral hydrate	Salicylates
Chlorpropamide	Sulfonamides
Chloroquine	Tetracycline
Cytotoxic agents	Zomepirac
Doxepin	

* May involve lips, palate, tongue

micro-organisms enmeshed in hyperplactic filiform papillae. It has been observed to appear following the use of antibiotics, particularly tetracycline or chlorhexidine used in the form of a mouthwash. If candidosis has complicated drug therapy, the disorder usually resolves as the oral microflora returns to normal following withdrawal of the offending drug. In some cases, though, the candidal infection may persist. The clinician must then consider the use of antifungal therapy. Most often used is amphotericin B or nystatin, the latter agent in the form of an ointment.

Cytotoxic Agents and Oral Disease

The use of cytotoxic drugs is increasing. Even in therapeutic doses, their use can lead to a wide variety of side effects, of differing severity. These agents interfere with cell division (the property on which their therapeutic effect is based) but do so, unfortunately, in an indiscriminate manner. Thus, they are capable of causing many clinically serious oral disorders. These include generalized inflammatory changes of the gingival and oral mucous membrane, ulceration, erythema multiforme, lichenoid reactions, vesiculogullous lesions and xerostomia. Thus far, unfortunately, only supportive measures are available to the clinician in the management of these problems. These consist of increased oral hygiene using soft toothbrushes and frequent rinsing with hypotonic saline mouthwashes. Antibacterial mouthrinses are indicated when mucosal ulceration is present.

Immunosuppressive Agents and Oral Disease

The use of immunosuppressive drugs is rising. Oral lesions have been reported following the use of immunosuppressive drugs, such as the corticosteroids. Candida albicans and herpes virus (non-genital) type 1 are two opportunistic micro-organisms which most frequently take advantage of immunosuppression which leads to a depressed defense mechanism. Elderly hospitalized patients and residents in nursing homes, who often suffer from protein-calorie malnutrition, would be particularly at risk, since this condition even further depresses their defense mechanism.

Drugs that Disturb Hemopoiesis and Oral Disease

Similarly, drugs that disturb hemopoiesis (the formation and development of blood cells) such as cytotoxic drugs, antimicrobials, analgesics, anticonvulsants, diuretics, antirheumatic agents, phenothiazines, and antithyroid agents can have secondary oral effects.

TABLE V
Drug-Induced Leukopenia and Neutropenia*

Barbiturates	Quinine
Chloramphenicol	Sulfonamides
Phenothiazines	Thiouracil
Phenylbutazone	Tolbutamide
Pyribenzamin	Trimethadione

* May result in non-specific inflammations, ulcerative lesions

TABLE VI
Drug-Induced Erythema Multiforme*

Barbiturates
Carbamazepine
Chlorpropamide
Clindamycin
Meprobamate
Penicillin
Phenylbutazone
Phenytoin
Rifampin
Salicylates
Sulfonamides (long-acting)

* In serious cases, vesicles or bullae appear in the mouth

Agranulocytosis, a primary side effect of these drugs, can present with severe necrotizing ulcers of the buccal mucosa due primarily to lowered resistance to infections. In aplastic anemia with pancytopenia, the mouth can be the site of serious infective and hemorrhagic disorders.

Drug-Nutrient Interactions Resulting in Oral Disease

The possibilities of drug-nutrient interactions, with resultant depletion of nutrients, are increasingly being recognized. The elderly patient would be particularly at risk to these interactions. Subclinical malnutrition and chronic drug therapy, which may be the cause of further nutrient depletion, are thought to be wide-spread among the elderly.

The risk to the elderly is heightened because they suffer from multiple pathology, which in itself can induce nutritional deficiencies. Elderly also often have marginal food intake, still increasing the risk to drug-nutrient interactions.

These interactions can occur at many different physiologic sites. Unquestionably, these are complex interactions in many cases. For example, it has been proposed that vitamin B_{12} is required for methionine synthesis and methionine is a key source of single carbon units for formate synthesis. Formate, in turn, is necessary for the formation of formyltetrahydrofolate and the folic coenzyme, folate polyglutamate. Interruption of this chain would then compromise folate levels.

Secondary oral effects are seen in vitamin deficiencies, which may be drug-induced (Table IX). Riboflavin deficiency, possibly induced by chronic use of antitubercular drugs in patients with subclinical malnutrition,

TABLE VII
Drug-Induced Lupus Erythematosus Involving the Oral Mucosa

Gold salts
Griseofulvin
Hydralazine
Isoniazid
Methyldopa
PAS
Penicillins
Phenylbutazone
Procainamide
Streptomycin
Sulfonamides
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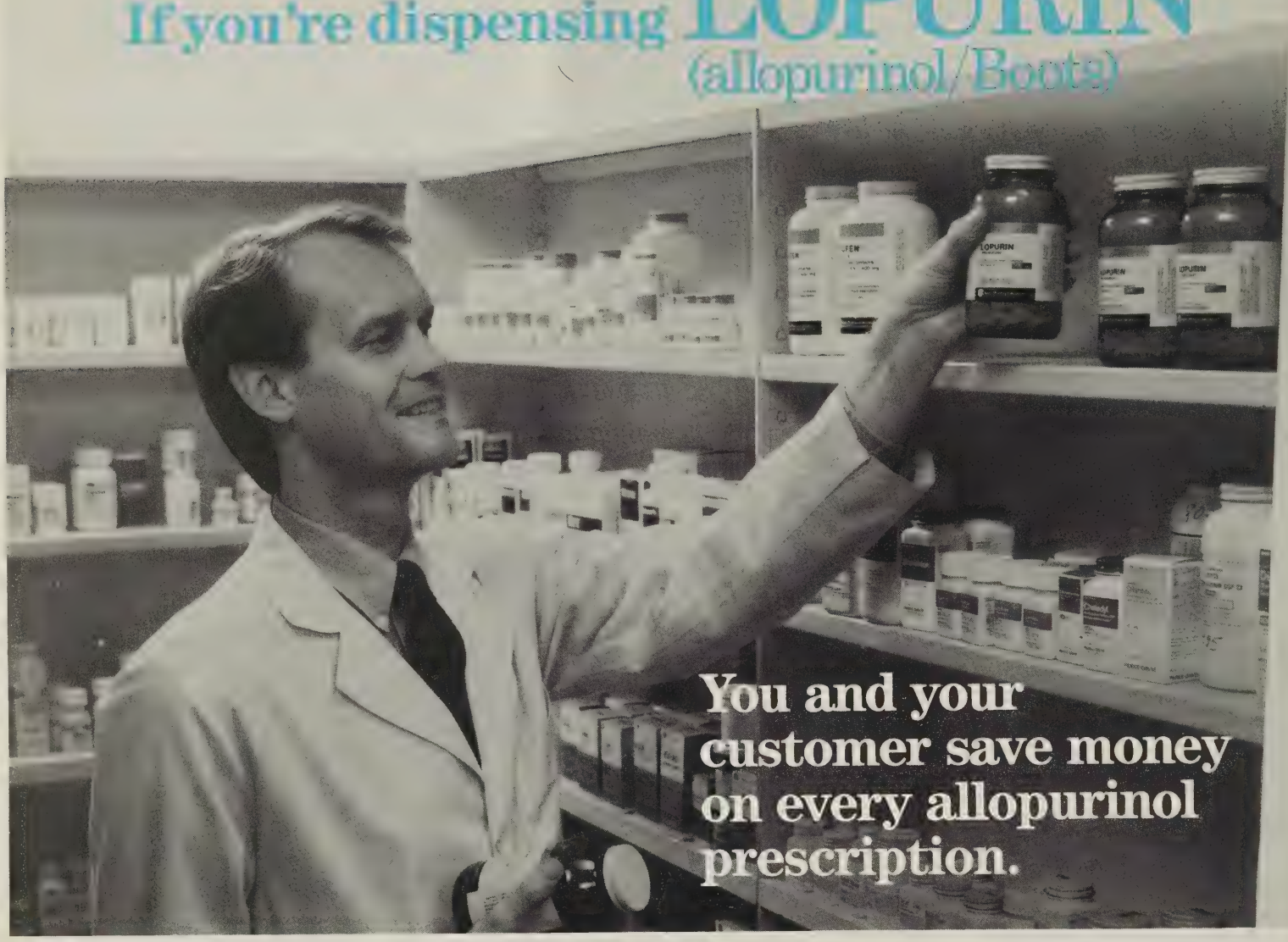

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and pyridoxine deficiency both have been associated with cheilitis, atrophic glossitis, and musocal ulceration.

Phenytoin and Gingival Hyperplasia

The most frequently reported drug-induced adverse effect on oral health is probably phenytoin-induced gingival hyperplasia. The use of phenytoin, too, is increasing, the drug now not only being used as an anti-seizure agent but also as an anti-arrhythmic agent. Phenytoin-induced gingival hyperplasia affects the fibrous connective tissue of the attached gingiva. Here, too, the mechanism of action of this adverse effect is not yet understood.

Anticoagulants predispose patients to the formation of petecheal hemorrhages or purpura of the oral mucosa following trauma.

Erythema Multiforme

Many drugs are associated with involvement of the oral mucosa in erythema multiforme, among them tetracycline, penicillin, clindamycin, sulfonamides, salicylates, barbiturates, phenytoin, and carbamazepine. Large areas of the oral mucous membrane can be sloughed off following the formation of vesicles of bullae at a subepithelial level. About 25 per cent of patients manifest intraoral lesions (ulceration and gingivitis) in drug-induced discoid lupus erythematosus. Drugs implicated are hydralazine, procainamide, phenytoin, isoniazid, methyldopa, primidone, and thiouracil.

A number of drugs can cause intraoral lichenoid reactions characterized by irregular ulcers covered with a fibrinopurulent exudate in any of the oral mucosal surfaces.

TABLE VIII
Drug-Induced Trigeminal Nerve Neuritis*

Antibacterial drugs
Beta blockers
Hydralazine
Hypoglycemics, oral
Tricyclic antidepressants

* Numbness, tingling or burning of face or mouth

The Elderly and Drug-Induced Oral Mucosal Problems

The oral mucosa changes a great deal with aging, and oral pathology is frequent among elderly patients. As many as 50 percent of the elderly experience painful traumatic lesions of the oral cavity, which may be ulcerative, atrophic (lichen planus) or hyperplastic (31).

Why are the Elderly More at Risk?

Several reasons can be cited to explain this high incidence of problems. In post-menopausal women, for example, decreased secretion of hormones may lead to atrophy of the oral mucosa. A deficiency of insulin, relatively common among the elderly, can decrease vascular supply and salivary flow. The oral mucosa is then more susceptible to disease, a problem that can further be exacerbated when patients receive corticosteroids, particularly over long periods of time. This would increase patient risk to bacterial, fungal, or viral infections. Oral candidiasis, for example, may be precipitated by corticosteroids, antibiotics, cytotoxic agents, and immunosuppressive therapy. Moniliasis may follow, which occurs more frequently in elderly than in younger people. It is seen most often on the underside of the tongue, the floor of the mouth, mucobuccal fold, and soft palate.

TABLE IX
Drug-Induced Vitamin/Iron Deficiencies

Deficiency	Drug(s) Causing	Oral Manifestations
Iron	Aspirin	Glossitis, dysphagia, mucosal atrophy, ulcerations Predisposes to hyperkeratotic lesions which may become malignant Monilial infections
Folic acid	Alcohol Anticonvulsants Antituberculars Aspirin Triamterene	Glossitis
Niacin	Antituberculars	Lesions of tongue and oral mucosa Raw, beef-red tongue
Riboflavin	Antituberculars	Angular cheilitis, characteristic split tongue, burning of oral tissue
Vitamin C	Aspirin	Gingivitis (elderly males?) Reduced penetrability of oral mucosa

* Long-term administration of drugs to nutritionally depleted elderly may induce vitamin deficiencies.
Long-term salicylate administration may induce iron-deficiency anemia by inducing gastro-intestinal bleeding.

Any drug that can impair the clotting mechanism, including aspirin, may cause spontaneous bleeding (gingival hemorrhage) following tooth brushing or even eating.

Cytotoxic drugs used in the treatment of cancer may cause ulcerative stomatitis, mucositis, and ulceromembranous gingivitis. There may be lingual or labial edema, soreness of tongue, and a generalized burning sensation. Alveolar bone resorption may also occur. The risk of cell damage and mycotic infections increases with addition of corticosteroids and antibiotics to the cytotoxic regimen. It also places the patient at greater risk for acute exacerbation of pre-existing periodontal disease.

Twenty percent of the elderly complain about dry mouth. It can be caused by mouth breathing, decrease of salivary flow with age, drugs with anticholinergic action, drugs that cause volume depletion, and diseases of disorders such as depression, anemia, diabetes, or nephritis.

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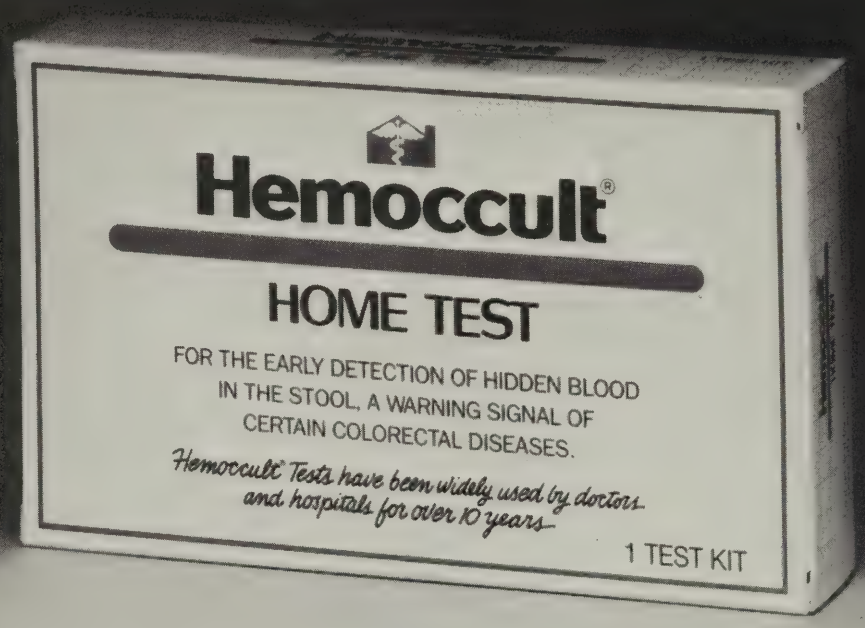

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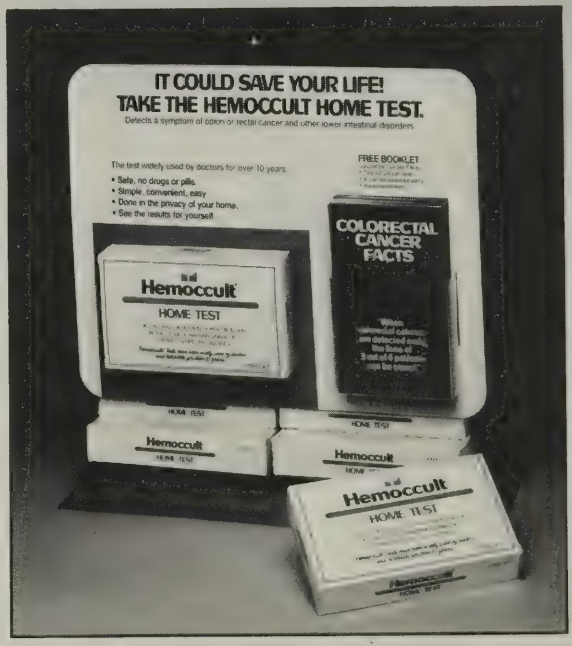

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Pain and salivary glands may also be drug-induced, sometimes occurring after administration of one tablet only (33), in this case, nitrofurantoin. The parotid and submandibular glands are often involved. There may be involvement of the thyroid and angioedema of the eyelids.

Clinical Approach to Drug-Induced Oral Lesions

Dentists must develop a high "Index of Suspicion", since many oral lesions closely resemble various naturally occurring diseases, which poses difficulties in the differential diagnosis.

When a lesion is suspected to be drug-induced, withdrawal of the offending drug is indicated. This, of course, would mandate full consultation between dental and medical practitioner, as it is sometimes not possible to change the patient's therapeutic regimen. In the latter case, individualized supportive treatment must be devised to insure that adverse effects, both localized and systemic and an overall adverse effect on the patient's general health status are minimized to the extent possible.

Summary

Unwanted and undesirable drug-induced oral disease may be induced directly or indirectly. In the latter case, drugs may deplete patients, already suffering from subclinical malnutrition without any overt signs, of further nutrients, and the resulting deficiency may present in the form of oral lesions.

Adverse drug effects, presenting as oral lesions, may lead to increased health problems if left untreated. Almost all classes of drugs, particularly those used chronically, are known to be able to cause drug induced oral disease.

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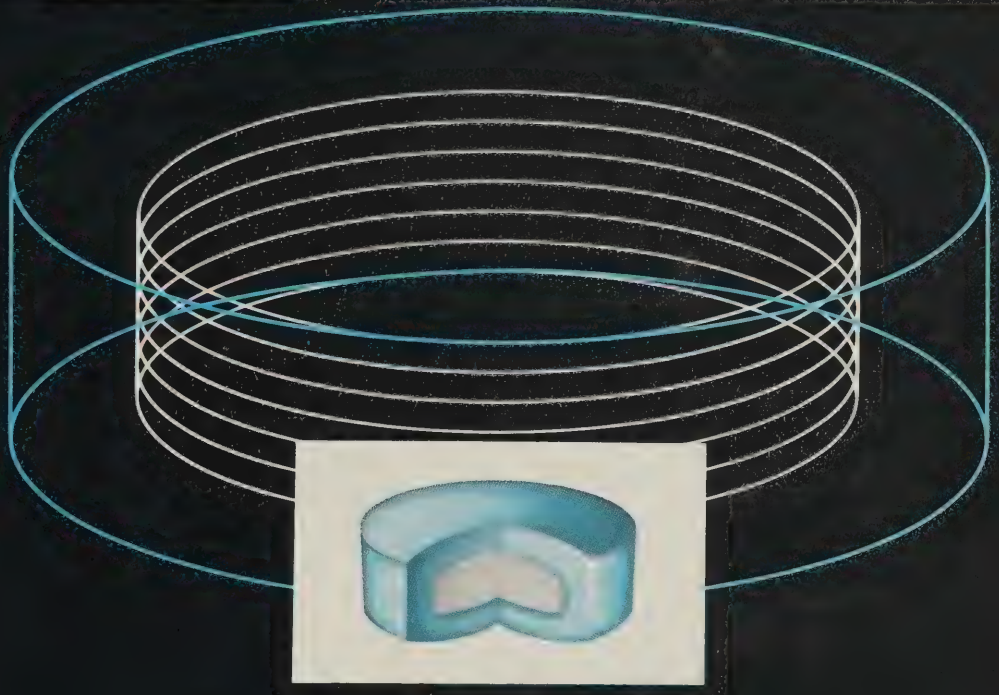

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Before prescribing, please consult brief summary of Prescribing Information on next page.

126-7849-A

This and That About Pharmacy

by Leon Weiner

Attention: All Clipper Pills (Examples are Ronald Maggitti, Tony Petralia, Ray SienKelewski, Greg and Ted Sophocleus, Stanley Protokowicz and Willy Weiner). All of the above and many other are registered pharmacists who had the great pleasure of attending Patterson Park High School. After much consideration, it has been decided to have an informal meeting of all Patterson and Pharmacy graduates at Jack's Corn Beef Deli, Sunday September 16, 1984 at 1:00 p.m. Please put the date on your calendar at once and call any friends who also are graduates of both schools. Contact person is William Weiner, Director Merchandise Marketing for Spectro Drug-phone 301-485-8100. The meeting will be at Jack's located at Lombard & Central Ave in Baltimore City.

Eugene R. Balcerall, University of Maryland 1953, is a very happy supervisor for Rite Aid Drug Company these days. And why not? His attractive daughter, Kathleen Theresa, a recent University of Maryland Pharmacy graduate, is now engaged to be married to Jeffery Alan Hamilton.

Where is Marvin? Marvin L. Edell, University of Maryland Pharmacy School 1956. Fled the Baltimore scene and is now relocated in the Ocean City area. We understand he is working in a pharmacy in Berlin, Maryland. Hope he gets to enjoy some of the water and sun.

Phillip Weiner, University of Maryland Pharmacy School 1961 visited Israel with his family recently. While there, he commemorated a grove of trees in Martyr's Forest in memory of his late father, Sol Weiner, University of Maryland Pharmacy School 1934.

Note: Effective July 1, 1984 Exempt preparations (Schedule 5) will require prescriptions for the entire state of Maryland. Before that time, exempts could be legally sold in Maryland without a Prescription with the exception of Baltimore City and Baltimore County.

Dick Crane, University of Maryland School of Pharmacy 1950, will retire May 31, 1984 as a Drug Inspector for the Maryland State Dept. of Health. Prior to this job, Dick worked for many years as a Geigy Drug Detail Man. Good Luck, Dick.

It is with deep regrets that we note the passing of Daniel A. Santoni, a retired drug inspector. Mr. Santoini worked 15 years for the State Department of Health before retiring in June 1983. The pall bearers at the funeral, April 18, 84, consisted of all pharmacists who are members of the Division of Drug Control. They were Robert Chang, Richard Crane, Jack Freedman, John O'Hara, Charles Tregoe and Leon Weiner.

The following are new pharmacies which opened up about March-April 84.

Martina's Pharmacy
180 Church Street
Westerport, Md. 21562

Safeway Pharmacy #1415
760 S Crain Highway
Upper Marlboro, Md. 20772

Dart Drug # 278
218 N. Frederick Road
Gaithersburg, Md. 208789

Change of address
Rite Aid #346
5116 Park Heights Ave
Baltimore, Md 21215

The following old Sav A Lot stores are now People's Drug Store.

People's Drug Store #1420
1028 Joppa Farm Road
Joppa, Md. 21085

People's Drug Store
5485 Harper's Farm Road
Columbia, Md. 21044

People's Drug Store #1423
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Summer 1984

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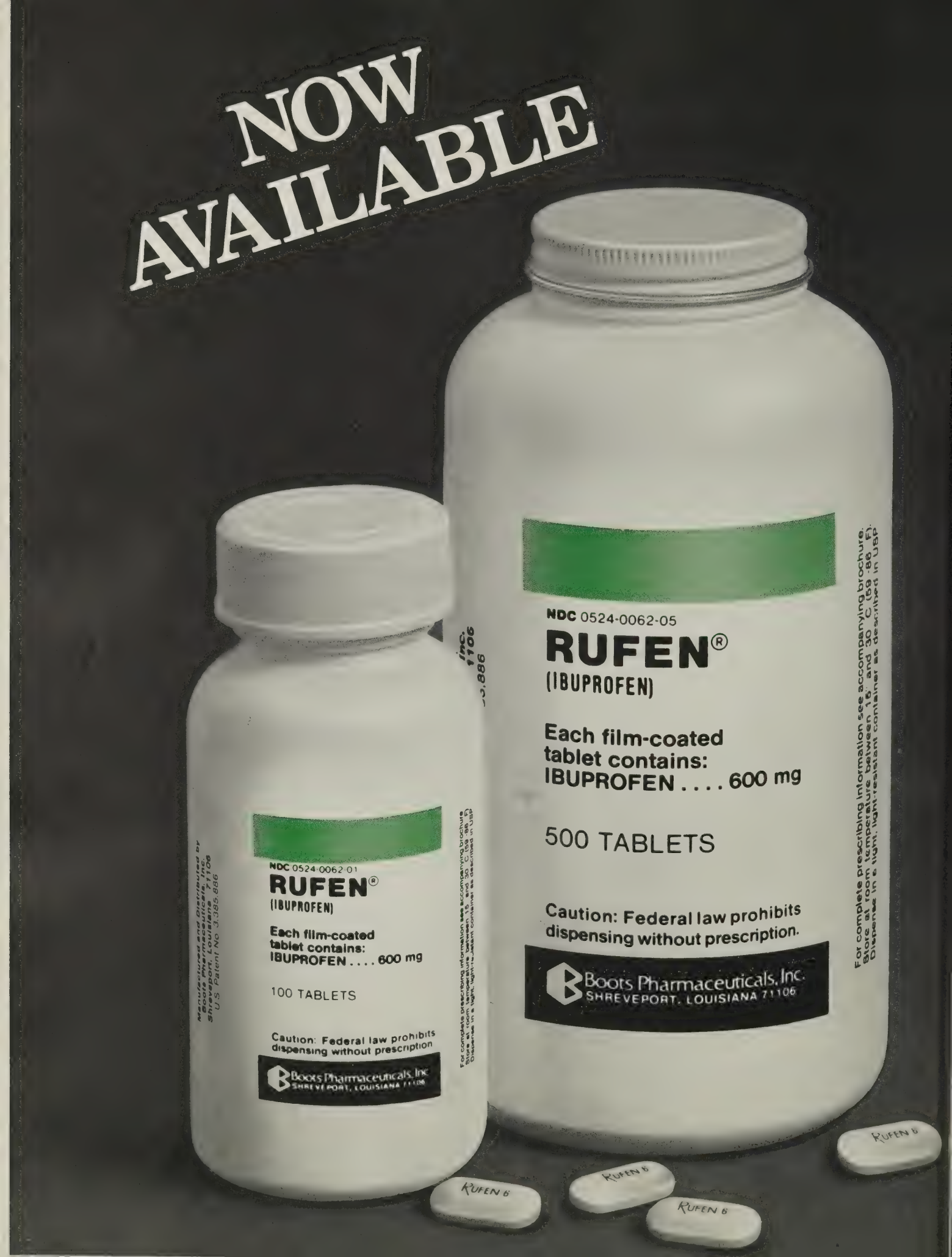
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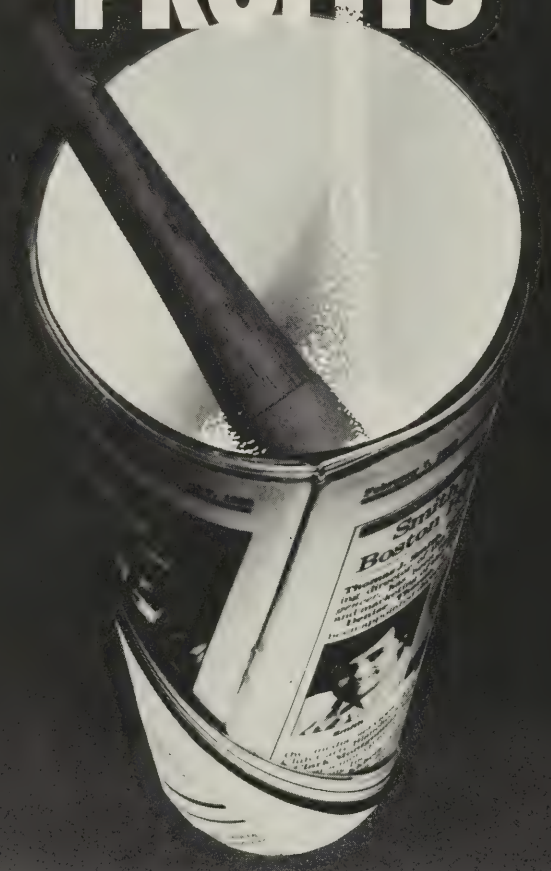

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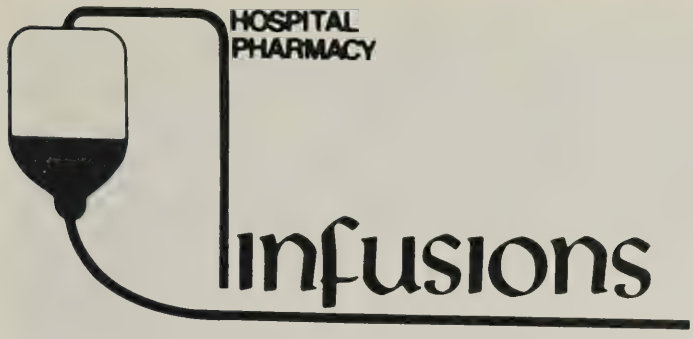

Information contributed by the Maryland Society of Hospital Pharmacists.

Contributor: Stephanie L. Peck
Pharmacy Resident
The Johns Hopkins Hospital

The stability of amphotericin B is dependent upon the variables of pH, composition of solvent, concentration and light. The purpose of this article is to characterize the effect of pH, solvent vehicle, concentration and light on the stability of amphotericin B.

The commercially available 50 mg vial by Squibb (Fungizone® Intravenous) contains 50 mg of amphotericin B, 41 mg of sodium desoxycholate and 20.2 mg of sodium phosphates. Amphotericin B complexes with sodium desoxycholate, a bile salt and solubilizing agent, to form a colloidal dispersion[11]. Phosphates are present to act as a buffer because at pH less than 5, amphotericin B may precipitate out of solution[13].

The amphotericin B colloid is most stable at a pH range between 6.0 and 7.0 in 5% Dextrose and Water (D5W)[11]. The manufacturer has added sufficient phosphate buffer to raise the pH of a D5W bottle with an initial pH 4.2 or greater to a pH greater than 5.0. For the occasional D5W bottle with a pH less than 4.2, 1 to 2 mls of sterile phosphate buffer must be added. (The composition of the buffer is provided in the package insert.) Thus, the manufacturer, to avoid liability, recommends that each bottle of D5W be tested for pH before use. This practice may be impractical because it risks compromising sterility and consumes labor and resources. In major hospitals interviewed by phone this practice is rarely done[5,7].

Amphotericin B is reported by the manufacturer to be soluble in D5W at a concentration of 1 mg/10ml. In general, the drug is unstable in electrolyte solutions,[12,16] resulting in a turbid solution with precipitate within hours. Amphotericin B has been reported to be stable in D5/0.2% NaCl at a concentration of 50mg/L with no significant loss of *in vitro* activity for 8 hours at 23°C.[15] However, the presence or absence of turbidity was not discussed. Clinical reports using amphotericin B as a *bladder irrigant* in the treatment of candidal cystitis have demonstrated that amphotericin B in a concentration ranging from 50 to 750 mcg/ml in Sterile Water for Irrigation has been used successfully with no reports of physical instability of the solution.[17] To date, no specific studies have been published to substantiate the stability of amphotericin B in Sterile Water. The issue arises, particularly in patients on hyperalimentation, whether amphotericin B is stable in Dextrose 10% and Water (D10W). Since clinical studies have not been reported, the manufacturer cannot advocate the use of amphotericin B in D10W.[13]

The manufacturer's recommended concentration for intravenous infusion of amphotericin B is 0.1mg/1.0ml. The Johns Hopkins Hospital Department of Pharmacy adheres to this guideline. There is no published literature to date to support the safety and efficacy of using a more concentrated solution. However, in practice, more concentrated solutions are commonly given to patients who are closely monitored for signs of toxicity. In a recent telephone survey, maximum concentrations of amphotericin B were reported as follows:[1,5,7]

Johns Hopkins Hospital	1mg/10ml in D5W over 4 to 6 hours
National Institutes of Health (NIH)	1mg/kg every other day in 250 to 500 ml of D5W given over 3 hours
University of Maryland Cancer Center (UMCC)	0.6mg/kg/day in 250ml of D5W over 1 to 2 hours
M. D. Anderson	2mg/kg/day in 500ml of D5W over 6 hours

It appears that in practice that solutions more concentrated than the manufacturer's recommendation are administered. However, it is unclear as to whether or not these increased concentrations cause more or less toxicity than more dilute solutions. Carefully controlled clinical studies are necessary to elucidate the maximum concentration of amphotericin B that may be safely administered.

The amphotericin B molecule contains a nonpolar region in which 7 carbon double bonds lie in conjugation. This region is sensitive to photooxidation which results in loss of bioactivity.[14] Indeed, one article reports that the amphotericin B molecule is damaged by wavelengths of light between 380 and 410 nm.[8] Glass IV bottles shield wavelengths of light less than 350nm. Thus, the manufacturer recommends that amphotericin B be protected from light. However, published studies suggest that amphotericin B may be exposed to fluorescent light for up to 24 hours at a constant temperature of 25°C without significant loss of *in vitro* activity.[4] Significant loss of activity is more likely to occur if IV bottles of amophotericin B are exposed to direct sunlight for a period of time.[12]

In conclusion, the stability of amphotericin B is dependent upon pH, composition of the vehicle, concentration and exposure to light. Well-done controlled studies are needed to further characterize these important variables.

References Available on request

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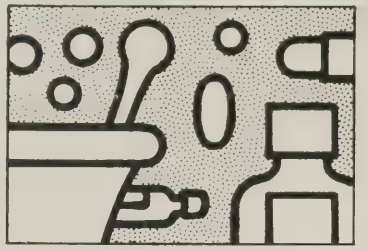
Things You Should Know FOR YOUR GOOD HEALTH



About Your Medicine

When purchasing a medicine, whether over-the-counter (non-prescription) or with a physician's prescription, you may have questions about the best way to take it, possible side effects, and advisable precautions. For instance, some medications make you drowsy, others may tend to keep you awake. Some should be taken with meals while others should be taken on an empty stomach. Below is a listing of the most commonly dispensed prescription medicines, with a few of the major uses as well as common side effects.

1. **Valium** (diazepam) is the most frequently dispensed medicine. Why is this product so popular? At least three reasons exist: (1) It is indicated for problems that seem to trouble many individuals ... tension and anxiety. (2) In spite of frequent news items and feature articles that point to the side effects of this product, it still appears to be relatively safe. Considering the enormous amount of Valium ingested, side effects of a serious nature (when taken as directed) are few. Drowsiness appears to be the most frequent adverse side effect. (3) Valium has several uses in addition to relief of the symptoms of anxiety and tension. It is also indicated as a muscle relaxant, in treatment of certain seizure disorders, and prior to dental, medical, and surgical procedures. Valium must be taken as directed by the prescriber . . . not in excess and it should *not* be taken when alcohol is consumed.
2. **Inderal** (propranolol) is the prototype of the beta blockers which are receiving more and more attention in the news. The drug is very versatile and is commonly used to control or reduce the symptoms of high blood pressure, angina pectoris, migraine headaches, irregular heart beat (arrhythmias), and several other health problems.
3. **Dyazide** is a combination of the diuretics hydrochlorothiazide and triamterene. These two ingredients reduce blood pressure and provide the major use of the combination product. Dyazide is popular because, in many instances, a potassium supplement need not be taken along with it (a common need in some individuals with some diuretic antihypertensives).
4. **Lasix** (furosemide) is a powerful diuretic and is a frequently dispensed medicine for high blood pressure. Potassium supplements are sometimes required with this diuretic (especially if the user is also receiving a digitalis-type medicine such as Lanoxin). Because furosemide is an effective diuretic, it is used in several conditions characterized by edema such as congestive heart failure.
5. **Motrin** (ibuprofen) is a popular drug used in the treatment of pain of a general nature, specifically pain associated with rheumatoid and osteoarthritis. The most commonly reported side effects with Motrin are related to the gastrointestinal tract (nausea, cramps, pain, diarrhea and constipation).

It is important to remember that medicines are complex and may act differently for different people. For complete information about your medicine or its possible side effects, ask your pharmacist.

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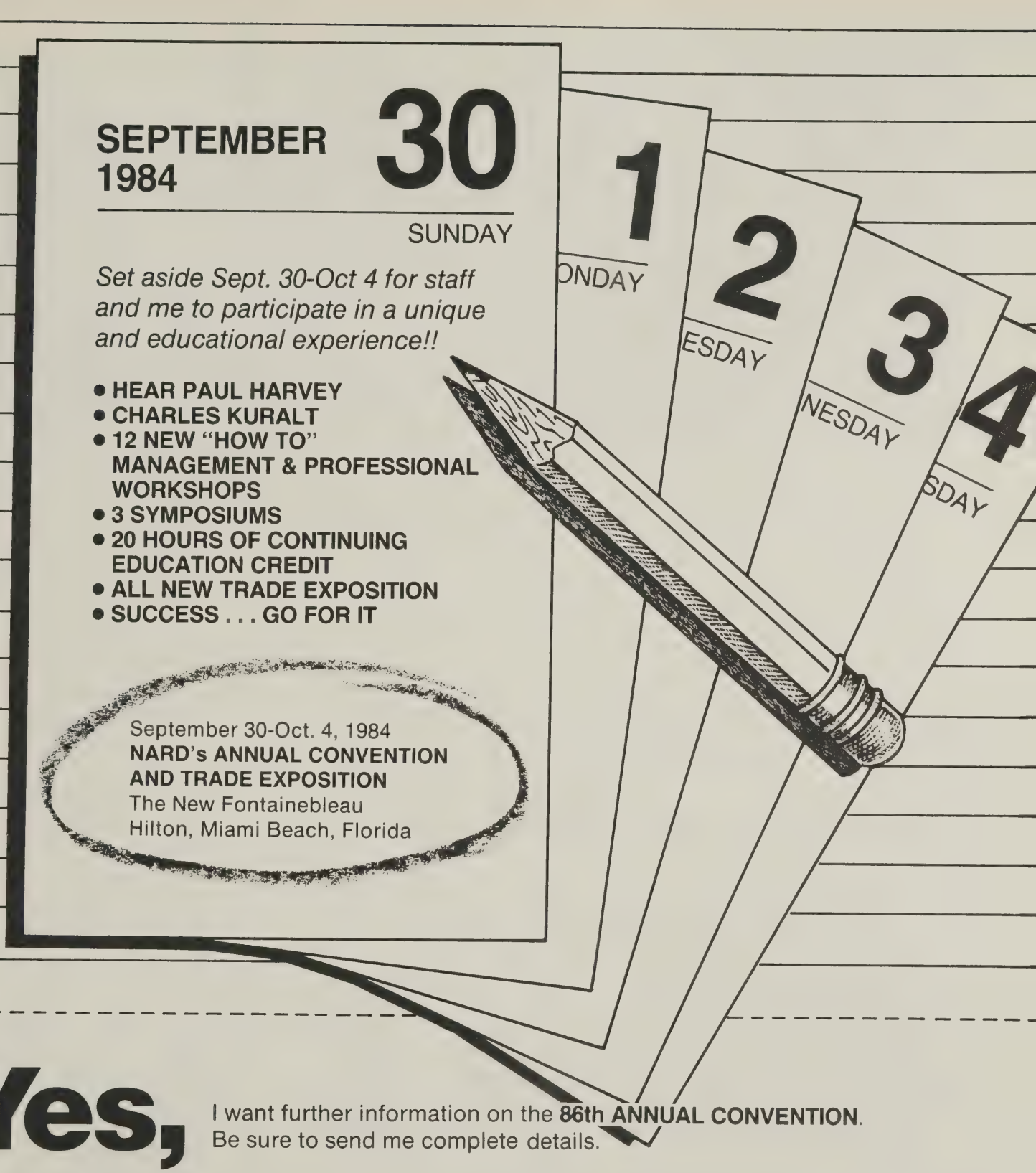

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Mail Order Editorial

by Brian Sanderoff

One of the major concerns facing Maryland Pharmacy today is the recent increased utilization of Mail Order Prescriptions Houses. What will be the long term effects of this new type of practice and will it present any type of benefit to the general public? Several thoughts come to mind.

Let us consider the average customer, Mr. Smith, and let us presume that he has been a regular customer of B & D Pharmacy for several years. Mr. Smith is a union member and has just been offered the opportunity to use their mail order prescription service. To make the offer more appealing, if Mr. Smith mails away his maintenance prescriptions, he will not have to pay the deductable on his prescription card, which is $2.00.

Mr. Smith is a hypertensive currently on Lasix and Inderal. He comes into the pharmacy and states that he forgot he was running out of his medications and neglected to mail in for his refill two weeks before running out, as requested by the mail order house. This situation can put the pharmacist in a precarious position. The pharmacist could call Tallahassee or Hackinsack for a copy but Mr. Smith will have to pay for the call, plus the deductable. He will not be too happy about this. Mr. Smith could keep an extra prescription for just such an occasion, but to keep two prescriptions for the same medication in two different pharmacies is inappropriate. What if Mr. Smith did remember to mail the refill but it was delayed or lost in the mail?

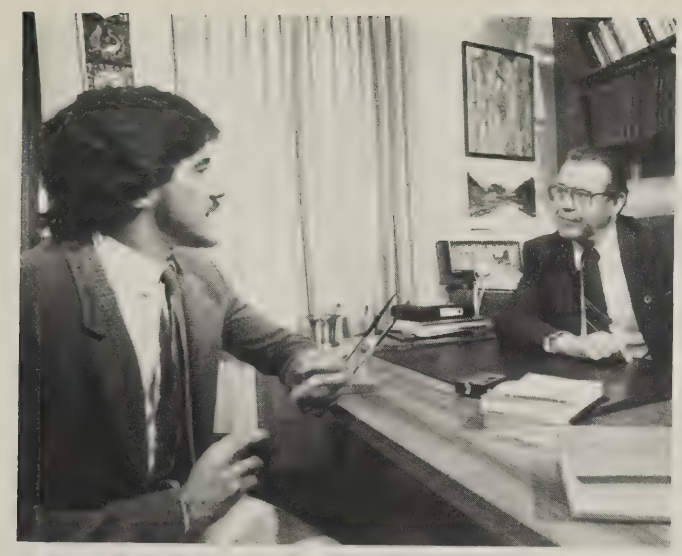
Another related question is how will the pharmacist monitor Mr. Smith's drug therapy. There is a remote possibility that the mail order pharmacy may keep patient profiles (although this does not appear to be the most inexpensive way to operate), but even if profiles were utilized, only his maintenance drugs would be recorded. And if Mr. Smith develops a new disease state, like diabetes, and the pharmacist is totally unaware of it, how can he counsel Mr. Smith on the OTC products he buys. Suppose he now gets Tolinase from the mail order pharmacy and walks into B & D asking for Nyquil (20% alcohol). How will the pharmacist know not to give it to him because of a possible antabuse-like reaction?

What should the pharmacist do when Mr. Smith calls on the phone asking questions about his new conditions or medications. In the past, such information was given freely in exchange for patronage at B & D Pharmacy. Now that he gets most of his prescriptions filled through the mail order service the pharmacist has lost a lot of his business. The pharmacist would not like to eliminate the one service that he is most trained to give but he will require compensation for his time and effort. Should the patient be charged for a consultation every time he asks a question? That doesn't seem appropriate either. Undoubtedly Mr. Smith will have questions concerning the new color and shape of his tablets (generics). The Pharmacist will not call Hackinsack to find out what brand of Furosemide they used to assure Mr. Smith that he was given the correct medication.

The whole question of generics is another source of confusion. We all know the background about generic equivalence and the possible variance between companies. This variance can be significant, especially with the elderly. It is highly probable that the mail order houses are going to use generics wherever possible. However will the pharmacist check to see if a patient is already stabilized on a certain brand? Or a better question may be will the pharmacist be allowed to use this professional judgement at all? Also, concerning generics, how are we to insure that the out-of-state pharmacies will adhere to our state formularies and substitution laws.

Should dangerous substance be sent through the mail service? Our Postal Service has shown us that objects can get lost in the mail or put in the wrong hands. Clearly this poses a potential problem. That is why prescription medications are not put in vending machines. After considering all of the possibilities, it appears that there might be a certain type of person perfectly suited for the use of mail order prescriptions without trouble or danger to one's health. This would be a rare person, indeed. He would need to have a perfect memory, a complete library of pharmacy texts, and only suffer from chronic diseases. For all of the rest of us, mail order prescriptions can present a significant danger to our health with little or no apparent benefit.

Brian is a recent graduate of the University of Maryland School of Pharmacy and completed this article while participating in a one month special studies rotation with the Association.



Geraldo Rivera (left), the popular television reporter for the program "20/20," interviewed Dr. Peter Lamy during a visit to the School of Pharmacy in May. The ABC-TV program plans to include a segment on drugs and the elderly sometime during the summer.

David Banta, MPhA Executive Director (right) presents Robert Whitney, Executive Director of the Commerce and Industry Combined Health Appeal, with the Maryland Society of Association Executive's Past President's Award. Whitney had served as MSAE President for two years. Banta is the new President.

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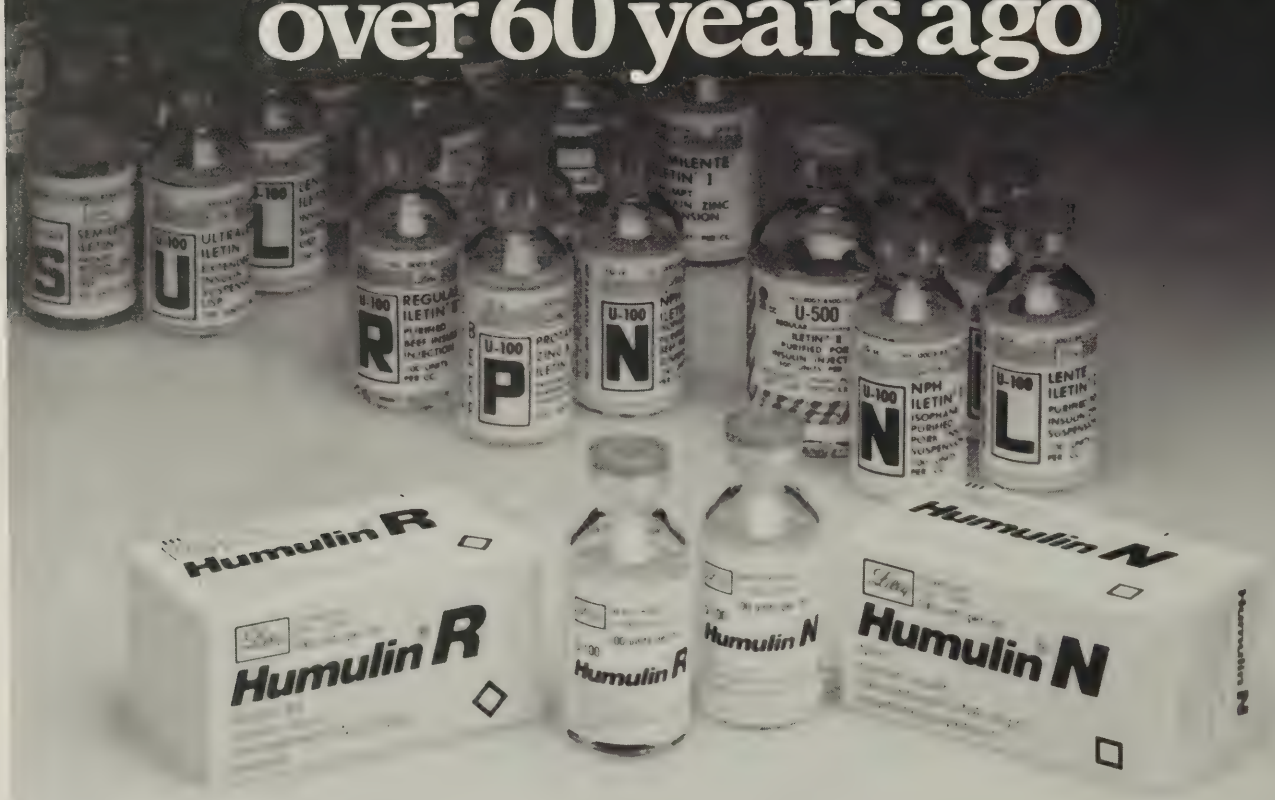

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Dean William J. Kinnard, Jr.; Martin Mintz, President of BMPA; and Elwin Alpern, BMPA Chairman of the Board (left to right), recently toured the Baltimore Metropolitan Pharmaceutical Association Undergraduate Pharmacy Laboratory in the new School of Pharmacy Building. The Laboratory was furnished through a donation to the School from BMPA.

MPhA President-Elect, Madeline Feinberg (center) presents Tai Dang (left) and Dominique Newcomer (right) with $300.00 checks from the MPhA Scholarship Committee. The Annual Scholarship Award is presented to second professional year pharmacy students to help assist them during the PEP summer rotations and they are based on scholarship and need.

William Heller, Executive Director of the United States Pharmacopeial Convention, was the recipient of the Alumni Association's Honored Alumnus Award. The presentation was made May 24th at the Annual Alumni Graduation Banquet honoring the new pharmacy school graduates and the fifty year class of 1934.

Harry Bass (left) receives the Alumni Association's Past President's Award from the new Alumni Association President Melvin Rubin.

ABSTRACTS

Excerpted from PHARMACEUTICAL TRENDS, published by the St. Louis College of Pharmacy; Byron A. Barnes, Ph.D., Editor and Leonard L. Naeger, Ph.D., Associate Editor

CESSATION OF SMOKING AND WEIGHT GAIN:

Patients who stop smoking often complain of an increase in body weight. Studies show metabolic rates are comparable before and after smoking, so general differences in metabolism cannot explain the weight gain. Specific enzyme systems were studied to attempt identification of the cause of this phenomenon. It seems that cigarette smoking induces adipose tissue lipoprotein lipase in some patients. This enzyme is associated with mobilization of fat and is more active during the smoking phase. Cessation of smoking decreases this enzymatic activity in some patients thus causing them to accumulate fat at a greater rate and thus gain weight. *N. Engl J Med,* Vol. 310, #10, p. 614, 1984.

ANTIHYPERTENSIVE THERAPY:

Diuretics have been used to reduce blood pressure for several decades. The mechanism is not well understood, but is dependent on sodium ion depletion since ingestion of excessive sodium can blunt the effectiveness of therapy. Vascular volume is initially reduced, but will return to near normal levels with chronic therapy. Peripheral resistance drops as does blood pressure. Chronic administration of thiazide diuretics can lead to potassium depletion in some patients so investigators have looked for ways to reduce the risk of this electrolyte imbalance. Chlorthalidone (Hygroton) is said to be maximally effective as an antihypertensive agent in doses of 25 mg/day, and higher doses only increase the likelihood of hypokalemia. Hydrochlorothiazide, when combined with a beta-adrenergic blocking agent, can also be used at one-half the regular dose, thus reducing the risk of electrolyte imbalance without sacrificing antihypertensive activity. *Clin Ther,* Vol. 6, #2, p. 198, 1984.

PHENYTOIN-INDUCED ACNE:

For years it has been taught that the use of phenytoin (Dilantin) is accompanied by an increase in the severity of acne. A prospective study has shown that this is not correct and that there is no association between phenytoin use and the severity of acne. *Br Med J,* Vol. 287, #6406, p. 1669, 1984.

ALCOHOLISM:

Alcoholics are susceptible to various gastrointestinal disorders as expected, but a number of extraintestinal manifestations are noted to be present. Evidence recently accumulated suggests that many of the extraintestinal diseases in alcoholics may be due to increased intestinal permeability to otherwise non-absorbable toxins. *Lancet,* Vol. I, #8370, p. 179, 1984.

PRACAINAMIDE:

The use of procanamide (Pronestyl) is associated with the development of anti-nuclear antibodies and subsequent lupus-like reactions in some patients. In addition, common side effects such as nausea, vomiting, diarrhea, psychosis, joint and muscle pain, fever, urticaria, etc. are noted but resolve when the drug is discontinued. Neutropenia is a rare complication. Since procainamide requires administration every three hours in order to produce adequate antiarrhythmic blood levels, sustained release preparations are used to increase patient compliance. Only 17 cases of agraulocytosis have appeared in the English language literature by 1980, but 8 cases have appeared in one institution within 20 months. Patients involved are all taking sustained release procainamide thus prompting investigators to look more closely at the "inert" components of this preparation. *Ann Intern Med,* Vol. 100, #2, p. 197, 1984.

DIVALPROEX:

Valproic acid (Depekene) has been able to produce excellent control of certain types of seizure disorders, but its effect on the gastrointestinal tract is often one of irritation and discomfort. A dimer of valproic acid, divalproex, has been synthesized and prepared as an enteric coated tablet. Using this agent twice daily, patients have found that the seizure control was comparable to that produced by the original formulation but that the gastrointestinal side-effects were much reduced. *Clin Pharmacol Ther,* Vol. 34, #4, p. 501, 1983.

SULPIRIDE:

Some women may not be able to breast feed their infants because of insufficient or erratic milk supplies. Oxytocin has been used in some cases, but a new drug, sulpiride, seems to work very well in this disorder. The drug causes an increase in prolactin levels, the hormone responsible for promoting lactation. Side-effects of this drug on the infant must be studied extensively before it can be recommended for general use. *Am Med News,* Vol. 27, #4, p. 23, 1984.

ETHANOL AND CARDIOVASCULAR DISEASE:

Ethanol has been found to reduce the severity of cardiovascular disease if it is taken in moderation. Some have suggested that the beneficial effects are due to the enhanced concentrations in plasma high-density lipoproteins. Others seem to feel that the protective mechanism is due to the ability of alcohol to inhibit the synthesis of thromboxane A-2 without interfering with prostacycline snythesis in the endothelial cell wall. This

may also help explain the increase in gastric hemorrhage found in patients after bouts of excessive alcohol consumption. *Br Med J,* Vol. 287, #6404, p. 1495, 1983.

ALINIDINE:

Alinidine, a derivative of clonidine, (Catapres) has been used successfully to treat angina pectoris. The drug acts independently of the alpha, beta, or muscarinic receptor. An unidentified direct action seems to be involved. *Clin Pharmacol Ther,* Vol. 34, #6, p. 770, 1983.

MEPTAZINOL:

Meptazinol is an opiate analgesic which is said to selectively stimulate the mu-1 receptor site. Analgesia is produced after administration of the drug, but respiration seems not to be affected. Meptazinol also appears to be void of narcotic antagonistic activity. Perhaps we are getting closer to identifying an agent which is a potent, non-addicting analgesic. *J. Pharmacol Exp Ther,* Vol. 228, #2, p. 414, 1984.

CAT SCRATCH DISEASE:

Cat scratch disease is a painful but benign condition which is often undiagnosed or misdiagnosed. Its etiology was unknown, but was thought to be due to a viral invasion. The condition, also known as non-bacterial lympadenitis, was reported in 1950 but had been recognized prior to that. A person is scratched by a cat (other sources of infection include splinters, fish hooks, etc.) and a pustule develops. A painful swelling of the area lymph nodes follows and complications such as respiratory tract inflammation, nausea and vomiting, chills, etc. may be present. Investigators have found the cause of this disease to be delicate plemorphic Gram-negative bacillus. Researchers are trying to develop a vaccine against it as well as to find an antibiotic which may be useful in controlling the growth of the organism. *JAMA,* Vol. 250, #20, p. 2745, 1983.

ENZYMATIC INDUCTION:

Various drugs produce activation of the endoplasmic reticulum, thus enhancing the metabolic decomposition of various drugs. A new non-invasive technique has been found which can evaluate the status of a patient suspected of having experienced enzyme induction. The method involves measurement of a urinary metabolite of cortisol, an endogenous substance metabolized by this system. *Clin Pharmacol Ther,* Vol. 34, #6, p. 818, 1983.

OSTEOCALCIN:

Osteocalcin is a protein which accounts for 10% to 20% of the non-collagenous protein in the body and is said to play a role in the onset of mineralization and maturation of prepared bone matrix. It is carboxylated via a vitamin K-dependent mechanism to the active form. Neonatologists have noted that phenytoin (Dilantin) and phenobarbital can produce hemorrhage in infants, so they decided to see if these agents might also interfere with bone mineralization. It was concluded that not only did these agents enhance the metabolism of vitamin D which can lead to decreased mineralization of bone, but they may also interfere with production of normal osteocalcin and allow for abnormal bone formation. *Clin Pharmcol Ther,* Vol. 34, #4, p. 529, 1983.

LEUKOTRIENES:

Leukotrienes C_4, D_4 and E_4 are substances formed from arachidonic acid which have potent bronchoconstrictive actions. To study the activity of these substances, an inhibitor is needed. A group of investigators at Smith, Kline and French Laboratories have synthesized an antagonist to these leukotrienes which can block their actions. The substance is an analog of leukotriene D_4. *J. Pharmacol Exp Ther,* Vol. 227, #3, p. 700, 1983.

VASOACTIVE INTESTINAL PEPTIDE:

Vasoactive intestinal peptide (VIP) has been studied extensively in the past, especially in connection with the etiology of pancreatic cholera. Recent information suggests that VIP is not merely a marker of this condition, but is responsible for producing the watery diarrhea associated with pancreatic cholera. *N Engl J Med,* Vol. 309, #24, p. 1482, 1983.

MAD AS A HATTER:

For years, most people have been taught that Lewis Carroll patterned the Mad Hatter in Alice's Adventure in Wonderland after hatters of the day who dipped the pelts into hot mercuric nitrate solutions in poorly ventilated rooms to make the stiff hairs on the pelts more pliable. Another author has suggested that actually Carroll patterned the Mad Hatter after a furniture dealer named Theophilus Carter, a man known for his eccentric ideas and for using a top hat. He invented an alarm clock which simply tipped the sleeper out of the bed to awaken him. It is possible that Carroll used this gentleman as the model for his fictional character and that he was not referring to hatters at all. *Br Med J,* Vol. 287, #6409, p. 1961, 1983.

ETHMOZIN:

Phenothiazine tranqulizers have been noted to have some antiarrhythmic activity. Ethmozin is one such agent which has been shown to have significant effects against arrhythmias and thus was tested to see if it might be a useful agent against these cardiovascular abnormalities. Some of the ventricular effects of ethmozin are similar to those produced by lidocaine (Xylocaine). *J. Pharmacol Exp Ther,* Vol. 227, #3, p. 578, 1983.

URINARY FLOW RATES:

Healthy people generally excrete more urine during the working hours, thus allowing for uninterrupted sleep. Elderly patients excreted proportionally more urine at night, thus accounting for complaints of nocturia and sleep disturbances associated with this subgroup of patients. *Br Med J,* Vol. 287, #6406, p. 1665, 1983.

Do you know a pharmacist who has won this Upjohn Achievement Award?

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Burroughs Wellcome Representative, Donna Lewis (left), is pleased to congratulate Kathryn Fader at Caton AID Pharmacy for being the winner of the BW Pharmacy Education Award.

Management Handbook

—The Upjohn Company is offering a management handbook to pharmacy practitioners. The book, which is available at no charge, provides 12 contact hours of pharmacy continuing education credit.

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The book, *Management Handbook for Pharmacy Practitioners: A Practical Guide for Community Pharmacists,* was funded by a grant-in-aid from The Upjohn Company to the Health Sciences Consortium, which developed the content.

More than a dozen leading pharmacy administration faculty members contributed to the book, which discusses the following: cash flow; business records; advertising; tax considerations; accounts receivable management; inventory; break-even analysis; and nonprescription merchandising and planograms.

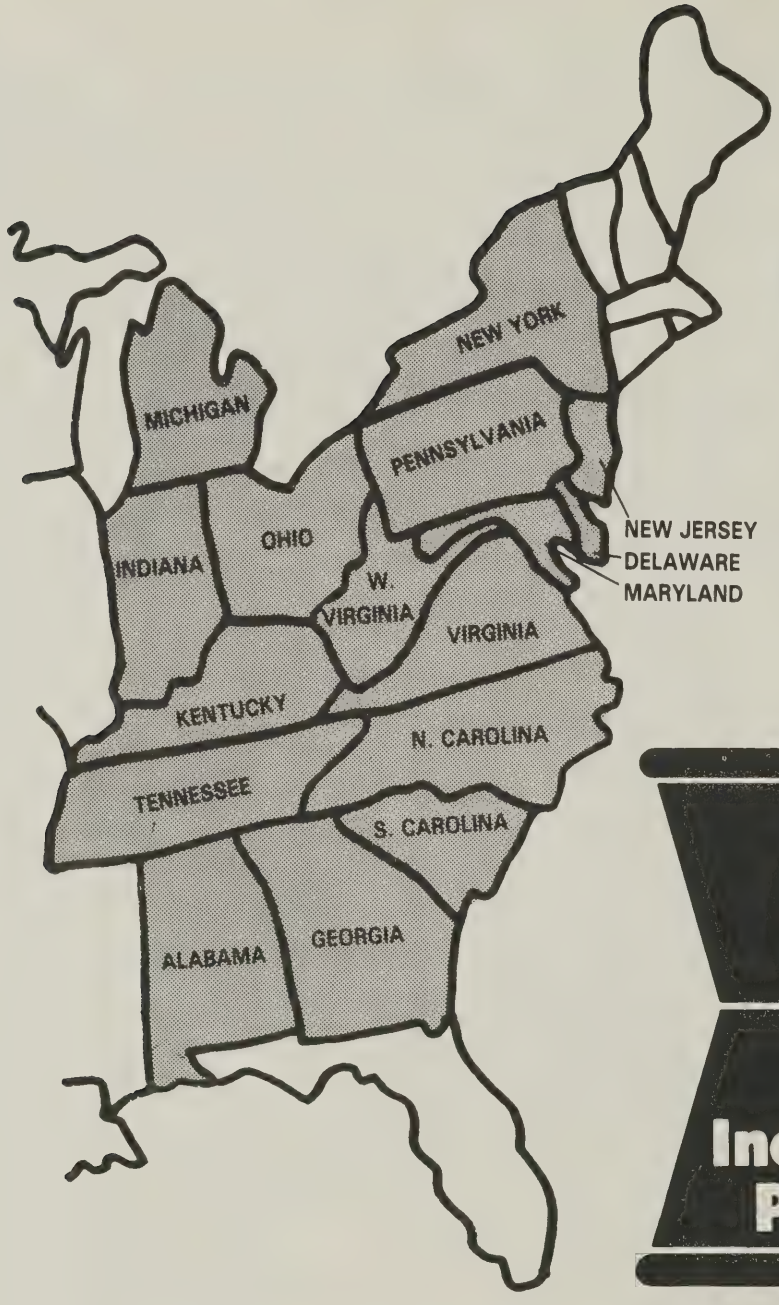
The handbook is available through Upjohn sales representatives or the Maryland Pharmaceutical Association. It is shipped with a post-test which, if the pharmacist wishes may be completed to the Health Sciences Consortium. For a small fee, the Consortium administers all aspects of this PCE program.

Contact the office for the order form at MPhA, 650 W. Lombard St, Baltimore, Maryland 21201.

calendar

Aug 30–Sept. 2—AACP Annual Meeting—Hyatt Hotel, Baltimore, Md.
Aug 30–Sept. 2—Southeastern Pharmacy Education Gathering—Orlando, Fla.
Sept 30–Oct 4—NARD 86th Convention and Trade Exposition, Miami Beach
Oct 12–20—**MPhA TRIP TO PARIS ** SOLD OUT**
Oct 19–27—**MPhA SECOND TRIP TO PARIS—CALL TO SEE IF SEATS ARE AVAILABLE**
Oct 29 (Sun)—**MPhA DINNER THEATER AT OREGON RIDGE**
Nov 11 (Sun)—Alumni Association Annual Dinner Meeting
Nov 16, 17, 18—Virginia Pharmaceutical Association National Symposium on Women in Pharmacy.

Every Sunday Morning at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the Pharmacy Public Relations Program "Your Best Neighbor," the oldest continuous public service show in Baltimore.



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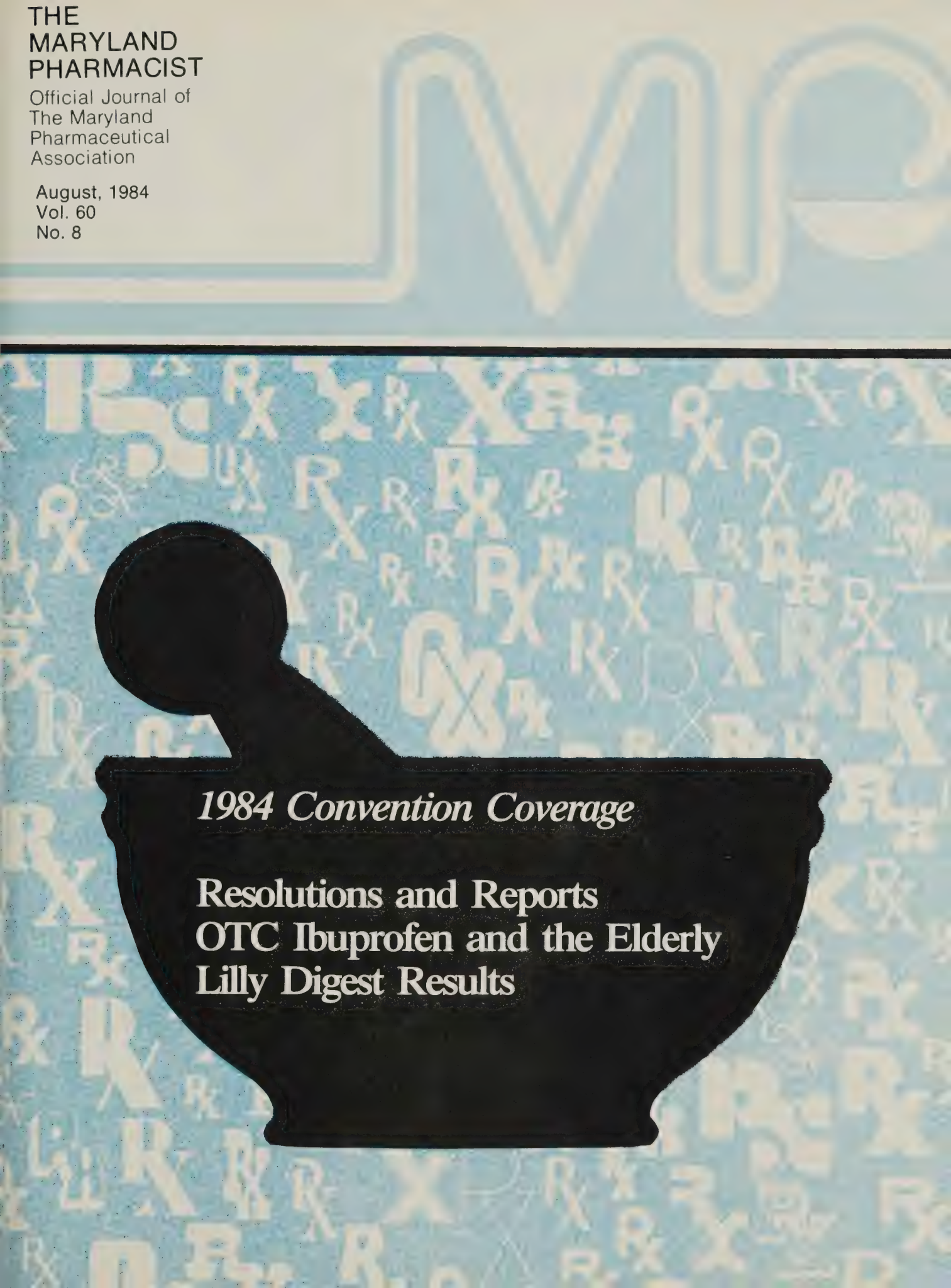

1984 Convention Coverage

Resolutions and Reports
OTC Ibuprofen and the Elderly
Lilly Digest Results

THE MARYLAND PHARMACIST

650 WEST LOMBARD STREET
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TELEPHONE 301/727-0746

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DAVID A. BANTA, *Editor*
BEVERLY LITSINGER, *Assistant Editor*
ABRIAN BLOOM, *Photographer*

Guest Message

We used to talk a lot about the definition of clinical pharmacy. We don't do that very much now. I don't know why. The confusion still exists. Pharmacists frequently use the term clinical pharmacy and Pharm.D. interchangeably. When thinking of clinical pharmacy, pharmacists usually conjer up an image of a long white coat and a pager; a pharmacist who talks to physicians and calculates drug doses. A number of hospitals have hired pharmacists with advanced training in order to have a clinical pharmacy. But unfortunately, in many of these hospitals, clinical pharmacy activities go on vacation with the clinical pharmacist. Clinical pharmacy shouldn't only be practiced by a minority of pharmacists with advanced training.

Back in the days when there wasn't such a thing as a hospital pharmacist (but rather a pharmacist practicing in a hospital) we were learning to refer to the people we served as patients rather than customers. We launched on an era of technical achievement, developing unit dose distribution systems, I.V. admixture services, and drug information centers. We also became more organizationally and politically sophisticated. The pharmacy has risen out of the basement and the Director has become an influential member of the administrative team. All too often, however, our enthusiasm and technical successes have overshadowed the original premise that our focus should be people and their health problems rather than drugs, pharmacology, equipment, and policies and procedures. And this, I believe, is the real essence of clinical pharmacy.

Whether or not someone is a clinical pharmacist is more a matter of practice attitude than a matter of skills, a job description, location of practice or the professional or academic degree one holds. In fact, there are clinical pharmacists all over the state in the least expected practice settings. You and I know them as the pharmacist who thinks nothing of skipping lunch or staying late to locate some information about a prescription; the pharmacist who recognizes the person who needs to ask a question and gives them the opportunity to ask it. We know them as the pharmacist who keeps current professionally by reading late or taking a Sunday away from family and recreation to attend a continuing education meeting. These are the pharmacists who know when a question from a patient or a nurse is unusual and tactfully check into the situation to make sure everything is in order. It is the pharmacist who risks being chastised by a physician in order to raise a therapeutic question. They are the pharmacists who will compound a prescription for a patient who is having trouble finding someone to do it, or who will telephone other pharmacies to help a patient find an unusual medication. This is clinical pharmacy because it focuses on people and their drug needs. It doesn't require special training (no doubt it helps), just a willingness to put oneself out for others.

Clinical pharmacy is a responsibility that we all bear. We need it for the professional satisfaction and pride that it provides. Our public needs it for better health care.

Barry Means

PRESIDENT

Maryland Society of Hospital Pharmacists

Each morning session of the Convention had its traditional "early bird" prize drawing. Here (left to right) Gerry Epley, Mark Golibart, Dave Banta, William Hill and Melvin Rubin kept the prizes rolling.

"Hands on Home Health Care: Beyond DME" was the theme of the Tuesday morning continuing education program presented by (left to right) Michael Gum, Ilene Zuckerman, and William Hawk.

William C. Hill, President of the Maryland Pharmaceutical Association, cuts the ribbon which officially opened the exhibit hall on Monday morning.

Maryland at its

The 102nd Annual

With 29 exhibits, this year's Exhibit program was the largest in recent years. The Association conducted a "Sweepstakes" drawing for a new television for those who visited each of the exhibits.

LAMPA increased its membership during the Convention and conducted a fashion show on coordinating fashion styles and colors.

MPhA Officers and Trustees are shown shortly after the annual banquet are: (bottom row left to right) Chairman of the Board, William Hill; President, Ronald Sanford; President-elect, Madeline Feinberg; Trustee, Norma Schapiro; Executive Director, David Banta; Treasurer, Melvin Rubin; (top row) Honorary President, Joseph Dorsch; Trustee, James TerBorg; Trustee, Stanton Brown; Vice Speaker, Elwin Alpern, Vice President, George Voxakis; and Trustee, Harry Hamet. (Not shown are Trustee, Martin Mintz; Speaker, Lee Ahlstrom; and SAPhA Representative, Ann Hom.)

Pharmacy Best MPhA Convention

Betty Alpern, President of LAMPA (left), presents Bea Friedman with the Honorary President's Award at the Annual Banquet.

Roslyn Scheer, Executive Director of the Board of Pharmacy (right), enjoys the square dance following the Crab Feast with Luigi DeBoni, an exhibitor with Redbook Data Systems.

Out-going President, William Hill (right) congratulates the new "captain of the ship", President Ronald Sanford (left). Exchanging the skipper's hat has become a recent MPhA tradition.

1984 Resolutions Adopted at the Annual Convention June 27, 1984, Ocean City, Maryland

Resolution number One

Whereas, mail order prescription drug plans violate the patient's right of freedom of choice for pharmaceutical services, and

Whereas, every patient has the right to a personal, consulting relationship with the dispensing pharmacist, and

Whereas, it is not desirable for patients to receive medications from separate sources which makes it impossible to monitor drug therapy for drug interactions, adverse reactions and counter indications, and

Whereas, mail order prescription plans located outside of Maryland are dispensing medications to Maryland citizens without a Maryland License and without proper supervision by the Board of Pharmacy, and

Whereas, the Medical and Chirurgical Faculty of Maryland has condemned Mail order prescription drug plans,

Therefore, be it resolved that the Maryland Pharmaceutical Association condemns the practice of mail order prescription drug services as being unprofessional, and

Therefore, be it resolved that the Maryland Pharmaceutical Association develop a public education program to alert consumers to the advantages of community pharmacy practice and the hazards of mail order prescription drug services.

Resolution number Two

Whereas, the increase in the treatment of cancer using multi drug therapy has led to an increase in the number of anti neoplastic agents prepared by pharmacy personnel, and

Whereas, health professionals including medical, nursing and pharmacy have recognized the hazards of handling these agents, and

Whereas, home health care companies are increasingly preparing these agents outside of established institutions and clinics,

Therefore be it resolved that the Maryland Pharmaceutical Association urge all employers to properly protect these employees from the hazards of handling anti neoplastic agents by following guidelines recommended by the American Society of Hospital Pharmacists and other health care organizations.

Resolution number Three

Whereas the profession of Pharmacy has a code of ethics which governs conduct and practice, and

Whereas lie detector tests have proven to be unreliable, and

Whereas lie detector tests represent a personal affront to the dignity and integrity of professionals,

Therefore be it resolved that the Maryland Pharmaceutical Association opposes any attempt by any employer to use the results of lie detector tests as a basis for employment or denial of employment of professionals.

Resolution number Four

Whereas Dr. John Schlegel has been appointed President and chief executive officer of the American Pharmaceutical Association and represents a new era in national pharmacy leadership, and

Whereas the Maryland Pharmaceutical Association, as an affiliated state, has traditionally worked closely with the American Pharmaceutical Association, and

Whereas it is in the best interests of Pharmacy to maintain unity,

Therefore be it resolved that the Maryland Pharmaceutical Association extends its sincere congratulations to Dr. Schlegel and pledges continued support of the American Pharmaceutical Association and its programs.

Resolution number Five

Whereas prescription drug orders are meaningful when created by prescribers on an individual and case by case basis, and

Whereas, the use of the preprinted expression "Dispense as Written" or similar words impinges upon the pharmacists's professional judgement in exercising drug product selection, and

Whereas this practice may place the patient at a disadvantage by denying access to less expensive, quality medications,

Therefore be it resolved that the Maryland Pharmaceutical Association encourages Maryland prescribers to indicate in their own handwriting on a case by case basis the extent to which drug product selection is appropriate.

Resolution number Six

Whereas a prescription orders written by a person licensed to prescribe in the State Maryland should contain all information necessary to enable the accurate dispensing of medication by the pharmacist, and

Whereas many prescription orders are written by prescribers on institutional prescription blanks, such as those available in hospital or community health clinics and

Whereas these prescription orders often do not contain the exact location form where the prescription emanates within the institution (such as the Emergency Room, Outpatient Clinic, Ward or Floor location) and

Whereas a telephone number where the prescriber can be reached is often not indicated, and

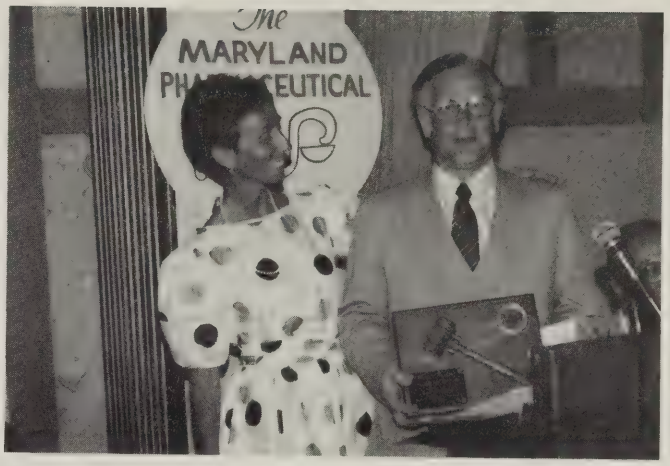
Whereas the prescriber often fails to print his name legibly on the prescription orders in addition to the signature, which is already required by Maryland Law,

Therefore, be it resolved that the Maryland Pharmaceutical Association seek legislation this year to require that the following information be legibly printed on all prescription orders.

1. Location or exact address of prescriber.
2. Telephone number where prescriber or his agent can be reached.
3. Written *and* printed name of prescriber with financial penalty imposed if this information is omitted, and

Be it further resolved that all Maryland Pharmacists assist the Association by forwarding original prescriptions (excluding Schedule II prescriptions and patient identity) to the Association to produce a visual record of the extent and severity of the problem for the members of the Maryland Legislature.

Kathy Gauthier, a Student APhA Delegate, rises to explain to the House of Delegates the background for Resolution number nine, which was submitted and sponsored by the Student Delegation.



Madeline Feinberg, Toastmistress for the Annual Banquet (left), presents Harry Hamet with the Award for the Out-going Speaker of the House of Delegates. Harry presided over both the Convention and the Mid-Year sessions of the House of Delegates.

Resolution number Seven

Whereas, certain patient populations (such as homebound, patients in nursing homes or in correctional institutions, patients receiving radio pharmaceuticals) may require special pharmaceutical services, and

Whereas, current law requires that all pharmaceutical services must be delivered by a pharmacy which offers complete pharmacy services, and

Whereas, there is a need to contain health care costs,

Therefore, be it resolved that the Maryland Pharmaceutical Association support legislation which permits special use pharmacies to meet these patient needs.

Resolution number Eight

Be it resolved that the Maryland Pharmaceutical Association actively pursue through legislative action the institution of continuing education for pharmacists as a requirement for re-licensure.

Resolution number Nine

Whereas pharmacists are the most available source of accurate drug information in the community; and

Whereas, pharmacists are concerned with irrational drug use and abuse in the community, and

Whereas members of the public and particularly parents are becoming increasingly aware of this problem and are demanding accurate information, and

Whereas, the "Pharmacists Against Drug Abuse (PADA)" program has recently been developed by an independent foundation created and funded by McNeil Laboratories for the purpose of providing accurate information on drug abuse to parents in the community through the community pharmacists,

Therefore, be it resolved that MPhA actively support the national Pharmacists Against Drug Abuse Program, and

Be it further resolved that MPhA encourage the active participation of pharmacists in the PADA program.

EXECUTIVE DIRECTOR'S REPORT

by
David A. Banta, C.A.E.

In order to prepare for this report each year, I review the minutes from the Board of Trustees, the Committee meetings and my own personal notes regarding the accomplishments since our last convention. My own personal approach to my work is pretty task-oriented. That is, I usually do not dwell on a project once it has reached a conclusion. I guess I have the old "what have you done for me lately" syndrome. But, since this is my only annual report to the membership on the state of the Association from my perspective of as Executive Director, the forced review is very useful for me. I would have to say that we have had a very successful year.

Please take a minute to review the report of the Legislative Committee. This past session may well have been the most productive lobbying effort for Maryland Pharmacists in recent years. We managed to preserve the $.20 Medicaid fee increase—bringing the professional dispensing fee to $3.45—in the face of much uncertainty in the budget process itself and general cut backs in the Medicaid budget. We repealed the poison register, put the exempt narcotics on prescription, passed the emergency prescription refill bill and changed the state CDS registration period to every other year. We accomplished much more, as you can see from the Legislative Committee report and the membership promotion brochure which was developed to highlight these successes.

On a Federal level, I am most pleased to report that the Federal Pharmacy Crime Legislation has been passed by Congress and signed into law by President Reagan. Many organizations worked for the passage of this legislation over an extended period of time. Members of the MPhA testified before a Congressional Committee Chaired by Senator Mathias last Fall on this matter. Making the burglary of a Pharmacy a Federal Crime may help slow the steadily rising rate of violence directed at Pharmacists.

The Association worked very closely with the Medicaid program on the Generic Drug Price Regulations and appeared to have reached a compromise that was acceptable to everyone. Unfortunately, there have been complicated delays in this process and the outcome or even the implementation of state regulations regarding the use of generics under the Medicaid program that includes compensation to the pharmacist provider for associated overhead is in doubt. We have better news with the Association proposed Drug Utilization Review program. The Medicaid program has appointed an internal task force to study our proposal and there appears to be substantial interest. The Department of Health and Mental Hygiene is also currently developing regulations to govern the delivery of Home TPN's in Maryland. The Home Health Care Task Force has been monitoring this activity closely as part of its overall activity in this area. During this past year, the Task Force has also developed a position paper on "The Role of the Pharmacist in Home Health Care" and I urge you to take a minute to review that information which is available at this convention.

Mail order prescription drug programs became a special concern of President William Hill's early in his administration. Shortly after the Ford Motor Company announced its Mail Order plan, Hill wrote to Ford and joined hundreds of Pharmacists nationwide voicing their disappointment at this development. At his direction, the Third Party Committee developed a patient education brochure on this subject as a major Committee project for the year. Copies of this brochure, entitled "Why your Community Pharmacy is the best place to get your medicines," are also available for distribution to the public through the Association.

Membership development is always one of the vital signs of a healthy Association and we have, once again, had a successful year in that regard. The Membership Committee developed several new, specialized membership applications which were mailed to refined non-member prospect lists developed by the Association's Word Processor. The results have been encouraging. Membership totals have been well-ahead of previous years. I anticipate that further refinements in our membership recruitment and retention programs will continue this trend.

This past year saw improvements in the fringe benefit program as well. We offered improved Health insurance programs and a new disability and liability program. Over 160 persons are scheduled to attend the MPhA trip to Paris this Fall—our largest attendance in recent history. The new Mid-Year Meeting format appeared to be a big hit with the membership and this was reflected in the increased attendance at that meeting held in Annapolis.

Personally, I also experienced a year of progress. I completed my year as President of the National Council of State Pharmaceutical Association Executives, during which time the Council released a major study on third party prescription drug plans. I was recently installed as President of the Maryland Society of Association Executives.

Major changes appear to be on the horizon for pharmacy organizations on the state and national level. After twenty-five years, the American Pharmaceutical Association has a new chief executive officer in Jack Schlegel. Those of us who work so closely with grass-roots issues are hopeful that we are on the verge of greater cooperation between all pharmacy organizations and increased sensitivity to the needs of our members.

I wish to thank to Officers and Members of the Board of Trustees for their help and friendship. I am pleased to have been a part of the work and accomplishments of the year just ended. I look forward to continued progress for the Association and its members. Thank you.

Joseph Dorsch (left), receives the Honorary President's Award from out-going President William C. Hill (right) at the Annual Banquet in recognition of Joe's long years of service and many contributions to the profession of Pharmacy in Maryland.

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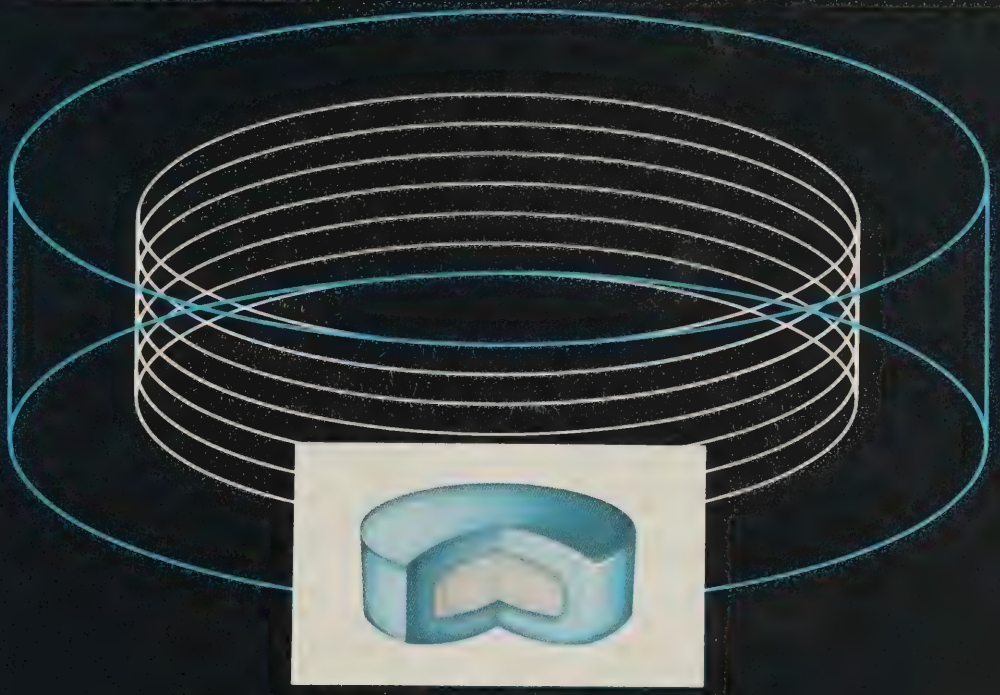

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SCHOOL OF PHARMACY REPORT TO THE MARYLAND PHARMACEUTICAL ASSOCIATION

by
Dean William J. Kinnard, Jr.

This past year has been an exciting one for the School of Pharmacy, not only because of the continuing improvement in its professional education programs, but also because of the strengthening of its graduate programs with the addition of the doctoral degree program in Pharmacy Practice and Administrative Science. In addition, more faculty members are attracting research funding in the basic science and clinical areas. In the latter case, the School has attracted a number of clinical trials in conjunction with the medical school. The public service programs continue to receive national recognition, and the financial support by our alumni and friends of the School have exceeded our goals.

The School is currently going through a planning process as part of the necessary review prior to the arrival of the accreditation team of visitors this coming year. One of the issues that clearly needs discussion is student enrollment—its numbers, as well as the mix of students.

During the early and mid 1970s the enrollment of the School rose as a large number of qualified individuals were available in the applicant pool. The School usually admitted 90 students into the baccalaureate program and 6 students into the doctor of pharmacy program. The number of applicants dropped drastically in pharmacy and all the health professions in the late 70s so that the academic structure of the classes changed. While there was a slight increase in the number of students with 3.5 and higher grade point averages, there was also a large number of students with lower GPAs than the School had usually taken. That change plus the perceived excess of pharmacy school graduates around the country caused the School to change its enrollment mix. The School now admits 80 new students to the baccalaureate program and 10–15 students to the doctor of pharmacy program, the intention being that the market for our graduates should drive enrollment.

It now appears that the chain pharmacy industry is calling for increased enrollments, not only here in Maryland, but all over the country. This comes at a time that the number of applications to the School have also increased. Maryland is a state that imports a lot of pharmacists, only about half of those being licensed each year come from the University of Maryland. To increase or not to increase, that is the question!

A complication to the planning for the School's enrollment is the long range impact of the increased percentage of women entering schools of pharmacy. The 10–15 percent level changed to 50 percent women in classes by 1980. Last year several schools reported enrollments of over 60 percent women. This year our School will admit a class that has 68 percent women. Whether or not that increase is a one year abberation will be determined in future years, but initial estimates indicate that it is not.

Will the increase in women in the pharmacy work force change the work patterns in the profession? Some employers are actively seeking women to work part-time in their pharmacies, since part-time employment doesn't carry with it the same fringe benefit package that is required for full-time employment. While many predict that the total number of pharmacists in the work pool will decrease because women will tend to move in and out of the

work force as family needs require a change, others say that there is, and will continue to be a stable work force.

The School would like to hear from the Association and its individual members on the matter of enrollment. What are, and what will be the real employment opportunities for our graduates?

Maryland Society of Hospital Pharmacists Message

Patricia A. Ensor, President

The Membership, Board of Directors, and Officers of the Maryland Society of Hospital Pharmacists are pleased to bring greetings to your 102nd annual meeting. In years past, this message has been a request for, and a reiteration of the need to combine efforts of our two societies in achieving outcomes to address common needs. Thank to the leaders of both organizations, that relationship has prospered over the years to one of true cooperation, in my opinion. In recognition of someone who has been instrumental in bringing our two group closer, the Board of Directors of MSHP this year presented a special commendation award to Dave Banta, for his significant contribution in this area. On the Tripartite Committee and the Continuing Education Coordinating Council, members of each of our assocations have worked together this year. In addition, the MPhA has donated a page to MSHP in your monthly publication and we sincerely appreciate the opportunity to communicate with your group this way.

I Feel we have made strides together for the profession of pharmacy and I am optimistic that our future leaders will continue these combined efforts and expand them as the need arises.

Tripartite Committee Report

by

Estelle G. Cohen, Chairperson

MEMBERS

Estelle Cohen, Chairperson—Maryland Board of Pharmacy
David A. Banta, Executive Director—Maryland Pharmaceutical Association
Lee Ahlstrom—Maryland Pharmaceutical Association
Melvin Rubin—Treasurer—Maryland Pharmaceutical Association
Harry Hamet—Maryland Society of Hospital Pharmacists
Ralph Shangraw—Professor—University of Maryland School of Pharmacy
Frank Palumbo, Associate Professor—University of Maryland School of Pharmacy
Robert Kerr, Associate Professor—University of Maryland School of Pharmacy

The Committee met twice in 1984. Among topics discussed were:

1. The satisfactory progress of the Pharmacy School's Mental Health Program. Dr. Jan Iwata is director of the project's administrative pharmacy.

2. The University of Maryland's task force has undertaken an extensive review of the PharmD. Program to be completed by the Fall of 1984

3. The School of Pharmacy will undergo an accreditation process by the American Council on Pharmaceutical Education on January, 1985

4. For the first time, the Maryland Society of Hospital Pharmacists is awarding a research grant of $1,500 to one of its members.

5. The State Kidney Disease Program proposed to the Maryland Pharmaceutical Association that State money be used to help kidney transplant patients without means to purchase Sandimmune.

6. The Board of Pharmacy Commissioners have been making PEP visitations at various sites. A report will be sent to the School of Pharmacy regarding these results.

7. Once again, the Board is in the process of writing regulations; including regulations on Computers.

8. Confusion over the interpretation of the Drug Product Selection Law was discussed and solutions are being considered.

9. Current legislative matters were discussed.

10. Drug Control review of the frequency of inspection violations was discussed with emphasis on violations #4 and #32 (please see attached).

11. The Maryland Health Department's proposed Home Health Care (TPN) regulations are receiving much attention by the Committee.

12. The topic of Mail Order prescription drugs is under discussion.

13. HMO exclusive contracts with specific pharmacies is also under discussion.

14. Dispensing doctors whose numbers have greatly decreased in Maryland is under discussion.

15. The Program of inspecting all sites in Maryland where drugs are dispensed is under discussion.

Having merely touched on some of the issues under discussion at the Tripartite Committee meetings, we invite any queries you may have on our work, any suggestion you may have on matters of mutual concern.

We meet again in September. Contact the Board of Pharmacy if you would like information on attending this meeting.

Thank you.

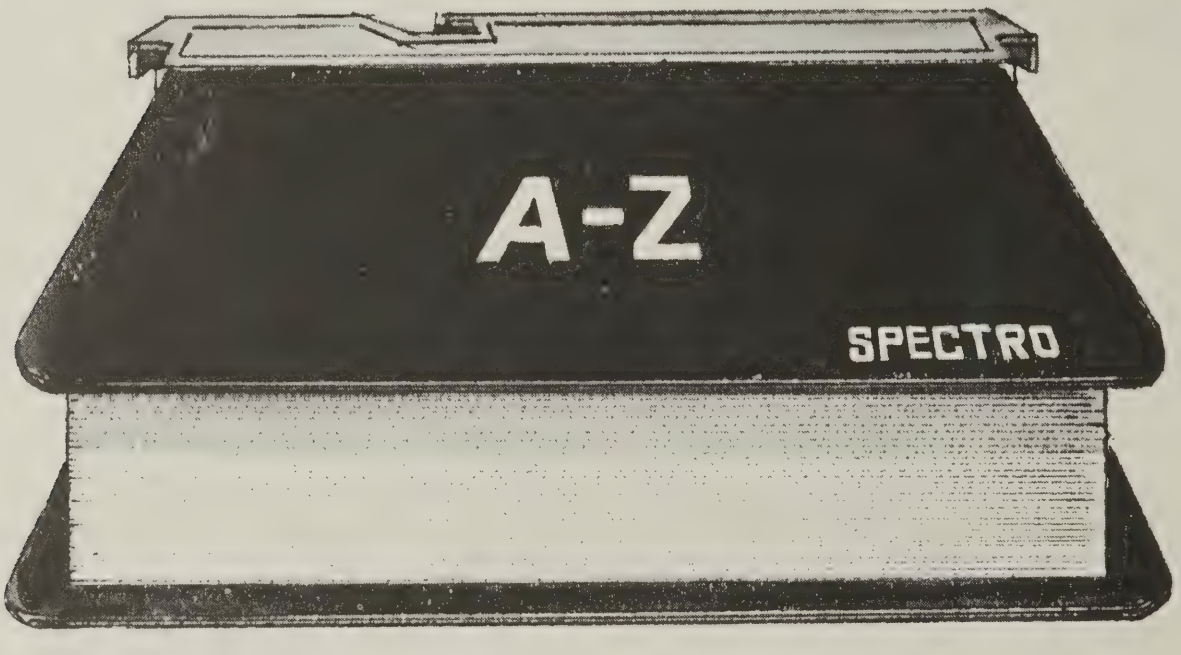
(From a Department of Health and Mental Hygiene Memo dated 1/11/84)

"A review of the inspection records of 798 community Pharmacies as conducted by the Staff of the Division of Drug Control for 43 individual items reveals violations on a percentile basis ranging from 0 to 14.66%, 26 items were found to bear violation values of less than 5%, 9 items from 5% to 10% and 8 items in excess of 10%.

Items in the latter category and the percentage violation are as follows:

No.	Item	%violation
4	New and refill Rxs recorded as required with date and pharmacist's initials	12.66%
10	CDS inventory taken and properly recorded with signature, month, year and time.	10.15%
11	Schedule II, IV and V invoices dated when received.	10.65%
13	Third copy of Federal order form properly filled in.	10.40%
14	Patient address on CDS Rxs.	14.66%
20	Schedule II emergency Rx procedure	10.53%
32	Pharmacy kept clean and orderly	11.28%
37	Paraphernalia register maintained for syringes, needles, etc	10.15%

22,000 Items. Now that's healthy!



You'll find in this book the most comprehensive listing of items available to your pharmacy. You'll also find we can deliver everything we list and do it within 24 hours.

This book is only Volume One in our library. Sales ideas, pricing, services, and time saving procedures, are all contained in the table of contents. Please call us.

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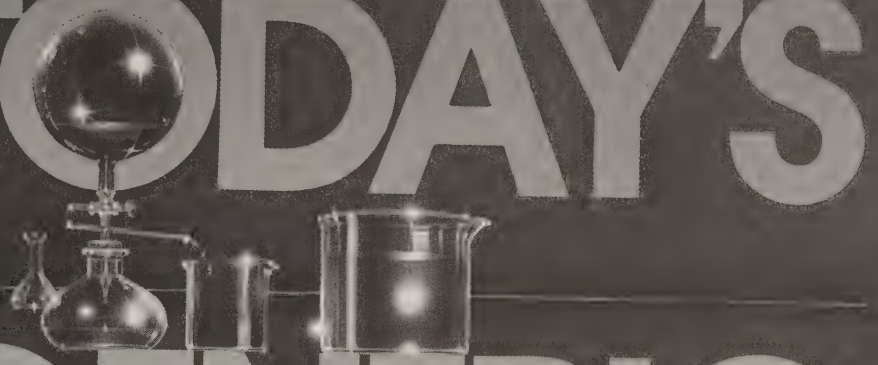

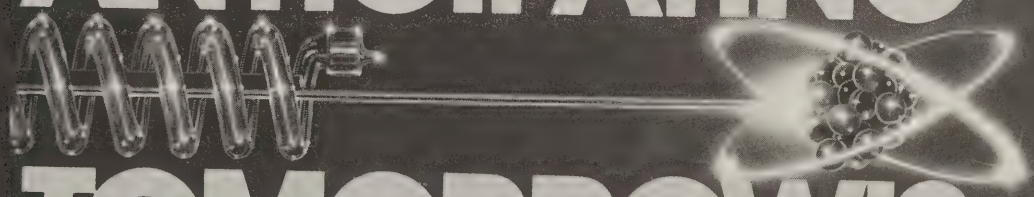

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SPEAKER OF THE HOUSE REPORT

by
Harry Hamet, Speaker of the House

It is a distinct honor and privilege to be able to address this meeting of the House of Delegates. During the last two years as Vice-Speaker and Speaker of this illustrious body, I have become keenly aware of the number of dedicated individuals that give so unselfishly of the precious free time for the advancement of their profession. The untiring efforts of so many unsung heroes has impressed me the most about the type of individual that continues to make this organization the respected one that it has become.

Last year the House of Delegates passed a resolution directing the Board of Trustees to consolidate the two regional meetings into one mid-year meeting and that programming be developed consistent with the educational needs and interests of the members. In following this edict, one mid-year meeting was held January 29, 1984 at the Annapolis Hilton. The program, which was very well attended, including a Pharmacy law review panel whose members represented the Board of Pharmacy, Medical Assistance Compliance Administration, Medicaid Pharmacy operations, and the DEA. Needless to say, a lively give and take discussion followed the panel's opening remarks. This was followed by an excellent presentation by Thomas Gossell and J. Richard Wuest on Prescription to OTC switch, and an update on New Drugs and Trends in pharmacy—1984. A Short House of Delegates session then concluded the program.

I would be remiss if I did not take this opportunity to thank the officers and Board members and especially Executive Director David Banta for his invaluable support and guidance, not only in the planning and directing of the Mid-year meeting, but in getting me through my year as Speaker.

In closing, I would like to leave you with this final thought. This Association and specifically the House of Delegates is only as strong as the members that make it up. You, by being here, are already involved. Help get some one else involved this coming year. Transmit your enthusiasm, spread the word when you return to your respective communities and help make the Maryland Pharmaceutical Association truly a speaker for *all* pharmacists in Maryland.

TRAVEL AND CONVENTION REPORT

by
Elwin Alpern, Chairman

Our 1983 Convention at the Carousel in Ocean City had an attendance of 300 people. There were 7 exhibitors in 1983 and their fees totaled $2,045.00 and we received contributions of $3,620.00. The registration fees accounted for $12,274.00. The net profit was $6,983.66. It is the continued thinking that as long as Ocean City is so well attended we should continue to have our convention there.

October 10–25, 1983 we offered a "Scenic Europe." We had 30 persons at 15.00 per person or $450.00 profit for the association. Our price of $719.00 for 2 weeks in Europe was a real bargain plus the strength of our American Dollar made a very inexpensive vacation for those attending.

In January 1984 we offered a trip to Acapulco, Mexico. Not only did we offer a real competitive price, we had an exceptional response. We netted $2,100.00 for the Association treasury. Our Seminar while there were very well received.

The total amount of money from June 1983 to June 1, 1984, collected by the Travel and Convention efforts was $9,578.00. This committee welcomes suggestions at any and all times.

Thank you.

INDUSTRY RELATIONS COMMITTEE REPORT

by
Mark Golibart, Chairman

The Industry Relations Comittee of the Maryland Pharmaceutical Association met several times during the past year and at each meeting discussion concerning important issues was always lively.

The Committee continues to be concerned regarding excessive quantities and there was discussion regarding the continuing conversation with Med Chi on this matter. For the first time, the Committee has considered broadening its activities to include liaison with Computer Companies. This comes at the specific request of a member who had a complaint with a system which he purchased. The Committee will ask for representation from that field to participate in Committee deliberations.

The Committee has also been following the on-going negotiations between the Association and the Medicaid Program regarding the Generic Drug Price Regulations (GDP) and the Drug Utilization Review Proposal (DUR).

The Committee was pleased that the Association staff has developed a special membership application exclusively for Associate members. This specialized attention should assist the Committee in its on-going task of recruiting non-pharmacists members into the Association.

The Committee continued its on-going ombudsman activity with regard to return goods policies. On behalf of the Committee, staff made several inquiries throughout the year to help pharmacists establish constructive dialogue and productive results from manufacturers on this issue.

The Committee continues to be open to suggestions from the membership and openly solicits, at this time, your suggestions concerning issues involving Pharmacy—Industry relations. I appreciate the work of the Committee members and the special contributions of the office staff to the work of the Committee.

THIRD PARTY COMMITTEE REPORT

by
Chairman Stanton Brown

The Committee met four times during the year and set two goals for its' work this year. 1) to produce a slide program on the filling of third party prescriptions based on the A. H. Robins produced program presented at this convention a year ago, and, 2) to produce a pamphlet for the purpose of educating that portion of the public that will be affected by their providers' consideration of requiring, or offering, mail order prescription service to subscribers, as to the disadvantages of such services.

The first goal did not progress past the initial consideration of the script. The issue of mail order services be-

came paramount and, therefore, it was tabled. The second goal, we are very pleased to report, was brought to fruition in the form of a fold-out pamphlet that will be distributed to Maryland pharmacists, for the purpose of distribution to users of pharmaceutical service. This pamphlet, it is hoped, will inspire significant reconsideration of the use of mail-order services as a cost-cutting measure, as we belive that the patient has more to lose than to gain if he severely reduces the use of local pharmacy service currently available in every community.

In addition to this work, this committee is constantly being consulted with to pursue complaints and to look into inquiries. Thanks to Dave Banta's attention to these matters the work of the committee continues on a daily basis.

Ray Langston, representing the A.H. Robins Co. (left), presents the Bowl of Hygeia Award to Phil Cogan for Phil's impressive record of Community service involvement.

PROFESSIONAL AFFAIRS COMMITTEE REPORT

by
Chairman Madeline Feinberg

Pharmacist role in home health care delivery was targeted by the Board of Trustees as an issue of major concern for the association. Consequently members of the professional affairs committee were invited to participate in the selection of members to serve on a Task Force on Home Health Care established by the Board as its December meeting. Since its inception, the Task Force has been active in identifying issues of concern, and goals for the association and has acted in behalf of the Professional Affairs Committee with regard to this issue.

Several Goals were set by the Task Force:

1. Inform the membership of opportunities which exist for the pharmacy in the delivery of home health care.
2. Prepare a position paper by the association for distribution to other professionals in the health care system, to home health care agencies, to legislators and to the public. Opportunity for comment, additions and deletions from the general membership were requested prior to final drafting.
3. Promote the Maryland Pharmaceutical Association advisory role at the regulatory level to enhance pharmacy input in the development of policy regarding the home health care industry.
4. Assess the needs of the home health care agencies to determine where pharmacy input can effectively used and explore issues or reimbursement for pharmaceutical services.
5. Assess the activities of MPhA membership in the home health industry at present to identify (a) extent of involvement, (b) those individual who have developed new ideas who may act as "role models" or innovators.
6. Cooperate with national professional organizations to promote Maryland pharmacy interest and concerns when national issues are identified for the profession.

The Chairman is pleased to report that several goals have been achieved due to the enthusiastic support and cooperation of the Task Force membership.

A three hour workshop on Home Health Care will be presented at the annual convention by Task Force members currently working in home care. Entitled "Hands-On Home Health Care—Beyond Durable Medical Equipment" this program will explore innovative practice situations and suggest ways that pharmacists may tap into existing resources within the industry.

A position paper has been completed and will be presented to the membership at the Annual Convention. Members will be ask to distribute, or suggest target individuals and groups to received the position paper. The association executive director is planning a mailing as directed by the Task Force. In addition, to this end, the Task Force has recommended a legislative Open House to be held in the Fall at which time Maryland delegates and their staff will be invited to an informal meeting to discuss pharmacy issues, including delivery of home care services.

Proposed regulations for the delivery of home parenteral nutrition and TPN's were sent to the Maryland Pharmaceutical Association for comment, correction, additions prior to drafting of final regulations.

Finally, the American Pharmaceutical Association has announced the formation of a section on home health care within the Academy of Pharmacy Practice. Several members of the MPhA Task Force have volunteered to serve and await selection of members. The Task Force intends to keep close tabs on the work of APhA as discussed above.

Finally, the surveys described earlier have been drafted but not completed. The Task Force needs to determine, from the Board of Trustees, the availability of financial resources to conduct such surveys.

Paul Frieman, Secretary of the Board of Pharmacy (right), is the recipient of the MPhA's Professional Achievement Award for his specific contributions to the profession, given by William C. Hill, out-going President of the MPhA (left).

STUDENT AMERICAN PHARMACEUTICAL ASSOCIATION REPORT

by
Anne Hom, President

This past year has been an exciting one for the University of Maryland Student APhA Chapter. Elections were held last last fall with Sarah Donegan (2nd year BS), Jay Scherr (1st yr BS), Rick Benchoff (2nd year BS), Anne Hom (1st year Pharm.D) elected to serve respectively as Secretary, Treasurer, Vice President and President. The Pharm.D and B.S. programs were thus together represented on the Executive Board for the first time. Also a new Executive Board position was created this past Fall for the Editor-in-Chief of the Student APhA publications and the officer elected was Kathy Gauthier, who had been functioning in that capacity since last Spring. Our new professional newsletter, the *Pharmakon,* under the very effective editorship and direction of Karin Calis, flourished. Four issues were published and each was well received by all the students and faculty of the Pharmacy School.

The Fall membership campaign conducted before the present officers were elected resulted in a total membership of 83. Sales of the OTC Handbook, traditionally a very successful and practical fund raiser, went well. The Regional meeting was hosted this year by the Philadelphia College of Pharmacy in December and was attended by seven students.

At the first Executive Board meeting of the new calendar year, we set our goals for a successful Spring coffeehouse, a speakers series, a T-Shirt design and sales campaign, and a large turnout for the annual Student APhA meeting in Montreal. With lost of effective work and participation by students, we were able to meet all of these goals. The coffeehouse provided, as usual, a popular showcase for all sorts of previously unknown talent from magic to stand-up comedy to folk, pop and rock music! It was very ably managed by Jay Sherr. The T-Shirt design contest elicited a number of creative designs. The winning design featured a silk screen print of the University of Maryland Terrapin holding a mortar and pestle and chemist's flask on the back, and an insignia on the front with the motto (in latin) "Nothing without work." Our Spring lecture series featured three speakers, with something for everyone. Harry Finke, P.D. spoke in a lively and entertaining fashion to those interested in community practice in a talk entitled "Owning your Own Pharmacy." Next representing the industry view, we were fortunate to be able to have Paul Baumgartner of Merck, Sharp and Dohme, Speaking on "Excellence." Finally, with an accent on clinical pharmacy, we were pleased to have Dr. Kevin Olden, Associate Professor of Internal Medicine at Stanford University, speak to use on "Current Concepts in the Drug Treatment of Alcohol and Substance Abuse." This lecture was jointly sponsored by Student APhA and SCODAE.

Finally, we were very successful in meeting our goal of encouraging attendance at the Annual Meeting in Montreal. Eleven students attended from the University of Maryland from both the B.S. and Pharm.D. classes. Generous help from the MPhA allowed all of these students air fare, registration fees, and airport-to-hotel ground transportation to be paid from our treasury. This was surely a most powerful incentive for participation! In response to this help, and as a way to allow the students to "earn their way", members of the chapter are participation in MPhA's membership campaign by contacting practicing pharmacists across the state to encourage membership in MPhA. Each student who attended gained a great deal in first hand knowledge of their professional organization and in meeting new and old friends from around the country. Anne Hom moderated a session on Home Health Care presented by Drs. Lamy, Fedder, Beardsly and Feinberg from the University of Maryland. All the students who went to Montreal attended both business meetings and professional/educational sessions. Rick Benchoff, our chapter Vice-President, was our voting delegate in the House of Delegates.

In addition, all the students were able to form an effective support group for the candidacy of Anne Hom for Delegate to APhA elected at the Annual Meeting. The campaign was successful, and the University of Maryland thus has a national Officer for the 1984–85 year. There are three Delegates to APhA elected at the Annual Meeting, chosen from among students from all over the Country. Each sits on one of the standing committees of the APhA during the year, and reports on the actions of that Committee to the students at the following Annual Meeting of the Student APhA.

Finally, the University of Maryland Chapter is winding up its year with participation in the MPhA Annual Meeting; sending out a summer mass-mailing to all incoming and returning students to encourage membership and promote OTC Handbook and T-Shirt Sales; meeting the incoming first-year students; and in September, our annual election of officers. All of us in the Student APhA Chapter have learned a great deal this year, and we hope to be able to continue to serve the needs of students and to advance our understanding and participation in our professional Association throughout the coming year. All of us attending the meeting here in Ocean City look forward to the opportunity of meeting all of you!

MEMBERSHIP COMPARISON REPORT

Marty Mintz
Committee Chairman

	6/22/83	6/22/84
TOTAL MEMBERS TO DATE:	938	1007
NEW MEMBERS TO DATE:	104	96
COMPARISON: 1983 TO 1984		
MEMBERS TO DATE:		+69
New Members to date:		−8

	6/22/83	6/22/84	COMPARISON
BREAKDOWN:			
OWNER-MANAGER	185	193	+8
NON-OWNER	422	451	+29
PLEDGE—1ST YEAR	56	61	+5
—2ND YEAR	32	30	−2
HOSPITAL	33	27	−6
GRADUATE	2	6	+4
RETIRED	89	116	+27
NON-RESIDENT	80	85	+5
JOINT	7	9	+2
ASSOCIATE	32	29	+3
Comparison:	938	1007	+69

I would like to extend my fullest appreciation to the Membership Committee, David Banta and the MPhA staff for their time and efforts this year. The statistics show that we are making steady progress in membership when compared to previous years. I would like to invite new volunteers to be a part of this committee. A few hours a year spent in any Committee work really gives one a sense of great accomplishment.

CONTINUING EDUCATION COORDINATING COUNCIL REPORT

by
David A. Banta

The Continuing Education Coordinating Council has again experienced a productive year and is a model of cooperative effort among the three organizations that participate. The MPhA, the MSHP and the School each have representatives on the Council and over the past several years the Council has succeeded in developing a high standard for programming. As in the past, the Council solicits for volunteers who are interested in the process of providing quality educational experiences for Maryland Pharmacists to assist the Council in this important work.

Last season's programs included successful day long seminars on the subjects of Pain Management, Gastro-Intestinal Diseases, Critical Care Management and Nutrition. In addition, the traveling "Road Show" on new drugs was again made available to local associations to assist them with their program needs. The Council met throughout the year to review program plans with the various Chairmen who have major responsibility for ogranizing these continuing education programs.

I am very pleased to report that the Council has received approval from the American Council on Pharmaceutical Education (ACPE) as an approved provider of Continuing Education programming. The Council will now be able to offer programs with ACPE approval without the necessity of co-sponsorship with the School of Pharmacy. In addition, the Council is working on co-sponsorship guidelines whereby other organizations might produce C.E. programs but offer ACPE credit through the Council.

The Council is working to gain a special non-profit tax status to help lower the cost of state-wide mailings by taking advantage of lower postal rates. The Council has again initiated an elaborate planning process for the coming season and has begun the task of raising necessary financial support for these programs. The Subcommittee on planning has presented a list of proposed programs for the 1984–85 season. Additional information on the new C.E. season will be available in the Fall.

In addition, the Council will continue the work of the "Road Show". Selection of program topics is based, in part, on input from pharmacists who attend programming and participate in the Council's evaluation process.

I would like to thank all of the volunteers who have served on the Council, its subcommittees and as program chairmen, for all of their hard work in developing and executing these programs. Thank you.

THIS AND THAT ABOUT PHARMACY

BY LEON WEINER, P.D.

(Note: The "Clipper Pills" Reunion date has been changed from Sept. 16th to Sept. 23rd).

Dr. Stanley P. Kramer, a nationally well known chemist, passed away on April 17, 1984. Kramer, 60, was a lifetime resident of Baltimore and was on the faculty staff of University of Maryland Pharmacy School as an assistant in chemistry in 1951–1953.

A tale follows: Once upon a time, a tall, handsome Ronald A. Lubman, University of Maryland 1957, met intelligent beautiful Nancy Sappe, University of Maryland 1961. They played tennis, fell in love, played tennis, got married, played tennis, raised a family, etc. Now when Ron & Nancy play tennis, they have their two young pretty daughters join them whenever possible. Cindy Lubman, the oldest, has just completed her first year of Pharmacy School. Before entering Pharmacy School, Cindy was a high school state mixed doubles champion and also played for two years on the varsity tennis team at the University of Maryland at College Park. The youngest daughter Debra, is a 3 time high school doubles champion and has ranked since age 12 in Mid Atlantic States. At the present time, Debbie is working in her parent's drug store before entering Duke University this fall. Let us hope that the Lubmans all live happily ever after.

Deep regards to Samuel P. Jeppi, retired drug inspector, on the loss of his beloved wife, Marie.

Congratulations to Margaret Beatty administrative Aide, at the University of Maryland School of Pharmacy for completing 35 years of service. Working with two Deans at the same time I'm sure was no cinch.

PHARMACY CHANGES—(APPROX. MAY 1984)

The following are new pharmacies in the state of Maryland.

American Continue Care
7674 Standish Place
Rockville, Maryland 20855

Pharmacy at Fairmount Hill
100 North Broadway
Baltimore, Maryland 21231

People's Drug Store 1130
Coastal Highway & 119th Street
Ocean City, Maryland 21842

Pathmark Super Drug (1)
1401 Merritt Blvd.
Dundalk, Maryland 21222

The following is change of address.

People's Drug Store 1226
The Market Place
3226 Superior Lane
Bowie, Maryland 20715
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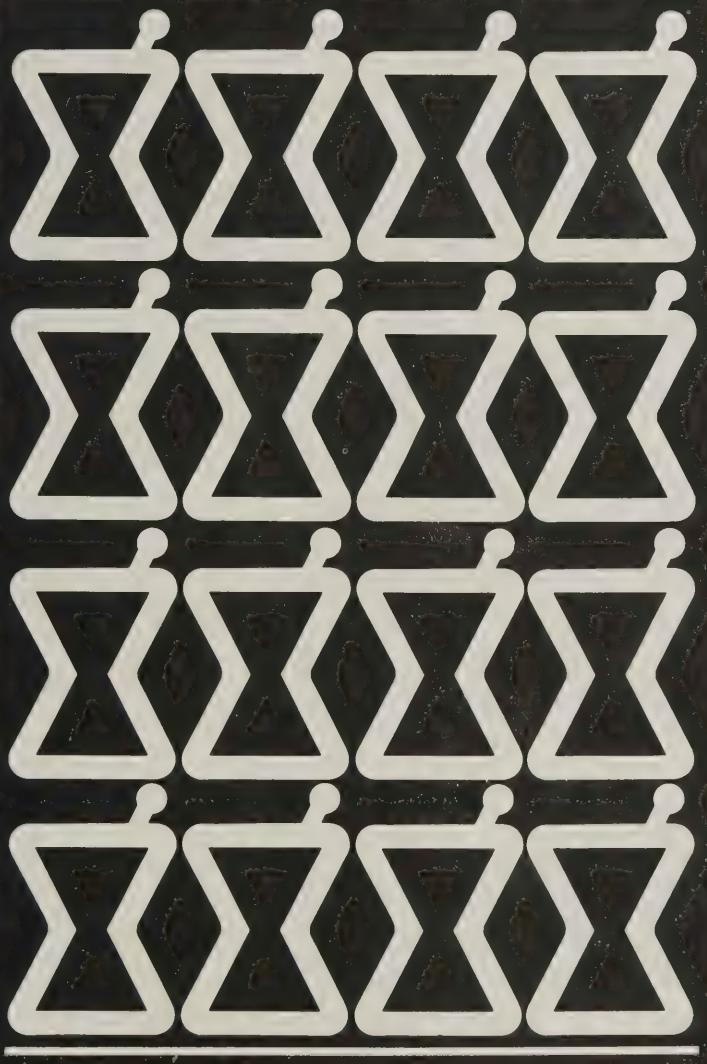

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OTC IBUPROFEN AND THE ELDERLY: A CONCERN TO PHARMACISTS

by Peter P. Lamy, Ph.D.

On advice of the FDA Arthritis Advisory Committee, the FDA has now permitted the marketing of an OTC ibuprofen. It is the first addition to the OTC analgesic market in almost three decades, acetaminophen being the last in the late 1950s.

This follows the announcement in 1983 that ibuprofen will be marketed in the UK for over-the-counter sales by pharmacists. It is not expected that the analgesic market will expand, but that it will be more competitive. A recent evaluation found that ibuprofen is safer in *overdosage* that either aspirin or acetaminophen (1). Is it safe for the elderly?

Needed: Behavioral Changes

In June 1982, then-HHS Secretary Schweiker sent the final report of the 1981 White House Conference on Aging to the President and Congress. From these recommendations, Schweiker developed a National Policy on Aging. A primary recommendation in the "Health" section of the Policy emphasizes developing and disseminating education materials for the elderly:

> Be it resolved that . . ." (1) The elderly be further educated in the safe and effective use of nonprescription medicines"

No major effort can as yet be discerned in this regard, but it speaks to a need. That need is bolstered by a recent CBS report (2) which indicates that more than two-thirds of those polled considered information on diseases and drugs highly important, yet slightly more than three-fourths felt only "somewhat informed" or "not informed at all".

Because the Advisory Committee was very concerned about the high-frequency of cross-reactivity between allergy to aspirin and ibuprofen, a "boldface" warning to that effect is included in the labeling. One must question, however, whether the elderly, at least 50 percent of whom are vision-impaired, can read that labeling and whether, indeed, they can follow it.

Elderly for whom 80 percent of all anti-arthritic medications are prescribed, have learned that aspirin should not be taken together with an NSAID. The label now states that acetaminophen should also not be taken concurrently. Yet many elderly probably have received acetaminophen along with an NSAID and are used to this regimen. They are likely to overlook this caution note.

This note is based on the fact that a NIH Health Consensus Conference recently concluded that long-term use of analgesic/antipyretic combinations, if taken in high doses, can cause kidney disease and chronic renal failure.

For the elderly, who are probably the most likely long-term analgesic users, this must be reinforced. This would mean a campaign of re-education, which, at best, will be difficult.

It is generally agreed that patients, and the elderly are no exception, do not convey to either their physician or pharmacist all of the OTC preparations they take, nor do providers always ask. Indeed, one study of comparatively healthy elderly found that only 12 percent talked to their physicians about their OTC use (3).

It is, therefore, not unreasonable to assume that many elderly, receiving NSAIDs for rheumatoid arthritis or osteoarthritis, may indeed purchase the new OTC analgesic without realizing that they may actually take the same drug on prescription and non-prescription. Elderly need to be very well informed about this potential problem.

IBUPROFEN AND THE ELDERLY

The United States Pharmacopeia (4) cautions potential ibuprofen users to inform their physician, before use of this medication, if they suffer from asthma, bleeding problems, colitis, stomach ulcers, other stomach problems, heart disease, high blood pressure or kidney disease. Potential users should also inform their physician (or pharmacist) if they are taking anticoagulants, aspirin or other salicylates, furosemide, heparin, or any anti-inflammatory medication. Patients are cautioned not to drink alcoholic beverages while taking this medicine and that the drug may cause some people to become drowsy, dizzy, lightheaded, or less alert than they are normally.

Previously, ibuprofen has been mentioned as one of many drugs that could cause insomnia, a problem of which many elderly suffer already and which, more often than not, is treated symptomatically with hypnotics.

A more recent publication (1), lists a series of pos-

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sible side effects, including gastrointestinal, renal, cardiac, central nervous system, hematological, hepatic and still others. Some of these will be discussed in relation to the elderly.

Mental Status Changes:

A major goal of geriatric medicine is to enable the elderly patient to live independently as long as possible, being careful not to decrease the patient's quality of life. The keystone to quality of life is mental acuity, the ability to think and act for oneself. Yet, intoxication with medical drugs is probably the most frequent single cause of delirium in the elderly (5). It is, therefore, of concern to note that in the elderly, NSAIDs, including ibuprofen, can cause memory loss, inability to concentrate, confusion and personality changes (6).

Dysphagia:

The elderly suffer from swallowing difficulties more so than do younger persons. Most at risk are those with hiatal hernia, an enlarged left atrium due to mitral valve disease, or stricture. Patients with gastroesophageal reflux should avoid regular use of non-steroidal anti-inflammatory drugs, as their continuous use could lead to esophageal stricture (7). Ibuprofen has been identified as one of the NSAIDs that could be responsible for the formation of stricture. Indeed, this association between use of NSAIDs and benign stricture of the esophagus has been noted also in other cases (8).

Unmasking of Other Diseases:

Twelve percent of community-living elderly are estimated to suffer from inflammatory bowel disease (9). The unmasking of idiopathic inflammatory bowel disease has been reported with NSAIDs (10,11) and increased use of ibuprofen may lead to similar reports.

While most chronic diseases are declining among the elderly, there are two that are still increasing: cancer and tuberculosis. Scattered reports are now appearing in the medical literature that there appears to be a significant relation between the reactivation of tuberculosis and the use of NSAIDs. Physicians should keep in mind that NSAIDs are potent anti-inflammatory agents and may thus activate, spread, and mask infections (12).

Cardiovascular Problems:

There is no question that the cardiovascular diseases are most frequent among the elderly. Indeed, of the top nine drugs prescribed for the very old, six are cardiovascular drugs (13). Ibuprofen can cause sodium retention and can, therefore, aggravate congestive heart failure. This is a time- and dose-dependent phenomenon (14).

Management of Hypertension:

If a patient, treated for hypertension, also uses non-steroidal anti-inflammatory drugs, the clinical effect may be significant. Systolic blood pressure may rise by about 15 mm Hg and diastolic pressure by seven to 10 mm Hg, regardless of whether the patient is treated with a beta blocker, a converting enzyme inhibitor, or a diuretic. The dose of the antihypertensive, therefore, will have to be increased (15).

Renal Problems:

Although a large study of both institutionalized and ambulatory elderly patients receiving NSAIDs showed no relationship between these drugs and deterioration of renal function (16), one ought to measure serum creatinine concentration before and during therapy in the group of patients most at risk to acute renal failure. These would be the elderly, and patients with volume depletion, receiving diuretics, in heart failure, with liver disease or underlying renal disease (17). Special attention should be given to patients receiving drugs excreted unchanged in the urine, such as digoxin.

The widespread use of NSAIDs has been accompanied by the sporadic occurrence of several different syndromes of nephrotoxicity (18) and careful monitoring of the effect of OTC ibuprofen seems therefore to be only prudent. One of the more recent reports speaks to the fact that the NSAID-induced nephrotic syndrome is reported with increasing frequency (18).

WHAT MUST PHARMACISTS DO?

Clearly, this new OTC drug may, on widespread use, be found to cause a number of different adverse effects in the elderly, depending on dosage use and duration of use. Thus, at the minimum, pharmacists must reinforce with their elderly patients that:

- this drug should not be used on a long-term, chronic basis
- this drug is intended for pain and not for chronic treatment
- if pain continues, the patient should seek help from a physician

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A PREVIEW OF 1983 INDEPENDENT COMMUNITY PHARMACY

This year's preliminary *Lilly Digest* report, based on the 1983 operating statistics of 860 independent community pharmacies, indicates that the higher cost of goods sold was offset by lower total expenses resulting in a percentage net profit unchanged from the previous year. When the income and expense statement items are compared with *Lilly Digest* figures for 1982, they show that . . .

Total sales reached a new high of over $537,000, up almost 8 percent (more than $39,000) over the 1982 figure. This rate of increase is somewhat lower than the average annual growth of 9.7 percent observed during the past decade. Prescription sales advanced 13.5 percent over the previous year's figure and significantly outpaced other sales, which grew just 1 percent. Prescription sales continued to grow faster than other sales and accounted for 57.6 percent of the average store's volume.

Gross margin declined to 33.2 percent of sales (down from 33.6 percent in 1982). Historically, this is the lowest gross margin level since 1953. Total expenses decreased to a new low of 30.3 percent of sales (down from 30.7 percent in 1982). The combined effect of these changes was that net profit before taxes remained at 2.9 percent of sales.

Although total expenses fell percentagewise, they did rise in dollars (up over $10,000, or 6.7 percent from the 1982 figure). Also, the average proprietor's salary was higher in dollars (up about $1,700) but decreased as a percent of sales to just under 6 percent. Similarly, employees' wages rose in dollars but fell to 11 percent of total sales, the lowest level since 1956. Rent remained unchanged at 2.4 percent of sales, but was about $1,000, or 8.4 percent higher for the year. Miscellaneous operating costs rose over $5,000, an increase of 9.3 percent. However, these miscellaneous costs took the same share of sales dollars as the previous years—11 percent—and resulted in a somewhat longer patient stay (7.5 days) than that of the previous year. Consistent with an earlier trend, the largest segment of reporting hospitals was the private, non-profit institution.

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Lilly Digest Results for

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A PREVIEW OF 1983 HOSPITAL PHARMACY OPERATIONS

Selected operating statistics from 1,091 hospital pharmacies in the United States were compiled to create a composite profile of the "average" hospital pharmacy for operating year 1983. Since this hypothetical hospital pharmacy represents a wide range of information, the figures may be too general to use for comparative purposes. However, trends can be observed by comparisons with similar statistics published in earlier editions of the *Lilly Hospital Pharmacy Survey*.

Table 1 shows that bed capacity for the average hospital was 233 in 1983—a 5.1 percent decline from the previous year. With the implementation of prospective reimbursement (DRG's) and the continuing emphasis on cost containment, it is not surprising that the "functional" bed capacity of this hypothetical hospital declined. It is also interesting that all other major categories showed reduced figures when compared with 1982 data. Census fell from 71 percent to 68 percent. Admissions were also lower in 1983—down 12.2 percent—and resulted in a somewhat longer patient stay (7.5 days) than that of the previous year. Consistent with an earlier trend, the largest segment of reporting hospitals was the private, non-profit institution.

The number of hours the central pharmacy was open as well as the hours worked by pharmacists, technicians, and support personnel declined substantially during 1983. Overall, the total hours worked per week by the hospital pharmacy staff fell almost 13 percent when compared with the figure for the year earlier. The number of hours of pharmacist time required for each hour the central pharmacy was open during 1983 was 2.7—somewhat lower than the 2.9 reported last year. The ratio of technician hours worked to hours open also declined but to a lesser degree (from 2.7 to 2.6). Support personnel hours worked per hours open also fell—down from 1.2 to 1.1 during 1983.

The dollar values reported for inventory and purchases were lower for the operating year 1983 (down 11.0 percent and 1.2 percent respectively). The estimated turnover rate showed another significant increase, from 6.6 to 7.2 times. Interestingly, if the turnover rate had remained at 6.6 times during 1983, inven-

cent. Dollarwise, net profit before taxes showed an $845 increase—up almost 6 percent from the previous year. Total income (proprietor's salary plus net profit before taxes) gained 5.7 percent in dollars, but decreased slightly as a percent of sales from 8.9 to 8.8 percent.

Prescription and merchandise inventory required more dollars during 1983; however, both declined as a percent of sales (from 10.9 to 10.7 percent and from 20.7 to 20.6 percent respectively). The prescription department's sales productivity moved up to $9.31 per stock dollar (1.3 percent higher), whereas other merchandise productivity rose to $4.85, up one penny from the previous year.

The share of new prescriptions increased by 728 to 49.1 percent of total prescriptions dispensed (up 5.4 percent from 1982). Renewed prescriptions were higher by 560 (up 4 percent) over the previous year's figure and accounted for 50.9 percent of total prescriptions dispensed. As a result, total prescriptions continued a three-year growth trend, with an increase of 1,288 prescriptions dispensed. At 28,789 prescriptions dispensed during 1983 (up 4.7 percent), a new high was established. The average prescription charge rose to $10.74 during 1983, an increase of 83 cents (8.4 percent) over the 1982 figure of $9.91. This was the first time in *Digest* history that the average prescription charge exceeded $10.

Merchandise selling space in the average independent community pharmacy fell by 20 square feet during 1983, but remained essentially in the 2500 square foot range. Sales productivity per square foot of floor area advanced $16.46 from the year earlier (up to $211.54), an 8.4 percent increase. The hours of operation in the typical *Lilly Digest* pharmacy remained unchanged during 1983 at 62 hours per week.

The following table summarizes the preliminary *Lilly Digest* report of the operating figures of 860 independent community pharmacies and compares these with the 1983 *Lilly Digest* averages from 1,528 pharmacies. The annual *Lilly Digest* will be completed and distributed during September of this year.

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Community & Hospital Pharmacy

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tory would have been about $10,000 higher, down only about 1 percent from 1982. Also noteworthy is the fact that hospital pharmacy managers have improved their turnover rate more than two full turns since 1977—from 5.1 to 7.2 in 1983. This suggests that managers of hospital pharmacy operations are continuing their efforts to exercise more control over inventory investments.

Hospital pharmacy managers have indicated that comparisons between data representing two or more years' operations may be more conveniently expressed in terms of patient days. During 1983, inventory equaled $1.75 per patient day, a 1.1 percent reduction over the previous year. Purchases were $12.69 per patient day, a rise of 8.5 percent. Since these data do not account separately for inflation, it is impossible to single out its influence on inventory and purchases statistics from patient use of drugs and related items.

Services offered by over 60 percent of hospital pharmacies that contributed data to the *Survey* remained unchanged from the previous year. Drug therapy consultations showed the largest growth rate during the two-year period, with 69.6 percent offering this service in 1983 as compared with 65.9 percent in 1982. These data suggest that clinical services among reporting hospital pharmacists continue to expand.

A comparison of selected operating statistics over the eight-year history of the *Lilly Hospital Pharmacy Survey* shows the following trends:

—Pharmacy hours open rose from 74 to 90 (an increase of 21.6 percent).
—Pharmacist hours worked per week advanced 61.2 percent from 152 to 245), or almost 8 percent per year.
—Technician hours worked per week varied but increased overall from 129 to 231 (a 79.1 percent increase, or about a 10 percent increase per year).
—Inventory investment rose 47.4 percent, an annual growth rate of about 6 percent for the eight-year period. In terms of patient days, the increase was 78.6 percent at an annual rate of almost 10 percent.
—Purchases grew 125.6 percent during this time span, with an annual growth rate of over 15 percent. In terms of patient days, the increase was 173 percent, which reflects an annual rate of 21.6 percent.

The 1984 edition of the *Lilly Hospital Pharmacy Survey* will be distributed during August of this year.

Averages per Pharmacy	1983 860 Pharmacies	1982 1,528 Pharmacies	Amount and Percent of Change
Sales			
Prescription	$309,307— 57.6%	$272,527— 54.7%	+$36,780—13.5%
Other	227,803— 42.4%	225,494— 45.3%	+$ 2,309— 1.0%
Total	$537,110—100.0%	$498,021—100.0%	+$39,089— 7.9%
Cost of goods sold	358,583— 66.8%	330,577— 66.4%	+$28,006— 8.5%
Gross margin	$178,527— 33.2%	$167,444— 33.6%	+$11,083— 6.6%
Expenses			
Proprietor's or manager's salary	$ 31,663— 5.9%	$ 29,965— 6.0%	+$ 1,698— 5.7%
Employees' wages	58,906— 11.0%	56,454— 11.3%	+$ 2,452— 4.3%
Rent	13,022— 2.4%	12,018— 2.4%	+$ 1,004— 8.4%
Miscellaneous operating costs	59,523— 11.0%	54,439— 11.0%	+$ 5,084— 9.3%
Total expenses	$163,114— 30.3%	$152,876— 30.7%	+$10,238— 6.7%
Net profit (before taxes)	$ 15,413— 2.9%	$ 14,568— 2.9%	+$ 845— 5.8%
Total income	$ 47,076— 8.8%	$ 44,533— 8.9%	+$ 2,543— 5.7%
Value of inventory at cost and as a percent of sales			
Prescription	$ 33,238— 10.7%	$ 29,642— 10.9%	+$ 3,596—12.1%
Other	46,924— 20.6%	46,574— 20.7%	+$ 350— 0.8%
Total	$ 80,162— 14.9%	$ 76,216— 15.3%	+$ 3,946— 5.2%
Annual rate of turnover of inventory	4.6 times	4.5 times	
Number prescriptions dispensed			
New	14,149— 49.1%	13,421— 48.8%	+ 728— 5.4%
Renewed	14,640— 50.9%	14,080— 51.2%	+ 560— 4.0%
Total	28,789—100.0%	27,501—100.0%	+ 1,288— 4.7%
Average prescription charge	$10.74	$9.91	+$ 0.83— 8.4%
Size of floor area	2,504 sq.ft.	2,524 sq.ft.	
Sales per square foot	$211.54	$195.08	+$ 16.46— 8.4%
Hours open	62 hours	62 hours	

	1983 1983 (1,091 Hospitals)	1982 (2,169 Hospitals)	Percent of Change
Bed capacity	233	245	− 5.1%
Class	Private (nonprofit)	Private (nonprofit)	
Profile	General	General	
Census (beds occupied)	68%	71%	
Admissions	7,716	8,657	−12.2%
Length of patient stay	7.5 days	7.3 days	
Hours central pharmacy open/week	90	95	− 5.6%
Pharmacist hours/week	245 (6.1 F.T.E.)	278 (7.0 F.T.E.)	−13.5%
Technician hours/week	231 (5.8 F.T.E.)	255 (6.4 F.T.E.)	−10.4%
Support hours/week	100 (2.5 F.T.E.)	117 (2.9 F.T.E.)	−17.0%
Inventory	$101,162	$112,262	−11.0%
$ 1.75/Patient day		$1.77/Patient day	− 1.1%
$ 434/Bed		$ 458/Bed	− 5.5%
$ 640/Occupied bed		$ 645/Occupied bed	− 0.8%
$13.11/Admission		$12.97/Admission	+ 1.1%
Purchases	$733,989	$742,734	− 1.2%
$12.69/Patient day		$11.70/Patient day	+ 8.5%
$3,150/Bed		$3,032/Bed	+ 3.9%
$4,645/Occupied bed		$4,270/Occupied bed	+ 8.8%
$95.13/Admission		$85.80/Admission	+10.9%
Inventory turnover rate	7.2 times	6.6 times	
Floor area (central pharmacy)	1,495 sq. ft.	1,600 sq. ft.	
Services offered by over 60 percent of pharmacies:			
Monitoring patient profiles		Monitoring patient profiles	
Monitoring drug interactions		Monitoring drug interactions	
Providing drug information services		Providing drug information services	
Drug therapy consultation		Drug therapy consultation	

William C. Hill, the 1983–84 MPhA President (left), presents Ronald Sanford, the 1984–85 MPhA President (right), with the NARD Leadership Award.

This Buds for you! The volunteer firemen at the Berlin, Maryland firehall once again put on a great annual Crab Feast for Maryland Pharmacists and friends.

Vera Bogus (left) receives a special award at the MPhA Annual Banquet from Ronald Sanford (right) in recognition of her contributions to and support of the Association over the past year.

There is nothing like crabs and beer in a firehall followed by a round of square dancing. Just ask these folks.

ABSTRACTS

Excerpted from PHARMACEUTICAL TRENDS, published by the St. Louis College of Pharmacy; Byron A. Barnes, Ph.D., Editor and Leonard L. Naeger, Ph.D., Associate Editor

ALLOPURINOL-6-MP INTERACTION:

Allopurinol (Zyloprim) is capable of inhibiting the enzyme zanthine oxidase, the same enzyme which degrades 6-mercaptopurine. When used orally, a dosage reduction to about 25% of normal is required for the antineoplastic agent because allopurinol inhibits its metabolism. However, it has been found that this activity is essentially associated with the gastrointestinal tract and that when the antineoplastic agent is used by intravenous injection, it should be used in conventional doses. *Clin Pharmacol Ther,* Vol. 34, #6, p. 810, 1984.

ALCOHOL AND CANCER:

Over 8000 Japanese men living in Hawaii were studied to determine if increased alcohol intake could be associated with the development of neoplastic growth. Investigators feel that consumption of more than 15 liters of beer/month will increase the risk of rectal cancer while those drinkers who consume large quantities of either whiskey or wine were found to be at increased risk of developing lung cancer. No correlation was found to exist between alcohol intake of any type and development of cancers of the stomach, colon or prostate. *N. Engl J Med.* Vol. 310, #10, p. 617, 1984.

ANTIHYPERTENSIVE REGIMENS:

Patients whose blood pressure was not controlled with a thiazide diuretic and a beta-adrenergic blocking agent were given either a placebo hydralazine (Apresoline), prazocin (Minipress), methyldopa (Aldomet), minoxidil (Loniten), or labetolol (Trandate). All drugs were more active than placebo, and minoxidil was the most potent. Hydralazine proved to be the most generally suited third drug, followed by prazocin. Labetolol was used in low doses even when replacing full doses of previously administered beta-adrenergic blocking agents. *Br Med J,* Vol. 288, #64ll, p. 106, 1984.

INSURANCE PREMIUM REDUCTION:

Patients with elevated blood pressure readings have a higher risk of mortality and thus higher insurance premiums. Most life-insurance companies are willing to reduce the cost of yearly premiums if pressure is controlled for several years. This may be another way of increasing patient compliance. *JAMA,* Vol. 251, #6, p. 756, 1984.

CEFTAZIDIME:

Ceftazidime is a cephalosporin derivative which has recently been introduced for general use in Great Britain. Ceftazidime has sufficient antipseudomonal activity that it can be used without addition of an aminoglycoside in neutropenic patients and newborn infants. The drug is expensive and should be reserved for use in those patients with high risk of mortality. *Lancet,* Vol. I, #8371, p. 2160, 1984.

VITAMINS AND CANCER:

Some studies have suggested that low carotene intake and low levels of retinol may be associated with an increased risk of neoplastic growth. Patients were studied in 1973 and the activity of vitamins A and E determined. Of the group, 111 patients developed cancer. The plasma level of these vitamins were compared to 210 controls matched for age, sex, race and time of blood collection. Data collected suggests that there is no association between vitamin deficiencies and cancer and that low levels of vitamins in cancer patients is due to the disease rather than a cause of the problem. *N Engl J Med,* Vol. 310, #7, p. 349, 1984.

THIAZIDE DIURETICS:

Patients with hypertension are often given thiazide diuretics to control the pressure. These patients have been noted to have good bone density as measured radiologically. Since thiazide diuretics tend to increase calcium levels in the plasma, it is thought that the increased bone density may be directly due to this alteration in calcium excretion. *N Engl J Med,* Vol. 309, #6, p. 344, 1983.

CANCER IN CHILDREN:

The mortality among children with cancer in this country has dropped substantially over the past 40 years. Improvements continue for patients with leukemia and non-Hodgkins lymphoma but seem to have reached a plateau for Hodgkins, kidney cancer and bone carcinoma. This decrease is due to improvement in drug therapy. *JAMA,* Vol. 251, #12, p. 1567, 1984.

ASTHMA:

In 1859, it was noted that "strong cofree" was effective in asthmatic patients. Theophylline and aminophylline acts by mechanisms identical to caffeine and investigators have concluded that caffeine is therapeutically effective for young asthmatic patients. *N Engl J Med,* Vol. 310, #12, p. 1743, 1984.

DIGOXIN-QUINIDINE INTERACTION:

Quinidine has been found to displace digoxin from tissue binding sites and increase plasma levels of the glycosides. Investigators have suggested that this alteration will actually reduce digoxin activity instead of increasing it. *Clin Pharmacol Ther,* Vol. 35, #3, p. 317, 1984.

ZINC AND SICKLE CELL ANEMIA:

Adult patients with sickle cell anemia have been found to be deficient in the metal zinc. Zinc supplies in the body can be measured by a variety of methods, but these authors feel that the concentration of zinc in the neutrophiles most accurately reflects the overall status of the metal. It is possible that supplementation with this ion will help reduce the severity of sickle cell anemia in adolescent patients. *Ann Intern Med,* Vol. 100, #3, p. 367, 1984.

PHENOLPHTHALEIN:

The laxative effect of phenolphthalein is well documented but the mechanism of action was not well defined. Investigators have found that certain inhibitors of prostaglandin synthesis, e.g., indomethacin (Indocin), aspirin, etc., can reduce the effectiveness of this laxative, thus suggesting that prostaglandins play a role in its mechanism of action. *J Pharm Pharmacol,* Vol. 36, #2, p. 132, 1984.

HEPATIC COMA:

Patients experiencing hepatic coma develop cardiovascular disturbances of unknown origin. Serum analysis of this group of patients was compared to analytical results obtained from other critically ill patients as well as healthy controls. Data suggest that the cardiovascular effects associated with hepatic coma are due to elevated levels of substance P, a vasodilator which is secreted by the gastrointestinal tract and normally destroyed by first pass metabolism. *Lancet,* Vol. I, #8375, p. 480, 1984.

PRESCRIPTION VIALS:

Vials containing prescription and over-the-counter drugs are often fitted with "childproof" caps, thus making them difficult for arthritic patients to open. Manufacturers have designed new caps which have unusual design features to enable easier access for the arthritic patient. Most caps have a sharply angulated or "wing" design which were fitted on a tall, thin angulated base. Flip-off caps and one with numerous threads were least preferred by arthritis patients. *Br Med J,* Vol. 288, #6418, p. 699, 1984.

HEPATITIS:

Patients with viral hepatitis usually are found to have indications that the infections have been caused by hepatitis A virus, hepatitis B virus, Epstein-Barr virus or cytomegalovirus. However, some cases of non-A, non-B hepatitis are diagnosed and no causative agent is identified. Investigators suggest that overdoses of acetaminophen can produce symptoms identical to those seen in these patients with non-A, non-B hepatitis and thus they urge clinicians to investigate the possibility of acetaminophen overdose in patients where no cause of hepatitis can be identified. *Br Med J,* Vol. 288, #6410, p. 50, 1984.

KETOCONAZOLE AND WARFARIN:

Although ketoconazole (Nizoral) has been used for several years, no mention of an interaction with warfarin (Coumadin) has appeared in the literature. One patient has apparently demonstrated increased warfarin activity while taking the antifungal agent. The study was well controlled and the author suggests that more frequent evaluation of warfarin's effect be undertaken while the patient is receiving ketoconazole. It may be necessary to reduce the dose of warfarin by as much as one-third. *Br Med J,* Vol. 288, #6412, p. 188, 1984.

MORPHINE AND HEROIN:

The use of opiates via intrathecal injection has been found to be advantageous in certain circumstances. Morphine and heroin were administered intrathecally and extradurally and the efflux from these tissues measured. Heroin, the more lipophilic of the drugs, was found to have a shorter half-life when administered in this manner and thus may be preferred when an opiate is required for use in the spinal cord. *Clin Pharmacol Ther,* Vol. 35, #1, p. 40, 1984.

INDOLAPRIL:

Captopril (Capoten) was the first orally active angiotensin converting enzyme inhibitor marketed in this country. Side-effects have somewhat limited its use. Enalapril is a similar substance which has been experimentally in place of captopril and more recently indolapril has been investigated. The new drug exerts its action by inhibiting the angiotensin converting enzyme and by other yet undetermined mechanisms. Parke-Davis/Warner-Lambert Pharmaceutical Research Division is actively engaged in the study of this new compound. *J Pharmacol Exp Ther,* Vol. 228, #2, p. 319, 1984.

ENCAINIDE:

Encainide is an orally effective agent similar to procainamide in structure. It has been found to be useful in controlling ventricular arrhythmias. The drug is subject to metabolism which varies dependent on genetic factors. Slow metabolizers experience benefit because of the parent drug actions, but the patients who metabolize the drug rapidly benefit from action produced by an active metabolite of the encainide. *J Clin Invest,* Vol. 73, #2, p. 539, 1984.

NETILMICIN:

The renal toxicity of the aminoglycoside antibiotics is said to be associated with the ability of the drug to concentrate in renal tissue. Measurements of gentamicin and netilmicin in various areas of the rat kidney show that netilmicin is less concentrated than is gentamicin. This observation explains the clinical observation that netilmicin produces less nephrotoxicity than does gentamicin. *J Pharmacol Exp Ther,* Vol. 228, #1, p. 65, 1984.


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The Maryland
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September, 1984
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No. 9

Poison Ivy/Oak and Their OTC Remedies

—Thomas Gossel
—J. Richard Wuest

Annual Report of the Board of Pharmacy

—Paul Freiman

This and That About Pharmacy

—Leon Weiner

THE MARYLAND PHARMACIST

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SEPTEMBER, 1984 VOL. 60 NO. 9

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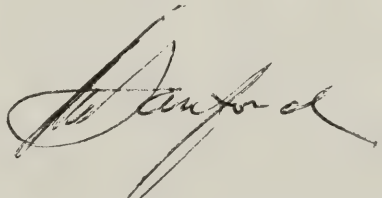
You do! By your election of Officers and Trustees and members of the House of Delegates. Yet I have heard time and time again; "the M.Ph.A. is run by a select few and they don't care about my needs or represent me! Although your president is Director of Pharmacy for a 68 store chain, he is one vote on the Board of Trustees. Although your president-elect is a member of the acedemic community and an employee in an independent pharmacy, she has but one vote. Other "one-vote" members of the Board include two independent Pharmacy owners, a Hospital Pharmacy Director, a chain employee pharmacist, a consultant pharmacist and a representative of the Student A.Ph.A. All of these pharmacists were elected by you and represent you, at the same time offering to you and the Association a wealth of varied expertise in their practice type. You are well represented and very much in charge.

Rounding out the administration of the Association is Dave Banta, who unfortunately is also sometimes accused to be "running the Association". Unlike all the volunteers identified earlier, Dave is an employee of the Association and is thus employed by you, the membership, and addresses issues according to the policies made by the Association, not according to his own opinions. No organization could ask for a finer spokesman than Dave Banta. If you don't believe it, come to Annapolis sometime and see Dave in action.

I urge you—anytime you feel you are not represented, volunteer for a committee appointment or run for office and become "in-charge". You will find reward in the participation, you will also find that we are quite a democratic organization. I look forward to my "one vote"; I look forward to your support in the upcoming year of my Presidency.



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Poison Ivy/Oak Reactions and Their OTC Remedies

By Thomas A. Gossel, R.Ph., Ph.D.

and J. Richard Wuest, R.Ph., Pharm. D.

University Consultants, Inc.

Goals

The goals of this lesson are to:

1. discuss the etiology and self-treatment of poison ivy and poison oak;
2. review the pharmacology and therapeutics of agents used to treat poison ivy and poison oak.

Objectives

At the completion of this lesson, the successful participant will be able to:

1. choose the appropriate OTC agent for treating poison ivy and poison oak;
2. properly advise consumers on the selection and use of OTC poison ivy/oak remedies.

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This continuing education for Pharmacy article is provided through a grant from MERRELL DOW PHARMACEUTICALS INC.

"Leaflets three, let them be!" This adage best describes how the plants that cause poison ivy and oak dermatitis should be handled. They should be left alone! Everyone *should* recognize poison ivy and poison oak plants, and not worry about coming into unexpected contact with them. But, it is reported that very few people recognize these plants or can accurately identify them as being poisonous. Sixty-five to seventy-five percent of all Americans are thought to be sensitive to them.

This lesson identifies many of the common myths that exist about poison ivy and poison oak. It also discusses current treatment of poison ivy and poison oak dermatoses. Since most victims of plant-induced contact dermatitis visit a pharmacist before a physician, and since the vast majority of poison ivy and poison oak cases can be safely and effectively treated with OTC medication, this lesson is aimed at assisting in providing advice. Some of the common myths about poisonous plants and the resulting dermatitis reactions follow.

Most everyone recognizes poison ivy and poison oak!

Actually, the 3-leaf arrangement may be the only characteristic of these plants that remains constant. Many people, including those who spend prolonged periods of time in the outdoors, still admit to having trouble recognizing the plants. One reason is that the plants can assume a wide variety of sizes, shapes and colors, depending on where they are growing. Figure 1 depicts line drawings of poison ivy and oak plants.

Poison ivy (*Toxicodendron radicans*). The poison ivy plant (formerly called *Rhus toxicodendron* and *Rhus radicans*) usually grows as a woody vine attached to trees, rocks, fences, or other objects. Sometimes it may grow along the ground as a creeping vine. One of the authors cultivated, in the backyard of his country home, a free-standing (and beautifully-shaped) shrub measuring a full 6 feet tall, with a stem diameter exceeding 1½ inches, not realizing it was poison ivy. Shrubs and bushes exceeding this size by several feet have also been reported.

The leaves grow on a stalk usually 3 to 4 inches long. They are odorless, pointed and oval-shape. During the spring and summer they appear green. During dry spells, or later in the summer and into autumn, they appear in various shades of yellow to red to brown.

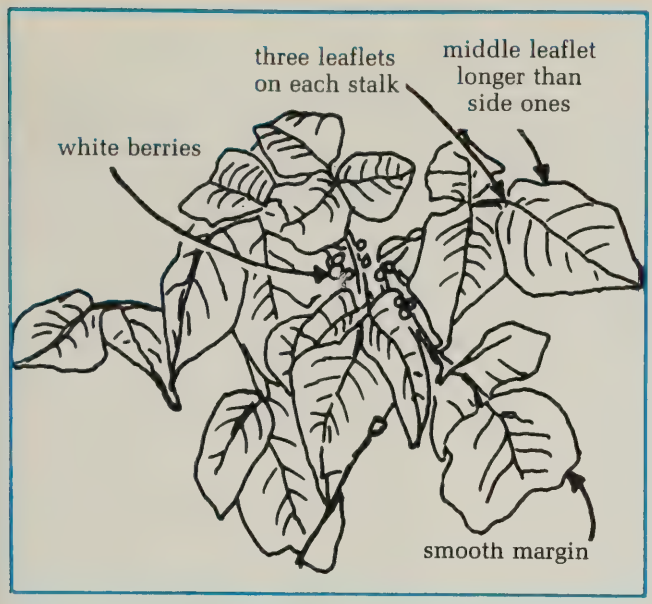
The plant may or may not have flowers arranged in loose irregular clusters at the axis of the leaves which appear green-to-white in color. Grayish-colored, waxy fruits with vertical grooves are sometimes present. These fruits may remain attached throughout the winter.

Poison oak. Two varieties are common. Eastern poison oak (*Toxicodendron toxicarium*) is an erect, perennial plant that normally grows as a low, woody shrub that does not climb. It is often found along sandy areas, or, in the dry soils of oak or pine groves.

Western poison oak (*Toxicodendron diversilobum*), on the other hand, grows as an upright shrub with numerous stems emerging from the ground. Or, it may appear as vines growing on trees, telephone poles, or on other vines.

Poison oak leaves, also found in 3-leaflet clusters, are irregularly lobed and resemble oak leaves. The plants have green-to-white flowers which may or may not mature into flattened, berry-like fruits. These may also remain on the plant throughout the winter.

The shape and color of poison oak leaves vary depending on where the plants are growing as well as the time of year. In extremely shady areas, leaves are narrow and very thin.



(A)

(B)

FIGURE 1.
Poison ivy (A) and poison oak (B) leaves.

Leaves on plants growing in the shade tend to be broad and dull. In full sun, they are thick and glossy. Alongside dusty roads, they are normally dull and lusterless.

Poison sumac *(Toxicodendron vernix)*. As can be seen in Figure 2, poison sumac leaves do not look like either poison ivy or poison oak. Its 7- to 13-leaflet clusters are arranged in pairs, with a single leaflet projecting from the middle. Poison sumac generally grows as a tall woody shrub, or coarse small tree.

Some people may not recognize these plants because they do not all grow in all parts of the country. Poison ivy is found throughout most of the U.S., except for parts of California and Nevada. Eastern poison oak grows within a large triangle formed by New Jersey, Texas and Florida. Western poison oak is found along the west coast from southern Canada to Mexico. Poison sumac is found from southern Quebec to central Florida, confined mostly to areas east of the Mississippi River. It prefers swampy, moist, boggy areas.

Thus, it is possible that a person who has never been away from the west coast may not have seen poison ivy or poison sumac. An individual from a metropolitan or large urban area who visits the countryside infrequently may see any of these

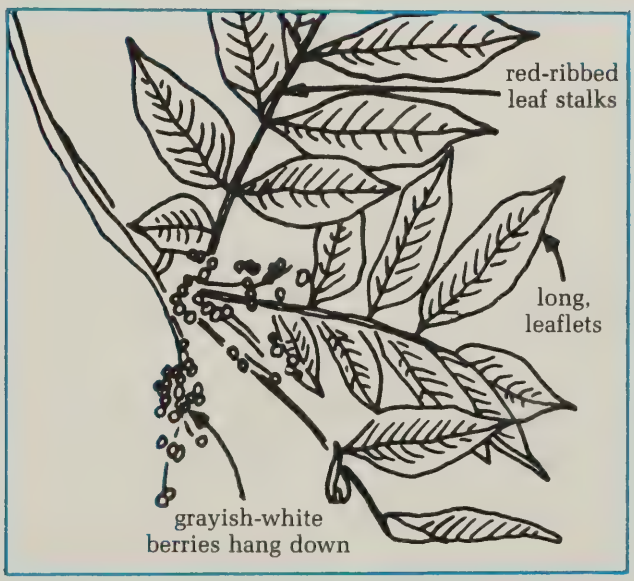


FIGURE 2.
Poison sumac leaves.

plants at different periods in their development, and not associate any particular feature with the potential to cause a dermatitis rash.

The one factor that each of these plants has in common, however, is that they all contain the same active allergen, an oleoresin complex called **urushiol.** As a group, these plants are the most common cause of plant-induced dermatitis in this country. An individual who is sensitive to any plant of the genus Toxicodendron will likewise be sensitive to any other plant of the genus.

Poison sumac is the least common cause of plant-induced poisoning of the group because it is generally found in uninhabited areas. Therefore, the remainder of this lesson is concerned mostly with poison ivy and poison oak. What is stated about the medical problems with these two types would also be characteristic of poison sumac. To simplify matters, we will refer to poison ivy and oak simply as poison ivy.

You only "get" poison ivy in the summer!

Question: What do you call a person who believes this? Answer: A fool who itches a lot in the winter!

Urushiol is distributed to all parts of the plant except the flowers, pollen and epidermis, through a canal system located within the plant structure. Simply touching a plant or rubbing against it will not cause a rash. However, when the plant is bruised or injured, urushiol is exposed and can contaminate any person or thing that touches it. As little as one microgram can initiate a rash in a susceptible person.

The danger of poisoning is greatest in the early spring and summer when the sap flow is most active. However, in the early fall when leaves are dry and fragile, an equally great danger exists. Also, even though the plant is dormant during the winter months, it is still alive and urushiol is still present. Thus, plant poisoning can occur during the winter as well.

Over the past few years, pharmacists have reported an increasing number of patients with poison ivy/oak dermatoses during the colder months. The problem has always existed around Christmas in nursery employees and others who dig or cut their own trees. It is now seen with more frequency because many Americans heat their homes during the winter with wood. Firewood may be cut fresh and brought into the home to be burned, or, it may have been cut and stacked months before. Either way, if poison ivy or oak vines growing on it are injured and then touched, dermatitis can occur, even months after the plant injury.

Direct contact with the plant is necessary to produce a reaction!

This misconception apparently originated with persons who swear they did not come into contact with an actual plant. But what most people do not recognize is that urushiol may be transmitted on clothing or shoes, garden tools, toys (golf clubs, etc.!), and animal fur. It may have been picked up several weeks to months before onto a pair of shoes which were set aside. Now, as the shoes are put on, the victim is contaminated and the reaction is initiated. Or, the family pet may have frolicked among poison ivy plants, and urushiol was deposited on its fur. As the pet's owner strokes the animal, contamination occurs. Time will slowly reduce the allergic quality of the causative oleoresin found on clothing and other inanimate items. Washing in hot, soapy water or dry cleaning the items if appropriate is the best way to remove the danger of subsequent contamination. Shoes should be cleaned with leather soap and polished. Contaminated animals should be bathed using rubber gloves.

Dermatitis rash can be prevented by washing after exposure!

There is some truth to this. If the area is washed with soap and water within 5 to 10 minutes of exposure, a reaction may be aborted, except in highly sensitive persons. Also, washing removes urushiol from under or on the nails, in the hair or from other areas where it may later come into contact with the skin.

One study involved persons who were slightly sensitive, and other persons who were highly sensitive to urushiol. Bruised leaves were applied directly to their forearms. Washing within 30 minutes prevented the reaction in some, but not in all of the less sensitive people. Washing within 60 minutes was totally useless in all of the individuals, regardless of their degree of sensitivity.

Urushiol rapidly penetrates into the skin, and attaches to skin protein. At this point, only minutes after exposure, it cannot be removed, not even with the best surgical soap, or even grandma's strongest lye soap!

Some people are naturally immune to poison ivy!

We all know people who have never experienced a poison ivy reaction. These people believe they are immune to it.

The fact is, they have probably never been sensitized! It is true that individuals' immune systems respond to antigenic challenges at different rates. Some people are highly susceptible to antigenic challenge and others are weakly susceptible. No one is one hundred percent immune.

Development of sensitivity. Urushiol is a mixture of four chemicals called catechols, all of which can cause sensitivity. It is termed a hapten because it is not antigenic by itself, but must combine with a protein within the body to form antigens.

Urushiol that contaminates the skin binds to skin proteins to begin antigen production. Special cells produced in the lymphatic system collect in the area and transport these antigens to the reticuloendothelial system. There, antibodies are formed which are then carried back through the vascular system where they are deposited ("fixed") under the skin.

An individual's first contact with urushiol initiates this reaction, and each subsequent contact adds to the total number of antibodies produced. The initial contact may even occur without the person's knowledge. The degree or extent of derma-

tological response is dependent on prior sensitization, which may have occurred weeks or years before, and on the number of antibodies formed.

Once sensitized (antibodies are formed and present under the skin), the individual may experience poison ivy dermatitis reactions every time he comes into contact with urushiol, for the rest of his life. However, as with other immune processes, the extent of reactivity normally recedes with advancing age. Additionally, some individuals who have experienced an especially severe reaction at one point early in life are less sensitive thereafter. This may be due to a condition similar to hyposensitization which is discussed later.

Occurrence. As stated above, as many as 75 percent of all Americans are sensitive to poison ivy and oak. Occurrence is somewhat related to age, as depicted in Figure 3.

Infants and very young children seldom contract poison ivy. Remember, sensitivity must be acquired from exposure to the plants. Also, the reticuloendothelial system (specialized cells that produce antibodies) of small children is not sufficiently functional to produce antibodies. This system develops with age.

Between ages 20 and 40, the incidence of urushiol poisoning reactions seems to decline, probably because people devote more time to their careers than to outdoor activities. The increase in incidence of reactions noted during our 40's and 50's represents our quest for renewed vigor or search for "youth", a pursuance of a second (more relaxed) career or lifestyle while living in the suburbs or country, or simply to taking time out to play ball with the children or grandchildren. And then, as the years roll on, the reticuloendothelial system becomes less responsive and antibodies which were perhaps formed years before are less reactive with antigens. With advancing years, many people are exposed to the cause less frequently. Thus, they experience a lowered incidence of allergic reactions.

Allergic reactions due to exposure to other sources of antigen. Individuals who are sensitive to plants of the genus Toxicodendron may also experience dermatitis following exposure to components of plants from other genuses. For example, an oil from the cashew nut shell or from the skin and stalks of the mango fruit tree can cause the response. The Japanese lacquer tree is the source of a rich lacquer that is used to finish fine furniture. Unsuspecting persons may find elbows or arms itching if they come into contact with such pieces of furniture.

Poison ivy is contagious and is spread by blister juice!

This is one of the most common misconceptions. It is perpetrated because a rash frequently appears initially on one area of the body, then, perhaps days later, may appear on another area. Or, "streaking" of the rash appears after scratching an area. The person interprets this "secondary" reaction as a response of having *spread* the disorder through scratching the original rash and contaminating the other sites with blister juice.

Poison ivy blister juice does not spread the rash. This liquid is serum that collects as a response to an antigen-antibody-induced inflammatory reaction occurring beneath it. There is no antigen present in it. In fact, experiments have demonstrated that when the liquid from blisters of one individual is placed on the skin of another sensitized individual, the second person *DOES NOT* develop the rash.

The appearance of a rash at some other site occurs because various parts of the body have different sensitivities to the allergen. The same reasoning holds for "streaking." Streaking occurs because this is the pattern in which the specific antibody, formed in response to antigens, becomes fixed to the skin. But the concentration varies in different areas of the body. A sensitized individual who comes into contact with the antigen will most likely experience the initial rash at or near the same site, regardless of where the urushiol was absorbed. This corresponds to the site of greatest antibody concentration. Then, with time, as other sites (having lesser antibody concentrations) become activated by interaction with circulating antigen, they also develop the typical rash. So the appearance of the delayed response is independent of scratching the initial rash, or contamination of one part of the body with blister juice from another.

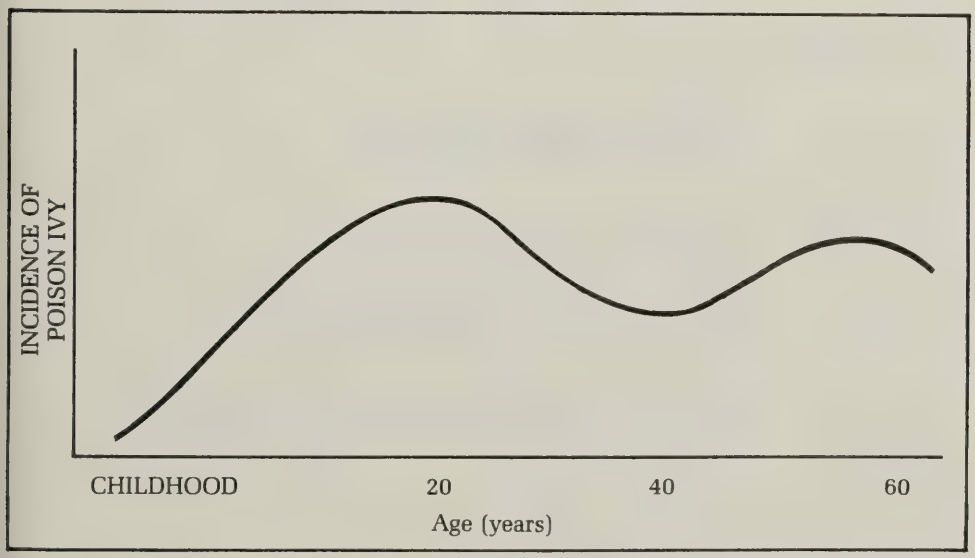


FIGURE 3.
Incidence of poison ivy expressed by the individual's age.

Symptoms

Symptoms of poison ivy generally appear within 12 to 24 hours although they may not show for 3 days. The first symptom is itching, followed by redness, inflammation, warmth, and blisters. Tender, thin skin (e.g., eyelids, genitalia) is more frequently involved than hairy areas of the body.

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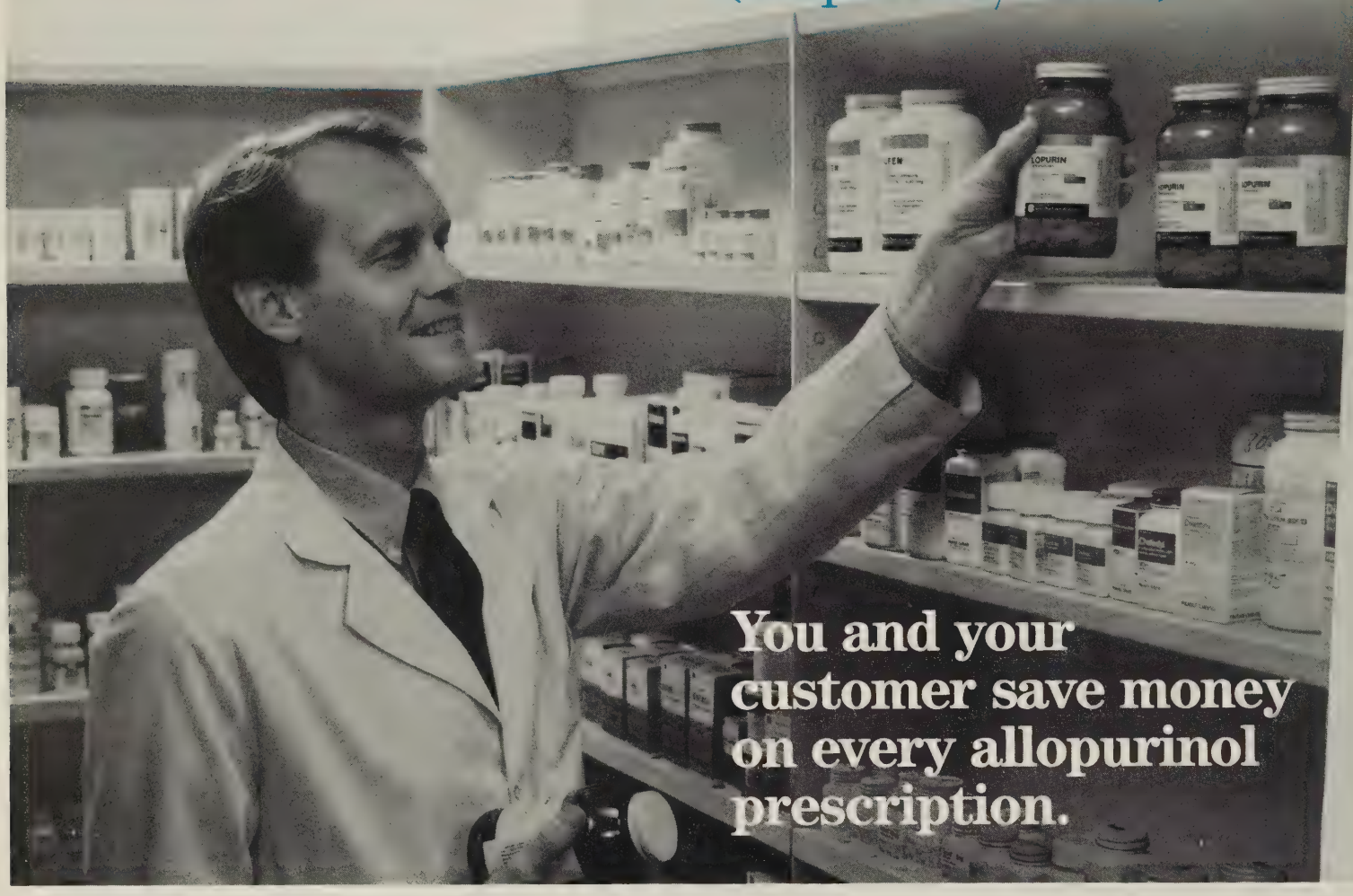

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TABLE 1
Commercially Available Poison Ivy Remedies

Product	Astringent	Counterirritant	Local Anesthetic	Antihistamine
Caladryl	Calamine	Camphor	—	Diphenhydramine
Calamatum	Calamine, ZnO	Camphor, menthol, phenol	Benzocaine	—
Calamox	Calamine, ZnO	Camphor, phenol	—	Pyrilamine
Calamycin	Calamine, Zn0, Zirconium oxide	—	Benzocaine	Pyrilamine
Dalicote	ZnO	Camphor	Diperodon	Pyrilamine
Hista-Calma	Calamine	—	Benzocaine	Phenyltoloxamine
Ivarest	Calamine	—	Benzocaine	Pyrilamine
Ivy Dry cream	Tannic acid	Camphor, menthol	Benzocaine	—
Ivy Dry liquid	Tannic acid	—	—	—
Rhulicream	Zirconium oxide	Camphor, menthol	Benzocaine	—
Rhuligel	—	Camphor, menthol	—	—
Rhulihist	Calamine, ZnO	Camphor, menthol	Benzocaine	—
Rhulispray	Calamine	Camphor, menthol	Benzocaine	—
Sting-Eze	—	Camphor, phenol	Benzocaine	Diphenhydramine
Surfadil	—	—	Cyclomethycaine	Diphenhydramine
Tyrohist	Calamine	Camphor, menthol	Benzocaine	Pyrilamine
Ziradryl	ZnO	—	—	Diphenhydramine

Most cases heal without permanent damage. If itching is not relieved and the victim scratches ravishingly, infection may result. On occasion, severely affected individuals will develop complications including blood changes, kidney damage, occasional psychotic reactions, dyshidrosis (disturbance in sweat production or excretion) and pigmentary changes.

Treatment

The choice of treatment depends on the severity of the reaction and the affected sites. The primary objectives are directed toward relieving itching and discomfort, and protecting damaged skin until the acute reaction has subsided. Normally, poison ivy reactions are self-limited to 1 to 3 weeks.

A variety of OTC medications are available to assist in attaining both objectives (Table 1). These are largely the same products that have been discussed in previous lessons in this series. Additionally, wet soaks (explained in a recent article, "Advising Patients on Dermatitis and its Treatment") are extremely useful for relieving itching when the blistering is severe, or anytime between applications of antipruritic products. Oftentimes, plain water will help. Hot water should be avoided. Even though it may initially produce a slight numbing effect, overall it generally intensifies the itching once the area returns to its normal temperature.

Antihistamines. Topical antihistamines are not recommended by many experts for treating poison ivy reactions. These agents offer little benefit in suppressing contact dermatitis reactions. Although they provide a mild antipruritic activity (through a local anesthetic action), they may sensitize the user to additional complications of an allergic nature. Systemic antihistamines help some patients and, in large doses, may provide a slight sedative action to lessen the severity of the itch sensation. This effect is nonspecific, however, and it is unacceptable to some individuals who must remain mentally alert.

Local anesthetics prevent the generation and conduction of action potentials in sensory nerve fibers. As such, they inhibit the transport of impulses from the area to which they are applied, and thus reduce itching. Benzocaine, diperodon and lidocaine are among the local anesthetics that have been ruled to be safe and effective by the FDA panel reviewing external analgesics.

Antiseptics. Alcohol and other antiseptic agents are included in poison ivy products. However, they are not needed if care is taken to prevent the skin from severe damage by vigorous scratching. On the other hand, alcohol can be an effective antipruritic. It is thought to be the "active" ingredient in witch hazel. When alcohol-containing products are used, the benefits are probably due to this activity rather than reducing bacterial growth.

Astringents. Through the years, astringents have been used to treat weeping lesions, such as those caused by poison ivy. Traditionally, topical astringents have been defined as substances which are applied locally to precipitate skin proteins, and contract (wrinkle) the tissue. They harden the cement substance of the capillary endothelium, which inhibits movement of plasma proteins across the capillary membranes. This reduces local edema/exudate, and, therefore, dries the area.

The astringent with the best track record, as it relates to proof of effectiveness for poison ivy, is aluminum acetate (Burow's solution). In fact, it is the only astringent that the FDA Advisory Panel on External Analgesics ruled to be safe and effective for such use. The panel concluded that, based on the current literature and wide clinical usage, aluminum acetate in a 2.5 to 5 percent (1:40 to 1:20) strength can be indicated for: "Use as a wet dressing, compress or soak for relief of inflammatory conditions and minor skin irritation due

to allergies, insect bites, athlete's foot, poison ivy or swelling associated with minor bruises and ulcerations of the skin."

The panel ruled that witch hazel was a safe and effective astringent for some of these indications, but did not include poison ivy.

Other astringent agents that are claimed to be effective in treating poison ivy include iron salts, tannic acid, zinc oxide (and calamine) and zirconium oxide. There is no doubt that ferric chloride and tannic acid have astringent activity. However, absolute proof of their safety and effectiveness in treating poison ivy has not yet been demonstrated.

One problem with ferric chloride is that it can stain the skin. The FDA panel that reviewed tannic acid for use in treating burns commented that its safety, when applied to damaged skin, is questionable.

Zinc oxide and calamine (which is basically zinc oxide with 0.5 to 1% ferric oxide added for color), while only slightly astringent, was ruled to be an effective adsorbent/drying agent. The panel that was responsible for OTC skin protectants indicated that zinc oxide and calamine, along with aluminum hydroxide gel, corn starch, dimethicone, kaolin and zinc acetate, are safe and effective for topical application to alleviate the "wetness" of poison ivy. These agents do not, however, improve the condition or relieve the itching as does aluminum acetate solution.

Not everyone agrees that the use of zinc oxide, calamine, and other "shake lotions" on poison ivy lesions affords relief to the patient. These agents dry on the skin to form a paste, and opponents of their use feel that the "drawing" effect that results is a sensation that is more objectionable than the original itching. They further claim that when these substances dry, they impede the ability of subsequently applied effective medications (e.g., hydrocortisone cream) to penetrate down to the affected area.

One final "astringent" is zirconium oxide (or carbonate). Since its introduction into poison ivy remedies, it has accumulated a far greater number of opponents than proponents (except, of course, the manufacturers). *Remington's Practice of Pharmacy* states that it is not only an ineffective astringent, but it actually can cause granuloma formation through an allergic process. The FDA panel that reviewed external analgesics listed it as an inactive ingredient.

Counterirritants. Camphor, menthol and phenol all produce a local anesthetic action through their "cooling" sensation. In low concentrations, they depress the skin's receptors that respond to itching. However, their use in effectively treating the itching of poison ivy has not been proven.

Steroids. Topical hydrocortisone products are rational therapy and are approved by the FDA for treating poison ivy dermatitis. Their use, directions, and overall utility have been discussed in previous lessons in this series. OTC products that contain 0.5 percent hydrocortisone are effective for reducing itching and protecting underlying skin in mild cases. Patients should be advised not to expect immediate relief. It may take a day or so for the antipruritic effect to become evident. Applying the hydrocortisone product in large amounts or more often than directed will induce no additional benefits. Instead, it will waste the consumer's money.

Should blisters be broken? If the dermatitis is sufficiently severe to cause blistering, these vesicles (blisters) may be opened. This will allow for easier penetration and absorption of topical medication into the dermis where it is needed. As stated above, blister juice is the body's serum and will not cause a further reaction if it touches another part of the body or another person. Although many physicians advise that blisters should only be opened aseptically by them, others state that this can be safely done at home. Conscientious consumers can be directed to carefully lance the blisters at their edge (not on top) so the serum can drain. Slight pressure can be applied to express the juice if necessary. The skin on the top of the blister should be preserved because it protects the epidermis beneath it from injury and infection, and assists the healing process. Once drained, an emollient cream or ointment product (versus a liquid) should be applied to keep the area soft and moist.

Hyposensitization

American Indians were known to chew poison ivy leaves to prevent getting the rash. This is a very risky procedure and is not recommended. Reports of intense swelling of the mouth and tongue, pharynx and anal region attest to the potential danger.

Hyposensitization of a severely sensitized person is utilized by some dermatologists. The procedure reduces the severity and duration of response in some patients. It doesn't completely desensitize them, and often sensitivity to poison ivy/oak normally returns within 6 months. Also, administering urushiol to an extremely sensitive person is associated with certain risks.

Hyposensitivity procedures involve administering a series of doses of urushiol, orally or intradermally, beginning with diluted concentrations, which are increased over a period of time. The idea is based on the antigen's ability to stimulate formation of high blood levels of a specific immunoglobulin (antibody) which then combines with urushiol from plants if contact is made later on. If urushiol binds to this circulating antibody, the complex keeps the antigen away from the fixed antibody which would normally initiate the inflammatory response.

Killing The Plants

A large variety of herbicide products which are claimed to eradicate poison ivy and oak plants is available. Pharmacists should advise persons who have these plants growing near their homes to destroy them if possible. A highly recommended product contains 2,4-D (2,4-dichlorophenoxy acetic acid). This herbicide should be applied to the leaves during the active growing season. It will be transported throughout the plant and kill it from within. Within a couple of days, the plant will begin to wither and eventually die, although a second application may occasionally be needed. After the plant has died, it can be carefully removed and discarded.

If the dead plants are then burned consumers should be reminded to avoid contact with the smoke. While urushiol itself cannot be carried

through the air, it can be carried by smoke particles. Because of the nature of smoke contamination, much more severe reactions may result than if the antigen came into contact with only a limited area of skin.

Pharmacist's Note

It is estimated that approximately one-half of all persons with poison ivy, oak or sumac can be successfully treated with OTC medications and home remedies. Occasionally, a person may experience an intensely severe reaction. When this occurs, the patient should be referred to a physician. As with most severe inflammatory responses, systemic steroids may be the treatment of choice for alleviating the person's discomfort. Additionally, if swelling is severe, respiratory distress may be encountered.

THIS AND THAT ABOUT PHARMACY

by Leon Weiner, P.D.

Among the group of 74 pharmacists that graduated from the University of Maryland Pharmacy School this year were some that have strong roots in pharmacy. Examples are:

Deborah Bass—Father Harry Bass, P.D., Md. State Dept of Health; Marian D. Chodnicki—Father Marion R. Chodnicki, P.D., Drug Fair; Linda Plempel Cooper—Father Alfred Plempel, Jr., P.D., Sav A Lot Drugs; Joseph A. DeMino—Father Leonard DeMino, P.D., People's Drugs; Mark H. Lapouraille—Grandfather C. Howard Lapouraille, P.D., Un. Of Md. 1907; David M. Posner—Father Alan Posner, Loewy Drug Company; Craig M. Roth—Father Marty Roth, P.D., Rite Aid Drug; Carol A. Steinhilber—Father Richard Steinhilber, P.D.—Eckerd Drug.

Nathan Levin, University Of Maryland Pharmacy 1936, retired from state service on November 1, 1983 after working 15 years as Pharmaceutical Chemist for the Md. State Department of Health. Since that time, he has been working as a regular volunteer in the same capacity.

Recently while working in Western Maryland, I was delighted to see a story about one of our current University Of Maryland Pharmacy graduates featured on page 1 of the Cumberland Sunday Times—dated June 24, 1984. The article, along with a photo, dealt with Murray A. Mease, of Cumberland. Murray recently received his Doctor of Pharmacy Degree. The article noted that he was a graduate of Fort Hill High and Frostburg State College. Dr. Mease, who was recently married, has been awarded a one year appointment to the Fellowship in Oncology Pharmacotherapy which is to be conducted at the Clinical Center, N.I.H. in Bethesda.

Daniel F. Mackley, University of Maryland Pharmacy, 1976, has left the hospital scene in Frederick and headed westward to Frostburg where he has bought a pharmacy. Frostburg Pharmacy, located at 307 E. Main Street, is the former Deist Pharmacy owned by a Freeman Deist. Mackley, a tall, handsome, bachelor, was encouraged to buy this store because of the closeness of Frostburg State College.

PHARMACY CHANGES—ABOUT JUNE 1984

The following are new pharmacies:

New England Critical Care
9130 A. Guilford Road
Columbia, Maryland 21046

Home Health Care of America
10200 Old Columbia Road Suite D
Columbia, Maryland 21046

People's Drug Store 1415
6510 Baltimore National Pike
Baltimore, Maryland 21228

The following store closed:

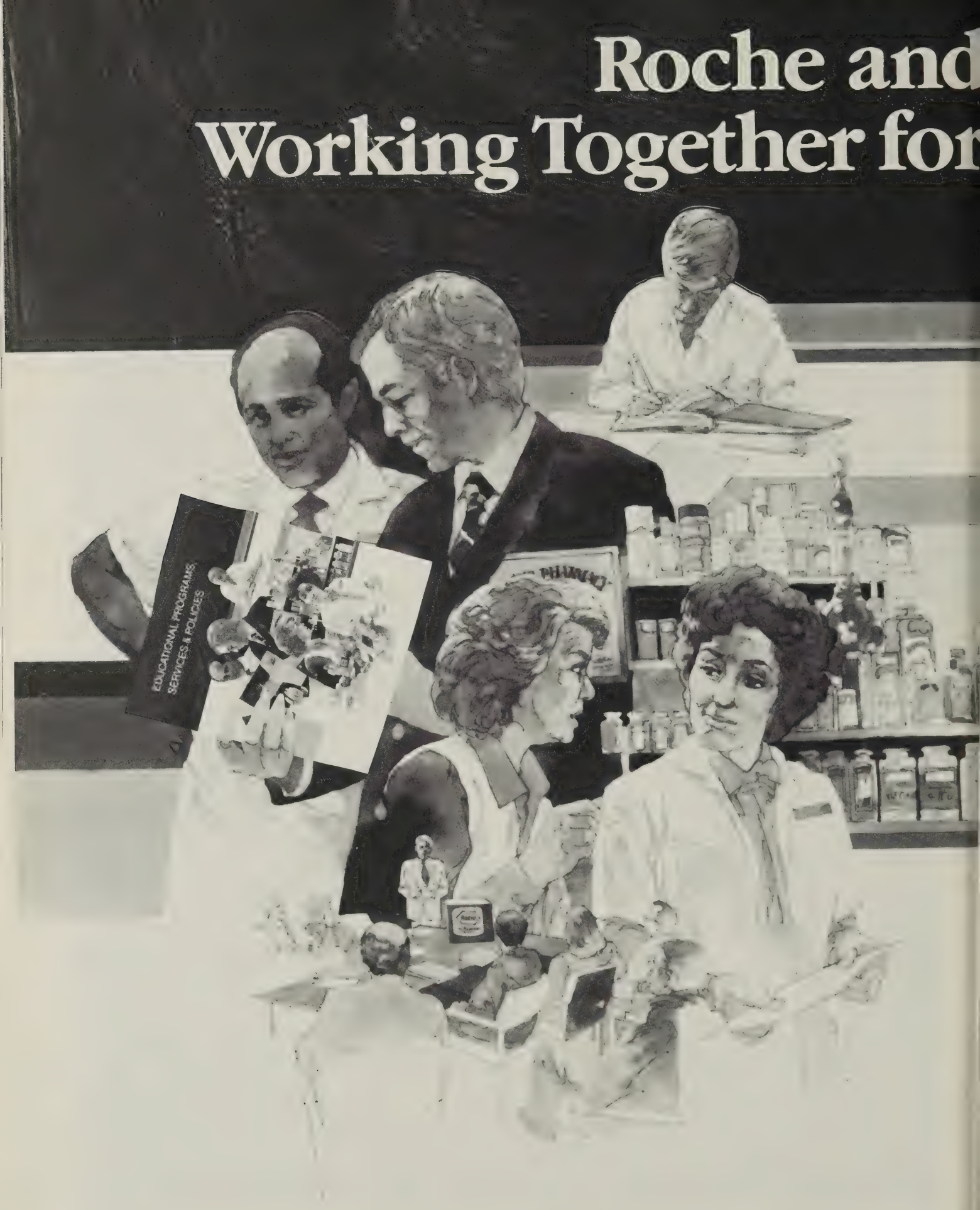
Chapel Oaks Farmer's Market Pharmacy
5354 Sheriff Road
Chapel Oaks, Maryland 20743

The following Changed ownership & name:

CO-OP Pharmacy
121 Centerway
Greenbelt, Md. 20770
Formerly: Consumer's Pharmacy

Frostburg Pharmacy
307 E. Main Street
Frostburg, Maryland 21532
Formerly: Deist Pharmacy

Greenbelt Professional Pharmacy
6201 Greenbelt Road
College Park, Maryland 20740
Formerly: Professional Pharmacy and
Home Health Care Pharmacy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Convention Report

ANNUAL REPORT OF THE MARYLAND BOARD OF PHARMACY

by
Paul Freiman, Secretary

In compliance with the provisions as set forth in the Health Occupations Article Section 12–205 of the Annotated Code of Maryland, this report is submitted to the Honorable Harry Hughes, Governor of Maryland and to the Maryland Pharmaceutical Association. This is the ninetieth report to the Governor and the eightieth report to the Association. The report covers the activities of the Maryland Board of Pharmacy for the fiscal year ending June 30, 1984. This report is also being submitted to the Secretary of Health and Mental Hygiene, the McKeldin Library of the University of Maryland, the Enoch Pratt Free Library, the Department of Legislative Reference, the Hall of Records and the State Library.

MEETINGS

During the year the Board held 20 meetings, 9 of which were held at the School of Pharmacy of the University of Maryland, for the purpose of conducting examinations for registration of pharmacists.

OFFICERS

Bernard Lachman was elected President and Paul Freiman was elected Secretary-Treasurer of the Board.

PERSONNEL

The staff consists of Roslyn Scheer, Executive Director; Margaret Lloyd, Office-Clerk II, Lisa Kraft and Robert Wolfe, Steno Clerk III.

EXAMINATION

The Board conducted examinations for registration of pharmacists during the year. They were held at the School of Pharmacy of the University of Maryland on June 28, 29, and 30, 1983 and September 13, 14, and 15, 1983 and January 24, 25, and 26, 1984.

The applicants who were examined in June of 1983 were licensed in July, 1983 which is in F.Y. 1984. There were eighty-seven (87) applicants for the Board in June, 1983. Seventy-nine passed both the theoretical and practical portions of the examination and were subsequently registered. Eight failed the examination.

Having previously passed the theoretical portion of the examination, one candidate took the practical examination in June. The candidate passed and was subsequently registered.

There were twenty-nine (29) applicants for the Board in September, 1983 (F.Y. 1984). Eight passed both the theoretical and practical portions of the examination and was subsequently registered. Seven failed the examination. Fourteen candidates took the FDLE Jurisprudence exam *only*.

There were nine applicants for the Board in January, 1984 (F.Y. 84). Five passed both the theoretical and practical portions of the examination and were subsequently registered. Four failed the examination. Having previously passed portions of the examination, one candidate took the practical examination, passed and was subsequently registered.

Data relative to the June 1983 examination will be given in the next Annual Report.

The pharmacist licensure examination is given in two parts. Part I is the NAPBLEX from the National Association of Boards of Pharmacy which consisted of the following subjects:

Chemistry
Pharmacy
Mathematics
Pharmacology
Practice of Pharmacy

Part II consists of:

Laboratory
Maryland Law
Federal Law

The Federal Law Exam is obtained from NABP. The Maryland Law Exam was compiled by members of the Board. The laboratory examination, requires the compounding of four prescriptions per applicant. The following table shows the number of pharmacists who were registered by examination during the past ten years.

Year	Number of Pharmacists
1974–1975	113
1975–1976	109
1976–1977	166
1977–1978	150
1978–1979	137
1979–1980	180
1890–1981	183
1981–1982	100
1982–1983	116
1983–1984	92

As in the past, many pharmacists applied for reciprocal registration in Maryland in order to accept positions with their employers who are opening stores in Maryland. Those applicants who did not meet our requirements concerning practical experience prior to or after registration in another state were advised that they must take our practical examination in order to verify their qualifications.

In all cases, an applicant for reciprocal registration must appear for a personal interview. The entire Board must act on whether or not to grant registration to such applicants, who must sign an agreement to comply with Maryland's law pertaining to drugs and pharmacy.

The following table shows the number of pharmacists granted registration by reciprocity and the number who were certified to register by reciprocity in other states during the past ten years.

Fiscal Year	Reciprocity	Certification
1974–1975	76	45
1975–1976	89	44
1976–1977	78	68
1977–1978	91	77
1978–1979	113	42
1979–1980	73	69
1980–1981	88	72
1981–1982	85	51
1982–1983	103	60
1983–1984	119	58
TOTAL	915	586

The table shows Maryland gained 329 pharmacists by reciprocity during the past ten years.

New permits to operate a pharmacy were issued to 41 firms for the 1984 Fiscal Year.

PHARMACY PERMITS

Location	1983–1984
Counties:	
Allegheny	1
Anne Arundel	7
Baltimore	10
Frederick	1
Harford	4
Kent	2
Montgomery	5
Prince Georges	5
County Totals	35
Baltimore City	6
State-Wide Totals	41

MANUFACTURERS PERMITS

New permits to manufacture drugs, medicines, toilet articles, dentifrices, or cosmetics during 1983 were issued to two firms.

DANGEROUS DRUG DISTRIBUTORS PERMITS

The Board issued twelve new permits to sell, distribute, give or in any way dispose of dangerous drugs during 1983.

OTHER PERMITS

The total number of pharmacies in the State of Maryland for 1984 fiscal year is 935 and the total number of pharmacists is 5,460.

LEGISLATION

The following legislation which affects the profession of pharmacy either directly or indirectly was enacted by the 1984 Maryland General Assembly. This list of Bills includes the purpose as it pertains to pharmacy.

HB 128 Controlled—Dangerous Substances Registration: Changes CDS registration from yearly to every two years.

HB 231 License—Application Fee: Allows the Board to set the pharmacist licensure exam fee by regulation and requires the fee not to exceed the cost of purchasing and administering the exam.

HB 455 Medical Prescriptions—Opiates: Prohibits the sale or possession of certain cough syrups containing opium or codeine withough a prescription.

HB 604 Controlled Poisons—Poison Register Repeal: Repeals Poison Register related Laws.

HB 606 Barbiturates—Control: Repeals Barbiturate Law which was superceded by CDS laws.

HB 1136 Consolidated Bill: Authorizes the issuance of subpoenas and the administration of oaths in connection with Board investigations or proceedings; grants civil immunity to certain persons acting in good faith in giving information to the Board or participating in its activities.

SB 317 Pharmacists—Executive Director: Permits the Board of Pharmacy to designate one of its staff an Executive Director.

SB 782 Pharmacists—Emergency Refill of Prescriptions: Permits pharmacists to issue emergency refills under certain circumstances when the prescriber is not available.

The Board maintained cooperative activities with the State Department of Health and Mental Hygiene, the School of Pharmacy—University of Maryland, the Maryland Pharmaceutical Association, the Federal Drug Administration, the Food and Drug Administration, City, County and State Police and all Boards and Pharmacy Schools throughout the country.

DISCIPLINARY ACTIVITIES

The Board of Pharmacy receives complaints from the public concerning problems with the Board's licensees. The wide range of complaints varied in severity. Listed below are statistics concerning the types of consumer complaints for the period April 1983 to April 1984.

miscellaneous*	22
mislabeled prescriptions	3
communication	14
incorrect drug dispensed	14
expiration date	3
generic substitution	3
refilling prescription without prescription	2
infrequently prescribed drug-hard to find	1
wrong dosage dispensed	8
Medicaid fraud	2
shortages of controlled drugs	6
concentrated form drugs	2
TOTAL CONSUMER COMPLAINTS	80

*Complaints are on pricing, cleanliness and professionalism.

Other complaints were received from the Division of Drug Control, Medical Assistance Compliance Administration, and the State of Maryland Courts. Seven pharmacists were charged with violation of the pharmacy laws. No formal disciplinary hearings were held; all cases were resolved by Consent Agreements. Three pharmacists' licenses were revoked. Three pharmacists' licenses were suspended, immediately stayed and the individuals placed on probation under certain conditions. One pharmacist was reprimanded and placed on probation under certain conditions. One license which had been suspended in a prior year was reinstated.

FINANCES

All funds of the Board of Pharmacy are deposited to the credit of the Treasurer of the State of Maryland and disbursements covering the expenses of the Board are paid by voucher by the State Comptroller.

FINANCIAL STATEMENT

The Board of Pharmacy had revenues of $38,027 in 1982 and $210,813 in 1983. The Board of Pharmacy had expenditures of $72,305 in 1982 and $95,865 in 1983. The Board's budget is $117,165 for 1984 and $119,710 for 1985.

OTHER ACTIVITIES

In addition to the President, Bernard Lachman and Secretary-Treasurer, Paul Freiman, the Board consists of the following commissioners: Ralph Quarles, Robert Snyder, Leonard DeMino, Anthony Padussis, Estelle Cohen, and Phyllis Trump. All the Commissioners are registered pharmacists in the State of Maryland with the exception of Ms. Cohen and Ms. Trump who are consumer (public) members of the Board.

The Board promulgated or amended the following regulations:

1. Formal hearings
2. Examination for Licensure and Internship Programs
3. Removal of Expired Prescription Drugs
4. Reinstatement of Expired Licenses for Pharmacists

The following regulation was repealed:

1. Posting of Prescription Prices and Services

At this time the Board is in the process of proposing for promulgation or amendment regulations concerning:

1. Pharmacy Equipment
2. Civil Penalties;
3. Closing of Pharmacy;
4. Parenteral/Sterile Enteral Compounding

In 1984, the Board continued its excellent relationships with the Department of Health and Mental Hygiene. The cooperation and courtesy extended to the Board of Pharmacy by all members of the Department is appreciated by all the Board members.

Again the Board must commend our Executive Director, Roslyn Scheer, for her continued excellent management of the Board's business. Through her efforts the Board continues to operate smoothly and efficiently. In addition, the Secretary-Treasurer must commend all of our excellent secretaries Margaret Lloyd, Lisa Kraft, and Robert Wolfe for their excellent work and cooperation.

All of the Commissioners actively participated by serving on various committees appointed by the President, attending numerous meetings throughout the State, and being available for consultations and special meetings when necessary.

During this year, the Board has increased its activities into the distribution of prescription medications in areas other than pharmacies. In cooperation with the Maryland Commission on Correctional Standards regulations were promulgated which control the distribution of medication in all correctional institutions in Maryland.

This increased activity is a result of the Board members visiting various institutions throughout the State and reviewing their methods of dispensing and administering medication. As a result of these efforts, we believe that in the future recipients of prescription medication, wherever it is received in Maryland, will be assured of the same high standards and protection that exist in the licensed pharmacies in our State.

The Board of Pharmacy is working with the Committee for Impaired Pharmacists of the Maryland Pharmaceutical Association. The Committee is a viable support system of peers and acknowledged specialists working on the premise that chemical dependency is an illness of complex behavioral and physiological origins.

This year marks the end of the terms for two members of our Board. Ralph Quarles served twelve years on the Board during which time he witnessed and participated in the growth of the Board of Pharmacy to its present status and served as its President for a period of time. Phyllis Trump a public member of the Board actively participated in Board activities. The Board of Pharmacy will sorely miss both of these two individuals, and wish them well in their future endeavors.

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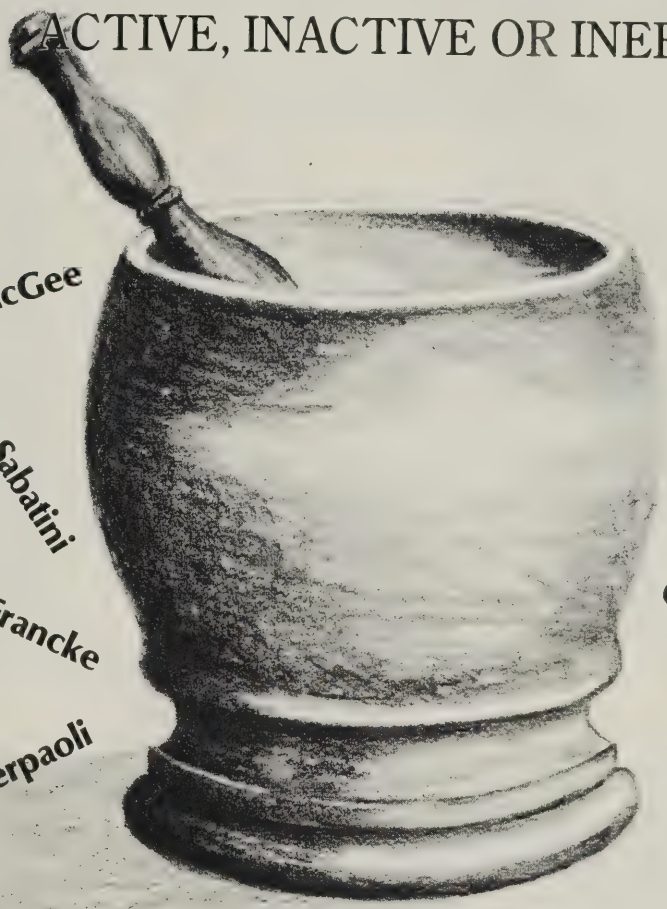

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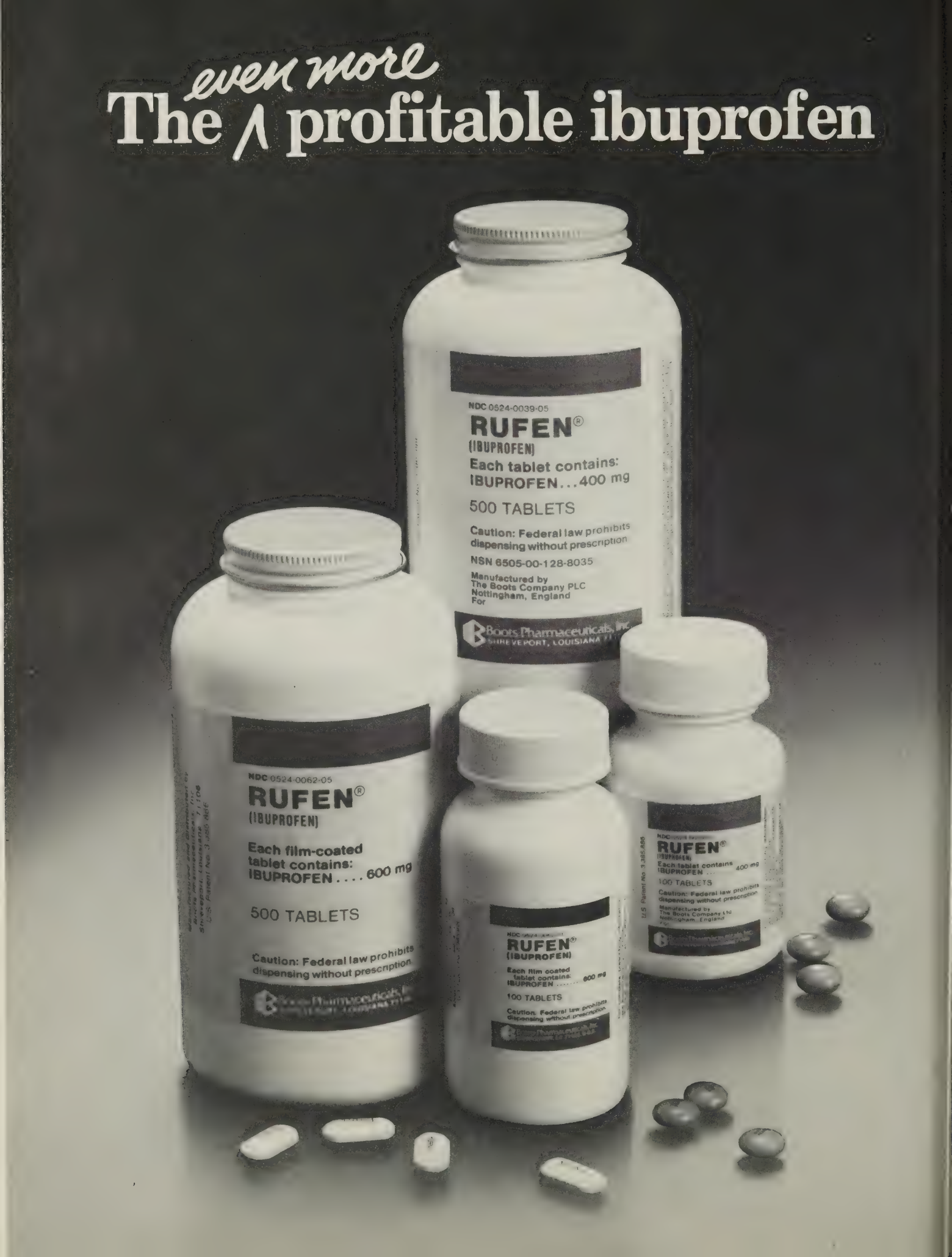
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RUFEN 400 mg MOTRIN 400 mg	100 100	$ 10.80 $ 13.85	**$ 3.05 (22%)**

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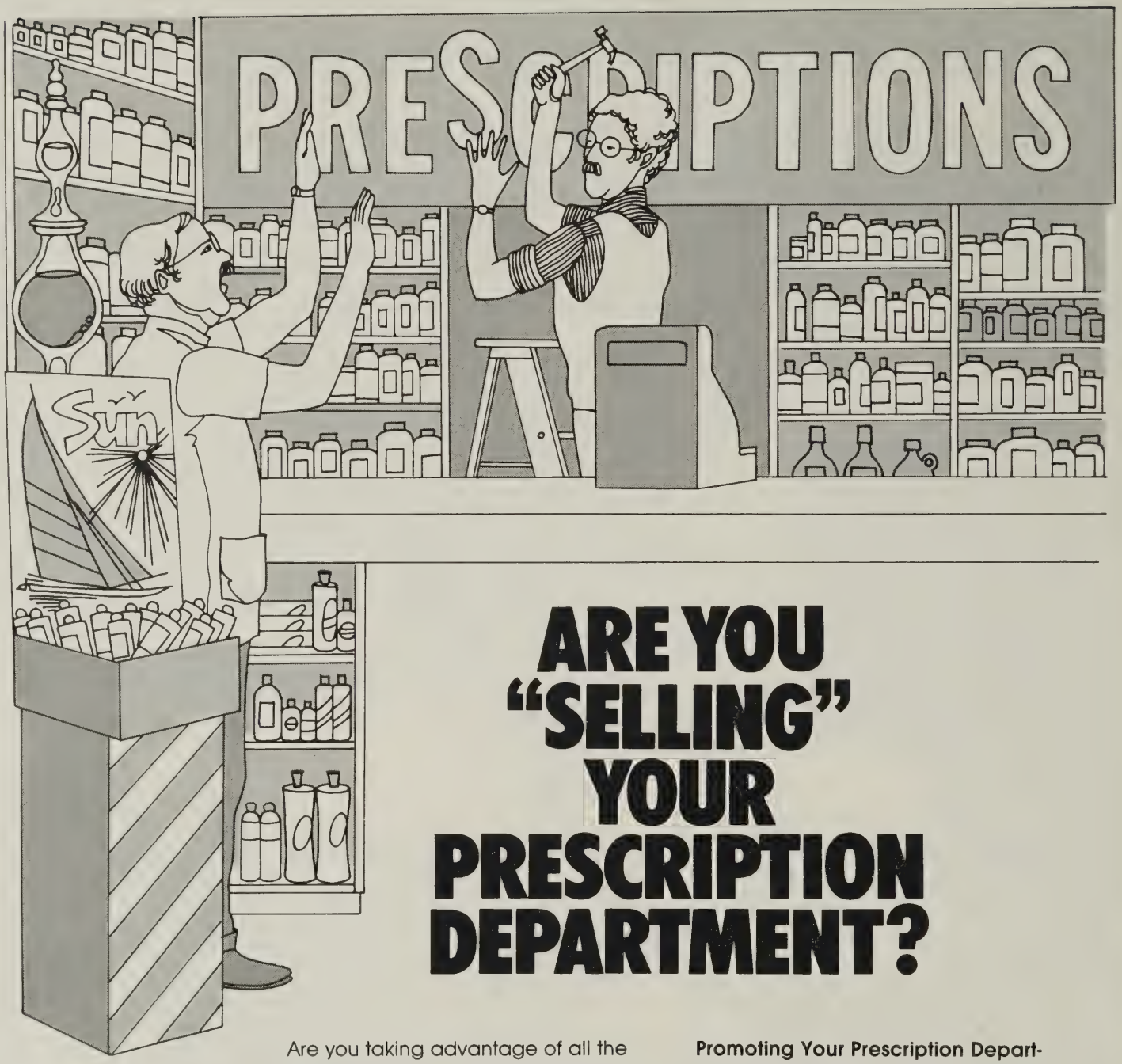

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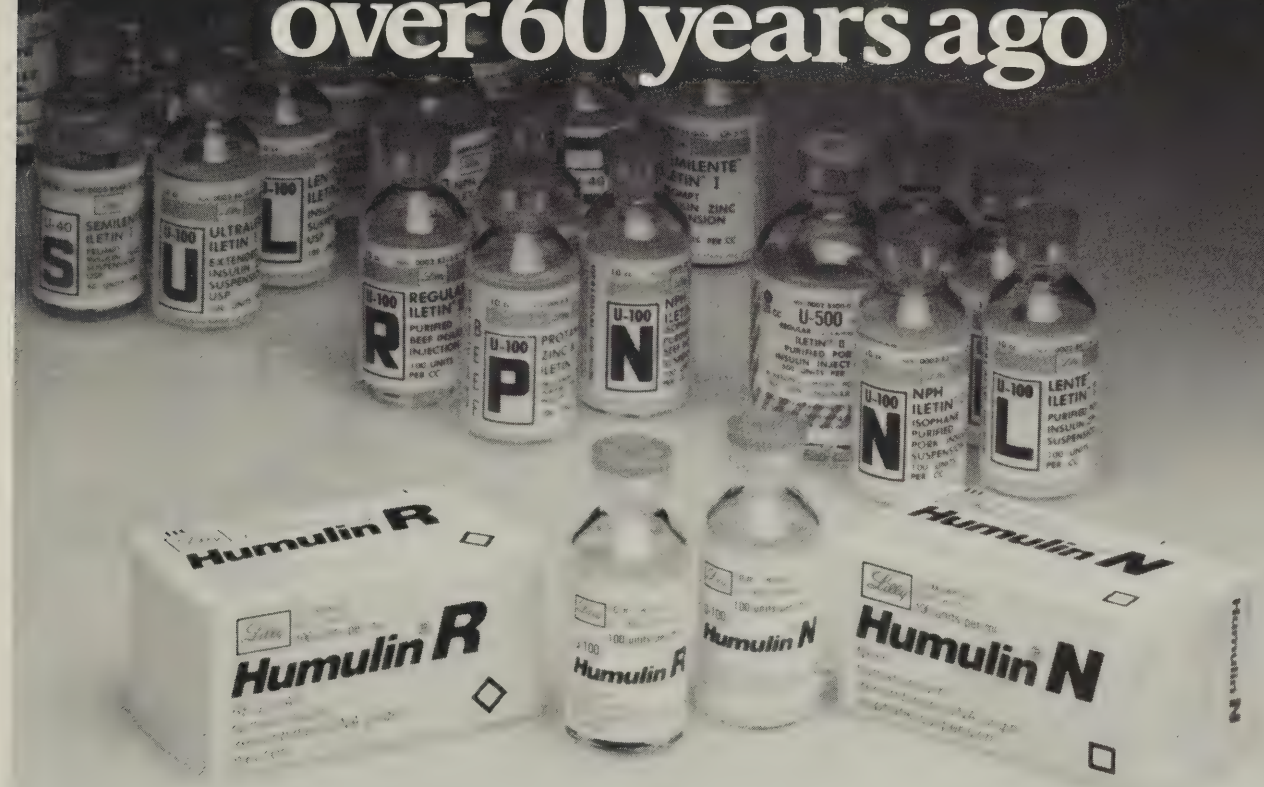

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LETTERS

Dear Mr. Banta:

During the Ninth International Congress of Nephrology a group of concerned nephrologists participated in a press conference on drugs which adversely effect kidney function in general, with a specific focus on the potential problems which could result from the OTC availability of ibuprofen (as Advil or Nuprin). Many physicians recognize that the general availability of ibuprofen may result in health difficulties not only in patients with kidney disease, but also in individuals with high blood pressure, liver disease, and the elderly in general.

We were unanimous in concluding that in our opinion the best solution was a return to ibuprofen solely as a prescription drug. This, however, will require action by the FDA, which may not be forthcoming until reasons for review, such as documented illness due to OTC ibuprofen, have occurred. It is recognized that alternative solutions are available. One would be to create a new package insert for patients purchasing OTC ibuprofen which detailed the specific groups of patients at risk from ibuprofen. However, many people may be unaware of a health problem which should stop them from using ibuprofen, and a package insert *alone* may not be sufficient.

The Illinois Association of Community Pharmacists has taken a direct action in recognition of the potential health care problems posed by OTC ibuprofen. A prescription drug involves at least two health care professionals—a physician and a pharmacist—before a patient can obtain a medication. An OTC preparation is usually available without any specific guidance. The Illinois group has made OTC ibuprofen available only after reviewing with the purchaser the possible "life threatening side effects of the drug."

I am enclosing copies of some newspaper articles concerning events over the past six weeks. I would appreciate it if you would review these with the members of your Association. It is my hope that your Association will agree that this is a responsible act on the part of pharmacists as health care professionals.

If you want any additional information, please feel free to get in touch with me. Indeed, given the general concern among nephrologists, you can also contact those in your community for a review of the potential problems associated with OTC ibuprofen.

WALTER FLAMENBRAUM, M.D.
Chief, Division of Nephrology
and Hypertension
Professor of Medicine
Mt. Sinai School of Medicine
New York, New York

Dear Dave,

On Monday evening, July 16, CBS Evening News reported that Illinois pharmacists are restricting sales of Advil® and Nuprin® be requiring pharmacist-only dispensing of ibuprofen in their stores. The pharmacists claim that consumers need to be warned of the dangers of this drug; the reporter claims that pharmacists are using this drug to control sales in order to enlarge their share of the marketplace. He states that the vast majority of sales of non-prescription medications are in mass-merchandized retail outlets, such as supermarkets and "chain" drug stores, while only 14% of non-prescription medications are sold through small independent pharmacies.

On July 6, prior to this televised report, several pharmacists describing themselves as "concerned professionals" held a press conference to raise the issue of the need for a third class of drugs. The Chicago Sun-Times, July 7th, quotes the pharmacists, "this drug can lead to kidney failure and high blood pressure problems if high doses are taken and can be hazardous to diabetics, pregnant women and patients with liver or heart conditions." The pharmacists are hoping to create a national movement by pharmacists to place these two products behind the counter. Not surprisingly, reports from Illinois indicate that as a result of the publicity, several patients have returned bottles of Advil® and Nuprin® because they heard it was unsafe. (We remember that Chicago was the scene of the Tylenol® sabotage.)

Such concerns have been raised in anticipation of approval of OTC ibuprofen. The NARD sites ibuprofen as a case to support the issue of pharmacist-legend drugs. They quote an FDA official in the March, 1984 journal who stated that "We fully expect to see some deaths out there in patients who are sensitive to aspirin."

What are the legal implications of publically restricting sales of products approved for OTC use?

Certainly pharmacists have a responsibility to patients to assure proper use of medications. We have always kept certain products behind the counter, for example opthalmics, which we felt require pharmacist supervision both with regard to tampering as well a patient use. We need to be sensitive to the issues raised with ibuprofen. Perhaps, we can take APhA past president Maurie Bectel's suggestion and place a sign over ibuprofen to "See your pharmacist before purchasing this product." We need to anticipate potential problems with ibuprofen and promote our professional responsibilities to our patients. Let us take this opportunity and rise to the challenge!

Madeline Feinberg, Pharmacist
Rock Creek Pharmacy, Silver Spring

(Editor's Note: See the article appearing on page 22 of the August, 1984 Issue)

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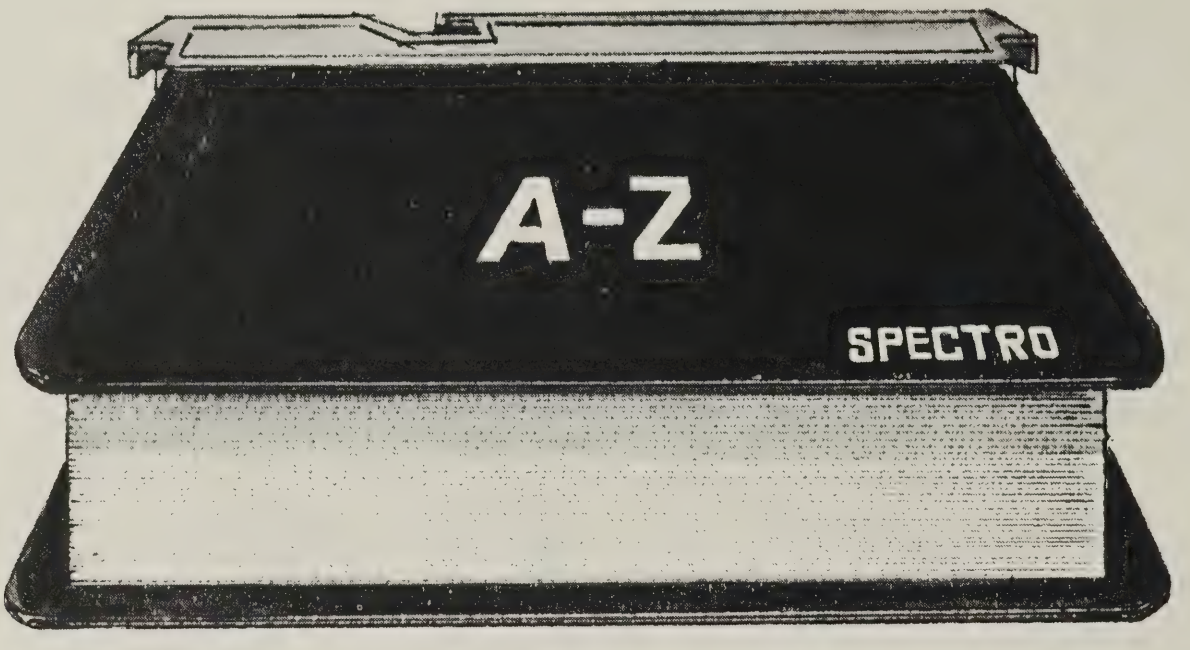

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SPECTRO INDUSTRIES

Brian Sanderoff (left) and Mark Zellhoffer (right) are recent graduates of the School of Pharmacy and each worked in the Association's office in a four week special studies PEP rotation. During that time they learned about Association management and, at the same time, accomplished several valuable projects for the Association.

Donald O. Fedder, Pharm.B.S., Dr. P.H., has been elected Chairman of the Maryland High Blood Pressure Commission for the fiscal year beginning July 1, 1984. Dr. Fedder is Assistant Professor of Pharmacy Practice and Administrative Science and Director of Community Pharmacy Programs at the University of Maryland School of Pharmacy and has served as Vice Chairman of the Commission for the past two years.

The Maryland High Blood Pressure Commission, created by the State legislature, is charged with the responsibility to educate the public about high blood pressure (HBP), a serious health problem affecting 60 million Americans, 600,000 in Maryland alone. The Commission, a multidisciplinary body appointed by the Governor, establishes standards for HPB programs and works to coordinate services for the effective treatment and control of HBP.

Dr. Fedder replaces R. Patterson Russell, M.D., Associate Professor of Medicine, the Johns Hopkins School of Medicine, who has served as Commission Chairman since its inception in 1976. Dr. Fedder is active in a variety of professional and civic activities, including the American Hearth Association—Maryland Affiliate, where he serves as Secretary of the Board of Directors and Chairman of the Hypertension Sub-committee.

ABSTRACTS

Excerpted from PHARMACEUTICAL TRENDS, published by the St. Louis College of Pharmacy; Byron A. Barnes, Ph.D., Editor and Leonard L. Naeger, Ph.D., Associate Editor

CLONIDINE:

Clonidine (Catapres) produces hyperglycemia in animal models, and may exert a similar effect in humans. The reaction is said to be caused by a central alpha-2 agonistic action as well as by enhanced gluconeogenesis. *J Pharmacol Exp Ther,* Vol. 228, #1, pl 168, 1984.

CIMETIDINE-ACETAMINOPHEN INTERACTION:

Acetaminophen overdoses can lead to hepatotoxicity and death. The formation of an active arylating metabolite leads to degeneration of the macromolecular structure of the liver. Since oxidation is associated with the formation of the metabolite, a known inhibitor of oxidation (cimetidine-Tagamet) was used as an antidote in experimentally poisoned animals. Toxicity was reduced and the authors suggest that cimetidine be considered as an antidote for acetaminophen toxicity. *J Clin Invest,* Vol. 73, #2, p. 383, 1984.

CELLULAR RETRANSPLANTS:

Some bone marrow cells can be removed from patients scheduled for antineoplastic therapy and then replaced after drug administration. This prevents alterations from occurring in the normal healthy marrow cells and reduces the likelihood of drug-induced anemia. Since some of the cells which are removed may be neuroblastoma cells, it was found beneficial to remove these cells prior to retransplantation. A system was developed using antibodies conjugated to magnetic microspheres. Using a magnetic device, these abnormal cells can be removed before the cells are retransplanted thus increasing the success of the entire procedure. *Lancet,* Vol. I, #8368, p. 70, 1984.

MOUNTAIN SICKNESS:

Much press has been given acetazolamide (Diamox) and its effectiveness against the development of mountain sickness. Investigators have found that a potent synthetic glucocorticoid, dexamethasone, will help minimize the symptoms of this condition. Since steroids can reduce cerebral edema, symptoms of mountain sickness may be due to such fluid accumulation and thus administration of 4 mg of dexamethasone every 6 hours for 24 hours prior to exposure may be able to help prevent symptomology. *N Engl J Med,* Vol. 310, #11, p. 683, 1984.

ENTERAL FEEDINGS:

Many different types of commercial products are available for enteral feedings. The amount of vitamin K contained in these preparations will vary considerably, and thus should be evaluated before administering these feedings to patients who are receiving warfarin therapy. *Br Med J,* Vol. 288, #6416, p. 557, 1984.

ALCOHOL:

Alcohol has been linked to both improved cardiovascular function as well as hypertension. Ingestion of large amounts of ethanol (80 grams per day or more) seems to increase the risk of hypertension in men. Restriction of alcohol from the diet allows values to return to near normal. The mechanism of this effect is unclear but it is thought to be due to an effect of the drug itself rather than to a reflex or to withdrawal phenomena. *Lancet,* Vol. I, #8369, p. 119, 1984.

HUNTINGTON'S CHOREA:

Huntington's chorea is a serious disorder affecting adults. Studies of DNA material indicates that a marker or a chromosome can be used to identify patients who have a greater risk of developing this condition. By identifying these patients ahead of time, early treatment can be suggested. *Br Med J,* Vol. 287, #6405, p. 1567, 1984.

DIGOXIN:

Digoxin (Lanoxin) has been used as an example of a drug which is not subject to metabolic alteration and thus depends primarily on the kidney for removal from the body. Recent studies have suggested that digoxin does indeed undergo a variety of metabolic alterations but that these metabolites remain reactive to the antibodies used in the radioimmunoassay systems employed to measure digoxin levels. *Clin Pharmacol Ther,* Vol. 35, #1, p. 34, 1984.

ARTERIOLAR MUSCLE RELAXANTS:

The relaxation of arteriolar smooth muscle is apparently mediated by activation of the second messenger system within the muscle cell. Nitrogen oxide-containing vasodilators such as nitroglycerin and sodium nitroprusside apparently increase the cellular concentration of cyclic GMP to produce relaxation while beta-adrenergic agonists such as isoproterenol (Isuprel) act by increasing the concentration of cyclic AMP. *J Pharmacol Exp Ther,* Vol. 228, #1, p. 33, 1984.

VASOACTIVE INTESTINAL PEPTIDE:

Vasoactive intestinal peptide has been identified as a 25 aminoacid peptide found in nerve fibers throughout the body. Its function is still unclear, but it is said to act as a transmitter for non-adrenergic-non-cholinergic nerve fibers. Studies show the peptide to increase 20-fold during tumescence and erection, thus indicating that this peptide may be useful in treating patients with penile erectile dysfunction. *Br Med J,* Vol. 288, #6410, p. 9, 1984.

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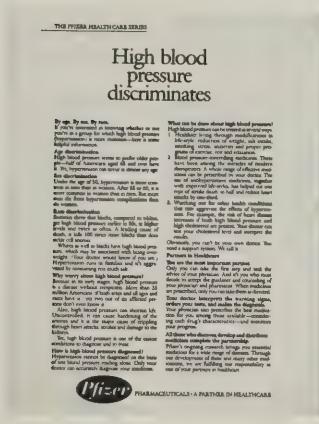
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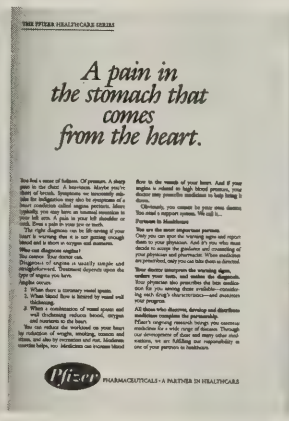
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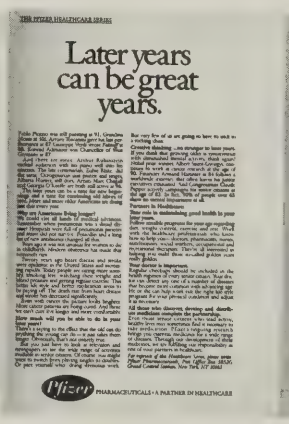
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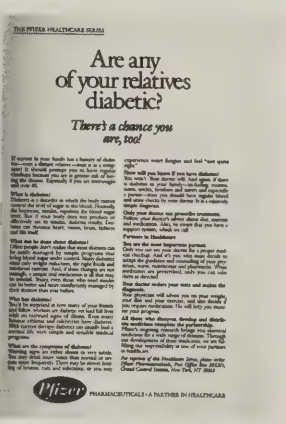
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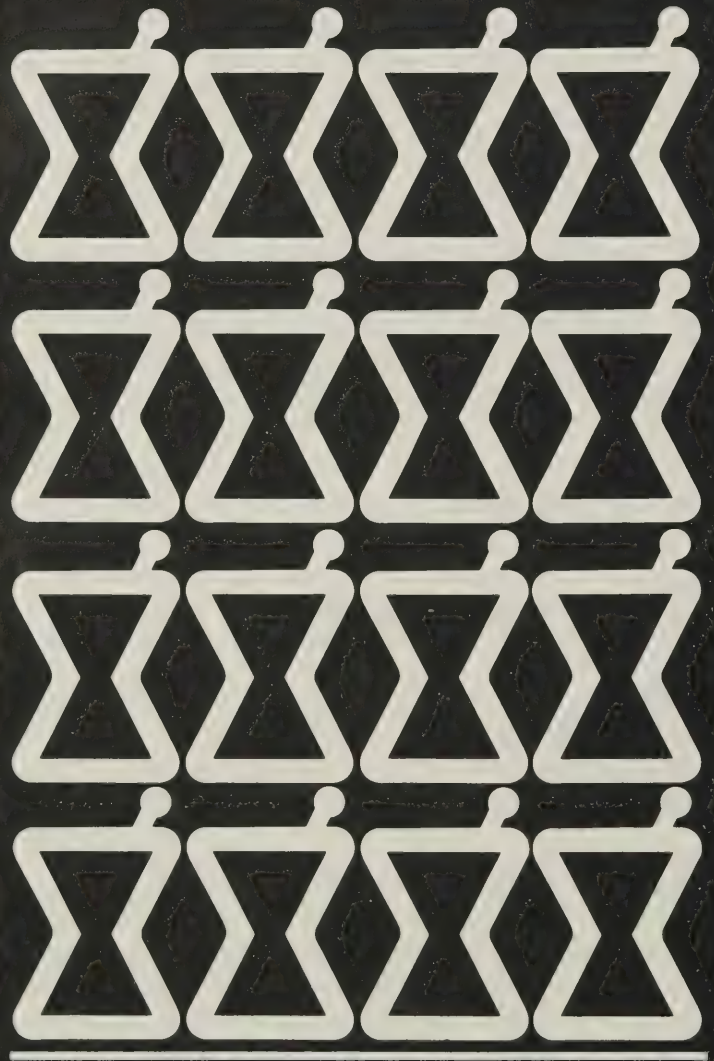

Professional liability claims against pharmacists have increased over the past few years. Both store-owners and employed pharmacists have been the target of these suits.

Pharmacy owners usually purchase druggist liability insurance; however, in most cases the insurance is limited to the products sold in the store.

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A one-year project to train faculty of the University of Maryland School of Pharmacy in the use of computers has been funded by SmithKline Beckman through the American Association of Colleges of Pharmacy. Dr. Alan McKay wrote the proposal, assisted by Dr. Stuart Speedie and Dr. Robert Kerr.

Dr. McKay says that the $18,000 grant provides for a graduate research assistant, secretarial support, software, travel and access to other seminars and workshops. It will also encourage faculty participants to train other faculty members.

"This is the second consecutive year the UM School of Pharmacy has received a SmithKline Beckman grant through the AACP," Dr. McKay reports, "which makes us one of a very few schools in the United States so honored." He added that the 1983-84 grant was for student recruitment.

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calendar

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Sept. 30—CECC Seminar "New Concepts in Psychiatry"
Oct. 12–20—MPhA Trip to Paris **SOLD OUT**
Oct. 19–27—MPhA Trip to Paris **SOLD OUT**
OCT. 26–NOV. 3—MPHA TRIP TO PARIS 3rd section—a few seats remaining
Oct. 29 (Sun)—MPhA DINNER THEATER AT OREGON RIDGE
Nov. 11—Alumni Association Dinner Meeting
Nov. 11—CECC Seminar "Alcoholism/Drug Dependence"
Nov. 16–18—Virginia Pharmaceutical National Symposium on Women

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THE
MARYLAND
PHARMACIST
Official Journal of
The Maryland
Pharmaceutical
Association

October, 1984
Vol. 60
No. 10

Special

Third Party Issue

Plus

Advising Consumers on Acne

— J. Richard Wuest
— Thomas A. Gossel

Note

This valuable issue of the *Maryland Pharmacist* is being sent to all members of the Association as a special fringe benefit of membership. This issue is available to non-members at $25.00 per copy. This amount can be applied to partial payment of dues. Call (301) 727-0746 for details.

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OCTOBER, 1984 VOL. 60 No. 10

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DAVID A. BANTA, *Editor*
BEVERLY LITSINGER, *Assistant Editor*
ABRIAN BLOOM, *Photographer*

Why Don't You Do Something About It!

Hardly a day goes by that one of the officers of the Association is not questioned about why the association is not doing something about this or that. More often than not, we are, but the communication links from the Association to you sometimes are astray.

Or—perhaps the action we are taking is confidential in nature and cannot be conveyed to you via the newsletter or journal.

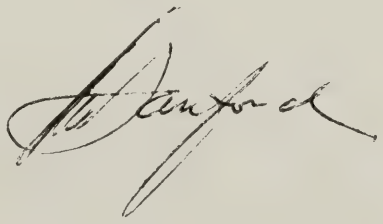
Or—perhaps no one brought the matter to our attention in the first place.

Or—perhaps it's a matter that legally the Association cannot be involved in.

In any event, if you feel we aren't doing our best, we want to know about it. It could be we could use your help. Remember, the Association is only as strong as its membership. There are always positions open on committees that can use your support.

So, the next time you call Dave Banta or one of the other Officers or Trustees wanting to know what we're doing about an issue, come forth and volunteer to help us do something about it. I solicit your help and support.

Sincerely yours,



Ronald A. Sanford, P.D.

PRESIDENT 1984–85.

SCOPE

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION • VOL. I, NO. 8

Advising Consumers on the Self-Medication of Acne

by J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

and Thomas A. Gossel, R.Ph, Ph.D.
Professor of Pharmacology
Ohio Northern University
Ada, Ohio

Goals

The goals of this lesson are to:

1. discuss the etiology and treatment of acne;
2. review the pharmacology and therapeutics of OTC medications used to treat acne.

Objectives

At the completion of this lesson, the successful participant will be able to:

1. choose the appropriate OTC agent for treating acne;
2. explain the proper technique for applying these OTC agents;
3. refer the consumer to a specialist when self-treatment is not appropriate.

in the service of pharmacy

This continuing education for Pharmacy article is provided through a grant from MERRELL DOW PHARMACEUTICALS INC.

Acne is a condition that most of us can relate to because it is so prevalent. While there are several dozen different types of "acne-like" lesions, and nearly all of them are relatively rare, the teenage nemesis *acne vulgaris* occurs in an estimated 80% of Americans as they pass through puberty. It can, however, begin at any age.

For most individuals, *acne vulgaris*, hereafter referred to simply as acne, consists of just a few pimples here and there. For others (estimated at less than 15%), numerous eruptions occur, some of which can result in permanent pock marks. This severe form of the disease is approximately ten times more common in males than in females. The milder forms of acne will clear up as pubertal changes are completed—with or without therapy.

One of the problems with acne is that it occurs at an awkward age, the teenage years. Except for the pock marks seen with the more severe (nodulopustular or cystic) variety, there is really no physical damage involved. However, there are strong psychological and emotional factors that contribute substantially to the youngsters' self-perception of the situation. They are approaching adulthood, while adjusting to new personal, social and sexual relationships. Social acceptability and personal appearance are extremely important at this age. So, most of them are going to seek some type of "treatment" whether or not it is really necessary.

Several surveys have shown that most youngsters will try to treat acne with an OTC medication before seeking the advice of a dermatologist. They will look to their peers and television/radio/magazine ads, and windowshop for the latest "cure". Unfortunately, there is no cure for acne short of the prescription drug, isotretinoin (Accutane®), for severe cystic acne unresponsive to antibiotic therapy. If the patient can tolerate the side effects of isotretinoin, results are dramatic.

However, if the goals of therapy are to reduce pimple count and inhibit pustular acne and permanent scarring of the skin, OTC anti-acne medications are very effective. It is an important area for pharmacist involvement because of the counseling involved and because the drug store share of the 150 million dollar annual acne treatment market stands at an estimated 70%.

Types of Acne Lesions

Comedo (comedones) is the most commonly used medical term associated with acne. They are the primary lesions of acne, consisting of keratinous (dead cell) debris, bacteria, sebum, and hair fragments which plug the opening of the pilosebaceous duct. A comedo results from distension of the hair follicle (pore) due to a plug formed at the surface. In the early stages, it is barely noticeable, but as it becomes further distended, it results in a closed comedo or "whitehead".

Whiteheads begin as small, firm elevations on the skin which may be difficult to see. As follicles continue to enlarge, the opening to the surface becomes obstructed even more. If the follicular wall ruptures, the lesion will become inflammed and more visible. When the materials within the closed comedo accumulate to a greater extent, they cause the opening in the comedo to dilate, pushing the material to the skin's surface. This marks the beginning of an open comedo or **blackhead.**

The dark material within the blackhead is not dirt; the black coloration is caused by *melanin*, the pigment produced by melanocytes and

contained within the keratinous debris. These materials have risen to the skin's surface but the lesion has not ruptured. Neither the closed comedo nor the open comedo is serious in itself. However, in either instance, (more likely with the whitehead than blackhead) they can become inflammed leading to a papule, nodule or pustule.

When comedones become inflammed and red in color, they are called **papules.** This type is more likely to develop from closed comedones and is less serious than nodules and pustules. Papules can either continue development into these two types of lesions, or may resolve spontaneously after several weeks.

The large, reddened, often painful, inflammatory acne lesions that contain pus and can lead to scarring are called **nodules.** They are deep-seated lesions which mainly affect the dermal (inner) layer of the skin. Nodules develop from rupture of closed comedones; if others are close-by, they may fuse to form large lesions. Patients who have a number of these fused nodules are said to have **cystic acne.**

A **pustule** is a raised inflammatory lesion that is filled with pus and develops from papules. Trapped follicular contents gain access to the dermis through the lining of the follicle resulting in inflammation. As the lesion enlarges and pushes toward the surface, it fills with pus. Superficial pustules generally resolve after a few days and rarely cause visible scarring, whereas deep-seated pustules may require several months to resolve. They can cause scarring, especially if they are picked or squeezed.

All of these blemishes are called **pimples** (zits) which, if not widespread and/or deep-seated, are not that bad. They represent nature's method of removing and neutralizing irritating agents so that healing can occur. However, the prolonged or severe inflammation associated with them can lead to the characteristic "ice-pick" scarring. Picking pimples causes trauma which may lead to greater irritation, increased dissemination of the materials into the dermis, and scarring.

What Causes Acne?

The exact cause of acne is unknown, but several factors are definitely implicated. Foremost among them are sebum, androgens, and the bacterium *Propionbacterium acnes,* previously called Corynebacterium.

Sebum is a mixture of triglycerides and oily substances secreted by the sebaceous glands (Figure 1). Normally, sebum moves up the duct common to the hair follicles (pilosebaceous duct) to the skin, where it mixes with existing oils to form a lubricating film. The physiological function of this film is to protect the skin against excessive loss of water, and prevent dry, itchy skin.

The sebaceous glands are generally small and relatively nonfunctional prior to puberty. At this time, under the influence of androgens, the sebaceous cells differentiate and enlarge. They accumulate lipid materials and produce sebum. This, in turn, is acted on by propionbacteria whose lipases hydrolyze triglycerides to diglycerides, monoglycerides and fatty acids. Propionbacteria use the di- and monoglycerides formed for food to reproduce and grow. The fatty acids are considered to be a highly contributory factor to the irritation that occurs with acne lesions.

The propionbacteria are normal inhabitants of the skin. They are nonpathogenic and do not "cause" acne. However, they do contribute to the development of inflammatory acne by breaking down sebum into these irritating chemicals (fatty acids) within plugged pilosebaceous ducts.

Androgens are a third contributory factor to the development of acne. Recall that androgens are the male hormones produced in relatively large amounts within the testes. They are also formed to a lesser extent in the ovaries and the adrenal glands in the female. Androgens serve a major role in bone and muscle development in both sexes. The

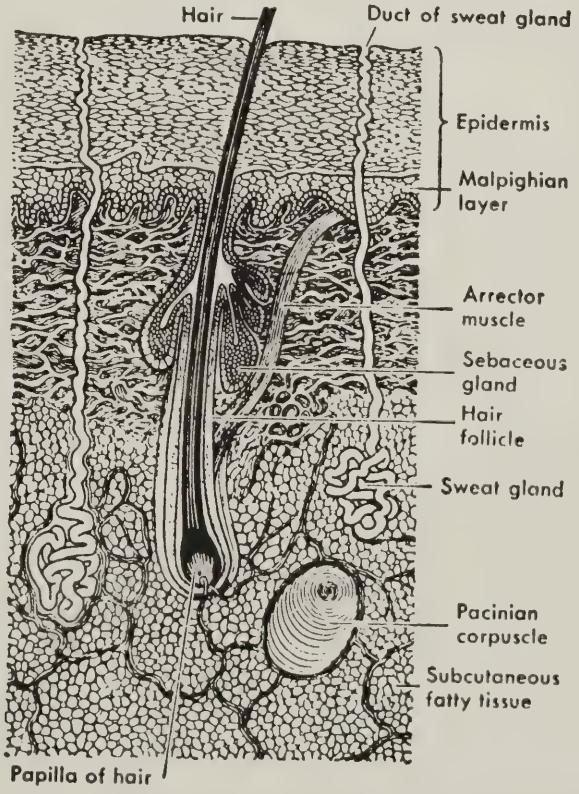


FIGURE 1.
Vertical section of the skin, showing the sebaceous glands.

generally larger size and musculature of the male is due to the greater production of androgens within his body than that in a female.

Androgens also stimulate the growth and development of the sebaceous glands. In patients with acne, there is an increased conversion of testosterone (up to 20 times greater than normal) to dihydrotestosterone (DHT). It is DHT that actually stimulates the cells of the sebaceous glands to increase protein synthesis and accelerate cell division and cell turnover. These sebaceous glands become larger until they surround and completely dominate the hair follicle. Acne usually occurs on the face, upper chest and back because there are more pilosebaceous units there.

Acne does not appear to be merely a function of androgen production. Current evidence leads to the conclusion that acne patients do not suffer from excessive androgen production. Young women with low androgen production can often experience a worse case of acne than young men with higher androgen production. Patients who develop severe acne are thought to have a greater sensitivity to DHT.

Acne is believed to result when DHT-induced increased production of sebum spills over into the pilosebaceous canal and the lipophilic propionbacteria that normally reside there have a heyday. They produce increasing amounts of lipolytic and proteolytic enzymes which result in a high level of fatty acids, which in turn produce irritation to the lining of the canal. If all of the produced material moves up and onto the skin, there is no problem.

If the duct becomes impacted or obstructed, it may lead to the closed comedo (whitehead) or an open comedo (blackhead). Through irritation of the lining of the pilosebaceous duct, these substances can leak out into the dermis. As more and more seep out and irritation increases, they accumulate to form nodules, papules and/or pustules.

Other factors that contribute to acne formation and flareups include the size of the hair/shaft in the duct, humidity, menses, cosmetics, trauma and drugs. For example, thin, small hair strands may be unable to keep the duct open, and hair can trap the plug contributing to comedo formation. On the other hand, facial or scalp hair can push the plug to the surface of the skin and prevent the comedo from forming. Humid weather and heavy sweating will lead to excessive keratin hydration and swelling of the skin tissue. This will decrease the size of the follicular orifice and aggravate acne.

For some unknown reason, the pilosebaceous duct orifice is significantly smaller between days 15 and 20 of the menstrual cycle. This increases the chance of acne lesion formation. Greasy cosmetics such as "cleansing" creams, suntan oils, and heavy makeup bases contribute to the clogging of the canal and are best avoided. Trauma from pressure, friction, squeezing and rubbing (including that from tight clothing) can increase acne lesion formation. Several drugs, including bromides, corticosteroids, isoniazid, iodides, phenytoin, progestins, and exogenously administered androgens have all been implicated in causing acne-like eruptions.

Diet

Diet is one of the more controversial areas in the management of acne. Some feel that diet is very important, and claim that at least three types of foods should be avoided. These include cream, seafood and methylxanthines (e.g., caffeine-containing soda pop and chocolate). They reason that the fatty content of cream is too high for acne patients. The suggestion is made that youngsters with acne problems drink skimmed milk, eat sherbet rather than ice cream, consume low-fat cheese, and use margarine rather than butter. Proponents of this view make a strong case against eating seafood (i.e., ocean fish) stating that levels of iodides and bromides in this type of fish are too high. They claim that these agents are secreted in sweat and stimulate the production of sebum and, therefore, advise individuals to eat freshwater fish rather than ocean fish.

Others feel that diet is not really important. There does not appear to be good evidence that food (including "junk food", chocolate, nuts, sweets, fatty foods, or cola drinks) causes or aggravates acne. The FDA Advisory Panel on OTC Topical Drug Products agreed with this view.

When counseling consumers, however, if the patient states that acne flares when he or she eats certain foods, those types should be avoided. A number of physicians feel that deprivation is a major part of the psychological treatment of acne. They feel that depriving the youngster of some types of food is beneficial because "something" is being done.

Acne Therapy

The patient's perception of the severity of the problem is probably the most important guide to acne therapy. The basic goals are to decrease the amount of sebum produced, decrease the bacterial population in the pilosebaceous duct, reduce the amount of fatty acid formation and, of course, remove the keratin plugs at the surface of the pilosebaceous duct. While there is no evidence that any treatment program prevents the onset of acne, it is considered good therapy to reduce the formation of new acne lesions.

As far as the youngster is concerned, the major goal of therapy is to improve his or her cosmetic appearance. It is generally agreed that patient acceptance of therapy is as important as the effectiveness of the OTC acne medications. Consumers generally want therapeutic products that work, but are not too harsh or unpleasant smelling. They like a product that can be easily applied, feels good, and perhaps may even have a lathering property which enhances the sense of feeling clean and leaving the skin soft. Teenagers reportedly most dislike the stinging/itching sensation, the dryness/peeling that results, and the odor produced by anti-acne medications.

In reality, these effects are a major part of therapeutic activity. Patients should be encouraged to put up with the unpleasantness for the short period the product will be used. The better they comply with directions, the more likely the condition will be short-lived.

Down through the years, the mainstays of acne therapy have been proper washing of the face, abrasive

scrubs and keratolytics. More recently, benzoyl peroxide, tretinoin/isotretinoin and antibiotics have been added. It has been determined that the first four types of therapy mentioned above can be carried out without direct physician intervention. The use of tretinoin, isotretinoin and antibiotics (both topically and systemically) requires medical supervision and, hence, a prescription.

Even though dirt does not play a significant role in acne lesions, facial cleanliness is a must. Washing the face and other acne areas two to three times a day with soap and warm water is important. A washcloth will remove excess sebum and oily materials from around the openings of pilosebaceous ducts. There is no real evidence that "medicated" soaps are better than ordinary soap.

The thorough, gentle, and continual rubbing of the skin will produce a mild redness and a drying effect. The use of a washcloth will lead to barely visible peeling which will loosen the comedones. In fact, the washcloth may be more important than the soap. Whenever it is inconvenient for the person to wash with soap, one of the cleansing-pad products (e.g., Stri-Dex) can be used instead. Frequent shampooing is also helpful since it reduces the amount of sebum coming down from the scalp area.

There is some controversy associated with the use of **abrasive scrubs.** Current evidence points to the fact that their use may be more psychological than therapeutic. It has not been conclusively proven that the use of abrasive scrubs either significantly reduces the number of new comedones, or removes those that are already formed. Acne is not a disease that forms on the surface. It forms beneath the surface of the pilosebaceous duct. Therefore, comedones cannot be physically washed out. If overused, abrasive scrubs may cause irritation, and occasionally actually aggravate the acne condition. Complexion brushes are also felt to cause more harm than good.

Nonetheless, abrasives are very popular with patients. It may be because the patients believe that conscientious scrubbing will clean clogged pores, and that they are playing a major role in improving their condition. It has also been noted that some individuals have stopped picking their pimples when advised to use abrasive scrubs because the routine apparently replaced their emotional need to scrutinize and express each lesion.

Advising consumers on the use of abrasive scrubs is a matter of professional judgement. There is a lack of evidence that abrasive scrubs either alleviate or prevent the formation of acne lesions. The OTC Advisory Panel on Topical Acne Drug Products has recommended to FDA that no such claims be allowed by their manufacturers.

Keratolytics (i.e., sulfur, resorcinol, and salicylic acid) have been used in acne therapy for years. While their exact mechanism of action is not known, the result is a peeling away of keratin debris (keratolytic action) and removal of dead cells (exfoliative effect). Some authorities state that these agents are effective first-time treatment for promoting removal of comedones. Others argue that they are more cosmetic than therapeutic, and may do more harm than good. The FDA advisory panel determined that sulfur is definitely a safe and effective anti-acne remedy. However, resorcinol and salicylic acid have not yet been conclusively proven to be safe and effective as single entity anti-acne agents.

Sulfur, used medicinally for centuries, has shown the most evidence of effectiveness as a keratolytic agent. Its exact mechanism is not known, but the predominant theory is that it helps to peel away and remove keratin debris by being converted into hydrogen sulfide when it comes into contact with skin tissue. The FDA advisory panel has ruled that sulfur, in concentrations of 3 to 10 percent, is safe and effective for treatment and prevention of acne.

Even though **resorcinol** has antibacterial, antifungal and mild keratolytic activity, the panel ruled that there is a lack of evidence to prove that the substance used by itself is effective in treating acne. Actually, such use in the treatment of naturally occurring (i.e., non-laboratory-induced) acne has never been studied. The panel did conclude that the combination of sulfur (8 percent) with resorcinol (2 percent) is safe and effective for use in the treatment of acne. Resorcinol enhances the activity of sulfur, so this combination is rational. The panel strongly recommended that OTC's be labeled to warn consumers not to use the combination on broken skin, or to apply it on large areas of the body.

Salicylic acid has been used for over a century in treatment of acne and other diseases amenable to keratolytic agents. It is considered by some to be the best of all available agents, but it has never been studied as a single agent in the treatment of acne. Salicylic acid is thought to be both anti-inflammatory and comedolytic, and it increases the turnover and decreases the cohesiveness of keratin cells. Therefore, salicylic acid was placed in the "needs more study" category. The panel recommended that at least one double-blind vehicle-controlled clinical trial be undertaken to determine its effectiveness in the treatment of acne. The recommended strengths for salicylic acid range from 0.5 to 5 percent.

Proponents of salicylic acid claim that a solution of it in alcohol is the best available keratolytic. This is because the alcohol will dry and leave no film, and the salicylic acid does not have the odor associated with sulfur.

Other keratolytic combinations for which the FDA panel had inadequate data to make definite statements of effectiveness are listed in Table 1. When any keratolytic is being used, the consumer must realize that the affected area should be thoroughly washed before the agent is applied. Otherwise its effectiveness will be compromised.

Benzoyl peroxide, in a 2.5 to 10 percent gel formulation, is considered by many experts to be the best of all anti-acne remedies available. It is both keratolytic and antibacterial. Benzoyl peroxide is decomposed by cysteine, an amino acid on the skin, to benzoic acid which has mild keratolytic activity, and oxygen which accounts for the exfoliative and antibacterial activities. The oxygen kills bacteria it comes in contact with and causes a peeling of the

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TABLE 1

Combination Anti-Acne Agents Ruled* To Need Further Study

Alcloxa — resorcinol — salicylic acid
Alcloxa — resorcinol — sulfur
Aluminum chlorhydrex — sulfur
Benzoic acid — boric acid — zinc oxide — zinc stearate
Calcium polysulfide — calcium thiosulfate
Resorcinol — salicylic acid
Resorcinol — salicylic acid — sodium thiosulfate
Resorcinol — sulfur — thymol — zinc oxide
Salicylic acid — sulfur

**by the FDA Advisory Panel on OTC Topical Acne Remedies*

outer layer of the skin. Thus, benzoyl peroxide significantly reduces the number of skin bacteria and the amount of fatty acid on the skin where it is applied. It is also comedolytic in that it increases the epithelial cell growth rate leading to an increased sloughing, which weakens the structure of the plugs within the follicles. It also may have an astringent activity which would help draw the oil out of the pores. Benzoyl peroxide is an excellent agent to suggest for the initial treatment of mild acne and is considered to be the agent of choice in the treatment of mild inflammatory acne.

Consumers purchasing benzoyl peroxide should be aware that the product will cause a slight tingling sensation and a feeling of warmth and redness. These actions are a part of its therapeutic activity. It should be applied to the point that mild redness and dryness are noted, but not to the point of discomfort. Benzoyl peroxide should be applied at bedtime to the entire involved area, not just to the zits. This will help prevent new pimples from forming. It is wise to start with a 2.5 percent product and then increase to 5 and then 10 percent, if needed, with twice a day applications as tolerated. It must be remembered that approximately three percent of users are hypersensitive to the product. Consumers should be advised of this in advance. They should also be informed that the substance is an oxidizing (bleaching) agent so it should be kept away from clothing.

It is of some interest to note that even though benzoyl peroxide and sulfur are available OTC, their combination product is available on a prescription-only basis. FDA is convinced that even though the combination is effective, it is not safe for self-medication. There is considerable evidence that sulfur enhances the sensitization potential of benzoyl peroxide to the point that medical supervision is required. The OTC advisory panel concurred with this concept, and did not recommend that the combination be shifted to OTC status.

Ineffective/Unsafe Agents

A number of anti-acne agents were found by the panel to be either unsafe, ineffective, or neither safe nor effective. These include the aluminum salts, boric acid, coal tar, estrogens, and the zinc salts. Table 2 contains a list of ingredients suggested for the "banned from future use" category.

Aluminum salts so ruled are alcloxa, aluminum chlorhydrex, aluminum hydroxide, and magnesium aluminum silicate. **Alcloxa** is purported to have both soothing and healing properties. When applied to the skin, it is reported to disassociate into its two components — aluminum chloride and allantoin. Alcloxa has been used for decades for the treatment of a wide variety of skin problems including eczema, acne, athlete's foot, diaper rash, impetigo, itching, psoriasis, and sunburn. However, the panel could not find any clinical studies which established the effectiveness of this combination in treating acne. Nor could it find any evidence that the aluminum salts, through their astringent activity, effectively treat acne.

Boric acid has been considered to be both antibacterial and antifungal. Although the panel concluded that it and the borate salts were safe for use on unbroken skin in concentrations less than five percent, it could find no evidence to prove their effectiveness in the treatment of acne. While sodium borate may act as a mild

TABLE 2

Agents Ruled* To Be Unsafe/Ineffective For OTC Topical Treatment Of Acne

Not effective — Questionable safety
- Phenyl salicylate
- Thymol
- Vitamin E

Not safe — Questionable efficacy
- Dibenzothiophene
- Phenol/Sodium phenolate

Safe — Not effective
- Alkyl Isoquinolinium
- Aluminum salts
- Benzoic acid
- Boric acid
- Camphor
- Chlorhydroxyquinoline
- Chloroxylenol
- Magnesium sulfate
- Resorcinol
- Sodium thiosulfate
- Zinc salts

Neither Safe nor Effective
- Benzocaine
- Coal tar
- Estrogens
- Tetracaine

**by the FDA Advisory Panel on OTC Topical Acne Remedies*

physical abrasive for removing superficial pustules, there is inconclusive evidence that it effectively removes the primary lesions of acne (i.e., blackheads and whiteheads) because these are deeply rooted in the follicles.

Coal tar was placed in this category because there are no clinical studies supporting its effectiveness for the treatment of acne. In fact, it has been found to actually *cause* acne in some human volunteers and in workers exposed to it in their occupations. Also, there has been considerable data accumulated demonstrating a carcinogenic potential following long-term exposure to crude coal tar preparations. It is of some interest to note that this has been the general finding of every OTC panel which has reviewed coal tar preparations.

Estrogens need to be considered from several different viewpoints. In physiological amounts, they do not exert a significant role in sebaceous gland activity. However, in pharmacological doses, estrogens cause an

anti-androgen effect by reducing circulating androgens, and may actually block DHT receptor sites in the sebaceous glands. Estrogens inhibit adrenal gland androgen production in females, and may be useful in severe or otherwise unresponsive cases in young women. In regards to OTC use, topical estrogens are readily absorbed through the skin and can cause systemic effects.

It was the panel's feeling that estrogen-containing compounds should not be available for OTC use in the treatment of acne. It concluded that although most studies reported favorable results, very high concentrations must be applied topically for sufficient amounts to be absorbed systemically to produce an anti-acne effect. This requires medical supervision. Therefore, the panel stated that doses of estrogenic agents safe for self-medication are too low to be effective for OTC topical use in the treatment of acne.

Zinc salts were reviewed by the panel in topical and oral dosage forms. Topically, zinc oxide, zinc stearate and zinc sulfide have been used as astringents, protectants and antiseptics for many years. White lotion (containing zinc sulfate, sulfurated potash and water) is still prescribed for treatment of mild acne. The panel concluded that any beneficial effect of white lotion on the dermatological condition resulted primarily from the sulfur content of the lotion, and that none of the few available studies attributed therapeutic activity to the zinc salt content. It therefore placed topical zinc salts in the ineffective category.

Although the panel's mission was only to review the use of topical agents used in the treatment of acne, it did comment that there is some concern about the unexplained wide variation in the results of double blind studies on the use of *oral* zinc salts that have been conducted in different countries. In Sweden, investigators believe that zinc is valuable in the treatment of acne. Investigators in Denmark and the United States remain unconvinced of its efficacy. The contrasting results among studies from various countries suggested to the panel that environmental factors such as seasonal variations and ultraviolet light exposure, the amount of zinc in the natural diet, and the dosage form used may have influenced the studies. Swedish investigators, for example, used an effervescent zinc sulfate complex that is not available in the U.S.

In this country, the use of oral zinc remains controversial, although it is the current "darling" of the mineral promoters. Some investigators claim beneficial results from 200 mg of zinc given twice a day. The more conservative view is that oral zinc is ineffective and should not be used unless the patient is known to be zinc deficient.

Anti-Acne Agents of Questionable Efficacy

The panel felt that more studies are needed before a final ruling can be made on the effectiveness of three anti-acne medications: povidone-iodine (e.g., Betadine), calcium polysulfide-calcium thiosulfate (Vleminckx's solution) and sulfur-aluminum chlorohydrex.

The panel felt **povidone iodine** may be an effective acne treatment, but the studies presented contained flaws, one of which was the lack of vehicle control. It could not be determined whether the vehicle itself contributed to its action. Also, other drugs were used at the same time and the method of evaluating patients for results was not well defined. The panel recommended that at least one additional clinical trial be conducted to determine the effectiveness of this agent in the treatment of acne.

Vleminckx's Solution (also known as sulfurated lime) has been used in dermatology for over a century. It is recommended for severe pustular or cystic acne. The FDA panel reviewed the study on the use of the recently devised method of administering sulfurated lime, i.e.,the medicated face mask that is applied to the acne area. It showed that although the face mask containing the medication was more effective than the nonmedicated mask in reducing comedones, it was no more effective than the nonmedicated mask on papules and pustules. The panel concluded that a truly effective anti-acne medication should be shown to have therapeutic activity against all types of acne lesions.

The panel reached much the same conclusion with **sulfur-aluminum chlorhydrex**, but for the opposite reason. Evidence was submitted to show that this combination was significantly more effective on papules and pustules, but it did not have a statistically significant effect on whiteheads and blackheads. In both instances, the panel suggested that further studies be conducted to prove that they are effective against all types of acne lesions before they can be fully approved as being safe and effective.

The panel also recommended that some warnings be required on the labeling of OTC acne remedies. They are listed in Table 3.

TABLE 3

Label Warnings For OTC Anti-Acne Agents

1) For All Products:

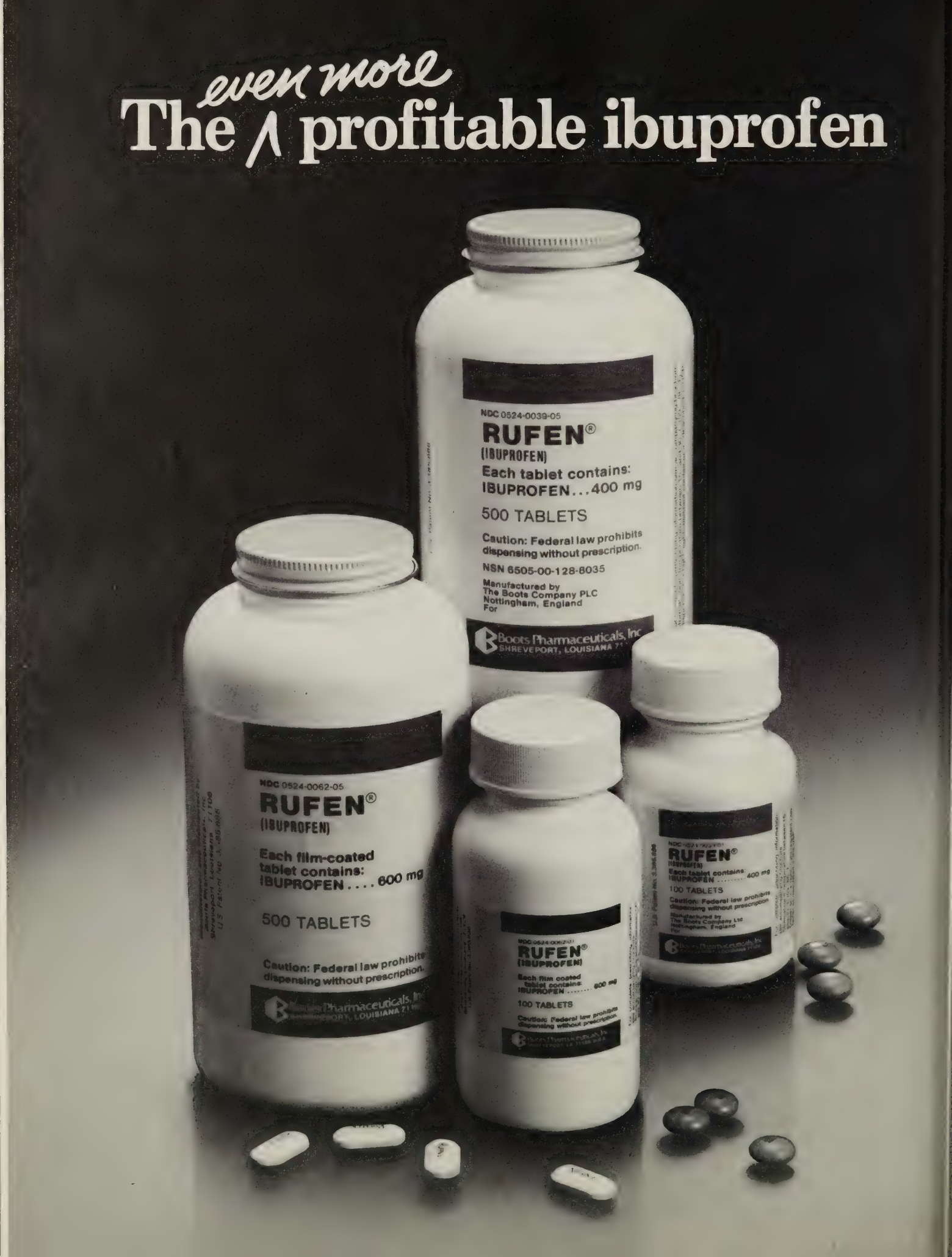
- For external use only: Other topical acne medications should not be used at the same time as this medication

2) For Benzoyl Peroxide Products:

- Do not use this medication if you have very sensitive skin or if you are sensitive to benzoyl peroxide. This product may cause irritation characterized by redness, burning, itching, peeling or possible swelling.
- More frequent use or higher concentrations may aggravate such irritation. Mild irritation may be reduced by using the product less frequently or in lower concentration.
- If irritation becomes severe, discontinue use. If irritation still continues, consult a doctor or pharmacist.
- Keep away from eyes, lips, mouth and sensitive areas of the neck.
- This product may bleach hair or dyed fabrics.

3) For Sulfur — Containing Products:

- Do not get into eyes. If excessive skin irritation develops or increases, discontinue use and consult a doctor or pharmacist.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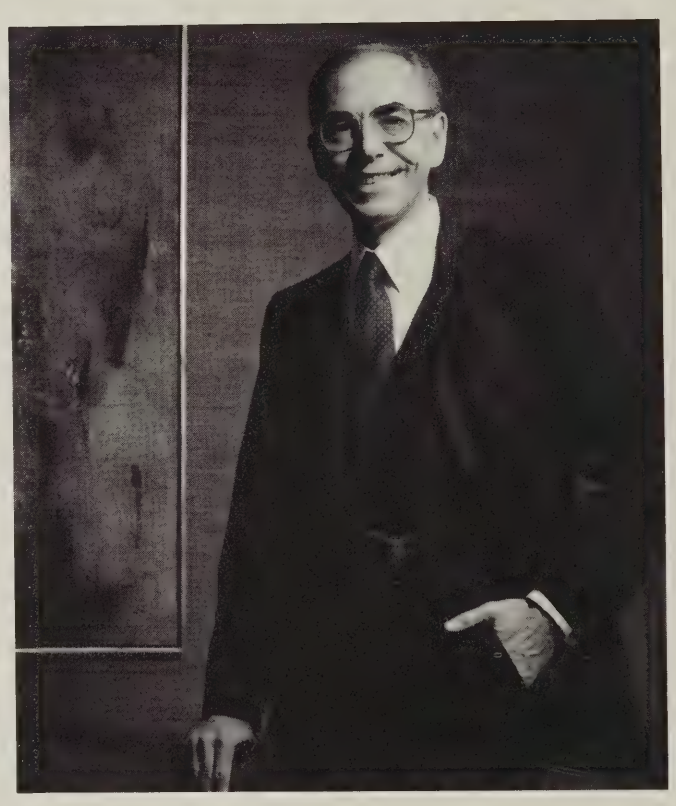

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1 year	see chart "A" preauthorization needed over $40.00	Hard copy printout	15th, 30th	See Chart "A"	See Chart "A"	See Chart "A"	Yes	Plan 9	Additional reimbursement for compounding
1 year	34 day. See Chart "B" Maintenance list of 34 day/ 100 doses; Mack Truck/ G.M.—200 doses; Baltimore City—100 day maintenance	Tape hard copy	Daily	Group 6275 only	No	All inj.	Up to 4 vials cost + 20%	Mack Truck and G.M. pay for syringes with insulin only. P 26 Blue Cross Guide limit on quantity	
5 times within 6 months	34 day; maintenance—90 days, 100 doses	Hard copy	15th, 30th	Fund 001, 002, 003 } yes Others—no	No	Home use	Yes	No	
5 times within 6 months	Greater of 34 days or 100 doses	Hard copy	15th	No	No	No	Yes	No	Must include drug name on form
2 within 100 days if on original	100 day maximum including refills. Preauthorization needed over $60 u/c	Tape hard copy—for nursing home only	Every Wednesday	Six months allowed no preauth. for price needed (2 refills max.)	Nutritional Formulas with Preauth.	Yes—home use Not M.D.	Yes	Syringes	"F" card—no deductible "S" card—50¢ yellow & white card—$1.00; must use state form see lists of nonreimbursements chart "D" special numbers needed for syringes, compounds
1 year	Varies from 34–100 days; some 200 doses allowed; they will reduce payment if you dispense above limit of day supply	Tape hard copy	Weekly	Some plans	Some plans	Yes	Yes	No	NABP # is ID G.E. retirees pay $2.00 deduct. plus all above $10.00 of your u/c medimet pays maximum of $8.00. Some paper cards
By law	34 days/100 doses	Hard copy	1st, 10th, 20th	Plan 1 and 3	No	Yes	Cost + 50%	Plan 3, 4 syringes Rx	Pays Lower of Cost Plus Fee or U/C
Per M.D.	*Most plans 34 days supply with some 100 day items	Tape hard copy	Bimonthly	Plans 2D, 04, 4F, 4X, 4A, 06, 6F, 6C, 6I 2D, 6D—pays for diaphragms	No	Yes, except plan 6C	Yes	Yes, except 2, 2A; Special numbers to use when dispensing syringes P32 of paid 10/82 catalog	*indicates—see chart "C". Be sure your plan number is on each form. Plans 2A, 2S, 2P, 3M, Excludes "Desi" Drugs
3	34 days or 100 doses	Tape	Claims in by about 20th paid in about 3 weeks	Yes	No	Yes	Yes	Only funds 503, 515, 519, 505, 569, 531, 542, 544, 551—syringes and supplies	Must use Generics on "Generic" only cards
5	34 days except maint. Lists up to 100 doses	Hard copy/ tape	Bimonthly	Some programs	No	Some	Yes	Some	Must use plastic card; be sure your plan number is on each form; some programs list dependent name on plastic card; programs too numerous and varied to summarize—see manual
Per M.D.	Greater of 34 days or 100 doses	Hard copy printout	On receipt	No	No	Yes	Yes	Bendix plan 158600 pays for insulin syringes with insulin Rx only	Must send transmittal; some groups have paper cards use NABP number
Per M.D.	34 day, 34 day or 100 doses on maintenance list	Printout	On receipt	No	No	Call	Yes	No	Use universal or local 1199E form; Doctor's signature not required

ASSOCIATED PRESCRIPTION SERVICES
PLAN FORMATS
Chart A

As we add new accounts, unless there is a special feature to the FUND, there will be no bulletin sent out. If there is no plan on the I.D. card refer to the Fund Description.

A PLAN will consist of a NUMBER which defines coverage and LETTER(S) indicating limitations and exceptions.

ALL Plans shall cover Legend Drugs UNLESS specifically excluded by the Plan.

ALL Plans shall EXCLUDE immunological agents and appliances UNLESS otherwise indicated.

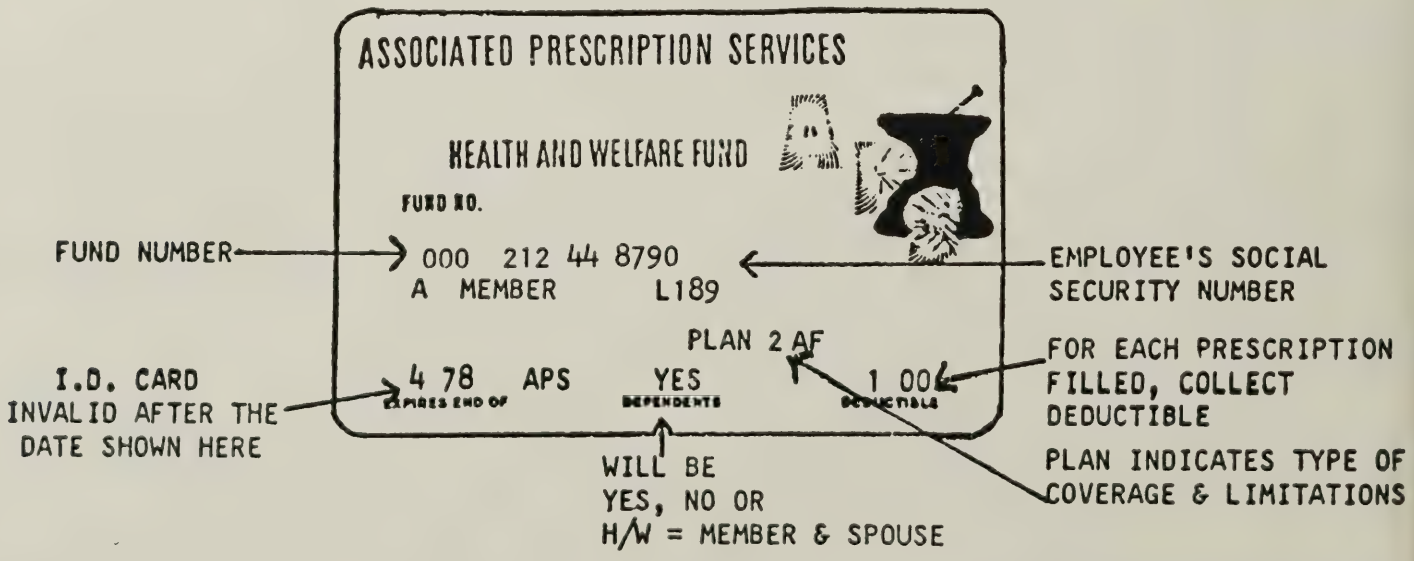
ALL Plans include Compounded Medications if at least one ingredient is a Federal Legend Drug in a therapeutic amount.

PLAN NUMBER	ORAL CONT.	CERT. OTC	INJECT.	INSULIN	MISCELLANEOUS
1	YES	YES	YES	YES	
2	NO	NO	NO	YES	
3	YES	YES	NO	YES	
4	NO	YES	NO	YES	
5	YES	NO	NO	YES	
6	NO	NO	YES	YES	
7	YES	NO	YES	YES	
8	NO	YES	YES	YES	
9	NO	NO	NO	YES + Syringes	NO Rx Vitamins

LIMITATIONS AND EXCEPTIONS

A = Up to a 100 Day Supply
B = Up to a 34 Day Supply or 100 Doses, whichever is greater
C = Up to a 34 Day Supply Only
D = Up to a 34 Day Supply/100 Days Supply for Approved Maintenance Drugs
E = Up to a 34 Day Supply or 100 Doses, whichever is greater. Up to 100 Days for Approved Maintenance Drugs
F = ON PRESCRIPTION ONLY—insulin syringes, needles (two), disposable syringes and needles, sugar test tape or tablets, acetone test tablets, clinistix, clinitest kit, Benedict's solution or equivalent, Glucalgon injection.
N = NO VITAMINS—whether legend or not
S = ON PRESCRIPTION ONLY—syringes and needles

For all accounts, the cost of ingredients should not exceed $40.00 without prior authorization UNLESS the medication is for less than a fourteen (14) day supply.



BLUE CROSS MAINTENANCE LIST

Chart B

The quantity of prescription drugs which may be dispensed pursuant to an original prescription order or a refill is limited to a supply sufficient for thirty-four (34) consecutive days. However, drugs prescribed for "chronic conditions" may be dispensed in maximum quantities of a 34-day supply or 100-unit doses, whichever is greater. The following is a list of maintenance drugs that can be dispensed in 100-unit doses:

Acetazolamide
Acetohexamide
Allopurinol
Bendroflumethiazide
Benzthiazide
Chlorothiazide
Chlorpropamide
Colochicine
Colochicine Probenecid
Conjugated Estrogens USP
Digitalis Leaf
Digitoxin
Digoxin
*Diphenylhydantoin Sodium**
Furosemide
Gitalin
Hydrochlorothiazide
*Isoniacide**
*Levothyroxine**
*Liothyronine**
Metolazone
*Methyclothiazide
Nitroglycerin
*Para-aminosalicylic acid**
Pentaerythritol Tetranitrate
Phenylbutazone
Phenytoin (Diaphenylhydantoin)
Polythiazide
Potassium Chloride Liquid
Primidone**
Probenecid
Propranolol Hydrochloride
*Propylthiouracil
Quinidine Sulfate
Reserpine
Spironolactone
*Thyroglobulin**
*Thyroid, Natural**
Tolazamide
Tolbutamide
Trimaterene
Trichlormethiazide

These generically listed entities are covered in the Program in all brands marketed.

*Products listed with a single asterisk on the left (*) may be dispensed in *200 unit dose quantities* or a 34-day supply, whichever is greater, for only those subscribers whose ID cards exhibit a $3 copayment amount. All of these cards will state "MOTORS" *and* a group number of X010 through X099.

**Products listed with two asterisks on the right (**) may be dispensed in *200 unit dose quantities* or 34-day supply, whichever is greater, to Mack Truck employees whose ID cards exhibit a $2 copayment and a group number of: K214, K258, K701, K703, K704, K709.

—Preparations which require a prescription under Maryland Law
—*Compound Prescriptions*—must contain at least one legend drug.
—*Insulin*—up to four vials.

Benefits are *not* provided for the following:

—*Over-the-counter preparations*
—*Contraceptive Drugs—in any form,* even if prescribed for other than contraceptive purposes. If this benefit is offered in the future you will be notified by special bulletin.
—*Devices of any type*—even if prescribed. This includes hypodermic syringes and contraceptive devices.

Four Pharmacy students recently completed a ten week industrial internship with the Merck, Sharp and Dohme Co. They are: (left to right) Richard C. Benchoff, II, University of Maryland School of Pharmacy; Catherine H. Daniel, Medical College of Virginia; Pamela L. Gore, University of Kentucky College of Pharmacy; Stuart T. Haines, Massachusetts College of Pharmacy; and R. Paul Baumgartner, Manager of Pharmacy Relations for Merck.

The USP and Student APhA have combined forces to launch a National Student Patient Counseling Competition. The Maryland Student APhA Chapter has announced it will enter the competition. Shown reviewing the details are: (left to right) David B. Brushwood, Assistant Professor, Philadelphia College of Pharmacy; Stacey A. Ferguson, Executive Secretary of Student APhA; and Alice E. Kimball, USP Director of Professional Affairs.

NOTICE

IF YOU HAVE A BLUE CROSS, UNION OR STATE ASSISTANCE PRESCRIPTION PROGRAM CARD

☐ PLEASE PRESENT YOUR CARD WITH THE PRESCRIPTION OR IDENTIFY THE CARD WHEN PHONING

☐ EACH PROGRAM HAS SOME LIMITATIONS SUCH AS:

- ☐ A MAXIMUM AGE FOR DEPENDENTS ALLOWED TO USE THE CARD
- ☐ LIMITATION OF DAYS SUPPLY. SOME MEDICINES ARE LIMITED TO 34 DAYS, SOME TO 100 DOSES, USUALLY YOU CAN GET EXTRA REFILLS WHEN QUANTITIES ARE RESTRICTED.
- ☐ A FEW PROGRAMS LIMIT THE DOLLAR AMOUNT PER PRESCRIPTION
- ☐ MOST PROGRAMS WILL NOT PAY FOR DRUGS WHICH DO NOT REQUIRE A PRESCRIPTION BY LAW EVEN IF DOCTOR ORDERS IT. (INSULIN IS USUALLY ALLOWED)
- ☐ STATE ASSISTANCE PROGRAMS HAVE MANY OTHER RESTRICTIONS
- ☐ MANY PROGRAMS WILL NOT PAY FOR BIRTH CONTROL PILLS.
- ☐ SOME PROGRAMS LIMIT REFILLS—BUT USUALLY THE DOCTOR CAN BE CALLED FOR A NEW PRESCRIPTION.

WE WILL HELP YOU AS MUCH AS POSSIBLE WITHIN THE LIMITATIONS OF YOUR PROGRAM

Member—Maryland Pharmaceutical Association, the state-wide professional society of Pharmacists.

TEAR AND POST

CLIP AND REPRODUCE

Below is a camera-ready brochure prepared for your use in discouraging individuals and companies/unions from using mail order pharmacies. You may use it as a counter piece or as a mailer to your patients. You may also customize it. To reproduce this brochure, simply cut it out of the journal and take it to your nearest printer. For a nominal price you can reproduce hundreds. (This Third Party Committee Patient Education Campaign is a result of the adoption of Resolution number one at the 1984 Annual Convention.)

YOUR COMMUNITY PHARMACY

- Your Pharmacist is the "Drug Expert" and today attends at least five years of college to receive a license to practice Pharmacy.
- Your Community Pharmacist is the most accessible of all of the health care professionals.
- Many Pharmacists keep patient profiles to watch for potential drug interactions, overuse, underuse and misuse of prescription drugs.
- Patient Profiles allow Community Pharmacists to catch drug interactions when more than one prescriber is involved.
- Pharmacists can use the Patient Profile to check for drug allergies.
- Pharmacists consult with patients when they have questions about prescription and non-prescription drugs.
- In Community Pharmacy practice, the pharmacist can monitor how the patient is taking medication to make sure he or she is following the physician's instructions.
- The services of the Community Pharmacist are conveniently located with accessible hours of operation.
- Many Community Pharmacies provide delivery and emergency prescription services to their patients.

PRESCRIPTIONS

- Prescription drugs are the most cost-effective component of the health care delivery system.
- Prescription drugs represent only a small part of the total health care budget.
- When compared with other forms of health care, the cost of prescription drugs has risen at a lower rate.
- The quality and length of our lives has been increased as a result of the modern "Miracle" of prescription drugs.
- Prescription drugs are more powerful and complex than ever before and require careful supervision for safe use.
- Prescription drugs can intereact with one another or with non-prescription drugs.
- Prescription drugs may cause side effects or adverse reactions which should be monitored.
- It is generally not wise to "stockpile" large quantities of prescription drugs because of accidental poisoning, changes in therapy by the doctor, and the expiration of the usefulness of the medicine.

MAIL ORDER RXs

- When you are compelled to use a mail order provider, you lose your right to the "freedom of choice" of where you may purchase your medicines.
- Everyone has a right to the services of a professional pharmacist who serves as your personal prescription and non-prescription drug consultant.
- Delays in the mail can mean injury to patients—even "maintenance" drugs can have emergency uses.
- Mail Order Prescription Services cannot check for drug interactions, since not all prescription and nonprescription drugs are acquired from the same outlet.
- Purchase of large quantities of medicine can lead to abuse and waste.
- Mail Order Services drain off business from Community Pharmacies, a vital part of the small business economy of our country.
- Mail Order is confusing for patients who must be aware of different lists of drugs to be obtained from different outlets.
- Mail Order Systems interrupt the traditional Physician/Pharmacist/Patient relationship in which feedback and prompt adjustments in therapy are very important.

Chart C

PAID Prescription, Inc.
Summary of Plans

JULY 1984

PLAN	QUANTITY LIMITS AND SPECIAL EXCLUSIONS	BENEFIT COVERAGE					
		COST	ORAL CONTRA-CEPTIVES	DIA-PHRAGM	INJEC TABLE	STATE RESTRICTED	NEEDLES & SYRINGES FOR INSULIN
IN	Dispense as written up to a 35 consecutive day supply or up to 105 consecutive day supply for maintenance drugs.	AWP	NO	NO	YES	YES	NO
IV	Same plan as IN except vitamins are NOT covered even if Federal Legend.						
02	Dispense as written up to a 34 day supply. Natural thyroid and nitroglycerine are to be dispensed in quantities up to 100 units.						02-2A-NO
2A	Dispense as written up to a 34 day supply. Give up to 100 units (or 200 as indicated) of listed maintenance drugs.	NET ACQ. COST	NO	NO	YES	NO	
2S	Same as plan 2A except insulin syringes covered when prescribed with insulin. There are special Billing Procedures.						2S YES, ONLY WITH INSULIN
2P	Same Plan as 2A except insulin syringes covered with or without insulin. Special Billing Procedures with insulin.						2P YES
2D	Dispense as written up to the greater of a 34 day supply or 100 units.		2D YES	2D YES	2D YES	2D YES	2D YES
2E	Same as plan 2S except; different maintenance list, 90 days supply of maintenance, greater of 34 day or 100 unit dosage on others.						
03	Dispense as written up to and including 100 day supply.						
3B	Same as Plan 03 except OTC drugs covered on Prescription only.						
3W	Dispense as written up to a 34 day supply except up to 100 doses if greater than 34 day supply of maintenance drug list. Also—Adrenalin, Aveeno and Acetaminophen N.F are covered.	NET ACQ. COST	NO	NO	YES	YES	NO
3S	Same Plan as 3W except Insulin needles and syringes are covered. (See special Billing Procedures for 2-S syringes) Also see list of maintenance drugs that may be dispensed up to 200 units						3S YES
04	Dispense as written to the greater of 100 Units or a 34 day supply.						
4F	Same Plan as 04 except fertility drugs NOT covered.	AWP	YES	NO	YES	YES	NO
4X	Same Plan as 04 except DESI drugs NOT covered.						
4A	Dispense as written up to a 100 days supply.						
05	Dispense as written up to the greater of 100 units or 34 day supply.						
5F	Same Plan as 05 except fertility drugs NOT covered.	AWP	NO	NO	YES	YES	NO
5A	Dispense as written up to 100 days supply.						
5B	Dispense as written up to 60 days supply.						
5M	Dispense as written up to a 34 day supply. Give up to 100 units (or 200 as indicated) of listed maintenance drugs.						

JULY 1984 PLAN	QUANTITY LIMITS AND SPECIAL EXCLUSIONS	COST	BENEFIT COVERAGE ORAL CONTRA-CEPTIVES	DIA-PHRAGM	INJEC TABLE	STATE RESTRICTED	NEEDLES & SYRINGES FOR INSULIN
06	Dispense as written up to the greater of 100 units or 34 day supply.			NO	YES	YES	YES
6F	Same Plan as 06 except Fertility Drugs NOT covered.	AWP	YES				
6C	Dispense as written up to a 90 day supply.				6C NO		
6D	Same as Plan 06 except diaphragms are covered.			6D YES	6D YES		
07	Dispense as written up to the greater of 100 units or a 34 day supply.						
7B	Same Plan as 07 except Insulin does NOT require a prescription.						
7F	Same Plan as 07 except that fertility drugs are NOT covered.	AWP	NO	NO	YES	YES	YES
7X	Same Plan as 07 except that DESI drugs are NOT covered.						
7K	Same Plan as 07 except that Fertility Drugs and Prescription Vitamins are NOT covered.						

The following Plans require reference to the Pharmacy Manual and or PAID Reports:

8K Similar to Plan IV except NO Coverage for injectables (except Insulin), Immun/Biolog.

80 Similar to Plan 5A except NO Coverage for injectables (except Insulin) and coverage for various O.T.C.'s and diabetic supplies.

81 Similar to Plan 06 except coverage for various over-the-counter and diabetic supplies.

82 Similar to Plan 05 except NO coverage for Injectables (except Insulin) and Immun/Biolog.

83 Similar to Plan 04 except NO coverage for Injectables (except Insulin), Immun/Biolog, and Fertility Drugs.

84 Similar to Plan 6D except NO coverage for Injectables (except Insulin), Fertility Drugs, Immun/Biolog and needles and syringes.

Chart D

LIST OF DRUG CURRENTLY DETERMINED TO BE LESS THAN EFFECTIVE AND NON REIMBURSABLE ON MEDICAID AS OF FEB 1, 1982

AVC Suppos/oint
Actifed C. Expect
Ambenyl Expect
Ananase
Arlidin
Avazyme
Belladenal
Belladenal S
Bentyl/Phenobarbital
Cantil/Phenobarbital
Chardonna 2
Cartrax
Chymoral
Combid
Cordran-N
Corovas
Cortisporin Cream
Cyclandelate
Cyclospasmol
Dainite
Dainite-KI
Daricon PB
Deprol
Dimetane Expect
Dimetane Expect DC
Diutensen
Donnatal Extentabs
Donnatal Liq & Tablets
Dimetapp Liq & Tablets
Equagesic
Isordil/Pb
Isoxuprine HCl
Levsin PG
Librax
Lufyllin-EPG
Marax
Mepergan Fortis
Midrin
Milpath
Miltrate
Myco Triacet
Mycolog
Naturetin/K
Neo-Aristocort
Neosporin G
Nylidrin HCl
Nysta-Cort
Orenzyme
Oxaine M
Papase
Parafon Forte
Pathibamate
Peritrate/Phenobarbital
Phenergan Expect
Phenergan Expect Codeine
Phenergan Expect VC
Phenergan Expect VC Codeine
Potaba
Pro-Banthine/Pb
Propazine
Quadrinal
Quibron Plus
Rautrax
Rautrax N
Roniacol
Synalgos
Synalgos DC
Terra-Cortril
Tigan
Tri-Statin
Trocinate
Tussornade
Tussornade Liq & Tablets
Valpin PB
Vasocon-A
Vasodilan
Vioform-Hydrocortisone
Vytone
Wyanoids HC
Zactane
Zactirin
Zactirin Compound 100

All generic and brand names are less than effective if one name appears on this list. Note: Aug. 1, 1984 a number of combination antibiotic-steroid topical products were removed from the list making them reimbursable.

NOTE: New formulas of Actified C Expectorant (NDC 00081-0025), of Synalgos DC (0082-4170) and Equagesic (NDC 00008-0007) are reimbursable with these NDC numbers. Cortisporin ointment was expected to be reinstated as reimbursable in September, and the new formulation of Phenergan *syrups* are expected to be reimbursable.

Chart E

ADDITIONAL MEDICAL ASSISTANCE RULES

NON-REIMBURSABLE ITEMS UNDER MEDICAID

NO ANORECTIC MAY BE DISPENSED ON A MEDICAID PRESCRIPTION UNLESS THE PHYSICIAN WRITES IN HIS OWN HAND 'Hypokenesis' or 'Narcolepsy.

Following is a list of the most widely used drugs falling under this rule. All Anorectics are affected.

Biphetamine	Didrex	Obetrol	Presate
Bontril	Fastin	Phenteramine	Sanorex
Desoxyn	Notrol	Plegine	Tenuate
Dexamyl	Obedrin	Pondimin	Tepanil
Dexedrine			Voranil

Note that Ritalin is *not* restricted by this rule.

MEDICAID NOTES:

MAC may be overridden by physician if he specifies 'medically necessary' in his own hand on each Rx and the pharmacist places 'X' in the block in lower left corner of claim.

You must bill the State the same price you charge the cash customer before any special discounts. You will be paid the lesser of that amount or the cost as defined by the State plus $3.45 professional fee.

If U&C charge is over $60.00 you must call for preauthorization and may request the right to reduce quantities. You cannot reduce quantities on your own. Baltimore area: 383-7716 Other areas: 1-800-492-6008

LETTERS

Dear Dave:

Since I receive inquiries from practitioners regarding the Professional Experience Program (PEP) each year I thought perhaps this could be printed in the *Maryland Pharmacist*.

The goal of PEP is to provide a select group of practitioner teachers willing to provide experiential training to pharmacy externs. This differs from "work experience" in that the preceptor is expected to teach the student to function effectively as a practitioner. The student is not only shown the mechanical/technical aspects of pharmacy practice, he/she is informed of the how's and why's as well. Most importantly, it is expected that the student will be an active participant in the pharmacy's operation and not just a technician.

The financial rewards are limited (there is a yearly honorarium for participating) so the preceptor should have a desire to return something to the profession by teaching students that which he/she has learned through experience.

A preceptor must:

1) have both the desire and the time to teach the judgement, competencies and skills necessary to provide quality pharmacy services.
2) be willing to access students strength and weaknesses and endeavor to correct the latter.
3) evaluate the student and discuss his/her performance objectively.
4) at a site and in a manner that would be appropriate for a student to emulate upon graduation.

Any pharmacist who wishes to return some of what he has gained from the profession by teaching those who are just beginning can obtain further information by contacting me.

Marvin L. Oed, Pharm.B.S.
Clinical Assistant Professor and
Director Professor Experience Program
Department of Pharmacy Practice and
Administrative Science
University of Maryland School of Pharmacy
20 N. Pine Street
Baltimore, Maryland 21201

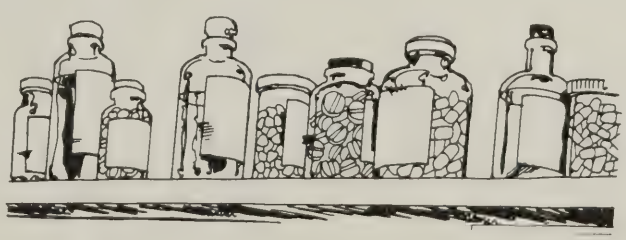


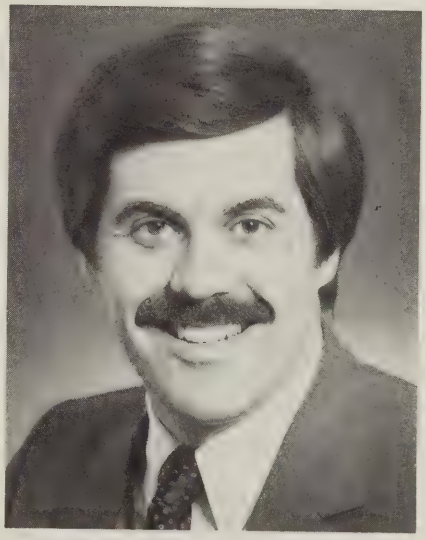
CHART F
MEDICAL ASSISTANCE
PHARMACY INVOICE ERROR CODE LIST

CODE	DESCRIPTION
01	INVALID RECIPIENT NUMBER
03	INVALID COUNTY (FIRST 2 DIGITS OF RECIPIENT NUMBER)
04	RECIPIENT NAME MISSING
05	INVALID PROVIDER NUMBER
07	INVALID PRESCRIBING PROVIDER ACCOUNT NUMBER
08	INVALID DATE DISPENSED
09	SERVICE DATE GREATER THAN 12 MONTHS FROM DATE RECEIVED
18	COLLECTIONS RESULT IN A CREDIT BILL (USUAL AND CUSTOMARY CHARGE LESS THAN CO-PAY)
20	RECIPIENT NOT ON ELIGIBILITY MASTER FILE
21	RECIPIENT NOT ELIGIBLE FOR MEDICAL ASSISTANCE ON DATE OF SERVICE
22	INVALID TOTAL AMOUNT CHARGED
24	NAME DOES NOT MATCH RECIPIENT ID NUMBER
25	PROVIDER NUMBER UNMATCHED
26	PROVIDER LOCKED
29	SERVICE DATE CONFLICTS WITH THE PROVIDERS AUTHORIZED PERIOD IN MEDICAID PROGRAM
31	INVALID NDC (NATIONAL DRUG CODE)
32	INVALID PRESCRIPTION NUMBER
33	INVALID REFILL NUMBER
36	INVALID DATE PRESCRIPTION WRITTEN OR DATE WRITTEN GREATER THAN DATE DISPENSED
37	DAYS SUPPLY MISSING OR NOT NUMERIC OR ZERO
38	QUANTITY DISPENSED MISSING OR NOT NUMERIC OR ZERO
51	RECIPIENT IS ENROLLED IN EAST BALTIMORE MEDICAL PLAN
52	PATIENT IS RESTRICTED TO PROVIDER
53	RECIPIENT IS ENROLLED IN WEST BALTIMORE COMMUNITY CENTER
55	RECIPIENT IS ENROLLED IN CHESAPEAKE PHYSICIANS
58	RECIPIENT IS ENROLLED IN THE CONSTANT CARE COMMUNITY HEALTH CENTER
67	DRUG DISPENSED BEFORE DRUG EFFECTIVE BEGIN DATE
68	SERV STOP DATE IS GREATER THAN 31 DAYS PRIOR TO PERIOD ENDING DATE
69	SERV START DATE GREATER THAN 31 DAYS FROM PERIOD ENDING DATE
70	SERV START DATE GREATER THAN SERV STOP DATE OR SERV STOP DATE GREATER THAN PERIOD ENDING DATE
71	INVALID SERVICE STOP DATE
73	UNIT DOSE PACKAGE SIZE FOR SINGLE SCRIPT PRESCRIPTION
75	DAYS SUPPLY GREATER THAN MAXIMUM ALLOWED
78	DRUG DISPENSED AFTER DRUG EFFECTIVE END DATE (NOT CURRENTLY PAYABLE)
79	NEEDLES AND SYRINGES USUAL AND CUSTOMARY OVER $7.50
81	USUAL AND CUSTOMARY CHARGE OVER $60 WITH NO PRIOR AUTHORIZATION NUMBER
82	NDC DOES NOT MATCH FORMULARY
83	QUANTITY DISPENSED GREATER THAN ALLOWED BY FORMULARY
84	QUANTITY DISPENSED LESS THAN MINIMUM ON FORMULARY
85	DATE DISPENSED GREATER THAN CURRENT DATE
86	DATE WRITTEN TO DATE DISPENSED GREATER THAN TEN (10) DAYS
87	REFILL DISPENSED GREATER THAN 100 DAYS AFTER ORIGINAL
88	COMPOUND PRESCRIPTION OVER $7.50
90	REFILL GREATER THAN 180 DAYS FROM ORIGINAL FOR BIRTH CONTROL
E-5	DUPLICATE INVOICE
E-6	DUPLICATE INVOICE
E-7	DUPLICATE INVOICE
T-5	DUPLICATE INVOICE
T-6	DUPLICATE INVOICE
T-7	DUPLICATE INVOICE

Paul T. Cuzmanes (right) accepts the James Hartley Beal Award from Michael DeLeonardis, Director of Trade Relations for Geigy Pharmaceuticals. MPhA Member Cuzmanes co-authored the paper entitled "Insurance Protection—Product Liability" with Walter J. Smith, Jr., to win the Award at the annual meeting of the American Society for Pharmacy Law.

The National Association of Retail Druggist's new headquarters building includes a display area for a model pharmacy. The NARD is seeking suggestions for layout and artifacts to be displayed. Contact NARD for details.

San Antonio will be the site for the American Pharmaceutical Association Annual Meeting on February 16-21, 1985. Here the famous San Antonio Riverwalk winds through downtown San Antonio.



Michael F. Brady has been assigned to the Cumberland, Maryland territory to represent Abbott Laboratories. He recently completed a training period with Abbott and has two degrees from Frostburg State College.

TAXES

By Jo Ann Zito, CPA, Comprehensive Accounting Services, Towson, Md.

Did you know that you can exclude up to $125,000 of gain on the sale of your residence if you are age 55 or older?

A homeowner who has reached age 55 or older can exclude from his/her income up to $125,000 of any gain on the sale or exchange of his/her principal residence.

To qualify, the homeowner or spouse must have reached age 55 years or older and sell the property which he owned and has used as his principal residence for three or more years during the five-year period ending on the date of the sale and elect to exclude the gain. This election can be made only once in a lifetime and only one election can be made for married couples. In the event the married couple is divorced after having once made an election, no further election can be made by either of them.

Careful consideration must be given to the making of he election since it can only be used once in a lifetime on the gain realized from the sale of a principal residence. In the event the homeowner made the election to exclude $40,000 of gain on the sale of a home after reaching age 55, he could not make the election again if he subsequently sold another principal residence at a $85,000 profit. Since the Internal Revenue code allows for deferrals of the gain on the sale of a principal residence if the proceeds are reinvested in a new residence within 24 months, you may be ahead by selecting this alternative, rather than using the $125,000 exclusion. Careful consideration must be exercised before making the once-in-a-lifetime election to exclude $125,000 of gain on the sale of a principal residence.

If you (or you spouse) are nearing your 55th birthday and plan to sell your home for a smaller home or apartment, you should consider deferring the sale until after you celebrate your birthday. The IRS will reward you with a nice present.

CHART G

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Payments of claims	**383-6893**	**Provider enrollment**	**383-6898**
Policy matters	**383-2658**		

***Outside metropolitan Baltimore calling area within the state for prescription preauthorization and nutritional formulations Toll Free 1-800-492-6008.**

Additional Phone Numbers

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State Board of Pharmacy	383-7245
Maryland Pharmaceutical Assn.	727-0746

Special Medicaid NDC numbers

Icc Insulin Syringes	00966-2222-00
1/2 Syringes	00966-3333-00
Other Syringes & needles	00966-1111-00
Compounded	00998-0000-00
No NDC Number	00999-0000-00

THIS AND THAT ABOUT PHARMACY

by Leon Weiner, P.D.

All too often we hear of the shooting and killing of our pharmacist kin. Again, in June 1984, a pharmacy owner in Baltimore City was brutally killed. However, this story is about a pharmacist who does the shooting. Maurice Cummings, University of Maryland Pharmacy 1951, has been a big game hunter for many years. He has hunted in many of our western and southern states as well as Alaska, Mexico, Canada and British Columbia. Cummings has shot and mounted 6 species of deer, elk, moose, 3 species of bear and 3 species of wild boar. He has also been on one safari in which he hunted and bagged 2 lions. At the present time, Maurice has been hunting mostly ducks and geese. He is currently working at Bethany Pharmacy in Ellicott City.

In the July issue of *"The Maryland Pharmacist"* an article about Kathleen Theresa Balcerak appeared. Because of misprint, we repeat. Kathy, a recent University of Maryland Pharmacy graduate, is now engaged to be married to Jeffery Alan Hamilton. She is the daughter of Eugene R. Balcerak, University of Maryland Pharmacy 1953, who works for Rite Aid Drug Company.

It is very interesting to report that a survey taken in late July 1984 of 10 pharmacies revealed no copies of Penthouse Magazine in stock. P.S. all of the magazines had been sold out.

Twenty years ago, Myron J. Wright, University of Maryland Pharmacy 1944, owned a successful pharmacy in Northeast, Maryland. Then fate stepped in and struck him a cruel blow. One night as he was driving home from his pharmacy, his car had a bad collision with a horse. As a result, he was severely injured and was forced to sell his pharmacy. In sports talk, Myron no longer is pitching in the game of pharmacy, but he now does have his pharmacist son throwing strikes for him. Joseph M. Wright, Philadelphia College of Pharmacy and Science 73, is his son who is currently working for Rite Aid Drug Company in the Baltimore area. Joe, registered in Maryland in 1974, has worked in the Elkton area before moving to Baltimore to work for Read's Drugs and Chemical Company.

Thomas P. Starken, University of Maryland Pharmacy 1982, who is now working for Drug Fair in the Cumberland area, has had a lot on his mind recently. Within four months, Tom has acquired a new pharmacist job, moved to a new area of the state, married a Minnesota girl and bought a new home. Before moving westward, he had been born in Carroll County and worked in a pharmacy in Anne Arundel County.

Worcester County Commissioner Bennett Bozman, who is also a registered pharmacist, has moved north a few blocks to the new People's Ocean City Store. Bennett, University of Maryland Pharmacy 1959, used to work at the Golden Coast Mall Drug Fair.

PHARMACY CHANGES—JULY 1984

The following are new pharmacies in Maryland:

T. L. C. Pharmacy Services, Inc.
617 E. Stemmers Run Road
Essex, Maryland 21221

Rite Aid 1422
Emmorton Rd (Rt 24) at Abingdon Road
Abingdon, Maryland 21009

Safeway Pharmacy #105
10 King Street
Waldorf, Maryland 20601

White Oak Pharmacy
11259 B Lockwood Drive
Silver Spring, Maryland 20901

Pathmark Super Drug
7311 Ritchie Highway
Glen Burnie, Maryland 21061

Travacare Pharmacy
6655 L Amberton Drive
Baltimore, Maryland 21227

The following—change ownership and name:

Allied Pharmaceutical Service
6105 Montrose Road
Rockville, Maryland 20855
(Formerly—Lanham Nursing Home Service)

Bon Secours Heartlands, Inc.
2000 W. Baltimore Street
Baltimore, Maryland 21223
(Formerly West Baltimore Health Center Hospital Pharmacy)

Francis Scott Key Medical Center Pharmacy
4940 Eastern Avenue
Baltimore, Maryland 21224
(Formerly—Baltimore City Hospital Pharmacy)

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Widow of pharmacist would like to sell pharmaceutical scale and weights. Maybe Antique. Reasonable offer accepted. Call 484-7034 after 2:00 P.M.

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MPhA office has just received a new shipment of "P.D." patches. These attractive, fabric, blue and white patches can be sewn on pharmacy jackets to identify you as a professional. The Patches sell for $2.00 each and can be ordered from Beverly at the MPhA Office at (301) 727-0746.

Management Handbook

—The Upjohn Company is offering a management handbook to pharmacy practitioners. The book, which is available at no charge, provides 12 contact hours of pharmacy continuing education credit.

"We're offering the manual and the opportunity to gain PCE credit," says Douglas P. Johnson, Pharmacy Relations Manager, "as a service to pharmacists. We hope to assist in their continuing effort to strengthen pharmacy management skills."

The book, *Management Handbook for Pharmacy Practitioners: A Practical Guide for Community Pharmacists,* was funded by a grant-in-aid from The Upjohn Company to the Health Sciences Consortium, which developed the content.

More than a dozen leading pharmacy administration faculty members contributed to the book, which discusses the following: cash flow; business records; advertising; tax considerations; accounts receivable management; inventory; break-even analysis; and nonprescription merchandising and planograms.

The handbook is available through Upjohn sales representatives or the Maryland Pharmaceutical Association. It is shipped with a post-test which, if the pharmacist wishes may be completed to the Health Sciences Consortium. For a small fee, the Consortium administers all aspects of this PCE program.

Contact the office for the order form at MPhA, 650 W. Lombard St, Baltimore, Maryland 21201.

calendar

Oct. 12–20—MPhA Trip to Paris—SOLD OUT
Oct. 19–27—MPhA Trip to Paris—SOLD OUT
Oct. 26–Nov. 3—MPhA Trip to Paris—check to see if seat available
Oct. 28 (Sun)—MPhA DINNER DANCE—OREGON RIDGE
Nov. 11 (Sun)—Alumni Association Dinner Meeting (note: CECC Program Scheduled this date has been changed)
Nov. 13 (Sun)—BMPA Annual meeting and election of officers.
Nov. 18 (Sun)—CECC Seminar on Drug and Alcohol Abuse
Jan. 12–19—MPhA TRIP TO ST. MAARTEN
Mar. 10 (Sun)—BMPA Dinner Dance

Every Sunday Morning at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the Pharmacy Public Relations Program "Your Best Neighbor," the oldest continuous public service show in Baltimore.

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Insect Bites and OTC Sting Remedies

— Thomas A. Gossel
— J. Richard Wuest

This and That About Pharmacy

— Leon Weiner

Toxicity of Iron Dextran Complex

— Gail H. Rosen

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DAVID A. BANTA, *Editor*
BEVERLY LITSINGER, *Assistant Editor*
ABRIAN BLOOM, *Photographer*

Your Opinion Does Count—Let Me Hear From You!

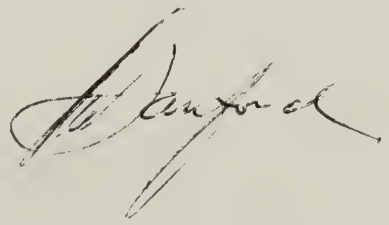
As you probably know, your Delegates at the June Convention passed a resolution calling upon the Legislative Committee to seek by legislation, mandatory continuing education for the Pharmacists of Maryland. In speaking to a number of Pharmacists, I get the impression that at least some of you out there are not in support of the resolution and would have voted against the resolution had you been at the Convention in Ocean City.

Before I go any further, so as to not give you the impression that I am on my soapbox for a personal issue, I am required, to maintain my Deleware license, to complete 30 hours of CE for each registration period. Therefore, the outcome of this issue has no direct effect on me—but it does on you unless you have a license in a state requiring CE.

Unfortunately we do not have the ability to submit this issue to a "referendum" vote, but your opinion on this matter is of importance to me and to the Legislative Committee. I urge you to "speak your mind" and communicate with me your thoughts on this issue. Send me your opinions in care of the Association office. I really want to know how you feel about this issue or any other issue that we are tackling on your behalf.

Remember, we can only represent you on an issue if we know how you feel. We cannot represent the silent majority. Unfortunately, silence doesn't convey much of an opinion except apathy. Let us hear from you.

Sincerely yours,



Ronald A. Sanford, P.D.

PRESIDENT 1984–85.

SCOPE
STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION • VOL. I, NO. 9

Advising Consumers on Insect Bites and OTC Sting Remedies

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, OH

and J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, OH

Goals

The goals of this lesson are to:

1. discuss the etiology and treatment of insect bites and stings;
2. review the pharmacology and therapeutics of OTC medications to treat insect bites and stings.

Objectives

At the completion of this lesson, the successful participant will be able to:

1. choose the appropriate OTC agent for treating insect bites and stings;
2. explain the proper technique for applying these OTC agents;
3. refer the consumer to a specialist when self-treatment is not appropriate.

in the service of pharmacy

This continuing education for Pharmacy article is provided through a grant from MERRELL DOW PHARMACEUTICALS INC.

Introduction

Allergic reactions resulting from insect bites have been reported since earliest recorded history. The first documented death due to allergy resulted from an insect sting. King Menes of ancient Egypt allegedly died from the sting of a wasp or hornet in 2621 B.C. Today, there are 100 or more deaths in the U.S. each year, more than twice the number that occurs from bites of venomous animals. Serious but non-fatal reactions develop in approximately one American per 100,000 each year. Many millions more are stung by various insect pests and experience non-serious, but nevertheless uncomfortable effects such as localized pain and itching. It is even possible that stinging insects kill more people than the official figures indicate; more deaths thought to have resulted from heart attacks or some other "natural" cause, may actually be due to insect stings.

No locale in the United States is devoid of insect pests. Damp, warm swampy areas may harbor more, but insects are also found in cold climates, and in bright and clean high-rise office buildings in the middle of large cities.

The purpose of this month's lesson is to study means available for self-treatment of insect and arachnid (spiders, ticks, and mites) bites and stings. The major pests that are associated with warmer climates will be discussed. Unless otherwise specified, when we speak of insects in this article, we will use the term inclusive of all these pests.

Pharmacists receive numerous questions from consumers concerning insect bites and stings. Little is normally taught about this subject in most professional curricula and few continuing education experiences deal with it. A good working knowledge of these pests, their habits and usual nature of their involvement with humans will aid consumers in avoiding them, and knowing how and when to treat their bites and stings.

Systematic Classification

The critters under study in this lesson are classified in Table 1.

TABLE 1
Classification of Arthropods that Bite and Sting

I.	*ARACHNIDA* (Scorpions, spiders, ticks, and mites)	
II.	*INSECTA* (Insect)	
	A.	Bees, wasps, ants (Hymenoptera)
	B.	Fleas
	C.	Flies and mosquitoes
	D.	Etc.
III.	*DIPLOPODA* (Millipedes) and *CHILOPODA* (Centipedes)	
IV.	*CYMOTHOIDEA* (Crustacea)	

Stinging and biting pests are members of the phylum arthropoda, the largest division in the entire animal kingdom. Arthropods are elongated invertebrates that are segmented and have jointed, true appendages, and a hard shell exoskeleton. The two classes of arthropods discussed in this lesson include *arachnida* and *insecta* (insects). Insects do not require further defining. Arachnids have a segmented body divided into two portions; the anterior part bears four pairs of legs but no antennae.

Hymenoptera

Insect members of the order Hymenoptera ("membranous wings") are more commonly responsible for

Figure 1. Bees. (A) Honeybee and (B) bumblebee. Not drawn to scale.

stings to humans. The order is subdivided into three families, Apoida, Vespoidea, and Formicidae.

The most important members of **Apoida** are the honeybee and bumblebee (Figure 1 and Table 2). Bees tend to sting only when provoked. Stings are more rare with bumblebees than honeybees. This latter bee may sting if the hive is endangered. But a sting by the honeybee is also a sounding of the insect's own death knell. The honeybee is the only stinging insect that dies once it stings a victim. Death occurs because its stinger is barbed and, after it is inserted deep into a victim's skin, these barbs prevent its withdrawal. As the insect pulls away, it leaves its stinging apparatus behind, along with the venom sac that is actually part of the insect's internal organ system. The venom sac will continue its pumping action for the next 2 to 3 minutes driving the stinger and poison deeper and deeper into the tissue. However, this same process inflicts self evisceration (disembowelment) causing death to the insect.

The **Vespoidea** family includes wasps, hornets and yellow jackets. Wasps are frequently encountered in honeycomb-like nests constructed under eaves or overhanging structures of buildings. They commonly build nests on farm equipment, probably attracted to the heat that metal provides as sun warms it during the day. It is not uncommon for farmers operating tractors in the fields to be suddenly attacked by a group of wasps as they emerge from their nests.

TABLE 2

Hymenopteran Insect Descriptions

HONEYBEE — Golden brown, fuzzy. Barbed stinger
BUMBLEBEE — Yellow-black, fuzzy, slightly larger than honeybee
HORNET — Black with white or yellow striped body
YELLOW JACKET — Black body with yellow stripes
WASP — Red-brown, long
FIRE ANTS — Similar to common ant, but larger body and head

Yellow jackets build hives in the ground or under logs. Hornets construct large papier-mache, oval nests that hang from trees and shrubs.

The results of numerous studies with large population groups collectively show that about 0.4% of the population has had a previous systemic reaction from a sting by one of these insects. About 40% of these positive reactors also have a history of atopic disease (see the lesson *Counseling Patients on Dermatitis and Its Treatment* in this series for further details). The ratio of stung men to women is 2:1, probably reflecting their extended occupational roles in the outdoors, rather than a sexual difference. Most sting victims are under 20, also likely suggesting an increased exposure factor. The majority of deaths, however, occur in older adults.

Identification of the cause of an insect sting is often extremely difficult since the insect attacks and flees quickly. Sometimes the sting may be on the back or leg area, away from the area of sight. On other occasions, the insect may be seen when the initial pain is felt, but it will not be recognized. A stinger left in place is a positive sign for a honeybee sting.

Yellow jackets are reported to be the most common insect cause for allergic reactions, followed in order by bees, wasps, and hornets. When the insect cannot be seen, clues as to its identity may be found by looking for nearby nests.

Most Hymenopteran encounters occur during the daylight hours since these insects are relatively inactive once darkness prevails. Most fatal stings occur near home, rather than at work or during recreation. Therefore, assuring that the home area is relatively free of these insects and their nests will greatly decrease the chance for an unsuspected confrontation. Additionally, for some reason, bee and yellow jacket stings usually occur in suburban settings more so than in rural or farming areas.

Reactions. Reactions to insect stings may be localized in nonallergic individuals, or result in anaphylaxis in sensitized persons. Hymenopteran venom varies among different insects, but most venom contains a host of components including some that are extremely allergenic in nature (Table 3). Local reactions generally include mild-to-severe pain at the site of stinging, with erythema (redness) and swelling. The mildest reactions will generally disappear after several hours to a day. More severe responses may cause swelling and pain that extend several inches or more away from the original sting. It is not uncommon for reactions originating in the finger to be felt along the entire length of the arm. Discomfort may last for several days or more. When swelling and pain persist over a period of

days, this generally signals an early stage of allergic sensitivity. A person experiencing such a reaction should be urged to consult a physician to determine whether a mild allergy does exist. If so, desensitization procedures may be undertaken. The person will need to take special precautions to avoid future encounters with such insects, and perhaps even keep an emergency insect sting antidote kit available.

TABLE 3

Components of Hymenopteran Venoms

1. Histamine
2. Serotonin
3. Acetylcholine
4. Various protein-like substances
5. Enzymes (including phospholipases and hyaluronidase)
6. Various kinins and other vasoactive substances
7. Melitin
8. Apamin

Anaphylaxis to a Hymenopteran insect sting includes the symptoms shown in Table 4. Onset may occur within 2 to 15 minutes or be delayed for hours. Most deaths occur within an hour of stinging and, as a rule, such victims have a single sting. The more rapid the onset of the reaction, the more life-threatening the encounter will be. There are no OTC treatment measures for these reactions. A victim of an insect sting who displays symptoms of anaphylaxis must be taken to an emergency medical facility without delay.

Cross-sensitivity between members of Hymenoptera may be present, or the sensitized person may be allergic to one insect but not to the others. From an immunology standpoint, there is a common antigen present within the body of both the bee and wasp, but it is not in their venoms. Another similar body antigen is found in the venom of both the bee and yellow jacket. On the other hand, the wasp and yellow jacket possess a common antigen in both their body and their venom. Whether

TABLE 4

Symptoms of Anaphylaxis Resulting from Insect Stings

1. Flushing
2. Urticaria (generalized); hives
3. Pruritus
4. Mucous hypersecretion
5. Angioedema
6. Upper airway (i.e., pharynx, epiglottis, larynx, trachea) edema*
7. Bronchospasm
8. Circulatory collapse*, hypotension, shock
9. Myocardial infarction
10. Gastrointestinal symptoms (nausea, vomiting, diarrhea, spasm)
11. Uterine contractions
12. Urgency to urinate

**Usual causes of death*

a cross sensitivity reaction will occur depends on the means by which the sting or bite took place. In other words, the antigen that is actually passed on to the victim must be considered.

Treatment. As is so often the case, the best treatment is prevention. Areas known to be heavily occupied by stinging insects should be avoided until after the insect population is brought under control. Food and garbage attract insects. Bright, white and pastel colors, cosmetics, perfumes and colognes, after shave lotion, and hair spray attract insects. Therefore, highly susceptible individuals ought to avoid those items and types of clothing. They should also use insect repellents liberally. These agents will be discussed later in this lesson.

Local reactions are best treated with applications of cold packs and antipruritics. Mild reactions may respond appropriately to 0.5% hydrocortisone topical products; more severe reactions will not. For these, oral steroids (prescription only) may be needed. Oral antihistamines (e.g., chlorpheniramine, diphenhydramine, etc.) and analgesics can be recommended, if needed. Remember, for an antihistamine to be effective, it should preferentially have first access to the histamine receptor. Therefore, a couple of alternatives can be selected. Persons who are planning an outdoor event and just "know they are going to be stung," can begin antihistamine therapy a day or two in advance of the event (provided they are not allergic to the drug). This will lessen the extent of any reaction should an encounter with an insect occur. Alternatively, a liquid or chewable tablet form of antihistamine rather than other solid dosage forms should be used immediately after a bite. These will have faster access to the blood and, hence, will reach the histamine receptors more quickly than the other forms. Patients should be advised to initiate therapy at the first indication that stinging has occurred.

An imbedded bee stinger should be grasped carefully with tweezers, without squeezing the venom sac, and removed. A sharp finger nail, credit card edge, or similar item may be able to dislodge it by moving the item along the skin. Again, special care must be observed to avoid squeezing the venom sac.

Fire ants. The fire ant (family Formicidae) has become an especially bothersome insect to both people and crops in a dozen southern states in the Gulf Coast area. Fire ants have by now largely supplanted most other species of ant in that area. They were accidentally brought into the United States from South America in the 1930's.

The fire ant bites its victim, then pivots around the head stinging in a circular pattern at several sites. Its stinger is located on its abdomen. At the site of the sting, a red flare measuring up to 50 mm appears almost immediately. Within a minute, a wheal up to 10 mm is seen and persists for an hour. The area collects fluid over the next 8 to 12 hours and eventually becomes pus-filled. By the end of 24 hours, the sites form sterile pustules which last for several days. These then harden into macules (solid eruptions) and nodules which persist for weeks or longer. Pain and swelling are usually in-

tense (hence, the name "fire ant") and may last for days.

Less is known about reactions to fire ants than to those occurring from other Hymenopteran members. One or more common antigens are found in fire ants and other stinging insects. Although cross sensitization is possible, sensitivity to fire ants does not usually imply similar sensitivity to the other insects.

Fleas

Several flea species are parasitic to humans and spend their entire life on human hosts. Most flea infestations that bother people, however, are ectoparasites (live on the exterior of a host) of other animals such as cats, dogs and horses. They are normally found on hairy areas of the host where they feed and deposit their eggs. Once a pet has fleas, or they are present within a household, it is difficult (but not impossible) to eradicate them. Their life-span, when conditions are favorable, is up to 26 months. Within a building, they may produce a new generation every 3 weeks, with each female laying 400 to 500 eggs.

Figure 2. An adult flea.

Fleas (Figure 2) are wingless insects with strongly developed rear legs that enable the insects to jump several feet (including from one person to another). They are more common in the northern states during the warm months, April through September. In the south, they are a year-round problem.

Flea bites occur on covered areas of the body and are generally innocuous in most people, causing little more than mild itching. However, in a sensitized individual, intense itching along with blistering or even pus-forming reactions may occur. Oftentimes flea bites are multiple, occurring in a linear fashion of three bites, loosely referred to as "breakfast, lunch, and dinner." Some fleas are carriers of serious human diseases including plague and typhus. However, currently these are unusual cases rather than common encounters in America.

Flies and Mosquitoes

More than 1500 species of mosquitoes are found around the world. They comprise the single most important insect group from a health standpoint. Aside from being pests and the cause of frequent bites that result in intense itching episodes, they may harbor and transmit a wide variety of diseases, many of which can be life-threatening. Mosquitoes will bite any exposed portion of skin, and can bite through clothing. Mosquitoes, upon biting, secrete antigenic compounds in their saliva which are the cause of itching and discomfort.

Sand flies (also called gnats, punkies, biting midges and "no-see-ums") are tiny insects that attack during the day, most commonly at dusk when the wind has subsided. They seek any exposed surface, especially the scalp, neckline, beltline, and shoe top areas. Their bite causes intense itching. The area develops into blisters, papules, and nodules which persist for several days.

The term "sand fly" also describes another insect species. These are small hairy insects with long legs. Their bites produce similar symptoms as those mentioned above, but in addition, these insects are carriers of serious infectious diseases.

A large group of flies variously known as horseflies, deer flies, gadflies and three-corner flies inflict extremely painful, bloody bites. They attack silently, usually on warm, sunny days.

Treatment. It is rarely necessary to treat a fly or mosquito bite except for itching. Topical antipruritic products may bring relief.

The Arachnida (Spiders, ticks and chiggers)

Spiders. These are readily distinguished from insects by their eight (rather than six) legs, absence of antennae, and division of their body into two major parts. The legs are attached to the front segment, and the other part is a baglike abdomen.

Two species are responsible for most serious spider bite encounters in the U.S. These are the black widow, see Figure 3, (located throughout the U.S. and Canada) and the brown recluse spider (found in the midwest, southern and southeastern states).

Figure 3. Black widow spider hanging from its web. Notice the hourglass figure on the ventral side.

Only the female black widow spider is dangerous. The venom is more powerful than snake venom, but only a small quantity is injected. She's glossy black, with a body size about 1 cm in diameter. Her legspan measures about 5 cm. There's a characteristic red "hour glass" marking on the abdomen. This may signify that "it's time for another victim!" However, it is strongly advised that inquisitive individuals not go looking at female spider bellies just to see whether or not an hour glass mark is present.

The black widow is aggressive and bites without provocation. Most bites occur between April and October. About 500 bites are reported each year in the U.S. with a mortality rate of 1%, usually children and the infirm. Black widow spider webs can be seen spun on wood piles, in basements, sheds and privies.

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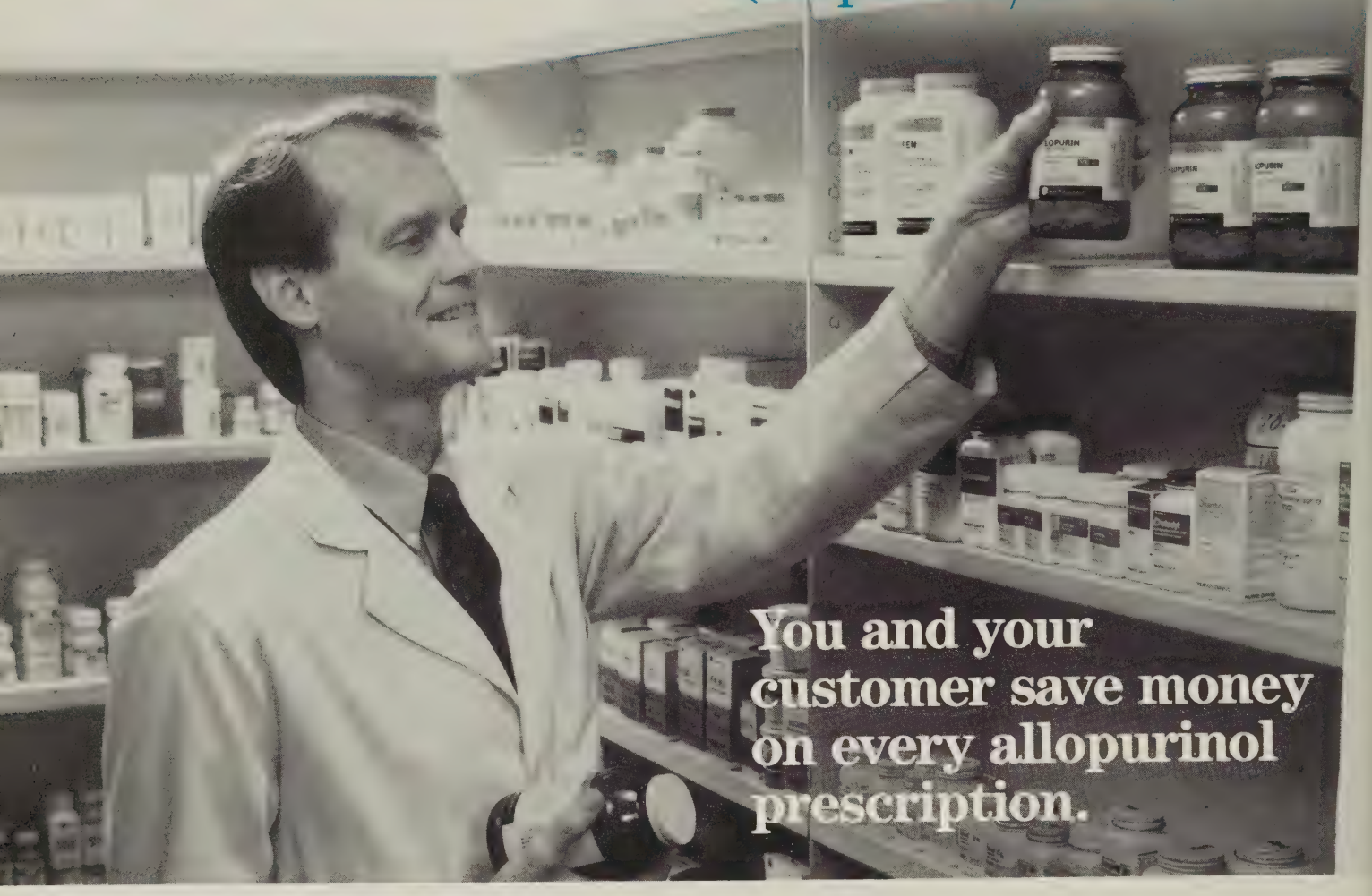

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A sharp pain is felt at the site of the bite, followed by cramping in 15 to 60 minutes. This spreads and may involve the trunk and all extremities. The abdomen may become rigid with pain occurring in waves. It may be excruciating with the victim tossing and turning about, crying out in severe agony. The venom causes diffuse central, pepipheral and autonomic nervous excitement, muscle spasm, hypertension and vasoconstriction. Symptoms persist for several hours to three days.

The brown recluse spider is much smaller than the black widow, with a body diameter less than 0.5 cm, and a legspan of 1 to 2 cm. It is found in dark, undisturbed places.

A bite from the small brown recluse spider usually produces pain within 2 to 8 hours. Other symptoms include erythema, blistering and tissue necrosis with sloughing. The most potentially dangerous symptom is necrosis which occurs because the venom activates the blood's clotting mechanisms which in turn reduces blood flow into the area. Necrotic lesions continue to increase in size for up to a week. They are most effectively treated by surgical excision.

Systemic reactions, including fever, muscle pain and a morbilliform (resembling measles) rash 24 to 48 hours after the bite, occur. Deaths have been reported in children.

Heavy gloves and long-sleeved shirts buttoned at the wrists should be worn when disturbing rubbish or wood piles in any area where it is suspected that these varmits may be lurking. The underside of outdoor privy seats and dark areas of sheds and garages should be sprayed with creosote every 3 to 4 months to repell black widow spiders.

There are no OTC products designed to treat spider bites. Victims should be advised to apply cold packs and consult a physician at once. A tourniquet should be applied centrally to the affected area of an extremity if the bite was from a black widow spider.

Ticks. All developmental states of ticks (i.e., larvae, nymph and adult) can infest man and other animals. When one considers ticks, dog ticks frequently come to mind. However, ticks can feed off any warm blooded animal including mice, rats, rabbits, squirrels, cattle, horses and humans. As with mosquitoes, ticks are parasites that feed on the blood of their hosts. They cause inflammation and ulceration at the site of their bite; a few species are venomous and can cause paralysis, even death. Ticks may also be carriers of serious infectious disease, including Rocky Mountain spotted fever, Q fever, and tularemia.

Adult ticks puncture the skin and insert their mouth parts into the host. This allows them to hold firmly until engorged with blood. While the male retains his original size on feeding, the female may increase in size many times. Ticks mate while on the body of the host and, once impregnated and full, the female drops to the ground to lay as many as several thousand eggs. This can occur indoors as well as outdoors.

After several weeks, the eggs develop into six-legged larvae which, after finding a suitable host, feed for 3 to 7 days. They then fall back to the ground and spend another 1 to 4 weeks transforming into the nymph stage. Tick nymphs have eight legs and they also feed on the nearest available warm-blooded animal. This stage lasts about one week. At the end of this period, the nymph, fully engorged, drops to the ground and soon emerges as an adult.

Tick bites are painless, so ticks are not normally detected for several days after attachment. At that time, itching develops and the area around the tick appears swollen and red. If the tick falls off spontaneously, the reaction generally continues for another 2 to 3 weeks. Some bites have been known to persist for months to years. Other symptoms and complications of tick bites are outlined in Table 5.

Removal of adult ticks should be undertaken with extreme care so as to avoid severing the mouth parts and leaving them behind. These embedded remnants left in the host can cause persistent and intense itching with development of nodules.

While there is no sure way to remove an adult tick, several alternative means may be suggested. Pulling slowly and steadily on the tick may work. Applying a small amount of ether, gasoline, kerosene, oil, petrolatum, or possibly fingernail polish may cause the tick to slowly withdraw its mouth parts on its own. Touching the tick with a hot nail or lighted cigarette sometimes results in the tick quickly letting go for easy removal. This procedure is not recommended, though, for the individual may be easily burned. In the instance of dog ticks, it is good advice to wash the animal with one of the commercially available tick soaps or shampoos because there may be other larvae or nymphs present that are too small to see by the unaided eye. The area around the dog's sleeping quarters should also be sprayed with an anti-tick product to rid it of developing nymphs and larvae.

TABLE 5

Symptoms and Complications of Tick Bites

1. Fever
2. Intense burning and itching
3. Inflammation and ulceration
4. Patchy alopecia
5. Paralysis (reversible with removal of tick)
6. Rickettsial diseases (e.g., Rocky Mountain spotted fever, Q fever, tularemia, relapsing fever)

Chiggers (harvest mites, redbugs). Chiggers are parasitic larval mites that attach to human hosts with hooked mouth parts. They may be found from southern New York west to South Dakota and south to the Gulf of Mexico. They are also reported in other states.

The adult female chigger lays her eggs on the ground, most often in damp places covered with undergrowth. Adult chiggers do not attack animals. They feed on vegetable material. The eggs hatch into emergent six-legged larvae (about 0.4 mm in length) which crawl up the surrounding grass blades and plants to await a passing animal or human host. When they make contact, they may advance along the skin until (for some yet unknown reason) they are

satisfied it is the right site. Chigger bite location is also dependent on the type of clothing worn. They seem to like areas of friction. Thus, the areas where belts, garters, brassiers or stocking elastic are worn are popular for chigger bites. They bite into the skin and secrete saliva containing a digestant which enzymatically disintegrates the surrounding cells. Unlike another common mite, scabies, chigger larvae do not burrow under the skin.

The skin then hardens around the chigger, where it continues to feed. The mite feeds on the host until it is engorged with blood and drops to the ground to develop into an adult. This feeding process is necessary before the larvae can molt. While on the host, however, irritation and intense itching occur, often within hours of the bite. This irritation results from salivary secretions. Inflammation and even blistering may result. These symptoms may persist for days to a week or more, even after the insect has dropped off. Itching may be more intense at night.

Chiggers can be prevented by sprinkling sulfur powder or applying one of the commercially available insect repellent products. These should be applied to exposed areas of the skin before entering places likely to contain chiggers. Shoes, socks, cuffs and waistbands are also good areas for application of these agents.

Local treatment of chigger bites centers on asphyxiating the mite and reducing the itching. This can be safely performed by applying mineral oil or flexible collodion. In some individuals, application of clear fingernail polish may do the job. Several OTC products specifically labeled for relief of itching associated with chigger bites are available, but these are no more effective than clear nail polish. Care must be observed, however, since some people may be sensitized to nail polish and a rash with more itching may develop.

As with any other mild inflammatory condition, oral antihistamines and topical steroids may be beneficial.

Insect Repellents

Many investigators have attempted to define what attracts insects to humans. Most of these studies have involved mosquitoes. Heat, moisture, and various secretions have been studied. It is generally felt that body odors are more important in attracting insects from a distance, whereas heat and moisture are the attractants for insects close-by. A lipid component of sweat seems to *repel* mosquitoes. When this substance is removed from sweat, mosquitoes become more attracted to people. If this finding is significant, variations in the amount of this lipid material in the sweat of different people may explain why some victims are ravaged by mosquitoes while others seem to be hardly affected at all.

Oral Insect Repellents. Of all the substances suggested as insect repellents over the years (including flowers of sulfur and garlic) only thiamine (vitamin B_1), has been evaluated to any significant degree.

As early as 1943, investigators reported that thiamine ingestion or injection repelled mosquitoes. Daily doses of the vitamin ranging from 200 to 300 mg, and in one study, up to 1 gm/day, were shown to reduce the number of mosquito bites. However, these studies have for the most part been uncontrolled; their results have failed to show significance over controls, or their findings have not been reproducible by other investigators.

Thiamine is one of the B-complex vitamins that is generally safe even when taken in very high doses. It is water soluble and is quickly eliminated from the body in urine. Its supposed activity in repelling mosquitoes is due to its deposition under the skin which imparts a disagreeable odor that is repulsive to mosquitoes.

FDA's Advisory Panel on OTC Miscellaneous Internal Drug Products reviewed the available data on thiamine. The panel reported that doses up to 40 mg per day are generally recognized as safe. (It's interesting to note that the panel did not state that doses greater than 40 mg per day were unsafe).

Thiamine was placed in Category II (ineffective) as an internal insect repellent because there were no clinically significant data to prove that thiamine does repel insects. The advisory panel reported its conclusions to FDA. FDA has published its intention of not allowing manufacturers of OTC thiamine-containing products to claim that their products repel insects.

External Insect Repellents. Synthetic insect repellents were developed during World War II. Prior to that time, various substances were used including oils of citronella, turpentine and cedarwood. None of these substances has shown significant repellent action against more than a small number of insect species.

During the development of better repellents, substances were sought that would repel a large variety of insects, have an innocuous odor to the user, be effective for several hours, be non-toxic and non-sensitizing when applied to the skin, and be non-injurious to clothing. Of the more than 15,000 chemicals that have reportedly been tested, only a few meet these criteria.

Today, the market is dominated by two chemical repellents: N, N-diethyl-m-toluamide (e.g., Off™) and ethohexadiol (e.g., 6-12™).The former is usually stated to be the better repellent, having the greater deterrent action against the broadest variety of insects. However, this notion may be hotly contested by persons who have success with the other chemical. Either product is adequate to control attacks of most insects that bother humans in the U.S. and Canada. Since each repellent has an action against a slightly different group of insects, combining the two may increase the spectrum of activity beyond that which would be expected from a single product.

Treatment of Insect Bites and Stings

Aside from specific measures already discussed, little more can be done for treatment of most bites and stings. Unless the patient is allergic to insect venom, or the offender is a black widow or brown recluse spider, most attention should be directed toward relief of pain, itching, and secondary bacterial infection.

Pain and itching may be controlled with topical application of a

product containing a local anesthetic. Oral antihistamine-containing products may effectively control itching. While topical steroid products are of some value in reducing swelling, they may only provide marginal relief since these symptoms appear almost immediately and steroid drugs require some time to take effect. Cold packs aid in pain and itch control and in delay of the spreading of venom.

While there are no clinical studies to prove it, many people believe that meat tenderizer worked into a paste with water and applied to the bite or sting area brings relief of pain and itching. If this is true, it is probably because meat tenderizer destroys proteinaceous material and may help to break down antigenic principles.

There are other products on the OTC market which claim to be useful for treating bites and stings. They are referred to as "neutralizers". Claims are made that, as the designation implies, these products are beneficial because they chemically neutralize or inactivate insect venom.

Of the ingredients for which such claims are made — ammonium hydroxide, calamine, camphor, ferric chloride, menthol, peppermint oil, sodium bicarbonate, sodium borate, triethanolamine, turpentine oil, zinc oxide and zirconium oxide — only ammonium hydroxide (ammonia water) and triethanolamine have demonstrated any proof of effectiveness.

They are thought to be beneficial in alleviating pain and itching of insect bites because they are alkaline and, therefore, they neutralize the acidic components of insect venom.

However, the FDA panel that reviewed these two agents ruled that there is insufficient evidence to prove their effectiveness. The panel stated that while there are acidic substances in some insect venoms (e.g., formic acid in ant venom), most venoms are far more complicated in that they also contain enzymes, kinins, peptides, and in a few instances, chemicals that are actually alkaline in their own right.

The panel concluded that the use of ammonium hydroxide and/or triethanolamine for treatment after an insect bite is based on the erroneous assumption that acids are the sole causative agent for the pain and itching. On the other hand, the panel did find at least one (limited) study which showed they gave a faster response time for reduction or elimination of pain than did a placebo. Therefore, their continued OTC availability will be permitted while their manufacturers conduct further studies.

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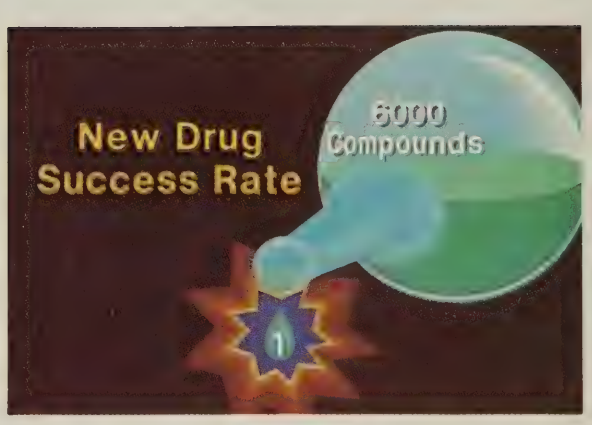

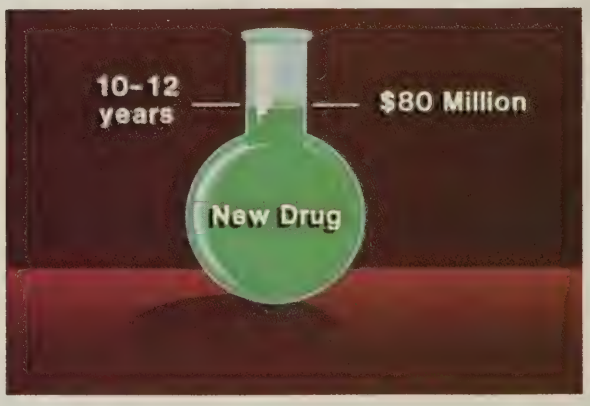

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Facts and figures

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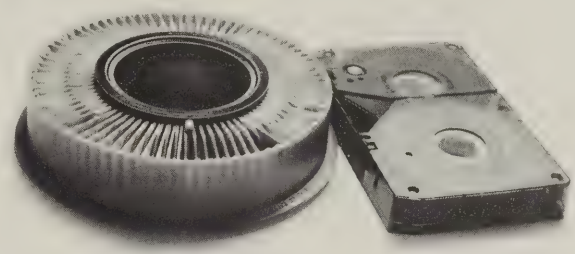

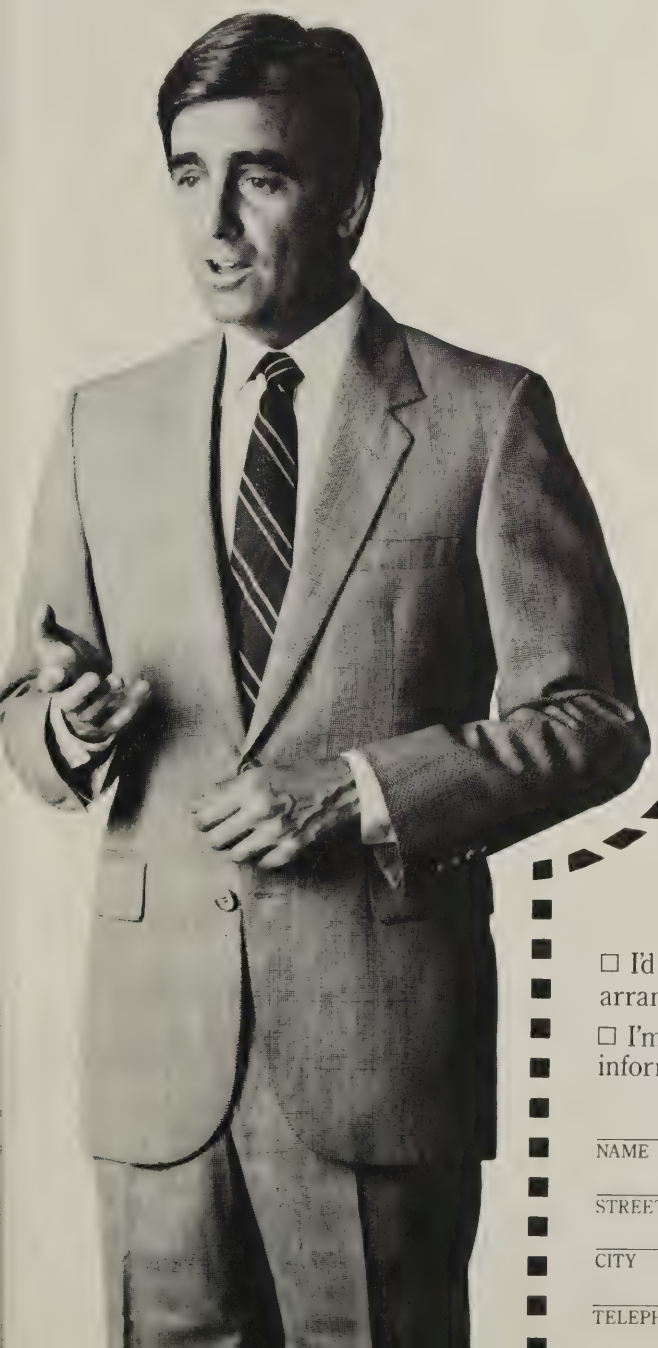

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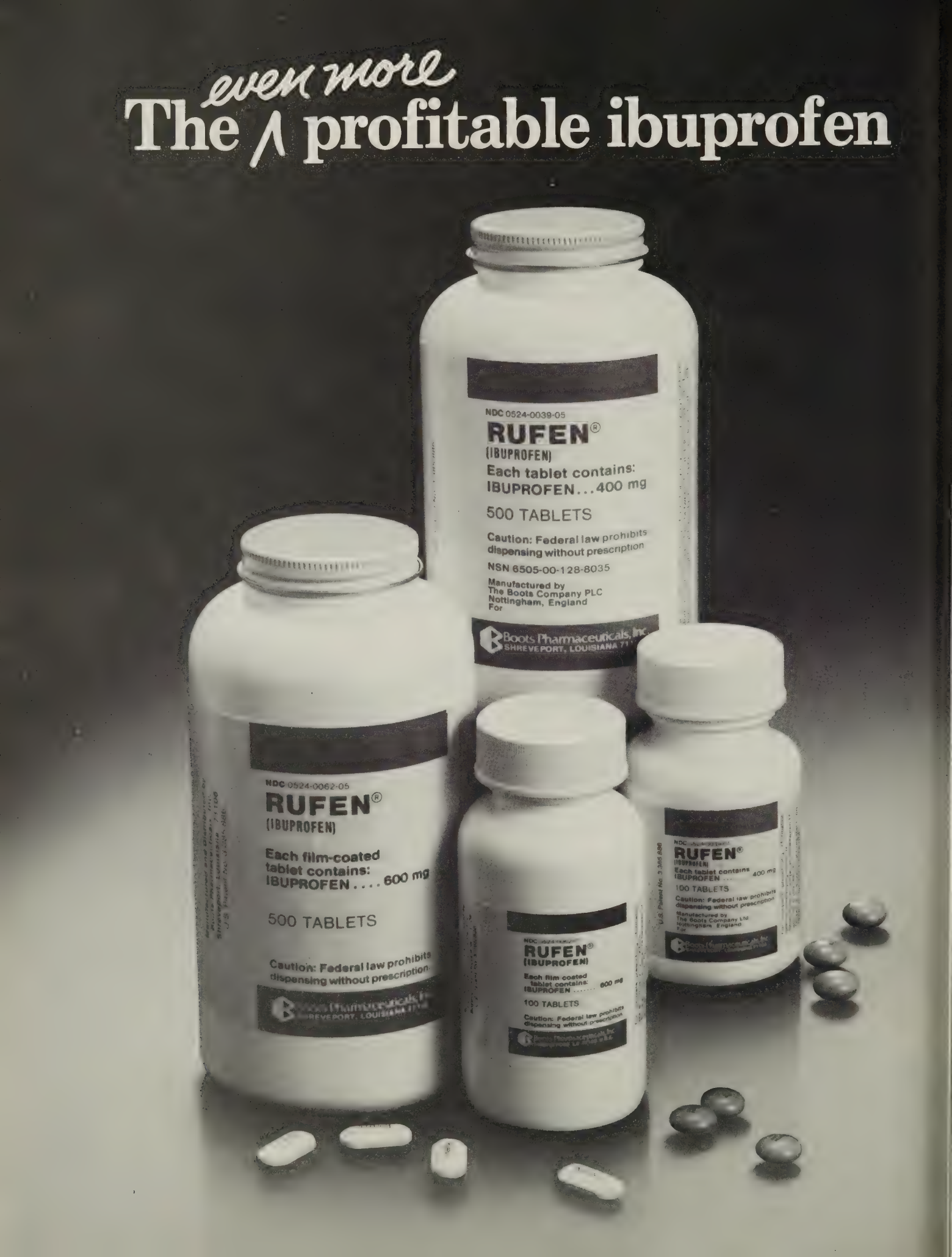
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**Redbook, August 1984.

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LETTERS

Dear Dave:

In mid-August, my wife and I visited Europe for the first time. Of the four cities we covered, I do not remember seeing a Pharmacy in Salzburg, and it was on our second night in Amsterdam when I noticed the first Pharmacy. Since it was Friday night, and therefore, the weekend, I did not have a chance to meet colleagues there. But in Vienna and in Zurich, I did and this is my report. I had had a request from a patient for a rectal suspension that the patient had gotten in Mexico last year. I had written the company in Mexico but did not receive a reply. I photocopied the insert, which gave no idea of content of ingredients and took this with me on our sojourn. While walking around Vienna, we spotted what appeared to be an old established Pharmacy. As it turned out, the present owner, Dr. Rammigen, Mag. PH. was the grandson of the original owner, A. Moll. I discussed my drug product problem with my Viennese colleague, and he promptly produced a pack of 5 ml rectal suspensions with a very similar name. I was looking for Microlax, and he had Microkist. Microkist is made by Pharmacia Laboratories but is not available in the United States. I obtained a box of the suspensions to further my investigation and the good doctor was nice enough to give me a professional courtesy.

In Zurich, we stayed at a small hotel in the old section. Just across the street, about 15 feet, was the Rosen Apothacary. This pharmacy was just 200 years old. In its present state, it sold in addition to prescriptions and patent medicines, perfumes and cosmetics. The owner, who was not present on this day, had his doctoral degree; the woman pharmacist, who was in her early 30's, gave me a tour of the facility. A full compounding laboratory on the second floor contained much more of the equipment we see in our chemistry laboratories. Old chemical bottles and jars were still used to store the chemicals as these chemicals came to the Pharmacy in prepacked bags, not jars or tins as we get ours. In one of the drawers she showed me, I noticed that they had Ludiomil in 10 mg. strength that we do not have, and they did not have Limbitrol 10/25 that we have. Strange, but true. Both experiences were pleasant as were both of our Eurpoean colleagues. I hope we show the same courtesy to Pharmacists who visit us.

Phill Weiner, P.D.

This and That About Pharmacy

Leon Weiner

As the saying goes, you can't judge a book by its title. When one meets Ralph Small, Jr., the first thing that strikes you is his impressive size. Not small at all, Ralph stands a tall 6 foot plus. After a short period of time, you also realize he's quite big in personality and in general niceness. These are some of the reasons everyone is very happy at the news that Ralph became a member of the Board of Pharmacy on July 15, 1984 for a period of 5 years. Married, and the father of a 2 year old son, Small had previously worked for Eli Lilly before becoming a partner of Northwest Professional Pharmacy in Baltimore City. Ralph was a University of Maryland Pharmacy graduate in 1974.

Barbara Durkin, a local Dundalk girl, recently wrote a book on her younger days called "Oh You Dundalk Girls, Can't You Dance The Polka." In the book, the author mentioned many times Lillich Pharmacy which is located in the heart of Dundalk. Feeling very good about that, Lillich Pharmacy had a big book sale in which 200 Durkin books about the local community were sold. Besides all this excitement, Terry Crovo, the pharmacist at Lillich Pharmacy, married Patricia Barditch, another pharmacist, on June 10, 1984. Pat, who does part time work at the pharmacy, graduated from University of Maryland Pharmacy School in 1978 and this year graduated cum laude from the University of Maryland Medical School. While starting her internship at the University of Maryland Hospital, she and her husband are now residing in East Baltimore. Terry graduated from University of Maryland Pharmacy School in 1980.

For years, I have heard that Dean William J. Kinnard, Jr. is a ladies' man. When Dr. Kinnard came to University of Maryland Pharmacy School in 1968, about 4.5% of the students attending pharmacy school were females. Now 16 years later, in 1984, the percentage of female students has jumped to about 55%. Figures do not lie. Our Dean must be a ladies' man to attract so many of the fair sex.

Love and Marriage

1. Dr. Dean E. Leavitt and Wife—Announce the engagement of daughter Elizabeth Anne to Theodore J. Stetz. A graduate of University of Maryland Pharmacy 1954, Dr. Leavitt has been associated with School of Pharmacy ever since. At present time, he is Associate Dean for Administration and Professional Services.

2. Cynthia Brown, P.D. Married Barry Levine September 3, 1984. Cynthia, a 1979 graduate of University of Maryland Pharmacy School, is a pharmacist at North Charles General Hospital.

3. Irvin Jack Albert and Wife announce the engagement of daughter Lisa Rose to Craig Hoffman. A graduate of University of Maryland Pharmacy 1952, Irving is a pharmacist for Dart Drug Company.

4. Daniel B. Satisky, P.D.—Married to Terri Gumnit. Dan, a University of Maryland Pharmacy School 1981 graduate, is the son of Mr. & Mrs. William Satisky. William is a 1955 University of Maryland Pharmacy graduate who works for Dart Drug Company.

5. Beryl Lerner and Wife announce the engagement of son, Steven Paul to Diana Lynn Stefanini. Beryl, 1961 University of Maryland Pharmacy graduate, works for Giant Drug Company.

Recent Pharmacy Deaths

1. Carl C. Caplan, P.D. died July 21, 1984. Came to Maryland from Georgia in 1924. Owned Victory Villa Pharmacy. Worked for Harris Pharmacy in Baltimore City.

2. Arthur Nattans, Jr. Died July 26, 1984 age 69. Retired owner and vice president of Read Drugs and Chemical Company.

3. Michael S. Patton, P.D. died July 27, 1984 age 33. Graduated University of Maryland School of Pharmacy in 1977. Worked for People's Drug Store.

4. Herbert Damazo, P.D. died August 6, 1984 age 52. Graduated George Washington University 1955. Retired pharmacist who was one of the founders of the Merdian Nursing Center, a 75 bed nursing and rest home in Frederick, Maryland.

calendar

Nov. 11 (Sun)—Alumni Association Dinner Meeting (note: CECC Program Scheduled this date has been changed)
Nov. 13 (Sun)—BMPA Annual meeting and election of officers.
Nov. 16–17—National Symposium on Women in Pharmacy.
Nov. 18 (Sun)—CECC Seminar on Drug and Alcohol Abuse
Jan. 12–19—MPhA TRIP TO ST. MAARTEN
Jan. 27—Mid-year meeting, Annapolis Hilton
Feb. 16–21—APhA meeting—San Antonio, TX
Mar. 10 (Sun)—BMPA Dinner Dance

Every Sunday Morning at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the Pharmacy Public Relations Program "Your Best Neighbor," the oldest continuous public service show in Baltimore.

A Report from the Center for the Study of Pharmacy and Therapeutics for The Elderly

The Center's last year has been a successful one.

Education:

With a grant of $200,000, the Center has established the Park Davis Center for the Education of the Elderly. It is planned that, starting in fall, the Center will publish a newsletter, *Eldercare,* which is to be sent quarterly to community pharmacists nationwide. It will address issues of drugs, nutrition, new medical discoveries, and oral health in abstract form.

Continuing Education:

The Center has sponsored or co-sponsored a number of continuing education programs, the latest one on Home Health Care, co-sponsored with the Veterans Administration Medical Center of Baltimore.

Other Programs:

The Center presented three fully-funded programs at the Annual Meeting of the A. Ph.A. in Montreal, directed to Student American Pharmaceutical Association, the State Association Executive Secretaries, and the Academy of Pharmacy Practice. This followed a similar effort at the A. Ph.A. meeting in Montreal and Las Vegas. Under the auspices of PD Elder-Care and the Center, an AV tape, The Medicated Generation, has been prepared which will be distributed to all Pharmacy Schools and State Associations.

Research:

The Center has been in discussion with several pharmaceutical companies about evaluation of different drugs. The Center is also cooperating with individual faculty members in identifying possible patients for drug studies.

Drs. Lamy and Fedder have received a grant from the Merck Sharpe & Dohme ($60,000) has been received to study home health care. Dr. Palumbo has received an NIH grant of $225,000 to study antibiotic use in long-term care institutions. Dr. Myron Weiner has received a grant from the National Institute on Aging to study the effects of age on antidepressant kinetics and short-term memory loss. Dr. Larry Lesko is a co-investigator on the project.

Peter P. Lamy, Ph.D.
Director

Meet Dr. Bob

Dr. Bob Singiser was awarded his Ph.D. in Pharmacy from the University of Connecticut in 1959, shortly after joining Abbott as a Research Pharmacist. He became Vice President of Scientific Affairs of the Pharmaceutical Products Division in 1970.

HE KNOWS BOTH SIDES OF THE BENCH

As head of our divisional product development operation, Dr. Bob Singiser will tell you that meeting compendial specs is sometimes just the beginning of the job.

He knows that things like flavor, tablet size, stability, and odor (or lack of it) can be critical to patient compliance. That's why he and his people are always striving for the "leading edge" in formulation technology.

But Bob's commitment isn't confined to our side of the bench. He is very active in local and national pharmacy activities. You'll often find him lining up speakers for pharmacy school or association meetings. Or coordinating a student internship program (we had six students with us last summer). Or setting up a visiting professor program for pharmacy school faculty members.

This isn't written into his job description here at Abbott. It's something he chooses to do. And when the administrative work begins to pile up, he's apt to remind us, "Hey guys, remember—I'm a pharmacist."

As though we'd ever forget.

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Second Prize: A trip for two to the 1985 APhA or NARD convention.*

Third Prizes: *Remington's Pharmaceutical Sciences*, or a set of apothecary jars, or a contribution toward the cost of CPE credits.

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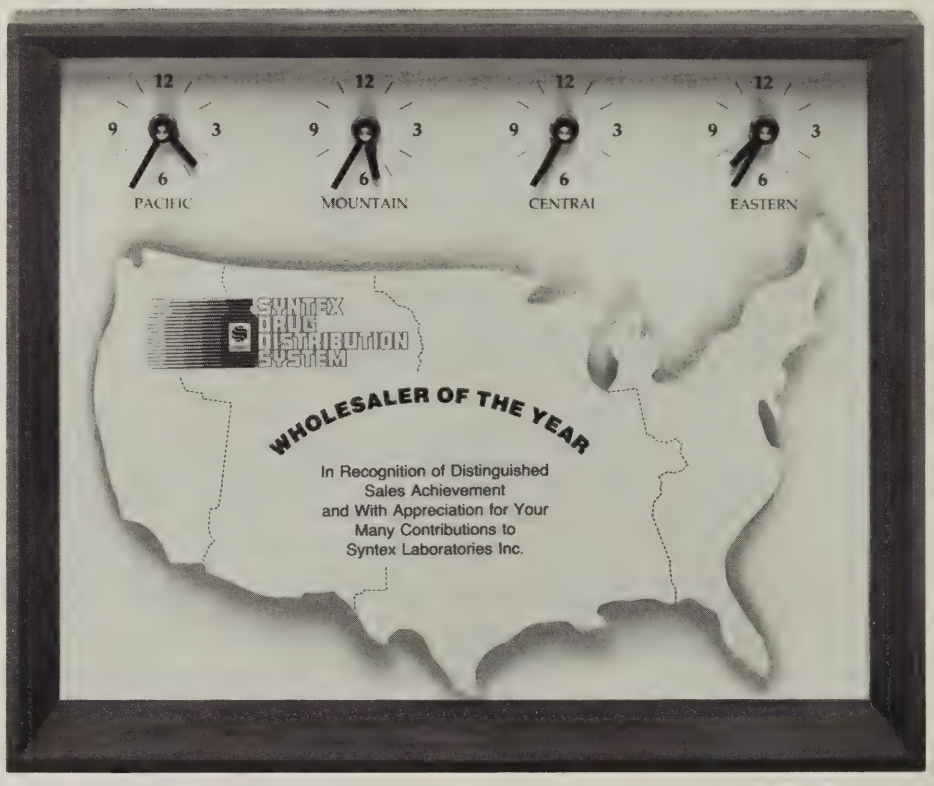

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Information contributed by the Maryland Society of Hospital Pharmacists.

Infusions

Contributor: Gail H. Rosen

Toxicity of Iron Dextran Complex

Two milliliters of undiluted iron dextran is the maximum daily dose recommended by the manufacturer. When given intramuscularly, iron dextran should be injected deeply into the muscle mass of the outer quadrant of the buttock, using a Z-track technique.[1] Intravenous therapy may be favored when patients have a decreased muscle mass, the presence of a bleeding tendency or excessive discomfort with IM injections.[2] Intramuscular injections have been associated with lipomyodystrophy, allergic puepura[3] and sarcomas. The latter association, however, is difficult to prove because of the time that elapses between the administration of the agent and the appearance of the anomaly, and the lack of a common histological pattern in the published case reports.[4] If direct intravenous administration is elected, it should be performed slowly, at a rate not to exceed 1 ml per minute. Injection rates of 100mg per minute (2 ml/min) have been associated with flushing, warmth, and a mettallic taste in the mouth that was alleviated by stopping or slowing the infusion.[5]

Before iron dextran is given, a test dose should be given to detect immediate reactions. Anaphylactoid reactions have occurred in patients receiving iron dextran by both the IM and the IV route.[6,7] The recommended test dose is 25mg (0.5ml) given IV over fifteen minutes or IM as previously described, followed by an observation period of at least one hour prior to the administration of the remainder of the initial dose. If sudden onset of dyspnea, chest pain, flushing, urticaria, bronchospasm, or hypotension occurs during the test dose period, the remaining injection should not be administered.[2]

As mentioned previously, 2ml is the maximum daily dose recommended by the manufacturer and approved by the FDA. However, numerous studies in the literature have appeared regarding the use of total dose infections (TDI). The total dose is calculated using the equation found in the package insert and is given by direct IV administration or diluted in 200 to 1000 ml of fluid. Normal saline is the diluent of choice as thrombophlebitis has been associated with the use of dextrose.[8] The safety of this method has been reported by several investigators[8,9,10] while others have reported incidences of adverse reactions as high as 13.5%.[11] These reactions can be divided into immediate and delayed reactions. The immediate reactions have a similar profile as with other routes of administration and can be predicted by the use of a test dose.[12] The latter are unpredictable reactions that are characterized by arthralgia, myalgia, headache, lymphadenopathy and fever, occurring singly or in combination. The onset is typically within 4 to 48 hours of injection and duration is 3 to 7 days.[5] All reports in the literature of delayed reactions occur when patients were given iron dextran by total dose infusion.[5,13] However, conversations with the distributor of iron dextran confirm that delayed reactions have occurred with intramuscular and low dose intravenous injections. There is only one study that compares TDI with other routes of administration. The response to single IV dose versus multiple IM administration was assessed in 27 children. Minor reactions manifested by urticaria occurred in two patients, one from each group. No delayed reactions were noted in either group.[14]

Patients with rheumatoid arthritis represent a subgroup of patients with iron deficiency anemia that may have an altered iron metabolism.[15] Acute exacerbations of joint pain have been associated in this subgroup with the use of total dose intravenous iron dextran.[5,15] Of seven patients treated by Reddy and Lewis, five of the seven experienced acute increases in swelling, heat and pain in joints already afflicted with rheumatoid arthritis. Two of the reactions were accompanied by fever greater than 100°F. Both patients who experienced febrile episodes were treated with doses of one gram or more. The flare in arthritis was seen in dosage ranges of 0.2 to 3.0 grams.[15] Hamstra reports three patients, two with rheumatoid arthritis and one with lupus erythematosus. In the three patients, doses of 50mg did not cause a reaction, 100mg doses caused arthralgia and myalgia that was not disabling and doses of 250mg caused disabling pain for a day or two.[5] Patients not having rheumatoid arthritis have not demonstrated a dose-related incidence and severity of delayed adverse reactions. Exacerbations of rheumatoid arthritis in patients treated with iron dextran may be due to deposition of iron in the synovial fluid[15] due to their altered metabolism and therefore may be a different mechanism then is seen in patients with delayed reactions without underlying arthritic disease.

(References Available upon request)

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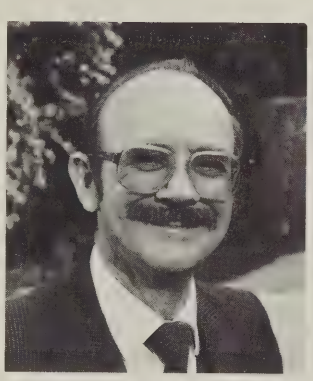

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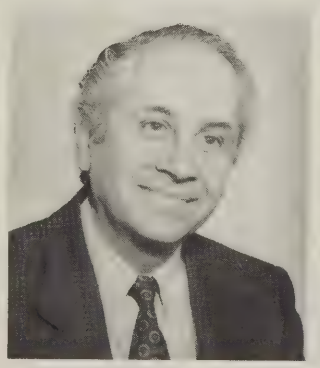
Community Pharmacist
Lubbock, Texas



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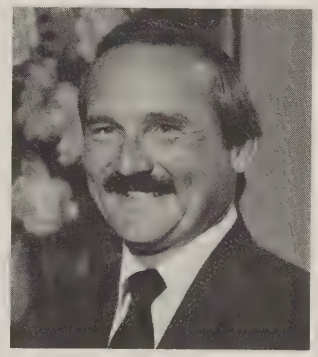

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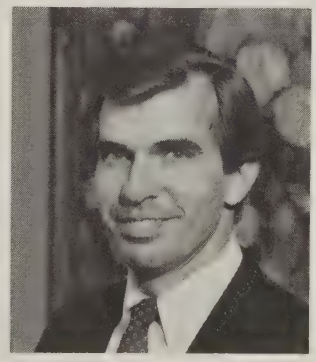

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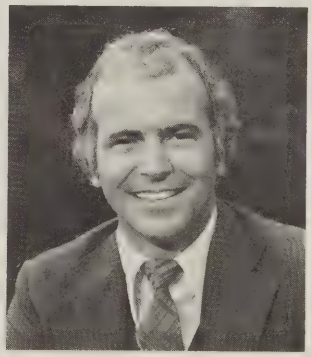

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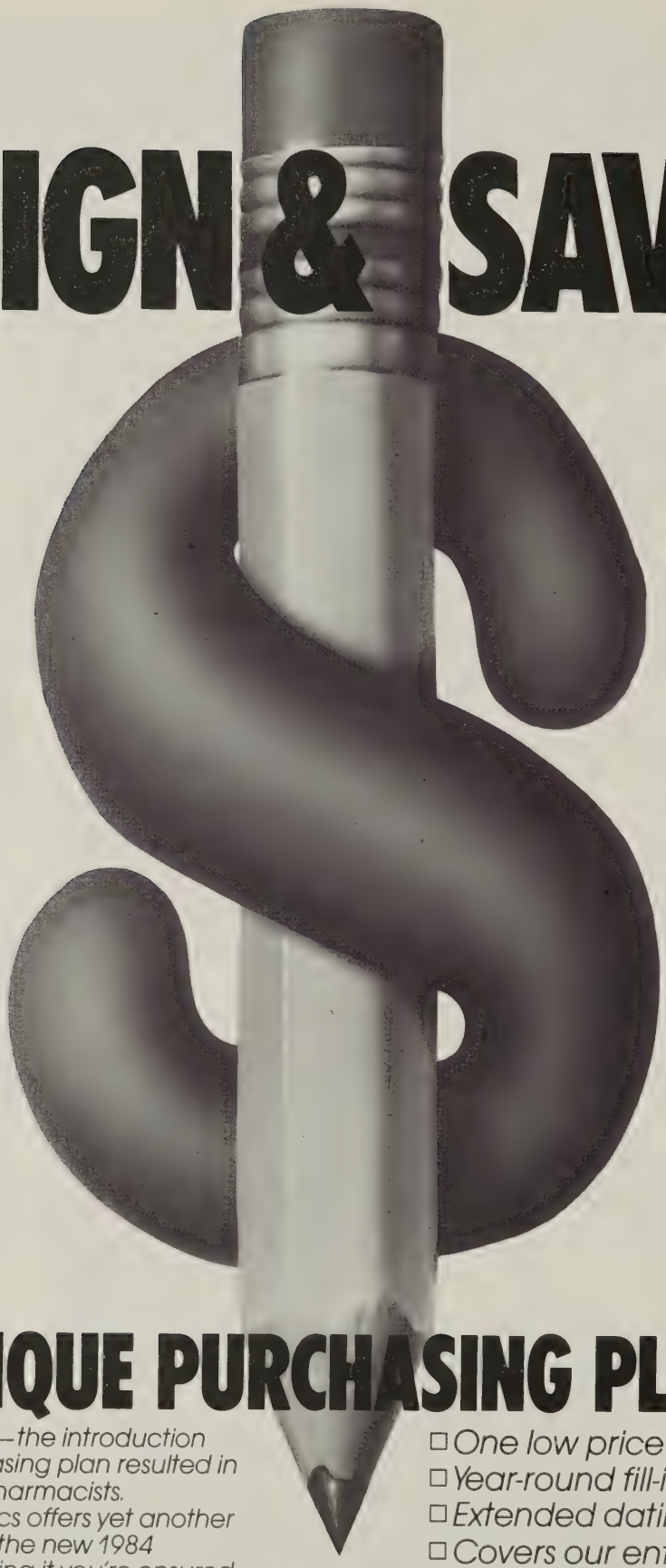

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ABSTRACTS

Excerpted from PHARMACEUTICAL TRENDS, published by the St. Louis College of Pharmacy; Byron A. Barnes, Ph.D., Editor and Leonard L. Naeger, Ph.D., Associate Editor

ON-OFF PHENOMENON IN PARKINSON'S DISEASE:

Patients receiving L-DOPA to control Parkinson's disease often experience beneficial results followed by a dramatic reversal and increased symptomatology. Studies conducted in patients experiencing this reversal have shown that these exacerbations were associated with reduced plasma levels of the drug. Further investigation found that the bioavailability of L-DOPA is reduced if the drug is ingested with a meal, suggesting that other amino acids contained in the food compete with L-DOPA for active uptake sites in the stomach and intestine. Systemic mechanisms may also be involved because the activity of the drug can also be reduced by intravenous administration of phenylalanine, leucine, and isoleucine. Glycine and lysine do not alter its effectiveness. *N Engl J Med,* Vol. 310, #8, p. 483, 1984.

PHARMACEUTICAL MANUFACTURING IN SPACE:

For some time scientists have been developing plans to manufacture certain biological products in space. Actually the term purifying better describes the process of continuous electrophoresis within a microgravitational field. In June of this year, the first pharmaceutical production specialist will be aboard the Discovery Space Shuttle Craft to activate and maintain the continuous operation. J & J have collaborated with McDonnell-Douglas in the project. If all goes according to schedule, commercial manufacturing via approved FDA methods will begin in 1987. Substances which may be separated by this unique process include beta cells from the pancreas, alpha-1-antitrypsin, antihemophilic factor, erythropoietin, growth hormone, immune serum globulins, somatomedins, and urokinase. *FDC Rep,* Vol. 46, #11, p. 3, 1984.

THEOPHYLLINE-PHENYTOIN INTERACTION:

The influence of phenytoin (Dilantin) administration on the metabolic disposition of theophylline was studied in six healthy, non-smoking adult volunteers. The three major excretory products of theophylline were found in greater concentrations in the urine after initiation of phenytoin therapy. The authors suggest that doses of theophylline be increased in patients receiving phenytoin. Plasma levels should be determined and used as a guide for dosage adjustment. *Clin Pharmacol Ther,* Vol. 35, #5, p. 666, 1984.

VISUAL HALLUCINATIONS:

Three children aged $2\frac{1}{2}$ years through $3\frac{1}{2}$ years experienced severe and disturbing hallucinations for periods of time ranging from one week to four months. A thorough study of each child showed that the only common factor in all children was the administration of tablets containing triprolidine and pseudoephedrine (Actifed). When a child presents with visual hallucinations, one should ask about recent decongestant use. *Br Med J,* Vol. 288, #6427, p. 1369, 1984.

MORNING DIP:

The inhalation patterns of normal individuals will vary with respect to circadian rhythm, but these fluctuations are more pronounced and can even be life-threatening in asthmatic patients. Deaths from these "morning dips" can be prevented by inhalation of albuterol (Ventolin) and beclomethasone (Beconase). *Lancet,* Vol. I, #8387, p. 1143, 1984.

DOPAMINE:

Dopamine (Intropin) has been used a cardiac stimulant and has been beneficial in patients with certain types of cardiac insufficiency. Since dopamine is not available as an oral preparation, L-DOPA was used as a substitute in patients requiring cardiac stimulation L-DOPA is converted into dopamine by aromatic acid decarboxylase enzyme systems. Beneficial hemodynamic effects were probably achieved through dopamine-induced activation of beta-1, dopaminergic-1 and dopaminergic-2 receptors. *N Engl J Med,* Vol. 310, #21, p. 1357, 1984.

RED TIDE:

Blooms of *Ptychodiscus brevis* are responsible for massive fish kills in the Gulf of Mexico and along the Florida Coast. Known as the red tide, toxicity to humans can occur if one ingests seafood contaminated with the toxin or if the toxin is inhaled along with overspray from waves. Two lipid soluble toxins have been isolated from cultures of these organisms, and they have been named Brevetoxin B and Brevetoxin C. These substances are apparently capable of opening sodium channels in muscle tissue thus causing fasciculation of skeletal muscle and fibrilation of cardiac muscle. *J Pharmacol Exp Ther,* Vol. 229, #2, p. 615 1984.

GOLD:

Gold salts have been used for many years to treat patients with arthritis. Recent investigations show the metal, when administered as gold sodium thiomalate, is capable of interacting with the cysteine-cysteine disulfide bridges of the thrombin molecule thus producing an antithrombin effect and possibly protecting the patient from vascular occlusive disease. Clin Pharmacol Ther, Vol. 35, #5, p. 627, 1984.

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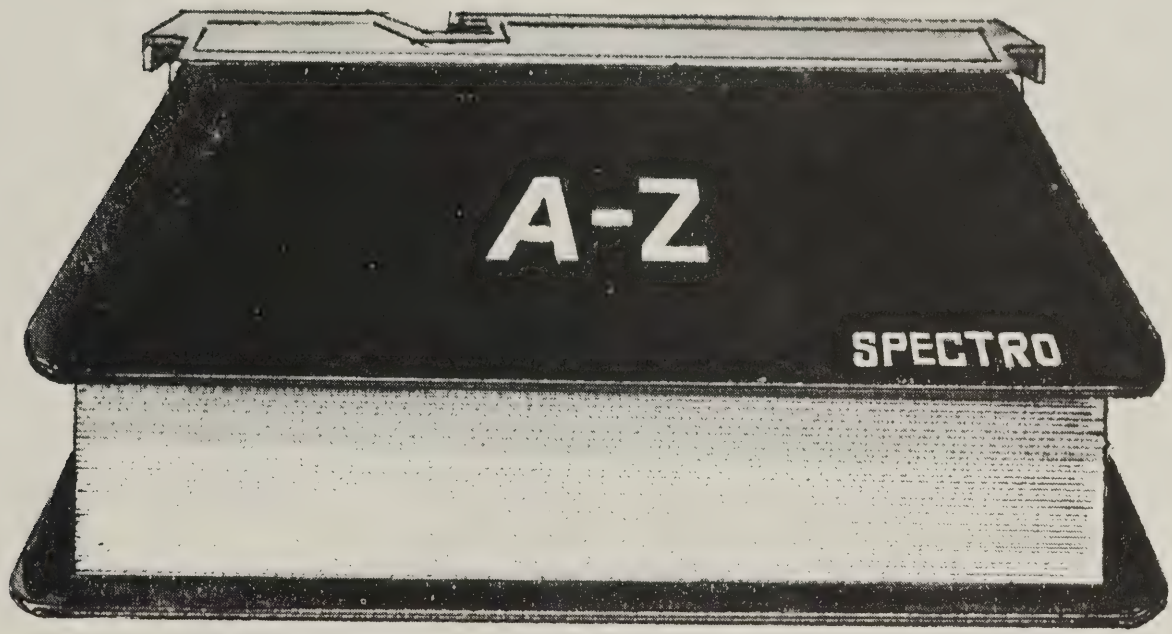

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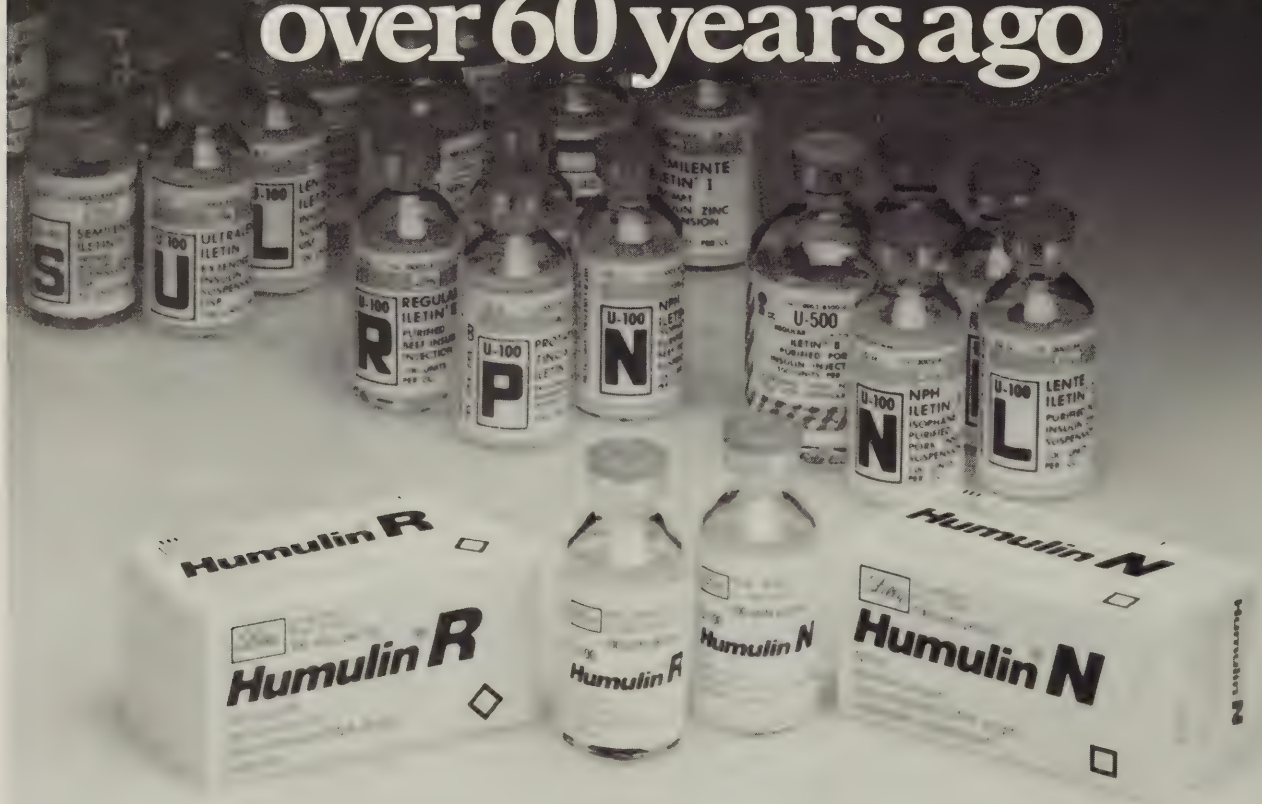

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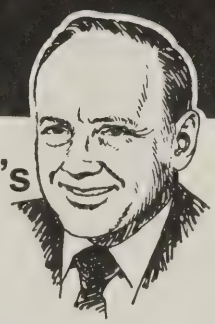

Honoring Pharmacy's "Extra Effort" People

Again this fall, current year recipients of the A. H. Robins "Bowl of Hygeia" Award, selected by their peers through their professional pharmacy associations in the 50 states, the District of Columbia, Puerto Rico, and the 10 Canadian provinces were invited to be guests of our company for a special salute in our Richmond headquarters.

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Let's Have Some Fun This Month

Quietly the computer has crept into our lives, sitting there, whirring and humming, reducing our lives into electronic impulses, printing our labels with only the errors we typed in, keeping track of our inventories, our patients and our finances. Keeping us hopefully on the positive side of cash flow. Are these machines always for business, business, business, or can we also derive some pleasure from them. This month instead of my usual message about communication, I give you some pleasure from my computer. The mortar and pestle below contains twenty-six diuretics, triturated by the computer. The words can run in eight directions—left to right, right to left, bottom to top, top to bottom, southeast to northwest, northwest to southeast, southwest to northeast or northeast to southwest. Can you find all twenty-six? The first ten correct answers received at the M.Ph.A. office will win you absolutely nothing. The answer to the puzzle will appear in next month's Journal. Happy hunting.

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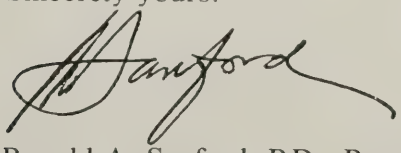
Please accept my good wishes to you and yours for a happy holiday season and a healthy and prosperous new year.

Sincerely yours.



Ronald A. Sanford, P.D., President

P.S. If you would like a copy of the program, just let me know.

SCOPE
STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION •

Counseling Consumers on Treatment of Fever Blisters and Canker Sores with OTC Remedies

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Goals

The goals of this lesson are to:

1. discuss the etiology and treatment of fever blisters and canker sores;
2. review the pharmacology and therapeutics of OTC remedies for fever blisters and canker sores.

in the service of pharmacy

This continuing education for Pharmacy article is provided through a grant from MERRELL DOW PHARMACEUTICALS INC.

Objectives

At the completion of this lesson, the successful participant will be able to:

1. choose the appropriate OTC agents for treating fever blisters and canker sores
2. explain the proper technique for applying these OTC agents;
3. know when to refer the consumer to a specialist when self-treatment is not appropriate;
4. differentiate canker sores from fever blisters.

Introduction

Canker sores and fever blisters are often mistaken for one another and referred to erroneously. They are, however, totally different.

Canker sores are painful, annoying, and recurring ulcers that occur on the gums, lips, inner cheek, soft palate and tongue. From 20 to 50 percent of the population reportedly has had a canker sore. They are not contagious.

Fever blisters occur most commonly on the lips and within the mouth. Like canker sores, fever blisters are also irritating, painful and recurring. Reference has been made that about 15 percent of the population has them; a more accurate estimate now places the incidence of persons susceptible to a primary herpetic infection (the cause of fever blisters) at 50 to 60 percent of all Americans aged 20 to 40 years. Unlike canker sores, fever blisters are contagious.

With this limited information, it is difficult to distinguish between the two disorders. Since their etiologies and treatments differ, it is important to be able to identify each of them.

This lesson has been prepared to aid pharmacists in properly advising consumers on these two similar looking, but totally different skin/mucous membrane disorders. It will discuss the major factors that precipitate the disorders and the means to control their symptoms, and suggest specific advice appropriate for patient counseling.

Mouth ulcers in general are quite common. Not all oral ulcers are harmless, and many diseases cause them. For example, an early symptom of several potentially fatal blood disorders (i.e., agranulocytosis, etc.) is the appearance of a mouth ulcer. Oral cancer normally appears first as a mouth ulcer. Oral cancer is of special concern because its causes are not known. Table 1 lists specific symptoms which may indicate the presence of oral cancer. Several major infections may also incite them.

TABLE 1
Warning Signs Of Oral Cancer

- Sore on lips or in the mouth that does not heal
- Persistent bleeding of the tissues in or around the mouth
- Feeling of numbness, pain or tingling
- Swelling on the palate or other oral areas

There is no easy, absolutely reliable method for pharmacists to readily distinguish between canker sores and fever blisters, and more serious oral disorders. However, if the symptoms and patient's description match the information discussed in this lesson for canker sores and fever blisters, chances are one of these afflictions is present. But even symptoms can be confusing. Bad mouth odor, for example, may signal fever blister formation or certain other serious infections. If recurrent or severe ulceration raises any questions about the patient's conditions, he or she should be directed to a physician or dentist for further assessment. Thus, professional consultation should be sought whenever a sore in the soft tissues of the mouth fails to heal within 2 to 3 weeks.

Canker Sores

The exact cause of canker sores, also known as **aphthous ulcers** and **aphthous stomatitis,** is unknown. A currently popular theory is that canker sores are caused by an alpha-hemolytic streptococcus, *Streptococcus sanguis,* strain 2A. Formerly, canker sores were described as originating from herpes simplex infections, and this misbelief is part of the reason for much of the current confusion that exists between the two disorders. Fever blisters are caused by a virus. Herpes virus has never been isolated from canker sores; *S. sanguis* has been found in over 90 percent of all attempts. Still, not all reference sources yet admit to this organism as the absolute cause.

In addition to the suspected bacterial cause, a cell-mediated localized auto-immunity reaction may be partly responsible for canker sore development. This can be demonstrated experimentally. Lymphocytes taken from persons with recurrent canker sores have a much greater cytotoxic action on mucosal epithelial cells in *in vitro* experiments than lymphocytes taken from persons without canker sores.

Factors that Favor Development of Canker Sores. Although not a contagious disorder, the offspring of parents who have recurrent canker sores also have a significantly greater incidence of canker sore formation. The greater the number of recurrent episodes in adults, the more frequent will be the occurrence of canker sores in their youngsters. Young children of such parents who have an active canker sore process often seem to be constantly battling the condition.

These findings taken together, then, strongly suggest an *hereditary connection.* In fact, when canker sores appear in different members of the same family (a common event), the condition is medically referred to as *familial epidemic aphthasis.*

Various **physiological factors** contribute to canker sore development. Menstruation increases their incidence while pregnancy decreases it. Whether or not this is related to plasma estrogen levels (i.e., low estrogen level will stimuate their formation) is not proven.

Certain **stressful conditions** or **emotional factors** seem to increase canker sore development. In susceptible persons, examples may be mild anxiety, arguments with a family member or friend, the death of a loved one, etc. Canker sore activity is especially high during the college years, with about 50 percent of all students reporting canker sore development.

Trauma to the lips, cheeks or mouth increases development of canker sores. Biting the cheek or lips, and ill-fitting dentures are also well known potentiating causes. Likewise, certain foods (e.g. citrus fruits, spices and the other items listed in Table 2) enhance formation of canker sores.

TABLE 2
Examples Of Foods Which May Cause Exacerbation Of Canker Sores

Chocolate
Citrus fruits
Nuts
Highly spiced foods
Sour substances
Tomatoes

Although each of the aforementioned factors has been demonstrated to cause canker sores in susceptible persons, it must be emphasized that these factors will not cause the condition without the presence of *S. sanguis* (or whatever the other, yet unidentified actual cause). These factors reduce the body's immunological system of defense and the actual cause then takes it from there!

Symptoms. The first symptom of canker sores is usually a burning or tingling (hyperesthesia) that leads, within the next 24 hours, to intense pain. At that time, an observable ulcer on the mucous area is evident. Ulcers are most common on the buccal and labial (lip) surfaces of the mouth. They range in size from 3 mm to more than 15 mm in diameter. On occasion they may coalesce to form single large ulcers (major aphthae) which are much more painful and require a longer healing period. This occurrence signifies a difference in the host rather than cause.

Canker sores vary in intensity from person to person. One individual may develop a solitary lesion, while another person may have several dozen at any one time. Most commonly, 2 to 3 ulcers occur at one time. Some persons are never completely free of canker sores. As some heal, others form.

Canker sores occur to almost the same extent in either sex, with females developing them slightly more often than males. Blacks are rarely affected.

Canker sores normally appear shallow and ovoid, and have a slightly raised yellowish border. This is surrounded by a bright red zone. Within the next 5 to 7 days, the lesions become covered with a yellowish opaque substance which consists of dried tissue fluids, oral bacteria, and white blood cells. The pain lasts 3 to 4 days, although a feeling of slight pressure or irritation generally remains for several more days. Recurring lesions typically occur with less and less severity.

Systemic manifestations are rare and the affected person usually experiences no other symptoms. In severe cases, fever and malaise may be present.

Fever Blisters

Fever blisters are also called cold sores and herpes simplex labialis. Unlike canker sores, fever blisters are highly contagious. They occur in great proportions in persons living in crowded areas of the country, and in persons of lower socioeconomic status. They are especially prevalent in areas of communal living (e.g., dormitories, prisons, nursing homes, etc.). If a person living in such surroundings develops a fever blister, special care must be taken to avoid touching others while the active process is underway.

Herpesvirus hominis Type 1 is the cause of fever blisters. Lesions caused by Type 1 virus must be distinguished from the more serious and, certainly, more contagious genital herpes (herpes genitalis), caused by *H. hominis* Type 2 (Table 3).

TABLE 3
Distinctions Between H. Hominis Type 1 and 2

	TYPE 1	TYPE 2
Association	Fever blisters	Herpes genitalis
Contact	Direct, usually from mucosal secretions, saliva, etc.	Direct, usually through sexual contact

Herpes simplex viruses are deoxyribonucleic acid (DNA) viruses and consist of two forms. Type 1 virus is usually (but not always) associated with fever blisters. These lesions commonly occur at the junction of the mucous membrane and skin of the lip and nose. Thus, herpes infections of the mouth (Type 1) are referred to as *herpes labialis*. Lesions may occur anywhere on the body.

Type 2 herpes simplex virus is usually, but not exclusively, the cause of lesions on the genital area. Thus, this condition caused by the Type 2 virus is known as *herpes genitalis*. It is a venereal disease that has reached epidemic proportions. Since this is a topic of great scope in its own right, we will limit this current lesson to a discussion of herpes labialis.

A *primary* infection is one in which the condition is present for the first time. When an infection arises on adjacent tissue or another area of the body, it is referred to as a secondary herpetic infection. Afterwards, each flare-up at a previously infected area is called a recurrent *infection*, and this happens to some persons at one to several month intervals.

Primary and Secondary Herpetic (Type 1) Infections. Fever blisters appear as vesicles (blisters) on the mucous membranes of the mouth. The gums, tonsils, and regional lymph nodes may also be involved. There may also be a high fever. If the virus enters the blood, a generalized vesicular eruption on the skin (*herpeticum eczema*) may develop. The eyes may be involved, resulting in **keratoconjunctivitis**. If the central nervous system becomes infected, this results in **meningoencephalitis**.

Primary infections are, fortunately, self-limiting and often so mild as to not cause irritating symptoms. Sometimes an individual cannot recall when the first bout was experienced. They do persist longer than recurrent infections, perhaps lasting two weeks. During this period, the body is establishing antibodies to combat the infection. Once infection has occurred, the virus may be maintained in the body for the remainder of the individual's life.

Between intervals of fever blister flare-ups, the virus is thought to remain dormant within the sensory ganglia neurons that innervate the site of the primary infection. Normally the body's defense mechanisms keep the infection dormant and under control until some stressful situation occurs that lowers the body's immunity (Table 4).

TABLE 4
Factors Known To Activate Recurrent Herpes Infections

Fever
Chilling
Sunburn
Windburn
Menstruation
Upset stomach or GI disturbance
Emotional stress
Excitement
Minor infections
Dental treatment
Allergy to certain foods
Any disease that increases the metabolic rate
Fatigue

Most adults have developed some immunity (antibodies) to Herpes Type 1 virus. Therefore, children are usually born with passive immunity of the same magnitude as that of the mother. But by the end of the first few months of life, this immunity disappears. At this point, children are especially prone to development of fever blisters. Around age 5 years, an active immunity begins to develop via exposure to the virus.

There is no cure or treatment for the condition, only palliative relief of symptoms. Therefore, special precautions should be observed by persons with a history of fever blisters to minimize the factors shown in Table 4.

Recurrent Herpetic (Type 1) Episodes. Each recurrent bout of herpes labialis starts with a feeling of slight burning or itching. The area feels firm or "full" due to local edema. Shortly afterwards, papules (solid elevations of the skin) and then blisters form. The area may appear reddened because of capillary dilation. These lesions may last for hours before the blisters break. At that time, they take on a yellowish, crusted appearance. The recurring episodes produce less irritation than the primary encounter. For most, they are usually mild and little more than embarrassing, or annoying. A physician's help is usually not required. OTC remedies can offer palliative relief of symptoms.

Vesicles should not be arbitrarily broken because the fluid contains the virus and can transmit the infection to other areas or persons. When the blisters do rupture, special care must be taken to minimize future contamination of other parts of the body or other persons.

Healing normally occurs in 7 to 10 days without scarring or further problems. On occasion, a secondary bacterial infection occurs especially if the lesions are large. The presence of pus under the crust of a fever blister indicates a possible bacterial infection. Whenever healing doesn't occur within a week, the patient should be advised to seek medical care. These lesions may indicate the presence of a much more serious condition.

Treatment of Canker Sores and Fever Blisters with OTC Remedies

There are no specific remedies for curing or preventing canker sores or fever blisters. Thus, the primary goal of therapy for both disorders is the same — *to relieve symptoms*. This includes lessening the pain, decreasing the duration, and, by another nonspecific protective effect, reducing the recurrence rate.

A variety of OTC products is promoted to accomplish these goals (Table 5). According to an FDA advisory panel, many contain ingredients that offer little rationale for use. One of the problems encountered during our research efforts was conflicting uses for the term "cold sore." Sometimes "cold sore" was used to denote fever blisters, and other times it seemed to be used to define canker

sores. Medically, cold sores are fever blisters, not canker sores. The following section presents information on what may be expected to help each condition. When appropriate, the findings of the FDA advisory panels that reviewed these remedies will also be mentioned.

TABLE 5
Representative OTC Products Claimed To Be Effective In Treating Canker Sore And Fever Blister Symptoms

Product	Ingredients
Anbesol	Benzocaine, phenol, 70% alcohol
Bacid	Lactobacillus acidophilus organisms
Blistex	Camphor, phenol, peppermint oil, spirits of ammonia
Campho-Phenique	Camphor, phenol
CanKaid	Carbamide peroxide
Dentaid	Benzoin, camphor, menthol, myrrh
DeWitts Cold Sore Lotion	Benzoin, camphor, menthol, phenol, 90% alcohol
Gly-Oxide	Carbamide peroxide
Herpecin-L	Allantoin, pyridoxine, sunscreens
Kank-a	Benzocaine, benzoin, cetylpyridinium chloride
Lactinex	Lactobacillus acidophilus organisms
Lysine	Lysine
Numzident	Benzocaine, clove oil, peppermint oil
Periolav	Carbamide peroxide
Proxigel	Carbamide peroxide
Resolve	Dyclonine
Rexall Cold Sore Lotion	Benzoin, camphor, menthol, phenol, 90% alcohol
Tannac	Benzalkonium chloride, benzocaine, tannic acid

*Product labeling is very confusing as to whether they are promoted for canker sores, fever blisters or both. Additionally, any orally-applied product containing a local anesthetic should be effective in treating pain associated with either condition. For explanation, see text.

Canker Sores. Pain and irritation are best controlled with topical application of a local anesthetic ointment or gel. Benzocaine and butacaine have long been used for this purpose. More recently, a dyclonine-containing product (Resolve) has been marketed. Local anesthetic action can be enhanced when the substance is formulated in a base such as Orabase. This product adheres to mucous membranes much better than other solid forms, and prolongs the local anesthetic effect. Also, Orabase and similar substances place a lubricating shield over the lesion. If the site of irritation is caused by improperly fitting dentures or similar irritants, this action will help minimize further irritation. These products also help soften crusts, which improves the feeling. Many experts suggest that the use of products containing camphor, eugenol, menthol and phenol be discouraged. They believe that each of these substances may cause significant local irritation and potentiate the ulcer condition.

Products containing carbamide peroxide (e.g., CanKaid, Gly-Oxide) have not yet been shown by scientific testing to be universally effective in relieving oral pain. However, they continue to be widely used. The FDA panel on dental products that reviewed carbamide peroxide stated that there is some, but inconclusive, evidence that it may be effective in cleaning out debris and facilitating healing. The panel recommended that at least one double-blind clinical study be performed to determine whether the substance is truly effective.

Old time remedies such as benzoin, myrrh, and peppermint oil have not accumulated any data of effectiveness, and there is little likelihood that manufacturers will undertake expensive studies to champion their cause.

Fever Blisters. Some authorities suggest that fever blisters should be kept moist to minimize cracking and fissuring which might enhance bacterial contamination. Astringents are, therefore, not universally recommended on these types of lesions. For smaller areas, there is no problem and there is some feeling that depriving the virus of moisture is beneficial.

In fact, there is growing evidence of value in the traditional remedy of placing ether or alcohol on fever blisters. Testimony was given to the advisory panel that, in guinea pigs, drying herpes lesions stimulated the immune system against the infection. The opinion was presented that ". . .the quicker the drying of the herpes cell, the faster it can be controlled from spreading to surrounding cells. Once the spread of herpes is slowed, the antigen antibody reaction starts to inactivate the herpes virus."

Tannic acid has long been used in fever blister products for its astringent action. One FDA OTC advisory panel has reported that when tannic acid is applied to abraded tissue, it precipitates a protein-tannate film. This mechanical seal of the area can encourage growth of bacteria under the crust, and it strongly advised against its use for extensive burns. However, when used on small areas such as a fever blister, another panel reported that tannic acid is safe. But there is insufficient data to show that it is effective for relieving pain or improving the outcome of fever blisters.

As with canker sores, bland ointment-based products alone, or those containing a local anesthetic, can provide palliative relief of fever blister pain.

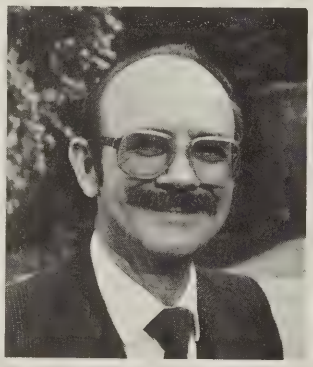
Once highly touted for treating fever blisters and canker sores, silver nitrate and phenol are no longer recommended by the scientific community. The potential for serious damage is much too real. While these substances do relieve pain, they may actually enlarge the ulcer.

Topical application of 0.5% hydrocortisone-containing products is not recommended for any viral infection because steroid suppression of natural immunity may allow for the spread of the infection. On the other hand, some authorities have provided convincing data which imply that some benefit may be gained from steroids. But, this assumes treatment is under the direct supervision of a physician. Only time and further study will answer this question. In the context of advising consumers on OTC's, however, hydrocortisone products should not be recommended for self-medication of fever blisters.

A favorite therapy for fever blisters, as mentioned above, is alcohol or ether, or spirits of camphor. These substances will immobilize the herpes virus. This is the basis for use of 70% alcohol in many OTC products including camphor spirits and tinc-

Our best friends are our severest critics and our greatest assets.

Meet our 1984 Pharmacy Consultant Panel.



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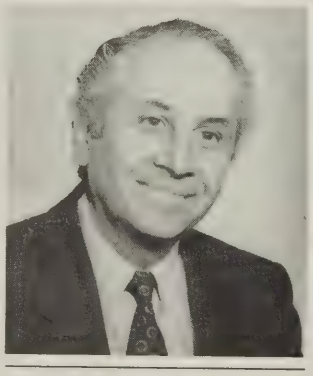

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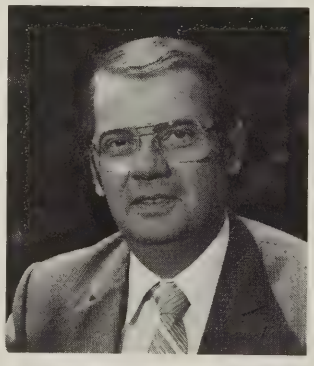

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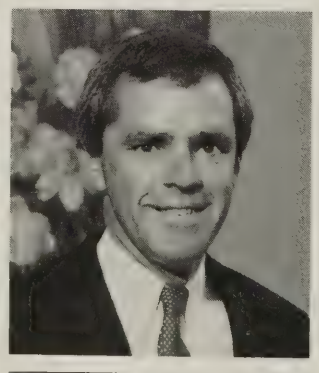

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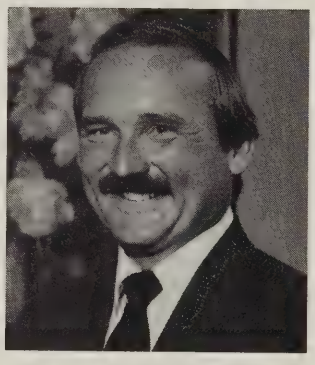

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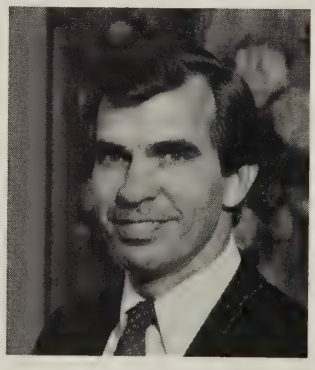

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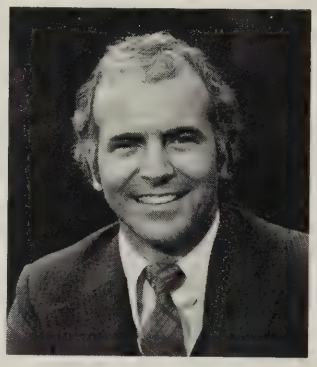

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No diplomatic double talk.

We need the advice of pharmacists in order to do a better job for pharmacists. The bad news and the good.

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ture of myrrh used for self-treatment. Efficacy of these measures has not yet been established, but these agents nevertheless continue to be used.

Another "old time" remedy is local application of aspirin to the ulcer site. When systemically taken, aspirin can reduce pain; however, consumers should be advised against holding aspirin in the mouth for a prolonged period. Not only is this practice ineffective against local pain, it is potentially harmful and a cause of further ulceration.

Peroral (swallowed) Products for Treating Fever Blisters. Orally taken substances used empirically over the years for treating fever blisters were reviewed by one of the FDA OTC advisory panels. Five ingredients were placed in Category II (i.e., claims are unproven); and none were placed in Category I (proven safety and effectiveness) — see Table 6.

TABLE 6
Recommendations Of An FDA OTC Advisory Panel For Orally Administered Remedies For Fever Blisters

Category I	None
Category II	Acetaminophen Caffeine Chlorpheniramine Phenolphthalein Phenylephrine
Category III	Lactobacillus organisms Lysine

Viewing those items listed as Category II for treating fever blisters, it is difficult to comprehend how an analgesic/antipyretic (acetaminophen), CNS stimulant (caffeine), antihistamine (chlorpheniramine), decongestant (phenylephrine) or laxative (phenolphthalein) could have any beneficial effects on these afflictions. Nonetheless, they have been recommended and used in the past. The panel could not find any justification for such claims.

The Category III agents have also been used for many years. Lactobacillus organisms (*L. acidophillus* and *L. bulgaricus*) are normal constituents of milk and yogurt. They are also among the normal flora in the G.I. tract that are involved in the proper digestive processes. Just how they would benefit a patient with fever blisters has not been elucidated, but a proposed mechanism is that they induce production of human saliva which normally inhibits herpes virus growth.

The advisory panel reviewed information from a number of studies and determined there is limited evidence that Lactobacillus organisms are effective in treating fever blisters. A point to bear in mind whenever recommending their use is that, if they are to be effective, these microorganisms must be kept alive. Therefore, close adherence to their storage requirements (i.e., refrigeration at 36° to 46° F) is extremely important. Outdated products should not be used.

While the case for lysine in preventing/treating fever blisters was not pleaded by any manufacturer, the substance was found to possess sufficient evidence of effectiveness to place it in Category III. Lysine is one of the essential amino acids found in abundance in many foods.

Both the lay and nutritional press have widely recommended lysine as a means to prevent and ameliorate a number of herpes-induced infections, including fever blisters. The OTC advisory panel did, in fact, find several studies in the scientific literature which suggested that lysine:

(1) may exert an inhibitory effect on herpes simplex multiplication in human cells *in vitro;*
(2) may lead to rapid resolution of herpetic lesions in humans; and
(3) may suppress herpetic lesion formation, resulting in new blisters failing to appear, more rapid healing of those formed, and reduced recurrence of the blisters.

However, these studies were uncontrolled, and, therefore, not satisfactory to the FDA for proving efficacy.

The properly controlled study that has been done showed no significant effect of lysine on healing rate, appearance of lesions or intervals of recurrence. However, lysine, taken 500 mg b.i.d., protected a greater number of patients from recurrence than did a placebo. The panel concluded, therefore, that further study of lysine effectiveness in treatment of fever blisters is warranted before a final ruling is made on whether such a claim is allowed.

Patient Advice

Table 7 contains various factors that can be used as guidelines for differentiating canker sores from fever blisters. Since the goal of therapy for both conditions is to alleviate pain and help the body to heal itself as much as possible, the best advice to give patients is to use whatever local anesthetic and/or systemic analgesic that works best for them.

TABLE 7
Is It A Canker Sore Or A Fever Blister?

	Canker Sore	Fever Blister
Symptoms		
Pain	Intense	Intense
Fever	No	Yes
Halitosis	No	Yes
Salivation	No different	Increased
Malaise	No*	Yes
Other	No effect on neck glands	Swollen neck glands
Appearance	Gray to grayish-yellow skin lesions surrounded by erythematous halos. Usually 3mm or more in diameter	Yellow-white ulcer surrounded by red halo. Gum margins swollen and red.
Contagious	No	Yes
Duration	10-14 days; healing without scarring**	10-14 days; healing without scarring**

*If condition is severe, malaise may be a symptom
**Large lesions may leave scars

Recent thinking is that benzocaine, butacaine, and dyclonine are appropriate but that camphor, menthol and phenol may do more harm than good.

Orabase-type topical vehicles have shown good evidence of keeping local anesthetics at the site they are needed longer than other ointment bases.

For canker sores inside the mouth, carbamide peroxide products have demonstrated evidence of cleaning debris and foreign particles out of the ulcer crater and, thus, assisting healing.

An important point to keep in mind about canker sores is that they

New Hydrochlorothiazide Dosage Guidelines from High BP Joint National Committee

START WITH 25 mg.

The 1984 Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure recommends starting with the smallest effective dose in diuretic therapy. For hydrochlorothiazide the initial dosage recommended is 25 mg.

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DYAZIDE® also contains 50 mg. of triamterene—the initial dosage of that agent recommended by JNC III.

In Hypertension*...When you want the safety and efficacy of low dosage thiazide therapy plus potassium conservation

DYAZIDE®

Each capsule contains 50 mg. of Dyrenium® (brand of triamterene) and 25 mg. of hydrochlorothiazide.

Serum K^+ and BUN should be checked periodically (see Warnings and Precautions).

Before prescribing, see complete prescribing information in SK&F CO. literature or *PDR*. The following is a brief summary.

* **WARNING**
This drug is not indicated for initial therapy of edema or hypertension. Edema or hypertension requires therapy titrated to the individual. If this combination represents the dosage so determined, its use may be more convenient in patient management. Treatment of hypertension and edema is not static, but must be reevaluated as conditions in each patient warrant.

Contraindications: Concomitant use with other potassium-sparing agents such as spironolactone or amiloride. Further use in anuria, progressive renal or hepatic dysfunction, hyperkalemia. Pre-existing elevated serum potassium. Hypersensitivity to either component or other sulfonamide-derived drugs.

Warnings: Do not use potassium supplements, dietary or otherwise, unless hypokalemia develops or dietary intake of potassium is markedly impaired. If supplementary potassium is needed, potassium tablets should not be used. Hyperkalemia can occur, and has been associated with cardiac irregularities. It is more likely in the severely ill, with urine volume less than one liter/day, the elderly and diabetics with suspected or confirmed renal insufficiency. Periodically, serum K^+ levels should be determined. If hyperkalemia develops, substitute a thiazide alone, restrict K^+ intake. **Associated widened QRS complex or arrhythmia requires prompt additional therapy.** Thiazides cross the placental barrier and appear in cord blood. Use in pregnancy requires weighing anticipated benefits against possible hazards, including fetal or neonatal jaundice, thrombocytopenia, other adverse reactions seen in adults. Thiazides appear and triamterene may appear in breast milk. If their use is essential, the patient should stop nursing. Adequate information on use in children is not available. Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma. Possible exacerbation or activation of systemic lupus erythematosus has been reported with thiazide diuretics.

Precautions: Do periodic serum electrolyte determinations (particularly important in patients vomiting excessively or receiving parenteral fluids, and during concurrent use with amphotericin B or corticosteroids or corticotropin [ACTH]). Periodic BUN and serum creatinine determinations should be made, especially in the elderly, diabetics or those with suspected or confirmed renal insufficiency. Cumulative effects of the drug may develop in patients with impaired renal function. Thiazides should be used with caution in patients with impaired hepatic function. They can precipitate coma in patients with severe liver disease. Observe regularly for possible blood dyscrasias, liver damage, other idiosyncratic reactions. Blood dyscrasias have been reported in patients receiving triamterene, and leukopenia, thrombocytopenia, agranulocytosis, and aplastic and hemolytic anemia have been reported with thiazides. Thiazides may cause manifestation of latent diabetes mellitus. The effects of oral anticoagulants may be decreased when used concurrently with hydrochlorothiazide; dosage adjustments may be necessary. Clinically insignificant reductions in arterial responsiveness to norepinephrine have been reported. Thiazides have also been shown to increase the paralyzing effect of nondepolarizing muscle relaxants such as tubocurarine. Triamterene is a weak folic acid antagonist. Do periodic blood studies in cirrhotics with splenomegaly. Antihypertensive effects may be enhanced in post-sympathectomy patients. Use cautiously in surgical patients. Triamterene has been found in renal stones in association with the other usual calculus components. Therefore, 'Dyazide' should be used with caution in patients with histories of stone formation. A few occurrences of acute renal failure have been reported in patients on 'Dyazide' when treated with indomethacin. Therefore, caution is advised in administering nonsteroidal anti-inflammatory agents with 'Dyazide'. The following may occur: transient elevated BUN or creatinine or both, hyperglycemia and glycosuria (diabetic insulin requirements may be altered), hyperuricemia and gout, digitalis intoxication (in hypokalemia), decreasing alkali reserve with possible metabolic acidosis. 'Dyazide' interferes with fluorescent measurement of quinidine. Hypokalemia is uncommon with 'Dyazide', but should it develop, corrective measures should be taken such as potassium supplementation or increased dietary intake of potassium-rich foods. Corrective measures should be instituted cautiously and serum potassium levels determined. Discontinue corrective measures and 'Dyazide' should laboratory values reveal elevated serum potassium. Chloride deficit may occur as well as dilutional hyponatremia. Concurrent use with chlorpropamide may increase the risk of severe hyponatremia. Serum PBI levels may decrease without signs of thyroid disturbance. Calcium excretion is decreased by thiazides. 'Dyazide' should be withdrawn before conducting tests for parathyroid function.

Thiazides may add to or potentiate the action of other antihypertensive drugs.

Diuretics reduce renal clearance of lithium and increase the risk of lithium toxicity.

Adverse Reactions: Muscle cramps, weakness, dizziness, headache, dry mouth; anaphylaxis, rash, urticaria, photosensitivity, purpura, other dermatological conditions; nausea and vomiting, diarrhea, constipation, other gastrointestinal disturbances; postural hypotension (may be aggravated by alcohol, barbiturates, or narcotics). Necrotizing vasculitis, paresthesias, icterus, pancreatitis, xanthopsia and respiratory distress including pneumonitis and pulmonary edema, transient blurred vision, sialadenitis, and vertigo have occurred with thiazides alone. Triamterene has been found in renal stones in association with other usual calculus components. Rare incidents of acute interstitial nephritis have been reported. Impotence has been reported in a few patients on 'Dyazide', although a causal relationship has not been established.

Supplied: 'Dyazide' is supplied as a maroon and white capsule, in bottles of 1000 capsules; Single Unit Packages (unit-dose) of 100 (intended for institutional use only); in Patient-Pak™ unit-of-use bottles of 100.

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are usually caused by "something" else. If that other factor is ill fitting dentures, for example, professional advice should be sought.

With fever blisters, old standbys such as tinctures of myrrh and benzoin have not been proven effective by scientific standards. Perhaps it is the alcohol content that works by drying the virus. There is some, but inconclusive, evidence that Lactobacilli organisms and lysine may be helpful.

On the other hand, it can be (and is) argued by some that these agents have not been proven not to be effective. Many believe that they are helpful for them, and these people have the right to use them.

Placed in proper perspective, in the case of fever blister remedies or any other OTC product, the point of the FDA review is to determine what ingredients have proven safety and effectiveness, and what claims the manufacturers can truthfully make. This is a scientific decision that must be based on clinical documentation, not hearsay and testimonials.

In the "real world" of practice however, we all know that there are consumers who swear by certain remedies and aren't concerned about double-blind cross-over studies. While we will not continue to repeat this concept in every lesson, we ask the reader to keep in mind that the final answer of what to do in each pharmacist-consumer encounter lies with professional judgment. It is our goal to offer all sides of each issue to help in making that decision.

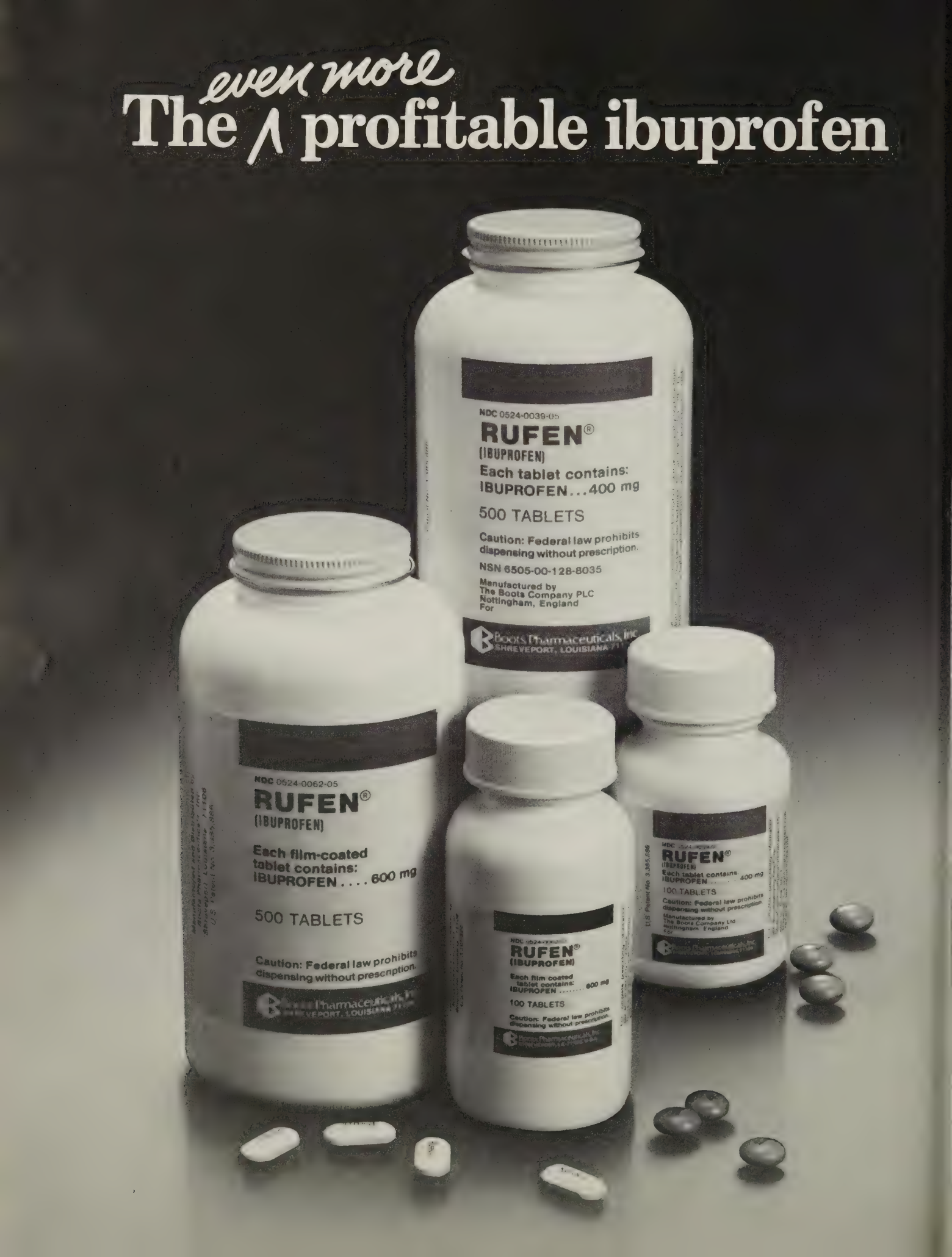
This lesson ends with a reminder that since both canker sores and fever blisters are self-limiting and usually clear within two weeks, whenever they worsen with OTC therapy, last longer than two weeks, or continue to recur, medical advice should be obtained.

Since fever blisters are contagious, the affected individual should be careful to avoid transmitting the virus to other parts of the body or to other persons. One final point is that while they cannot be cured, fever blisters should likewise not be ignored.

Lilly Digest Figures for Mid Atlantic Area

FOR: DELAWARE *MARYLAND* D.C. SOUTH CAROLINA WEST VIRGINIA AVERAGES PER PHARMACY	1983 *SOUTH ATLANTIC STATES* (215 Pharmacies)	1982 SOUTH ATLANTIC STATES (204 Pharmacies)	1983 UNITED STATES Average (1,547 Pharmacies)
SALES			
Prescription	$ 321,130— 61.2%	59.6%	58.5%
Other	203,422— 38.8%	40.4%	41.5%
TOTAL SALES	$ 524,552—100.0%	$ 455,486—100.0%	$ 528,864—100.0%
COST OF GOODS SOLD	346,901— 66.1%	64.4%	66.9%
GROSS MARGIN	$ 177,651— 33.9%	35.6%	33.1%
EXPENSES			
Proprietor's or Manager's Salary	$ 33,482— 6.4%	6.3%	6.0%
Employees' Wages	58,936— 11.2%	12.3%	10.8%
Rent	11,597— 2.2%	2.3%	2.4%
Miscellaneous Operating Expenses	55,420— 10.6%	11.1%	11.0%
TOTAL EXPENSES	$ 159,435— 30.4%	32.0%	30.2%
NET PROFIT (before taxes)	$ 18,216— 3.5%	3.6%	2.9%
TOTAL INCOME OF SELF-EMPLOYED PROPRIETOR (before taxes on income and profit)	$ 51,698— 9.9%	9.9%	8.9%
VALUE OF INVENTORY AS A PERCENT OF SALES			
Prescription	$ 33,874— 10.5%	10.9%	10.7%
Other	41,610— 20.5%	21.0%	20.9%
TOTAL INVENTORY	$ 75,484— 14.4%	$ 68,334— 15.0%	$ 78,946— 14.9%
ANNUAL RATE OF TURNOVER OF INVENTORY	4.8 times	4.4 times	4.6 times
NUMBER OF PRESCRIPTIONS DISPENSED			
New	14,892— 47.5%	46.9%	48.9%
Renewed	16,463— 52.5%	53.1%	51.1%
TOTAL PRESCRIPTIONS	31,355—100.0%	28,800—100.0%	28,404—100.0%
PRESCRIPTION CHARGE	$ 10.24	$ 9.43	$10.89
NUMBER OF HOURS PER WEEK			
Pharmacy was open	63 hours	61 hours	62 hours
Worked by proprietor	47 hours	47 hours	47 hours
Worked by employed pharmacist(s)	40 hours	37 hours	39 hours

* Source: 1984 *Lilly Digest*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Product	Size	A.W.P.–Rufen Direct Cost–Motrin	Savings
RUFEN 600 mg MOTRIN 600 mg	500 500	$ 67.20 $ 94.00	**$26.80 (29%)**
RUFEN 600 mg MOTRIN 600 mg	100 100	$ 15.12 $ 19.65	**$ 4.53 (23%)**
RUFEN 400 mg MOTRIN 400 mg	500 500	$ 48.00 $ 66.00	**$18.00 (27%)**
RUFEN 400 mg MOTRIN 400 mg	100 100	$ 10.80 $ 13.85	**$ 3.05 (22%)**

*MOTRIN® (ibuprofen) is a registered trademark of The Upjohn Manufacturing Company M, Barceloneta, Puerto Rico 00617.
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Laughter makes the burderns of the day seem not quite so heavy. Laughter at yourself keeps your head on straight. Laughter releases the tensions aand exposes the dark doubts and fears to sunshine.

We are all little children, hungering for acceptance and recognition. We travel in our safe little group of people who know the "Truth" as written by the prophets Francke, Brodie and California et al.

Come with me among the unclean, the unbelievers, and let us lay hands on them—because we know the truth shall make us equal . . . to Marcus Welby.

My Son, the Clinical Pharmacist

by David M. Angaran

I love my mother, my father, my brothers, my sister, and all my family. All my family is generic for an assortment of uncles, aunts, cousins, nieces and nephews, who number in the hundreds.

I have tried my best, as the dutiful son, to please my Mother and Father. My Father was my idol and example, but it was my Mother who understood. She understood my early cries, my pimples, my first date, my dropping out of school, and my enlistment in the Air Force.

Through it all she understood. But now she doesn't understand. What doesn't she understand? She is not quite sure what I do for a living. Because she is not sure the rest of my generic family doesn't understand.

My Dad is a practical soul. He's all for education, as long as the rewards are suitable. Rewards like money. Therefore, he wonders why I teach and do not practice "Store Pharmacy"—where the money is.

It's not that the family doesn't respect teachers, but as my Dad puts it, "Teachers eat apples, seeds and all," and that's not class.

Why do I worry if my generic family understands what I do for a living? Because when *they* understand the whole world will understand and the clinical pharmacist will have come of age.

My family probably represents the majority of the nonmedical public in this country. They are not quite sure of what *we,* pharmacists, are doing but they are willing to give it a try . . . as long as it doesn't cost anything.

Let me introduce you to my Uncle the skeptic, and my Aunt the believer—oh how she believes.

I will recreate a little scene some of you might recognize. I have just entered my Folks' home for a visit. My favorite Aunt and Uncle are visiting.

My Uncle is a building contractor with an eighth grade education and at the age of fifty-five is semi-retired. He could buy and sell me. My Aunt is a drug nut and has been working her way through the PDR, alphabetically. I think she's on the Wallace Company.

"Hi, Uncle," I say as we reach to shake hands. The hand is steel from gripping a hammer for thirty years and my papier-mache' palm crumples. I look at the blood vessels in my arm and watch them engorge and stand tall.

"Ha! Ha!," roars my Uncle, "I hope I didn't hurt your cash register hand."

I mumble, through the pain, something about never playing the piano again.

"Say, your Mother tells me you're a doctor now."

"I'm not, I'm a pharmacist."

"Stick out your tongue, I want to see if there are any labels stuck on it."

"I don't do that. I teach pharmacy students and take care of patients."

"What do you teach your students?"

"I teach them to count to ten by two's without moving their lips."

By now I have that feeling. It's like a cold stone that I have swallowed. I know I am never going to get out of this. Oh, for the comfort of that hospital and the people who know the "Truth."

My mother, her eyes shining, "Tell your Uncle how you save lives and make sure all those fancy doctors do the right thing."

Oh Mom, I love you, but geez, I'm thinking deep inside as I look at this little lady hovering over me. Waiting for the single explanation that she can sally forth with and wave in the face of those other mothers.

My Uncle's eyes light up. I saw that look on Zoo Parade. It was on the face of a tiger going in for the kill.

"What do you do with those fancy doctors?"

"I advise them on drug therapy."

"They're fancy, why do they need advice?"

"They don't know everything." I am on the defensive.

"You know more than Doc Culvert?"

Oh no, not that question again!

Doc Culvert, 109 years old, deliverer of 40,000 babies, who sees 102 patients a day, and is the world's record holder for consecutive penicillin shots without a throat culture. Twenty years!

What can I say. Here is the man who delivered me in that back bedroom, saved my Dad's life, and is revered by everyone. I once talked to him about the penicillin shots and by golly he switched. To Loridine, unwarmed, because it reminded him of procaine penicillin and the patients didn't know the difference.

Before I can answer he fires another question: "Describe to me exactly what you do to earn that ridiculous salary of yours."

"I teach and give patient care."

"You fill prescriptions?"

"No, I go on rounds and give advice."

"You type labels?"

"No, I counsel patients!"

"You fill money orders?"

"No, I give green stamps!"

"What if the Doc doesn't like your advice?"

"He doesn't take it."

"Can you do anything about it?"

"No!"

"You get a fee for what you do?"

"No, I'm salaried by the school."

"Any patients ever ask for just you—like, Quick! Quick! Get a pharmacist, I'm dying!! or, Is there a pharmacist in the House?—Ha! Ha!"

"Real funny!"

"Well, let me see. It seems to me you are giving advice to people who shouldn't need it, and don't have to follow it, for patients who didn't ask for it but have to pay for it anyway. Now tell me again, what kind of druggist are you?"

"I am a specialist in drug therapy."

I know what's coming. Good grief. It's like being staked out spread eagle on the passing lane of a freeway. It's just a matter of time before something goes boom.

"I thought you guys specialized in Japanese radios."

"I don't!"

"What about those guys at the chain?"

"They're different."

"You mean they sit down to pee?"

"No, they only count and pour."

"You mean they're not pharmacists?"

"No, they are pharmacists but they aren't drug experts."

Now come the questions. "If these guys aren't drug experts, how come they make more money than you do? How come you educators are letting these guys practice on the public? You need to go for five years to do what they do?" And finally the crowning blow, "If you're so smart, why didn't you go to medical school and cut this petty stuff out?"

My Dad, "You know I really don't know what's so new about this New Pharmacy. Hell, old Doc Charley used to take care of us before you were born."

Yeah, old "Doc" Charley. The pharmacist in our town. The dispenser of a thousand Rx's and ten thousand cherry cokes. The keeper of the poor, a one man medicare and traveling medicine show, and the guy who told Doc Culvert to use the Loridine unwarmed because it would be long-acting that way.

That cold stone in my stomach suddenly lurches upright on its rough edge. Over my Uncle's shoulder I see my Aunt coming to the table with her "medicine bag."

Oh, no, not the "medicine bag." I know her doctor; he mumbles and spits a lot when you mention her name.

She's smiling and reaching in the bag.

I can see the bottles. Hundreds of them. Labeled and unlabeled. Filled with those generic brands.

Do you realize my Aunt has a running correspondence with Gaylord Nelson? She calls him Senator Lord.

She's arranging the bottles by therapeutic class. You know she has memorized every medical article ever written for the *Reader's Digest*.

Oh, no, I see her dragging out the package inserts. And they're underlined in red!

"Davey," I hear her calling, "don't let your Uncle give you a hard time. You come over here and talk to your Auntie."

Said the spider to the fly.

My mind is racing for a way out.

My Uncle and my Dad are smiling at each other, like two shoe salesmen waiting to watch someone run a 100 yard dash, barefoot, on a bed of nails.

Good God, she's pulling out the *AMA Drug Evaluations* and it has book markers in it.

I'm frantically signaling my wife to do something. She immediately responds by rushing past me to the bathroom where I hear muffled laughter . . . Later, at home that night I lie and stare at the ceiling. The stone has warmed somewhat but it's still there.

All things I might have said are ricocheting about in my head.

The love of my life lies beside me rubbing my feverish brow. As my body begins to relax I hear her sweet voice say, "Honey."

"Yeah," I grunt.

"How come you don't get your own store?"

Legal Aspects of Purchasing and Selling a Pharmacy in Maryland

By William J. Skinner, P.D., J.D.

Presented at the annual meeting Maryland Pharmaceutical Association, Ocean City, June 28, 1984

Pharmacy ownership is an attractive venture for a decreasing percentage of the pharmacist population. While owners income has gone up about $2,500 per year in preliminary figures reported by the *Lilly Digest* for 1983–84 to a total of $47,000, the percentage of gross sales which this combined income and net profit figure (net profit alone was 2.9%) represents remains essentially the same 8.8%. Nevertheless this income level must be measured in the decision-to-buy-or-sell equation with the 62 hours per week that these *Lilly Digest* pharmacies are open and with the other advantages and disadvantages of ownership.

In 1960 at the Chicago APhA meeting, author publisher E. B. White, of *Advertising Age* magazine, predicted the extinction of the corner drug store. This idea was rejected and there was complaint from people like John Dargavel and Willard Simmons and a few remarks of disbelief from members of APhA, ACA and other speciality groups. But if one looks, for example, at the numbers of general, all purpose, mom and pop drug stores that have disappeared from the corners of Baltimore, Rockville, Cambridge, St. Mary's and Hagerstown, Mr. White's prediction was not far off the mark.

The 1960's were an era of other kinds of pharmacists as well. A pharmacist in Berryville, Virginia, opened one of the first modern era pharmacy consultation offices with very few or no products visible on display. Just a few miles from Washington, D.C., in a northern Virginia farming community, a pharmacist started and made a financial success of advising, counseling and helping patients with over-the-counter medication, plus dispensing prescription drugs. The community of Berryville has supported this concept of pharmacy practice and the concept with some interesting variety has spreaded across the land, catching fire here and there, where the private entrepreneurial spirit had prepared the pharmacist for taking a chance.

Pharmacists in California, in Indiana, Minnesota and in many other states also became individual pioneers in the stand alone, consulting service pharmacy. Then a minor explosion began to be seen by the expansion of franchise units like Medicine Shoppe, Medicine Box and so on today. Wholesalers and fixture suppliers promoted the concept to pharmacists. Consultive pharmacies either stand alone or in clinics, are mare making a strong comeback as the general population seeks safe and trustworthy alternatives to high priced physician office visits. Not only has the increased cost of medical care driven people to pharmacists, but many people have learned that you can trust your pharmacist.

But more than this realization by consumers, the simplicity and need for self help, home care and preventive medical care are all being promoted for the first time by government and by associations of home health providers and businesses, many of which are as powerful as the American Medical Association in their practical effect on Federal reimbursement policy and the like.

These are some of the reasons that pharmacy ownership in Maryland, and in other states as well, is on the rebound. One can safely say today that the pharmacist is riding on top and can expect to stay there for the foreseeable future *if*.

The *IF* is a big one and depends on individual pharmacists, state and local associations of pharmacists, the boards and especially the schools of pharmacy to supply the prepositional predicates for the objects of the "if".

These predicates are knowing the business end of pharmacy. Profit and loss statements are generated from data on accounts receivable and accounts payable. Income journals and expense journals makeup the entries in a general ledger. Buy or sell decisions depend today on form of ownership questions and to a great degree on tax questions. These are what we want to take a brief look at today. Frankly, we'll cover only an overview and we will refer you back to the IF for more information.

At the outset let me refer you to a couple of excellent resources that cover some of the buy-sell questions in greater detail. First, the Bureau of National Affairs (BNA) has published a booklet on "Choice of Entity" in its Tax Management series in 1983. This publication will be found only at law school libraries, and in libraries of large law firms or accounting firms. But it is worth your effort to locate it. Secondly, the Maryland

Institute for Continuing Professional Education of Lawyers (MICPEL) has published "Purchase and Sale of a Small Business" in 1980. This too, will give you some guidance.

Purchasing or selling a pharmacy requires that you consider both the tax and non-tax consequences of the form of ownership whether sole proprietorship, partnership, limited partnership, corporation or Subchapter S corporation. Let's look at these briefly.

Sole proprietorship. The individual owns it all and has unlimited personal liability. All of the tax consequences are reportable by the owner on a Federal form 1040 or Maryland form 502.

Partnership. A partnership is treated as a separate entity for tax and non-tax purposes. While it is not Federally taxed, there are returns to be filed to pass the partnership data on to the individual partners based on the partnership agreement. Generally partners are subject to unlimited personal liability and partnership interests may be transferred only with the consent of all partners.

Limited Partnership. The limited partners' liability for debts is limited to their capital contributions. The general partners have unlimited liability for partnership obligations. A limited partnership is treated the same for tax purposes as a general partnership.

Corporation. This is a distinct legal entity, a new "person", that is created by filing papers under the law of the state. In Maryland, the Articles of Incorporation are reviewed and approved by the State Department of Assessments and Taxation. Once created, the corporation takes on a separate existence requiring the payment of taxes, filing of reports and completion of meetings to re-elect officers and directors.

The earnings of a corporation are taxed at the corporate level and if dividends are distributed, at the shareholder level as well. Corporate losses may not be used to offset personal income from other sources.

Shareholders are generally limited from any liability and, in the absence of any agreement restricting transferability, the shares are freely transferable.

Close Corporation. Maryland, as in many other states, provides for a form of corporation known as a close corporation. This always limits the number of shareholders and who may be owners of shares and requires *all* shareholders to agree in the sale of any stock to new parties.

Subchapter S Corporation. This is simply a corporation that elects to be treated in a special way for Federal income tax purposes. The IRS limits the number of shareholders to 35 and the class of stock to one class. Such a corporation cannot be affiliated with other corporations, nor can they be financial institutions or insurance companies. A partnership is not an eligible shareholder, but the estate of a Chapter 11 bankrupt may qualify as a shareholder in a Subchapter S corporation. A non-resident alien may not a shareholder.

Income Tax Considerations

In a sole proprietorship, partnership, limited partnership or Subchapter S corporation, the profits and losses pass through to the pharmacy owners. A corporation is treated as a separate entity.

Sole proprietors use a schedule C in a form 1040. Individual tax rates go up to 50%, so at some point it may be advantageous to organize as a corporation to pay a lower rate.

Partnerships are not taxed directly, but the returns pass through the profits or losses. However, short term capital gains, gains or losses in §1231 property, charitable contributions, dividends, interest, taxes paid to foreign governments and the like are excluded from the computation of partnership income and become a part of the distributive share and the partnership is by passed. Because of this, partners get favorable tax treatment not accorded shareholders of a corporation. For example, tax exempt income increases a partner's basis in the partnership if not distributed, but if distributed it retains its tax exempt status. On the other hand, tax exempt income to a corporation retains the exempt status to the corporation, but results in increased earnings and dividends which *are* taxed to the shareholders.

Corporations. Multiple level taxation results from corporate ownership, but there are three ways to reduce the effect of this. These are: 1) pay reasonable compensation to shareholder-employees; 2) pay other deductible payments to shareholders; and 3) retain earnings in the corporation.

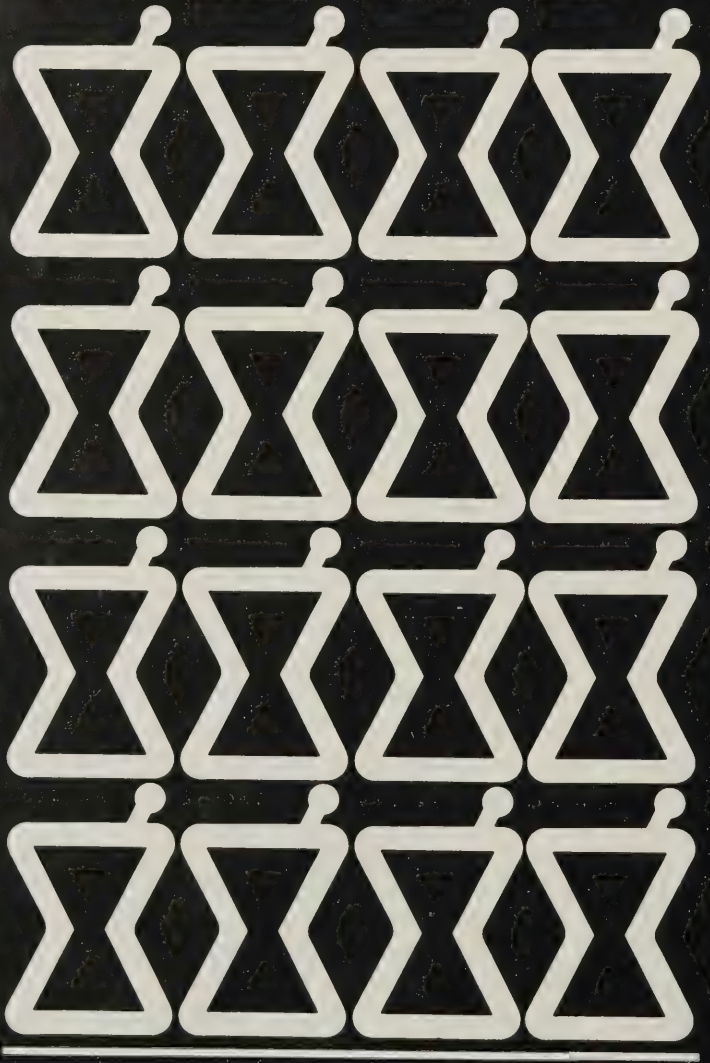
Salaries are deductible by the corporation under §162 unless "unreasonably high;" other payments to shareholders that are deductible include interest on loans by shareholders; rent on property leased by the corporation from the shareholder and royalties on patents and licenses owned by the shareholder; retained earnings defers payments of taxes and is subject to two limitations. If more than $250,000 is retained by most corporations, an accumulated earnings tax is paid. This is 27½ percent on amounts below $100,000 and 38½ percent on amounts above $100,000. There is also a holding company tax if 5 or fewer individuals own more than 50 percent of the stock and 60 percent of the corporation's adjusted gross income is personal holding company income such as interest, dividends, rents and royalties. The corporate tax rate is 46% maximum at this time.

Subchapter S Corporation. Although these are regular corporations giving limited liability to shareholders, a Subchapter S corporation has elected to be taxed as an individual income earner. Capital gains, however, are taxed at the corporate tax rates under §1374.

In the early years of operation, when losses are expected in a business, the election permits individual shareholders to deduct losses against income; then in later years, when real profit is realized, the election can

Pharmacist Professional Liability Policy

For protection against negligence suits



Professional liability claims against pharmacists have increased over the past few years. Both store-owners and employed pharmacists have been the target of these suits.

Pharmacy owners usually purchase druggist liability insurance; however, in most cases the insurance is limited to the products sold in the store.

As a professional, you need your own professional liability insurance that will cover you 24 hours a day, every day of the year.

The Maryland Pharmaceutical Association has made special arrangements to make this coverage available to members at a reduced cost of only $60 per year for a million dollar policy.

Take advantage of this opportunity to protect yourself and call today for an application.

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be dropped.

In this regard, if losses are foreseen and funds are needed, it may be preferable for a shareholder in an S corporation to borrow the funds directly from a bank and then lend the funds to the corporation. Thus, the shareholder increases his basis and the amount of corporate loss he may deduct.

Beginning on January 1, 1983, Subchapter S corporations became subject to two additional taxes. One is the investment tax credit recapture tax which is imposed on early dispositions of §38 property. And the second is an excess passive income tax on accumulations of earnings and profits from prior Subchapter C years of operation.

One way a pharmacist who organizes a new business can use tax laws to assist is in the choice of fiscal year deferral. For example, as an individual, the pharmacist reports income on a calendar year basis. If he incorporates a business, elects Subchapter S status, and selects January 31 as the tax year, then compensation paid by the corporation to pharmacist during January is deductible by the corporation for the year ending January 31; however, the pharmacist need not report the compensation and pay tax until April the following year, thus deferring when ultimate taxes paid.

Sale of Interest in Business

Even if you are buying now, you need to look ahead to the time of sale of a business to adequately consider what will happen at the time of sale. Barring a complete change in the individual/corporate income tax structure, a major concern is whether a sale of an interest in the pharmacy will bring a capital gain or loss, or an ordinary gain or loss.

A. **Sole Proprietorship.** A sole owner is in an unique position when s/he sells a business, as the business is not considered to be a separate asset. Each asset is considered as being sold separately and the nature of each asset will determine whether ordinary income or capital gain is realized. When a pharmacy is sold in bulk for one purchase price, as may be the usual case, the price will have to be allocated to each asset, including good will.

B. **Corporation.** Usually shareholders will be treated to a capital gain or loss, except in three situations: 1) if the holding period is not met; 2) if the shareholder is a dealer in securities; or 3) if the corporation is a collapsible corporation.

If the criteria are met, a shareholder may deduct 60% of the net capital gain and if he is in a 50% tax bracket, the tax paid will amount to only 20% or capital gains from the sale of stock.

C. **Partnership.** Generally the sale or exchange of a partnership interest will result in a capital gain or loss. However, if the partnership has unrealized receivables or substantially appreciated inventory, the rule does not apply. The amount of or fair market value of property received by a transferor partner, attributable to unrealized receivables or appreciated inventory, results in realizing ordinary income. The selling partner is treated as having sold his proportionate interest in all of the partnership assets.

FIGURE 1

Example:

ASSETS	Basis	Value
Cash	$10,000	$10,000
Accts Receivable	0	10,000
Inventory	20,000	30,000
Land	16,000	20,000
Total	$46,000	$70,000
LIABILITIES AND CAPITAL		
Liabilities	$30,000	$30,000
Capital		
A.	8,000	20,000
B.	8,000	20,000
Total	$46,000	$70,000

If A sells his interest to B for $20,000, the amount realized is $35,000, (selling price plus A's share of liabilities of $15,000), allocated $5,000 to accounts receivable, $15,000 to inventory and $15,000 to cash and land. A will be required to recognize upon the sale, $5,000 ordinary income attributable to receivables and $5,000 ordinary income attributable to the appreciated inventory. The remaining $2,000 will be taxed at the capital gains rate. This is not necessarily a favorable tax scenario; so it obviously speaks strongly for reducing receivables and having inventory that does not appreciate. Since most pharmacy inventory does not appreciate as would real estate, if the receivables are reduced, the tax effects may not be disastrous.

Retirement or Death of Shareholder or Partner. One must consider whether an estate will be able to sell the decedent's interest and whether there will be ordinary income treatment or capital gains.

If a corporation redeems a shareholder's stock from his estate, the estate will recognize and receive capital gain, but the corporation will not receive any deduction with respect to the transaction. A qualifying redemption must be planned for to get this favored tax treatment, so one must consult his attorney or tax advisor to plan a retirement. Obviously, one cannot always plan a death, but one can be ready at certain ages and under certain illness situations to plan for death.

In partnership, a new partner may be brought into purchase a retired or deceased partner's interest or the r/d partner's interest may be liquidated under §736, in which payments are made by the partnership to the r/d partner. Otherwise, the partnership must be completely liquidated.

Practical Hints

The previous paragraphs were intended as a broad overview of the numerous tax consideration and non-tax considerations that should be on your mind when you buy or sell a pharmacy. You should consult an attorney or tax advisor about the specifics of your situation. Now for the practical side of things.

As pharmacists you ought to have the inside edge on picking a business to buy but that is not necessarily so. It presumes that you have some knowledge of current market conditions, have the ability to survey the location, analyze the prescription base of the location, the proximity to prescribers offices and other factors, including the need for auxillary business or profit centers such as supports/braces/sick room supplies/hypoallergenic cosmetics/respirators/TNS units/vitamins, etc.

Next, one must be able to evaluate the business. First, one must make assumptions about the accuracy of financial statements supplied by sellers. It is important to realize that to the extent a small business owner has accurately reported the data, the financial statement may be relied upon. Nevertheless, it may become evident that the financial statements do not reflect the actual take from the business and this will only become appreciated by comparing the financial data with know parameters for similar businesses.

Buying and selling a pharmacy may not be a clinical function, but it is professional and somewhat risky, and it can be exciting and especially practical for economic survival. One could even say owning a pharmacy can be lifesaving, since ownership can feed and house a family, permit a good living, maybe some investments and a livelihood where one can go home evenings and feel good about the day.

*Author's Note [The discussion which followed this presentation was very worthwhile to those participating. Subjects asked about and discussed included: what kind of zoning problems has anyone experienced when adding to the building where the pharmacy is located; how do you transfer the pharmacy license; are sales contracts based on guaranteed dollars per day income proper if the sales are all cigarettes; when should a sole proprietor incorporate; what about insurance for a sole proprietor's store liability versus liability as a corporation; what about buying a pharmacy as fixtures, inventory and goodwill; what does it take to borrow money from a bank.

These are the subjects that need more discussion among pharmacists. Answers are not always clear, but answers can be obtained with professional help, and ownership can become a reality easier than you think.]

THIS AND THAT ABOUT PHARMACY

By Leon Weiner, P.D.

Albert Katz, University of Maryland Pharmacy 1962, was given a special award from the State of Israel for his work with Israel Bond Sales in June 1984. In the same month, he was given an award from the Associated Jewish Charities for serving as chairman in the Walk for Israel for the last 5 years. He is currently President of the Bernard Rosenthal Lodge and Vice President of the State of Maryland B'nai Birth. Albert's wife, Ellen and their sons, Jeffrey and Josh, have been actively involved in charity work. They are well known for their "Clown Performances" in the Baltimore area. Currently, Albert is the owner of Arundel Pharmacy on Ritchie Highway in Glen Burnie. Before buying his pharmacy he worked for many years with the Read Drug & Chemical Company.

He stands erect, has all his hair and acts very youthful. However, they call him Grandpop. Frank J. Mackowiak, University of Maryland Pharmacy 1962; is a part owner of Levay Pharmacy, Fort and Riverside Ave in South Baltimore. On July 26, 1984 Frank's oldest daughter, Denise, gave birth to his first grandson. Thus, he became a grandfather at the tender age of 44. He has another child, Frank D. Mackowiak, who is entering his last year in Pharmacy School and hopes to graduate in 1985.

Pharmacist Leon Rosen, University of Maryland 1962, recently acquired Westport Pharmacy, 2244 Annapolis Road, Baltimore, Maryland. He had previously owned Rex and Park Ave pharmacies. It is possible that the fact his daughter, Lauren Beth, is entering pre pharmacy this coming fall helped him decide on this move. Regardless, all who know Leon do wish him the best of luck.

Pharmacists, like other people, are always interested in what other positions are available. Using the help wanted section of the Sunday Sun Paper for a number of weeks, the following information was obtained. If you wish to change jobs. This may be the time to make a move, and then again it may not.

HELP WANTED—PHARMACIST

Date	Hospital	Chain Stores	Private Stores, etc.	Total
Sunday July 29, 84	7	3	4	14
Sunday Aug. 5, 84	8	4	6	18
Sunday Aug. 12, 84	5	2	6	13
Sunday Aug. 19, 84	6	2	2	10
Sunday Aug. 26, 84	6	2	5	13
Sunday Sept. 2, 84	5	3	5	13

Charles H. Tregoe, B.S., L.B., J.D., Chief of the Division of Drug Control, Maryland State Department of Health & Mental Hygiene, has recently been commissioned as an Officer of the Federal Department of Health Education, and Welfare. The Commission, on behalf of the Federal Government, authorizes, Charles to conduct examination, inspections, and investigations, copy and verify records, and receive and review official FDA documents. As a commissioned officer, he has the same authority as that of a regular FDA officers.

The School of Pharmacy Alumni Association, University of Maryland had its first meeting of the 1974–75 year at the home of President Melvin N. Rubin on the evening of Tuesday September 11, 1984. Attending were Thomas Patrick, Karen B. Demsky, Melvin Rubin, Ronald A. Sanford, Harry Bass, Leon Weiner and Brian Sanderoff. The main item discussed dealt with the Annual Dinner Meeting scheduled for Sunday November 11, 1984 at Martin's Eudowood, Towson and featuring Dr. William Howard, who is noted for Sports Medicine. If interested in the activities of the Pharmacy Alumni Association, please call President Melvin Rubin at 247-1244.

The Morning Sun of September 3, 1984 reported two accident. In the more serious incident, Hans Morgenroth, 63, of the 6000 block Park Heights Ave was rushed to the intensive care unit of Sinai Hospital after he was hit Saturday afternoon, September 1, 1984 by a police patrol car. He was listed in serious condition with unspecified injuries. Hopefully, long before this is printed, we hope he is up and out in good health. A little research indicates that Hans Morgenroth is a graduate pharmacist from the University of Maryland 1948 class. Born in Germany, Hans came to the United States where he decided to go to pharmacy school. While in school, he became very interested in photography and helped organizing the class year book. He worked at several pharmacies in the Baltimore area including Gera Drugs, Lindy's Dundalk Pharmacy and Lindy's Linthicum Pharmacy. Once again, we all wish the best for Hans Morgenroth in his recovery.

HANS MORGENROTH

PHARMACY CHANGES —AUGUST–SEPTEMBER 1984

The following are new pharmacies

Brooks Drug #690
Route 550 Thurmont Plaza
Thurmont, Maryland 21788

Dart Drugs #284
6875 New Hampshire Ave
Takomas Park, Maryland 20914

Drug Fair #770
119 W. Lexington St
Baltimore, Maryland 21201

Medicine Shoppe
1003 A Oldtown Road
Cumberland, Maryland 21502

People's Drug #1416
8212 Liberty Rd.
Randallstown, Maryland 21207

Whitesell Pharmacy
Rt 2 #4 at Oliver Road
P.O. Box 261
Lusby, Maryland 20657

The following pharmacies have changed locations:

Rite Aid 350
3429 Belair Road
Baltimore, Maryland 21213

Northwest Professional Pharmacy
4415 Park Heights Ave
Baltimore, Maryland 21215

The following changed ownership and name:

Rite Aid 1490 (Formerly-Plaza Drugs)
2244 Hanson Plaza
Edgewood, Maryland 21040

Recent Pharmacy Deaths

Davis N. Bishop, died September 4, 1984—Age 69. Graduated University of Maryland School of Pharmacy. Owned Idlewood Pharmacy for more than 30 years.

Samuel Markin, died September 22, 1984—Age 70. Graduated University of Maryland School of Pharmacy in 1914.

Ferdinand Pross, Jr., died October 9, 1984—Age 91. Graduated University of Maryland School of Pharmacy in 1914.

Sister Mary Saint Henry Riordan died October 20, 1984. Age 79. Former director of pharmacy at St. Joseph Hospital in Towson, Maryland. Graduated from George Washington University of Pharmacy.

Abraham Schapiro, died October 27, 1984. Age 77. Graduated University of Maryland School of Pharmacy in 1930. Owned Wylie Drug Store in Baltimore, Maryland.

Oncology Center Survey

The Johns Hopkins Oncology Center is considering the implementation of a pharmacist to pharmacist telephone consultation service. The intent of this service is to provide current useful and practical information to hospital and community pharmacists on chemotherapeutic agents and supportive care to oncology patients. All questions would be answered by pharmacists practicing in the field of oncology and there would be no charge for this service.

Before implementing such a service, we need to know if the service would be useful to pharmacy practioners and if useful, what types of information would be needed.

Will you please take some time to answer the following questionnaire and return it to the following address:

Johns Hopkins University Cancer Communications
Room 307 550 Building
Johns Hopkins Medical Institutions
Baltimore, Maryland 21205

1. Type of Practice
   - Teaching Hospital ☐
   - Community Hospital ☐
   - Retail Pharmacy ☐
   - Other _____
2. What type of patients do you service?
   - Ambulatory ☐
   - Inpatient ☐
   - Specialty _____
   - Other _____
3. What type of information would be useful?
   - Antiemetic Therapy ☐
   - Antibiotics in Compromised Patients ☐
   - Intrathecal Therapy ☐
   - Chemo Therapy ☐
   - Treatment of Stomatitis ☐
   - Methotrexate Monitoring ☐
   - Pain Management ☐
   - Compatibility Data ☐
   - Special Handling of Chemotherapy ☐
   - Investigational Drug Requirements ☐
   - Extravasation ☐
   - Patient Education ☐
   - Drug Storage ☐
   - Other Problems _____
   - Reconstitution, Preparation or Administration ☐
4. How are you presently obtaining this information
   - Other Pharmacists ☐
   - Literature Sources ☐
   - Drug Information Center ☐
   - Manufacturer ☐
   - Other _____
5. Would you use this service?
   - Yes ☐
   - No ☐

   How often would you use this service?
   - Once a Year ☐
   - Once a Month ☐
   - Once a Week ☐
   - Daily ☐
   - Other _____

Maryland was the host state for the National Association of Boards of Pharmacy annual District II meeting. (left to right) Roslyn Scheer, Executive Director of the Board of Pharmacy; David Banta, MPhA Executive Director; Karen Davis, Director of Health Policy and Management at Johns Hopkins; Bernard Lachman, President of the Board of Pharmacy; and Robert Snyder, Board of Pharmacy member.

The National Aquarium in Baltimore was the site for a social function held as part of the meeting. (left to right) Rosyln Scheer, Executive Director of the Board of Pharmacy; Rolly Mulitz; Wendell Hill, Dean of the Howard University School of Pharmacy and Ben Mulitz of the Loewy Drug Co.

Photos courtesy Larry Rosen

Ilene Harris Zuckerman Joins the MPhA Board

Ilene Harris Zuckerman received her B.S. in Pharmacy from the University of Maryland School of Pharmacy in 1981, and her Pharm.D. in 1983. She worked part-time in Community Pharmacy throughout the undergraduate and graduate training, and became interested in the application of clinical pharmacy skills in community practice. As the School of Pharmacy was also interested in developing community pharmacy practice sites for clinically trained pharmacists, she was hired upon graduation as an Assistant Professor of Clinical Pharmacy to develop programs of community-based clinical pharmacy practice utilizing home health care agencies, community pharmacists and primary care centers in the community. She currently serves as a Clinical Pharmacy Consultant to the Sinai Hospital Home Care/Hospice program and the Visiting Nurse Association. She is working with the VNA to develop a model for consultative pharamcy services with financial support provided by Merck Sharp & Dohme. She has developed, and serves as the preceptor for a new Pharm.D. Clinical rotation entitled "Home Health Care," in which students participate in Hospice Conferences, consult with public health nurses, and make home visits to monitor for drug efficacy and toxicity.

by: Anne C. Hom, Pharm.D. Candidate

Pharmacy Crime Warning Poster

(clip, reproduce and post)

WARNING

Drug Theft is Now A Federal Crime!

Armed Robbery or Burglary of this Pharmacy Can Result in FBI Action and Federal Prosecution

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AMERICAN PHARMACEUTICAL ASSOCIATION

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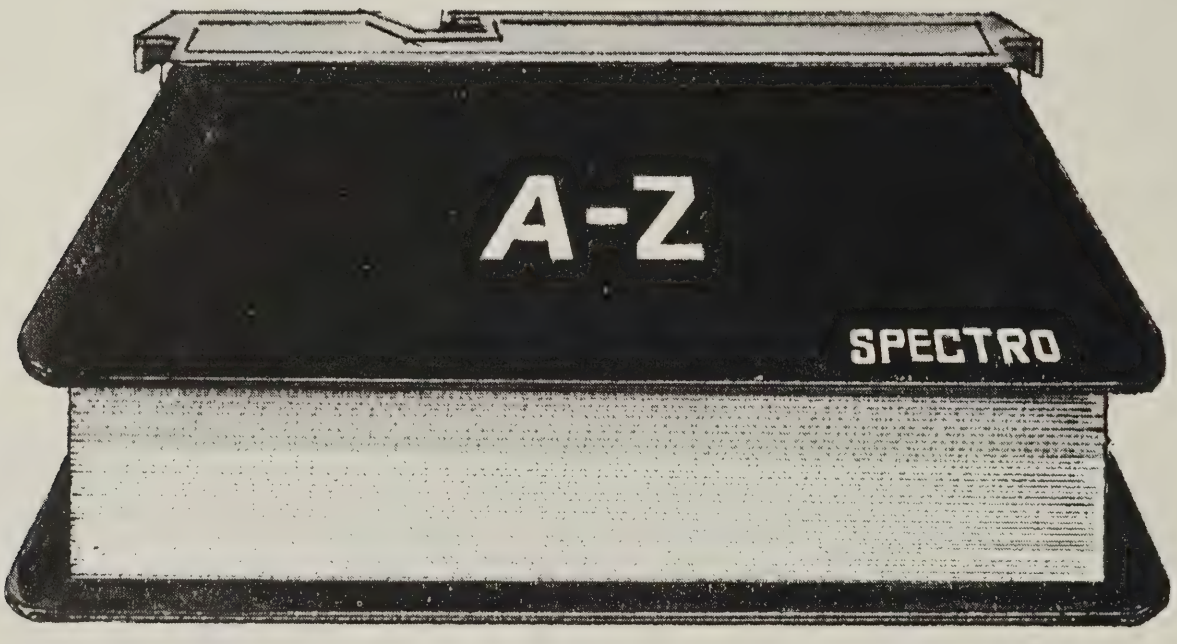

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1985 Tax Dates

The following are due dates for federal and state taxes that most affect you. Taxes that are due four or more times during the year are identified by abbreviations explained below the chart. Note that if a tax is due on a weekend or holiday, the due date is advanced to the next business day, causing some taxes due the last of the month to be payable early the next month.

January 1985	
Thursday, January 3	FD(a)
Tuesday, January 15	FI
Monday, January 21	ST
Thursday, January 31	FQ, FU, SQ, SU, FD(c)
February 1985	
Tuesday, February 5	FD(a)
Friday, February 15	FD(b), SD
Thursday, February 21	ST
March 1985	
Tuesday, March 5	FD(a)
Friday, March 15	FD(b), SD Calendar year corporations must file income tax return or pay 50% of unpaid taxes & file for 3 months automatic extension. Accrual basis corporations declare accrued expenses by this date (2 1/2 months after end of taxable year).
Thursday, March 21	ST
April 1985	
Wednesday, April 3	FD(a)
Monday, April 15	FCP, FI, SC Federal & State Income Tax due or you must pay estimated amount due & file for 60 day extension. Interest will be paid on amount paid after April 15. State corporation tax due. 60 day extension may be requested. State personal income tax due.
Monday, April 22	ST
Tuesday, April 30	FQ, FU, FD(c), SQ, SU
May 1985	
Friday, May 3	FD(a)
Wednesday, May 15	FD(b), SD
Tuesday, May 21	ST
June 1985	
Wednesday, June 5	FD(a)
Monday, June 17	FD(b), FC/P, SC, SD, FI
Friday, June 21	ST, Annual State and Federal tax if extensions were received.
July 1985	
Wednesday, July 3	FD(a)
Monday, July 22	ST
Wednesday, July 31	FQ, FU, FD(c), SQ, SU
August 1985	
Monday, August 5	FD(a)
Thursday, August 15	FD(b), SD
Wednesday, August 21	ST
September 1985	
Thursday, September 5	FD(a)
Monday, September 16	FD(b), FC/P, FI, SD, SC
Monday, September 23	ST
October 1985	
Thursday, October 3	FD(a)
Monday, October 21	ST
Thursday, October 31	FQ, FU, FD(c), SU
November 1985	
Tuesday, November 5	FD(a)
Friday, November 15	FD(b), SD
Thursday, November 21	ST
December 1985	
Wednesday, December 4	FD(a)
Monday, December 16	FD(b), FC/P, SC, SD
Monday, December 23	ST

clip and post

FD(a)	Last payment due on Federal income and social security taxes withheld during the previous month if over $3000 was withheld. You are required to deposit the amount withheld within 3 banking days after you reach $3000 at the end of any eighth-monthly period (these periods end on the 3rd, 7th, 11th, 15th, 19th, 22nd, 25th, and last day of the month)
FD(b)	Federal income and social security taxes withheld must be deposited by this date if between $500 and $3000 was withheld during the previous month. Earlier deposit is required when $3,000 is reached prior to this date.
FQ	Federal Quarterly income and social security taxes withheld must be paid.
FU	Federal Unemployment tax must be paid.
FC/P	Federal estimated corporation and partnership taxes must be paid if on calendar basis (note—fiscal year corporations pay this tax on 15th day of 4th, 6th, 9th, and 12th month of their year)
FI	Federal estimated individual tax for previous quarter due.
FD(c)	Federal social security and withholding tax if any due domestic workers.
ST	Maryland State Sales Tax due.
SQ	Maryland State income tax withheld due for previous quarter.
SU	Maryland State Unemployment taxes due.
SD	Maryland State estimate of income tax withheld the preceeding month must be deposited.
SC	Maryland State Estimate of corporation tax due.

John Schlegel, President of the American Pharmaceutical Association, addressed the Maryland Society of Hospital Pharmacists Meeting of October 11th. It was one of his first major speeches since assuming his position and received wide-spread publicity.

The MSHP meeting was held in historic Davidage Hall on the UMAB Campus, one block from the MPhA Kelly Memorial Building.

Over 250 Maryland Pharmacists, family and friends participated in the Association's group travel trip to Paris. Here members listen to the an explanation of a famous art object in the Louvre Art Museum.

Recently returned from a trip to Europe, MPhA member Phillip Weiner (right) reported that our professional colleagues in other countries were very friendly. (see "Letters to the Editor" in the November, 1984 issue of the Journal).

ABSTRACTS

Excerpted from PHARMACEUTICAL TRENDS, published by the
St. Louis College of Pharmacy; Byron A. Barnes, Ph.D., Editor
and Leonard L. Naeger, Ph.D., Associate Editor

ALZHEIMERS DISEASE:

Alzheimers disease has been said to be due to an acceleration in the aging process. Brains of patients who had died with the disease were examined and compared to matched controls. Younger patients, aged 70 to 80 years, had widespread and severe cholinergic deficiencies along with abnormalities in norepinephrine, gamma-amino butyric acid, and somatostatin activity. Older patients showed a reduction in choline activity in the temporal lobe and hippocampus and reduced somatostatin concentrations in the temporal cortex. Investigators suggest that Alzheimers disease in patients under the age of 80 years may represent a distinct type of presenile dementia which differs in many biochemical aspects from dementia of old age. *Br Med J,* Vol 288, #6422, p. 961, 1984.

ESTROGENS:

Estrogenic substances have been used to treat stress urinary incontinence in postmenopausal women, but no defined explanation for the successful results has been determined. Experiments conducted with animal tissue indicate that an increase in the sensitivity to norepinephrine in these tissues may be a result of an estrogen-induced increase in the number of post junctional alpha-2 adrenergic receptors. *J Pharmacol Exp Ther,* Vol. 229, #2, p. 557, 1984.

DISOPYRAMIDE:

Disopyramide (Norpace) has been used in this country since 1977 as an orally effective antiarrhythmia agent. Previous studies have shown the antiarrhythmic agent to be less effective when used intravenously. Recent clinical studies show that when the drug is used in doses greater than those used initially, the drug is effective intravenously in 60% of the patients with ventricular arrhythmias. No serious toxicities were reported. *Clin Pharmacol Ther.,* Vol. 35, #5, p. 610, 1984.

BENZODIAZEPINE ABUSE:

Patients were studied to determine their preference for placebo, diazepam (Valium) or oxazepam (Serax). There was an apparent increased preference fo diazepam. This is probably due to the more rapid absorption of this drug when compared to the absorption of the oxazepam. The decreased rate of absorption reduced the intensity of central nervous system effects noted immediately after drug administration and thus may decrease the likelihood of dependence. *J Pharmacol Exp Ther,* Vol. 229, #2, p. 501, 1984.

TRIMOPROSTIL:

A new anti-ulcer medication similar to prostaglandin E-2 was administered to volunteers to determine its effect when given in the absence and in the presence of food. The drug, trimoprostil, acts by reducing gastric acid secretion, stimulating bicarbonate secretion reducing pepsin concentrations and enhancing mucoprotein synthesis to protect the gastric membranes. Food tends to reduce the rate of absorption of the drug without altering the extent of the absorption. This causes a more prolonged duration of action. *J Clin Pharmacol,* Vol. 24, #4, p. 194, 1984.

ANTICONVULSANT THERAPY:

Blood levels of anticonvulsant drugs can be determined by routine analysis. Although several problems may appear during the evaluation and interpretation of data, authors suggest that one can minimize problems by sampling the plasma in the early morning. They feel this level will correspond with trough concentrations and will be valuable in guarding against failures caused by subtherapeutic blood levels. *Ann Intern Med,* Vol. 100, #6, p. 854, 1984.

DRUG METABOLISM:

It has become apparent that drug metabolism may differ dependent on the sex of the person involved. Benzodiazepine derivatives have been shown to have their metabolism and excretion vary dependent on sex. Women taking oral contraceptives should also be considered as a special group metabolically because estrogens can modify the disposition of several drugs. When designing experiments to study any drug, the possibility of sex-related differences in metabolism should be considered. *Clin Pharmacokinet,* Vol. 9, #3, p. 189, 1984.

THEOPHYLLINE OVERDOSES:

Patients experiencing toxicity due to overdoses of theophylline can be at risk of death. Normally hemoperfusion using activated charcoal or hemodialysis is required to remove the drug. These procedures are invasive and expensive, so experiments have been conducted with activated charcoal to see if it might be effective as an antidote when administered orally. Researchers have found that using 50 grams of activated charcoal every six hours for several doses is an effective way to reduce the concentration of the anti-asthmatic agent in the plasma. The duration of therapy should be determined by monitoring the plasma level and discontinuing therapy when toxic levels are no longer present. *JAMA,* Vol. 251, #23, p. 3130, 1984.

Classified Ads

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Pharmacy Location—Built to suit next to existing High Volume Food Market. David Gordon—962-1162 Erwin L. Greenberg Commercial Corporation.

MPhA office has just received a new shipment of "P.D." patches. These attractive, fabric, blue and white patches can be sewn on pharmacy jackets to identify you as a professional. The Patches sell for $2.00 each and can be ordered from Beverly at the MPhA Office at (301) 727-0746.

Management Handbook

—The Upjohn Company is offering a management handbook to pharmacy practitioners. The book, which is available at no charge, provides 12 contact hours of pharmacy continuing education credit.

"We're offering the manual and the opportunity to gain PCE credit," says Douglas P. Johnson, Pharmacy Relations Manager, "as a service to pharmacists. We hope to assist in their continuing effort to strengthen pharmacy management skills."

The book, *Management Handbook for Pharmacy Practitioners: A Practical Guide for Community Pharmacists,* was funded by a grant-in-aid from The Upjohn Company to the Health Sciences Consortium, which developed the content.

More than a dozen leading pharmacy administration faculty members contributed to the book, which discusses the following: cash flow; business records; advertising; tax considerations; accounts receivable management; inventory; break-even analysis; and nonprescription merchandising and planograms.

The handbook is available through Upjohn sales representatives or the Maryland Pharmaceutical Association. It is shipped with a post-test which, if the pharmacist wishes may be completed to the Health Sciences Consortium. For a small fee, the Consortium administers all aspects of this PCE program.

Contact the office for the order form at MPhA, 650 W. Lombard St, Baltimore, Maryland 21201.

Jan. 7—Maryland General Assembly convenes
Jan. 12–19—MPhA Trip to St. Maarten
Jan. 27—MPhA Annual Mid Year Meeting, Annapolis
Feb. 16–21—APhA Annual Convention—San Antonio, Texas
March 10—BMPA Annual Dinner Dance
May 23—Alumni Association graduation Banquet

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