

103
ALTERNATIVE MEDICINE

Y 4. AP 6/2: S. HRG. 103-146

Alternative Medicine, S. Hrg. 103-14...

HEARING
BEFORE A
SUBCOMMITTEE OF THE
COMMITTEE ON APPROPRIATIONS
UNITED STATES SENATE
ONE HUNDRED THIRD CONGRESS
FIRST SESSION
SPECIAL HEARING

Printed for the use of the Committee on Appropriations



U.S. GOVERNMENT PRINTING OFFICE

70-276 cc

WASHINGTON : 1993

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402
ISBN 0-16-041294-3

103
ALTERNATIVE MEDICINE

Y 4. AP 6/2: S. HRG. 103-146

Alternative Medicine, S. Hrg. 103-14...

HEARING
BEFORE A
SUBCOMMITTEE OF THE
COMMITTEE ON APPROPRIATIONS
UNITED STATES SENATE
ONE HUNDRED THIRD CONGRESS
FIRST SESSION
SPECIAL HEARING

Printed for the use of the Committee on Appropriations



U.S. GOVERNMENT PRINTING OFFICE

70-276 cc

WASHINGTON : 1993

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402

ISBN 0-16-041294-3

COMMITTEE ON APPROPRIATIONS

ROBERT C. BYRD, West Virginia, *Chairman*

DANIEL K. INOUE, Hawaii
ERNEST F. HOLLINGS, South Carolina
J. BENNETT JOHNSTON, Louisiana
PATRICK J. LEAHY, Vermont
JIM SASSER, Tennessee
DENNIS DECONCINI, Arizona
DALE BUMPERS, Arkansas
FRANK R. LAUTENBERG, New Jersey
TOM HARKIN, Iowa
BARBARA A. MIKULSKI, Maryland
HARRY REID, Nevada
J. ROBERT KERREY, Nebraska
HERB KOHL, Wisconsin
PATTY MURRAY, Washington
DIANNE FEINSTEIN, California

MARK O. HATFIELD, Oregon
TED STEVENS, Alaska
THAD COCHRAN, Mississippi
ALFONSE M. D'AMATO, New York
ARLEN SPECTER, Pennsylvania
PETE V. DOMENICI, New Mexico
DON NICKLES, Oklahoma
PHIL GRAMM, Texas
CHRISTOPHER S. BOND, Missouri
SLADE GORTON, Washington
MITCH McCONNELL, Kentucky
CONNIE MACK, Florida
CONRAD BURNS, Montana

JAMES H. ENGLISH, *Staff Director*

MARY S. DEWALD, *Chief Clerk*

J. KEITH KENNEDY, *Minority Staff Director*

SUBCOMMITTEE ON DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES

TOM HARKIN, Iowa, *Chairman*

ROBERT C. BYRD, West Virginia
ERNEST F. HOLLINGS, South Carolina
DANIEL K. INOUE, Hawaii
DALE BUMPERS, Arkansas
HARRY REID, Nevada
HERB KOHL, Wisconsin
PATTY MURRAY, Washington

ARLEN SPECTER, Pennsylvania
MARK O. HATFIELD, Oregon
TED STEVENS, Alaska
THAD COCHRAN, Mississippi
SLADE GORTON, Washington
CONNIE MACK, Florida
CHRISTOPHER S. BOND, Missouri

Majority Professional Staff

ED LONG, JAMES J. SOURWINE, CAROL C. MITCHELL, and MARGARET STUART

Minority Professional Staff

CRAIG A. HIGGINS and BETTILOU TAYLOR

Administrative Support

GLADYS CLEARWATERS and SUSAN A. MCGOVERN

CONTENTS

	Page
Opening remarks of Senator Harkin	1
Opening remarks of Senator Mikulski	4
Opening remarks of Senator Gorton	5
Opening remarks of Senator Reid	6
Statement of Dr. David Eisenberg, associate in medicine, Boston's Beth Israel Hospital, and instructor in medicine, Harvard Medical School	7
Prepared statement	9
Statement of Robert F. Lehman, president and chief executive officer, Fetzer Institute	12
Prepared statement	13
Statement of James J. Carbone, Massachusetts	25
Prepared statement	28
Letter from Edward H. Chapman, American Institute of Homeopathy	29
Statement of Sharon Herman	36
Statement of Ryan Werthwein	36
Statement of Susan Di Matteo	41
Statement of Hon. Claiborne Pell, U.S. Senator from Rhode Island	45
Prepared statement	45
Prepared statement of Dr. J. Jamison Starbuck, president of the American Association of Naturopathic Physicians	49
Statement of Brian M. Berman, M.D., director, University of Maryland Pain Center	51
Prepared statement	55
Statement of Harvey Kaltsas, D.A., president of the American Association of Acupuncture and Oriental Medicine	57
Prepared statement	61
Statement of Charles B. Simone, M.D., Simone Protective Cancer Center	67
Prepared statement	72
Statement of Hon. Berkley Bedell, former U.S. Congressman from Iowa	95
Prepared statement	102
Statement of Joseph J. Jacobs, M.D., director, Office of Alternative Medicine ..	110
Prepared statement	115
Prepared statement of Dr. Jay Moskowitz, National Institutes of Health	119
Questions submitted by Senator Gorton	142

MATERIAL SUBMITTED SUBSEQUENT TO CONCLUSION OF HEARING

Statement of Joseph M. Helms, M.D., on behalf of the American Academy of Medical Acupuncture	146
Statement of the American Chiropractic Association	153
Statement of Jennifer Jacobs, M.D., on behalf of the Evergreen Clinic	156
Statement of Ed McCabe, on behalf of the Foundation for the Advancement of Oxygen Therapies	159
Letter from Dr. Philip Maffetone, on behalf of the Foundation for Allied Conservative Therapies Research	167
Statement of Peter Barry Chowka	168
Biographical sketch	171
Letter from Hari M. Sharma, M.D., professor of pathology, Ohio State Univer- sity Hospitals	172
Supporting statement of Dr. Seymour Brenner, radiation oncologist, on behalf of Dr. Emanuel Revici	173
Statement of Dr. Emanuel Revici	174
Letter from Seymour M. Brenner, M.D., radiation oncologist	180

ALTERNATIVE MEDICINE

THURSDAY, JUNE 24, 1993

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN
SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10:20 a.m., in room SD-192, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Reid, and Gorton.

Also present: Senators Mikulski and Pell.

NONDEPARTMENTAL WITNESSES

STATEMENTS OF DAVID M. EISENBERG, M.D., ASSOCIATE IN MEDICINE, BOSTON'S BETH ISRAEL HOSPITAL AND INSTRUCTOR IN MEDICINE, HARVARD MEDICAL SCHOOL

OPENING REMARKS OF SENATOR HARKIN

Senator HARKIN. The Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies will come to order.

First of all, I want to apologize to all of you here. We had back-to-back votes on the Senate floor; very contentious, very difficult votes. It consumed a lot of our time and that is why we are late starting. I am sure you all know these votes are on the budget. So I apologize, and I apologize to Senator Mikulski for being a little late getting here.

The hearing this morning will focus on the Office of Alternative Medicine at the National Institutes of Health, which is funded through this appropriations subcommittee.

In October 1991, this subcommittee provided \$2 million to establish the Office of Alternative Medicine for two main reasons: first, to take a serious look into the potential of alternative medical practices; and second, to break down the bias in medical research against review of worthy treatments not in the mainstream of conventional medicine. And since then, another \$2 million has been provided to this end. Today, we want to examine the progress the office is making and look at how effective it has been in meeting its congressional mandate.

I guarantee what you are about to hear this morning may be completely different from everything else you have ever heard about health care. But the fact that one in three Americans has reported using one form of alternative medicine or another makes this subject worth investigating.

In the next few hours, we are going to hear from several people who turned to alternative medicine after conventional medicine failed them. Some suffered great pain from their ailments, and others were literally on their deathbeds before finding an alternative treatment that either cured or significantly improved their conditions.

Some of it may sound out of the ordinary, but keep in mind that as recently as 50 years ago, nitroglycerin was considered a crazy, wacky idea for treating heart attack victims, and antiseptic techniques were dismissed as quackery because many did not believe that germs caused disease. Medical science has always been skeptical of the unknown. But sometimes, that which is conventional has proven in the long run to be mere quackery. Remember that bleeding people with leeches, including George Washington, was accepted practice by conventional medicine for many, many years.

The fact is, the American people have placed a great deal of faith in alternative medicine in recent years. We will hear from the author of a recent survey, published in the "New England Journal of Medicine," which showed that Americans are spending a staggering \$10.8 billion a year on alternative treatment, which is nearly as high at the \$12.8 billion spent on out-of-pocket hospital care in America. Americans have justified our investigation of these alternative treatments with their pocketbooks.

What is more, in 1990, a record 425 million visits were recorded to providers of unconventional therapy, which, by the way, is more than the 388 million visits to all primary care physicians in the same year. The American people are trying to tell us something. Again, as I have said, at least one and maybe more than one in three Americans have reported using one form of alternative medicine or another.

I might add that I was very skeptical when I first started hearing about alternative medicines, even after setting up the office 2 years ago. I was raised, like everyone else, to think that conventional medicine is the only way to go. But I am going to take the time here to open this hearing by telling about what an alternative therapy did for me, as recently as 2 months ago.

For many years, I have been plagued with allergies. We all know that President Clinton also has allergies. In fact, many, many people have allergies. In recent years, my allergies have been getting worse. So I started taking Seldane a couple of years ago, and that worked fine. It really helped me get through the springtime. It always hit me right in the springtime worst of all, sometimes summer; spring and summer. So Seldane worked for a couple or 3 years. Finally, by this year, it was so bad that a double dose of Seldane did not work.

And about 2 months ago I was using an inhaler at night. I was waking up about 3 in the morning, driving my wife nuts getting into these sneezing fits in the middle of the night. I was taking four Sudafed and two Benadryl every 6 hours just to get through the day, plus using nasal sprays and everything else. A friend of mine came to see me. I was having one of my bad days and he said, "Look, I know this guy in Arizona who claims he can cure any allergy. Would you see him?" I said, "If he pays his own way up, I will see anybody."

So he came up. I met him in my office at 8:30 on a Wednesday morning. We spent 1 hour there. He cures allergies with bee pollen. Well, I have never taken bee pollen. I eat honey on bread once in a while and that is about it. But I looked at the ingredients, and he had this intriguing way of curing allergies. You take a lot of these. You take 12 of these at one time, and they are not small tablets. These are pretty big tablets. Then you wait 5 or 10 minutes; if you do not feel some relief, you take 12 more. If nothing happens, you take 12 more.

So I started out. I took 12; waited 10 minutes; took 12 more. I thought I felt better. I thought, well, maybe that is just my mind telling me that; right? Then I had to go to a committee hearing. He said, "Well, if you get another attack, just start that process all over." So that day I took 24 of those pills that day. The next day I took 60 of them. I took 36 in the morning; I took 24 in the afternoon. The next day I took about 48. Well, to make a long story short, in about 5 days I took about 200 of these. Oh, more than that; maybe 250.

By the sixth day, I had no allergies. And since that time, I have not taken one Sudafed, one Benadryl, not one Seldane. I have not used one nasal spray since then. I sleep all night. I have no more allergies. It is the most bizarre thing that has ever happened in my life. I just cannot tell you what it is like not to have to use all those sprays and take those drugs.

Now, will it work for everyone else? I cannot attest to that. But I know it worked for me. And something has to be done to investigate these things, because it sure worked for me and I am living proof of it right now.

Well, anyway, the 425 million visits provide clear and compelling evidence that people are not just passively following doctor's orders anymore. Consumers want more control. They are playing a bigger role in their own care, and they are making more of their own decisions. And Government must play a role in facilitating that process and letting people make those kinds of decisions. Now, alternative medicine may be unconventional, but I think Government has a responsibility on behalf of consumers to investigate the most promising therapies, explore their merits to figure out what works and what does not work. And, I might add, to separate out legitimate alternative treatments from misguided and unsubstantiated claims.

At a time when America is evaluating the quality and effectiveness of conventional health care, I think we have an obligation to do the same for alternative treatments. The Government should not play big brother, but I believe it does have an obligation to ensure that the information that consumers receive about treatments is accurate. So that is the mission of the Office of Alternative Medicine. Hopefully, it will separate the wheat from the chaff, get rid of quacks and find ways to bring alternative treatments safely into the mainstream. And we are going to find out how well they are doing that today.

I want to make one final point. Our traditional health care system emphasizes high-technology medicine and I think too often dismisses approaches that may be less costly and more preventative in nature. One of the interesting aspects of many alternative therapies is the emphasis on prevention and education. One of the short-

comings of the training of physicians in this country is the lack of attention paid to prevention, even clearly accepted ideas, such as diet and nutrition.

One of my hopes for the Office of Alternative Medicine is that it results in greater communication between conventional and alternative providers. I believe that there are many areas where they can learn from each other, and prevention is one of those areas.

Again, at this time, I will leave the record open for a statement by our distinguished ranking member, Senator Specter, who, as you know, is recovering from an operation. His health is improving every day and we are all very thankful for that. Now, I want to thank our witnesses for being here today, and I will yield to my colleagues for any opening statements they have. Now, I will recognize the distinguished Senator—whoever was here first. I always like to recognize who was here first. That is sort of the way we go. Senator Mikulski.

OPENING REMARKS OF SENATOR MIKULSKI

Senator MIKULSKI. Thank you very much, Mr. Chairman. I would like to thank you for not only holding this hearing, but also for the leadership that you have provided in this field. The fact that you are the founding father of the Office of Alternative Medicine at the National Institutes of Health is a tribute to your leadership, which has been both bold and sustainable. And we look forward to working with you on this issue.

You spoke very eloquently and specifically about your own experiences with alternative medicine. I would like to also say that I, too, utilized alternative medical care. I have used it and I continue to use alternative medical care, specifically acupuncture, as a significant part of my own health care arrangement.

Many years ago, when you and I were both in the House of Representatives, I sought out acupuncture when I faced health problems where Western medicine offered me only platitudes or pharmaceuticals. As a woman, I was not taken seriously, and, also, the solution to that was to load me up on every drug in which I would have been a walking test tube with earrings. Acupuncture helped me get well, but acupuncture has been a significant tool in helping me stay well.

I believe that alternative medicine, like any other health care modality, should be examined and we should look at it from the standpoint of safety and efficacy; the same tools that we provide in a Western society in order to help people. I also believe that health care should be done by practitioners who do meet standards of practice in order to deliver those modalities.

In my own home State, Senator, I look to the Center for Traditional Acupuncture in Columbia, MD, for such care. The center is a national resource turned to by the Governor of Maryland and others for expertise in the field. They have high standards for practice and use an ethical framework based on efficacy and safety. Those are the models I think we need to look to.

My own experience with alternative medicine is probably like many other Americans. It is not about Western medicine versus alternative modalities. It is about a third way; a way that values both practices. That is why I prefer the term "complementary medi-

cine" to "alternative medicine" because, as a citizen in a Western democracy, I believe we turn to both worlds.

Such approach is embodied, I believe, in my own advisor on these matters, who is with me today, someone I would like to bring to your attention, Charlotte Kerr, who is a registered nurse, has a degree as a nurse practitioner from Chapel Hill as well as a certified acupuncturist with a master's degree in acupuncture, committed to education and healing, well versed in the modalities of public health, formerly ran the diabetic clinic at the University of Maryland, from where we will hear from Dr. Berman, and now she is a leader in the field of acupuncture.

When we look at these modalities, if we think of a complementary world where we use the best of both, but we do not close our minds or close doors to those alternative methods. There is no doubt that Americans are turning to alternative methods. This has been articulated in the Eisenberg study. The Bill Moyer special brought together a cornucopia of possibilities that lie before us in alternative medicine. And, now, at my own University of Maryland, there is Dr. Berman, who is working on studying alternative medical practices and also seeing how to mobilize that, even in the medical school curricula.

What has happened is good people turn to foundations because there is no clear public policy. That is why I believe the Office of Alternative Medicine at NIH is so important. We do need to do those protocol studies that any rigorous scientist would agree to as the standard methodology to compare what really is safe, what really does work so we get rid of the quacks, we get rid of the false claims and we get rid of the gimmicks, but we do keep those modalities that are around that can be tested, evaluated and their practitioners can be certified and licensed.

But what so shocks me about NIH and the medical community is the very people who are scientists, who pride themselves on having an open mind, have closed doors to the people in these alternative fields who are themselves professional and who ask for a clear approach to research. That is why your Office of Alternative Medicine is so important at NIH. I look forward to hearing Dr. Jacobs' testimony as well as the others. But I have been concerned about the pace of activity and progress at the office, like I know that you have too.

I think we need a strategy. I think we need a plan. And I think we need a sustained funding approach to this. Private philanthropy cannot be a substitute for public policy, and I compliment you on being the leader in establishing the public policy.

Senator HARKIN. That is great. Thank you, Senator Mikulski, for a very strong statement. I agree with everything you say. You hit every nail on the head.

Senator Gorton, I know you have also had a long-time interest in this and have been supportive of it in the State of Washington.

OPENING STATEMENT OF SENATOR GORTON

Senator GORTON. I do want to thank you, Mr. Chairman. As you know, we cosponsored a number of pieces of legislation in this area in which you are very interested.

Today, in a sense, I simply want to spread on the record that one of your witnesses you had asked to be on the second panel at the request of Senator Murray, who is now indisposed, and the witness, unfortunately, was caught by a storm in Minneapolis and will not be able to attend. So I just want to ask you to do what I am sure you would have done in any event, and that is to include the written testimony of Dr. Starback, a naturopathic physician, in the record as if she had been here. And I would also like to ask you to submit to her on behalf of the subcommittee a series of questions which I would have presented to her had she been able to attend.

The naturopathic movement is particularly successful in Washington State. It has perhaps a greater following there than it does at any other place in the country. And, as we discuss alternative forms of medicine, it is an important element of that study. So I just want to express the hope that the unfortunate absence of both Senator Murray and of Dr. Starback does not cause it to be overlooked.

Senator HARKIN. Senator Gorton, I assure you it will not be. I did not know until just now that they were caught in Minneapolis. I guess there are some pretty severe storms and flooding out there. I read Dr. Starback's statement at home last night. I really look forward to meeting her. And, if they are still coming in, I would still like to meet her if our schedules permit; maybe tomorrow or something. Maybe she is turning around and heading back. I do not know.

Senator GORTON. I do not have the answer to that.

Senator HARKIN. If you find out, let me know. I would sure like to see her.

Senator GORTON. Fine.

Senator HARKIN. But we will make sure that their statements are part of the record, without any objection, and your questions and answers, too.

Senator Reid?

OPENING STATEMENT OF SENATOR HARRY REID

Senator REID. Chairman Harkin, I am sorry I have been involved in budgetary matters most of the morning, but I wanted to drop by here and announce my public support for your holding these hearings. I think everyone should understand that it is not easy to hold these hearings for Chairman Harkin. There are all kinds of other people demanding time, most of which are led by groups that are so-called mainstream medical groups, and he did not do that. And I am grateful, Tom, for this.

Senator HARKIN. Thank you.

Senator REID. I think that we in Nevada have been willing to try some different things. We were the first State to legalize acupuncture and we have been the first State to legalize a number of things. And so I am glad we are looking into this in the detail that we are. This is typical for you, Chairman Harkin. You have always been willing to do things a little different, and I am personally appreciative of that.

Senator HARKIN. Senator Reid, thank you very much for those kind words. And, again, I thank you. Senator Reid is being overly modest. Again, he is very interested in this area and was one of

those that helped us in the beginning when we set up the Office of Alternative Medicine to get us the kind of support that we needed to get it through the Appropriations Committee and to hold onto it through conference. Senator Reid was one of our best supporters on that, and you have been overly modest in not mentioning your role in this. And I thank you for your help in the beginning stages and your continued help and support for this. I appreciate it very much, Senator Reid.

SUMMARY STATEMENT OF DR. DAVID EISENBERG

Senator HARKIN. Our first panel will provide an overview of alternative medicine. We will hear about the changing attitudes and expectations of Americans concerning health care and the growing number of Americans turning to alternative therapies. Dr. David Eisenberg will be our first witness. I call Dr. David Eisenberg to the table.

Dr. Eisenberg is an instructor at Harvard Medical School and an internist at Beth Israel Hospital. He recently completed a study about the use of alternative medicine by Americans, which Senator Mikulski referred to.

Joining Dr. Eisenberg in this panel is Rob Lehman. Mr. Lehman is President and CEO of the Fetzer Institute, which supports research on a broad range of alternative therapies and is involved in efforts to educate health professionals about these therapies.

I thank you both for being here this morning. Again, my apologies for holding you up for so long. I will say this just once this morning. All of the statements will be made a part of the record in their entirety. Again, please proceed as you so desire.

Dr. EISENBERG. Mr. Chairman, I am pleased to be here and I appreciate this opportunity to speak with you and members of the subcommittee on issues relating to alternative therapy. I hope it is clear from the background material I sent to you that, in addition to being a practicing physician and academic researcher at Beth Israel Hospital in Boston and Harvard Medical School, I have also been a student of alternative therapies. During the time I lived in China, I studied acupuncture, herbal medicine, massage, meditation. Over the past decade, I have investigated many of these alternative therapies. Therefore, my education really has included both conventional and alternative approaches to health and illness.

I would like to address three issues in my comments this morning; first, a summary of the prevalence of alternative therapy in the United States. Many of those numbers have been cited by you, and I am very flattered by that. I will then speak to the need for courses at medical schools to education physicians in how to discuss alternative therapies thoughtfully and responsibly with their patients. And, last, I would like to share with you a personal view that there is an increasing receptivity on the part of the conventional medical establishment, even the most conservative members, to engage in the process of rigorously assessing alternative therapies. As you have articulated, Senator Mikulski, there is a need for rigorous, authoritative, unbiased research. My colleagues wish to participate in that process.

With regard to prevalence, alternative therapies are difficult to define because they mean so many things to so many people, they

encompass so many techniques and beliefs. Functionally, they can be defined as therapies that we are not taught in medical school and which are not available in most hospitals.

My colleagues and I performed a national survey, which you flat-ter me by mentioning. I will review some of the data from that survey, which is part of my written testimony and which appeared in the "New England Journal of Medicine" this past January.

As you mentioned, one in three Americans report using an alternative therapy to treat a serious illness in the past year. The reference year here is 1990; 7 out of 10 people who used alternative therapies did not inform their medical doctors of this practice. The majority of people who use alternative therapies use them for chronic illness, chronic pain, insomnia, and anxiety. They do not use them for life-threatening illnesses. In fact, from a numeric standpoint, cancer and AIDS which are perceived as sort of the leaders here, account for only 4 percent of all the alternative therapy use in this country.

Doing the mathematics, you pointed out that we estimated 425 million visits to offices of alternative therapists in this country, a number which exceeds the number of visits made by all Americans to all primary care physicians in the same year. Financial costs attributed to alternative therapies are in the range of \$14 billion, three-quarters of which are spend out-of-pocket. And, as you pointed out, Senator Harkin, in your testimony, that amount is comparable to the amount Americans spend every year out-of-pocket for all hospital care in this country. So we concluded that the prevalence of alternative therapy and the costs are far greater than we had ever anticipated.

Physicians are typically not informed by their patients about the use of alternative therapy. We strongly recommended rigorous clinical studies to test the safety, efficacy and cost-effectiveness these techniques. And we also thought it was necessary for medical schools to develop courses in this area.

That brings me to my second point. Physicians today know so little about alternative medical practices that they are not able to discuss these techniques in a thoughtful and responsible way with their patients. I am pleased to tell you that at some of the leading medical schools in this country courses are being designed to educate health providers about alternative therapy. I have submitted as part of my written testimony the syllabus of a course I directed at Harvard Medical School, which is devoted exclusively to alternative medical practices. Other courses pertaining to this area are being developed or have been given at Stanford University, Georgetown University, Tufts University, the Universities of California, Arizona, Kentucky, and Virginia. I suspect there are many others that I am not yet aware of.

This brings me to my third and final point. I am convinced that there is a growing receptivity on the part of my conventional colleagues, even the most skeptical among them, to participate in research in this area. In my written testimony, I have given you a series of suggestions of clinical trials that I think are literally crying out to be done. The first few examples from the list include the treatment of low back pain; people with chronic low back pain.

That one illness makes up the largest portion of disability in this country.

What if the next 1,000 people with chronic low-back pain at a big HMO in the Northwest or in the East were given the opportunity to have conventional care and chiropractic, or acupuncture, or conventional care and massage? Would those additional modalities reduce symptoms and pain and suffering and would they reduce costs? We do not know. We have to find out.

The most commonly used unproven cancer therapies. I understand we will hear a bit about shark cartilage. We may or may not hear about antineoplastins. Many Americans are using these techniques. They deserve a rigorous clinical test.

Acupuncture: Does it work for chronic pain? Tinnitus, ringing in the ears. Does it work for the treatment for people who are addicted to cigarettes, to food, to alcohol? Claims abound, but we do not have valid data from which we can make a recommendations.

So these kinds of studies must be done. I think they will be complicated, scientifically, and methodologically. They will be expensive. And, most importantly, they will require an unprecedented collaboration on the part of the conventional establishment, people in white coats with stethoscopes working side-by-side with people who are acupuncturists and homeopaths and chiropractors, working on the same project together.

From an administrative standpoint, there is a choice to make in how to coordinate this. In my written testimony, I have laid out options. One option is to use the Federal agencies that already exist; NIH, the Agency for Health Care Policy and Research. They can oversee these by expending more resources. Or perhaps we should think creatively about developing new centers that are leading medical schools built explicitly for the purpose of testing each of these therapies. What if the best medical schools in this country had centers made up of their best researcher scholars engaged in the process of designing those authoritative, unbiased tests that need to be done? It is a model for discussion.

PREPARED STATEMENT

I will close with a favorite Chinese proverb of mine, if you do not mind. I will translate it. It says, "Zhen Jing Bu Pa Huo Nie," literally is translated as "Real gold is not afraid of the hottest fire." And I think that applies, because those alternative therapies which are effective and safe and save money will withstand the most rigorous testing, and then we will be able to make sound recommendations for the tens of millions of Americans who are using these techniques every day.

Thank you very much for this opportunity.

Senator HARKIN. Thank you very much, Dr. Eisenberg.

[The statement follows:]

STATEMENT OF DAVID M. EISENBERG, M.D

Mr. Chairman, I appreciate the opportunity to speak with you and members of the Subcommittee on issues relating to alternative medical therapies. My comments will focus on three areas: (1) the prevalence of alternative medicine in the United States; (2) medical educational programs involving alternative medicine; and (3) the growing receptivity of academic medical institutions to rigorously evaluate alternative medical therapies.

I. Review of the Prevalence, Costs and Patterns of Use of Alternative Medicine in the United States

Alternative (a.k.a. unconventional, mind-body, complementary) therapies are difficult to define because they encompass a broad spectrum of practices and beliefs. "Many are well known, others are exotic and mysterious and some are dangerous."¹ From a sociologic standpoint, alternative therapies refer to those medical practices that are not in conformity with the standards of the medical community.² In functional terms, alternative therapies can be defined as practices used for medical intervention, health promotion, or disease prevention which are not routinely taught at U.S. medical schools or routinely paid for by third-party payers within the U.S. health care system. Examples include chiropractic, massage, meditation, homeopathy and acupuncture.

Findings from a national survey on alternative medicine, published in the *New England Journal of Medicine* January 1993 (enclosed), included:

- One in three respondents reported using at least one alternative therapy (e.g. chiropractic, massage, relaxation techniques) to treat a serious or bothersome medical problem during 1990.
- Little sociodemographic variation distinguished users of alternative therapy from nonusers.
- The majority used alternative therapies for chronic, as opposed to life-threatening, medical conditions. (Less than 4 percent used alternative therapies for cancer or AIDS.)
- Seven of ten users of alternative therapy did not inform their medical doctors of their alternative therapy use.
- Extrapolations to the U.S. population suggest that Americans made an estimated 425 million visits to providers of alternative therapy in 1990. This exceeds the number of visits to all U.S. primary care physicians (388 million) during this period.
- Expenditures associated with the use of alternative therapies were \$13.7 billion in 1990, three-quarters of which (10.3 billion) was paid out-of-pocket. This is comparable to the amount spent out-of-pocket annually for all hospitalizations in the U.S (\$12.8 billion).

My co-authors and I conclude that:

- The prevalence and costs associated with alternative medical therapies are far greater than previously reported.
- Doctors are typically not informed of their patients' use of alternative therapy.
- Medical schools should offer courses to assess alternative medical practices and enhance patient-doctor communication.
- Randomized controlled trials are necessary to evaluate the efficacy, safety and potential cost effectiveness of alternative medical therapies.

II. Medical Curricula to Educate Conventional Medical Providers

Last January, Harvard Medical School offered a course entitled, "Nonconventional, Unorthodox Medical Techniques: Implications for Clinical Practice and Research" (syllabus and evaluation enclosed). The objectives were:

One, to understand the basic theory and practice of alternative medical therapies commonly used in the United States.

Two, to rigorously assess the efficacy of alternative therapies based on reviews of controlled trials.

Three, to learn to discuss alternative therapy use with patients.

This course received the support of Harvard Medical School's Deans and Office of Educational Development. Most importantly, it received high praise from students and doctors in training. Continuing medical education programs for health care providers will be developed based on this model. Other courses dealing with alternative medicine are being developed at Tufts University, Georgetown University, Stanford University, the Universities of California, Arizona, Kentucky, Toronto and Virginia.

III. The Need for Research Centers to Rigorously Assess the Safety, Efficacy and Cost-Effectiveness of Alternative Therapies

There are currently too few clinical investigations to comment on the safety, efficacy or cost-effectiveness of alternative medical practices. To remedy this, centers capable of applying the highest standards of methodologic excellence must be devel-

¹ Murray RH, Rubel AJ. Physicians and healers—unwitting partners in health care. *N Engl J Med* 1992; 326:61-4.

² Gevitz N. Three perspectives on unorthodox medicine. In: Gevitz N, ed. *Other healers: unorthodox medicine in America*. Baltimore: Johns Hopkins University Press, 1988:1-28.

oped to assess alternative medical therapies. These would, ideally, be situated within leading medical institutions and work in concert with the National Institutes of Health (NIH) and Agency for Health Care Policy Research (AHCPR).

Protocols to evaluate the safety, efficacy and cost-effectiveness of individual alternative therapies would be developed and carried out at health maintenance organizations and corporate worksites, in addition to hospitals and clinics (examples below). Financial and efficacy data from these studies would be analyzed and made available to third-party payers and policy makers. These studies would require the collaboration of alternative medicine practitioners and researchers from leading medical institutions. Protocols to be considered include the following:

Back Pain.—Randomized controlled trials to investigate the effects of standard orthopedic and rheumatologic care with and without alternative interventions (chiropractic, acupuncture or relaxation techniques) in the treatment of chronic back or neck pain (cervical radiculopathy). In addition to subjective and objective clinical parameters, outcome measures would include overall health care costs and days of work lost. The study design should include an investigation of co-payment options to explore whether the addition of alternative therapies is cost effective in a variety of pre-payment or co-payment settings.

Unproven Cancer Therapies.—Randomized controlled trials to assess the safety and efficacy of selected unproven cancer therapies (e.g. antineoplastins, shark cartilage). Phase I, II and III trials can be conducted at multiple institutions within departments of oncology under strict academic guidelines. (Note: Center staff and advisory boards will include academic oncologists).

Acupuncture as Treatment for Addictive Disorders.—Randomized controlled trials to assess the efficacy of acupuncture in the treatment of addictive disorders including, but not limited to: smoking cessation, obesity, alcohol, heroin or cocaine abuse. There has been extensive reporting by the lay press in this area but few well-designed controlled investigations.

Acupuncture to Treat Pain and Neurologic Dysfunction.—Randomized controlled trials assessing the efficacy of acupuncture for refractory facial (Bell's) palsy, tinnitus, or degenerative arthritis.

Homeopathic Remedies.—Randomized controlled trials of standardized homeopathic remedies for pediatric ear infection (otitis media), adult asthma, hay fever (seasonal rhinitis), or acute (viral) upper respiratory infection.

Minimizing Side-effects of Chemotherapy.—Randomized controlled trials to test the assertion that Chinese herbal preparations, when used as adjuvants to standardized doses of chemotherapy, are effective in reducing bone marrow suppression (anemia), hair loss (alopecia), and loss of appetite (anorexia).

Coronary Heart Disease.—Randomized trials to follow up on provocative preliminary findings regarding the efficacy of nonpharmacologic approaches (e.g. diet, exercise, yoga) in reversing coronary artery disease (i.e. the work of Dean Ornish, M.D., et al.)

Breast Cancer.—Randomized trials to follow up on provocative preliminary findings suggesting that psychosocial supports may alter the course of breast cancer (i.e. the work of David Spiegel, M.D., et al.).

Psychological and Behavioral Therapies to Treat Common Disabling Conditions.—Randomized controlled trials assessing the efficacy of cognitive behavioral interventions (e.g. hypnosis, relaxation, biofeedback, guided imagery) in the treatment of common problems such as recurrent tension headache or migraine. Studies would compare the efficacy of cognitive therapies with drug therapies or combinations of cognitive and drug therapies. Similar designs would be applied to the assessment of cognitive therapies for a range of illnesses, such as insomnia, premenstrual syndrome, chronic fatigue, irritable bowel syndrome, etc.

AIDS and Cancer.—Survey research indicates that a high percentage of individuals suffering from AIDS or cancer use alternative therapies. Those alternative practices used most commonly by individuals with AIDS or cancer should be evaluated by means of randomized controlled trials in order to assess their safety, efficacy and cost-effectiveness.

A research center to assess alternative therapies has been proposed at Harvard Medical School and Beth Israel Hospital (draft proposal enclosed). Additional centers, affiliated with other prominent medical institutions are being planned. Precedents exist for the public funding of such centers, as has occurred with funding for NIH centers on aging and centers to address addictive disorders. The interests of an estimated sixty million consumers of alternative medicine will be served by the development of centers to assess alternative medicine at major universities throughout the United States.

Given the existing financial climate, if additional appropriations for these centers cannot be secured for fiscal year 1994, efforts should be made to encourage the NIH

and the AHCPR to devote more of their resources to clinical research pertaining to the safety, efficacy and cost-effectiveness of alternative medical therapies. The advantage of creating new centers, however, has to do with the fact that alternative medicine research will likely remain a low priority at NIH and AHCPR. By contrast, alternative medicine research will be the only priority of centers funded for this purpose.

IV. Conclusion

The prevalence and costs associated with alternative medicine in the U.S. are far greater than previously reported. Efforts are underway within mainstream medical institutions to educate medical providers about alternative medical therapies. The academic medical community is increasingly receptive to proposals for rigorous investigation to assess the safety, efficacy, cost-effectiveness and basic science of alternative medicine. Collaborative investigation involving expert researchers and practitioners of alternative medicine must be implemented to generate sound recommendations for Americans. Research centers, working with the NIH and AHCPR, should be developed to achieve this goal.

Thank you for your consideration.

STATEMENT OF ROBERT F. LEHMAN, PRESIDENT AND CHIEF EXECUTIVE OFFICER, FETZER INSTITUTE

Senator HARKIN. I do have some questions for you, but we are going to turn to Mr. Lehman. Mr. Rob Lehman, who is the president and CEO of the Fetzer Institute.

Mr. LEHMAN. Thank you, Mr. Chairman, members of the Senate. Dr. Eisenberg closed with a quote. It reminds me of a quote I will open with. In times of great change, it is said there are two kinds of leaders, "those who usher out the old and those are called pallbearers, and those who usher in the new and those are called torchbearers." And I think we are in room amongst a lot of torchbearers today. I am pleased to be here.

What I would like to do is just say a few words about what we see as the importance of the kind of statistics that Dr. Eisenberg has described. I would like to suggest, first of all, that the traditional health care system in this country suffers from a blind spot, a significant blind spot that obscures our capacity to see a way of health care, a form of health care that is broader, that indeed could significantly improve health in this country and could practically reduce costs in health care in this country. The blind spot is due, in part, to the brilliant glow of modern medical science and technology and the miracles that have occurred over the past 50 years. But it has blacked out some very, very important areas that we are beginning to talk about here today. The fact is, however, that modern medicine is unable to deal successfully with a lot of the illnesses that we are faced with in a pervasive way in our society today.

I would like to illustrate what I mean by asking us to imagine the following circumstance. Imagine that a line of new drugs had just been discovered that, through very preliminary research, had demonstrated the following health benefits. That, first, had shown the promise of doubling the life expectancy of women with advanced metastatic breast cancer. That, second, had shown the promise of reversing coronary artery disease and dramatically reducing the \$14 billion that is spent each year in America for bypass surgery that has to be redone again in 5 years. Third, the promise of increasing the capacity of individuals to deal with chronic pain. Chronic pain in this country is estimated to cost our economy over \$100 billion a year. Imagine further that this new line of drugs had

been shown to be effective in reducing the symptoms of illnesses that make up about 75 percent of all doctor office visits in this country: allergies, pain, back pain, migraine headaches, and high blood pressure. And, finally, imagine that a common characteristic of this whole line of new drugs was that people were able to leave hospitals earlier, reduce the amount of medication they take, reduce of the number of doctor office visits they make and get back to work earlier and miss fewer days of work.

The question I think that this imaginary scenario poses is: Given this enormous potential for improving our health care in this country and reducing costs, would we not do everything possible to bring private and public research together to determine whether or not these preliminary findings could hold up in critical controlled trials? I think the answer to that would be an unequivocal yes.

We are suggesting today that the cost of doing that over a 5-year period, taking what Dr. Eisenberg has described as the alternative therapies and mind-body therapies and testing those in controlled trials, the cost of that would be less than 25 percent of what it would cost to research, develop and have a new drug approved by FDA.

Now, of course, my story has one big change and that is that there are no new drugs that do any of these things. But there are in fact a line of alternative therapies and mind-body therapies that seem to promise these approaches to improving health care.

We, at the Fetzer Institute, have been investigating these over the past few years. I think we have learned a lot. I think experience in this area, as Dr. Jacobs will tell you, is very, very important. There is an old saw that says, "Good judgment comes from experience and experience comes from bad judgment." We have a lot of experience. I can tell you about that.

I think what we are faced with right now is a very, very opportunistic time, because what we are seeing is that there are mainstream, top-notch research universities that are poised and ready to take on these questions. There are medical schools, nursing schools and hospitals that are opening up to these modalities and these therapies. And, of course, there is in fact a public movement out there behind this. There is, as one of my trustees says, an invisible mainstream out there that is clamoring for this. We, at the Fetzer Institute, sponsored the Moyer series, and we were just struck with what that series revealed. And the series is fast becoming the most popular documentary ever on public television. The book is on the best-seller list for the 18th week. Schools across this country and study group circles around the country are using it.

PREPARED STATEMENT

So this is a very, very important time to look at these questions. I am very pleased to be here with the committee as it investigates and asks these very important questions. Thank you.

[The statement follows:]

STATEMENT OF ROBERT F. LEHMAN

The American people are creating a new vision of health and health care. This vision arises out of personal initiative and responsibility and provides the opportunity for the enrichment of medicine and health policy.

We, in the Western world, see medicine as one of the principal means of improving the quality of our personal lives. It has become abundantly clear, however, that standard medical practice in the United States fails in many ways to meet human needs. Individuals are increasingly seeking the benefits of "alternative" or "unconventional" medicine that their own physicians do not practice.

The recent public television series "Healing and the Mind with Bill Moyers" has become the subject of a nationwide conversation, reaching millions of viewers, with its companion book rising swiftly to number one on the best-sellers' lists. A survey appearing in *The New England Journal of Medicine* on January 28, 1993, showed that in 1990 Americans paid \$10.3 billion out of pocket for alternative treatments, rivaling the \$12.8 billion paid out of pocket for all hospitalizations. In that year, one-third of Americans used some "alternative" approach for treatment of a serious or bothersome medical problem.

The message is clear, and it is two-sided: first, people found that the mainstream practice of medicine does not offer the range of interventions to provide an adequately rich quality of life, nor does it provide the sense of control or caring, healing environments that they value so highly. Second, people seek to assume more responsibility for choices about health care, and are willing to make changes in life-style and move to alternative medical approaches to improve their own health.

A health policy that hopes to improve the quality of life while controlling spiraling costs must take these messages into account and meet the American public on its own terms.

Alternative medicine incorporates a large number of different approaches. Some of these, for example, chiropractic and homeopathy, were developed by Western-trained physicians; some, like acupuncture, come from other cultures. The spectrum of alternative medical therapies includes a group of so-called "mind-body" approaches that build on principles that every physician recognizes to some degree, e.g., hypnosis, group psychotherapy, biofeedback, and stress-reduction techniques.

Many of these treatments are "alternative" treatments only because most American physicians know little about them and are untrained to use them—not because they require a philosophical departure from basic medical principles. In fact, many of these approaches are being used in major medical centers, and have shown substantial clinical benefits for many people. More significantly, these approaches often help in ways that existing drugs and conventional medical treatments cannot. For example:

- In a landmark study at Stanford University, women with advanced breast cancer who were enrolled in a support group survived twice as long as women with the same level of disease who did not get this emotional support. No known drug could have given them the same benefit.

- At Harvard Medical School and elsewhere, relaxation training is being used to help people with a wide variety of problems, including hypertension and Type II diabetes. Relaxation often enhances the effects of medical treatment for these conditions, and sometimes makes drug treatment unnecessary.

- At the University of Massachusetts Medical Center, a form of medication called mindfulness meditation has been taught to many people with chronic pain and has offered them greater relief than pain-killing drugs have been able to.

- In a study at Minneapolis Children's Medical Center, children with migraines who learned hypnosis had greater relief from their headaches than those who were given the most commonly used migraine-preventing drug.

- Biofeedback, an electronic means of teaching the mind to control the body, is now being used to help stroke victims learn to use new muscles, and is also being used in a variety of ways for relaxation, pain control, incontinence, and hyperactivity in children.

There are several other indications that treating emotional and physical aspects of health together—a defining characteristic of "alternative" medicine—can be highly cost effective. For example:

- By some estimates, chronic pain may cost \$100 billion a year in lost productivity and disability payments. Many alternative approaches can minimize the effects of pain and improve productivity.

- Psychological preparation for surgery reduces hospital stays by 2.4 days on average, according to several studies; in one study, it saved \$1,200 per patient.

- Americans spend \$14 billion per year in heart bypass surgery. One-half of these patients must return within five years for another bypass. Evidence is available that life-style changes, involving low-fat diet, exercise, relaxation techniques and group support, can actually reverse coronary artery disease.

THE TASKS AHEAD

Despite the existing momentum in the field, there are many major challenges yet to be met to achieve a practice of medicine that has been enriched to the fullest degree, increases the responsibilities of individuals for their own health, and enhances the sense of caring medical environments. Responses to these challenges are primarily in the areas of research and education.

RESEARCH

In the area of research there is a need for a map of the territory of unconventional medicine that identifies what is known and what is not, and pinpoints the most promising areas of opportunity. There is a need to design and conduct randomized controlled clinical trials, testing not only the safety and efficacy of alternative medical therapies, but also comparing them with mainstream approaches. For example, one such trial might investigate the effects on chronic back pain of standard orthopedic and rheumatologic care with and without alternative medical interventions such as chiropractic, acupuncture, massage, and relaxation techniques. The investment of a few million dollars in such investigations might save billions of dollars lost annually in disability compensation and lost productivity.

Other opportunities include the use of acupuncture in the treatment of smoking or alcohol withdrawal and the use of Chinese herb preparations in reducing some of the side effects of chemotherapy. It is also important to develop improved tools for the measurement of quality of life and other outcomes and to investigate the mechanisms of action of alternative medical therapies.

Safety and effectiveness are not the only concerns, however. We must also consider cost effectiveness. Will a new procedure reduce the number of visits to the doctor? Can it reduce the amount of medication required? Will it get the patient out of the hospital sooner? Back to work sooner? Will it enhance the quality of life? These key questions are not easily answered. We have little idea of the cost effectiveness of even well-established procedures such as surgery or radiation for prostate cancer.

EDUCATION

Once a new discovery in health care occurs, it is of no use unless the public and the medical community learn about it. An individual sharing responsibility for his or her health must be able to make informed choices among different therapies and preventive measures and must rely on those within the medical community for the knowledge needed to make such choices. New knowledge must also be transmitted to individual and institutional health care providers by means of articles in scholarly journals, new medical school curricula, continuing education courses, and other forms of education. Policymakers must also be educated and informed in order to formulate policies that contain incentives for the enhancement of individual responsibility and the enrichment of medicine while removing barriers that hinder such developments.

Proven mind-body prevention education programs, for example, should be offered in elementary and secondary schools and by hospitals. These could be offered at very low cost. The potential returns would be enormous in terms of teaching people how to honor their bodies, maximize the likelihood of staying healthy across the entire life span and, therefore, reducing dramatically the cost of taking care of people in the latter third of life.

RECOMMENDATIONS

More specifically, we encourage support for initiatives that will:

One, expand the use of alternative medical therapies, including mind-body approaches, with proven efficacy, safety, and cost effectiveness in prevention and treatment of illness and disease.

Two, extend the enrichment of medicine through thoughtful and rigorous research on the efficacy, safety, and cost effectiveness of alternative medical approaches.

Three, improve educational opportunities for: (a) the public, to enable individuals to make informed choices from an expanding area of proven options for health care; (b) health care providers, to help them make similar choices and to mobilize the power of individuals in the prevention and treatment of illness and disease; and (c) local, state, and federal policymakers to help them provide incentives for sound research, education, and health care practice and to remove obstacles to their implementation.

Senator HARKIN. Mr. Lehman, thank you very much. I just want to say that you are right, it is an invisible mainstream. I am just amazed at how many people that I speak with, people I have known, people I associate with have used alternative medicine or someone in their family. I was having lunch with a couple the other day and it came up.

It just happened this morning. I was coming over from the Capitol with a woman who is sort of doing a study on how Senate operates and I was telling her about this hearing, and she was quite intrigued by it because she had used homeopathy and alternative therapies for her children. Her 2½-year-old child had ear infections for a couple years and had been taking antibiotics, and she felt this was bad to keep giving this kid antibiotics. She took him off and got him into homeopathy, and the kid's ears cleared up and no problem.

I mean, unless you talk about this, people do not talk about it with you.

Mr. LEHMAN. Right.

Senator HARKIN. So it is kind of invisible out there. But I am just shocked at how many people I talk to. I had an interview, even before my allergies were cleared up. I had a television interviewer and this woman was talking about this office we had set up. I came to find out that she had used alternative therapies. So just one after another. It just goes on and on and on. So they are out there, and people are looking for different courses to take.

I will just ask some more formal questions for both of you. I will start with Dr. Eisenberg, since he came first. How do you respond to the critics who charge the jury has come in on most alternative therapies and that they have been discounted; that we are wasting money in these investigations; that, if they had any validity, they would have been investigated by now? I hear this all the time. How do you respond to that kind of a criticism?

Dr. EISENBERG. I do not think there has been a fair test. I think it is very difficult to assess these techniques in a thoughtful, balanced, prospective way. Show me a study on low back pain that really authoritatively tests whether or not chiropractic or acupuncture is helpful in a prospective trial that is big enough to be conclusive, which has included chiropractors and acupuncturists in designing a relevant experiment. Show me a trial on homeopathy for middle-ear infection that has been balanced and, at the outset, would satisfy both the homeopaths and the conventional skeptics. Show me one of those trials before we can pass judgment.

I think that is what we need. We need studies. We need unbiased studies from people who have no vested interest, researchers who are paid for a living to design fair tests. And we need to bring into that design the actual practitioners, the homeopaths, the acupuncturists, the chiropractors, and have them sign off before the study begins that both sides are satisfied that this is a fair playing field and that there are enough patients in the study to come up with a definitive result and that both camps are satisfied at the beginning. That is what we need. And I think if those trials are done, and if they are negative, which they will be in some cases, then we can come to that conclusion. But not 1 day before.

Senator HARKIN. Following up on that, let me get back to your testimony. I read it last night. There was something. You talked about the new research centers being set up.

Dr. EISENBERG. Right.

Senator HARKIN. Harvard, Beth Israel Hospital. You said:

Efforts should be made to encourage the NIH and the AHCPR to devote more of their resources to clinical research pertaining to the safety, efficacy, and cost-effectiveness of alternative medical therapies. The advantage of creating new centers, however, has to do with the fact that alternative medicine research will likely remain a low priority at NIH and AHCPR. By contrast, alternative medicine research will be the only priority of centers funded for this purpose.

Can you expound on that?

Dr. EISENBERG. Yes; gladly. I am very excited by the prospect of developing a center at Beth Israel Hospital and Harvard which is prototype for centers that I think should be developed at other major medical schools that would actually recruit some of the best health services researchers in the world to come to a place, be paid to get up in the morning and think about bee pollen, think about homeopathy for kids with middle-ear infections, think about whether chiropractic will save the Harvard Community Health Plan money in its thousand patients with chronic low back pain.

These researchers are statisticians, epidemiologists, orthopedic surgeons, health economists. They do not have a vested interest, but what they love to do is think about the design of beautiful experiments. If you have a group of talented, passionate, world-class scientists who are brought together for the explicit purpose of testing each of these therapies completely, in an unbiased fashion, and they are open enough to work with chiropractors and homeopaths to design a relevant study, then you have a place where the work gets done.

My concern is NIH and the Agency for Health Care Policy Research will see alternative medicine as a lesser priority. They will not get up in the morning thinking which of these studies should be done first, fastest, by whom, at which HMO. But centers, such as the one at Harvard and Beth Israel which I have proposed and others which you will hear about I believe, could bring together the best researchers who, by the way, see this as a great methodologic challenge.

Senator Mikulski, I just want to acknowledge and accentuate how you wanted to take the labels off. We are looking not to label something as "complementary" or "alternative" or "conventional" but a therapy; does it work? Is it helpful? Is it safe? Forget the labels. These are people who love the challenge of a fair test. You bring those people together in a department of medicine at a Harvard, a Stanford, a Johns Hopkins—that is what they do for a living.

They just did it with prostate cancer. They just proved that maybe it is not worthwhile taking men's prostate out. Somebody had the courage to say, "We are not sure; let us test it." They put those people in a room for 3 years and said, "Go. Do it. Here is the money. Tell us the answer."

That is what we need. And I think those kinds of centers at the most prestigious medical schools will work. That is a strategy which engages both sides fairly and openly. Now, not everybody

would sign up. Not every health care researcher will want to do that for a living. But I am flooded with requests by Ph.D's, by faculty from other medical schools, saying:

How can I work with you to study alternative medicine, to study how the mind impacts physiology? This is why I went into medicine and research. How can I help you?

I have a stack of papers from people with blue chip credentials who you would never expect would want to do this for a living. That is what they wanted to do when they went into health care. They wanted to see what helps patients.

So that is the center model. And, by building it within universities and having the chairman of orthopedics, oncology, and medicine as advisors at each of these centers, you have an automatic safety net. No study is going to be done at those universities unless the chairman of medicine, surgery, and orthopedics says, "This is relevant. This is doable. This is methodologically sound. And we know we have the people and the patients to do it. Go." That is what I mean.

Senator HARKIN. So you do not think you will have any trouble finding qualified researchers?

Dr. EISENBERG. I do not; absolutely do not. And I think, if Federal and private funds are available for these kinds of centers, you will see all of the major universities work like the dickens to create these kinds of centers.

Senator HARKIN. I do not expect an answer to this question right now, but you might think about it and get back to me later. But right now the funding for NIH is about \$11 billion for all of the Institutes. And I want to say at the outset I think they do a magnificent job. They are underfunded. As you know, I am trying to raise additional moneys for medical research.

Dr. EISENBERG. Right.

Senator HARKIN. But we put \$2 million into the OAM ; \$4 million actually; \$2 million 1 year and \$2 million the next. Thinking ahead to the next year, if we had some independent centers out there, how much in the next 2, 4, 5 years could legitimately be absorbed in funding these centers?

Dr. EISENBERG. I can be explicit, and part of my written testimony gives you line-item budgets. There is a line-item budget on the entire center at Beth Israel Hospital and Harvard. Our best guess is that the direct costs are between \$2 and \$3 million a year to have these people in place, to have them do this for their daily work from all the disciplines.

Senator HARKIN. That is for one center?

Dr. EISENBERG. For one center. So, if you have five centers at \$2 or \$3 million each—now, that does not cover indirect costs, which are a different issue—but direct costs to pay these people and to do feasibility trials at hospitals, clinics, and health maintenance organizations, \$2 to \$3 million each at five places, I think you would have a critical mass of talent to throw at this area. And they would get up in the morning to do this. They would not be told, "By the way, we are under political pressure to have something in alternative medicine." This is their job and they would love it.

Senator HARKIN. You come from mainstream medicine, if I can use that word.

Dr. EISENBERG. Right.

Senator HARKIN. And you are obviously very knowledgeable. You are very well respected in your profession. How receptive have your medical colleagues been to your interest in alternative medicine?

Dr. EISENBERG. Much more receptive than I had anticipated. And I think the strategy there is making them offers they cannot refuse. I never showed that paper on alternative medicine to my chairman of medicine until it was accepted by the New England Journal of Medicine. I did not send it to the New England Journal until I thought it was good enough to value their input. I did not submit a course on alternative therapies to the curriculum committee until we had spent 3 years researching it and putting together thousands of scholarly references.

I think the issue is that it has to be delivered in the language of conventional medicine with a sense of integrity and honesty that the conventional community is comfortable with. It is just common sense. If these studies are designed in a dispassionate way by people who are thoughtful, there is enormous receptivity. And that was the main point of my testimony. The receptivity is far greater than I think people imagine. Physicians want the answers, too.

Senator HARKIN. Mr. Lehman, I have one question of you, but you had something you wanted to add?

Mr. LEHMAN. I just wanted to comment on this because I think, as David Eisenberg has described, what is needed here is a level playing field. It does need to be tilted in either direction. But the issues here are, I believe, as much sociological as they are scientific. I think there is a lot of good research that has gone on with real pioneers and courageous pioneers that have been on the frontier of the mainstream.

What needs to happen today is, as you suggested, a strategy for bringing this into the mainstream. And the strategy, I think, that Dr. Eisenberg proposes is one that could really work and save a lot of money. For many years at Fetzer we have been sponsoring piecemeal, fragmented research studies—very good ones—around this country, but they are not listened to.

Senator HARKIN. What have been some of the most promising ones that you have funded?

Mr. LEHMAN. Well, the most promising ones were the David Spiegel, for example, I quoted earlier. And that was the study at Stanford that you are familiar with on breast cancer. Dean Ornish's study on reversing coronary artery disease. The work with pain control, Jon-Kabat Zinn.

Now, each one of these took place in a mainstream institution and each one was very carefully designed research. And they broke great ground. But if we were a little bit more strategic—and by strategic I do not mean manipulative. I mean by just setting up a way, at four or five centers as David Eisenberg is suggesting, where these modalities could be tested and compared and replicated, I think within a 5-year period we could have really moved through a lot of these therapies and done a great public service in understanding their efficacy, their cost-effectiveness, and their safety.

Dr. EISENBERG. I would just add that we would break new ground methodologically because we would invent new ways of

doing clinical experiments in areas we have never ventured before. It is very difficult to test the power of a belief or a mental act in intervening in an illness. That is more difficult than testing a pill or a scalpel. We will need new methods. And this is why I mentioned before that the people who love the challenge of methodologic design will line up. They will be breaking ground in their respective fields of research.

Senator HARKIN. Very good, Doctor. I turn to Senator Mikulski for any questions she has.

Senator MIKULSKI. Thank you, Senator Harkin. Many of the questions that you have asked are right along my own train of thought. I would like to say, Mr. Lehman, I have referred to the Eisenberg study but Fetzer has really been, indeed, a pioneer. And I believe the funding of the Moyer series was one of the really important breakthroughs in creating public awareness of alternative or complementary modalities, and the emphasis was on healing and being, getting, and staying well as compared to cures. And I thought that was a very interesting approach, and it is actually going to go to my line of questioning.

And I felt, also, one of the most important parts of the study was when you talked in the body-mind area, which has been shocking to me, as we often talk to other professionals in the field, that based on Freud, Jung, all of the great psychological and psychiatric thinkers, we have accepted the notion that the mind can hurt. But then we refuse to believe that the mind can heal, which is the corollary. And I felt the series so pointed out the tremendous potential of the mind in terms of the healing process. And, if I might say, that it is not all woo-woo. I think one of the things that you face is not only the concerns around quackery, which is one dimension, but the fact that this is not real science.

Dr. EISENBERG. Yes; we can turn it into real science very quickly if we have the resources.

Senator MIKULSKI. Well, then, I want to come back to the real resources, which will go to my questions and, in this obviously friendly atmosphere, my skepticisms. I would like to raise them, too.

First, Mr. Lehman, I really liked the difference between being a pallbearer and being a torchbearer. I am going to use that in my subsequent speeches. But I think what the people in this room should be aware of is that torchbearing has come from Congress. It has not come from the mainstream people at NIH, FDA, or HHS.

If I could, again, turn to my colleague, Senator Harkin, it was the Congress that established the Office of Women's Health at NIH when, for years, women were not even included in the protocols of this so-called unbiased environment. Again, through the boldness of Congress, you know the Office of Women's Health was established.

Senator Harkin established the Office of Alternative Medicine. We feel that the torchbearing is coming from the Congress itself. What we have also seen, and I believe we have learned from lessons learned from the Office of Women's Health which has been larger and has received a lot more financing at this point, is our concern about what gets funded, where the research goes on, and are we creating just a whole new class of grant junkies with the

old attitudes that want the new money? So note when I raise these issues where I am coming from.

One of the questions I have, Dr. Eisenberg, for you is, first, the funding using the framework of NIH as we know it: intramural and extramural. There are 13 Institutes at the National Institutes of Health. The whole idea of the Office of Alternative Medicine is not to have its own research budget but to make sure that the other Institutes are incorporating this. It would not be feasible at this point to target all 13 Institutes. But, within the framework of funding among the 13 Institutes, what would you say would be the top five priority Institutes that we should focus on for both intramural and extramural research?

Dr. EISENBERG. I suspect Joe Jacobs is the most qualified to comment on that. In this instance, Rob Lehman at Fetzer has actually been meeting—his staff have been meeting—with NIH Institute directors. Since I have not met with them, maybe he can talk to the issue of which ones have been most receptive.

Senator MIKULSKI. But you understand, that is exactly it.

Dr. EISENBERG. Right; receptivity.

Senator MIKULSKI. Receptiveness as well as open-mindedness.

Dr. EISENBERG. Right.

Senator MIKULSKI. When you talk about this unbiased approach, I would hope for that. But my experience, again, in women's health is that researchers do not see what they believe. It is not what they see that they believe; they see what they believe.

Dr. EISENBERG. Right.

Senator MIKULSKI. So they bring their attitudes in and, as you know, this has often resulted in overlooking serious issues or minimizing or trivializing or viewing it as deviant.

Dr. EISENBERG. I also want to acknowledge your extraordinary pioneering efforts in women's issues. And not only am I so pleased to see that, but I would like to learn from your experience. In this context, I wonder, have you found many women researchers who are so thrilled by the opportunity to work together on women's issues and have been able to put together critical mass of talent?

Senator MIKULSKI. Well, one of the things that we have learned in women's health—and this is why the barriers and so on—we in the Congress, the House, women and myself, could not have established the Office of Women's Health without the Galahads within the United States Senate. We did this without authorization. And the way we were able to do it is we moved it in the Kennedy committee, and this guy here put it in an appropriation when we had no authority and, in fact, we had open resistance and hostility.

Dr. EISENBERG. Right. Well, it is an extraordinary achievement.

Senator MIKULSKI. It is an extraordinary achievement and it is because we were the torchbearers.

Dr. EISENBERG. Yes.

Senator MIKULSKI. But I want to come back to, if we use the model at NIH—in fact, I will be saying goodbye to Bernadine Healy in about an hour.

Dr. EISENBERG. Let me defer to Rob Lehman and Joe Jacobs on that, because I am not the best.

Mr. LEHMAN. I will just mention a few of the Institutes that we have been meeting with. The doors have opened up widely since

the Moyer series, quite frankly, which is interesting. That was unanticipated. The National Institute on Aging is doing some very interesting work in looking at spiritual factors, religious and spiritual factors and the effects on disease in the aging population. The National Heart, Lung and Blood Institute has been working in stress, social support, hostility, and cardiovascular disease. The Dean Ornish work, in part, was sponsored there.

Of course, the National Institute of Mental Health has been working with David Spiegel's work in a followup study on breast cancer. And a project we sponsored with Dr. Sheldon Cohen relating stress to the common cold is being followed up also through NIMH.

Senator MIKULSKI. Mr. Lehman, that is what is going on now. But if we were going to fund work, you need to say what institutes would be our first level for this year. And I am trying to identify, and perhaps then that will come from Dr. Jacobs, where it would go. NIH has two ways that it does research: intramural and extramural.

Mr. LEHMAN. Right.

Senator MIKULSKI. And the intramural, of course, goes on at the Bethesda campus. And then it gives grants in the community for extramural. So, looking at the 13 Institutes, where would we target our initiatives? Learning from women's health, for example, it was done in Cancer, Aging. We did not go to all 13. We focused on a few.

Mr. LEHMAN. I think two quick recommendations. One, I think the Institute on Aging. I think the quality of life in the aging population is a very, very important area to be working in. You can get some fast results in a lot of these alternative therapies. I think in rehabilitation. Rehabilitation, working with stroke victims and other forms of rehabilitation is an area to get some very quick studies going.

I do think, however, that the separate Institutes will only go so far in this area. They will always be a couple of steps behind, and that is why I think Dr. Jacobs' institute on alternative medicine will be really out there pulling this whole process and kind of breaking new ground as we go along. I think the combination—we will look back in 5 years and say the combination of the traditional institutes with the new office will have made the big difference in this area.

Senator MIKULSKI. Mr. Chairman, I just have two questions, one related to cure research and then the other related to health and wellness research. And about the medical school centers that Dr. Eisenberg raised.

One of the concerns that I have is that we are putting, again, old layers of thinking on new opportunities; that, as we focus on this, we have been talking about the research and cures. I certainly do not want to minimize that. That has led to extraordinary breakthroughs in this society and among other Western democracies.

But do you have thinking about also the research that is going on where what we are going to do is essentially search for new kinds of pharmaceuticals, but they might come from bee pollen, shark cartilage, and so on; and yet, at the same time, we are leaving out the issues around what helps people stay well in the first

place? What helps people stay well? Because it seems that people are now turning to the alternative approaches when everything else has failed, for it to be almost the 911 and the worst case scenarios for either addictions looking to be rescued, and even the research models are based on a cure model.

Now, is that the way to go, or should there be an additional dimension that really creates new ways of thinking, even for traditional Western medicine?

Dr. EISENBERG. May I try to answer? First, on a personal level, the one aspect of Chinese medicine that attracted me to it 20 years ago was the notion that the superior physician prevented illness, the inferior physician tried to intervene. So I share with you that premise.

The data from the New England Journal showed unequivocally that about one-third of the alternative medicine use in this country was not used for people's most serious medical conditions. We do not know why they used them. But our hypothesis is these were people, tens of millions of them, who used them for disease prevention and health promotion. I think that is a big portion of this alternative medicine use. Furthermore, research must be dedicated to that direction, and that brings me to my last point.

NIH is typically made up of people who design interventional studies, not people who design studies to see if something will prevent disease over a long period of time. The Agency for Health Care Policy Research does more of that but is still not designed explicitly for that purpose. The centers that I have suggested would have to take that on as a serious challenge and part of their core mission, because so much alternative medicine is used by people who do not see themselves as ill or sick or diseased, but want to maintain health or become even healthier. And we would have to design studies to look at that connection. Rob, I do not know if you had an additional statement.

Senator MIKULSKI. Mr. Chairman, if I could be indulged for just one last question.

Dr. Eisenberg, as you know, I am a great admirer of your work and your research. I would like to ask a challenging question on the medical center idea.

If that were adopted, my concern is that it would place all power and control for extramural research in the hands of medical schools. And, yet, do you also feel that there are other—and this is not to minimize medical school research. You cannot be a Senator from Johns Hopkins and the University of Maryland and not acknowledge that.

Dr. EISENBERG. What if a center was at the acupuncture school in Maryland?

Senator MIKULSKI. But this, then, goes to the whole issue of centers in the first place.

Dr. EISENBERG. I see.

Senator MIKULSKI. OK. That is what I want to challenge. Not that we do not have a robust extramural program in which a medical school could apply, a nursing school could apply. As you know, Doctor, some of the early massage therapy breakthroughs came from the nursing field.

Dr. EISENBERG. Right.

Senator MIKULSKI. Often not viewed as real stuff, but got real results.

So there would be a nursing school or it could be the center in Columbia or perhaps the one in New England, et cetera. But one of my thoughts would be that, to have a robust extramural program, rather than putting money into five medical schools where the research then would be controlled at a medical school—

Dr. EISENBERG. I can answer that.

Senator MIKULSKI. They are uneven.

Dr. EISENBERG. Right.

Senator MIKULSKI. And I wonder if what you are thinking is, rather than a more robust extramural approach where the facility most appropriate to do the research in conjunction with a Western modality, and I can understand why you want it at an academic teaching facility—or kind of plurality of applicants.

Dr. EISENBERG. I am an advocate for the plurality approach. I do not think it is an either or situation. I think we need to have both. And there are safeguards, I think, in the model to build these centers at medical schools, acupuncture schools, or chiropractic schools.

First, there is the safeguard of people on the faculty at each of those Institutions not allowing the funds to be used unless the studies meet the highest criteria. Second, that \$2.5 billion to \$3 million lets you get all the people together to design the studies and do pilot studies or feasibility studies or small studies. You then must take those data and put them back into the intramural/extramural big NIH pot. You then have preliminary data to say, "Chiropractic is effective for this." Now, we propose to the NIH that they set out perhaps a request for proposals to study this in an authoritative way at a budget that is much more expensive.

But these centers would get you to the first step and allow other Institutions to then participate in the process of taking the research to the next step. So I am agreeing with you. I would hate to see the authority limited to individual centers who then become, to use your phrase, grant junkies. I would also hate this to be one or two or three places. Ultimately, this has to be part of the departments of medicine and surgery of every medical school.

Senator MIKULSKI. That is exactly right.

Dr. EISENBERG. Just like women's health has to be just the way we think.

Senator MIKULSKI. That is exactly what we wanted to establish in women's health.

Dr. EISENBERG. Right. So I just proposed this as a first step, in conjunction with working with NIH and AHCPR, a few centers to get the ball rolling so faculties start thinking, you know, maybe I can make a career out of looking at health issues for women or whether alternative therapies are effective. Maybe that is a valid way to make a living as an academic at Hopkins, Harvard, Stanford, or an acupuncture institute. So they are all permissible.

Senator MIKULSKI. Mr. Chairman, I know you have a long list of witnesses, and I think what this shows is that we need a lot more conversation in this area. But this has been very enlightening; very, very enlightening and very informative.

Senator HARKIN. Again, thank you very much, Senator Mikulski.

Dr. EISENBERG. Thank you.

Senator HARKIN. Thank you. Do you have anything else to add before—

Mr. LEHMAN. No; thank you very much.

Senator HARKIN. Thank you both for being here.

Time is slipping away here. I think what I would like to do is bring up a panel of consumers of alternative therapies. We will bring up the people who have had treatments, three individuals who have been treated by alternative therapy. They will tell us about their illness and the circumstances and decisions that led them to turn to alternative therapy. I want to bring them up here. James Carbone, Sharon Herman and her son, Ryan, and Susan Di Matteo.

All three of you have, in one way or another, had certain alternative therapies. I am extremely interested to hear from you and to hear your stories. We have your testimonies. They will be in the record. But tell me in your own words what happened to you, who you are, and what you went through.

And I thank you all for being here. Some of you came a great distance, and I appreciate it very much.

STATEMENT OF JAMES J. CARBONE, MASSACHUSETTS

Senator HARKIN. James Carbone, we will start with you.

Mr. CARBONE. It is a pleasure to be here this morning, Mr. Chairman, and listening to Senator Mikulski. It is music to my ears to be in a room to hear this, because for so many years working in the nursing profession we talked a great deal about alternative medicine, but nothing ever came about it. So it is really a pleasure to be here, to be in this position.

My name is James Carbone and I live in central Massachusetts. I am married and have three children. I own and manage a health care company that I started in 1984. I have been in this business since returning from graduate school at the University of Minnesota in 1984. My graduate degree in public health capped 10 years of working as a registered nurse in several hospitals, in emergency rooms, burn units, psychiatric, and detox facilities. I am also a veteran and served in the U.S. Navy from 1969 to 1971. I might add, it was the GI bill that financed my nursing school in those early years.

My first exposure to alternative medicine happened in 1979 when my father was diagnosed with terminal cancer. After watching him suffer for 3 months, my family turned to me as the medical person in the family, and asked, "What can we do?" Knowing that he was being treated at one of the most prestigious cancer centers in the world, I felt rather silly talking to him about seeing a Roman Catholic priest who packed a local auditorium two times a year. This healer was having these seminars, and I brought my father to one of these seminars. As it turns out, my father—the folks at this prestigious institution gave him approximately 3 months to live.

The priest was walking down the aisle and held up his hand and said, "There is a man with stomach cancer over here." My father was shocked at how could he know that. He did not introduce himself and there were hundreds of people in the church. I am not a

religious person, and I must say that my father was not a religious person. To this day, no one in that prestigious center in Boston understands why his cancer went into remission, but it did. And he had 5 full years of life before he finally succumbed to cancer 5 years later. So that was my first introduction to alternative medicine.

A little while after that, I was in undergraduate school and one of my instructors was Dr. Chen from mainland China, and she was an acupuncturist. She still practices to this day in Worcester, MA. From there, my mind was open.

We started using alternative medicine in some ways, but it was not until my daughter's three ear infections and three surgical procedures that brought us to seek homeopathic care. And the doctor is a medical doctor from Harvard—and he practices homeopathy almost exclusively now; has almost a 2-year wait to get into his practice. He happens to be, I am fortunate to say, the president of the Homeopathic Institute. Dr. Chapman treated my daughter, Sarah, and her ear infections are gone and have been since.

My wife is a registered nurse and her father was a surgeon. So it was very difficult to get my wife to understand that maybe alternative medicine is the way to go. We only use alternative now, and I hate even using that word. I like the word "complementary" medicine, because the next incident happened to me, and this is really where it took its toll.

I was diagnosed by Dr. Chapman as having ulcerative colitis and suffered for about 9 months. My life really evolved around weight loss and bleeding and being pretty uncomfortable. What I did was, Dr. Chapman said that he would give me remedies that would cure or at least alleviate the symptoms to the point where I was fine, but they would return again in about 3 months. And he said that the stress factors that I was experiencing were just because of the way I dealt with life—running a business, three small children—and that I needed a different way of looking at life.

So he said that I should call Jon-Kabat Zinn at the University of Massachusetts Medical Center and get involved in his stress reduction program. He was also highlighted on the Bill Moyer's Journal, and Dr. Jon-Kabat Zinn is not only a wonderful man, but a very astute researcher. I finished his program. I have been in total remission since finishing his program. It sounds rather crazy. I meditate probably 20 minutes to 1 hour a day, every day. Sometimes I will close my office and my staff will know that I am just doing my thing. But it has given me a whole new focus of life. I could not have made the trip down here had I been suffering from ulcerative colitis. I have been in complete remission and I have lots of people to thank for that.

But when I heard Senator Mikulski talking about complementary, I think of the program at the University of Massachusetts, and for 15 years the physicians there have been referring to Jon-Kabat Zinn's program for people with chronic back pain, terminal cancer, and it is really mainstream. It is not a situation where it is alternative. I mean it is mainstream and it has been for 15 years.

PREPARED STATEMENT

So just to summarize, to be here on a panel and to discuss something that could be mainstream in a very big way in America, particularly since it is much less costly, is very exciting. One caveat I would like to add is that, when Dr. Chapman sent his bill in to the insurance company he asked for \$1 for research for homeopathic medicine. That was rejected every single time with the statement that it was experimental. It did save that carrier thousands and thousands of dollars, but it seems that the word experimental kept cropping up.

So, again, I just want to close by saying thank you. And it is a pleasure and very exciting to be here today in Washington.

[The statement follows:]

STATEMENT OF JAMES CARBONE

My name is James Carbone and I live in Central Massachusetts, 50 miles from Boston. I am married and have three children, ages 8,7 and 2. I own and manage a health care management company, which provides and manages mental health care and substance abuse services for clients in New England. I have been in this business since returning from graduate school at the University of Minnesota in 1984. My graduate degree in Public Health capped 10 years of working as a registered nurse in several hospitals, in emergency rooms, burn units and psychiatric and detox facilities. I am also a veteran and served in the US Navy from 1969-1971. I might add, it was the GI Bill that financed my nursing school education in the early 70's.

My first exposure to alternative medicine happened in 1979, when my father was diagnosed with terminal cancer. After watching him suffer for 3 months, my family turned to me as the medical person in the family and said, "What can we do?" Knowing that he was being treated at one of the most prestigious cancer centers in the world, I felt rather silly taking him to a very popular Roman Catholic priest who packed a local auditorium two times a year. My father, emaciated and weak, was brought to the service and was seen by the famous faith healer. To this day, nobody understands why my father went into complete remission, but he lived 5 very full years before finally succumbing to cancer in 1984.

Since that time my extended family has used a host of alternative methods to treat illnesses, including chiropractic medicine, acupuncture, and most recently, homeopathy and meditation. The adjustment from traditional to non-traditional medicine did not come easily. My wife's father was a surgeon and she is an RN. It took three years of chronic ear infections and three surgical procedures on my daughter's ears for us to finally seek help outside the traditional medical arena because we had been told that she would simply grow out of it. The help and cure came in the form of a board certified MD licensed to practice homeopathy. The results were immediate. Since that incident almost four years ago, we use Dr. Chapman almost exclusively for all our medical needs. The results have been dramatic. A caveat to this is that we have saved our insurance carrier thousands of dollars in procedures, many of them invasive which Dr. Chapman opted not to pursue. However, each time his bill was submitted, the "one"

dollar contribution for research in this field was rejected by the carrier, stating that homeopathy was "experimental."

Lastly, in November of 1993, my doctor diagnosed a problem I was having as ulcerative colitis. Naturally as a nurse having experience treating people with this disease, I was devastated. Each time he treated me with remedies, I got better, but my response to stress remained the same and my disease took more and more out of me. He then referred me to a program that changed my life. The program was the Stress Reduction and Meditation Program at the University of Massachusetts Medical Center in Worcester, Massachusetts. My teacher was Dr. Jon-Kabat Zinn, the founder of the program. Within days of the first class I found myself listening to tapes, meditating daily and practicing a concept called "mindfulness", otherwise known as "stop and smell the flowers."

I completed Jon's program last Fall and have been in complete remission since my third week of meditating and continue the process to this day. My trip here would have been impossible prior to the treatment, as my life evolved around pain, bleeding, weight loss and fatigue. It was a nightmare.

I hope that this committee opens the door to explore and research alternative forms of treatment used successfully for hundred and in some cases for thousands of years. My family and millions of families around the world have benefited greatly from these alternatives. Hopefully the climate for real change has finally arrived.

**LETTER FROM EDWARD H. CHAPMAN, AMERICAN
INSTITUTE OF HOMEOPATHY**

Michael Lux, Public Liason
Health Care Reform Working Group
White House - OEOB
Intake Center Room 287
Washington, DC 20500

March 31, 1993

To the Health Care Reform Working Group,

I appreciated the opportunity to meet with all of you on March 18, 1993. It felt like the beginning of a new era in which we can speak frankly about the concerns of the alternative medical community. Your openness and efforts to look at some of the basic assumptions behind the delivery of health care in the United States were refreshing.

I have had time to digest our conversations, and wish to highlight the following benefits of homeopathic care:

- **Utility** Homeopathy is utilized by people of all ages, at all levels within the health care system: in self-care by consumers and in the treatment of both acute and chronic illness by professionals, whether practicing at a primary care or specialty level.
- **Self Care** Homeopathy is easily adapted to self-care. People educated in the use of homeopathic remedies for first aid take an increased responsibility for their own health, and thereby use fewer health care resources.
- **Low Cost** Homeopathic medicines are extremely inexpensive with respect to current pharmaceutical prices. The average cost of a dose of a homeopathic medicine is a few pennies. In addition, their prescription is not dependent on costly diagnostic studies.
- **Safety** Homeopathic medicines are very safe. Adverse reactions are rare and have no abuse potential. Most homeopathic medicines are regulated as over-the-counter medications by the FDA.
- **Prevention** Homeopathic medicine offers primary prevention by dealing with the roots of illness in the individual. Homeopathy does not treat diagnoses. Rather it treats the individual who is sick by strengthening the homeostatic processes that are responsible for maintaining health.
- **Efficacy** While the effectiveness of homeopathic treatment has yet to be satisfactorily demonstrated by scientific standards, patients around the world have used homeopathy for almost 200 years. An estimated 2.5 million Americans use homeopathy as part of their health care, many as the primary modality.
- **Mystery** No one knows how or why homeopathy works. Homeopathy is a paradigm that has arrived before its time. Homeopathy defies current scientific theories. The unbiased study of the empirical phenomena evident within homeopathic clinical practice holds promise to expand the frontiers of medical science.

The American Institute of Homeopathy would like to make the following recommendations regarding homeopathic medical care in the context of Federal Health Care Legislation.

- **Access** Consumers must be guaranteed the right to choose homeopathic practitioners either for their primary care or in consultation. Managed Care organizations should be required to include alternative practitioners within their panels. The federal government must assure a level playing field in which alternative therapies can compete.

Legislation should include criteria by which new therapies can become part of a federally mandated, basic benefits package.

These criteria must include factors such as patient satisfaction and effect of a therapy on overall functioning and long term health, as opposed to simply a treatment's relative, short term efficacy in one diagnosis to the exclusion of the whole person.

NIH Research is needed into the basic science and clinical efficacy of homeopathy, as well as, many other alternative therapies. Continued support of the Office of Alternative Medicine at the National Institutes of Health is essential to this process. An appropriate percentage of the NIH budget should be allocated for this purpose; currently that percentage is less than one tenth of a percent.

HCFA Federal support of demonstration projects in the utility of homeopathic primary care in managed care settings will be needed to answer questions about cost savings, effectiveness, and patient satisfaction. HCFA should be requested to establish such demonstration projects through the Office of Coordinated Care Policy and Planning (OCCPP).

Licensure The legality of practicing alternative therapies has been challenged in several states. For instance, North Carolina prohibits physicians from practicing homeopathy. Homeopathy is practiced by medical, osteopathic, chiropractic, and naturopathic physicians, as well as, nurse practitioners, midwives, physician assistants, and acupuncturists. The scope of practice or even the availability of licensure of each of these providers varies widely from state to state.

Federal law must be enacted which "prohibits the censure by licensing boards of practitioners based on their use of unconventional therapies unless harm to patients can be demonstrated."

Federally mandated criteria for licensure of health care professionals should be established to assure that qualified alternative practitioners can practice in all states.

Education Federal funding of educational institutions in health sciences should be made dependent on the inclusion of basic information on alternative medical therapies within the regular curricula of those schools.

Homeopathic first aid can be taught in high school, college, and community-based health programs. Incorporation of homeopathic methodology into the education of all health care professionals would help bring safer and gentler medicine to all Americans.

I appreciate your giving these comments wide distribution among the appropriate working groups. Thank you for your consideration of these important issues.

Homeopathy - A Fact Sheet

About Homeopathy

Homeopathy is medical system considered to be an alternative medical therapy. It is a method of assisting the body to heal itself. Homeopathic medicines or "remedies" are derived chiefly from natural substances which are specially prepared by a rigorous pharmaceutical process. The prescribing principle of homeopathy is the "law of similars." Homeopathy is practiced by physicians and other health care practitioners throughout the world. Homeopathic remedies are licensed under the FDA as over-the-counter medicines, and are obtainable from manufacturing homeopathic pharmacies. The American Institute of Homeopathy founded in 1844 to represent homeopathic physicians is the oldest medical organization in the United States.

The Law of Similars "Like Cures Like"

Homeopathic practice is based on a few simple observations. 1) Any medicinal substance given to healthy people provokes a reproducible set of symptoms ("proving symptoms"). 2) When a sick person manifests these "similar" symptoms, a minute dose of that homeopathically prepared medicine is capable of stimulating a curative response in the body. 3) The curative response occurs without side effects, and often leads to the long lasting resolution of chronic symptoms.

The homeopathic model views the signs and symptoms of illness as representing the attempt of the organism to heal itself. The similar remedy acts by focusing and strengthening the healing efforts of the whole organism, rather than attacking a specific disease or symptom. The resemblance of the remedy's "proving symptoms" to the patient's symptoms renders the patient uniquely sensitive to its medicinal action.

The Classical Homeopathic Method

This method involves 1) an interview in which the "totality" of the person's mental, emotional and physical symptoms is noted in detail; 2) appropriate physical examination and diagnostic studies to ascertain the medical diagnoses; 3) the analysis of this data using homeopathic methods to find the most similar remedy; 4) the prescription of a single remedy, given in minute and infrequent doses; and 5) regular follow-up visits, at which the reaction to the remedy is determined, and the remedy is either repeated, changed, or allowed to complete its action without further assistance.

History of Homeopathy In the USA

Homeopathy was developed in Germany by Samuel Hahnemann around 1810; the first homeopathic physicians in the USA came from Europe in the 1825. By 1900 fifteen percent of all practicing physicians here used homeopathy, and there were twenty-two homeopathic medical schools. With the changes catalyzed by the Flexner report the popularity of homeopathy took a steep decline. In the last 15 years that there has been a resurgence of interest prompted by people's experience of the limitations of the present medical model. Currently there are an estimated 500 practicing homeopathic physicians in the USA. A recent report on the *New England Journal of Medicine*⁵ suggested that 2.5 million Americans used homeopathic medicines and 120,000 patients visited homeopaths in 1990.

Homeopathy Is an International Medicine

The contrast between the popularity of homeopathy in the United States and elsewhere in the world is dramatic. According to the World Health Organization homeopathy is the second most utilized health care system in the world. Throughout India, most of Europe and South America homeopathy has wide popularity and enjoys government recognition and support.

The following statistics help place American homeopathy in a worldwide context. In France, 36% of the population use homeopathic medicines; 68% of French physicians consider the medicines effective, and 32% use it in their practice; all pharmacies carry the medicines. The total costs per homeopathic physician per year, including fees, indemnities, lab test, and medications is 46% lower than for their allopathic colleagues. Because of the extra time spent with patients, fees per consultation are 35% higher and the average number of consultations is 25% less. But the overall cost per procedure is 9% less for homeopaths. They order 20% fewer lab tests, per diem indemnities are 50%, prescription costs are 23% lower. In Germany, 20% of the physicians use homeopathic medicine. 42% of British physicians refer patients to homeopathic physicians, and homeopathy is reimbursed by the National Health Service. 45% of Dutch physicians consider the medicines effective.

Homeopathy In Primary Care

The majority of physicians using homeopathy have training in family practice, primary care pediatrics, or general internal medicine, and practice in an outpatient setting. Two styles of practice are common: first, a family practice model with the homeopath serving as the primary care

physician, or alternatively, a referral type practice where patients are seeking alternative treatment for a chronic condition. In this second instance the homeopath functions as a specialist utilizing homeopathic therapeutics after the patient has tried traditional treatments finding them to be an unsatisfactory solution for that specific complaint. 82% of visits with the top 10 diagnoses (asthma, depression, otitis media, allergic rhinitis, headache, allergy, dermatitis, arthritis, high blood pressure) seen by homeopaths are for chronic complaints compared with 48 % of comparable primary care physician population.

Utilization of Health Care Resources by Homeopaths

To the extent that homeopaths are trained in primary care specialties they also serve as the managers of their patient's health care. It is well known that primary care physicians, particularly those trained in family practice, use hospitals and diagnostic procedures less frequently than their colleagues who have been trained in tertiary care facilities. Homeopaths utilize the above services even less than traditional primary care physicians.

The AIH survey indicated that the frequency of diagnostic testing by homeopathic physicians as compared to their orthodox colleagues was less than half (30% vs 68.5%). This behavior arises from the fact that homeopathic therapeutics are not diagnosis driven; rather the therapy arises directly from the patient's symptoms and the physician's direct observations of the patient. Therefore, diagnostic services tend to be used more frequently only in circumstances where the safety of the patient or need for diagnosis require further assessment.

Another important savings in resources arises from the common experience that homeopathy, rather than just controlling symptoms, generally improves the overall quality of a person's health. Homeopathy actually cures many chronic functional complaints, freeing patients from the need for long-term disease management. In addition, homeopathy empowers patients to take care of many of their own health care needs using the over-the-counter homeopathic medicines widely available. Training in self-care is encouraged by most homeopathic physicians.

Additional savings are realized because homeopathic medicines are very inexpensive, actually only pennies a dose. The savings in prescription costs are dramatic. The cost of homeopathic physician services are generally competitive with those of other physicians in the same geographic area.

If All This Is True Why Isn't Homeopathy More Popular ?

First and most obviously, the awareness of homeopathy is limited. The average lay-person or professional in America with no experience of homeopathy associates it with quackery. Nevertheless, most practicing homeopaths have many more requests for their services than they can accommodate. There is a relative shortage of homeopathic physicians. The following points probably explain the lack of physician interest or acceptance.

Despite being practiced for two hundred years, there are many gaps in the theoretical and basic science knowledge pertaining to homeopathy. For instance, what homeopathic medicines are and how they work in the body is beyond the scope of current scientific knowledge. There is no biochemical mechanism to explain the action of these highly diluted substances. The controversy over the activity of microdoses was exemplified by the turmoil following the publication of the now famous studies of Benvenist in *Nature*, (July 1 and 28, 1988). The accompanying editorial was titled "When to Believe the Unbelievable."

Homeopathy represents a change of paradigm. As explained above, it means approaching concepts of health and disease and the physician's role in the process from a very different perspective. Learning the system of therapeutics represents a commitment of time and an expense to already financially overburdened physicians leaving residency training.

Homeopathy is also more difficult to practice than conventional methods; to practice it proficiently requires many years of experience. Rather than choosing from a few medicines commonly prescribed for a specific diagnostic entity, as in the allopathic model, the homeopathic prescription requires individualization of each complaint and the choice of one of several hundred commonly prescribed homeopathic medicines. It is time intensive; patient visits take longer. Insurance companies reimburse by procedure; the time required to perform a service is generally not recognized. Therefore, reimbursement per unit time is decreased; incomes may be less.

Homeopathic Research

Basic science research in homeopathy has primarily involved investigations into the chemical and biological activity of highly diluted substances. Several studies have shown the effects of homeopathically prepared microdoses on mouse white blood cells⁸, arsenic excretion in the rat⁹, bleeding time with aspirin¹⁰, and degranulation of human basophils^{11,12}.

Recent clinical trials with human subjects in Europe have suggested positive treatment association when homeopathic medicines are used in the treatment of allergic rhinitis¹³, fibrositis¹⁴, and influenza¹⁵, while an earlier study showed no apparent effect in the treatment of osteoarthritis arthritis by homeopathy.¹⁶ *The British Medical Journal* ¹⁶ published a meta-analysis in 1992 of homeopathic trials which found 15 of 22 well-designed studies showed positive results and concluded that more methodologically rigorous trials should be done to address the question of efficacy of homeopathic treatment

What Is the Legal / Reimbursement Status of Homeopathy In America ?

The following statistics help place American homeopathy in a worldwide context. According to the World Health Organization homeopathy is the second most utilized health care system in the world. Throughout India, most of Europe and South America homeopathy has wide popularity and enjoys government recognition and support.

The contrast between the popularity of homeopathy in the United States and elsewhere in the world is dramatic. For example in France (data from Boiron Foundation compiled from French Ministry of Health), 36% of the population use homeopathic medicines; 68% of French physicians consider the medicines effective, and 32% use it in their practice; all pharmacies carry the medicines. The total costs per homeopathic physician per year, including fees, indemnities, lab test, and medications is 46% lower than for their allopathic colleagues. Because of the extra time spent with patients, fees per consultation are 35% higher and the average number of consultations is 25 % less. But the overall cost per procedure is 9% less for homeopaths. They order 20% fewer lab tests, per diem indemnities are 50%, prescription costs are 23% lower. In Germany, 20% of the physicians use homeopathic medicines. 42% of British physicians refer patients to homeopathic physicians, and homeopathy is reimbursed by the National Health Service. 45% of Dutch physicians consider the medicines effective.

In the US, however, the perception of homeopathy as outside the spectrum of conventional medical paradigm has led to the loss of at least one doctor's medical license. In North Carolina it is now expressly forbidden for a medical doctor to use homeopathy. A number of physicians have been harassed by their licensing board for using homeopathy. Three states (Connecticut, Nevada, and Arizona) have separate homeopathic medical boards. Two other states (Alaska and Washington) have passed laws making it illegal to censure a physician solely because he practices an unconventional system.

While most insurance companies reimburse homeopathic physician services as they would any other physician's, some insurance companies, including Champus, and several state Medicaid or Blue Shield plans have refused to pay for "homeopathic medicine". PPOs and other provider networks general will not include homeopaths on their rosters. The AIH is not aware of any physician practicing homeopathy in an HMO setting. Yet, physicians in HMO routinely refer patients "out" to homeopaths although the HMO will not reimburse patients for those services. These trends raise serious question with regard to the status of homeopathy in a "national health care system."

There are a number of homeopaths serving in under-served areas both urban and rural. The Indian Health Service has several homeopaths, but the reception of Indian populations to homeopathy has been mixed. Internationally, homeopathy is popular in many non-industrialized societies. In India, for instance, there are over 100,000 homeopathic physicians

Goals of the American Institute of Homeopathy

While homeopathic medicines have legal status under the Federal Food, Drug and Cosmetic Act of 1938, the status of homeopathic practice is tenuous. The American Institute of Homeopathy is currently involved in the pursuit of several goals: achieving recognition of homeopathy as a medical subspecialty; negotiating with HCFA and the AMA for the creation of CPT or HCFA codes that accurately describe homeopathic procedures, increasing the availability of introductory courses in homeopathy to physicians in primary care training and practice, protecting the ability of physicians to practice homeopathy within current state licensing systems, and lobbying for the inclusion of homeopathic practice, along with other alternative medical modalities, within the evolving national medical care system.

The AIH welcomes opportunities to present homeopathy to government and industry. We welcome initiatives like the current activity of the National Institute of Health's Office of Unconventional Therapies to investigate homeopathy. It is the AIH's belief that through basic science research in homeopathy answers will be found that will allow the homeopathic paradigm to be accepted on a much wider scale.

Summary

Homeopathy provides a safe, inexpensive, non-technologically dependent, therapeutic system. It can frequently offer cure rather than palliation, therefore, making it possible to improve the level of health of individuals and reverse the upward spiral of health care costs. The acceptance of homeopathy at this point depends upon either acceptance of historical data or personal experience of the action of homeopathic medicines. There is a great need for basic science and clinical research to substantiate the empirical observations of homeopathic practitioners over the last 200 years, so that homeopathy can take its place in complementing the health care currently available to the American people.

Bibliography

1. Drexler, Madeline. "The Homeopathic Approach". Boston Globe Magazine, 8/14/88.
2. Gorman, J, "Take A Little Deadly Nightshade". New York Time, 8/30/92.
3. Maddox. "When to Believe the Unbelievable" editorial. Nature, July 1, 1988.
4. Lawren, "The Case of the Ghost Molecules". Omni.
5. Eisenberg, et.al., "Unconventional Medicine in the United States". New England Journal of Medicine, 328:4, 246-252, 1/28/93.
6. Coulter, Harris, Divided Legacy, vol 3. North Atlantic Books, 1975.
7. Ullman, Dana. Discovering Homeopathy: Medicine for the 21st Century. North Atlantic Books, 1991.
8. Davenas, Poitevan B, Benveniste J. Effect on Mouse Peritoneal Macrophages of Orally Administered Very High Dilutions of Silica. European Journal of Pharmacology, 1987; 135:313-9.
9. Cazin J, Cazin M, Gaborit JL, et.al. A Study of the Effect of Decimal and Centesimal Dilutions of Arsenic on the Retention and Mobilization of Arsenic in the Rat. Human Toxicology, 1987; 6:315-20.
10. Doutremepuich C, et.al. Template Bleeding Time after Ingestion of Ultra Low Dosage of Acetylsalicylic Acid in Healthy Subjects. Thrombosis Research, 1987; 48:501-04.
11. Poitevin B, Davenas E, Benveniste J. In Vitro Immunological Degranulation of Human Basophils is Modulated by Lung Histamine and Apis Mellifica. British Journal of Clinical Pharmacology, 1988; 25:439-44.
12. Davenas E, Beauvais F, Amara J. Human Basophil Degranulation Triggered by Very Dilute Antiserum Against IgE. Nature, 1988; 333:816-18.
13. Reilly DT, Taylor MA, McSharry C, Atkinson T. Is Homeopathy a Placebo Response? Controlled Trial of Homeopathic Potency, with Pollen in Hayfever as Model. Lancet, 1986; ii:881-5.
14. Fisher P, Greenwood A, Huskisson EC, Turner P, Belon P. Effect of Homeopathic Treatment on Fibrositis. British Medical Journal, 1989; 299:365-6.
15. Ferley JP, Smirou D, D'Adhemar D, Balducci F. A Controlled Evaluation of a Homeopathic Preparation in the Treatment of Influenza-like Syndrome. British Journal of Clinical Pharmacology, 1989; 27:329-35.
16. Shipley M, Berry H, Broster G, et.al. Controlled Trial of Homeopathic Treatment of Osteoarthritis. Lancet, 1983; i:97-8.

Senator HARKIN. Mr. Carbone, thank you very much for coming down and telling us about that. Very intriguing. It is interesting that I had just met a woman this morning whose child had had ear infections and was cured with homeopathy, and you just told me the same thing. Interesting.

STATEMENT OF SHARON HERMAN

ACCOMPANIED BY RYAN WERTHWEIN

Senator HARKIN. Now, Sharon Herman and your son, Ryan. Ryan, welcome. Glad you could make it here today. Are you out of school for the summer?

Master WERTHWEIN. Yes.

Senator HARKIN. Oh, you are. I thought maybe we helped you get out of school a day here. I guess I cannot claim that now. But we are glad to have you here.

Sharon, welcome. I have been foretold about your story and what happened to Ryan. A very intriguing story. Please tell us.

Ms. HERMAN. In 1989, Ryan was diagnosed with a glioblastoma, stage 4, which is an inoperable brain tumor. I took him to New York University. He had Dr. Fred Epstein, Dr. Rick Abed, who are world-known neurologists. They did a stereotactic biopsy, which is a closed-head biopsy. During that, Ryan went into a hemorrhage. He hemorrhaged and went into a coma. They told me at that time that they wanted to do aggressive surgery to wake him up—to see if they could wake him up—but they did not know what damage would be done from that, if he would survive that. They did not know what damage was already done from the hemorrhage. They knew that it was a malignant tumor and that with radiation and chemotherapy he had at the most 6 to 12 months to live.

When I questioned them what would happen if we did not allow the surgery, he said that he would not come out of the coma; that he would die. After a lot of praying, I decided not to agree to the surgery.

They kind of beat me up over that, but with us it was not so much life at all costs; it was the quality. If my son had to die, my son had to die. But to have him suffer and be afraid and maybe not be the person he was, was scarier to me than to lose my son. And I remember telling them that if he was going to open his eyes, God would have to do it. And that is what happened. He came out of the coma by himself in 72 hours.

He was semicomatose for a long time after that. He had no short-term memory. They told us to take him home, make him comfortable. They suggested that we do radiation treatment and then an eight-drug experimental chemotherapy. I did not want to do any more harm to him. We decided to go along with the radiation as long as it did not hurt him, and we did not want to do chemotherapy.

We did the radiation treatment, 6 weeks after he was finished with that, they did another MRI. The tumor had stayed the same. The tumor was 2.5 centimeters in diameter. They again encouraged us to do chemotherapy. Some of the radiologists agreed with us not to. They told us that they expect him to have 6 to 10 months after radiation. They expected that may perk him a little bit, because he slept 22 hours out of a day, and that—enjoy him while we could.

I asked where did I go from there; they told me take him to Disneyland. In February 1990, we did take him. They said that would be his peak time.

Fortunately, after that, a newspaper ran a story about Ryan and I got a lot of phone calls, a lot of letters from different people, and I looked into everything. I looked into Dr. Ben Carson. I looked into the gamma ray surgery. I looked into a hotline for brain tumors by which to see if everything is done that can be done. I was told by all of them that we did everything that could be done. They had nothing. His tumor was too large. His tumor was too aggressive. Nobody mentioned any kind of alternative methods. The American Cancer Society—they were useless.

But one man from Arizona sent me a letter telling me that he knew of this doctor, Dr. Burzynski, out in Houston, TX, who had good success with brain tumors. It was a nontoxic drug that he used. I called up there. I sent for materials. I took him to doctors at NYU, his doctor at Robert Wood Johnson. They all told me the Houston doctor was a quack, that he picked on vulnerable people like myself who had no place to go, that they would bleed us for money.

Senator HARKIN. Who told you that?

Ms. HERMAN. Doctors at New York University, Dr. Abed, and Dr. Mandelbaum at Robert Wood Johnson, they did not believe in this treatment. After that, someone told me that they had seen Dr. Burzynski on a "Sally Jessie Raphael" program several years before that. I called Dr. Burzynski's. They had a tape of that. I asked for it. I watched it. There was a woman on there with a brain tumor. I called back and asked if I could have her phone number, because this was 2 years after, so I could see how she was doing. They gave me her number and five other patients who had similar tumors to my son's. I called all of them. I called Dr. Mandelbaum back and I asked him if he had the phone number of one person with what my son had that I could talk to 1 year later, and he had nobody.

So I decided that I had nothing to lose but money at that time. We did fund-raisers. We cashed in our pension. We cashed in on our IRA's. We took another mortgage out on our home. And we took Ryan to Houston. That was in April 1990.

In May 1990, we had another MRI done, because Ryan started showing symptoms—slurring his speech, being confused. The MRI showed that the tumor had drastically reduced in size. By November of that year, which was 6 months after treatment, there was no trace of the tumor at all. He had another MRI done.

Senator HARKIN. You mean it went away completely?

Ms. HERMAN. Completely; no trace. He had another MRI done 1 month ago and there was still no trace, which is now 2½ years of no trace.

I still take him to New York University. I still take him to Dr. Mandelbaum and I question them. I do talk about it. And they do not talk back. They do not want to know about it. They really do not.

The American Cancer Society—when I took him to Houston, one of the things about an alternative method is the restrictions they put on you. The treatment was supposed to be used and administered in Texas only. I have three other children here in New Jer-

sey. We live in New Jersey. And for Ryan to have this treatment, I was told I would have to move to Texas with him and stay there. And here they give him 6 months to live and they tell me take him out of school, take him away from his friends, take him away from his family. So I worked around that the best that I knew how to do that.

But he was then on the treatment for almost 3 years. He was on a 24-hour infusion pump in the beginning. And then, as the tumor reduced, they reduced the dosage and he is on oral capsules.

Senator MIKULSKI. What did Dr. Burzynski do?

Ms. HERMAN. He put him on an antineoplaston. He had no side effects from it. And I do not know exactly what it does, but whatever it did, from the time he started treatment, Ryan improved and his tumor decreased in size.

The American Cancer Society would not help us. The Hilton out in Houston has 15 rooms that they allocate as their contribution to American Cancer Society for the use of people taking their children for treatment. They would not accept us because of where we were taking our son. Ronald McDonald House would not accept us because of where we were taking our son.

Senator HARKIN. Let me back up. Wait. I have lots of things to do with Ronald McDonald House. Ronald McDonald House would not take your son because he was not going to what—a conventional hospital?

Ms. HERMAN. Because we were not going to M.D. Anderson. They thought we were going to M.D. Anderson in Houston. And when I told them we were taking him to Dr. Burzynski, they said that they only had rooms for people who were going to M.D. Anderson for cancer treatment.

The National Cancer Institute is in charge of some Angel Network Corp., that flies patients. It is a business; different businessmen who have planes that I guess are one-half empty most of time and they will fly people. They would not fly us because they did not approve of where we took our son, although there was no other treatment for him.

Senator HARKIN. I am sorry. Who was this?

Ms. HERMAN. It is called Angel Corp. Networking, and the National Cancer Institute has to approve of where you are going.

Senator HARKIN. They use business planes and stuff and they have seats and they fly. But they would not approve—

Ms. HERMAN. They would not take us.

Senator HARKIN. Simply because of where you were going.

Ms. HERMAN. Yes; they approved us at first when we said we were going. They said there was no problem, give them 4 days notice in advance when we would be leaving. And when I did they said, "Where are you going?" And I said, "To Dr. Burzynski Research Clinic in Houston, TX." And they told us that they were sorry, but the National Cancer Institute does not approve of that treatment and that we could not use their service.

Senator HARKIN. That is interesting that the National Cancer Institute did not approve it. I have here a document from the National Cancer Institute that verifies exactly what happened to Ryan.

Ms. HERMAN. Well, now they are getting involved in it. They are supposed to be starting clinical testing, but this is back in 1989 or 1990 when we started. At that time, they did not want to hear anything about it.

Since that time, this is the only treatment that Ryan has had. He is doing very well.

Senator HARKIN. He looks pretty good to me.

Ms. HERMAN. Yes; he looks pretty good. But he has had—he is not the person that he was born to be. He does have problems from conventional treatment, from the biopsy—

Senator HARKIN. I am not the person I was born to be either, but what the heck. [Laughter.]

Senator MIKULSKI. This is a no-fault environment.

Ms. HERMAN. The radiation treatments have burnt out most of his pituitary glands so he has stunted growth and puberty has been halted. His IQ has been lowered from radiation treatment. He has some demyelination showing in the MRI's from radiation treatment. He has problems with short-term memory and confusion from the biopsy. But, as far as the treatments he has had from Houston, he has had no side effects at all.

He has been back in school for a perceptually impaired class. He does have problems there. But he is happy. He is healthy, and it has been 3½ years now since he was first—almost 4 years since he was first diagnosed.

Senator HARKIN. How do you feel, Ryan?

Master WERTHWEIN. Good.

Senator HARKIN. Good, huh? You have a great smile, too. And freckles and red hair. That is pretty good.

Ms. HERMAN. And I have to say that, you know, I am hearing about alternative methods and everything. But, through the experience that we have gone through, I question whether everyone really wants a cure for things like cancer and AIDS. And I think one of the problems with alternative methods is that—like the American Cancer Society—there are millions upon millions of dollars a year awarded for the research done in conventional methods of cancer treatment, despite the poor history of advancement they have. And when it comes to alternative methods, it is the patients who are funding most of this.

Our bill with Dr. Burzynski had reached over \$300,000. Ryan's medicine was \$365 a day, plus the medical supplies, and our insurance—we have an HMO, and when it is anything outside of their's they have a board that meets and decides whether they should recommend you go or not. And, despite that, there is no one alive who has what my son has who is still alive 4 years later.

Senator HARKIN. Did your HMO pick up any of this?

Ms. HERMAN. They will not pick up any of it.

Senator HARKIN. They will not, even now, after the living proof of this?

Ms. HERMAN. No; they still will not pay off.

Senator HARKIN. They will not go back and pick up the tab or anything?

Ms. HERMAN. No; they will not. They will not.

Senator HARKIN. That is incredible.

Ms. HERMAN. Even with the medical supplies. While he was on infusion every 2 days, I had to change it. It had catheters and things. Even the medical supplies, they would not cover any of that. Anything that had to do with Burzynski's treatment they would not cover.

Senator HARKIN. I think that is unconscionable.

Ms. HERMAN. I do, too.

Senator HARKIN. Just totally unconscionable.

Ms. HERMAN. And I know that is one thing that stops a lot of people. I get very angry. I have a lot of people who call me now, as I called other people, and what stops a lot of them from going is, for one thing—I was very skeptical going. To be honest, I did not expect it to work. But I knew that it would not hurt him and I could not do nothing. I could not sit and do nothing at all. But what stops a lot of people is that you do have to go to Texas.

During the 3 years that Ryan has been on this medicine, there have been numerous times that they have threatened to close the clinic down. Dr. Burzynski has time and time again been in lawsuits from health insurance, lawsuits with—Right now, supposedly, they are trying to take his medical license away, the AMA. It has been a constant struggle. We are never secure in knowing that, yes, he can get his next supply of medicine. It is never there for us. You know, you are never sure.

And it is a very frightening thing to go through something like this. It is one of the worst things that I could think of a parent having to face. What I was not prepared for was the negativity from others for me choosing something that was not what the majority would choose to do. Even though I know that it was a good choice, it was frightening. I would have felt better with the comfort of security of numbers, even though those numbers were fatal numbers.

Senator HARKIN. Sure. That is a very compelling story. Very compelling. And to see Ryan here and to see him smile and looking pretty good, to me, I think is living proof, again, of what we are about here.

The fact that your HMO would not even pick up the tab; I just find that totally unconscionable, I will say that again, that you would be treated that way. I assume you probably cannot change either. I do not know.

Ms. HERMAN. No; we cannot. And with the existing condition—

Senator HARKIN. Preexisting condition. No other health insurer is going to pick you up.

Ms. HERMAN. Ryan has preexisting; no one will pick him up.

Senator MIKULSKI. Senator, if I could just say something about what Ms. Herman has faced. HMO's and most health insurance do not pick up the bill for anything. What she went through was high-risk, and she acknowledges that when she flew to Texas. High-risk and very expensive.

If you talk to your constituents in Iowa you will discover that most HMO's, preferred providers, or whatever, or even their standard insurance, will not reimburse for many things. Nor in many instances, for acupuncture. They will not for back pain or some of the other issues that the gentlemen and scientists have raised.

Senator HARKIN. Right.

Senator MIKULSKI. In many instances, there is a resistance to even reimbursing for chiropractic services. And I think it is an important lesson as we go forth in the health insurance reform debate around both prevention—the wellness aspects—as well as who is going to pay for what, because they could be cut automatically. Just arbitrarily cut out. And I think we need to put all this on our radar screen as we work on health insurance reform.

Ms. HERMAN. They would pay for the chemotherapy, if we chose to do that, the experimental chemotherapy. And they say that the treatment that Ryan has is experimental, but they would approve the chemotherapy—if a treatment does not work, it is experimental. All chemotherapy is experimental. There has been no proof that it works on any of these tumors like Ryan has or anything. I mean, they are experimenting, trying different combinations of drugs to see if it helps at all.

And usually, most of the times, what I have seen with other parents is it does not help. If anything, it hinders. It leaves these children sicker than they started out to be. So my question was: Why is chemotherapy covered by insurance and not considered experimental when alternative methods are considered experimental?

Senator HARKIN. Very true. Sharon, thank you, again, very much.

Ms. HERMAN. Thank you.

STATEMENT OF SUSAN DI MATTEO

Senator HARKIN. Now we will turn to Susan Di Matteo. Susan, again, I have read your testimony. It is very compelling. Please tell us in your own words.

Ms. DI MATTEO. My name is Susan Di Matteo. And on June 15, 1990, 2 weeks after my 26th birthday, I was diagnosed with ovarian cancer and it was advanced at that time. I had 7 months of chemotherapy. The intention was to have 8 months, but they felt it was not working. I had a second surgery in April 1991 for my second-look surgery and at that time had tumor debouching from my liver, spleen, diaphragm, and I had my bowel resected.

They did not know what to do after that point. They said with my age and everything, it is rare. They did not know what course to take next. Finally, in August 1991, it was decided on a bone marrow transplant, which I had at Hahnemann University. After that I did good for awhile. Then I showed progression of the disease. In April, May, and June, I had three treatments of Taxol. In November 1992 to January 1993 I had more chemotherapy; 5FU. And nothing was working.

My cousin told me about shark cartilage. She was in a health food store—

Senator HARKIN. Who told you?

Ms. DI MATTEO. My cousin. I thought it sounded pretty bizarre, but I said, "Well, the bone marrow transplant was kind of bizarre, also." That is what I told my oncologist—you know, I am always searching for these things and I do not know if he agrees with me. But, anyway, I looked into the shark cartilage because I figured I did not have anything to lose. She gave me the book, "Sharks Don't Get Cancer," and I read that. Then I started on supplements on my own.

Then I wanted to get more involved with it, and my aunt told me about Dr. Simone. I started going to him in February.

Senator HARKIN. Of this year?

Ms. DI MATTEO. Of this year. And I started working with him, and he has a vitamin program. Because prior to this time when I first started looking into this, I was really getting bad. I was in bed. I was weak. I could not eat. The disease was really getting the best of me. I was literally in bed. Then I started seeing him and started really getting involved with this, the shark cartilage and the vitamins. I did shark cartilage enemas.

Senator HARKIN. I am sorry. You did what?

Ms. DI MATTEO. Shark cartilage enemas.

Senator HARKIN. Starting this February?

Ms. DI MATTEO. Yes; and I started improving. I heard that results could be seen as soon as 4 weeks, and it was true. And I started getting stronger and was out of bed and was even starting back to work again. I was working part-time again. It really helped me a lot.

Senator HARKIN. Are you still on this treatment?

Ms. DI MATTEO. I am still doing it, yes. I had a bowel blockage last month and that set me back a little bit. But I am back on it again and getting stronger again.

Senator HARKIN. But what you are talking about, from bone marrow transplant, which I understand is pretty painful, too, to Taxol, this is the only thing that has made you feel better, has actually worked?

Ms. DI MATTEO. Well, I was really getting the effects of the cancer. And, you know, this brought my quality of life back. You know. I started a patch. I was on a pain patch also, but my CA-125, which is a tumor marker that they go by, dropped while I was on the cartilage. I went from—it was 1140 and it dropped to 1020. So I know the pain patch would not do that.

Senator HARKIN. That is interesting. Are you taking shark cartilage now?

Ms. DI MATTEO. Yes.

Senator HARKIN. You are now?

Ms. DI MATTEO. Yes.

Senator HARKIN. And the doctors that you have been seeing all along, are they seeing you now? I mean after you have taken this shark cartilage?

Ms. DI MATTEO. Yes.

Senator HARKIN. What have they said about it?

Ms. DI MATTEO. They do not really want to say. He says, "Well, maybe it helped." You know, he does not really say, my regular oncologist. But I know it has.

Senator HARKIN. I mean, obviously, if your markers went down. I do not know that much about the medical aspects, but it seems to me there are some proofs that this has helped. Is that right?

Ms. DI MATTEO. Yes. And Dr. Simone has paperwork.

Senator HARKIN. Where were you able to take this? You took it from Dr. Simone. We are going to hear from Dr. Simone. Where did this take place? In what State?

Ms. DI MATTEO. His office is in New Jersey, and I live in Pennsylvania.

Senator HARKIN. Interesting. How often did you have to take these treatments?

Ms. DI MATTEO. Every day. It is 14 teaspoons of shark cartilage mixed with water to make enemas every day.

Senator HARKIN. What did your oncologist say about your seeing Dr. Simone? Did he say anything about this? I mean, he knows about it; right?

Ms. DI MATTEO. Yes; he knows that I will always be looking for, you know, ways to help myself because he did not really have anything else to offer me.

Senator HARKIN. So, again, I guess from the three of you who are here, I am trying to figure out a common thread as to why you all decided to seek alternative therapies. And, again, tell me in your own words again, Mr. Carbone, why did you decide to seek an alternative therapy?

I have just been informed we have a 20-minute vote on. But please go ahead. Why did you decide to seek alternative therapy?

Mr. CARBONE. There were really two reasons. Now, the first reason is that I was trained as a registered nurse and, upon returning from the service, spent 10 years working in the traditional methods in different units; intensive care, burn units. And it was always working with people after they were injured or in diseases that I thought could be prevented. So I had little faith in the traditional medicine.

And after being exposed to Dr. Chen in acupuncture and what she was able to do, I really felt that there had to be a better way. So I really just got out of the mainstream totally.

Senator HARKIN. OK.

Mr. CARBONE. So that was primarily it. Also, in traditional medicine, I knew what the treatment was going to be—I will let you get that. If you are going to vote on the bill, go right ahead.

Senator HARKIN. Thank you, we have a few more minutes. Go ahead, please continue.

Mr. CARBONE. They wanted to treat me with cortisone, lower/upper GI, MRI's, when I was diagnosed with ulcerative colitis, in the traditional method. And I decided I was not going to put myself through that. So, again, it was out of an acute illness more than anything else.

Senator HARKIN. And, Sharon, again, you decided to seek this because nothing else was working?

Ms. HERMAN. And I found the conventional methods unacceptable. I read up on what chemotherapy and the effects of it and what the results were, what the expectancy of it doing anything for him. And it was not worth it. But I went for alternative because I did not want to lose my son.

Senator HARKIN. And, Susan, you sought out alternative therapies because you had tried so many things?

Ms. DI MATTEO. Right. And basically, at this point, I did not really want anymore really toxic treatments. I felt that I wanted to build up my body, and that would just bring me down. And this virtually has no side effects. So that was a big factor.

Senator HARKIN. Let me just ask you, at the point in time that you decided to try alternative therapies, were you a believer or would you say more skeptical? Did you say, "Well, I will try it, but

I am not so certain"? What was your state of mind at that time? Were you sort of skeptical of this?

Mr. CARBONE. I was skeptical until my brother-in-law's best friend, who was diagnosed with a very crippling form of arthritis, was in a wheelchair and he found a man that worked with bees in Vermont and, after 5,000 stings, is playing racquetball three times a day. Now, if I can go to a doctor who—

Senator MIKULSKI. Which in Congress—we have been stung so much.

Mr. CARBONE. That is right.

Senator MIKULSKI. Particularly this crowd here.

Mr. CARBONE. That is right. I mean, he literally carried around a jar of bees and would sting himself 10 to 25 times a day at least.

Senator MIKULSKI. We ought to take that into those Medicare negotiations. [Laughter.]

Senator HARKIN. I would rather stick with bee pollen.

Mr. CARBONE. That is right. So I figured that this was a much less painful way of going, by taking remedies in homeopathy and acupuncture. So that is why I went that route.

Senator HARKIN. How about you, Sharon? Were you kind of skeptical of this?

Ms. HERMAN. I was very skeptical. I did not expect it to work. I did not expect it. When I was out there in Houston I saw a lot of other patients, because we had stayed and we would take him every day to the clinic. And I met a lot of them. After seeing them, I saw that I started losing some of my skepticism. I do not know what happened to a lot of them afterward. There have been a lot of failures. A lot of people come as a last resort so they are very sick when they get there.

But for the majority of them, they improved. You know, I do not know if they stayed or if they are still alive now. Some I know are not. But their quality of life improved. Some children who had never been in school went to school, and they had a better life. So I lost a lot of my skepticism.

Senator HARKIN. I see one of the great promoters of looking at this whole area of alternative therapies, Senator Pell. Senator Pell is here. He is not a member of this committee, but a distinguished Senator, Chairman of the Foreign Relations Committee. I would like to invite him to come up. If you would like to come up, Senator Pell, and join us. I know we have a vote on here. And I see we have also been joined by Senator Reid from Nevada, who is a member of this committee.

Senator MIKULSKI. Senator Harkin, I have to excuse myself, not only for the vote but then for a goodbye conversation with Dr. Healy.

Senator HARKIN. Right. You mentioned that.

Senator MIKULSKI. I will not be able to return. But I look forward to working with you. Dr. Berman, I am sorry I am going to miss your testimony. And to all, if I could, those on the panel, Mr. Lehman talked about the pallbearers versus the torchbearers. Each one of you faced your family being a pallbearer. Then you have turned that tragedy into being a torchbearer yourselves, and we thank you for your heroism as well as your boldness. We hope that God continues to bless you.

STATEMENT OF HON. CLAIBORNE PELL, U.S. SENATOR FROM RHODE ISLAND

Senator HARKIN. Thank you very much. We are going to have to leave. Senator Pell, did you have any statements you would like to make?

Senator PELL. I have a statement that I would hope could be put in the record.

Senator HARKIN. Absolutely.

Senator PELL. I just wanted to come by to pay tribute to the initiative and leadership that you have given this whole project. I think it has given it a respectability that it did not have before by having the Congress itself establish it. I just wanted to wish you well. And anything I can do to help I would like to do.

[The statement follows:]

STATEMENT OF SENATOR CLAIBORNE PELL

Mr. Chairman, I thank you for your courtesy in allowing me to submit testimony for this important hearing. In addition to the many programs that your subcommittee funds that I care deeply about, including the Pell grant program, I am extremely interested in the subject of today's hearing—alternative medicine. I am also a strong supporter of the NIH's new Office of Alternative Medicine, whose mission it is to explore this important and developing area.

I strongly support the creation of this Office and I want to thank you, Mr. Chairman, and offer my sincere congratulations—from the bottom of my heart—for your initiative and leadership in establishing it.

Many Americans, and I include myself, are both interested in and use alternative medical practices to foster or regain good health. I have had some excellent experiences with alternative care, and I hear anecdote after anecdote about successes that are unproven, and that may even seem, at first glance, a bit unusual. I offer as one example an article that appeared in Tuesday's Washington Post. Entitled "Hope Springs Eternal," the article describes the dramatic improvements experienced by some multiple sclerosis patients after taking bee venom. I certainly don't know if bee venom does hold promise for these individuals, but I am sure that you would be as moved as I am to explore this possibility if you read this fascinating story. I would like to insert this article by Ken Ringle in the Record at the conclusion of my remarks.

Last March, I had the opportunity to go out to NIH to meet with the Director and staff of the Office of Alternative Medicine. I must say that I was very impressed by what I heard—by the commitment of its director, Joe Jacobs, and its small staff—to investigating and either substantiating or debunking practices that fall into the realm of "alternative" or "unconventional." And I was impressed with what appeared to be a slow but growing integration of the work of that office with the broader health research goals of the NIH.

Mr. Chairman, the very nature of good science is to formulate hypotheses and test them. It seems to me that we have heard people all over the country describe the successes of numerous alternative practices and therapies, and that we owe them a sound government analysis of those practices which appear to work. We also owe them a promise to rid the marketplace of charlatans, opportunists, and those who would—out of greed—give false hope to the sick or dying or deter them from seeking lifesaving care.

I would like to urge you, Mr. Chairman, to give your full support to the mission of this office and to increase the funds appropriated for this purpose.

I know that some concerns have been raised as to whether the Office of Alternative Medicine is fulfilling its mission. And I hope that this subcommittee will explore that issue fully, not only because taxpayer dollars are being used, but also because this Office needs the confidence of both the NIH and the American people if it is to succeed. But I also believe that it is very hard to accomplish one's mission on a shoe-string budget, and from what I understand, the Office of Alternative Medicine has been flooded with inquiries and requests for information since it opened. I hope that we can give it, and its small staff, the tools it needs to undertake the job that I believe needs to be done.

I thank you again, Mr. Chairman, for your courtesies and for your strong leadership in this area.

[From the Washington Post, June 22, 1993]

HOPE STINGS ETERNAL

(By Ken Ringle)

Pat Wagner's house looks much like any other suburban rancher in the Waldorf neighborhood of Pinefield—apple tree in the front yard, two-car garage and, on the kitchen window, stickers with slogans like "Grandmothers Are Special" and "Start Each Day With a Song."

But if you watch awhile you might notice the two beehives in the back yard, and you'd certainly note the traffic coming and going—crippled people in wheelchairs and electric carts, unsteady people with canes and walkers, wasted, twisted figures carried in and out through the extra-wide front door—all looking to get stung.

Most of those entering and leaving suffer from multiple sclerosis, the degenerative nerve disease for which there is no known cure, and for them 5431 Lucy Lane in Charles County has become a place of cautious hope.

From 11 a.m. to 2 p.m. each Monday, Wednesday and Friday, Wagner and an ever-shifting handful of volunteer assistants treat the lethargic, numbness and paralysis of a growing number of MS sufferers with bee stings. She needs no medical license because she asks for no fee and promises no cure, but with the zeal of a missionary among the tribes of the heathen, she urges those who seek her out to believe in an infant science called apitherapy. And under her hands—and as she insists, the hands of anyone attentive to the few known precepts of bee venom healing—some of the lame are walking, the numb are feeling and the physically drained say they're finding new life.

John Richert, a neurologist and the director of the Multiple Sclerosis Center at Georgetown University Hospital, says there is no scientific proof that bee stings benefit MS patients. "But while you have to be skeptical you can't just dismiss the anecdotal evidence that there's more to all this," he says.

"No one's ever done the sort of large double-blind study you need to evaluate something like this," he says.

Meanwhile, listen to Perry Holmes Jr., a 38-year-old Fort Washington real estate broker diagnosed with MS four years ago who, after four bee sting sessions with Wagner, reports increased strength in his legs, improved sense of balance and an enormous increase in his daily energy level.

"I'm not going to get my hopes up yet about the long-term benefits," he said last week, waving a still-unsteady hand at the two dozen people crowding Wagner's kitchen and living room, "but I promise you, something is happening in here. We can't all be crazy."

Part of the difficulty in evaluating any treatment for MS lies in the unpredictable course of the disease. It has no known cause and rarely affects any two people in exactly the same way. It usually strikes gradually (numbness in the feet is a frequent first symptom) and, as it progresses, inhibits any of a number of motor skills. But it can just as easily disappear entirely for months or years, or reduce a healthy person to a permanently frozen skeleton in a matter of months.

"Sometimes people show extremely dramatic improvements, for no clear reason, just as we're ready to give up on them," says Richert. "In fact, it's not at all clear that MS is just one disease. The symptoms we associate with MS may be the product of several diseases, one of which may respond to one kind of treatment while another does not."

Pat Wagner, 42, is her own best advertisement for bee stings. She was diagnosed in 1970 with chronic progressive MS, the most serious variety, and within four years she retired on disability from her job as a program assistant for the U.S. Department of Labor.

Over the next two decades she experienced recurring and increasingly severe periods of numbness in her legs, weakness in her arms and torso, muscle spasms, blurred vision, impaired hearing and balance, bladder and bowel incontinence and severe lethargy. By early last year, she was totally wheelchair-bound, couldn't read or even feed herself. Doctors told her there was little hope of improvement. Kristy Hickey, who lives just across the street, remembers attending a wedding where Wagner was so weak and helpless she had to be carried in.

But last year a friend of the family who had heard about apitherapy told Wagner about it and on March 24, 1992, she had herself stung for the first time. "When there's no hope, you try anything," Wagner explains.

A friend of a friend brought over some bees in a jar, she remembers. "He came into my bedroom—you have to realize none of us knew anything about how to do this then—and took out a bee and had it sting me on the inside of my left knee."

If you have MS, Wagner says, "your legs feel frozen . . . like ice water's running through your veins. But within 20 minutes it felt like warm blood was flowing down my leg. My whole leg began to get warm. I couldn't believe it. Then I took four or five more stings on my legs and three on the top of my body and soon my whole body felt warm. It was like this surge of energy through my veins. I no longer felt exhausted."

She was still largely immobilized and continued to suffer from blurred vision, she says. But after two months of additional stings, administered in a comparably haphazard fashion, "my hearing was totally back and I was out of the wheelchair and walking with a cane."

Even more significant, she says, was her sense of renewed energy and empowerment. "I had been taking all

this medication, yet I was exhausted all the time, and so depressed I'd cry at the drop of a hat. Now I felt I could do anything."

Today, though still troubled with minor vision problems and occasional uncertain balance, Wagner is a virtual whirlwind, organizing seminars on apitherapy, handing out literature, phoning up television stations to spread the word and turning her home into a free clinic.

She has knocked out a wall in her house to accommodate the crowds of wheelchairs, printed up bee-bearing business cards ("Ask the Bee Lady about Honey Bee Therapy") and written articles for the quarterly newsletter of the American Apitherapy Society, BeeWell.

"When you touch somebody's arm or leg and they feel nothing, that bothers me," she says. "I know what that's like. I can't stand it and I want to help."

Stuart Goodman, Wagner's neurologist at Southern Maryland Hospital in Clinton, confirms Wagner's description of her condition last year. But he says it's not unusual for an MS patient in that condition to improve so dramatically, bee stings or no bee stings. And what's least clear of all, he says, is whether the improvement is physical—i.e., organic—and permanent or merely symptomatic and temporary.

"For example," he says, "I have a number of MS patients now who've been taking bee sting treatments. I'm not sure any of them have actually repaired their nerve damage. But all of them say they feel better."

The Kitchen Clinic

It's a little before noon on a typical sting day on Lucy Lane, and the atmosphere in Wagner's house lies somewhere between a faith-healing session and a Tupperware party. Some two dozen people mill around inside, crowding all the way to the family room mantelpiece that holds the dance trophies of Wagner's daughter Jessica, a 1982 princess in the Waldorf Turkey Bowl.

At the kitchen table, under a ceiling-hung stuffed bee and next to an apitherapy license plate ("Bee All That You Can Bee"), Pat Wagner sits questioning her patients, teasing them, calling greetings and being cheerleader as much as therapist. On the crowded table beside her sits a large Breckenridge Farms Mixed Nuts jar, holes in its blue plastic lid, in which several dozen bees can be seen feeding on honey-soaked tissue and buzzing against the sides.

From time to time Wagner lifts the lid and sprays the bees with water from a plant mister "to quiet them down and make them easier to catch."

After learning the specific complaint of each patient and his previous dosage (patients work up to as many as 20 stings per session) she opens the jar, extracts a bee with a pair of long-handled tweezers and applies its abdominal stinger to a bared part of the patient's body, then drops the dying bee into an empty mustard jar.

"Here comes a bladder sting [for incontinence]. You're gonna love this," she tells a woman from Vienna, Va. "Just roll down the top of your panties. Just the top now! Everybody's watching and you're gonna be on 'Candid Camera.' Just tell your husband you got your BS degree at TSU. That's your bee sting degree at Ten-Second University."

The woman wants to be stung at home next time so she won't have the two-hour commute to Southern Maryland, so Wagner calls to her husband, Ray ("We call him 'Sting Ray'"). "Honey, we need a jar of bees to go!"

This is the fourth session for the Vienna woman, who says she's noticed no real improvement in her own troubled balance and uncertain walking, but has noticed improvement in others. "If you've got MS you grasp at straws," she says. "What do we have to lose?"

Wagner's visitors range from a Chilean economist retired from the Organization of American States to a tattooed firefighter with the Silver Hill Fire Department. The latter administers the test stings—antidote kit at the ready—on all first-time patients to test their allergic reaction before any treatment starts.

Some patients keep records for Wagner, others hand around liability waivers and literature. Treatment is roughly first-come, first-served, but if someone has a special need others willingly step aside.

"Those people in there are so warm and so caring it's unbelievable," says Reginald Herron, echoing the volunteered remarks of almost all of Wagner's visitors. Herron, 35, lives off Martin Luther King Boulevard in Southeast Washington and had brought his father for his first treatment. "It's like a big family for everybody in there . . . really beautiful."

Nobody, he says, asked him for any money or even mentioned it. He had to ask the whereabouts of the small honey jar marked "I live \$" where donations can be left. Wagner says her highest weekly take so far is \$65.

One of those getting stung is Ed McIver, 45, a wheelchair-using allergist, retired on disability, who was diagnosed with MS during his first year in Howard Medical School. He receives 14 stings in this, his third session, most of them in the back of his neck. Since starting such treatment three weeks ago he's noticed "a significant increase in energy," much easier breathing and speech, plus some additional mobility in his left hand, which he says was curled into a claw before and has somewhat straightened out.

"It's hard to know why this works," he says. "Emotions play so heavy a part in this disease it could be just the support group here . . . knowing someone who has the disease is getting better. It's so easy to be depressed with a disease that has no cure."

But in addition, he says, "the stings seem to stimulate the immune system and there is some indication the bee venom forces the adrenal gland to produce steroids. Steroids are one thing used to treat MS, often with some success."

It also helps, he says, "to believe in acupuncture. If you notice where she's stinging people, it's basically in the same trigger points they use for acupuncture."

Perhaps the worst case on hand is that of Irene Phelps, 46, of Upper Marlboro, whose thin body is curled in a wheelchair and who talks only with difficulty. She's suffered from chronic progressive MS for 11 years and has come for her sixth session, taking 20 stings.

Before treatment started, she says, she couldn't even straighten her legs. Now her body is much more relaxed and she's less tired.

"It gives you a little hope. Doctors give you no hope at all," says her husband, John, 55, a semi-retired contractor. Like most of those in the Wagner house, the Phelps learned of Wagner and apitherapy from a local television news show last fall, "and it looked like something natural that we should try," John Phelps says. "I'm a country boy and I know there are a lot of natural things we've forgotten that are better than what any doctor can do."

The Beekeeper's Discovery

Apitherapy probably started with the first bee, but most of its formal history in this country appears to lead back to a Middlebury, Vt., beekeeper named Charles Mraz. Mraz, now 88, says he's been "fooling with bees since I was 14, and all the old-timers then used to tell me bee stings were good for arthritis. And of course, being 14, I thought they were crazy."

Then, when he was 28, he was stricken with rheumatic fever, which left him not only heart-damaged but with pain in his joints so severe "I couldn't get out of a chair."

After suffering for six months, "I remembered what those old guys had said and decided what the hell and took a couple of bees and stung myself on either side of one knee. I woke up the next morning and the pain was entirely gone. And that was quite a shock."

In the years since, Mraz has talked up his treatment to doctors, and offered it free to anybody suffering from rheumatic diseases. Then, in 1986, he says, a woman came to him with MS. "I told her I didn't know anything about MS. She said, 'Well, you treated me for arthritis five years ago and the symptoms went away. When they came back I went to a doctor and he said they were really due to MS. So you were really treating MS last time and it worked. Treat me again.'"

Three years later he formed the American Apitherapy Society together with Bradford Weeks, a physician in general practice in North Hartland, Vt. Weeks says his role has been to "provide the scientific documentation for the extraordinary work done by Charles Mraz. People come from all over the world to be treated by him, but he keeps no records. Nor does he charge them. As he always says, he's not a doctor, he's just a beekeeper. So I started keeping records for him. We now have a computer database with about 6,000 patients on it, more than 300 of them with MS."

Their efforts, he says, have triggered extraordinary research interest in places like France and Korea, where he says he and Mraz have been flown in to lecture, and where major government scientific studies are underway. "But until recently there's been no corporate or government money available for major controlled studies in this country. The potential corporate profits just aren't there."

According to Georgetown Hospital's Richert, the most intriguing aspect of bee venom is a compound in it called apimin. The symptoms associated with multiple sclerosis, he points out, result from the inflammatory degeneration of the nerve sheaths that carry electrical signals to and from the brain. "When a sheath degenerates, it doesn't conduct electricity very well, so the nerve impulses get blocked. Apimin doesn't stop the degeneration, but it improves the conductivity of the degenerated sheath. That may very well be what's at work in the MS cases where bee venom therapy has shown success."

In addition, Weeks says, the venom contains two extraordinarily powerful anti-inflammatory agents, melittin and adolapin, which appear to fight the neural sheath inflammation itself.

Richert, however, says bee venom is merely the latest in a succession of natural substances touted as promising cures for MS in recent years. Co-

bra venom, for a while, was another.

He himself has tracked four patients being treated with bee venom therapy, none of whom, he says, has shown any long-term improvement.

Yet "there's more than a little evidence that beekeepers as a group are unusually healthy and long-lived, and may have unusual immune systems. Maybe bee stings have something to do with that. We have a grant application in to fund a major double-blind

study on bee venom, where neither the patient nor the physician knows who's getting the tested drug and who's getting the placebo. That's the only way to prove a treatment's effectiveness."

Meanwhile, Weeks says the immune-stimulating properties of bee venom have prompted its use in the treatment of other diseases such as lupus, asthma and, inevitably, AIDS.

It's only an experimental treatment for AIDS, he says. No one is calling it a potential cure. "We have 10 people with AIDS being treated with bee venom now," Weeks says. "The results are very, very preliminary. The biggest problem is that people with AIDS are taking so many drugs simultaneously it's almost impossible to say for sure which one is causing any beneficial effect. But there are some promising signs."

Anecdotal Evidence

Back at Pat Wagner's, Jane Terry is explaining how MS affects the social life of a modern young woman in Georgetown. "The biggest problem," she sighs, "is leaving puddles. If I could cure anything it would be the incredible weakness in my left leg and foot so when I know I have to, I could run to the john in time."

Terry, a wide-eyed 26, makes MS sound a bit like an unfair parking ticket—really annoying, but, like, what are you gonna do?

She was diagnosed with MS during her junior year at Mount Vernon College, and has tried "every therapy around. . . . Nothing did much. I was so lethargic it was all I could do to take my dog out. I was *pathetic!*"

But since beginning bee stings three weeks ago, she says, she's had "this huge rush of energy. I run around now all over the place. And though I still leave puddles occasionally—this is really gross and embarrassing but you can't imagine how you treasure small victories—I haven't wet the bed! For the first time since I had MS!"

Today she's had more bladder stings plus a number of stings on her left leg. As she's explaining how things could really be much worse, she suddenly stops and makes a startled "Oh!"

"I just crossed my legs!" she says.

It's true, she did.

"But you don't understand," she says. "I haven't done that for two years. And look at this!"

She holds up her left leg and rotates her foot. The ankle is red and throbbing, covered with bee stings, painful-looking as an open wound. But Terry is smiling like it's Christmas.

"Isn't that a hoot?" she says.

Senator HARKIN. You have been a great help and you have always been there to help us in getting this thing underway, and I appreciate that help and support very much, Senator Pell.

We are going to have to go vote. We will have a little recess here, and I will try to get back as soon as I can. It will probably be about 10 or 12 minutes. We will be back in about 10 or 12 minutes. I will excuse this panel right now, when we return we will bring up the providers panel. Thank you.

[A brief recess was taken.]

Senator HARKIN. Now, we will turn to our providers. We have Harvey Kaltsas. We have Charles Simone. And we hoped to have Jameson Starbach, but she is the one that was delayed in Minneapolis and I assume she has not showed up. And then we are going to hear from my former colleague, Congressman Berkley Bell.

Again, I apologize. You try to pick the best days for these hearings and Lord only knows what happens, and there is a big budget battle going on the floor and I have to be involved in that. So we had to have some meetings on that to try to work out some problems in the budget. Again, my apologies, but that is just life around here. You understand it Berkley. You have been through it for 10 years.

But, again, to me this is one of the most important hearings that I have had this year. And I want to state for the record, this will not be the last of these hearings this year. I intend to followup with more hearings. We are going to have a new director of NIH come in soon. I will be meeting with that person. We are going to have a whole new set of hearings sometime later this summer or early fall.

PREPARED STATEMENT OF DR. J. JAMISON STARBUCK, PRESIDENT OF
THE AMERICAN ASSOCIATION OF NATUROPATHIC PHYSICIANS

Dr. Starbuck, who could not be with us, a naturopathic physician, President of the American Association of Naturopathic Physicians. I will put her statement in the record in its entirety.

[The statement follows:]

STATEMENT OF J. JAMISON STARBUCK

Senator Harkin, members of the Subcommittee, ladies and gentleman: on behalf of the American Association of Naturopathic Physicians I would like to thank you for inviting me to provide you with important information about the naturopathic medical profession and our role in the growing field of alternative medicine. In particular, Senator Harkin, my colleagues and I would like to thank you for your leadership in establishing the Office of Alternative Medicine. And, Senator Murray, we appreciate your on-going support of the naturopathic medical option.

I am an attorney and a naturopathic physician and practice both law and medicine in the Pacific Northwest. I also serve as President of the American Association of Naturopathic Physicians (AANP), the national professional organization of licensed or licensable naturopathic physicians. The AANP National Affairs Department recently submitted an extensive document to the Task Force on Health Care Reform. I am pleased to be able to further our participation in federal attention to the issue of health care in America.

Like all naturopathic physicians, I am a primary care, general practice physician who specializes in the clinical use of natural therapeutics. I attended a four year graduate-level medical school where the entrance requirements are standard undergraduate premedical training and a Bachelors degree. Naturopathic medical training parallels that of conventional medical schools, including courses in basic and clinical sciences, diagnostics, therapeutics, and extensive supervised clinical train-

ing. Naturopathic physicians receive a Doctor of Naturopathic Medicine (ND) degree. In states where they are regulated, naturopathic physicians must pass national and state board examinations for licensure, and their actions are subject to review by a State Board of Examiners. There are approximately one thousand licensed or licensable naturopathic physicians in the U.S.

Naturopathic medicine represents a paradigm quite different from that of conventional medicine. It is holistic medicine at its best. Together with its emphasis on patient education and lifelong prevention, its many modalities offer great diversity at significantly lower cost. Modern naturopathic medicine in the U.S. has grown out of rich traditions in medicine around the globe. Naturopathic physicians are the only licensed primary-care medical providers in the U.S. who are specifically trained in the philosophy of natural medicine and the clinical use of natural therapeutics. Many of the methods used by our profession have been employed successfully for thousands of years by medical practitioners worldwide. Our key modalities—clinical nutrition, botanical medicine, homeopathy, hydrotherapy, physical medicine, counseling and oriental medicine—are used to both prevent and treat disease. Specific therapeutics are used in conjunction with a common commitment to treating each patient as a unique and integrated individual.

Naturopathic medicine has a long history in North America. In the U.S., naturopathic physicians have been licensed as primary care providers for over 75 years. The profession suffered a decline earlier in this century, primarily due to increased influences of technology and politics on the practice of medicine. During the past two decades, naturopathic medicine has experienced a resurgence as a growing number of Americans have come to understand the effectiveness of nutrition and natural therapeutics, and the importance of the mind/body connection. Naturopathic medicine has great depth and breadth to offer the American public in this critical time.

Rapid advances have come with renewed interest and increased participation in the naturopathic profession. Since 1975, our profession has achieved the following: the development of an independent nationally standardized licensing examination; the establishment of scientifically based natural medicine curriculum in naturopathic medical colleges; the creation of a national professional association (AANP) with an education based standard for membership; creation of an academic accrediting agency recognized by the U.S. Department of Education; the convening of an annual national convention for educational and political purposes; the establishment of a House of Delegates which meets annually to set national standards and develop professional policy (the House of Delegates consists of representatives from twenty-five state naturopathic associations, three naturopathic specialty societies, and the two U.S. Department of Education recognized naturopathic medical colleges); the development of research departments at naturopathic medical colleges and participation in federal investigations of alternative medicine; publication of a peer review journal; the expansion of licensure to two new states (Alaska, Montana); and the reinforcement of existing state practice acts and continuing on-going efforts at new state licensure.

The naturopathic medical profession is expanding swiftly. Currently, seven states license naturopathic physicians. Seventeen new states are moving toward licensure; a new medical school is scheduled to open in the fall of this year; applications to naturopathic medical schools doubled in last five years. The profession is demonstrating strong and healthy growth, in sync with sociological and cultural development.

The obstacles faced by the profession are primarily those of funding and of acceptance by the dominant school of medicine. While our medicine has a sound foundation in science and tradition, it has been extraordinarily difficult for us to compete in a political environment that discriminates against alternative systems.

In practice, naturopathic physicians frequently refer patients to a wide variety of other health care professionals, including medical doctors. Most medical organizations, however, while acknowledging the value of some naturopathic methods, generally oppose naturopathic medicine. Over ninety insurance companies currently offer reimbursement for naturopathic services, yet coverage is inconsistent from state to state and from company to company. Only a few states require insurance companies to consider naturopathic physicians as physician providers for reimbursement purposes. Unfortunately, the dominant medical establishment and federal and state governments have yet to fully recognize the therapeutic value and cost effectiveness represented by the naturopathic profession.

In recent years, when independent and objective bodies of scientists, educators and regulators have examined naturopathic medicine as it is practiced by licensed professionals, they have concluded that it is safe, effective, and cost-effective. (Reference to Safety, Effectiveness, and Cost Effectiveness in Naturopathic Medicine, a

publication of the American Association of Naturopathic Physicians.) Naturopathic physicians are able to put into clinical practice many credible elements that make up the broad panoply of alternative medicine. We have the potential to thoroughly research, through scientific data and clinical trials, the value of natural therapeutics. Since our doctors are trained as general, family practice physicians, we are well able to help fill the current critical health care needs arising in rural areas, in Public Health Service, in Indian Health Service, in migrant communities, and in underserved populations throughout the country.

As Dr. David Eisenberg pointed out in his January 28, 1993 article in the New England Journal of Medicine, consumers are hungry for medical options; in a one year time frame, 34 percent of Americans used some form of alternative health care. Senator Harkin, we applaud you for funding the Office of Alternative Medicine, and for bringing alternative medicine to a new level of well-deserved visibility and debate. Prior to the establishment of the Office of Alternative Medicine, the government was too often complicit in denigrating the alternative medical community and denying the consumers it serves from equity in federal funding. It is an unfortunate paradox that today, at the same instant that one branch of the federal government, namely the NIH through the Office of Alternative Medicine, is beginning to seriously consider the worth of non-traditional medicines, another branch of the government, the FDA, is taking steps to drastically narrow the availability of that medicine. The Office of Alternative Medicine is an excellent start in widening the scope of health care reform. It is now crucial to continue this shift in public policy.

Not all unorthodox therapies achieve the results they claim to, nor are they all safe; conversely, many so-called unconventional therapies are highly effective and deserve further attention, scientific investigation and government support for their use. We urge this office of the NIH to go forward in providing research dollars and to support truly multi-disciplinary approaches to health care. This strategy would well serve American citizens who are in need of more effective health care. It would also provide some measure of repair to our failing health care system and would allow an intelligent and reasoned exploration of viable medical options.

The American Association of Naturopathic Physicians is ready to assist in this process. Our physicians and administrative staff are available for your consultation, to offer information and to work side-by-side with both alternative and orthodox medical providers to improve the health of our nation.

Senator HARKIN. Dr. Harvey Kaltsas is a doctor of acupuncture and president of the American Association of Acupuncture and Oriental Medicine. He will testify about the growing acceptance of acupuncture and its use and its cost effectiveness.

Dr. Charles Simone will then testify about the treatment that he has developed for advanced cancers and the difficulty he has had in getting approval for his therapy. Dr. Simone runs the Simone Cancer Center and, as we heard earlier, treated Susan Di Matteo.

And we also have Dr. Brian Berman, the director of the Pain Center and the project for integration of orthodox and complementary medicine at the University of Maryland Medical School. Dr. Berman will describe the program at the University of Maryland and the integration of the program into the rest of the medical school.

Again, your statements will be made a part of the record. Dr. Berman, please proceed as you so desire.

STATEMENT OF BRIAN M. BERMAN, M.D., DIRECTOR, UNIVERSITY OF MARYLAND PAIN CENTER

Dr. BERMAN. Mr. Chairman and subcommittee, on behalf of the University of Maryland School of Medicine, I thank you for the opportunity to present our experiences and thoughts on the subject before us today.

I am the director of the University of Maryland Multi-Disciplinary Pain Center and, as you mentioned, the University of Maryland complementary medicine project. I have been on the Office of Alternative Medicine ad hoc advisory committee from its inception

and chair the NIH workshop on alternative medicine and followup meetings for the development of the OAM consensus report.

Prior to my return to the University of Maryland, I had a primary care practice combining traditional and nontraditional approaches in London, England. In September 1991, we initiated a 5-year project to integrate complementary medicine with orthodox medical care. The project is funded by a private foundation in Great Britain with matching funds from the University of Maryland's Department of Anesthesiology. The purpose of the project is to scientifically investigate the efficacy of complementary medicine and how these approaches can be integrated into modern medical care. There are three major components, which are clinical care, research, and education.

The complexity and chronicity of presenting medical problems has increasingly taxed American health care, and consumers, as well as providers, have been increasingly disillusioned. We have found our interdisciplinary team approach to these problems to be quite effective and satisfying for all concerned. While not unprecedented, these approaches are not the usual way of providing health care and require some new adjustments. The pooled resources of a variety of health care providers, however, has numerous advantages for both quality of care and comprehensive research.

We focused our initial clinical program on chronic pain and stress. And, as you heard earlier, the reason being that it is one of our most prevalent conditions and one of the costliest problems we have in medicine and one in conventional medicine we do not deal very well with. Our clinic consists of a multidisciplinary pain center using conventional medical treatments, such as anesthetic blocks, medications, and physical therapy working alongside of treatments such as acupuncture, homeopathy, Tai Chi, mind-body approaches such as relaxation training, and biofeedback. Through shared patient care, we have begun to develop a mutual respect and understanding of what these therapies may or may not offer, as well as providing a base for clinical research.

We have been asked by a number of other University of Maryland departments, the cancer center focusing on women with breast cancer, and the geriatric program most recently, to help develop similar treatments for their patients.

As far as research, at the University of Maryland, we have encountered a healthy degree of skepticism but an active interest in nontraditional approaches. We have developed collaborative relationships with a number of departments in the school of medicine and in the dental school, and we feel that the team approach of methodologists, complementary and conventional practitioners, and basic scientists is critical to sound, scientific evaluation of these treatments. We view research in complementary medicine as a continuum, beginning with efficacy studies to developmental research to basic science. In other words, first, do these therapies work and are they safe? Second, how do they work? And third, for whom do they work and under what circumstances?

To address the first question.

Senator HARKIN. Excuse me, Dr. Berman. I have a guy by the name of Bill Clinton on the phone here. I have got to take it. Just a second, if you will hold.

Dr. BERMAN. I think I can. I understand that.

[Pause.]

Senator HARKIN. I hate to say this again. There is another vote on the floor. I have 11 minutes left to make this vote. Did any of you get a chance to get a bite to eat or anything like that? OK; good. That is all I was concerned about. Well, we will take another 10-minute recess and I will be back in 10 minutes and we will pick it up then. Thank you.

[A brief recess was taken.]

Senator HARKIN. Let us try it again. The best laid plans, as they say. We planned this hearing 2 months ago or something like that, and we thought, well, this would be a good week to have it. It might even be a good day to have it. There will not be much happening this time of the month. So I do apologize again.

Dr. Berman, please refresh my memory. Where were you? And pick up again.

Dr. BERMAN. Basically, I was talking about the 5-year project that we have started at the University of Maryland. It is 2 years into it. It is to integrate complementary medicine to scientifically evaluate and to see how it can be brought into modern medical care. And it is in three parts: clinical care, research, and education.

The clinical care that we are doing is we are focusing initially on chronic pain and stress. We have a multidisciplinary pain clinic using traditional pain methods with complementary approaches such as acupuncture, Chinese medicine, homeopathy and mind-body approaches. And we feel that the clinical component to it is essential because it is through the shared patient contact and a sort of working together side-by-side with conventional physicians that we can really see what these therapies can actually do and not do. And we use that, then, as a base for clinical research.

The research component. You know, we have encountered, being a university medical center, a healthy degree of skepticism but a real willingness to collaborate. So we are working together with different departments in the school of medicine and in the dental school. We view research in complementary medicine as a continuum. You start with the first question. You are always asked, "Does it work at all and is it safe?" And then the second question that is asked right on top of that is, "Well, how does it work?" And then you can get into the more developmental types of questions, "Who does it work for, under what types of conditions, what types of therapies?"

So, to answer the first question of efficacy and safety, we have piloted two clinical trials in acupuncture. The first one is in osteoarthritis of the knee in the elderly, and the second study is in post-operative dental pain. Both of these are completed and both of them have positive results. We have also set up a—

Senator HARKIN. How long were those? How long were the studies?

Dr. BERMAN. They are sort of pilot feasibility studies, so we have about 12 patients in each study. And one has gone on for about 3 months. The other one, what it did was really to say, "This is the first step." The rheumatologists are asking us, "Does this work at all?" So we set up, with the Department of Epidemiology, the rheumatology, our acupuncturists and our methodologists, a clini-

cal trial with positive results. And now we can go on, on both of these, to develop a full clinical trial.

We have also set up an ongoing data base to look at outcomes. We want to look at, does this improve the quality of life, the effectiveness and the cost-effectiveness of our patients by integrating these two orthodox and complementary approaches? And then the second question that is always asked, "How does it work?" There, we have started two basic science studies in acupuncture where we are looking at the mechanism of action. We feel that as credibility is gained through these first two steps, then we can go into more what I call developmental research where we can start to look at where do these therapies work best, under what types of conditions, what types of patients. And that is when more new and innovative methodologies will probably be required.

As to education, our basic educational aims are to raise the awareness of the clinical and the scientific health communities about alternative medicine and encourage objective evaluations of some of the less well-understood forms of treatment. Educational activities that we currently have underway are an elective for the medical students where they have the option of being exposed to the clinical care of watching these therapies in action along side of conventional treatments. They can also be exposed to the concepts of complementary medicine, and they can work out a research project.

Recently, I have been appointed to the Medical School's Curriculum Revision Committee. And that is to consider including complementary approaches into the required medical curriculum. We also have core conferences for our residents and we have a fellowship in pain where they are both exposed to different forms of complementary medicine. We also give lectures within the university and the general medical community. And the feedback that we have been getting from lectures in this country and abroad is that there is a tremendous interest in alternative medicine. And what is being asked for now is a scientifically based research agenda to be implemented.

The Office of Alternative Medicine has been instrumental in enabling this to occur. For us, this has meant technical assistance in grant writing, raising the national awareness about complementary medicine and, most importantly, helping us to network within the NIH with other institutes and other researchers interested in complementary medicine. The forthcoming consensus report will provide a blueprint for a research agenda to evaluate alternative medicine, as well as to educate the public and the medical communities about these approaches.

The major aim of our project is to bridge the gap between conventional medicine and the less well-understood methods of medical care, and our ultimate aim is to establish an institute or a center of integrated medicine to continue this challenging work.

PREPARED STATEMENT

My only addition to what was said previously about the center is I think we can look at a couple of different models. We feel very strongly that it should be a three-pronged approach. You should have research and training, but you need to have clinical care in-

volved in there because that is really what medicine is about. And only between the rubbing of shoulders together between the clinical contact can you actually see what should be the next step. So we feel that should be included in the discussions of a center. And I think that there is room for different approaches to that.

Thank you.

Senator HARKIN. Thank you very much, Dr. Berman.
[The statement follows:]

STATEMENT OF BRIAN M. BERMAN, M.D.

Mr. Chairman, I am extremely honored to have been invited to this hearing on alternative medicine, and to present our experiences and thoughts on the subject before us today.

Concern for safe and cost-effective treatments for spiralling health-care problems is at an all-time high—particularly in the current climate of budget cutting and declining resources. Chronic health problems now on the rise in the United States are not being effectively addressed by present treatments, and this, too, has fueled the fever for health care reform. The failure of segregated medical services for conditions involving more than just physical symptoms provides yet a third impetus for more broadly conceived, interdisciplinary approaches to diagnosis, treatment, and prevention.

Under a variety of names, the popularity of alternative medicine has increased in the United States and Europe. A survey published recently in the *New England Journal of Medicine* reported that alternative medicine has an "enormous presence" in the US, with data indicating that one in three Americans used at least one alternative therapy in the past year (predominantly for chronic conditions), with an estimated \$13.7 billion in expenditures. This is consistent with other surveys in Europe concluding (1) that these approaches are interesting to both consumers and health care providers, (2) that their integration holds promise for improving the quality of care and quality of life, and (3) that their scientific evaluation, although difficult, is possible and necessary. Recent pilots of our own supported the interest of Maryland physicians in complementary-alternative medicine and the need for appropriate scientific outcome research.

While criticism of these approaches tends to cast unwarranted aspersions and derail efforts to evaluate them, problems associated with unwarranted claims are equally problematic. Any bias is detrimental to the health care agenda because it may deny the American people the benefits of validated complementary medicine where they are useful and appropriate. This issue has not escaped national attention, as evidenced by the establishment of a new National Institutes of Health Office of Alternative Medicine (NIH-OAM), which expressly mandates federal funding for the evaluation of "alternative medical practices". Having been on the Ad Hoc Advisory Board from its inception, and chaired the NIH workshop on alternative medicine and follow-up meetings for the development of the consensus report, I can tell you that there is a great spirit of public support from both the conventional and complementary medical communities about what the office is doing, and has the potential to do.

THE MARYLAND PROJECT

In September 1991, we began our Project for the Integration of Orthodox and Complementary Medicine at the University of Maryland School of Medicine, aiming to develop an interdisciplinary program of integrated clinical, educational, and research objectives to educate the medical community and the public, to scientifically test these approaches in a university medical setting, and to begin to develop models of their integration in the treatment of troublesome health care problems. As a family physician trained in traditional Chinese medicine and homeopathy, I started the project 18 months ago, and have watched enthusiasm and national attention grow about the potential of alternative medicine (particularly as a complement to good primary care). Our major goal at Maryland is not to replace conventional medicine, but to expand its boundaries by providing sound scientific bases for integrating some of the less-well-understood approaches. We believe that many "alternative" approaches work at least in part because of the greater attention paid to the person and their experience of illness—and that health care can be dramatically improved by re-integrating these crucial human dimensions.

THREE INTEGRATED PHASES

To give you some sense of what we're attempting, the Project has three phases—clinical care, research, and education—which we have planned for five years. (We are now into our second year.) Our principal objectives are to bridge the gaps between orthodox and alternative medicine, between science and practice, and between vital underserved health care needs and shrinking resources. To accomplish these ambitious aims, we believe that collaboration is imperative, and that integration must start with ourselves. We have a multidisciplinary staff: an American physician trained in traditional Chinese medicine; a Chinese-trained acupuncturist with a Ph.D. in physiology; and a clinical-research psychologist trained in behavioral medicine and interested in the emotional, behavioral, and spiritual dimensions of health and illness. We have found our day-to-day dialogue, conflict, and conflict resolution to be invaluable tools in our personal and professional growth.

Clinical care

Our initial effort has focussed on the development of an interdisciplinary staff and pain center offering comprehensive evaluation, treatment, and preventive services. Over the 18 months since we began, our clinical volume has increased 400 percent. Specific therapies in our program include acupuncture, anesthesiology, behavioral medicine, clinical psychology, family medicine, group therapy/education, homeopathy, physical therapy, relaxation training/biofeedback, Tai Chi, therapeutic touch, traditional Chinese medicine, and yoga. We also believe that culture and religion can be productively incorporated to improve health care. The approach we use is person-centered, and the use of complementary therapies is guided by patient response. This makes financial as well as medical sense because, by attending to patients' experience and the results of scientific studies of treatment effects, we are able to conserve resources, empower people, and develop the most efficient treatment plans.

Why chronic pain?

We selected chronic pain as our initial focus because it is pervasive and because it is well-suited to the collaborative, patient-involved treatment model we are developing. With severe emotional, economic, physical, and social consequences, we believe it is an appropriate metaphor for many chronic health problems.

Recent developments in behavioral medicine and interdisciplinary treatment have provided new avenues for addressing these personal dimensions of illness, and our own complementary therapies have shown promise with patients we have treated thus far. Moreover, research indicates that persons who participate in multidisciplinary chronic pain management programs tend to increase their functional activities, and decrease their use of addictive medications and visits to health care professionals.

Scientific evaluation

The establishment of a research staff and working database for ongoing investigation of the results of our own complementary and interdisciplinary treatments has been our major focus. Our efforts include a broad spectrum of developmental research from literature reviews and surveys (what is known) to clinical trials (efficacy), differential studies (what works with whom, under what conditions, what factors impact treatment response and outcome), and basic science (mechanisms). Because research priorities must be forged out of critical appraisals of available literature and creative solutions to novel methodological problems posed by complementary medicine, our "multicultural" team has been a real asset.

One clear need is that unsupported claims of efficacy or panacea be separated from reports of biomedical merit in rigorous scientific analyses. We also believe, however, that unexamined stereotypes of alternative medicine as "quackery" or "fraud" can be obstructive when they threaten the balanced perspective essential to objective investigation—or simply keep the important questions from being posed by serious researchers. For this reason, we are as committed to documenting the kinds and conditions of ineffective approaches as we are in validating potentially cost-saving, effective therapies.

Thus far at the University there has been a healthy skepticism, but also a willingness to listen and collaborate that has been very encouraging. For example, the Departments of Epidemiology, Family Medicine, and Rheumatology in the School of Medicine, Biochemistry, Physiology, and Pharmacology in the Dental School, and the Cancer Center have all expressed interest in collaboration. This interdisciplinary effort team has enabled us to bring together the clinical experts (in pain, osteoarthritis, post-operative emesis, for example), the scientific experts (in research methodology and biostatistics), and experts in several complementary approaches.

In this way, we are one of the few medical university-based centers engaged in coordinated clinical, educational, and scientific efforts to evaluate alternative medicine.

Our initial studies are clinical trials of acupuncture efficacy to treat osteoarthritis and post-operative dental pain. We are completing surveys of attitudes regarding complementary medical practices among primary care physicians, with a nationwide version in preparation. We are also investigating the role of anger and coping style among chronic pain patients, reviewing methodological problems which have stymied Western efforts to evaluate the effects of acupuncture, and looking into the incorporation of spiritual experience in health care contexts.

Education and training

The third aspect of the project encompasses an overarching set of educational goals, not only to increase interest and training in complementary approaches, but to stimulate new thinking about health, illness, and models of patient care. In our view, complementary medicine could reduce health costs in a number of ways by teaching healthy lifestyle and self-responsibility directly, by expanding the range of validated treatment options (some of which are less costly), and by modelling integrated care which targets functional status and quality of life. We are collecting data to support our belief that individuals with higher quality of life tend to use the health care system less.

Specific educational efforts to date include fellowships, training for residents, electives for medical students, and consultation for post-doctoral professionals, lectures on-campus and in the community, a Journal Club, and an international conference. Underpinning all of these is our aim to raise the awareness of the medical community regarding the existence, efficacy, and role of alternative medicine as a cost-saving component of optimal health care.

The way forward

In our view, effective evaluation of complementary medicine will enable massive preventive and educational efforts, and provide a scientific basis for the selection of validated "alternative" therapies to be used with standard medical approaches as appropriate. With the rising costs of many high-tech diagnostic and treatment procedures, the need for a wider range of less costly options is keen. Because of the nature and cultural origins of some complementary approaches, however, the scientific validation of "demonstrated efficacy" may require some innovative research strategies—and perhaps new models of interdisciplinary and inter-specialty collaboration—if we are to capitalize on these largely untapped resources.

Our own ultimate aim is the establishment of an Institute of Integrated Medicine, with endowed professorships and lectureships to develop effective models of researching, teaching, and integrating complementary approaches. Here in the United States, the need for and interest in alternative care has grown dramatically, but the scientific data is conspicuously lacking. Though we believe one benefit of our plan will be the improvement of the quality and cost-effectiveness of care, the real goal is to improve the self-determination and quality of life of those who want effective, affordable, and personal health care. Who, after all, does not?

STATEMENT OF HARVEY KALTSAS, D.A., PRESIDENT OF THE AMERICAN ASSOCIATION OF ACUPUNCTURE AND ORIENTAL MEDICINE

Senator HARKIN. And Dr. Harvey Kaltsas, president of the American Association of Acupuncture and Oriental Medicine. Again, Dr. Kaltsas, I have your statement. It will be made a part of the record. Please proceed.

Dr. KALTSAS. Thank you, Senator. Mr. Chairman, today I will highlight some of the dramatic cost savings already brought about by acupuncture, a 5,000-year old healing system of traditional Chinese medicine that includes the use of heat therapy, massage, herbs, diet, lifestyle, and exercise counseling.

The AAAOM requests continued support for research by NIH's Office of Alternative Medicine into this discipline. We specifically ask that the OAM include the participation of certified acupuncturists, who are the real experts in this field, in its research plans. We also ask for Senate support of bills now being in-

troduced in the House which will cover acupuncture under Federal health insurance.

Derek Bok, former president of Harvard University, once said, "If you think education is expensive, try ignorance." Well, unfortunately, the Federal Government is relatively uneducated about acupuncture, and its ignorance about what acupuncture can do is costing the Federal Government a great deal of money. For example, HCFA has recently ruled—well, 20 years ago ruled—that acupuncture is experimental, despite voluminous research on acupuncture's safety and effectiveness. HCFA has not reversed its ruling and, as a result—

Senator HARKIN. Is that ruling still in existence?

Dr. KALTSAS. It is still in existence. And acupuncture is not included under Medicare part-B.

Senator HARKIN. Is that FDA?

Dr. KALTSAS. No; that is HCFA, Health Care Financing Administration.

Senator HARKIN. HCFA?

Dr. KALTSAS. It was actually a rule promulgated in 1984 under a former administration. Starting with California and Nevada, 23 States, and the District of Columbia now license acupuncturists. Most recently is Iowa. On May 18, 1993, the Governor of Iowa signed into effect an acupuncture bill.

The health care consumers in Iowa called our national organization and requested that we not involve ourselves in any way in their legislative process. They did not want the legislators in Iowa to think that it was acupuncturists pushing to get licensed. They wanted the legislators in Iowa to know that it was consumers who wanted the service available to them. So we completely stayed out of it, and the law passed in Iowa.

The same thing happened 2 months ago in Louisiana where 10,000 consumers who were tired of driving to Texas for acupuncture treatments petitioned their legislature. Unfortunately, the bill failed in Louisiana, but it is being reintroduced.

Now, every year the public demands that acupuncture be included under Medicare and other Federal programs, but in response, many legislators wonder, "With a deficit this big, how can we possibly include another group of health care providers under Medicare?" Actually, the legislators should be asking, "Where can we replace high-cost, high-technology care with low-cost acupuncture?"

We have to ask, "Why do the patients fight to get acupuncture included?" It takes a lot to get legislatures to approve groups of practitioners. The main reason is that patients do not really want health care insurance. They do not really even want health care. They want health. And, for many patients, acupuncture is their only way to regain their health.

A study in Florida showed that 96 percent of all acupuncture patients have already been to the medical doctors for care and could not find relief, and they came to acupuncture as a last resort. And 80 percent of those very difficult patients got well.

How can acupuncture save the Federal Government money in this country? Let us look at China as an example for a moment. I know China has human rights abuses and it is not the ideal polit-

ical system, but when it comes to health care, we have something to learn from them. America spends \$3,200 per year per person on health care. China spends \$71 per person per year; \$3,200 versus \$71. We have something to learn from them.

How do they get their health care costs so low? They use two basic capitalist principles. They increase the supply of health care providers. They legalized 500,000 Doctors of Acupuncture who work hand-in-glove with the medical doctors. There is no competition, no hierarchical structure. The medical doctors and the acupuncturists work hand-in-hand together, and they both educate their patients on how to stay well. The focus of health care in China is not treating illness, it is promoting health. And until we start doing that in this country, we are going to keep on with an \$800 billion a year health care bill.

I think 80 percent of all the health care expenditures in China are spent on pregnant women and children in the first 5 years of life. Senator Dodd is always quoting that 75 percent or so of our health care expenditures are on patients in the last 6 months of life in our country. So we have got to shift the focus to prevention.

One way China reduces demand is by having widespread public health education campaigns and by encouraging the use of low-cost acupuncture therapies. One thing we desperately need in this country is a national cancer registry so that all cases of cancer are registered, like they are in China. In China, the Government knows how many cases of a particular type of cancer are in a particular region. They look to see if there is a lead smelter in that region spewing lead downwind, and they close it down and clean up the area so people do not get cancer from the lead that is being spewed out. We do not have statistics like that in our country, but we should and we should put the mechanization to collect them in place.

Most Chinese families practice some very simple acupuncture, massage, and dietary therapies at home as a way of preventing illness. For example, there is an acupuncture point right here, between your thumb and index finger. If you rub it, it is good for preventing constipation and good for preventing and treating headaches. How many Americans know about this point? Very, very few. But the Asian Americans know about this in our own country. And the Federal Government spends less for the care of Asian Americans than for any other ethnic group in the country. We have something to learn from our own Asian Americans, and from our own Federal statistics.

Senator HARKIN. Are you saying in America we spend less for the Asian American community on health care than any other sector?

Dr. KALTSAS. Yes; that is right. Those are from Federal census statistics. Every day, American acupuncturists are educating American patients with this basic preventive Chinese wisdom. And what else are we trying to do to bring the health care costs from \$3,200 down to \$71?

Acupuncture is now used on 90 percent of all drug-related felons going through Miami drug court. Hugh Rodham is the Public Defender of Dade County and he refers all of his drug-related cases to the Miami drug court where they are given a choice of receiving acupuncture; 90 percent of the felons elect to attend acupuncture

sessions. The cost for 1 full year of treatment is only \$750 per patient, and criminal recidivism among those who select acupuncture is now less than 7 percent. Normally, 50, 60 percent of people who have been through the criminal justice system get rearrested. The cost to process one case is over \$3,000. The cost for the acupuncture is only \$750.

New York City saves millions of dollars each year with acupuncture drug detox programs which dramatically reduce the time newborns must be sheltered while their mothers recover from crack-cocaine addiction. It is very expensive to keep newborn babies in hospitals instead of in their mothers' arms. Acupuncture puts the mothers back into their proper role of mothering by getting them off the crack-cocaine addiction.

Our own Veterans Administration researchers found that 61 percent of stroke patients with paralysis showed significant improvement following acupuncture. Our VA did the landmark studies of all the world acupuncture community by doing CAT scans of stroke patients' brains, finding out what part of the brain was damaged and then doing acupuncture with laser devices on those parts of the scalp.

In Czechoslovakia, they are doing the same type of work on brain-damaged babies and they do not have to institutionalize their children who have brain damage. Not keeping a child in a hospital saves millions of dollars for the countries of Czechoslovakia and Hungary. And I would like this to be instituted in our country. The laser device they use—you can get it from "Sharper Image." You know, it is the type they use to highlight things during speeches on the wall. It costs \$150. This is very inexpensive technology.

AIDS is another example where acupuncture is saving money. Yearly treatment with acupuncture in San Francisco Department of Health clinics costs less than \$3,400 per patient, and that figure includes herbs, weekly consultations and acupuncture treatments, lab work, and all administrative overhead. Clinical research that was just presented last weekend at a nationwide conference out in San Francisco shows that low-cost acupuncture and herbs are even more effective than treating AIDS with conventional, expensive Western therapies.

Acupuncture is very helpful in treating chronic pain syndromes. The FDA reports that acupuncture is used by doctors in 90 percent of German pain clinics; that the French National Health Plan covers acupuncture. The American Chiropractic, Osteopathic, and Veterinary Associations have all endorsed acupuncture as an effective therapy for the treatment of pain. Even Henry Kissinger's dog has been for acupuncture.

The conference report accompanying the National Institutes of Health Revitalization Act urges the Office of Alternative Medicine to coordinate research with other countries, foster training in alternative medicine, and disseminate its research findings. The AAAOM strongly supports the directive Congress has given OAM. China's Minister of Health, who is the brother-in-law of one of our AAAOM members, has assured our organization of full Chinese cooperation with United States research efforts. Other countries have made similar offers.

AAAOM requests that Congress fund the Office of Alternative Medicine to conduct domestic research staffed by State-licensed acupuncturists and to compile and translate acupuncture research done in Asia and Europe. It costs a lot less to translate than it does to conduct a new study. AAAOM also requests that the Senate pass a companion bill to parity legislation similar to legislation that was introduced in 1989 by Senator Barbara Mikulski.

The new legislation is being introduced in the House by Congressman Maurice Hinchey, and it guarantees that Federal workers have the right to choose a certified acupuncturist when receiving acupuncture care. Presently, the Federal Employees Health Benefits Plan covers acupuncture, but many of the policies only do so when it is provided by a medical doctor and you cannot go for acupuncture to somebody who is not certified in the discipline. We do not think this is fair.

The savings in drug detox costs alone for Federal workers could be substantial—15 percent of all the American population is affected by chemical dependency. It is a very substantial cost to our society. And our profession is the only one that offers training in the prevention of chemical dependency and the treatment of chemical dependency. Medical schools only provide 2 hours of training in chemical dependency treatment and prevention—2 hours in a whole course of medical school education. We offer 120 hours, leading to certification as certified addiction professionals. We want to teach the MD's how to approach their patients so they can prevent addiction and treat it when it develops.

We further request that the Senate pass companion legislation to a new House bill which includes acupuncture and acupuncturists under Medicare part-B. Blue Cross & Blue Shield of Maine estimated that covering acupuncture with their own policies, provided by licensed acupuncturists, costs less than \$1 per member per month.

PREPARED STATEMENT

To reiterate, "If you think education is expensive, try ignorance." As a society, we are now being presented with the bill for our ignorance of how to care for ourselves. We should learn from the example of Asian Americans and no longer dismiss their priceless medical heritage as experimental.

Senator HARKIN. Very good, Dr. Kaltsas. Thank you very much. [The statement follows:]

STATEMENT OF DR. HARVEY KALTSAS

Mr. Chairman and members of the Committee, I am Dr. Harvey Kaltsas, a Doctor of Acupuncture and the President of the American Association of Acupuncture and Oriental Medicine (AAAOM) which represents America's 7,000 state licensed acupuncturists. During this proceeding, I will illustrate some of the dramatic cost-savings already brought about by our profession, which has gained popularity in the USA only since President Nixon's visit to China in 1971. I will also request Senate support for research at NIH's Office of Alternative Medicine (OAM) into this discipline. I specifically request that OAM include the participation of state licensed acupuncturist in its research plan. I also ask for Senate support for bills now being introduced in the House which will cover acupuncture under federal health insurance.

I would like to start with a quote from Derek Bok, former President of Harvard University, "If you think education is expensive, try ignorance." The federal govern-

ment is relatively uneducated about acupuncture, and that ignorance is costing plenty.

Acupuncture is the most commonly known therapy within the 5,000 year old healing system of Traditional Chinese Medicine (TCM), a system which also includes the use of heat therapy, massage, herbs, and dietary, lifestyle, and exercise counseling. When I speak about acupuncture hereafter I am referring to the entire system of Traditional Chinese Medicine. The practitioners of Traditional Chinese Medicine understood the circulation of blood 2,000 years before William Harvey articulated the concept in the West. And one thousand years "before Richard Williamson pioneered a modern glucose level test, Chinese doctors had discovered another method for detecting sugar they had patients pass urine on a wide, flat brick to see if ants gathered to collect the sugar. As far back as 752 A.D., pork pancreas was recommended as treatment for this disease, an approach similar to modern treatment by insulin."¹

Yet this 5,000 year old system of healing has been ruled experimental by the Health Care Financing Administration (HCFA), which has ignored voluminous research on acupuncture's safety and effectiveness and has excluded acupuncture coverage under Medicare. This is most inconsistent, because Medicaid pays for acupuncture in states such as New York and California; the Federal Employees Health Benefits Plan covers acupuncture; millions of federal dollars are being spent on acupuncture drug detoxification programs, and Master's degree level programs in acupuncture are funded by the U.S. Department of Education, with over 500 new graduates each year.

We suspect HCFA is using the experimental label on acupuncture as a cost-containment measure. HCFA should reverse its acupuncture ruling immediately. By denying acupuncture coverage, HCFA is inflating costs instead of containing them. Ironically, the same research that shows that acupuncture is safe also shows that it is quite dramatically cost-effective.

The Office of Alternative Medicine (OAM) has an opportunity to save the federal government, literally billions of dollars by identifying specific safe and effective acupuncture treatments for specific ailments. This will remove the unjustified blanket label of "experimental" that has been placed over all acupuncture treatment during the past twenty years. But first OAM must reach out for the expertise of the acupuncture community, both domestically and worldwide.

Thus far, the OAM has relied primarily upon the expertise of MDs in approaching acupuncture. This is a serious mistake because practitioners of Traditional Chinese Medicine, with years of schooling are the real experts in the this field, not MDs, most of whom do not have the time to explore this discipline adequately. AAAOM strongly urges OAM to include state licensed acupuncturists on any future acupuncture research projects. Moreover, AAAOM urges that OAM follow up on offers from China, Taiwan, Japan, Russia and Europe to share its research. Translation is much faster and inexpensive than conducting new studies. OAM's recommendations can then spur the integration of acupuncture into other federal programs. Every year lost adds to needless human suffering and to the billions in wasted federal funds.

ACUPUNCTURE IN THE UNITED STATES

Over the past twenty years, since President Nixon's visit to China, some 6 percent or 15 million Americans have been treated with acupuncture.² This low-cost, benign therapeutic system is especially helpful for children, the elderly, the chemically dependent, and those whose immune systems are compromised. Acupuncture often precludes the need for chemical pain killers, cortisone, and surgery, all of which carry serious side effects.

Starting with California in 1976, twenty-three states and the District of Columbia now license, certify, or register acupuncturists. Most recent of these is Iowa, where on May 6, 1993 the Governor signed legislation which for the first time in Iowa allowed non-MD's to practice. Since so few MDs practice acupuncture, it had been virtually unavailable in Iowa heretofore. Not one acupuncturist nor one penny of practitioner support was involved in passing the Iowa law. This was 100 percent the effort of health care consumers in Iowa.

Why are these citizens demanding that acupuncture care be made available to them? Eric Hoffer, LBJ's favorite philosopher, once said, "You can never get enough of what you don't really want to make you happy." The simple truth is that Americans do not really want health care insurance. They do not really even want health care. They want health. And that's what acupuncture offers—a way for many to regain health who could not do so otherwise.

A 1987 Florida study revealed that 96 percent of Florida acupuncture patients had already been unsuccessfully treated with conventional western medical care and

then turned to a acupuncture as a last resort. Fully 80 percent of these difficult patients reported satisfactory results from acupuncture.³ Our patients are living proof that acupuncture has a unique contribution to make to America's health care system. What we offer is clearly not a replication of services.

Every year acupuncture gains in popularity. More than 82 private insurance carriers⁴ now cover acupuncture, and there has been growing public demand to include acupuncture under Medicare and other federal programs. In response, many legislators are asking "With the deficit this big, how can we possibly mandate coverage for another group of health care providers?"

Actually, legislators should be posing a more appropriate question, "What could the federal government save by including acupuncture in the American health care system?"

THE CHINESE EXAMPLE

Let us look at China for a moment. I expect that some don't want to hear about China because of its human rights abuses, and others don't like the fact that it is a communist country. But the simple truth is that China spends \$71 per person on health care per year, whereas America spends \$3,200.⁵ Granted the American population is healthier as a whole, but not by much. What accounts for this astounding discrepancy in health care costs per person?

China has observed two time-honored capitalistic principles to lower its costs, increase supply and reduce demand. First, China greatly increased its supply of medical providers in 1949 by giving equal legal and social status to an army of 500,000 doctors of acupuncture and Traditional Chinese Medicine who offer low-cost, low-tech care.

Second, China has reduced demand by improving food supplies, implementing massive public sanitation projects and widespread public preventive health education campaigns, and encouraging the use of low-cost acupuncture therapies. China's preventive measures are low-cost and low-tech. They combine western medical knowledge and practical measures we should have long ago implemented in our country (such as a national cancer registry) with Traditional Chinese Medical wisdom. Actually, acupuncture is not so much a disease treatment system as it is a health promotion system.

As a result, most Chinese families understand prevention and practice some very simple therapies at home. For example, there are over a thousand acupuncture points on the body that can be useful in reinforcing health. Most people in China know at least some of these points and massage them if a problem is developing.

I'd like everyone here to spread their thumb and index finger of your left hand. Now please take your right thumb and press on the webbed area between your left thumb and forefinger until you feel a tender spot. You've just located a point, Hoku. When used regularly, it is often helpful in treating headaches, constipation, and a number of other ailments. Does it cost anything to rub it? Of course not. How many Americans know about this point? Very, very few.

Similarly, very few Americans understand that drinking cold liquids on a regular basis can disturb the digestive function, thereby weakening the immune and circulatory systems. Americans drink ice water with meals. Chinese drink hot tea. Do Chinese know something we don't? Until very recently, western medicine did not acknowledge the role of diet in creating or preventing disease, something understood for centuries in China. Now this is common knowledge in the West. American acupuncturists are working every day to educate our patients with similar valuable knowledge.

What other steps are acupuncturists taking to bring that \$3,200 figure closer to \$71?

ACUPUNCTURE IN THE TREATMENT OF CHEMICAL DEPENDENCY

The experience of the Miami Drug Court shows that acupuncture is a safe, inexpensive way to help most felons succeed at treatment and avoid continued addiction, probable rearrest, and possible death. In fact, acupuncture is considered "State-of-the-Art Treatment" in the domain of chemical dependency.⁶ The State of Oregon concurred by mandating that "synthetic opiates [i.e. Methadone] shall be used only when . . . detoxification with acupuncture and counselling have proven ineffective or upon the written request of a physician . . . showing medical need. . . ."⁷

Why? Because acupuncture works, and it is very inexpensive. Eighty percent of arrestees, nationwide test positive for drugs. Hugh Rodham, Public Defender for Dade County, Florida, now refers all of his drug abusing clients for acupuncture through the Miami Drug Courts.⁸ Acupuncture provides the physical support which keeps felons enrolled in the treatment and counselling process, dramatically reliev-

ing the biochemical stress of withdrawal and rapidly accelerating physiological recovery.

In two full years of operation, 4,296 felony drug possession arrestees entered the Miami program. The 1,600 graduates have a 3 percent re-arrest rate. The 1,153 individuals still in the program have a 7 percent re-arrest rate. Cost is only \$750 per client for a full year of acupuncture treatment.⁹ What would it cost not to treat these patients with acupuncture? On a more positive note, imagine the savings if our national recidivism rate were only 3 percent. The City of New York also saves millions of dollars each year with acupuncture detox programs that dramatically reduce the time the City must house newborns while the mothers recover from crack cocaine addiction.¹⁰ Without acupuncture, what would the expense to society be? Bullock and Culliton noted that in a six month alcoholism treatment study, compliance and retention increased from 5 percent of the patient population without acupuncture to 35 percent with acupuncture.¹¹

Sir Jay Holder, Director of the 250 bed Village Addiction Treatment Center in Miami and the first American ever to be awarded the Albert Schweitzer Prize in medicine, conducted the first true placebo study of acupuncture in the treatment of chemical dependency. Dr Holder concluded that "patients who complete at least ten days of auricular [ear acupuncture] therapy and do not receive intercurrent medications would be ten times more likely [96 percent] to complete a thirty day residential program than they would without auricular therapy."¹²

In the realm of addictionology, these figures compare with Michael Jordan's performance in basketball.

The real key to resolving the problem of chemical dependency, which afflicts 15 percent of the population, is education—starting with health care professionals, who in turn should educate their patients on the nature, prevention, and treatment of drug addiction. However, acupuncture is presently America's only primary care profession which offers significant, comprehensive training leading to certification as a Certified Addiction Professional. Medical schools generally only teach two to three hours on the treatment of chemical dependency during the entire education of an MD. In fact, the western medical tradition is itself drug dependent and continually sends out a strong pro-drug message with every prescription written. Acupuncture does just the opposite.

In what other areas could our federal government save money by supporting the expanded use of acupuncture in the U.S.?

STROKE, PARALYSIS AND BRAIN DAMAGED BABIES

The Veterans Administration, in association with the Boston University School of Medicine, has conducted landmark research with the use of acupuncture to treat paralysis caused from stroke. Federal researchers found that "61 percent of the stroke patients with paralysis showed significant improvement following acupuncture", and are now able to predict with 95 percent accuracy which stroke patients are likely to benefit from acupuncture."¹³ Once again, acupuncture proves to be safe and cost-effective.

Dr. Margaret Naeser, one of the stroke study researchers, also reports the following on the use of acupuncture for the treatment of brain damaged babies in Czechoslovakia and Hungary: "The acupuncture is begun within the first 10 days post-birth, or within the first year, post-birth. Dr. Michaela Lidicka, from Czechoslovakia, has data which shows the brain-damaged babies who begin treatment with acupuncture within the first year of life, do not have to be institutionalized for care. Their records are complete up to 5 years, so far. This represents a great cost saving for medical care in their countries. Their results are better for babies born with brain damage due to lack of oxygen at birth, than for babies born with brain damaged due to genetic defect. The reputation of acupuncture in treating babies with brain damage has spread, in Prague and Budapest, and as a result, most babies born with brain damage are now routinely referred to these acupuncturists for treatment . . . as soon as possible, post-birth."¹⁴

AIDS

Acupuncture has proven to be a low-cost, benign complement to conventional medicine in the treatment of AIDS. At the First International Conference of HIV, AIDS, and CHINESE MEDICINE held in San Francisco June 18-20, 1993, research was presented attesting to acupuncture's popularity and effectiveness at treating AIDS related diseases. Acupuncture is especially effective for managing such AIDS symptoms as diarrhea, fatigue, hepatitis, irritable bowel syndrome, joint pain, night sweats, and peripheral neuropathy.

In patients receiving acupuncture treatment, CD4 cells, which indicate the strength of the immune system, showed a decline of only 4 percent after 2.5 years compared to 18 percent and 49 percent in non-acupuncture groups. A sizeable number of patients remained asymptomatic. In one study of 201 HIV patients, those using only acupuncture and herbs did better than those using a combination of Chinese medicine and western medications.

In 1992, the American College of Traditional Chinese Medicine (ACTCM) in San Francisco received a first of its kind contract from the Department of Public Health to provide acupuncture care. Even with such an expensive disease as AIDS, the yearly cost for weekly treatment in this public clinic setting runs less than \$3,400 per patient, and that figure includes herbal care, consultations, lab work, and administrative overhead. Once again, education is an essential part of managing this disease in the ACTCM program, which has a four month waiting list for entry.¹⁵

Sir Jay Holder considers acupuncture and Chinese herbs to be the most promising and cost-effective treatment for AIDS yet discovered. Dr. Holder asserts "There are very few things that can support the immune system as quickly, as effectively, and as inexpensively as acupuncture and traditional Chinese medicine."¹⁶

This is not to suggest that acupuncture is a substitute for all other conventional therapies. But when these treatments are coordinated, acupuncture provides a safe and gentle support system for patients too weak to withstand the side effects of pharmaceuticals or surgery.

CANCER

It is often said that there are tremendous medical discoveries awaiting humanity within the flora and fauna of the Amazon rain forests, and that we must save them to preserve their treasures for posterity. Within the world of acupuncture and TCM, many such treasures have already been found and developed. Over 5,000 herbs and 25,000 herbal formulae are now commonly used in TCM.

In China, herbs help significantly in the management of cancer when used as an adjunct to surgery, chemotherapy, and radiation. The Journal of the American Medical Association, 1/27/84, reported that life expectancy doubled for patients with rapidly advancing cancers when Chinese herbs [which cost pennies a day], were added to the treatment plan. JAMA noted that in general "patients who received Fu-Zheng [herbal] therapy survived longer and tolerated their treatment better than those patients who were treated by western medicine alone. . . . In addition, the five year survival rate was twice as high among patients with nasopharyngeal cancer . . . (53 percent v. 24 percent)."¹⁷

Another article in JAMA, 11/10/89, noted acupuncture's success treating nausea for chemotherapy.

PAIN

Acupuncture is perhaps best known for its ability to manage chronic pain syndromes. In one study of over 20,000 patients at UCLA acupuncture reduced both the frequency and the severity of muscle tension headaches and migraines.¹⁸ Other studies document acupuncture's marked ability to reduce neck and back pain, with 58 percent of the treatment groups maintaining improvement after 40 weeks.¹⁹

The American Chiropractic, Osteopathic, and Veterinary Associations have all endorsed acupuncture as an effective therapy. Even Henry Kissinger's dog has been treated with acupuncture!²⁰

And the AMA, while citing its shortcomings, acknowledges that "Acupuncture . . . is considered particularly effective in the treatment of migraine and tension headaches, but it is often used in the treatment of visceral pain as seen with cholelithiasis, appendicitis, gastritis, renal colic and peptic ulcer. . . ."²¹

A 1991 study from the FDA's Office of Science and Technology reports that acupuncture is used by doctors in 90 percent of German pain clinics and is covered under the French national health plan.²² This study goes on to quote R.H. Bannerman, a Programme Manager of the World Health Organization: ". . . the sheer weight of evidence demands that acupuncture must be taken seriously as a clinical procedure of considerable value."²³

REQUESTS FOR CONGRESSIONAL SUPPORT

Acupuncture represents the greatest unexplored treasure trove of medical information on the planet today, and China has freely offered us the benefits of literally millennia of research. One of our members, Cecilia Chang, is sister-in-law to the Minister of Health for all China, and he has assured full Chinese cooperation with almost any U.S. research effort. The Taiwanese, Japanese and Europeans have

made similar offers. AAAOM requests that Congress fund the Office of Alternative Medicine to support domestic acupuncture research and to compile and translate acupuncture research done in Asia and Europe.

We remind the Subcommittee that the Act reauthorizing the NIH Office of Alternative Medicine specifies that "[t]he purpose of the Office is to facilitate the evaluation of alternative medical treatment modalities, including acupuncture and Oriental medicine. . . . P.L. 103-43, Section 404E.

In the Conference Report accompanying the NIH Revitalization Act, H.R. Conf. Rep. No. 100, 103d Cong., 1st Sess., p. 117, the Conferees urged the OAM to accomplish the following: (1) formulate a plan for future research activities at NIH; (2) provide fellows authorized under this legislation the opportunity to engage in program and policy analysis, as well as perform clinical research; (3) coordinate research efforts with those of other countries; (4) develop databases which would support both research and information transfer functions; (5) foster training in the area of alternative medicine; and (6) disseminate its research findings through conferences and other forms of professional communication.

AAAOM strongly supports the directives that Congress has given to OAM. We specifically ask that OAM include the meaningful participation of state licensed acupuncturists, as research fellows, in the development, implementation, and evaluation of OAM's research plan to investigate acupuncture. We ask that as part of its research plan, OAM consult with representatives of HCFA to establish reasonable scientific criteria to remove the twenty year old "experimental" status of acupuncture.

AAAOM also requests that the Senate pass a companion bill to parity legislation being introduced by Congressman Maurice Hinchey which guarantees freedom of choice of health care providers for federal workers insured by the Federal Employees Health Benefits Program.

Some FEHBP policies presently cover acupuncture, but only when performed by an MD. The Hinchey legislation would leave insurance companies with the right to choose whether or not to cover acupuncture. But if they choose to cover acupuncture, then they must pay for the service when provided by a state certified, licensed, or registered acupuncturist. This sounds silly, but some FEHBP policies only cover acupuncture when performed by an MD, and not many MDs are well-trained in acupuncture. Savings in drug detox costs alone for federal employees could be substantial.

When similar parity legislation was reviewed by the State of Maine, its Mandated Benefits Advisory Commission concluded that "[s]ince the proposed mandate applies only to policies which already cover acupuncture, the financial impact would be minimal." The Maine study also explored the economic impact of requiring insurance policies to cover acupuncture and include acupuncturists as providers: "Blue Cross and Blue Shield estimate that addition of licensed acupuncturists as providers would add less than \$1 per member per month to pure premium if coverage of the service were mandated."²⁵

As a result, BC/BS of Maine has chose to provide acupuncture coverage for all State of Maine employees and school teachers. With this in mind, AAAOM requests that the Senate pass a companion bill to one being introduced by Congressman Kinchey which would include acupuncture and acupuncturists under Medicare Part B.

CONCLUSION

To reiterate, "If you think education is expensive, try ignorance." As a society, we are now being presented with the bill for our ignorance of how to care for ourselves. We must increase the supply of those who would teach us how to live in harmony with life. By so doing we can reduce the demand for expensive health care services.

U.S. Government research shows that Asian-Americans spend less federal health care dollars per person than any other ethnic group. We should learn from their example and not dismiss their medical heritage as "experimental." Frankly, we can no longer afford to do so.

REFERENCES

- [1] Keli Tomoshaitis, *Herbal Crossroads*, May, 1993, K'an Herb Co., Soquel, CA.
- [2] *Time/CNN* poll Oct. 23, 1991 by Yankelovich Clancy Shulman.
- [3] Dr. Christine R. Geiser, University of South Florida Anthropology Ph.d thesis, November 8, 1989, Tampa, Fl.
- [4] See Exhibit A, list compiled by AAAOM of insurance companies which have paid for acupuncture.

[5] Chinese expenditures on health care computed as 5 percent of \$1.7 trillion GNP divided by 1.2 billion population. U.S. figure computed by dividing \$800 billion expenditure by 250 million population.

[6] "Third National Conference on Drugs and Crime" booklet, 1/31-2/3/93, National Consortium of TASC Programs, 4444 North Capitol Street, N.W. Suite 642, Washington, D.C. 20001.

[7] Oregon Legislative Assembly, 1991 Regular Session, House Bill 2580.

[8] Personal interview with Hugh Rodham, 4/29/93; interview in the St. Petersburg Times, "The Good Points of Acupuncture," May 16, 1993, Page 2F.

[9] See Exhibit B, Summary of report from the Metropolitan Dade County, Office of Rehabilitation Services, Diversion and Treatment Program.

[10] See Exhibit C, "Acupuncture As a Treatment for Drug Dependent Mothers," Testimony presented by Michael Smith, MD to the NY City Council 4/11/88.

[11] "Acupuncture treatment of alcoholic recidivism; a pilot study" by Bullock, Culliton, et al., *Alcoholism—NY*, June 1987; reprinted in *Lancet*, 1989.

[12] See Exhibit D, Sir Jay M. Holder, DC, MD, Robert Duncan, Ph.D, et al. "A New Auricular Therapy Formula to Increase Retention of the Chemical Dependent in Residential Treatment" by Research study funded by the State of Florida, Department of Health and Rehabilitative Services.

[13] See Exhibit E, letter from Margaret A. Naeser, Ph.D. to AAAOM, September 9, 1991.

[14] See Exhibit E, op. cit.

[15] See Exhibit F, Report from Howard Moffett, on ACTCM HIV Clinic Program.

[16] Personal interview, June 16, 1993.

[17] See Exhibit G, JAMA, 1/2/84, "East meets West to balance immunologic yin and yang."

[18] Millman, B. "Acupuncture: Context and Critique," *American Review of Medicine* 28 (1977): 223-36.

[19] See Exhibit H, Coan, Wong, et al., "The Acupuncture Treatment of Neck Pain, *Am. Journal of Chinese Medicine*, Vol. IX, No. 4, pp. 326-332".

[20] Personal interview with Allen Schoen, D.V.M.

[21] See Exhibit I, AMA Resolution 126 (A-81).

[22] See Exhibit J, C.D. Lytle, Research Biophysicist, Health Sciences Branch, FDA, Division of Life Sciences, Office of Science and Technology, CDRH, "A Review of Acupuncture and Acupuncture Needles in the U.S.," 1991.

[23] See Exhibit J, C.D. Lytle, op. cit.

[24] See Exhibit K, State of Maine Mandated Benefits Advisory Commission, "Reports on Acupuncture," 1992.

[25] See Exhibit K, State of Maine, op. cit.

STATEMENT OF CHARLES B. SIMONE, M.D., SIMONE PROTECTIVE CANCER CENTER

Senator HARKIN. Dr. Charles Simone of the Simone Protective Cancer Center of Lawrenceville, NJ.

Dr. SIMONE. Thank you, Senator. Thank you for inviting me today. Let me just briefly go over my background. I am a medical oncologist trained at the NCI, an immunologist trained at the NCI, and then further training in radiation oncology at the University of Pennsylvania. So I am very, very conventionally trained in many aspects of cancer treatment. I got very involved in looking at ways of preventing cancer and wrote a book called, "Cancer Prevention," after I had seen a senior statesman from this country down there.

Let me just look over things with a graph to put things in perspective.

Senator HARKIN. OK.

Dr. SIMONE. This is a graph of cancer death rates in our country. You can see the graph goes from 1930 to the present. One curve has gone up dramatically; the death rate of lung cancer. Two curves have come down; stomach cancer, cervical cancer. With the advent of refrigeration in the twenties and thirties, stomach cancer has come down.

All of the other cancers, the death rates of every other cancer—we are not talking about children's tumors, but the other adult tumors, which represent 98 percent of all the tumors we see—they have remained the same. So a person who developed a cancer in 1930 died of it. A person who developed the same cancer in 1990 dies of it. And that is despite radiation therapy that began in the twenties and thirties. That is despite combination chemotherapy, despite immunotherapy, despite billions of dollars—\$100 billion last year for cancer treatment—MRI scans, fancy technology. Everything we have done thus far has not changed these curves one bit.

And worse yet, and perhaps even somewhat deceptively so, is the unrealistic prediction of a 50-percent reduction in mortality rate by the NCI and the American Cancer Society. Because of these dismal survival curves, we have to look to prevention and/or new substances.

I got involved with shark cartilage about 1 year ago, after having been introduced to Dr. William Lane, who has done some work with it. The reasons why I took the shark cartilage down to a foreign country were because of FDA procedural problems. For instance, the data that I had seen—Yes, sir?

Senator HARKIN. Wait a minute. I saw that "60 Minutes" program.

Dr. SIMONE. Yes.

Senator HARKIN. Were you part of that?

Dr. SIMONE. Yes; I was the physician who went down for review of the entire operation down there.

Senator HARKIN. Now I know where I have seen you before.

Dr. SIMONE. OK. You mean my mother did not send you my picture?

Senator HARKIN. Now I know. OK. Please proceed. It all comes back to me now.

Dr. SIMONE. Well, what we had done, because of the procedures of getting IND's and things like that in this country for FDA permission, because of that and because of the data that were so important—animal studies, test tube studies that have been done in this country from the seventies and eighties that were done in good laboratories, MIT, Harvard, lots of basic science worked out already for the issue of cartilage in general and the treatment of cancer in these studies. The data were so very good. The animal data was spectacular. I decided that it would not behoove anybody to waste this, since it was not a toxic treatment. No harm came to people. It has been around for centuries. Shark fin soup in the Orient, again, and there was no harm. So I decided to look at this clinically.

We looked first at patients in Mexico, and the data were intriguing. The data were not totally reproducible, but it was intriguing enough to pursue it. We then went down to Cuba and I reviewed everything down there. Of 15 evaluable patients, there were about four who had a real response, partial response. And that, again, got enough information for me to say that there was something here. Not good for everybody, but there was something intriguing enough in this information clinically to proceed.

We then got the permission of the Committee on Pharmacology and Biological Therapies, and it was recommended to us to proceed. So we have been accumulating patients here in this country. All the patients that have come to us had already started shark cartilage in some form or dosage prior to coming into the office. What we have done is simply guided them to the right dose and the right sequence of treatment.

Now, you heard from Susan Di Matteo. She, I think, understated her case. She was quite ill when she came in. And you saw her today, the young lady with ovarian cancer. Her markers did go down several hundred points. Her tumor mass in her abdomen/pelvic area decreased by about 20 to 30 percent. So she had a real partial response. No question about it.

There is a man here whose x rays I can point out to you very quickly that you will be able to see a difference. This is an older man, an Armenian man, who cannot speak English well, otherwise he would have been here. He had gallbladder cancer which metastasized to the liver. This is one of the bad-acting tumors that we have, like pancreas is a very bad tumor. He started shark cartilage. We saw him. After about 8 weeks of the proper dosage he has complete resolution of his liver disease. Let me just show you that.

Senator HARKIN. You think I can make heads or tails out of this?

Dr. SIMONE. I think so.

[Witness conferring with Senator Harkin.]

Senator HARKIN. Yes; you are right. I can see that. And he had no other treatment other than shark cartilage?

Dr. SIMONE. Oh, we had many treatments prior to that, but on the treatment, all these things continued to grow. Liver metastasis got bigger. He stopped it all because the doctors told him there was nothing left for him, to go home and make him comfortable.

He sought out the shark cartilage treatment, started taking it, came down to me. We put him on the right dose, and the thing completely resolved, as you saw. Same institution did the studies—Memorial Sloan Kettering. Good study. He administered the shark cartilage properly.

We have a couple other patients of about 20 patients now that we have accumulated, that we can evaluate over an 8-week period thus far since March, late March, and of those 20 people, four have had either a complete response like this, complete disappearance of tumor—I do not know how durable that will be but we will follow him to find out. And three patients have had a very good partial response. Susan DiMatteo is one of them.

We have an older man who had prostate cancer, came to us on a stretcher, moribund, and he had very high levels of a prostate blood-level antigen—prostatic-specific antigen. And the blood markers, you can see in the testimony, have all come down and he is driving his car now at age 80-some years.

Another patient, breast cancer to liver. And you can see her data there. I will not go through it.

The point is, this may not be a treatment for everybody but we have seen some remarkable changes in a number of people thus far. We are still accumulating patients. We are making sure that the patients have already started cartilage prior to coming to our office. And what we have done is put them on the right dose, guide

them through this, and serially look at the laboratory data, et cetera. So we now have about 80 or so patients total, but not all 80 have been through at least 8 weeks of treatment, so we will continue to accumulate that data.

I think it is important to know that in addition to the cartilage, we have put all these people on a modified program of our 10-point plan that we put in our book, "Cancer and Nutrition." And that includes dietary modification. Many of these tumors are diet-driven. Senator Mikulski raised the issue about what can we do first and foremost to help promote wellness. Sixty percent of all women's cancers and 40 percent of all men's cancers are related to nutritional factors alone. No. 1 cause of cancer. No. 2 cause of cancer is tobacco use—30 percent.

So, many of the dietary tumors have been studied, again, from the Far Eastern literature. The Japanese studies show very clearly that Japanese women rarely get breast cancer, but when they do they live longer than we do. Unlike those curves [indicating], their curves are different. Death rates are different for them in breast cancer, due mainly to two reasons. One, low fat, high fiber diet and they are less obese. So those two reasons keep them living longer.

In the mideighties, if you remember in this country, the NCI started such a protocol. Can we randomize women in our country to promote a longer life simply by maneuvering dietary manipulation? The study failed for two major reasons in our country. One, the doctor did not believe—like a religion, didn't believe—that there was any relationship between nutrition and cancer. And second, the doctor, once the patient did get down there, she simply did not want to give up pizza, yogurt, and that kind of thing.

But nutritional factors are important, so we put all these patients, all the patients I see, on a nutritional modification, low-fat, high-fiber diet. Certain nutrients. They are extremely important. There has been an explosion of information today about carotene, all the other free radical scavengers, the vitamin issue. This information is very solid medically, scientifically, and the whole issue of restricting the use of vitamins I think is silly and should not happen.

We have also looked to using nutrients to augment oncology care, looking at early stage breast cancer patients, minimizing the harmful effects of chemotherapy and radiation therapy, and we have been able to show that very clearly. We also have a young lady, a 3-year old, Korean-born, adopted girl, who has a very severe disease—not cancer, but recurrent laryngeal papillomatosis. This is a viral growth like a woman would have in her cervix, viral polyps. When a child gets pulled through the vaginal canal, many times, 4,000 of these children in this country develop polyps on their vocal chords. These polyps are not malignant, but they do over-grow and occlude the airway. When that happens, the child either dies or the polyps must be removed surgically.

This particular child, very common, had surgery, general anesthesia, and surgery every 2 weeks for about 1 year of her life. She came to me. We put her on simple doses of nutrients and a little cabbage extract because lots of data, in fact, originating from the NCI, has shown that certain enzymes in the cabbage family have

been shown to promote out the growth of various viruses. So she has been on that for over 72 weeks and has no problems at all.

The point I am trying to make is, it is a combination of lifestyle change and other things. Shark cartilage I think is an important issue to look at, but it may not be important for everybody. The only way we are going to know that is to rigorously look at it, and that is what we are trying to do.

All these issues go into looking at lifespan mortality curves, and quality of life. Quality of life is very different in all the people we have studied with shark cartilage. It has an anti-inflammatory component probably, and the other proteins that are active have already been worked out scientifically from the Harvard group and the MIT group.

PREPARED STATEMENT

All these issues lead to a common topic: How can we reduce health care costs? It is a voluminous topic. I have looked at it and put it in the testimony. I do not think we have to go through it now. But the issue mainly is that we can control health care cost. We actually can reduce it if we are bold, take the challenge. The Government must be more courageous about what they do, discarding lobbyists, and changing the things that we have talked about in the testimony.

I will be happy to answer any questions.

[The statement follows:]

STATEMENT OF CHARLES B. SIMONE, M.D.

INTRODUCTION

One of every three Americans will develop cancer today and by the year 2000 it will be two of five. Despite the enormous effort to combat cancer, the number of new cases of nearly every form of cancer and the number of cancer deaths has increased annually over the last century. Still worse: from 1930 to 1993 - despite the introduction of radiation therapy, chemotherapy, and immunotherapy with biological response modifiers, despite CT scans and MRI scans, and all the other new medical technology and billions of dollars - lifespans for almost every form of cancer (except lung, cervix, and stomach) have remained constant, which means that there has been no significant progress in the treatment of cancer (see Figure 1 and protocol on Treatment of Advanced Cancers Using Cartilage). And worse yet, perhaps even deceptively so, is the unrealistic goal set by the National Cancer Institute and the American Cancer Society of a 50 percent reduction in cancer mortality by the year 2000. Because of these dismal survival statistics, we need to redirect our attention to two important areas: *Prevention* of cancer and disease; and pursue totally *New Substances/Modalities* that show scientific merit for treatment.

SHARK CARTILAGE STORY AND FDA

My publisher introduced William Lane, Ph.D. to me. He had commissioned a French scientist/laboratory to perform animal experiments that showed shark cartilage caused regression of tumors. This, together with the fact that the basic science regarding cartilage and its effects on cancer had already been published in excellent national and international journals (*Science, New England Journal of Medicine, Cancer, Journal of Experimental Medicine, et al.*) intrigued me enough to suggest a small clinical trial be done in Mexico. The positive results on a small number of patients were unexpected and startling. I knew then that cartilage had to be tested on a larger number of patients and that I had to participate directly in the trial to verify results.

The Cuban trial evolved. Nineteen evaluable patients with advanced cancers were treated in Cuba using 70-100 grams of rectally administered shark cartilage per day. I personally was present to examine the patients and the supporting data at week 6, week 16, and week 20. Prior to going, I called and wrote on October 20, 1992 to obtain permission to go to Cuba and examine cancer patients there from Clara David and Richard Newcomb of Foreign Assets Central of the US Department of Treasury on Cuban Affairs (202-622-2480, 202-622-1657 Fax).

I did not see or examine the patients starting on day 1 of week 1. But at week 6, twelve patients had tumor regression, one continued to have growth, and six patients were unevaluable (too near death, no followable disease, or no evidence of disease at that time). At week 16, however, four patients continued to have regression of disease, seven started to regrow, two patients were unevaluable, five were dead, and one was stable. The patients had the following cancers: prostate cancer metastatic to bone; esophageal cancer, breast cancer metastatic to lung, liver or bone; ovarian cancers metastatic to liver or lung; colon cancer metastatic to liver; primary hepatoma, and two astrocytomas, one grade 2 and one grade 4. Those patients who had a response at week 20 included: two patients with ovarian cancer metastatic to liver and pleura; one patient with astrocytoma grade 2 status post 80% resection but who had cranial nerve VII palsy post-op which resolved completely as well as complete resolution of equilibrium with no other treatment; and one patient with prostate cancer metastatic to bone.

The reasons for doing this out of the U S were because of the Regulatory Procedures:

1) The above results were so important that cartilage had to be tested *quickly* in humans. Cartilage had been on the market, consumed by people as a supplement or food for years if not centuries and there was no harm documented, hence there was no danger. Given the normal protocol procedures in the US, a food like cartilage, undergoes a transformation to drug status when it is used specifically to *prevent, cure, or mitigate* an illness. Acquiring an Investigational New Drug status from the FDA requires a great deal of time. Time is precious because more than 1400 cancer patients die everyday in the United States.

Dr. Joseph Jacobs, chairman of the Office of Alternative Medicine, NIH met with me in Lawrenceville, NJ in early March 1993 after the February 28, 1993 broadcast of the Cuban trial. He invited me to discuss my findings at his meeting on April 1, 1993 in Virginia and Dr. Stuart Nightingale, Associate Commissioner for Health Affairs of the FDA was present, both of whom said they would help facilitate my protocol. On May 12, 1993 I submitted my protocol,

TREATMENT OF ADVANCED CANCERS USING CARTILAGE to the following people: Dr Joe Jacobs, Dr. Stuart Nightingale, Jay Moskowitz, now acting Director of the NIH, Frank Wiewel and Ralph Moss, Co-Chairpersons of the Committee for Pharmacologic and Biologic Treatments of the Office of Alternative Medicine at NIH, and Honorable Berkeley Bedell.

To this date, I have had no written communication from the FDA, so since the 30 calender days have elapsed, I assume the FDA is permitting my protocol to proceed. I have just received, June 21, 1993, application forms for IND.

2) It is a felony in some states (eg California) for a physician to use an "unapproved" substance that has not shown efficacy for cancer treatment and hence I did not want to get embroiled in any legalities. Curiously, existing FDA "approved" chemotherapeutic agents have not changed *survival* one bit (except for about 1%-2% of all cancers), and certainly, there is no efficacy shown by treating with third and fourth line chemotherapies. But this practice continues causing more pain and suffering to the patient, and raises the cost of health care since it is getting reimbursed. The FDA and the Federal Government should allow and reimburse only for substances which can palliate or change survival curves.

3) My experience with the FDA is that they are slow in certain instances to respond:

On November 5, 1991 I sent a letter to Donald Plumb, Assistant to the Director, Division of Regulatory Guidance, Center for Food Safety and Applied Nutrition requesting information on how to obtain approval for prescription status for a vitamin/mineral formulation. On March 19, 1993 James Tanner, Ph.D., Special Assistant to Director, Office of Special Nutritionals, Center for Food Safety and Applied Nutrition returned my original letter and the envelope with the November 5, 1991 postmark and replied by saying, "Because of the time since your letter was received, we are returning it to you with our apology. If the question is still a timely one, you may wish to resubmit it to the agency for a more timely reply."

In a completely unrelated matter, I called Dr. Gloria Troendle, Deputy Director, Division Metabolism and Endocrine Products on 1/29/92 requesting how to proceed to obtain prescription status for a drug *exactly* like an existing one, Berocca Plus. I called again on 2/27/92 and again on 3/3/92. This time Dr. Troendle seemed as if she had no idea what I was asking (even though I was told it is her division that reviews such requests). She asked me to write to her and she would "ask around." On March 6, 1992 I sent her the letter. No response. On May 6, 1992 I enlisted the help of Congressman Chris Smith to obtain this information. He in turn requested the help of Marc Scheineson, Associate Commissioner for Legislative Affairs at FDA on May 21, 1992. I continued to call. But finally on October 5, 1992 I received a letter dated September 23, 1992 and information from Richard J. Chastonay, Director, Division of Drug Labeling Compliance, Office of Compliance, Center for Drug Evaluation and Research. On November 28, 1992 I sent in the completed paperwork and stated to Mr. Chastonay that it took almost seven months for a response and the response was his letter and procedures and forms written in 1984, "so all your department had to do was stuff them in an envelope in March 1992."

4) Another reason for doing the initial cartilage trials outside the US is that I did not want what I read had happened to Dr Wright, a Harvard trained physician, happen to me. I read, and don't have any first hand information, that the FDA and other agency officials broke into his office with guns drawn because he was using intravenous vitamin B in his practice of medicine.

5) And finally, I questioned the wisdom of the FDA for removing from the market an essential amino acid, tryptophan. Remove contaminants, but not an essential amino acid that God and Nature considers important for the very life of the human species.

PRELIMINARY RESULTS USING CARTILAGE IN UNITED STATES

Since March 1993, after it was recommended to proceed with a study involving cartilage in advanced cancers by the Co-Chairpersons of the Committee for Pharmacologic and Biologic Treatment, Office of Alternative Medicine, National Institutes of Health, I have accumulated about 70 patients with advanced cancers. *All patients had taken shark cartilage as a food supplement in some form and dose prior to coming to see me.* Hence, I simply guided them with regard to shark cartilage, the Simone Ten Point Plan, and when to get follow-up studies.

Twenty patients have been followed for at least 8 weeks. The following are patients who have had either a complete response or a partial response.

J.M, 84 y o male - well differentiated adenocarcinoma gall bladder metastatic to nodes and liver
 8/14/92 Diagnosis made, surgical removal, having 2 positive lymph nodes
 10/92-12/92 - received 31 fractions of radiation with 6 boli of 5FU (Memorial Sloan Kettering)
 1/11/93 - CT scan: "Two fairly large but ill-defined foci of tumor within the median segment of the left lobe and the lower portion of the right lobe of the liver. Bilateral pleural effusions." Doctor at MSK recommended mitomycin but was reluctant to give due to lack of efficacy. Patient was ill, and told to go home. He, himself began shark cartilage for a week.
 3/19/93 - came to me ill, in pain, and short of breath. I instructed him on how to properly use shark cartilage which he administered rectally daily.
 4/21/93 - follow-up, patient felt better, less short of breath, quality of life improved.
 5/20/93 - Repeat CT scan: "Previous large poorly defined areas of decreased density in the liver seen on 1/11/93 have resolved consistent with interval improvement."

C.S. - 49 y o female locally advanced breast cancer metastatic to liver (biopsy proven). Instructed on the Simone Teu Point Plan.

4/30/92 MRI shows liver mets

5/8/92 - neoadjuvant conventional CMF (cytoxan, methotrexate, 5FU) started, good doses.

5/21/92 - Hepatic ultrasound - multiple liver masses in right and left lobes, biopsy done.

6/5/92 - palliative CAF began (cytoxan, adriamycin, 5FU). No toxicity seen.

10/1/92 - Repeat hepatic ultrasound, larger masses, and at my request, dimensions are defined.

 Patient began shark cartilage, I then advised her concerning it. She had a plateaued response to chemo so it was decided to "back of a bit on the aggressiveness of her therapy and change her from CAF to all IV, every 21 day, CMF."

2/1/93 - Repeat hepatic ultrasound: "On the prior study of 10/1/92 a hypoechoic region in the left lobe and 5 in the right. The left lobe lesion is unchanged. There are no lesions in the right lobe today."

3/15/93 - patient noted enlarging breast mass, indicating progressive disease, switched to mitomycin and vinblastin.

Although this is not a clear case, I am convinced that shark cartilage caused the liver lesions to regress, albeit temporarily, since it is highly unlikely CMF would be effective after CAF failed, and unlikely that CMF would be effective after CMF had been used initially and failed.

S.DM. - 30 y o female with ovarian cancer metastatic to liver and peritoneal/abdominal structures

6/90 Diagnosis established. Since then, has had multiple single and combination chemotherapeutic agents, had autologous bone marrow transplant, and then Taxol - all failing.

2/93 - patient began shark cartilage. Her doctors told her there was nothing left to do.

2/24/93 - I saw patient and instructed her. She was quite ill. CA 125 was 1140 (a blood test to measure activity of the disease).

3/19/93 - She was much improved, less pain, able to eat, and laugh.

4/14/93 - Much better; hemoglobin began to rise, CA 125 down to 1020, pelvic mass down by 40%, external subcutaneous mass left lateral chest down to 2X2.5X1 cm from 8X10X5.

5/12/93 - had to have diverting colostomy; CA 125 up to 1610.

6/3/93 - resumed cartilage.

In this case, shark cartilage produced a partial regression.

E.R. - 85 y o male with prostate cancer metastatic to bone.

15 yr ago - Diagnosis established, radical surgery, hormonal manipulation

1/92 - Bone scan positive, began Flutamide alone.

7/92 - Emcyte began alone.

1/20/93 - I saw patient for pain control. He looked very ill.

3/8/93 - Patient and family desired instruction on shark cartilage.

4/13/93 - No analgesics required at all, lots of energy, driving his car now

5/13/93 - More subjective improvement, quality of life 10+.

	Hgb	SGPT	LDH	Ferritin	PSA	PAP
3/8/93	10.8	47	92	468	53.4	4.5
4/13/93	11.5	46	nl	482	46.3	5.6
5/6/93	11.5	nl	nl	413	48	4.1
6/8/93	11.9	nl	nl	nl	48	3.4

Objective and Subjective response.

A total of 50 percent of these 20 patients experienced better quality of life with less pain, better appetite, etc.

USE OF THERAPEUTIC LEVELS OF NUTRIENTS TO AUGMENT ONCOLOGY CARE

Please refer to the attached abstract. The study shows that 50 consecutive early staged breast cancer patients had little or no side effects during chemotherapy and/or radiation therapy while they followed the Ten Point Plan which included taking certain nutrients in the correct doses.

USE OF NUTRIENTS AND CABBAGE EXTRACT FOR RECURRENT LARYNGEAL PAPILLOMATOSIS

L. S. - 3 y o adopted Korean born child required at two week intervals for over 18 months of her life, general anesthesia and surgical removal of papilomas on her vocal cords which would otherwise have caused her to suffocate if left unattended. A substantial amount of medical literature exists (Simone, CB, Cancer and Nutrition, Avery 1992) to suggest that certain nutrients and enzymes from the cabbage family have been successfully used to treat cervical papilomas. I applied the same logic in her case and she has not had the need for surgery for over 68 weeks. The ENT physician could not believe that she did not need surgery and demanded that the parents agree to having the patient be examined under general anesthesia on two different occasions - both times no growth.

EVERYTHING WE HAVE DISCUSSED, LIFESPAN AND MORTALITY CURVES UNCHANGED SINCE 1930, QUALITY OF LIFE, ETC ALL LEAD TO A COMMON TOPIC:

HOW TO REDUCE AMERICA'S RUNAWAY HEALTH CARE COSTS

In 1992, according to the Commerce Department, Americans spent \$847 billion on health care. By 2000 this astonishing figure is expected to expand to \$1.3 trillion. In 1990, despite "wellness" programs and growing efforts to contain hospital, physician and other medical costs, the costs of medical insurance plans increased by 25 percent.

ALLOCATION OF HEALTH CARE COSTS: 1960-90

	1960	1970	1980	1990	1993
Health Costs \$ billions	\$27	\$74	\$250	\$667	\$847
Hospital Care	34%	38%	41%	38%	-
Nursing Home Care	4%	7%	8%	8%	-
Program Administration / Net Cost of Private Insurance	4%	4%	5%	6%	-
Gov't Public Health	1%	2%	3%	3%	-
Physician's Services	20%	18%	17%	19%	-
Dental Services	7%	6%	6%	5%	-
Research /Construction	6%	7%	5%	3%	-

Yet, against this background of ever-upward-spiraling health care costs, we have seen surprisingly little progress in combating major diseases. Two in five Americans alive today will develop cardiovascular disease during their lifetimes -- despite \$70 billion spent on research and treatment in 1991 alone. In 1971, when President Nixon declared War on Cancer, there were "only" 337,000 cancer deaths; in 1992, 525,000 Americans died of cancer. In 1992, over 1,170,000 Americans were told they had a potentially life-threatening malignancy. One in three Americans today will develop cancer during their lifetimes; by the year 2,000 the odds will increase to two in five.

Our primary focus on treatment, with minimal attention to prevention, has created a cost-explosive situation that will grow exponentially through the rest of this decade and into the next century. Our losing war against cancer illuminates this grave challenge:

Despite the many billions of dollars that have been spent on cancer research and treatment over the decades (\$80 billion in 1992 alone), the number of new cases of every form of cancer has increased over the last 60 years. Despite the introduction of expensive treatments like radiation therapy, chemotherapy and immunotherapy; despite the expensive diagnostic advances of CT and MRI scans and all the other modern technologies, lifespans for persons afflicted with almost every form of cancer have remained constant - - which means, tragically, that there has been no significant progress in the treatment of cancer.

THE URGENCY OF PREVENTION:

Prevention, which requires individual self-discipline combined with the intervention of government, is not a readily popular formula. Only 5 percent of the \$2.1 billion National Cancer Institute budget is devoted to research and education on cancer cause and prevention -- the myth of finding a silver bullet prevails, while the results of treatment continue to be unimpressive:

- *Strict genetics have little to do with our chronic diseases.
- *Approximately 60 percent of women's cancers and 40 percent of men's cancers are related to nutritional factors.
- *About 75 percent of cardiovascular disease is caused by nutritional factors.
- *About 30 percent of cancers are caused by tobacco use.
- *These and other risk factors account for 95 percent of all cancers and heart disease.

This information is well known to some scientists and some physicians, but is still dimly comprehended by most of the medical community - - and even less so by the general public. And, alas, this knowledge has almost been ignored by Congress and by the Environmental Protection Agency.

Yet this continuing de-emphasis on causative factors, with a growing emphasis on treatment is the root contradiction in American life that must be addressed before health care costs can be contained.

About 90 to 95 percent of all chronic illnesses are preventable. The logic that should follow this transcendent fact stares us in the face: **Health care costs can be reduced** and not just contained **if people elect to modify their risk factors.** This is a process that can come into being through individual behavior combined with governmental actions.

Any such plan must permit complete freedom in choosing a physician, hospital, or other health care institution - rather than being forced into an HMO, hospital, etc., which may not be able to provide optimum care for a particular individual.

But such a plan, while relying heavily on individual behavior, can only take root through courageous initiatives by the Federal Government

These are the broad issues that must be addressed if we as a nation seriously wish to contain and reduce health care costs:

I. DISEASE-CAUSATIVE PRODUCTS AND PROGRAMS BY THE PRIVATE SECTOR MUST NOT BE GIVEN A BLANK CHECK.

(a) STOP PRICE SUPPORTS FOR DISEASE-CAUSATIVE PRODUCTS.

There should be no direct or indirect support for any industry or group whose products are connected to the development of chronic diseases such as cancer, cardiovascular disease, etc., no matter how loud and intense the outcry of their many lobbyists. These industries include tobacco, dairy, beef, pork, etc. One major side benefit: the government will no longer

"dump" these high-fat foods in schools, hospitals and nursing homes, where children and the elderly, the most vulnerable population groups, are seriously victimized.

(b) *RESTRICT ADVERTISING OF DISEASE-CAUSATIVE PRODUCTS.*

The advertising of tobacco and alcohol products in all media must end. We should focus on the need to place certain limits (time of viewing and frequency) on junk food and candies aimed at young people, especially children.

The entire subject of children-directed advertising cries out for more serious attention by the Federal establishment. The Surgeon General's recent "request" to RJR to end using Camel Joe in their advertising will have no effect despite clear evidence by the medical profession (JAMA 1991) and internal memos from RJR that this cartoon character is being used to target young children as potential consumers of Camel cigarettes.

And scientists should have academic freedom to investigate risk factors and disease, and directed advertising without fear of legal harassment by companies or lobbyists.

2. **COST-INFLATING GOVERNMENT MEDICAL SERVICES AND PROGRAMS MUST BE REVISED OR ELIMINATED.**

(a) *MEDICARE BENEFITS SHOULD BE LINKED TO INCOME.*

Present recipients of Medicare consume a disproportionately large share of America's health dollars. This milestone program of Lyndon Johnson's "Great Society" has helped millions of our elderly citizens deal with their health care costs - but almost thirty years later, reforms are mandatory. With the following redistributions of funds, the Medicare/Medicaid net can actually be extended to millions of people, not covered by insurance, but truly in need:

Income	Deductible	Pay Premium	% Covered
High	\$1000	YES	60%
Moderate	\$ 250	YES	80%
Low	\$ 100	NO	100%

(b) *OPEN THE FREE MARKET TO HOSPITAL DEVELOPMENT AND MEDICAL EQUIPMENT.*

In most states, hospitals enjoy a protective monopoly. The rules and regulations profoundly discourage the building of new hospitals. In most states, a hospital gets paid by a government agency for the number of beds they have **whether filled or empty!** Teaching hospitals are free to charge what they wish, while most hospitals simply tack on a hefty surcharge for those patients with good insurance to offset their losses from the under-insured or non-insured. This is just one of many egregious examples of unfair, "protected" practices that continue to inflate health care costs.

If we allow competition in the construction and "marketing" of new hospitals and medical equipment, the marketplace will dictate fairness; the consumer will then be able to select a hospital, treatment center, or diagnostic testing facility on the basis of pricing and services. If a hospital can no longer keep its beds filled -- for whatever reason -- then it must go out of business like any failing commercial enterprise. The Federal Government must eliminate its protective practices that have created flagrantly unfair monopoly practices. Outside auditing of hospitals, as one small reform, would dramatically demonstrate the high cost to the public of inefficiently managed hospitals.

(c) *CLOSE ALL VETERANS ADMINISTRATION HOSPITALS*

They are dinosaurs. They provide less than optimal medical care, require disproportionately high Federal budgeting to maintain, and this budgeting has **NO** limitation to its growth as does Medicare/ Medicaid. All eligible veterans should be enrolled in Medicare or Champus; and have their care anywhere. Savings - enormous.

3. **OTHER STEPS TO PROMOTE PREVENTION AND/OR REDUCE HEALTH CARE COSTS.**

(a) *PUT A CAP ON MEDICAL MALPRACTICE AWARDS.*

This horrendous problem that inflates medical costs astronomically should be solved as quickly as possible. One simple formula to resolve this: limit these awards as in present Workmens Compensation laws.

(b) *ELIMINATE THE "PATIENT'S LOOPHOLE".* As a parallel to eliminating the excesses of malpractice awards we must simultaneously provide assurance to all medical providers that

patients will pay their bills - particularly that large number of financially able people who transfer their assets to family or friends in the face of high impending medical bills. Legal access to these transferred funds should be enacted, with the date of liability to coincide with the date of diagnosis.

- (c) *TEACH OPTIMUM LIFESTYLE EARLY IN LIFE.* A program that sets the model for training children early in life for an optimum lifestyle is a **HEALTHY START**, which I created. **HEALTHY START** or similar programs should be encouraged in school systems throughout the country.
- (d) *TAKE CARE OF TERMINALLY ILL PATIENTS IN THE HOME.* A large percentage of health care dollars get expended during the last weeks of a patient's life - a time when *NO* intervention will make a difference.
- The terminally ill patient should enjoy **physical and mental comfort at home**. Expanded use of home care personnel - who need to know how to bathe, feed, and other minimal chores - should be reimbursed for a number of hours a day. The family is responsible for the rest of the 24 hour period. If the family elects not to provide for physical and mental comfort, then the family is taxed to offset the cost of increased utilization of home care personnel (deducted from family members' Social Security, etc.). If there is no family, then the cost would be borne by the Medicare/ Medicaid system. The savings for taking care of terminally ill patients in this manner is tremendous.
- (e) *UNINSURED MONEY-EARNERS MUST PAY HEALTH INSURANCE PREMIUMS ACCORDING TO INCOME - REPORTED AND "HIDDEN."*
- Almost 77 percent of the uninsured are in families with adult workers: 46 percent are working adults under age 65 and another 30 percent are their spouses and children (1987 National Medical Expenditure Survey by US Agency for Health Care Policy and Research). These workers are typically: self-employed; part-time; in small firms; earn less than \$5 an hour; temporary or seasonal; lower skilled; involved in construction, sales, entertainment, repair, personal services, and agriculture. The majority of these people are: between the ages of 19-24, unmarried, African-American, or Hispanic, living in the South or West. These money-earners should no longer be able to choose not to pay toward health care insurance.
- (f) *DISCONTINUE INEFFECTIVE TREATMENTS.* For example, chemotherapeutic agents for cancer are used continually even if it is known that the tumor is growing. When the first, and second line agents have been used without beneficial effect, then no further chemotherapy should be reimbursed.
- (g) *ENFORCE ALL SAFETY STANDARDS.* All safety standards must be enforced whether it involves seat belts, or warehouse safety, etc. Substantial fines should be implemented. Health care savings will be impressive.
- (h) *NO LANDFALL PROFITS IN THE PHARMACEUTICAL INDUSTRY.*
- Tax profits regardless of site of manufacture.
- (i) *UNIFORM AND SIMPLE HEALTH INSURANCE FORMS.* Hugh savings
4. **TAXES AND TAX CREDIT FOR INDIVIDUALS AND CORPORATIONS.**
- (a) *EXPAND SIN TAXES* Products to be taxed at point of sale should include those that are known to cause cancer, heart disease, or other chronic diseases: foods high in fat, foods high in sugar, junk foods, as well as all tobacco and alcohol products. The tax on each item must cover the increased health care dollars that would be needed to treat *its* abusers.
- (b) *TAX ALL HEALTH CARE FRINGES* All fringe benefits, including health care premiums for medical, ophthalmologic, dental, prescription plans, etc., should be counted as income and taxed
- (c) *PUNISH POLLUTERS.* Significant taxes and fines should be imposed on companies whose environmental laxity contributes to disease. The tax and fine should be ten times the cost of keeping the environment clean and safe.
- (d) *REWARD COMPANIES THAT ENCOURAGE PHYSICAL FITNESS.* Give tax credit to companies (size to be determined) which provide gym facilities or allow for membership in local gyms and encourage employees to use these facilities.
- (e) *REWARD COMPANIES THAT PROVIDE FITNESS INCENTIVES*
- Give tax credit to companies (size to be determined) which provide incentives to employees

that encourage disease prevention. Here are examples of this important private sector initiative that could have an impact on **prevention**, thereby reducing the high cost of **treatment**:

U-HAUL in Phoenix, AZ: employee pays \$120/year if smoker&overweight.

ADOLPH COORS CO., Golden, CO: pays 90% instead of 85% of employee's medical bills if that person is fit or swears to follow a health program.

FOLDRCRAFT in Kenyon, MN: employee pays \$900 deductible if high pressure and overweight.

BAKER HUGHES, Houston, TX: employee pays \$120/year if smoker; or earns \$100/yr if three (pressure, weight, cholesterol, triglycerides), are normal.

5. MONETARY REWARDS OR CHARGES TO EMPLOYEES AND/OR TAX CREDITS TO THOSE WHO PRACTICE DISEASE PREVENTION.

Disease prevention is no simple matter -- but by providing attractive incentives, we can alter the lifestyles of millions of Americans and thus reduce the towering health cost burden of **treatment** -- through a comparatively modest investment in **prevention** by offering employees a program of monetary incentives, expanding on the innovative examples of the above mentioned companies, who reward employees for practicing prevention. We should also consider *tax credits* for individuals who practice prevention.

Today, a person who is healthy and constantly modifying his/her disease risk factors is actually subsidizing someone else who goes through life with risk factors and does nothing to modify them. As observed previously, about 90 to 95 percent of all chronic illnesses are preventable (Simone, C.B., Cancer and Nutrition, A Ten Point Plan to Reduce

Your Risk of Getting Cancer, 1983 McGraw-Hill, 1992 Avery). **Health care costs can therefore be reduced**, not just contained, *if everyone elects to modify his/her risk factors*.

What is needed is a program that focuses on the average person's disease risk factors and then provides an incentive to modify them.

(a) *AN INCENTIVE PROGRAM FOR EMPLOYEES* Assess a person's risk factors through the **HEALTH STYLE QUESTIONNAIRE**, created by me to evaluate a person's lifestyle, with a prime emphasis on disease prevention, through computer scanning. Each factor is assigned a dollar amount to be charged or credited to the employee.

(b) *TAX CREDIT FOR THOSE WHO PRACTICE PREVENTION*. By isolating the seven most important risk factors and assigning a tax credit for staying within the acceptable level for for each risk factor, a simple but highly effective program of prevention can be implemented:

Cholesterol < 200	\$75/year	Triglycerides < 100	\$35/year
Blood Sugar 65-120	\$35/year	Normal Weight	\$50/year
No tobacco use	\$75/year	Minimal alcohol	\$ 5/year
Normal Blood Pressure	\$25/year		

By staying within the normal limits of all seven risk factors, a total tax credit of \$300 can be earned per year.

SUMMARY

With limited or no change in lifespans for most of our chronic illness we must redirect our research priorities to: Prevention, and new Substances/Modalities which may show promise in treatment no matter how odd they may seem. The true scientist/physician will keep an open mind. We must seek new paradigms which are usually always received with coolness and even mockery. Their discoverers are attacked for their heresy (Copernicus, Galileo, Pasteur, Mesmer, Newton, Einstein).

A new concept demands a complete change and most established scientists are rarely converted. Those who have worked industriously with the old are usually unable emotionally to give it up. Scientists/physicians must be responsive and seek

new paradigms. US Governmental agencies, established by voting Americans, must in turn be responsive to new findings and must act quickly so that Americans will benefit.

BRIEF BACKGROUND OF CHARLES B. SIMONE, M.D.

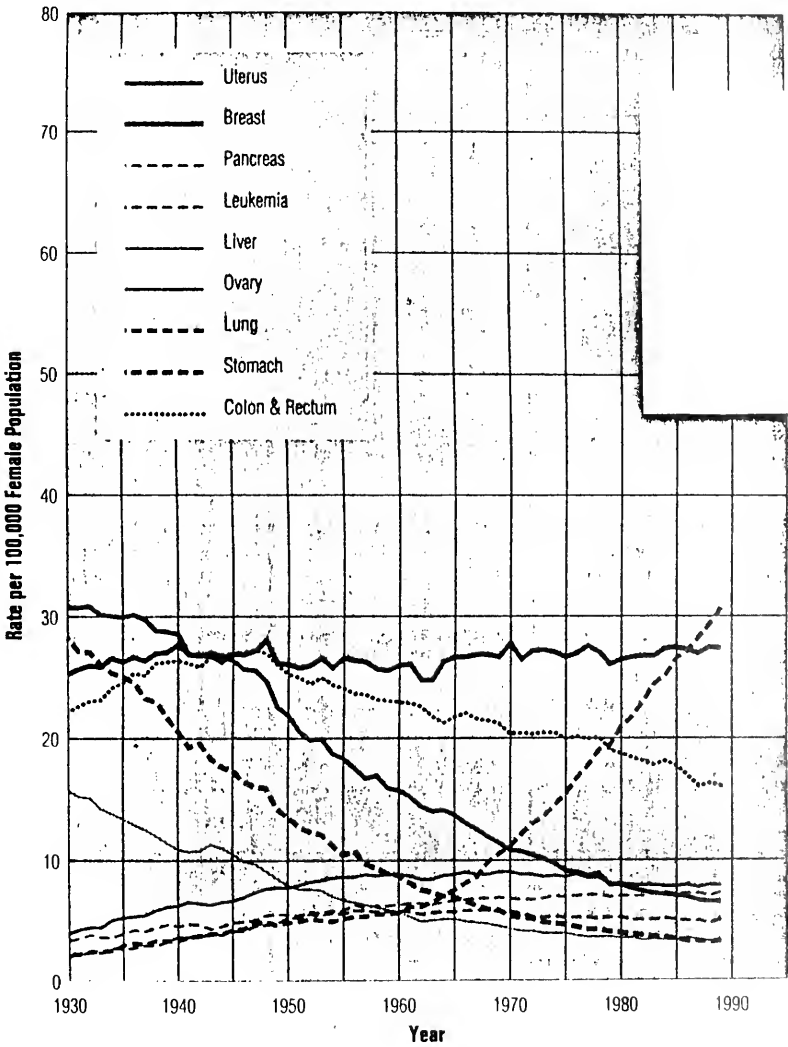
Charles B. Simone, M.M.S., M.D. graduated from Rutgers Medical College (1971-1975). He is an **Internist** (Cleveland Clinic 1975-1977), **Medical Oncologist** (National Cancer Institute 1977-1982), **Immunologist** (N.C.I. 1977-1982), **Radiation Oncologist** (University of Pennsylvania 1982-1985) - hence he has formal training in three of four ways of treating cancer.

While at the NCI, his basic science research uncovered the fundamental mechanism of how human white blood cells kill, helped show how "complement proteins" aid in killing, demonstrated how adriamycin works, and developed *directed effector cell killing*.

One of the first patients he saw at the NCI was an American senior statesman who was dying of malnutrition secondary to his cancer. Later, a man his own age with a newly pregnant wife came to him at NCI. The man had a rare cancer that spread throughout his body and asked Simone to keep him alive for the birth of his child. An intensive course of chemotherapy cleaned out the cancer cells, but the patient failed to improve. "I decided finally, at last resort, to put him on high doses of vitamins and minerals that quickly produced a seemingly miraculous, if temporary recovery." The man lived to see the birth of his son.

He began devoting some of his time investigating the effects of nutrition on cancer and the possibilities of cancer and disease prevention. The result was Cancer and Nutrition, A Ten Point Plan to Reduce Your Risk of Getting Cancer (1982 McGraw Hill, 1992 Avery). Other books Breast Health (in press), and A Healthy Start (in press).

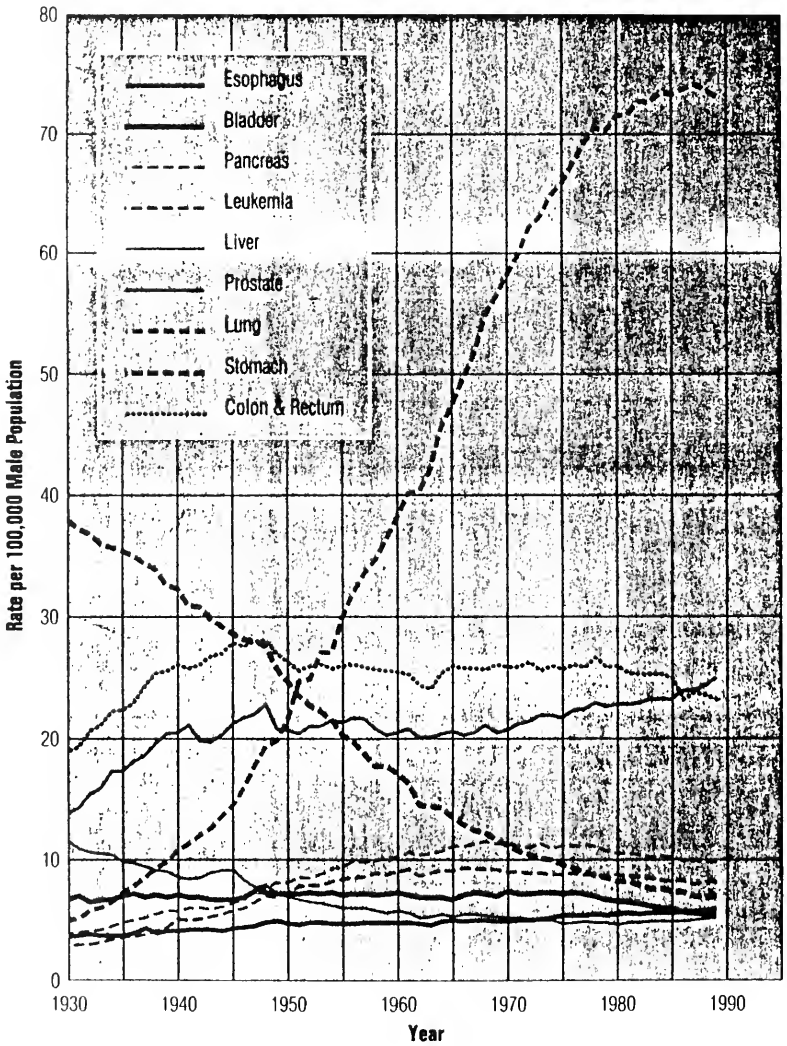
Age-Adjusted Cancer Death Rates* for
Selected Sites, Females, United States, 1930-1989



*Age-adjusted to the 1970 US standard population.

FIGURE 1

Age-Adjusted Cancer Death Rates* for
Selected Sites, Males, United States, 1930-1989



*Age-adjusted to the 1970 US standard population.

FIGURE 1

Protocol Number 1
TREATMENT OF ADVANCED CANCERS USING CARTILAGE

1 Introduction

One of every 3 Americans will develop cancer today and by the year 2000 it will be 2 of every 5. Despite the enormous effort to combat cancer the number of new cases of nearly every form of cancer has increased annually over the last century. Still worse: from 1930 to 1993 - despite the introduction of radiation therapy, chemotherapy, and immunotherapy with biological response modifiers, despite CT scans, MRI scans, and all the other new medical technology and billions of dollars - lifespans for almost every form of cancer (except cancers of the lung, cervix, and stomach) have remained constant, which means that there has been no significant progress in the treatment of cancer.¹ And worse yet, is the unrealistic goal set by the National Cancer Institute and the American Cancer Society of a 50% reduction in cancer mortality by the year 2000.^{2,3,4,5,6,7,8} Because of these dismal survival statistics, we need to redirect our attention to two important areas: prevention of cancer and also totally new substances which may show some merit scientifically in the treatment of cancer.

2 Background

Cartilage has been used since the 1950s for the promotion of wound healing^{9,10} Bovine cartilage has been administered both orally and parenterally¹¹ for the treatment of osteoarthritis, acute and chronic skin allergies, psoriasis, rheumatoid arthritis, ulcerative colitis, regional enteritis, and progressive systemic sclerosis. It has been shown in these studies to have potent anti-inflammatory and antiallergic properties.

In 1963, it was postulated that tumors were dependent upon angiogenesis.¹² As the tumor grows, there is an increase in new capillaries that converge upon the tumor every time there is an increase in tumor cell population.¹³ Both bovine and shark cartilage were found to contain inhibitors of tumor angiogenesis. Shark cartilage contains many of the same biochemical activities as bovine cartilage including lysozyme activity, cell growth promoting activity, inhibitory activity against type I collagenase, inhibitory activity against proteases such as trypsin, chymotrypsin, plasmin.^{14,15}

The angiogenic factors of various species were identified, purified, amino acid sequence determined, and their genes coded. The polypeptides identified included acidic and basic fibroblast growth factor, angiogenin, and transforming growth factors, alpha and beta.¹⁶

Shark cartilage has been used to treat osteoarthritis and solid tumors in animal and human studies.^{17,18,19} Other investigators continued experiments on angiogenesis, its inhibitors, and cartilage activity against cancer in vitro, animals, and in humans.^{20,21,22,23,24,25} In addition, some non-

neoplastic diseases have persistent angiogenesis as their dominant pathology. These diseases include diabetic retinopathy, retrolental fibroplasia, and neovascular glaucoma, rheumatoid arthritis, hemangiomas, psoriasis, angiofibromas.^{26,27,28,29,30,31}

In 1985, an investigator reported on the use of bovine cartilage in the treatment of 31 patients most of whom had advanced cancers.³² The following responses were reported: a complete response for 35 percent, complete response with relapse in 26 percent, partial response in 19 percent, partial response with relapse in 10 percent, and no change or progression in 9 percent. The patients studied had cancers of breast, ovary, cervix, prostate, leiomyosarcoma of the left broad ligament, colorectal, gastric, pancreas, lung, Hodgkins, renal, glioblastoma, basal and squamous cell of the skin.

The size of the inhibitory angiogenesis factors from shark cartilage has ranged from molecular weights of 1000 to 20,000 daltons or more. Both the shark cartilage and bovine cartilage has been administered enterally in human and animals. It has been shown that the intestinal membrane is permeable to macromolecules of up to about 50,000 daltons^{33,34,35} and hence the antiangiogenesis factors should readily pass as indicated by the positive clinical responses seen, but there have been no pharmacological studies or kinetic studies of the cartilages in humans.

The following animal and human studies using shark cartilage preceded the Cuban trial. Tumor regression was shown by Atassi of human xenografts in nude mice at an oral dose of 1200mg per kilogram. Giving 150mg per kilogram of shark cartilage to 16 dogs resulted in improvement in their osteoarthritis. And administering an oral dose of 12 capsules containing 740mg produced symptomatic relief in 5 of 6 patients with osteoarthritis as reported by Ng at the University of Miami, School of Medicine. Six of eight patients with advanced cancer treated at a Mexican clinic showed tumor regression when given 30gm per day of shark cartilage intrarectally or intravaginally.^{36,37}

Nineteen evaluable patients with advanced cancers were treated in Cuba using 70-100gm of rectally administered shark cartilage per day. I personally was present to examine the patients and the data at week 6, week 16 and week 20. I did not see or examine the patients starting on day 1 of week 1. But at week 6, twelve patients had regression, one continued to have tumor growth, and six patients were unevaluable, (too near death, no followable disease, or no evidence of disease at that time). At week 16 however, four patients continued to have regression of disease, seven started to regrow, two patients were unevaluable and five were dead, one was stable. At week 20 these numbers remained the same. The patients had the following cancers: prostate cancer metastatic to bone, esophageal cancer, breast cancer metastatic to lung, liver or bone, ovarian cancers metastatic to liver or lung, colon cancer metastatic to liver, primary hepatoma, and two astrocytomas, one grade 2 and one grade 4. Those patients who had a response at week 20 included: 2 patients with ovarian cancer metastatic to liver and pleura; one patient

with astrocytoma grade 2 status post 80% resection but who had cranial nerve VII palsy post-op which resolved completely as well as complete resolution of equilibrium with no other treatment; and one patient with prostate cancer metastatic to bone.

Unlike fumagillin and its analogs, petosan, heparin-cortisone combinations and other angiogenesis inhibitors,³⁸ there has been no reported toxicities of shark cartilage or bovine cartilage. Both are obtained in powder form or in capsule form.

3 Objectives

To further evaluate the potential efficacy of shark cartilage and bovine cartilage in the treatment of advanced human cancers.

4 Study Design

Patients with any advanced cancers will be studied. They will be clinically evaluated weekly and objectively at week 6 and 12 with laboratory or imaging work-up. The use of cartilage will be discontinued if tumor progression is demonstrated between weeks 8 and 12; or if clinical events dictate.

Each patient will also be instructed on the Simone Ten Point Plan which will be ideally implemented in every patient. The patients are to follow the pertinent applicable points of the Ten Point Plan. The Ten Point Plan is as follows:

4.1 Nutrition

Ensure proper caloric intake to maintain or increase the patient's ideal weight. The diet is to be supplemented with certain vitamins and minerals especially the antioxidants. Beta Carotene 30mg; Vitamin A 5,000IU; Vitamin D 400IU; Vitamin E 400IU; Vitamin C 350mg; Folic Acid 400mcg; Vitamin B1 10mg; Vitamin B2 10mg; Niacinamide 40mg; Vitamin B6 10mg; Vitamin B12 18mcg; Biotin 150mcg; Pantothenic Acid 20mg; Iodine 150mcg; Copper 3mg; Zinc 15mg; Potassium 30mg; Selenium 200mcg; Chromium 125mcg; Manganese 2.5mg; Molybdenum 50mcg; Inositol 10mg; Para Aminobenzoic Acid 1mg; Arginine 5mg.

4.2 Tobacco - Do Not Smoke, Chew, Snuff, or inhale other people's smoke.

4.3 Alcohol - Avoid all alcohol.

4.4 Radiation - X-rays only when needed. Use sunscreens.

4.5 Environment - Avoid unhealthy air, water, and electromagnetic fields.

4.6 Hormones, Drugs - Avoid unnecessary hormones and drugs.

- 4.7 Seven Warning Signs of Cancer - Learn them
- 4.8 Review Symptoms of organ involvement.
- 4.9 Exercise as tolerated and Relax regularly.
- 4.10 Physical Exam routinely

5 Chemical Composition of Shark Cartilage To Be Used

<u>Component</u>	<u>Approximate Percentage</u>
Protein	38%
Carbohydrates	6%
Ash	52%
Calcium	18%
Phosphorus	9%
Moisture	6%

When bovine cartilage is used it will be the product called Catrix supplied by Dr. John Prudden from the company called LesCarden, New York City.

6 Patient Selection Criteria.

Patients must have:

- *at least a 12 week life expectancy
- *histological diagnosis of cancer and prior treatment (except for renal cancer and melanoma) using surgery, chemotherapy, or radiation therapy; and despite this tumor continues to grow
- *objective measurable disease
- *baseline evaluation of CBC with differential, chemistry screening, and any pertinent screen markers or imaging studies prior to the initiation of cartilage
- *signed the informed consent which they understand

6.1 Exclusion Criteria

- *Radiation therapy to brain for primary brain tumor within 45 days prior to enrollment.
- *Use of cartilage concomitant with other therapy.

6.2 Patient Discontinuation

The investigator may discontinue a patient from the study any time when the physician believes this is in the best interest of the patient. Several examples include: progressive disease, patient's desire to withdraw from study, or patient's noncompliance, etc.

6.3 Definitions

Objective Responses

Complete disappearance of all clinical laboratory signs and symptoms of active disease for at least 4 weeks. Tumor masses totally disappear and no new lesions appear.

Partial 50% or greater reduction of the products of the longest perpendicular diameters of the measured lesions with no demonstrable disease progress elsewhere.

Stable disease no new lesions occur and no measurable lesions increase more than 25% in cross sectional area.

Progression appearance of new areas of tumors. Increase in any previously measurable lesion by greater than 25% in cross sectional area.

Subjective Responses

Quality of life scales, which are a series of qualities of life, are an acceptable way of evaluating any treatment or side effect not by the physician, but rather by the patient. The patient decides whether the treatment is beneficial or not in terms of side effects. The quality of life scales have been successfully used to evaluate treatments for cardiovascular disease, cancer, and other chronic illnesses.

The scoring system is simple. The patient decides if the treatment has improved, worsened, or has made no change in the patient's life during the treatment.

Quality of Life Scales

LIFE'S QUALITIES	IMPROVED	NO CHANGE	WORSEN
Physical Symptoms			
Skin reaction			
Fatigue			
Mouth sores			
Nausea/vomiting			
Dizziness/vertigo			
Lightheadedness			
Muscle cramps			
Performance			
General Well-being			
Cognitive Abilities			
Sexual Dysfunction			
Life Satisfaction			

7 Treatment Plan

All eligible patients will use shark cartilage with the chemical composition described previously. Starting dose is 70gm based on the Cuban trial. It can be self administered either orally or rectally.

Oral administration: 3 divided doses, 4 level teaspoons in the morning, 5 level teaspoons in the afternoon, and 5

level teaspoons at night. Each dose should be given just prior to ingestion of food in juice. The cartilage will not dissolve, so it must be stirred until all is ingested, juice ad libitum.

Rectal administration: Two doses each approximately containing 35gm to be put in one-third to one-half cup of tap water and administered rectally. The patient then is to lay on his/her left side for approximate 30 minutes to allow for absorption.

If there is no apparent response at week 6, the dose will be escalated to 90gm per day of shark cartilage.

Bovine cartilage will be used in patients who have the following cancers: lung, breast, brain, colon, and prostate. Every third protocol patient with one of these cancers will receive bovine cartilage. The dose will be 9 gm administered orally every day in three divided doses.³⁹

8 Study Schedule

- *Interview to determine eligibility
- *Informed consent by patients who have never taken cartilage before (many patients present to the physician already taking cartilage and simply want advice and monitoring).
- *History and Physical to be completed.
- *Define Karnofsky index.
- *Baseline laboratory tests: CBC + differential, blood chemistries, liver function tests, and any pertinent imaging studies. Pertinent laboratory studies and/or imaging studies will be performed at week six and week 12 to determine efficacy of cartilage treatment.
- *Define extent and sites of evaluable disease.
- *Flow chart to be filled in.
- *Ideally, clinical evaluation every week.
- *Post study: follow up data for time to disease progression and survival will be recorded if at all possible.

9 Withdrawal from Study

Participation in this study is voluntary. The patient may withdraw without penalty or loss of benefits to which he is otherwise entitled at any time. The patient need only to inform his/her doctor of the decision to withdraw. Any new information that develops during the course of this study that may relate to the participant's willingness to continue in this study will be provided to the patient. The names of the patients will not be made public to anyone outside the sponsoring institution, except for the FDA, should they choose to inspect the study records. The results of this study, however, may be made public without the inclusion of the names of the participants.

10 International Physician Network

We will be recruiting physicians from America and around the world to administer this protocol and others in the future. Through the International Physician Network, we will be able to quickly recruit hundreds of patients to scientifically determine if cartilage or any other treatment is efficacious.

Notes

1. Boring et al. 1993. Cancer Statistics, 1993. CA-A Cancer Journal for Clinicians. 43(1):7-26.
2. Bailar, J., and E. Smith. 1986. Progress against cancer? NEJM 314(19):1226-32.
3. Boyd, J., ed. 1985. NCAB approves year 2000 report. The Cancer Letter 11(28):1-6.
4. Kolata, G. 1985. Is the war on cancer being won? Science 229:543-44.
5. Boffey, P. 1984. Cancer progress: Are the statistics telling the truth? New York Times (Sept 18):C1.
6. Bush, H. 1984. Cancer cure. Science 84:34-35.
7. Blonston, G. 1984. Cancer prevention. Science 84:36-39.
8. Marshall, E. 1990. Experts clash over cancer data. Science 250:900-902.
9. Prudden, John et al. 1957. The acceleration of wound healing with cartilage. Surg Gynecol Obstet. 105:283.
10. Prudden, John. 1965. The clinical acceleration of healing with a cartilage preparation: A controlled study. JAMA. 192:352.
11. Prudden, John and Balassa. 1974. The biological activity of bovine cartilage preparations. Seminars in Arthritis and Rheumatism. Vol 3 (4):287-320.
12. Folkman, J. et al. 1963. Cancer 16:453.
13. Folkman, J. 1971. NEJM. 285:1182.
14. Folkman, J. 1976. Isolation of cartilage factor that inhibits tumor neovascularization. Science. 193:70-71.
15. Lee, A. and Robert Langer. 1983. Shark cartilage contains inhibitors of tumor angiogenesis. Science. 221:1185-1187.
16. Folkman, J. and Klagsburn, M. 1987. Angiogenic factors. Science. 235:442-447.
17. Atassi, G. 1989. Sept 1. Investigation of the antitumor effect of shark cartilage on human xenografts in nude mice. Institute Jules Bordet. Brussels. (Unpublished).
18. Lane, I W, E. Contreras. 1992. High rate of bioactivity observed in advanced cancer patients treated with shark cartilage material. J Naturopathic Medicine. 3(1):86-8.
19. Raus, J. 1991. Use of shark cartilage in the treatment of secondary osteoarthritis in the dog. British Small Animal Association Congress. Manchester, United Kingdom.
20. Stetler-Stevenson, Wm. 1993. Biological basis for neoadjuvant and adjuvant therapy: tumor invasion and metastasis (TIMP's). Neoadjuvant and Adjuvant Therapy for Selected Malignancies. Mar 5, 1993. UMDNJ.

21. D'Amore, P. 1988. Antiangiogenesis as a strategy for antimetastasis. *Seminars in Thrombosis and Hemostasis*. 14(1):73-78.

22. D'Amore and Klagsbrun. 1989. Angiogenesis factors and mechanisms from the pathobiology of neoplasia. Edited Alphonse E. Sirica. Plenum Pub Corp. p.513-531.

23. Moses, M., Sudhalter, Langer. 1990. Identification of an inhibitor of neovascularization from cartilage. *Science*. 248:1408-1410.

24. Pauli, et al. 1981. Regulation of tumor invasion by cartilage derived anti-invasion factor in vitro. *JNCI*. 67:65-63.

25. Sadove, et al. 1977. Inhibition of mammary carcinoma invasiveness with cartilage derived inhibitor. *Surgical Forum*. 28499-501.

26. Brim, H.J. Folkman. 1975. An inhibition of tumor angiogenesis mediated by cartilage. *J Ex Med* 141:427-39.

27. Moses et al. 1990. Identification of an inhibitor of neovascularization from cartilage. *Science*. 248:4961 p. 1408-10.

28. Pepper et al. 1991. Chondrocytes inhibit endothelial sprout formation in vitro: evidence for involvement of a transforming growth factor beta. *J Cell Physiol*. 146(1):170-9.

29. Takigawa et al. 1990. A clonal human chondrosarcoma cell line produces an anti-angiogenic antitumor factor. *Anticancer Research*. 10(2A):311-5.

30. Takigawa. et al. 1987. A factor and condition medium of rabbit costal chondrocytes inhibits the proliferation of cultured endothelial cells and angiogenesis induced by B16 melanoma: Its relation with cartilage-derived antitumor factor. *Biochem. International*. 14(2):357-63.

31. Oikawa, et al. 1990. A novel angiogenic inhibitor derived from Japanese shark cartilage. One extraction and estimation of inhibitory activities toward tumor and embryonic angiogenesis. *Cancer Letters*. 51(3):181-6.

32. Prudden, J. 1985. The treatment of human cancer with agents prepared from bovine cartilage. *J Biol Resp Modif*. 4:551-84.

33. Warshaw, et al. 1971. Small intestinal permeability to macromolecules: transmission of horseradish peroxidase into mesenteric lymph and portal blood. *Lab investigation*. 25:675-84.

34. Warshaw, et al. 1974. Protein uptake by the intestine: evidence of intact macromolecules. *Gastroenterology*. 66:987-92.

35. Williams, EW, Hemmings. 1979. Intestinal uptake and transport of proteins in the adult rat. *Proceedings Royal Society London. Br*. 203:177-89.

36. Lane. *Ibid*

37. Contreras. *Ibid*.

38. Folkman and Ingber. 1992. Inhibition of angiogenesis. *Seminars Cancer Biology*. 3(2):89-96.

39. Prudden, John. 1993. Personal Communication

USE OF THERAPEUTIC LEVELS OF NUTRIENTS TO AUGMENT ONCOLOGY CARE

By the year 2000, cancer will emerge as the number one cause of death in the United States. The successes in the treatment of cancer plateaued in the 1970's, and no real advances have been made since then. However, chemotherapy and radiation therapy continue to have a role in cancer treatment but produce morbidity. Using Quality of Life Analysis, we asked patients to evaluate treatment side effects of radiation and/or chemotherapy while taking therapeutic doses of nutrients.

We analyzed 50 consecutive early staged breast cancer patients who required primary radiation only (25 women with T1 or T2, N0, M0) or radiation and modified chemo (CF) (25 women with T1 or T2, N1, M0). Each patient took the following combination of nutrients 30 minutes before each therapeutic modality: Beta carotene 20 mg, vitamin A 5000 IU, vitamin D 400 IU, vitamin E 400 IU, vitamin C 350 mg, folic acid 400 mcg, vitamin B1 10 mg, vitamin B2 10 mg, niacinamide 40 mg, vitamin B6 10 mg, vitamin B12 8 mcg, biotin 150 mcg, pantothenic acid 20 mg, iodine 150 mcg, copper 3 mg, zinc 15 mg, potassium 30 mg, selenium 200 mcg, chromium 125 mcg, manganese 2.5 mg, molybdenum 50 mcg, inositol 10 mg, and L-cysteine 20 mg. In addition, they took the following at bedtime: calcium 1000 mg, magnesium 280 mg, boron 2 mg, L-lysine 2 mg, L-threonine 2 mg, and silicon 2 mg.

Quality of Life Scales, which are a series of qualities of life, are an acceptable way of evaluating any treatment/side effect not by the physician, but rather by the patient. The patient decides whether the treatment is beneficial or not in terms of side effects. These Scales have been successfully used to evaluate treatments for cardiovascular disease, cancer, and other chronic illnesses.

The scoring system is simple. The person decides if the treatment has improved, worsened, or has made no change in her life during the treatment period. Group I is composed of radiation only patients, Group II radiation and chemotherapy.

QUALITY OF LIFE SCALES

	GROUP I			GROUP II		
	Improve	No Change	Worsen	Improve	No Change	Worsen
Physical Symptoms	25			24	1	
Skin reaction						
Fatigue						
Mouth Sores						
Nausea/vomiting						
Dizziness, Vertigo						
Lightheadedness						
Muscle cramps						
Performance	23	2		23	2	
General Well Being	25			25		
Cognitive Abilities	25			22	3	
Sexual Dysfunction	25			15	10	
Life Satisfaction	25			25		

Senator HARKIN. I was going through your testimony previously. You have a whole section on some of your frustrations with FDA. Recount those again for me, just in your own words.

Dr. SIMONE. Prior to this, I have had personal experiences with the FDA, simply asking them for information about how to get a drug status for a vitamin/mineral formulation. I wrote on November 5, 1991, and 18 months later almost, March 1993, I was sent a letter that said:

Because of the time since your letter was received, we are returning it to you with our apology. If the question is still timely to you, please resubmit it.

That was one thing.

Another thing completely unrelated. I had to go so far as asking my Congressman to intercede to make them give me a reply on another issue. That issue was simply stuffing in an envelope information that was written in 1984. So nobody had to devise anything, but it took them almost 8 months to do that.

Another reason to looking to a foreign country for the issue of shark cartilage was, again, a problem. You take a glass of water, but if you tell the person to drink water because it's going to cure their cancer, that water now gets transformed miraculously into a drug. So, with a drug status, you need all this other paperwork. Shark cartilage has been around for centuries, been in the supplement stores for years, but as soon as you start using it as a drug for treatment, then you need all this paperwork.

So I did not want to waste the time because every day there are 1,400 people dying in this country of cancer. That is a lot of people. And if this had any merit at all, I wanted to see it quickly, so we went to the other countries for that.

In addition to that, about 1½ years ago a Jonathan Wright, Harvard-trained physician, was stormed by the FDA and other people, other government agencies, with guns drawn—Dr. Jonathan Wright in the Northwest area of the country—because he was simply using vitamin B injections, injectable. And that is the understanding that I have of the case. I do not have firsthand knowledge. I did not want that to happen to me. I did not want guns drawn, coming into my office with this issue.

Finally, I questioned the wisdom of the FDA on several issues, including the tryptophan issue. God and nature has determined that tryptophan is essential to the life of a human. The FDA in its wisdom has removed it from the marketplace.

Senator HARKIN. What is it called?

Dr. SIMONE. Tryptophan. They removed it because of contaminants, but they should remove the contaminants and not the essential amino acid. And that brings up the whole issue of what is evolving also today with vitamins, minerals, amino acids. They want to remove everything and put it in the hands of the physician and in the hands of the pharmaceutical industry. It is a \$6 billion industry, and I think other people want a hold of it.

So those are the frustrations I have had with them. I have submitted my protocol in early May to both the Office of Alternative Medicine and the FDA. I have not had any written communication from the FDA as yet, so I assume—after a 30-day period it is my understanding that they have agreed to allowing the protocol to

happen, but I simply have not received any written communication yet.

Senator HARKIN. What has been the response of the National Cancer Institute to your—

Dr. SIMONE. Well, at a meeting on April 1 to which Dr. Joe Jacobs invited me, I discussed the protocol and the findings I had in Cuba, and I was asked to talk to the people at NCI and a person was there as a representative. I think her name was Mary McCabe. And I shared with her and the whole audience that I would do anything I could to help inform them about what I did and share my information.

But I told them at the same time I would not be bogged down by bureaucratic morass, but I was moving along at the time with patients in my own center.

Senator HARKIN. Congressmen Bedell, it is my intention to finish questioning and responses from the providers. I will dismiss them and then we will get to you.

Dr. Berman, how much exposure do medical students and residents have to your program? Are they informed of it? How do they know about it, for example?

Dr. BERMAN. Partly by word of mouth. That is how it first started. In our department, I have appointments in family medicine because that was my boards in that, and anesthesiology. So our residents know about it through that. And now, it has just sort of grown and I have been asked to give a lot of grand rounds and lectures to the different medical students, both at our university and other universities around here.

We also then put in an elective course so the medical students can choose and actually come and participate in it. And the residents get exposed to it on a daily basis when they rotate through our pain center or through the family medicine. And the same thing with the fellows. So it is sort of a growing process. And as you get more credibility and they believe, and the administration is sort of more supportive, then they invite you on, as they have recently, and say:

Well, come onto the Curriculum Revision Committee and let us see about getting this actually as part of the actual curriculum.

Senator HARKIN. Are students pretty receptive, open to this?

Dr. BERMAN. The students are extremely receptive.

Senator HARKIN. How about your faculty?

Dr. BERMAN. The faculty, it is mixed. Some of them I would call it a healthy skepticism. But I have been really surprised about the willingness to collaborate. We have more people wanting to collaborate with us on research studies than we can actually handle right now, and the more people—especially like, say, the other director at the pain center, for example. He gets exposed to what we are doing. At first it was, "Well, let us send Berman the difficult cases." And in a chronic pain clinic those are very difficult cases. So you start to do that and you have a little bit of results.

And then 1 day he is sitting at the computer terminal with an acute neck pain, and I take him along and I treat him with an acupuncture treatment using ear acupuncture points in his opposite ear, and all of a sudden he can move his neck. The next week, I am getting all these patients coming along, saying, "Oh, Dr.

Millhowen thinks acupuncture works." And that is actually how things move along, and then it grows from there.

Senator HARKIN. You did a survey of attitudes about complementary medicine among primary care physicians. What about the results of that study?

Dr. BERMAN. Well, it is preliminary results right now. We piloted that one and we asked about, I guess, 200 family physicians, "What kind of background do you have in these methods," which was usually more—we broke it down and they had a background of, let's say, more relaxation type of approaches, meditation. Then we asked, "What are your attitudes toward this, and what kind of scientific evidence do you want to see?" And it was not that they wanted hardcore scientific evidence, they wanted to really see it worked in clinical practice, was the overall outcome of it.

And we hope to do this in more of a national survey now and ask different types of primary care physicians, what do you think about it. Because as we see it, there is a great demand by the people out there, but what are the people who are providing some of the care thinking about it, and what are they doing about it?

Senator HARKIN. Well, for any of you, I just wondered about the upcoming debate on health care reform. I have focused a lot of my attention on both prevention and research, and making sure that is part of the health care reform debate and part of hopefully what we are going to have as a bill sometime later this summer.

I must confess I have been a little derelict in not really focusing much attention in that context on alternative therapies or complementary procedures, therapies. I am just wondering if any of you have given any thought to how this might be worked into a national health care system. I imagine the initial response would be to somehow put it on equal footing, but it seems to me we will have to do some more research into some of these areas and again try to determine what is working. Perhaps there might be some modifications of some of the things that are being done.

Obviously, I have heard a lot about shark cartilage. I saw the "60 Minutes" program. If indeed it does work, and all indications are that it is having an effect on some people, is there a modification of that which might work even better? I do not know.

Dr. SIMONE. I think what needs to be done with shark cartilage is to isolate the active proteins that have already been identified. Right now we are administering cartilage ground up without the active proteins being isolated from it, and then use that in capsule form or some other way to get a better effect. So, right now, patients are taking a large amount of powder instead of the smaller amount of active component.

Senator HARKIN. Again, just generally, how do you see this working into national health care reform?

Dr. KALTSAS. Senator, I would suggest that we include State license providers. The States have done the work of finding out what is safe and effective in their own purview. Include State license providers under the health care plan.

For example, the Federal Government spends a lot of money on methadone. Before you are allowed to go for methadone treatment in the State of Oregon, the State requires you to go for acupuncture and counseling. They found that the acupuncture and counseling

works so well the patients no longer have to go on methadone, which they have to stay on for life. And it is a very expensive drug.

So, if we could have Federal legislation that says before the States can use Federal money for methadone programs, they first have to refer the patients for acupuncture and drug counseling, we could save a lot of money in the long run.

Dr. BERMAN. I think when you look at these types of therapies, it is really expanding primary care, is really what you are doing. And if you could take some of these approaches that are validated—and I think it is very important to have some validated complementary medicine—with then primary care, you are really expanding your treatment options. And by doing that, we then may be able to put our high-technology approaches where they are appropriately needed.

And that is done in some other countries. It is not like we have to reinvent the wheel. In Britain they do have a national health care system, and they do pay for homeopathy as part of that national health care system. They pay for healing, therapeutic touch. And they pay for things like acupuncture within that health care system, and it is just then a matter of how you are going to regulate who are the ones delivering that. But I think it can be done and should be done.

Dr. SIMONE. With regard to other treatments, I think, first, they need to be shown to be efficacious to be used. But you need to have good studies to show efficacy first.

But I think the most important thing—for instance, right here in Washington, DC, there is the most cancer in the country per 100,000 population than anywhere else, by far and away. When they look at the issues it is mainly dietary, alcohol, or tobacco.

So, if you want to do anything about containing health care costs, as I have shown in the testimony, you need to address the whole issue of prevention with dietary maneuvers, no alcohol, no tobacco usage. You can take a lesson right here. People say it is a very malignant situation in Washington.

Senator HARKIN. Right. Well, I have nothing else for you, unless you have something else you have thought about that you want to get on the record. If not, again, I thank you very much for being here and coming a long distance. I thank you for all the work you have done, and I hope that we can continue to be in contact with you as we move ahead, for any advice or suggestions that you may have.

As I said, this is not a hearing about developing legislation, although I have gotten a couple of ideas here in terms of getting HCFA to do some changes, and perhaps some change in the thrust of how the Office of Alternative Medicine operates. So I thank you very much for being here.

STATEMENT OF HON. BERKLEY BEDELL, FORMER U.S. CONGRESSMAN FROM IOWA

Senator HARKIN. Next, we will hear from a former colleague of mine, Congressman Berkley Bedell from Iowa. I have been a long-time friend of him and his family as we first came to Congress together in 1974. We served together for 10 years in the House, and Congressman Bedell served for 2 more years beyond that. A great

Congressman, a great public servant from northwest Iowa. A strong supporter of small businesses. He has always had a very broad interest in a lot of things that affect people in this country.

He has been a very close friend of mine for all those years in the Congress and now has become very interested in alternative medicines or complementary therapies—I guess maybe I will have to start changing how I say things now. And I have relied on him a lot for some information and, again, getting my thinking going on how we should start approaching this in the United States.

So, it is indeed a pleasure to have you here, Berkley. In the past, you and I sat up here together, so this is kind of a strange situation with you at the witness table. But I sure welcome you, and again, thank you very much for all that you have done to bring this to the public forefront. Please proceed.

Mr. BEDELL. As you know, I frequently went after the people testifying pretty viciously, and I plead with you not to be as vicious with me as I have been with others when they have been in this position.

Mr. Chairman, before I start, I just have to tell you how proud I am for the fact that I served with you, and how proud I am of you, coming from our great State of Iowa, and how pleased I am with what you are doing in this particular area.

Senator HARKIN. Thank you.

Mr. BEDELL. My name is Berkley Bedell. I am the founder of Berkley & Co., a major fishing tackle manufacturing company which I started in high school with \$50 saved from my newspaper route. I was the Nation's first Small Business Person of the Year and served in the U.S. Congress from 1975 until 1987.

I fully realize that this background does not qualify me as one of the scientific experts on health. I happen to think that is good. I start with no preconceived beliefs on health care that need to be changed.

I serve on the ad hoc advisory committee to this new Office of Alternative Medicine. I am knowledgeable about some of the problems it faces in conducting the "investigations and validations" called for in this legislation.

I left Congress because I came down with Lyme disease which I contracted while fishing at Quantico Marine Base and which conventional treatment failed to relieve. After three series of heavy doses of antibiotics infused into my veins over a period of 2 years, I finally turned to an unconventional treatment. My symptoms disappeared and today I am clearly free of Lyme disease. Let me tell you about that treatment.

There is a company in our own State of Iowa, Mr. Chairman, that produces a product for livestock by injecting killed germs in the udder of a cow prior to the time the cow has a calf. When the cow has the calf, they take the first milk that the cow gives, which is called colostrum, and process it into whey so that it will keep. The theory is that the cow will communicate the disease to the unborn calf and will develop the antibodies or whatever in the colostrum to protect the newly born calf from that disease.

After I took a teaspoon of this whey every 1½ hours for a few weeks, my symptoms of Lyme disappeared and I no longer suffer from that disease.

Because of the publicity of my case, I get frequent phone calls from desperate people who have been unable to get relief from Lyme with conventional treatment. It breaks my heart that I cannot tell them about my treatment because no one has been willing to spend the millions and millions of dollars necessary to get FDA approval to market this special whey. I can tell you that it cured what appeared to be arthritis in my knee in 15 minutes.

Recently, the company which produced the whey that I believe cured my Lyme disease made a homeopathic preparation from this whey, as homeopathics are exempted from some FDA regulations by law. I have talked to a doctor in Wisconsin who was using this material. He claims 80 percent to 90 percent success in treating patients like me for whom conventional treatments have not been effective. He has now been advised by the Iowa producer that the material will no longer be available because the producer fears the FDA.

Mr. Chairman, I wish you could hear the heart-breaking stories people relate to me about their disease. Just this week I had a call from a lady in Kansas City, MO, whose life had been literally ruined by Lyme. Her treatments have cost about \$100,000, and now her insurance has been canceled, she has no money, and the low-cost treatment which I believe cured me has been canceled because of the FDA policies. I think that treatment cost me \$35 a week for the material, Mr. Chairman.

Recently, the producer of this whey requested permission from the FDA to test it in the treatment of herpes. I have furnished the committee with a copy of part of the FDA reply. I am informed that these ridiculous requirements that the company run a whole series of tests which would take up to 5 years to find out why it works, absolutely kills the project.

Mr. Chairman, this is whey from milk with absolutely nothing added. We cannot even see if it is effective in curing disease without going through a whole series of FDA requirements. Unfortunately, little Miss Muffett is not available to testify that the curds and whey which she was eating is safe.

At a recent meeting which I attended, a practitioner asked the FDA representative if she could test the effectiveness of garlic in treating disease without going through the lengthy FDA approval process. The answer was, "no."

Mr. Chairman, Jonathan Wright has been mentioned previously. I should tell you that his clinic was raided in May of last year. No charges have been filed, and the Government is still holding the things that they took from him and confiscated in that raid, without any charges being filed against him is my understanding. Dr. Simone mentioned this.

Senator HARKIN. You know who this is?

Mr. BEDELL. Oh, yes; it has had a lot of publicity.

Senator HARKIN. What part of the country was it in?

Mr. BEDELL. Washington State. Kent, WA.

He also mentioned L-tryptophan. I should tell you that the issue on L-tryptophan is that apparently there was a contaminated batch from Japan of this amino acid which did cause some deaths in Europe and some problems. But it has not just been removed, the con-

taminant or anything. But no longer can anybody get L-tryptophan at all because of this one contaminated batch.

Senator HARKIN. I do not even know what L-tryptophan is.

Mr. BEDELL. It is an amino acid that was used very widely for medical purposes. And when we had the grapes problem we removed the bad grapes, but we did not say you cannot eat grapes anymore. And that is the action that has happened with L-tryptophan.

I relate this all to you to illustrate how current FDA policies prevent the testing and use of nontoxic alternative treatments. I am sure that most Members of Congress are not aware of this situation. In my opinion, to say that current FDA policies are a disaster to health care in America is a masterpiece of understatement.

I have included with my material a copy of a study that was done by a doctor at Tufts University. You will note on page 125 that the total cost per marketed drug for development and FDA approval was \$230 million. You will also note on this page that the cost of animal studies in phase 1, 2, and 3 trials required to get FDA approval to market a drug averaged \$75.2 million.

Mr. Chairman, people could argue whether the average cost of getting approval to market a medicine is \$25, \$75, or \$125 million. It matters not. The fact is that current FDA policies almost guarantee two things. First, under current policies, the chances of getting low-cost medicine into the system is practically zero. No one is going to spend millions of dollars to get permission to market a product unless they can charge a high enough price to at least get their money back.

You had testimony on shark cartilage. You should know that there are literally dozens of alternative treatments for several different disease which, in my opinion, hold equal or even greater promise and none of them can get a hearing unless this office can become activated. These include, among others, cancer treatment by Dr. Burzynski, which you have already heard about, cancer treatment in Russia by Dr. Galvallo, AIDS treatment by Dr. Fishman, the Nissance treatment which I believe was successful with my prostate cancer, and the Alzheimer's treatment by Dr. Fudenberg, to name a few.

Surely, we should at least check these treatments to see if they really are as effective as claimed. I am sure you are aware of the whole story of Dr. Burzynski with little Ryan. There is an effort at this time to take away his license to practice medicine and to confiscate all of his medicine, which means that little Ryan would no longer be able to be treated, if the Texas Department of Health and Medical Society are successful in those efforts.

I think you also know that our Office of Alternative Medicine gave \$750,000 of the first \$2 million appropriation to NCI in order to see that the Burzynski treatment was checked. And I hope you know that, at least in my opinion, all NCI has done is stall, stall, stall in that effort. And, in my opinion, only if this office can be sufficiently activated will that treatment be properly investigated.

Second, this policy gives exclusive rights to the big pharmaceutical companies and other large corporations. Small researchers, practitioners, and scientists do not have the money needed to go through the FDA approval process. All through history, most cre-

ativity has come from researchers, scientists and others working in small operations, not from giant corporations. And in medicine, current FDA regulations are most effective in shutting them out.

One of the indications of interest in this field of alternative medicine is the huge number of requests you have had from those who wish to testify at this hearing. You may want to have another hearing. I am delighted to hear you say you are likely to do so.

Senator HARKIN. I am. I guarantee it.

Mr. BEDELL. One of the practitioners which I recommended be allowed to testify but which time would not permit is a practitioner from Georgia who has had success in treating children with learning disabilities with amino acids. Amino acids are a comparatively safe, inexpensive treatment. They have been available over the country for years. I had hoped that she could come and testify with one of the learning disabled children who had been able to advance to the regular classroom because of this inexpensive treatment.

Mr. Chairman, last week, the FDA issued some proposed new rules which would require anyone selling herbs or amino acids to first prove to the FDA's satisfaction that they are safe. Unless there is a complete change in FDA's policies, this will result in the removal of all herbs and amino acids from the marketplace. I suppose it would not remove tobacco, but all other herbs, Mr. Chairman.

Senator HARKIN. That about says it all.

Mr. BEDELL. No one is going to spend millions of dollars for approval to market a product that everyone else could also then market. If this is an effective treatment for large numbers of children with learning disabilities, such treatment will no longer be able to be pursued, and those children that could be helped will be sentenced to continued placement in the learning-disabled class.

Under these new regulations, Mr. Chairman, the gentleman who treated your allergy with bee pollen could go to jail for telling you that it would help you. That is in the new regulations, the new proposed regulations.

Senator HARKIN. That FDA just issued.

Mr. BEDELL. Under the new proposed FDA regulations, for this gentleman to have made a claim to you that he could help you with your allergies would be sufficient for him to have to go to jail for doing that.

Senator HARKIN. Why is that?

Mr. BEDELL. Because you cannot make any claims unless they have approved of them ahead of time. So he would have to spend a lot of money to go through the approval process. You would still have your allergies, Mr. Chairman. He would have to spend a lot of money going to the FDA to try to convince them—which I think would be almost an impossibility—that his claim that he can help you is valid, before he could have done that.

Senator HARKIN. I assume those are open for comment period now, right, through the rulemaking procedure?

Mr. BEDELL. Yes; it will be a big battle on this issue.

Of course, someone might succeed in making a different amino acid or amino acid derivative on which a patent could be obtained, spend the million dollars necessary for FDA approval and sell it

through prescription for many times current prices. Is that what we really want as we try to address our health care costs?

Mr. Chairman, when I was in Congress I had no idea of the situation that exists in health care in our country. In medicine, we have a closed shop that is not open to anything new. For cancer, only those who use conventional medicine are allowed to practice. Conventional cancer treatment is surgery, radiation, and chemotherapy. Anyone doing almost anything else is labeled a quack.

The FDA's job is to protect the people from harmful and ineffective drugs. The safest way for a bureaucrat to do that is to set up procedures that make it almost impossible for anything new to get into the market. They not only do that, but the way the FDA goes after some alternative practitioners is unbelievable. In some States, the way the AMA and State medical boards go after anyone using something other than conventional therapy is a disgrace. And the NIH and NCI procedures for investigating new medicine are so costly and time consuming as to make the chance of an alternative therapy being fairly evaluated little better than zero.

That would not be so bad if current treatments were more effective. A recent study by a well-respected European scientist found that the average life expectancy of people with advanced epithelial cancer was exactly the same for people who had no treatment as compared to those given chemotherapy. Epithelial cancers are solid tumor cancers. These cancers make up 80 percent of cancer deaths.

In my opinion, this committee took one of the most important actions in the history of health care when you established this office with a mandate to "investigate and validate these alternative treatments." At this time, I see it as the only hope for getting low-cost, more effective treatments a hearing.

It may not be as scientific as some would like, but it is a comparatively simple matter to set up a protocol where patients will be checked by an outside clinic or laboratory to confirm the diagnosis before treatment and then have the same patients checked by the same clinic or laboratory after treatment to see if the treatment was effective. Since the treatment is performed by the practitioner on regular patients, as is proposed in the shark cartilage protocol with Dr. Simone, it involves very little government cost. It is called outcomes research, and that is what after 1½ years this office seems to be finally starting to institute.

Further scientific confirmation may be advisable if such checks confirm effectiveness of a treatment. But for most seriously ill persons, their main concern about a treatment is whether it has been shown to be effective, and there are many who need it now, not in 5 or 10 years.

Mr. Chairman, the reality is that NCI neither believes in alternative treatments or these low-cost outcomes evaluations. They get millions of dollars for inhouse research and to set up very expensive protocols for investigations. I am advised that they have only held three complete investigations of alternative treatments in all of their history. Until this office has a director and staff that is willing to function as an independent office with NIH, I see little hope of it fulfilling its legislative mandate.

Mr. Chairman, it is time for some straight talk. There are some powerful forces in our society that are doing quite well with things

as they are. The pharmaceutical industry and the AMA have a monopoly on the treatment of cancer and most degenerative diseases. They are both doing quite well financially. How could one expect them to welcome change that might challenge their monopoly? The FDA has unbelievable powers in regulating and controlling the health treatments in our country, and the NIH and NCI get large amounts of money to research medical treatments.

If this office were to confirm some low-cost effective treatments that could be administered by most any practitioners, it would be a tremendous thing for our people, but it would not exactly be a bonanza for the pharmaceutical companies. AMA, FDA, and NCI, these people are not bad people, but they have learned how the American system works, and one goal of any organization is to survive and thrive.

There are powerful forces which this office may well threaten if it can get its act together. The office, as you know, has been in operation for 1½ years without completing a single investigation of these alternative treatments. Some of us on the ad hoc advisory committee have been pushing with all our might to get this office to add the necessary staff and to start procedures to investigate and validate some of these treatments. We have been like pygmies trying to get an elephant to go where it did not want to go.

In my opinion, for this office to be successful in carrying out the investigations called for in this legislation, one of the requirements will be a director who is willing to stand up to these powerful forces. I am sorry to tell you that in my opinion, our current director has not yet shown that commitment. I hope this will change. I believe it must.

It is also true that some of these forces have in the past used all sorts of means to try to destroy the credibility of those who try to change the system. Mr. Chairman, you and I have already been branded as misled or misinformed by those who see anything out of the mainstream as "quackery."

PREPARED STATEMENT

I do not know for sure whether any of these treatments really hold the key to successful treatments of these serious diseases or not, but I have seen too many tragic deaths from cancer, too many people suffer from diseases where relief cannot be obtained from conventional medicine, to shrink from trying with all my power to see that every possible treatment for which effectiveness is indicated is fully investigated.

I hope you, Mr. Chairman, and the rest of this committee will not shrink from this task, no matter how great the obstacles and opposition. I pledge my continued help. Thank you, Mr. Chairman.
[Applause.]

[The statement follows:]

STATEMENT OF BERKLEY BEDELL

My name is Berkley Bedell. I am the founder of Berkley and Company, a major fishing tackle manufacturing company which I started in High School with \$50 saved from my newspaper route. I was the Nation's first small businessperson of the year, and served in the United States Congress from 1975 until 1987. I fully realize that this background does not qualify me as one of the scientific experts on health. I happen to think that is good. I start with no pre-conceived beliefs on health care that may need to be changed.

I serve on the Ad-hock advisory committee to this new Office of Alternative Medicine. I am knowledgeable about some of the problems it faces in conducting the "investigations and validations" called for in this legislation.

I left Congress because I came down with Lyme disease which I contracted while fishing at Quantico Marine Base, and which conventional treatment failed to relieve. After 3 series of heavy doses of antibiotics infused into my veins over a period of 2 years, I finally turned to an unconventional treatment. My symptoms disappeared and today I am clearly free of Lyme disease.

Let me tell you about that treatment. There is a company in our own state of Iowa, Mr. Chairman that produces a product for livestock by injecting killed germs into the udder of a cow prior to the time the cow has a calf. When the cow has the calf they then take the first milk that the cow gives, which is called colostrum, and process it into whey so that it will keep.

The theory is that the cow will communicate the disease to the unborn calf, and will develop the antibodies, or whatever, in the colostrum to protect the newly born calf from that disease.

After I took a teaspoon of this whey every 1½ hours for a few weeks, my symptoms of Lyme disappeared, and I no longer suffer from that disease. Because of the publicity of my case, I get frequent phone calls from desperate people who have been unable to get relief from Lyme with conventional treatment. It breaks my heart that I cannot tell them about my treatment, because no one has been willing to spend the millions and millions of dollars necessary to get FDA approval to market this special whey. I can tell you that it cured what appeared to be arthritis in my knee in 15 minutes.

Recently the company which produced the whey which I believe cured my Lyme disease made a homeopathic preparation from this whey, as homeopathics are exempted from some FDA regulations by law. I have talked to a Dr. in Wisconsin who was using this material. He claims 80-90% success in treating patients like me

for whom conventional treatments have not been effective. He has now been advised by the Iowa producer that the material will no longer be available because the producer is afraid of the FDA.

Mr. Chairman, I wish you could hear the heart breaking stories people relate to me about their disease. Just this week I had a call from a lady in Kansas City, Missouri, whose life has been literally ruined by Lyme. Her treatments have cost about \$100,000, and now her insurance has been cancelled. She has no money--and the low cost treatment I believe cured me has been cancelled because of FDA policies.

Recently the producer of this whey requested permission from the FDA to test this whey in the treatment of Herpes. I have furnished the committee with a copy of part of the FDA reply. I am informed that these ridiculous requirements that the company run a whole series of tests which could take up to 5 years to find out why it works, absolutely kills the project.

Mr. Chairman, this is whey from milk with absolutely nothing added-- and we cannot even see if it is effective in curing diseases without going through a whole series of FDA requirements. Unfortunately, Little Miss Muffet is not available to testify that the curds and whey which she was eating are safe.

At a recent meeting which I attended a practitioner asked the FDA representative if she could test the effectiveness of garlic in treating disease without going through the lengthy FDA approval process. The answer was No!!!

I relate this all to you to illustrate how current FDA policies prevent the testing and use of non-toxic alternative treatments. I am sure that most members of Congress are not aware of this situation. In my opinion, to say that current FDA policies are a disaster to health care in America is a masterpiece of understatement.

I have included with my material a copy of a study that was done by a Dr. at Tufts University. You will note on page 125 that the total cost per marketed drug for development and FDA approval was \$230 million. You will also note on this page that the cost of animal studies and phase 1, 2, and 3 trials required to get FDA approval to market the drug average \$75.2 million. Mr. Chairman, people could argue about whether the average cost of getting FDA approval to market a medicine is 25, 75, or 125 million dollars. It matters not. The fact is that current FDA policies almost guarantee two things.

First, under current policies the chances of getting low cost medicines into the system is practically zero. No one is going to spend millions of dollars to get permission to market

a product unless they can charge a high enough price for it to at least get their money back.

You have had testimony on shark cartilage. You should know that there are literally dozens of alternative treatments for several different diseases which in my opinion hold equal or even greater promise-- and none of them can get a hearing unless this office can become activated. These include among others: cancer treatment by Dr. Burzynski; cancer treatment in Russia by Dr. Govallo; AIDS treatment by Dr. Fishman; the Naessens treatment which I believe was successful with my prostate cancer; and the alzheimers treatment by Dr. Fudenberg, to name a few. Surely, we should at least check these treatments to see if they really are as effective as claimed.

Secondly, this policy gives exclusive rights to the big pharmaceutical companies or other large corporations. Small researchers, practitioners and scientists do not have the money needed to go through the FDA approval process. All through history most creativity has come from researchers, scientists, and others working in small operations, not from giant corporations.

One of the indications of the interest in this field of alternative medicine is the large number of requests you have had from those who wished to testify at this hearing. You may want to have another hearing at a future date to further explore this matter.

One of the practitioners which I recommended be allowed to testify, but which time would not permit was a practitioner from Georgia who has had success in treating children with learning disabilities with amino acids. Amino acids are a comparatively safe inexpensive treatment. They have been available over the counter for years. I had hoped that she could come and testify with one of the learning disabled children who had been able to advance to the regular classroom because of this inexpensive treatment.

Mr. Chairman last week the FDA issued some proposed new rules which would require anyone selling herbs or amino acids to first prove to the FDA's satisfaction that they were safe. Unless there is a complete change in FDA's policies this will result in the removal of all herbs and amino acids from the marketplace. No one is going to spend millions of dollars for approval to market a product that everyone else could then also market. If this is an effective treatment for large numbers of children with learning disabilities, such treatment will no longer be able to be pursued, and those children that could be helped will be sentenced to continued placement in the learning disabled class.

Of course, someone might succeed in making a different amino acid, or amino acid derivative on which a patent could be obtained; spend the millions of dollars necessary for FDA approval and sell it through prescription for many times current prices. Is that what we really want as we address the cost of health care?

Mr. Chairman, when I was in Congress, I had no idea of the situation that exists in health care in our country. In medicine we have a closed shop that is not open to anything new. For cancer only those who use conventional medicine are allowed to practice. Conventional cancer treatment is surgery, radiation and chemotherapy.

The FDA's job is to protect the people from harmful and ineffective drugs. The safest way for a bureaucrat to do that is to set up procedures that make it almost impossible for anything new to get into the market. They not only do that. The way the FDA goes after some alternative practitioners is unbelievable.

In some states the way the AMA and state Medical Boards go after anyone using something other than conventional therapy is a disgrace.

And the NIH and NCI procedures for investigating a new medicine are so costly and time consuming as to make the chance of an alternative therapy being fairly evaluated little better than zero.

That wouldn't be so bad if current treatments were more effective. A recent study by a well respected European scientist found that the average life expectancy of people with advanced epithelial cancer was exactly the same for people who had no treatment, as compared to those given chemotherapy. Epithelial cancers are solid tumor cancers. These cancers make up 80% of cancer deaths.

In my opinion this committee took one of the most important actions in the history of health care when you established this office with a mandate to "investigate and validate" these alternative treatments. At this time, I see it as the only hope for getting lower cost more effective treatments a hearing.

It may not be as scientific as some would like, but it is a comparatively simple matter to set up a protocol where patients will be checked by an outside clinic or laboratory to confirm the diagnosis before treatment, and then have the same patients checked by the same clinic or laboratory after treatment to see if the treatment was effective. Since the treatment is performed by the practitioner on regular patients, as is proposed on the shark cartilage protocol with Dr. Simone, it involves very little government cost. It is called outcomes research, and it is what after 1½ years this office seems to be finally starting to institute.

Further scientific confirmation maybe advisable if such checks confirm effectiveness of a treatment. But for most seriously ill persons, their main concern about a treatment is whether it has been shown to be effective. And there are many who need it now-- not in 5 or 10 years.

Mr. Chairman, the reality is that NCI neither believes in alternative treatments or these low cost outcomes evaluations. They get millions of dollars for in house research, and to set up very expensive protocols for investigations. I am advised that they have only held 3 complete investigations of alternative treatments in all of their history. Until this office has a director and staff that is willing to function as an independent office within NIH, I see little hope of it fulfilling its legislative mandate.

Mr. Chairman, it is time for some straight talk. There are some powerful forces in our society that are doing quite well with things as they are. The Pharmaceutical industry and the AMA have a monopoly on the treatment of cancer and most degenerative diseases. They are both doing quite well financially. How could one expect them to welcome change that might challenge their monopoly.

The FDA has unbelievable powers in regulating and controlling the health treatments of our country.

And the NIH and NCI get large amounts of money to research medical treatments.

If this office were to confirm some low cost effective treatments that could be administered by most any practitioners it would be a tremendous thing for our people. But it would not exactly be a bonanza for the pharmaceutical companies, AMA, FDA, and ~~NIH~~ NCI.

These people are not bad people. But they have learned how the American system works, and one goal of any organization is to survive and to thrive.

There are powerful forces which this office may well threaten if it can get its act together. The office, as you know, has been in operation for 1½ years without completing a single investigation of these alternative treatments. Some of us on the ad-hock advisory committee have been pushing with all our might to get this office to add the necessary staff, and to start procedures to "investigate and validate" some of these treatments. We have been like pygmies trying to get an elephant to go where it didn't want to go.

In my opinion, for this office to be successful in carrying out the investigations called for in this legislation, one of the requirements will be a director who is willing to stand up to these powerful forces. I am sorry to tell you that in my opinion

our current director has not yet shown that commitment. I hope this will change. I believe it must.

It is also true that some of these forces have in the past used all sorts of means to try to destroy the credibility of those who try to change the system. Mr. Chairman, you and I have already been branded as misled or misinformed by those who see anything out of the mainstream as "Quackery".

I do not know for sure whether any of these treatments really hold the key to successful treatments of these serious diseases or not. But I have seen too many tragic deaths from cancer, and too many people suffer from diseases where relief cannot be obtained from conventional medicine to shrink from trying with all my power to see that every possible treatment for which effectiveness is indicated is fully investigated.

I hope you, Mr. Chairman, and the rest of this committee will not shrink from this task, no matter how great the obstacles and opposition. I pledge my continued help.

Senator HARKIN. Thank you for pushing this subcommittee, and me in particular, and the other members of the subcommittee to move ahead in this direction.

Mr. BEDELL. Mr. Chairman, you asked the previous panel about legislation. May I have the privilege of telling you the legislation that I think would be the most important legislation ever passed in health care?

Senator HARKIN. Please.

Mr. BEDELL. In regard to health care and the cost of health care, if we would have an amendment passed—I wrote it up just now—that read as follows:

Any person shall have the right to be treated by whatever treatment that person may desire, and no practitioner shall be prohibited from or punished for administering such treatment so long as there is no evidence of danger to the patient, the patient has been completely advised of the contents of the treatment and any possible side effects, and the patient had signed a statement that they wish to be so treated.

Senator HARKIN. A lot of times people think, well, the FDA, they have to be consumer protectors and protect people from quacks and all that kind of stuff and therapies that do not work. I guess the one argument I hear all the time is that the average lay person does not know how to interpret all this. There are a lot of people out there willing to try to make a quick, fast buck. And we need the Government in the guise of the FDA to protect them from being fleeced out of their money in procedures and things like that, whether it is Laetrile or whatever, things we have heard about in the past.

How do you respond to that?

Mr. BEDELL. Can you tell me any other area in all of our society where the Government prohibits a person from doing something if that action in no way harms any other person or thing? The one area in our society where Government has said: "We know more what is good for you than you do for yourself" is in the field of med-

icine. And I believe most people have come to think that the Government is not always the best judge of everything in our society.

Senator HARKIN. I guess while you were saying that I was just thinking, in answer even to my own postulated question, we set up the FDA to protect people from losing their money by being fleeced by quacks out there; but we did not set up any agency to protect people from losing all their money at the gambling tables, or to go out and throw their money away on slot machines or whatever else. If they want to do that, they do it.

Mr. BEDELL. And if the study is correct that chemotherapy is completely ineffective for advanced epithelial cancer, we still say people can go ahead and sell them chemotherapy.

Senator HARKIN. That is right.

Why did you go to alternative medicine when you had Lyme disease? What led you in that direction? Were you taking antibiotics or something?

Mr. BEDELL. I had very heavy doses of antibiotics where they run something called Rocephin into your veins every day for anywhere from 3 to 6 weeks, were the treatments that I had. And I would feel better a little bit, and then I would get worse again. For 3 years I did that. I cannot tell you the total cost of all that treatment but I am sure it was more than \$25,000 that was paid for those treatments. And as I told you, the whey which I took was, I think, \$35 a bottle. A bottle lasts you a week, and for 10 weeks it probably cost me \$350 to take care of my Lyme disease with this alternative treatment.

Senator HARKIN. And you have not had any recurrence of it?

Mr. BEDELL. No; and you know that. You have been with me.

Senator HARKIN. Yes; I have seen you. I saw you when you looked pretty bad.

What is your assessment of NIH's record on proceeding with investigations of Dr. Burzynski's therapy? I understand they have tried to do something. I am going to get to the bottom of it.

Mr. BEDELL. Let me tell you the problem in my opinion. I have told you how outcomes research is a simple type of research that, at least in the first step, you go out and just simply find out whether what he claims is correct or not. You check patients before they are treated; you check them after they are treated.

NCI insists that the type of treatment should not be done by the practitioner that is having success. They insist that you should go to the Mayo Clinic or Sloan Kettering and have them set up a very expensive protocol where they decide how the patient is going to be treated and they do it.

Now, supposing they do that. Any one of two things could happen. One thing, if Dr. Burzynski is having success, they could maybe not do the same thing he is doing and they would not have success. There are some claims made, at least, and I am not here to say they are right. There are claims made that they may not particularly want to have success as they use his treatment as compared to what they are doing.

It seems to me the sensible thing to do in all of these cases is, when somebody claims they are having success, first go out and see if they are. Then if they are, if you want to go to Sloan Kettering or somewhere else, do that also. And the other thing is that these

outcome tests are low-cost tests that you can do first. And at least if I were Ryan's mother and I knew somebody had been to Dr. Burzynski and had been successfully treated, as she found out, for brain cancer, I would consider going there, rather than have to wait a long time to see whether Mayo Clinic said: "Yes; it is all right." Just like I do not believe the Government ought to say: "Yes; it is all right," or, "No; it is not all right."

Senator HARKIN. If I wanted to take an alternative therapy or treatment today for cancer or something like that, even if I signed off and said I absolve you from all liability, et cetera, et cetera, and I know what is going on, even then I cannot get it. FDA will not approve it, will they?

Mr. BEDELL. Of course not. They would not approve your bee pollen.

Senator HARKIN. Where did my bee pollen go? [Laughter.]

That is the darnedest thing that ever happened to me, and I have never felt better. Never felt better, in terms of not being plugged up and eyes watering and sneezing.

Mr. BEDELL. This office needs a healthy guy like you.

Senator HARKIN. Give me a couple of recommendations for the Office of Alternative Medicine. What should be its direction now?

Mr. BEDELL. First thing it needs to do is hire an adequate staff to do the job that was mandated. For the people who do not know, the report language and your letter clearly indicate—the report language said it should establish within the Office of Director an office to fully "investigate and validate these practices." That is very clear.

Second thing is, in February, over 1 year ago, you and Senator Specter sent a letter over saying there should be no fewer than five scientific investigators.

Senator HARKIN. How many are there?

Mr. BEDELL. They would like to call the stenographer who works in the office a scientific investigator.

Senator HARKIN. I will have Mr. Jacobs up here and we will find out.

Mr. BEDELL. OK. I do not see how you can very well call the Director of the office and the stenographer a scientific investigator.

Mr. Chairman, the point I would like to make is there are some powerful forces in NIH that are not keen on this office or are not keen on having it do these investigations.

There is something I have got to say. I like the Director and I think he is a very fine man. I have already said I feel there has got to be a change. I am hopeful that can happen. But unless we have someone in that Director's office who is not going to worry about the fact that NCI does not like what we are doing or who is going to really fight to say he has got to have the staff he needs to do the job, I do not think he is going to fulfill your mandate. And my plea is that that start to happen, and I do not think it has happened at least so far in that office.

Senator HARKIN. Perhaps what I might want to do—and I say this publicly. I am sure it will get back. But perhaps in the next hearing I have, I should have the Director of NCI, Dr. Broder down here.

Mr. BEDELL. I am not talking about the Director of NCI; I am talking about the Director of this office.

Senator HARKIN. I understand that. But I mean along with the Director of this office. And we will start figuring some things out here about how they are working together. And if I have to use the power of the purse strings, believe me, I know how to use the power of the purse string.

Mr. BEDELL. Good for you.

Senator HARKIN. I can get their attention real fast. I have been around here 18 years and I have figured out how to use the purse strings.

Mr. BEDELL. I helped to teach you, Mr. Chairman. [Laughter.]

Senator HARKIN. Well, again, there is another part of this, and one of the reasons I wanted to have you testify was because of the involvement of the FDA in this and the blockages and stoppages by the FDA.

Now, this subcommittee does not have jurisdiction over the FDA. I am second ranking on Agriculture Appropriations, and it does have jurisdiction over the FDA. And I am on the authorizing committee that authorizes for the FDA.

Mr. BEDELL. I called the Senator who is chairman to see if he could come but he was busy on the floor. I wanted him to hear my testimony.

Senator HARKIN. In fact, I talked to him. I talked to Senator Bumpers and he apologized. He has been on the floor, we have been busy today, he had amendments himself. And he would like to have been here but he just could not, as you know. So we will have that, too, and we are really going to have to take a look at FDA because that is an important piece of this puzzle that we have got to get figured out.

Mr. BEDELL. I would love to testify if you see fit. It should be obvious I am not afraid to say what I believe.

Senator HARKIN. I have never known you to be afraid to say what you believe, Berk. It is one of the things I like so much about you. I appreciate that very much.

I apologize. I have to go vote. I hope you can stay. I am going to have Dr. Jacobs next. I apologize to Dr. Jacobs for taking all day, but it has just been that kind of a day. We will come back and we will hear Dr. Jacobs and we will finish with that.

We will recess for about 10 to 15 minutes.

[A brief recess was taken.]

STATEMENT OF JOSEPH J. JACOBS, M.D., DIRECTOR, OFFICE OF ALTERNATIVE MEDICINE

ACCOMPANIED BY DR. DANIEL ESKINAZI, ASSISTANT DIRECTOR

Senator HARKIN. The subcommittee will resume its sitting.

In the last panel we will hear testimony from Dr. Joe Jacobs, the Director of the Office of Alternative Medicine. He is accompanied by Dr. Daniel Eskinazi, the Assistant Director of the office. Dr. Jacobs will review the activities of the office and the efforts that have been made to comply with the existing regulations.

Again, Dr. Jacobs and Dr. Eskinazi, my apologies, but this is one of those days when it is out of our control. But I again thank you for your patience and for being here. Your statement will be made

a part of the record in its entirety, and I ask you to proceed as you so desire.

Dr. JACOBS. Mr. Chairman, thank you very, very much. I am extremely honored to appear before you and your committee as the Director of what I consider the historic Office for Alternative Medicine at the NIH.

Before I begin, I would just like to say that we have also submitted testimony from Dr. Jay Moskowitz as well as my own formal statement, and right now I will express my oral comments at this time.

It is particularly important to me to be in this role because I feel my career in medicine and in public service has reached a pinnacle of achievement that would not have been expected from an individual with a background such as mine. I have had some critics in the alternative medicine community who feel that my lack of identity in that community did not qualify me for this job. My response to that characterization is that I feel I was born into alternative medicine since my mother was a full-blooded Mohawk from Canada and upstate New York who frequently availed herself of traditional herbal medicines for me and my siblings when the need arose.

Alternative medicine for me is not a political cause but a way of life. I feel I have an understanding of the proponents of alternative medicine because, like them, much of my life has been on the outside looking in.

I am extremely grateful to Dr. Jay Moskowitz for allowing me this unique opportunity to be an integral part of what clearly is an exciting time. His recognition of the experiences in my professional background when selecting me for this position illustrate his extreme sensitivity to the issue surrounding alternative medicine.

Selection of an American Indian at the NIH goes beyond affirmative action. He recognized the multiple dimensions and issues of alternative medicine which include the need to be sensitive to gender, ethnic, and cultural aspects of health; the imperative for scientific rigor; the requirement for a good understanding of what it means to provide care for people on a daily basis without the relatively compartmentalized experience that may be had in the basic science laboratory. The recognition of public policy implications and the ability to be able to navigate a difficult Federal bureaucracy have all tested my personal and professional experiences.

The most difficult challenge has been to convince the American public that the bold move you took in the fiscal year 1992 appropriations bill to establish this office was not only courageous but necessary at this time, as Dr. David Eisenberg so eloquently states through his study.

The clinical evaluation of alternative medicine is the study of the human condition. The tremendous response to the creation of the office is a reflection of the overwhelming need people have which they also feel is not being addressed by conventional medicine. The activities of the office, in my biased view, should have as a single-minded goal the clinical pursuit of those treatments that benefit patients. And I underline benefit. This is not science for the sake of science. The activities of the office reflect the learning curve that we are all trying to follow; that is, proponents of alternative medi-

cine, conventional researchers, physicians, the media, and the general public.

The tremendous media attention to the office and to me is a two-edged sword. On the one hand, the American public are being informed about the people and activities of a small office in the NIH. The very existence of the office at the NIH advances the credibility of alternative medicine. The down side of the attention is the toll that it has taken on me and my staff; 10- to 12-hour days have not been uncommon, reflecting both their dedication and commitment to advancing the cause of alternative medicine.

The attention has brought an avalanche of phone calls and mail to the office. Many calls to the office have been from patients who are seeking hope through alternative medicine, and those calls must be answered. A case in point. At around 3 a.m., last Saturday night, my wife and I were awakened by the telephone—my family happens to be in Connecticut waiting for our move back to Washington. The call was from a woman whose mother was in a coma from a stroke and mistakenly thought from a media publication that I was a traditional American Indian healer, and could I arrange to come to Ohio to pray for her mother.

Needless to say, I was startled by this request. I gently informed her that I did not have this power and that I understood her pain and frustration. I asked that she call me in the office on the following Monday. The call was a sobering reminder of a heart-wrenching call that we received 7 years before informing us that my wife's mother had finally died from a terminal stroke.

Unfortunately, I have not heard from that woman. This illustrates the hope that the office has created, Senator, and we do not take your charge lightly.

The tremendous attention paid to the office has also allowed us to articulate a vision that goes beyond the clinical validation of alternative practices. The American health care industry has and is experiencing several revolutions. The late 1960's saw the public demand for primary care. The primary care movement began to bring into focus the imperative for physicians and other caregivers to view the needs of patients in a holistic manner. This gave fertile ground for the consideration of various options for care—traditional physicians, nurse practitioners, physician assistants, and other midlevel practitioners.

The primary care movement paved the way for the introduction of acupuncture into the health care system. Unfortunately, the conservative nature of orthodox medicine provided barriers to its dissemination, but the acupuncture community prevailed and is alive and well.

Another revolution among us today is the recognition of what is called small area variations in the emergence of outcomes research, as Mr. Bedell referred to earlier, in conventional medicine. Dr. John Wennberg, director of the Center for the Evaluative Clinical Sciences at Dartmouth Medical School, stated in previous congressional testimony that variations in clinical practice,

* * * arise because of two fundamental defects in the health care markets. The first is weaknesses in the clinical science that occur because medical ideas and theories are not well tested. And, No. 2, weaknesses in the ethical basis for clinical decisionmaking that allow the physician's preferences for outcomes and treatments to

dominate the choice of treatment when the right choice properly belongs to the patient.

This is Dr. Jack Wennberg at Dartmouth, and I must say he has spawned a revolution.

These are rather significant conclusions that Dr. Wennberg has made of conventional medicine. They appropriately apply to the conduct of clinical investigation of various alternative medical practices. I have had to respond to detractors of alternative medicine, and my response has always included paraphrasing Dr. Wennberg's remarks. Claims of a lack of scientific validity of alternative medicine must be equally applied to conventional medicine as well. Congress recognized this fact by creating the Agency for Health Care Policy and Research to help sort out the issues, Dr. Wennberg and others have pointed out.

The second issue raised by Dr. Wennberg points to the need for meticulous avoidance of investigator bias in order to maintain the credibility of studies that seek to affirm the utility of alternative medicine. These challenges are being offered to conventional medicine which requires that we also apply these challenges to alternative medicine.

We obviously cannot eliminate all bias, but alternative medicine must be evaluated on a level playing field, as has been said before. We must also be mindful of the bias of the proponents of an alternative treatment and that it should not intrude on the conduct of the investigation. The proponent who claims that he or she can cure all diseases with a particular therapy must be approached with the same level of healthy skepticism that would be applied to claims that penicillin is a wonder drug that will cure all infectious diseases in all patients all of the time. I am sure many physicians harbored this belief in the early days of penicillin use. Today, we know full well the limitations of penicillin.

We have conducted field investigations of alternative medical practitioners with the intention of not only learning about proposed therapies, but also to teach these practitioners what I would call the art of reporting on their claims of clinical benefit. As many clinical researchers will attest, even physicians are not well versed in conducting good clinical research that will result in credible data. The American public has frequently witnessed the equivocal results reported about a particular clinical investigation. I cringed when it was reported in, I think it was, a Harvard study that coffee drinking was associated with pancreatic cancer, and I was quite relieved when a subsequent study from another, equally prestigious medical center reported conflicting results.

These types of conflicting results should be avoided in alternative medicine; otherwise, our efforts will be for naught. We hope to strengthen our activities in the field investigations as a result of new authorities given the office in Public Law 103-43 to hire clinical fellows that would ensure rigorous evaluation of alternative practices.

I must add that the science of clinical research is not an easy science. It is an emerging science the AHCPR has really been cultivating.

Our recently initiated grant program for evaluations of alternative medical practices is intended to solicit applications for grant

funds of up to \$30,000 that can be used for planning for studies of alternative medical practices. These grants encourage the collaboration between alternative medical practitioners and the health care institutions and will provide for the initiation of pilot projects to identify promising areas of research, emphasizing studies on clinical efficacy of alternative medical practices. To date, we have received over 800 letters of intent to apply for grant funds, and approximately 500 applications have been received and are currently being processed.

This program gives access to the entire alternative medical community and ensures that a peer review process is in operation in alternative medicine. The importance lies not in the size of the grant program but the historic nature of its existence at the NIH. These two programs help to protect the activities of the office from unfair characterizations from the detractors of alternative medicine as well as provide that level playing field.

Finally, we are coming into an age of enlightenment, Senator, whereby we are beginning to recognize the limitations of technology and what I would characterize as a decline in technological arrogance. A major hallmark of American medicine has been what I would call its ethnocentricity. The prevailing attitude seems to have been that clinical studies that have not been done on American soil are immediately suspect. As a minority, I wince when I have to deal with this type of bias. The bias extends further. That which is not done in major medical centers is also suspect.

I am reminded of the discovery of Lyme disease in the early seventies, as Berkley Bedell eloquently points out the difficulties of dealing with that disease. During that time, two mothers began to notice the frequent occurrence in children of what was thought to be juvenile rheumatoid arthritis. When they attempted to bring this to the attention of various health practitioners, their ideas were dismissed. It finally took a rheumatology fellow at Yale to recognize the obvious pattern that these mothers were seeing for some time. Conventional medicine is slowly rediscovering the art of listening.

There is an irony that I have observed about the American biomedical and educational system. The NIH, in effect, has cloned itself in research institutions, domestically and abroad. Many of these institutions have produced basic science and clinical research clones who have achieved professional levels of competence recognized by all. Once these researchers begin to address clinical research problems in alternative medicine, however, the value of their work diminishes precipitously.

PREPARED STATEMENTS

I see our role as supporting the efforts of these enterprising individuals in navigating the clinical research minefields. We are taking risks, which is what I believe you want us to do. The task is difficult, but it is made easier by keeping in mind that what we are doing is the right thing.

Senator, that concludes my oral remarks, and I and Dr. Eskinazi are available to you and the rest of the committee for any other questions you may have. Thank you.

[The statements follow:]

STATEMENT OF JOSEPH J. JACOBS, M.D.

Mr Chairman, I am extremely honored to be given the opportunity to provide testimony to the Subcommittee on Labor, Health and Human Services, and Education of the Committee on Appropriations.

The public response to the creation of the Office for Alternative Medicine (OAM) at the National Institutes of Health has been much larger than expected and in fact, nothing less than phenomenal. We are in the midst of a tremendous change in the relationship between complementary and orthodox medicine. This change can only be advanced in a positive way if we explore clinical evaluation of complementary medicine in a methodical, dispassionate manner, devoid of politics and bias.

In response to increasing Congressional interest in alternative clinical practices, the NIH rose to the challenge of bringing together the orthodox and complementary medical communities by creating this Office. Recently, Congress provided authorization for OAM in P.L. 103-43. A large organization like the NIH, with its \$10 billion budget requires a significant amount of bureaucratic effort to initiate a new program direction. This task is not unlike the preparations made by surgical staff prior to performing an operation to ensure patient safety during the procedure and the prevention of infection after it. Important issues such as determining the scope of the assignment and determining the magnitude of the solutions need to be addressed prior to initiating a major initiative.

The first challenge facing the NIH was in learning what alternative medicine is. The Institutes and Centers of the NIH were asked to provide nominations to an ad hoc advisory panel and a brief description of ongoing or recently completed activities that related to the assessment or validation of what was called at that time, unconventional medical practices. These responses provided the agenda for a public forum sponsored by the NIH to identify those issues to be addressed by the advisory panel. Approximately ninety individuals representing the alternative medicine community requested time to present their views to the advisory panel and the NIH on what was needed to evaluate alternative medicine in June, 1992.

The second challenge was to determine the methods of addressing the concerns expressed to the Advisory Panel by the alternative medicine community. Once the scope of the work and the direction of the Office were defined, a decision was made on the staffing needs of the newly created Office for Alternative Medicine. The process was initiated to hire clinical investigators whose skills could address specific program areas of the alternative medicine community. In September 1992, a larger meeting was held in Chantilly, Virginia, where invited members of the alternative medicine community were asked to participate in drafting a "strategic plan" that would outline a research agenda for the Office. We expect this report to be completed by the end of the summer.

The activities of the Office are being done in a changing health care environment in America. The emergence of alternative medicine as a major factor is one of multiple "revolutions" facing U.S. medicine. These other revolutions include:

- Recognition of the importance of primary care - Since the late 1960's, there has been renewed interest in the type of care given directly to patients in the traditional health care delivery system. Emphasis has been on holistic approaches to care giving.
- Recognition of "small area variations" and emergence of outcomes research - Dr. John Wennberg, Director of the Center for the Evaluative Clinical Sciences at Dartmouth Medical School has stated in previous Congressional testimony that variations in clinical practice "arise because of two fundamental defects in health care markets: (1) weaknesses in the clinical science that occur because medical ideas and theories are not well tested; (2) weaknesses in the ethical basis for clinical decision making that allow the physician's preferences for outcomes and treatments to dominate the choice of treatment when the right of choice properly belongs to the patient".

This observation of Dr. Wennberg's appropriately applies to the conduct of clinical investigation of various alternative medical practices. Meticulous avoidance of investigator bias is essential in order to maintain the credibility of studies that seek to affirm the utility of alternative medicine.

- An imperative to manage resource consumption by physicians and other providers - The early 1980's witnessed a rising imperative to reduce costs of health care delivery. This resulted in the creation of Diagnostic Related Groups (DRG) and the control of health care costs in the hospital setting. Control of health care costs in the outpatient setting is still problematic.
- The emergence of "mid-level" practitioners - As a result of the crises in the delivery of health care to the medically indigent, minorities and rural populations, there has been a rise in the importance of care givers other than physicians. These have included community health nurses, nurse practitioners, physicians assistants and other care givers.

Several functions related to the Office have evolved since I assumed the role of Director on October 26, 1992. These functions have included the following:

1. Field investigations were conducted to determine the relative clinical benefit of various unconventional treatments such as bee pollen, antineoplastons and visualization therapy. This was also conducted to determine the level of adherence to principles of human protection and scientific rigor by the provider. A methodology developed by the National Cancer Institute called the "Best Case Series" is the model we use in trying to guide our assessment of which investigations to pursue. The Office is effectively able to avoid controversy by ensuring that its activities, including direct involvement or expenditure of funds comply with existing regulations governing informed consent and peer review.

For example, on Thursday, February 11, 1993, a visit was conducted with Mr. Royden Brown, a proponent and distributor of bee pollen for various ailments. Mr. Brown supplied numerous anecdotal documentation from various individuals who have claimed symptomatic relief from the use of bee pollen. The site visit team consisted of Drs. Joseph Jacobs and Daniel Eskinazi of the Office of Alternative Medicine, Mr. Frank Wiewel of the Ad hoc Advisory Committee and Dr. Lawrence Prograis, Deputy Director, Division of Allergy, National Institute of Allergies and Infectious Diseases.

The discussion focused on the need to evaluate the clinical efficacy of bee pollen beyond the anecdotal reports from satisfied users so that possible benefits from this therapy, if verified, could become more widely available. The site visit team emphasized the need to establish a clinical trial of bee pollen by focusing on one clinical condition, such as hay fever symptoms. The trial would involve establishing a protocol that would be administered by physicians experienced in the treatment of patients with hay fever as well as being able to monitor their clinical progress. Mr. Brown reluctantly agreed to follow this line of analysis while still insisting that his therapy was equally valid for a large number of clinical conditions. We indicated that it would be necessary to clearly define the clinical conditions in which his therapy would work. We also suggested that he collaborate with a well established physician such as Dr. Wiel for protocol development and guidance. Mr. Brown has been in touch with Dr. Andrew Wiel of Tucson, AZ, who has indicated his reluctance to participate in a study with Mr. Brown. The Office then arranged a collaboration with a second physician, Dr. Robert Klein, Chief of Pediatrics, University of Texas Medical Center at Tyler, TX. A protocol has been developed by Dr. Klein and is currently under review by Mr. Brown. Funds for this study were not requested by Mr. Brown because of his desire to fund the evaluation himself. Administrative support will be provided by the Office in filing an IND by Dr. Klein with the FDA.

The proposed protocol would enable the testing of bee pollen in a verifiable and reproducible manner by selecting patients with pollen sensitive asthma and hay fever symptoms in a double-blind placebo controlled, inhalation challenge study. The patients

would be asked to undergo pulmonary function tests as well as testing for specific allergies as part of a "baseline". They would then be "challenged with an allergen and pulmonary function tests repeated to see the degree of decrease in breathing function (decrease of 20%). They would then be administered bee pollen or a placebo and rechallenged after treatment to determine any change in their pulmonary function. Execution of this type of study would require a controlled environment in the event of severe allergic reactions that could be life threatening. The methodology has been used in the evaluation of immunotherapy in cat-induced asthma. The objective of the study would not necessarily look at absolute benefit but equally as important, degrees of benefit to individual patients.

2. Provision of technical assistance to the alternative medicine community is essential. Technical assistance can range from the simple task of filling out an application for funding from the NIH, to developing sound research methodologies for good clinical trials. The Office has conducted several grant writing workshops that have had over 500 participants receiving information. Additionally, the Office, in conjunction with the National Cancer Institute is planning on sponsoring a workshop for alternative cancer therapists on the "Best Case Series of the NCI". This workshop would enable alternative cancer therapists to become aware of the importance of good data collection on patients undergoing their treatments as well as understand the imperatives for human subjects protection. The Food and Drug Administration has expressed a strong interest in participating in this type of workshop to explain the issues related to filing an IND for clinical investigation, thereby possibly avoiding administrative difficulties in the future.

3. Another function is that of being a clearinghouse for information related to alternative medicine as well as information dissemination about the activities of the Office. Queries from numerous sources have come to the Office, especially after media reports on alternative medicine activities. These sources have included the general public as well as alternative and conventional health practitioners. The Office has also fielded questions from cancer patients and patients with other diseases who are seeking information on alternative therapies. Some of these patients have been referred to the Office by clinicians at the Clinical Center of the NIH as well as other "orthodox" practitioners. Additionally, the Office has been involved in assisting several private sector organizations that have been interested in promoting the study and application of alternative medicine in different settings. These have included the Dogwood Institute at the University of Virginia, sponsored by Mr. John Kluge, The Fetzer Institute, the Fort Worth Education and Research Foundation for Pain Management, sponsored by Mr. Sid Richardson and the Bass family, and Mr. Helmut Shuman, founder of the Hitchcock Foundation at Dartmouth Medical School.

4. The Office is serving as a broker between the alternative medical community and the orthodox medical community. We endeavor to foster collaborative relationships between individuals with mutual interest in a particular area. For example, acupuncture as a treatment modality for subacute pain could be included as part of a larger clinical trial by one of the Institutes at the NIH interested in the management of pain in a particular group of patients. The Institutes have larger budgets and staff to execute these types of trials. Equally important, observed positive results appear more credible when an alternative therapy is included as part of a larger clinical trial.

5. The primary method of supporting research by the NIH is through the grant making process. A grant program for evaluations of alternative medical practices has been initiated through the publication of a Request for Applications (RFA) on March 26, 1993. This RFA is intended to solicit applications for grant funds up to \$30,000 that can be used for planning for studies of alternative medical practices. These grants encourage the collaboration between alternative medical practitioners and health care institutions, and will provide for the initiation of "pilot projects" to identify promising areas of research, emphasizing studies on clinical efficacy of alternative medical practices. To date, we have received over 800 "letters of intent" to apply for grant funds and approximately 500 applications have been received.

6. Until recently, the Office has been functioning under the advice of an ad hoc Program Advisory Committee as recommended in Senate Report 102-194. This Committee is mostly composed of members of the alternative medicine community and

provides advice on program direction as well as perform a "peer review" advisory function. Interest in serving on the Committee has been widespread. Interested individuals have included medical academicians from several medical schools in the country as well as the former Surgeon General, Dr. C. Everett Koop. This Committee will be converted to a National Advisory Council as provided for in P.L. 103-43.

The future looks very bright for alternative medicine. The increased media attention to the Office has not only reflected domestic interest but international interest as well. We hope to provide more attention to issues related to herbal and ethno medicine. This includes attention to traditional Native American Indian healing, Native Hawaiian and Hispanic healing practices. Traditional healing practices of African Americans have too long been neglected. Also, we cannot ignore the tremendous wealth of information beyond the borders and shores of the United States. Part of the task is to go beyond the "ethnocentric" view and technological arrogance of American medicine. We have recently been invited to meet with representatives of the Research Council on Complementary Medicine in England as well as with delegations from the People's Republic of China. The United States is now being recognized as a world leader in the pursuit of scientific investigation in the validity of alternative medicine, which to the rest of the world, is not alternative medicine but complementary medicine.

My fear for the Office is the tremendous expectations placed upon it. The American health care system is pluralistic in terms of modes of delivery through different systems of care, levels of technological sophistication, mechanisms of payment and types of regulation. It is a unique challenge to this Office to maintain a steady course in looking solely at the mandate to evaluate alternative clinical practices for clinical benefit. Holding on to the middle ground will surely advance the cause for advocates of complementary medicine. This does not only reflect my personal view but the views of many of the supporters of this Office and alternative medicine. The national expectations cannot be met by this Office alone and we must include the cooperation of the rest of the NIH, the other agencies of the Public Health Service, other departments of the Federal government and the conventional medical educational institutions of the Nation, working in cooperation with the alternative medicine community. I am not only encouraged by the reception that I have received to date from all sectors of the health care system, but am awe struck by the sincerity of the support.

Mr. Chairman, again, I appreciate the opportunity to appear before your Committee to discuss the activities of the Office for Alternative Medicine. I'll be pleased to answer any questions you may have at this time.

STATEMENT OF JAY MOSKOWITZ

Mr. Chairman and members of the Committee, I appreciate the opportunity to provide you with a progress report on how the National Institutes of Health is incorporating research on alternative medical therapies into the biomedical research enterprise. Our immediate goal is to establish alternative medicine research and clinical evaluation as an integral part of the our mission, which simply stated is "science in pursuit of knowledge to improve human health."

You and your colleagues in the Congress have historically committed yourselves to the ideals of the NIH. Your responsiveness to the call of the American people, for an expanded research effort that will add to the armamentarium of vital new therapies and treatments, has produced the necessary authority and funding for NIH to establish the Office of Alternative Medicine (OAM). From the beginning, Senator Harkin, you recognized the need to examine the full range of potential therapies, without prejudice, and as always with patient and public safety as an overarching objective.

Just three years ago the Office of Technology Assessment (OTA), in its report "Unconventional Cancer Treatments," presented a rather grim assessment of the extent of dialogue between the traditional and alternative medical communities. The report stated:

Research and clinical studies of unconventional cancer treatments generally have not been well designed and have not met with the approval of academic researchers. Supporters of unconventional treatments tacitly approve these reports in the absence of anything better. Thus, one of the major rifts separating supporters of unconventional treatments from those in mainstream medical care and research is a distinct difference in what they accept as evidence of benefit. Objective, informed examination of unconventional treatments is thus difficult, if not impossible, in the United States today. Acrimonious debate between the unconventional and mainstream communities reaches well beyond scientific argument into social, legal, and consumer issues. Sides are closely drawn and the rhetoric is often bitter and confrontational. Little or no constructive dialog has yet taken place.

I would like to apprise you of the successful steps NIH has taken to initiate a dialog between the traditional and nontraditional health communities, to seek out a diversity of research opportunities that merit consideration, and to undertake scientific investigations aimed at identifying viable treatments.

Since NIH established OAM in November 1992 in response to Congressional interest in alternative medicine, the public reaction to the creation has been nothing less than phenomenal. However, many challenges confronted us at that time and continue to do so. A large organization like NIH, with a 105 year history of funding traditional medicine, required a significant amount of bureaucratic and individual efforts to initiate this new program direction. Some even likened the task of laying the groundwork for the new office to the many months of preparation by Allies in the Persian Gulf. Although defining a research agenda for NIH is not on the same scale, it still is a significant undertaking. Important issues such as determining the magnitude of the assignment and envisioning the scope of the solutions needed to be carefully and fully addressed.

During its first year, the OAM had to define the scope of "unconventional medical practices," which revealed not only an enormous array of principles and therapies, but also the diverse cultures of both the users and practitioners of these therapies. This initial effort was designed to be long, structured, and comprehensive. The second step was to identify research issues that were relevant to the study of these therapies. From the beginning we have utilized a strategic approach to meet face-to-face with the members of the alternative medical community; to identify the diseases and disciplines involved; to develop with these individuals our shared priorities; and to design programs that for the first time have bridged the gap between these "disparate communities". Because,

as the OTA revealed, these communities have historically engaged in "little or no constructive dialog," the critical components of our approach have been to plan our activities with extreme care and continuous community involvement. Now, this wide array of individuals from a variety of cultures and medical perspectives are both talking to each other and to NIH, and we are planning research as one enterprise.

The Nation is in the midst of a tremendous change in the relationship between alternative and traditional medicine. This transformation will continually be effected as we explore clinical evaluation of alternative medicine in a methodical, dispassionate manner, devoid of politics and bias. This also has been no small task. We are continually confronting resistance to this venture both from within NIH and from many outside communities -- medical and legal. For example, a January 1993 N.Y. Times article highlighted some of these concerns when it quoted a high-ranking NIH scientist who viewed this initiative as merely a response to political pressure and a waste of research dollars. Further complicating the delicate balance, is the fact that some of the very alternative medical groups with whom we have been working have, because of broad health outcome claims, been under review by Governmental agencies including the Federal Trade Commission. In addition, some of the practitioners are continually concerned about their medical licensure or are threatened by state and local legal systems. For these reasons, we continue on a careful, systematic approach, while adhering to the principles of sound scientific investigation.

Our expanded venture is permitting us to capitalize on the creativity and innovative thinking of individuals both inside and outside the realm of conventional medicine. I am pleased to report to you that NIH has successfully completed the initial phases of these efforts.

THE NIH STRATEGIC PLAN

Recently, NIH has come to the end of a two-year process that has culminated in the development of its first strategic plan, "Investment for Humanity," an NIH working document, that creates a sense of common mission and goals, and articulates the vital areas of science and policy that NIH must address into the next century. The investigation of alternative medicine by NIH poses very interesting and exciting opportunities, well in line with this Strategic Plan. Examples of alternative medicine initiatives as they relate to the objectives of the Strategic Plan follow:

1. Critical Science and Technology -- *To assure that critical science and technology in basic biology, with impacts on human health and the national economy, are advanced as priorities across the Nation's biomedical research enterprise.*

The understanding of biology is implicit to the exploration of such disciplines as homeopathy or Qi Gong. The potential for these disciplines to be advanced may open entirely new areas of biological research at the molecular, cellular and organ levels.

2. Critical Health Needs -- *To strengthen the ability of the Nation's biomedical research enterprise to respond to current and emerging public health needs.*

It is of the utmost importance to determine how these new approaches to health care may complement our medical arsenal. A January article in the New England Journal of Medicine by Dr. David M. Eisenberg, et al, indicated that up to 34% of the adult American population has used one form or another of alternative medicine in the past year, and 72% of the users of alternative therapies did not inform their doctor of such use. The fact that many Americans already are using alternative therapies makes it all the more important to determine whether any of these forms might be either helpful or, on the contrary, useless or even harmful.

3. Intellectual Capital -- *To provide for the renewal and growth of the intellectual capital base essential to the biomedical research enterprise.*

The goal of OAM is to foster research training of alternative medical

practitioners, as well as foster alternative medical knowledge and understanding by conventionally-trained physicians and scientists. In addition to designing a training program to develop a new generation of research-based alternative practitioners, we plan to build a cadre of research-based individuals by bringing the practitioners of alternative medicine into a system that uses databases and controlled clinical trials.

4. Research Capacity -- To sustain and renew the capacity that is critical to the nation's ability to conduct health-related research.

Active scientific investigation is not only found in traditional academic and research institutions, but also in a number of non-academic institutions, clinics, and small businesses. OAM is presently considering plans to establish a Small Business Innovation Research (SBIR) Program for alternative medicine.

5. Stewardship of Public Resources -- To secure the maximal return on the public investment in biomedical research.

In a partnership with the alternative medical community, OAM already has created a new model that we call "field investigations," that encourages research and gathering of scientific data in a way that optimizes the Office's resources. Ultimately, if some forms of alternative medicine are validated and incorporated into routine health care, it is likely that significant savings of public funds will result.

6. Public Trust -- To earn continually the public's respect, trust, and confidence as we carry out our mission.

We strive to be sensitive to changing public health needs, and believe that this goal may be furthered by our pursuit of alternative medical therapies. Vitally important is the need to ensure the public trust in our research endeavors by applying the scientific method and also by paying close attention to the ethical dimensions of biomedical research. Progress in biology and medicine will depend upon public trust and understanding of ethical considerations which form the basis for scientific and medical decisions. This surely has been the case since the time of the earliest physician-scientists. Hippocrates said, "I will...never do harm to anyone...keeping myself far from all intentional ill doing." Although the horizons of science forever change, the humanistic concerns remain constant. Patient safety is our paramount concern. We must also reaffirm that scientific principles and rigor be applied to the research of these practices.

ALTERNATIVE MEDICINE -- CREATIVE SOLUTIONS FROM UNEXPECTED SOURCES

We have evidence that alternative medical practices can provide creative solutions to traditional medical treatment. Often scientists are surprised at discovering medicinal benefits from unusual sources. However, these discoveries must be affirmed by scientific research methods before recommendations can be made to the public. Some examples of discoveries from unconventional sources follow:

- o One recently approved anticancer agent, is the unlikely substance called "taxol," derived from the bark of the Pacific yew tree. As a result of comprehensive studies and clinical testing by the National Cancer Institute, it proved efficacious in the treatment of ovarian cancer.

There are more natural products out there. We hope that OAM can encourage and support researchers who will search for solutions to disease and disability in the world of botany, marine biology, and possibly other unlikely places.

- o A letter to the editor of the journal "Science" recounted the author's involvement in the screening of natural products, some based on folklore. The rosy periwinkle, once made into a tea to

treat diabetes, has yielded the vinca alkaloids: vincristine and vinblastine. Again, after intensive testing, these very potent chemotherapeutic agents are now used to treat certain cancers.

We must continue this screening and testing, not only for therapeutics but as potential agents to prevent the major killing and crippling diseases.

- o In ancient Greece and Egypt, the use of plants for the treatment of disease was widespread. In a number of instances, what is described is quite compatible with our current knowledge. For example, an Asian plant of the genus *Ephedra* was used in a condition whose description likens it to asthma, which is of course compatible with our current treatment of this condition with ephedrine, a vasoconstrictor originally derived from these plants and now synthesized.
- o Last year an article from The Washington Post, "At Migrant Clinic, Make-Do Medicine Must Go a Long Way," described a physician who treated migrant workers who had limited funds to spend on medical care and medication. One of the patients had pesticide burns on his feet from standing in pesticide-contaminated water. Normally, the burns would have been treated with the antibiotic ointment silver sulfadiazine. Concerned with the expense of this treatment, the physician sought a less expensive alternative. He learned that in some parts of the world honey was used to treat burns, and he also found credible medical literature to support this use. As the physician stated, "I put it directly on the burns, bandaged it up, and with frequent follow-up, the guy did fine." The Washington Post called it the ultimate over-the-counter substitute.

I believe we can look for more of these cost effective alternatives through our new programs in OAM.

One guiding principle in looking at unconventional medical practices acknowledges that treatments or diagnostic procedures considered unconventional today may gain acceptance and become conventional in the future. Throughout the history of medicine, many great discoveries have been based on theories that were ridiculed early in their use because they were viewed as radical for the conventional thinking of the day. Radiation therapy, chemotherapy, and biologic therapy are examples of practices that are now commonplace but were once considered to be very unconventional. In many cases there is intriguing, and to some extent promising, evidence that modern day alternative methodologies and practices could be employed in the treatment of disease and disabilities. NIH is committed to identifying better treatments, regardless of their source.

During the last few years, there has been increasing recognition and use of unconventional medical practices for the diagnosis or treatment of various diseases or conditions, including cancer, arthritis, anxiety, and depression. For example, just last month the National Institute of Allergy and Infectious Diseases released an announcement of a study to evaluate the effect of acupuncture and Amitriptyline on peripheral neuropathy in patients with AIDS. Another study, supported by the National Heart, Lung, and Blood Institute, will evaluate the effect of transcendental meditation on hypertension. We intend as an organization to learn more about these areas and are prepared to investigate innovative practices and provide technical assistance to those sincerely interested in generating valid data.

THE PHILOSOPHY OF THE OFFICE OF ALTERNATIVE MEDICINE

Consistent with its goals and its role in the biomedical research enterprise, NIH will offer technical assistance and financial resources for rigorous scientific evaluation of claims made about alternative medical practices. Research exploring the mechanisms by which some of these practices work is a major area of potential study. The purpose of OAM is to advocate and facilitate the non-biased evaluation of alternative medicine. Given that OAM is part of NIH, both assessment of scientific merit and determination of funding and

programmatic priorities must follow peer review and advisory committee action. These procedures are well established and provide a flexible framework that can readily be adapted to the evaluation of alternative medicine. We recognize that not all alternative medical practices are amenable to traditional scientific evaluation and may require deliberation and possible special consideration in establishing methods to measure their efficacy and safety. We are encouraging novel approaches. Some scientists may be interested in developing special instrumentation or techniques of measurement to be used to quantify or interpret changes in the systems or functions with which any particular alternative therapy interacts. Provided that care is taken to respect the principles being evaluated, our approach will foster acceptance of the results of investigations by both the conventional and alternative communities.

CURRENT ACTIVITIES OF THE OFFICE OF ALTERNATIVE MEDICINE

With thoughtful consideration regarding process and a firm commitment to the human element, NIH has undertaken many activities in the fulfillment of its mandate to conduct research on alternative medicine. We convened an ad hoc advisory panel in June of 1992 to identify the range of practices that fall within the scope of the Office of Alternative Medicine, to identify cross-cutting issues that would underlie these practices, and to discuss the opportunities for research into areas of alternative medicine. These efforts were continued during a September 1992 conference and will be the basis for an OAM strategic plan.

1992 also saw the first research projects being supported by OAM. These projects, identified by the NIH research institutes during the two-level (initial technical review group and Advisory Council) peer review process, included: Nursing Strategies for Perimenstrual Symptom Management, a study to evaluate experimental approaches to relieving the symptoms of Premenstrual Syndrome (PMS); Caregiver Touch and Health Outcomes for High Risk Infants, a longitudinal project addressing one of the most basic aspects of newborn care; Self-Management Therapy Following Sudden Cardiac Arrest, a project to compare frequency of sudden cardiac arrest before and after self-management biofeedback therapy; Antineoplastons A-10/AS 2-1, clinical trials of antineoplastons in adult patients with brain tumors; Evaluation of Imagery (Visualization) and Psychotherapy as Treatments for Patients with Adenoid Cystic Carcinoma, a clinical protocol to evaluate this biofeedback approach as treatment for adenoid cystic carcinoma; Conditioning of Immune Responses, an investigation of approaches to elicit desired immune responses with a non-specific stimulus after a conditioning period which administers the stimulus with immunoreactive agents; and Hydrazine Sulfate, a large scale clinical trial to evaluate the ability of hydrazine sulfate to improve the quality of life and/or increase survival in patients with lung and colon cancer.

Novel Approaches to Peer Review: A Dual Approach

From the outset, we recognized that the alternative medical community would need assistance in building its research base. We also knew that, at least initially, the funds available for supporting research in alternative medicine would be limited. Thus, as part of our strategic planning for initiatives in alternative medicine, we developed a dual approach. First, to reach out to the community and to build a foundation for participation in research, we have begun a program of "field investigations" in which we will encourage financially independent research in alternative medicine by aiding in the design and monitoring of certain non-NIH-funded research. We will provide help with designing and developing the study protocols, facilitating administrative requirements (obtaining approval of Institutional Review Boards and FDA to initiate the study), assisting in data collection in a manner that will allow meaningful analysis, and in monitoring patient safety. As the research itself will not be funded by NIH, this program will build the research base at a minimal expense to the taxpayer.

After the OAM ad hoc advisory panel first met last fall, we began this program with six site visits this year, two in February, three in March, and one in April. Concurrently, and still related to this program, the OAM has requested clinical research proposals from five of the six investigators who were site visited. Three of the five protocols have been received. A fourth one is

apparently ready to be sent to us. These visits were quite useful in that they allowed the OAM staff to conceive and test Phase I of the "field investigations" program. This program lays out a standardized, structured plan that will now allow OAM to follow up on the evaluation of the retrospective data considered during the initial contacts with the prospective investigators. This plan has now been formalized and submitted for comments to the members of the Program Advisory Committee, selected staff of the NIH research institutes with useful expertise, and to the Office of the General Counsel, Department of Health and Human Services.

As the second part of our dual approach, we announced the first Request for Applications (RFA) in 1992, inviting all interested practitioners to apply in any area of alternative medicine for exploratory grants to establish the value of their theory or practice. This RFA is quite unique in that it allows individuals to apply, as opposed to the usual academic institutions only (except in the case of the Small Business Innovation Research Program.) It also requested the collaboration of conventional investigators and practitioners of alternative medicine. The OAM made special efforts to reach out and help the community understand the administrative process of grant application by convening five grant writing workshops across the country that were attended by more than 700 participants. The general response from the alternative community to the RFA and the workshops was quite positive and strongly contributed to convincing the community that OAM is sensitive to the needs of the community. Simultaneously, the clear stance of OAM, that careful scientific standards and patient safety be applied to the evaluation of alternative medicine, has also convinced many in the conventional biomedical scientific community that funds will be spent wisely and that the resulting data will be reliable. As a result of these efforts by OAM, we have received more than 500 grant applications.

Our measured approach to stimulating the alternative medical community to establish a research base through solicited grant applications is similarly articulated in the findings of the 1990 OTA report:

In a time-limited demonstration project, the Federal Government, either through NCI or through another office, could provide funds for evaluating unconventional cancer treatments....The amount of funds that would be used for such a demonstration depends on balancing two conflicting factors: funds would need to be large enough to provide for a fair test of the program, but the Government needs to limit the amount to reasonable levels until the value of such an effort is demonstrated. During the first phase, research proposals would be solicited and reviewed. The review committee would be funded in this phase, but no actual research funds would be allocated. Estimates of annual funding requirements for phase two would be based on the quantity and quality of proposals received during the first phase.

Cooperation with Other Federal Agencies

The OAM has had numerous meetings with other Public Health Service, Departmental, and other Federal agencies to discuss the activities of the office. The Agency for Health Care Policy Research, the Substance Abuse and Mental Health Services Administration, the Food and Drug Administration, the Health Care Financing Administration, and the Indian Health Service have all played an active role in meetings sponsored by OAM. In addition, separate meetings have been held with individuals from the Department of Agriculture to discuss potential clinical applications of botanicals and natural products, the utilization of existing natural products databases, and botanical screening procedures.

The Office meets regularly with the FDA to develop procedures to review alternative medical practices. We appreciate the opportunity to work with the FDA in addressing challenges of the evaluation and approval process that will be encountered by alternative treatments.

FUTURE GOALS OF THE OFFICE OF ALTERNATIVE MEDICINE*Report of the Panel on Alternative Medicine*

From the very beginning of the establishment of OAM, we set in place a strategic planning process that will culminate in the development of a much needed Advisory Panel Report to guide our efforts and priorities in alternative medicine. The report, currently being developed by our Ad Hoc Advisory Panel, is expected to be completed this year. It will clarify present research barriers, future research directions, and future research priorities across the various alternative medical clinical fields, or subspecialties. Clinical subspecialties to be addressed include: structural and energetic therapies, bioelectromagnetic applications, pharmacological and biological treatments, traditional and ethnomedicine treatments, mind-body control interventions, lifestyle, and nutritional changes. The report also will discuss: improving research training, adapting the peer-review process to the evaluation of grant applications dealing with alternative medicine, improving research methodology for the evaluation of alternative medical practices, and informing the public through improved collection and dissemination of research resources. An appendix to the report will provide resource projections for OAM.

Need for Databases

Often, the scientific data base that can be readily analyzed is not readily available or simply does not exist for these practices. One of the concerns expressed in the 1990 Office of Technology Assessment report cited earlier and again in the report of your committee accompanying the FY 1992 NIH appropriation, is the need to test the validity of these alternative practices and to provide a centralized source for data on alternative methods.

The availability of specific information and data useful to practicing physicians and other health care providers on the safety and effectiveness of any particular therapy, regimen, or practice will determine the speed of its transition from use in unconventional practice to conventional medicine.

OAM is working with the National Library of Medicine to expand existing databases and to compile a reference library of alternative therapies. The OAM database will contain: 1) a compilation of past and current ongoing research, both basic and clinical, relevant to alternative medicine; 2) compilation of the names and addresses of alternative practitioners in various fields, by discipline; and 3) compilation of the names and addresses of organizations promoting the research and practice of alternative therapies. OAM also is making efforts to gain access to presently available private databases.

International Programs

The anticipated international programs of the OAM fall generally into two types of complementary activities. The first one involves primarily Western European countries, in which the exploration and utilization of alternative practices has been long standing. Given the goal of utilizing the breadth of already existing experiences with those European countries familiar with alternative approaches, the NIH Fogarty International Center has initiated contacts with American embassies in certain European countries to accumulate information regarding prominent alternative medical practices and organizations and to determine whether local governments are involved in promoting research or practices of alternative therapies.

The second type of international activity involves those countries with culture-specific practices considered alternative in the West. The aim is to promote research and understanding of those practices whose investigation may be difficult to separate from their cultural context. We are considering such projects as exploring traditional medicine in China and homeopathic and Ayur Vedic practice in India. In cooperation with the World Bank, we will examine other ethnomedical practices and sponsor collaborative research programs and conferences.

International interactions will increase this year as we develop plans to sponsor national and international meetings on ethnomedicine, ethnobotany, and Native American treatments. The commercial development of natural products, including the clinical evaluation, represents one of the greatest challenges to the Office due to the number of botanicals in use by native populations around the world.

Technology Assessment Conferences

OAM, in cooperation with the NIH Office of Medical Applications of Research, is planning a number of technology assessment conferences to be held over the next two years. We will convene a Research Methodology Conference late this year or in early 1994, that will include representatives from the Office of Alternative Medicine's Advisory Panel, the NIH research institutes, academia, and alternative medicine clinical researchers. The goal of the conference is to bring together this historically diverse group of professionals in order to produce a technology assessment document that will critically evaluate the strengths and weaknesses of the state-of-the-art of alternative medicine research. This conference will help define the research base upon which alternative medicine can build.

The conference will demonstrate the need to define parameters important in the research in alternative medicine and outline methodological approaches to deal with these. This should result in an increase of the frequency of publication in conventional peer-reviewed clinical journals.

We are planning a consensus conference in July 1994 on the role of electrical stimulation in promoting bone fracture and scar tissue healing. The efficacy of electrical stimulation as a therapeutic modality in promoting bone repair has been confirmed in double-blinded clinical trials. A conservative estimate is that more than 100,000 people have benefitted from such treatments. The purpose of this conference will be to determine what the scientific clinical research literature reports. These findings will be summarized and presented as a basis for arriving at clinical research consensus based on previously developed and applied OMAR consensus conference standards.

A substantial area of alternative medicine practice that has significant potential for growth as well as controversy is the role of the mind-body interface in aiding or limiting the impact of clinical treatment. We are planning an April 1994 assessment conference on this subject that will be a follow-up on the Report of the OAM Ad Hoc Advisory Panel and further characterize the mind-body field as well as the state-of-the-art of the research. Based on the findings found in quantitative research reviews, including systematic and meta-analytic reviews of peer-reviewed clinical journals, the conference attendees will recommend clinical and methodology priorities for research.

Other Future Goals

In addition to the aforementioned goals, OAM looks forward to other activities to advance research on alternative medicine. Among these are: training programs for medical fellows; the establishment of research centers of excellence in alternative medicine; and OAM-sponsored conferences and conference grants to foster communication between the alternative and traditional medical communities.

CONCLUSION

In conclusion, Mr. Chairman, the public and the scientific community, both outside and inside the NIH seem to be more sensitive to issues concerning alternative medicine. In particular, the fact that reliance by a large population of Americans upon alternative medicine has considerably increased, further justifies proper investigations of these approaches to health care. An additional source of support for research in this area is now coming from within well established academic institutions. While the proportion is certainly still quite low, a significant number of well known faculty members have contacted our office, recommending the evaluation of either isolated techniques or of whole ethnomedical systems. Among the majority of our NIH colleagues, we have found a somewhat unexpected openness, and even at times enthusiasm.

We have made substantial progress toward fostering a new receptivity to bridge the gap between the alternative and conventional medical communities. The tenets of our strategic plan together with the continued support of your subcommittee, Mr. Chairman, have opened new avenues of research that will afford ours and future generations with treatments and cures today unimagined.

Senator HARKIN. Thank you very much, Dr. Jacobs. We appreciate your testimony.

Let us, first of all, Dr. Jacobs, get right into this. You said you had 500 applications; right? These are for the grants.

Dr. JACOBS. Yes, sir.

Senator HARKIN. And you decided they would be up to \$30,000 each?

Dr. JACOBS. Yes.

Senator HARKIN. This is obviously an internal decision you made, or somebody made. I do not know.

Dr. JACOBS. Based on the amount of money that we felt we could allocate from the \$2 million, when you subtract out salaries—

Senator HARKIN. And these are grants to help these people write grant proposals, things like that.

Dr. JACOBS. Well, essentially plan the grants. Plan the studies. Not to help them write grant proposals but actually plan what they need to do. That is one of the objectives of the grant program.

Senator HARKIN. So you have 500 applications with up to \$30,000. What is your pot of money for that? How much money are you going to allocate for that?

Dr. JACOBS. We have allocated approximately \$600,000. We are hoping that, by the end of the year, if we have some additional funds we will hopefully transfer it into that \$600,000 and hopefully make more awards.

Senator HARKIN. And you have all of these applications. How do you decide who gets them? Is there some kind of peer review process?

Dr. JACOBS. Yes, sir; what we have done is we have utilized the mechanisms under the Division of Research Grants. They are actually processing the applications for us. They are setting up study sections, ad hoc study panels to review each application for technical merit. And they will all be scored, and then they will be given to us and the staff and we will review them with the Program Advisory Committee. And we will try to establish a priority of funding.

Senator HARKIN. How large a staff do you have out there now?

Dr. JACOBS. We have approximately—there is myself as the Director, Dr. Eskinazi is my Deputy Director. I am a pediatrician by training with an M.D., and an M.B.A., I am a generalist as a pediatrician. Dr. Eskinazi has a dental degree as well as a Ph.D., in immunology. We also have Dr. John Spencer who is a clinical psychologist Ph.D., who has a very strong interest in mind-body medicine. We do have a secretary, and we have one more position which is going to be filled within the next several weeks.

Senator HARKIN. With you and Dr. Eskinazi you have got three doctors there now, you have one secretary.

Dr. JACOBS. Correct.

Senator HARKIN. And that is it?

Dr. JACOBS. We also have Dr. Dave Larson, who is an M.D. psychiatrist who has a very strong interest in religion in psychiatry who is actually detailed to me on a temporary basis.

Senator HARKIN. From where?

Dr. JACOBS. He is from, I think, the Office of the Assistant Secretary for Planning and Evaluation.

Senator HARKIN. And how long has he been with you?

Dr. JACOBS. He has been with us approximately, I think it is 2 or 3 months. And I am hoping to maintain him beyond the detailed time.

Senator HARKIN. So he was detailed to you from the Office of Planning and what?

Dr. JACOBS. Assistant Secretary for Planning and Evaluation.

Senator HARKIN. In NIH?

Dr. JACOBS. No; that is in the Department of HHS.

Senator HARKIN. Oh, I see. And his name again?

Dr. JACOBS. Dr. Dave Larson.

Senator HARKIN. So your permanent staff is three doctors. That is you, the assistant, one doctor and one secretary.

Dr. JACOBS. That is correct. And we have one vacancy which we are in the process of filling right now.

Senator HARKIN. Is that staff large enough to fulfill the mandate that we gave you?

Dr. JACOBS. Well, sir, I think—what we are hoping to do with the reauthorization of the NIH, we have ERDA authority which I think is intramural research training awards, and we are hoping to hire fellows who will actually expand—doctoral level fellows who will actually expand on our field activities.

Senator HARKIN. Dr. Jacobs, when did you come onboard?

Dr. JACOBS. October 26, 1992.

Senator HARKIN. On February 3, 1992, Senator Specter and I wrote the NIH requesting that, without further delay, no fewer than five scientific investigators should be employed by the Office of Alternative Medicine. Why has that not been complied with?

Dr. JACOBS. As I indicated, I came on October 26. There were two national meetings that were held, one in June 1992 and one in September 1992, with the alternative medical community. As I understand it, the intention was that the alternative community would help define what the activities of the office would be, and then the individuals that would be hired would help to reflect that activity as defined by the community.

Senator HARKIN. I am sorry, I do not understand. We put this language in there; it has been in for 1 year and not quite a half now, and we have no scientific investigators. We put no less than five. Should I direct this question to the Director of NIH, or should I direct it to you?

Dr. JACOBS. I will attempt to answer it for you, perhaps in another way, sir. As I understand it from the past, the intention was—when the office was created, there was really no handbook as to how you create an office of alternative medicine. Part of the problem at the NIH is the NIH really did not know what was the alternative medical community. As I understand it, there was a lot of misunderstanding about what alternative medicine was.

The intention was to convene meetings with the alternative medical community to help define what the research needs and staffing needs would be for the Office of Alternative Medicine. At around September, which I think was when the job announcements went out for the office, that was around the time of the second major meeting in Chantilly, VA. In fact, I cannot remember exactly when I was—I think it was on October 2 when I was offered the position

as director. But it was my understanding that the community was going to be involved in at least helping to define what the staffing needs would be.

Senator HARKIN. Well, this was in our fiscal year 1993 bill. I do not need to read the language any longer, but I will just read the second sentence of this. It says:

An additional system of extramural and/or intramural review is also recommended in order to provide the advisory board the fullest information upon which to base its decision. Those treatments which offer promise should be presented to the advisory board for further review and decision.

Now, again, we wanted to get these five scientific investigators onboard. Here it is, it is now June. OK. So they are not on. You do not have them. Do you have plans to have them on?

Dr. JACOBS. Yes, we do, sir.

Senator HARKIN. OK. Tell me when.

Dr. JACOBS. Let me just say, though, that I do not think it is totally fair to say that I am not a scientific investigator. I do have an M.D. I am conventionally trained in medicine in pediatrics. In fact, I did work with the Aetna Life Insurance Co. on the whole area of clinical guidelines and the guidelines research. So I do not think it is totally fair to characterize me not as a clinical investigator. In fact, when I have made field trips, I have been able to convey a certain degree of information to the proponents of alternative medicine as well as questions which I think are fairly respectable. So I am not exactly sure I would characterize myself as not being an investigator.

Dr. Eskinazi has a significant background in clinical research. He comes from the National Institute on Aging. Dr. John Spencer I recruited out of the National Institute on Drug Abuse because of his tremendous research experience in the area of biofeedback and clinical psychology.

Senator HARKIN. Then again, perhaps we were not clear enough in the way we worded the language. I thought we were very clear. Maybe, I guess, we will have to rewrite it again and say no fewer than five, excluding the director and the associate director. That is not to say that I do not want you doing this.

Dr. JACOBS. I understand.

Senator HARKIN. But I would hope that you would be busy enough and your day would be full enough in terms of getting the peer review system set up, getting these applications through, working with the other Institutes at NIH. I have got to believe that takes a lot of time, and takes a lot of effort on your part and also on your assistant's part.

Dr. JACOBS. Yes, sir; it does.

Senator HARKIN. I do not know how you find the time, then, to go out in the field and travel around the country to do scientific investigations. I just want you to know, our intention was not to say, you and you, and then hire a couple more. We wanted five. And I thought it was clear, but now that I read it I guess I did not say, excluding the director and associate director.

Dr. JACOBS. Sir, one thing I might add, too, in my view, an office does not exist unless you have a secretary.

Senator HARKIN. And you probably need more than one.

Dr. JACOBS. Yes, sir; we do. In fact, we have a temporary. And we have volunteers who are working with us in the office, and it is tremendous. It is an embarrassment of riches in terms of what you have created. You have created something which has gone beyond.

Senator HARKIN. Let me ask you, have you gone to the Director of NIH? I wish I had asked her that before she left. I knew she was going out the door anyway. But we have a new director coming in, and do not worry, we will talk to that person, too.

Did you ever go to the Director, Dr. Healy, and say, "Look, this thing has mushroomed. I need more secretarial help. I need more office space. I need this." Have you ever gone to her?

Dr. JACOBS. Sir, I went to Dr. Moskowitz and he basically told me, do whatever it requires to get people onboard. Like I said, we have hired—well, I have the individual who was detailed in and am trying to maintain him on an almost indefinite time period. By the way, Dr. Larson is an eminent researcher in the area of religion and psychiatry, and I feel very fortunate to have him on the staff.

Dr. Moskowitz also is very supporting in my going out and hiring a temporary secretary to help us with the flood of mail and phone calls. And then we have also put out a small contract to another individual to help us do nothing but process the grant applications that have come through and the requests for grant applications. We had something like over 5,000 requests for grant applications from the time we announced the program until just a few weeks ago.

Senator HARKIN. I thought it was 500.

Dr. JACOBS. Applications that have come in. But these are requests for applications. Application kits.

Senator HARKIN. I see the difference. I understand.

Senator Mikulski has to leave and wants to ask some questions. I will defer to her.

Senator MIKULSKI. Thank you, Senator. Just a couple of quick questions.

Obviously, what has happened, Dr. Jacobs, is that you are getting inquiries as if you were an Institute rather than an office. Am I right?

Dr. JACOBS. Yes, Senator.

Senator MIKULSKI. So that what is happening is that the level of work coming in is acting as if you were an institute like on cancer, on aging, when what you are is an office, which was meant to go horizontal, and to get the other Institutes to focus on that.

Dr. JACOBS. Yes.

Senator MIKULSKI. And I think we have to be clear on how we fund them, Senator Harkin. Are we going to fund them as an Institute, or are we going to fund it as an office? But empower the office in a way where the other Institutes have to listen.

As you recall, in the Office of Women's Health, yes, Dr. Healy instituted the now longitudinal study but it was to get the Cancer Institute, the Aging Institute involved. And I think that is something we need to address.

Dr. JACOBS. It is a good model. It is a good model.

Senator MIKULSKI. Because are you an office or are you an institute? Because we cannot have the expectations of an institute.

The other would be—and this would go to a question I have—one would be the targets of opportunity for intramural research where the office would focus on a few key institutes, like we did with the women's research, Senator, in which you were extraordinarily helpful, and then also a model for the extramural research.

Now, what do you think of the Eisenberg model of these medical schools that would be the centers of excellence?

Dr. JACOBS. Well, I think there is some value to being able to take advantage of the expertise of different medical schools. There is some advantage to it for this decentralized role.

But I think—you know, it is a difficult question to answer, Senator, because some of the Institutes I think do have experience in funding centers outside of the NIH, but I am not familiar with how successful they are.

Senator MIKULSKI. I am not either, and I would be cautious on the Eisenberg request at this time for the simple reason, as I understand your work, you have gone out to the alternative medicine practitioners. They do not have offices in academia and so on. And, in fact, going to your site visit on the bee pollen research, particularly for asthma, they work in very small situations. Their data is not organized for research protocol purposes, and most of their information is anecdotal. Am I correct?

Dr. JACOBS. Yes; that is true.

Senator MIKULSKI. So that if we are then going to have the complementary medicine practitioners working alongside to do the so-called blind studies and so on whether it is on arthritis or other of the issues that we have talked about here today, you really need to have an extramural or an intramural program where these practitioners would come and work with these, so that it almost has to be like joint ventures.

Dr. JACOBS. Yes.

Senator MIKULSKI. Now, this is going to be a whole new kind of thinking, is it not, for the medical community? If I have devoted my life to the asthma research center where the bee pollen therapy seemed to have the greatest possibility, then along comes somebody who says: "Two hundred pills a day of bee pollen, man." First of all, even how to set up the research there is going to be difficult. Am I right?

Dr. JACOBS. Yes; there are some methodological problems in setting up these types of research, but I think you hit upon a very important objective that we had in the grant program. We wrote in the grant program specifically that if someone at, say, Harvard wanted to do a study with an alternative medicine, we indicated in there that they had to collaborate with an alternative practitioner.

Senator MIKULSKI. I think this is where it is important, rather than centers investing in medical schools who then are going to go searching and so on.

I have to go talk to Secretary Cisneros about some HUD problems, but I think we need to be clear on whether they are an Institute or an office and, therefore, the expectations about what they should do. And then, perhaps consider identifying a few of the other Institutes that we could really target and do things properly,

particularly where there are some of the most promising opportunities for research.

Dr. JACOBS. Yes; I was delighted—I was invited to a conference sponsored by the Arthritis Institute on fibromyalgia, the management of pain of fibromyalgia, and I went with a certain degree of trepidation, Senators, because I was anticipating derision, if you will, of alternative medicine. But after I gave my presentation, I was so amazed as to the interest on the part of these researchers in having to deal with the management of pain of fibromyalgia in patients. I was just absolutely elated over the interest at the Arthritis Institute.

Senator HARKIN. I have some followup on some of the questions that Senator Mikulski asked, but let me just again drive home this point on the scientific investigators. We heard testimony earlier from some of the doctors who were here, I asked this question specifically. I am sure it was Dr. Berman, yes, I asked the question specifically about any interest. Is there interest in research in this area among students, younger doctors, that type of thing, and he said there was a great deal. He was surprised at how much interest there is in this.

Have you gone out with any kind of notice that you want to hire five scientific investigators? Is this out there someplace?

Dr. JACOBS. As you know, the NIH and the rest of the Public Health Service is under an FTE freeze, or at least a mandate to reduce the number of full-time equivalents within the Public Health Service.

Senator HARKIN. Are you telling me you cannot hire five additional scientific investigators?

Dr. JACOBS. Well, all of the offices of the NIH and the Institutes and the agencies of the Public Health Service have FTE limits in terms of numbers of people they can hire.

Senator HARKIN. What is your FTE limit?

Dr. JACOBS. Well, for my little office it is only five. But I have had to—

Senator HARKIN. Wait a minute. That is five—

Dr. JACOBS. Full-time equivalents, which would be basically five bodies, five positions in the office, which includes me, Daniel, my secretary and two other staffers.

Senator HARKIN. That is how many you have now.

Dr. JACOBS. Yes.

Senator HARKIN. But there is no regulation or law, there is no one that says that is all you can have. There is? Who said that?

Dr. JACOBS. There is an FTE ceiling that we have to live under, sir.

Senator HARKIN. Who said you can only have five people in your office?

Dr. JACOBS. OMB.

[Pause.]

Senator HARKIN. I think staff has cleared this up for me. It seems to me that NIH does have an overall FTE allocation and the Director has allocated that to each office.

Dr. JACOBS. As I understand it, Senator, I think there is expected to be a 650 FTE decrease at NIH.

Senator HARKIN. I am further told that OMB sets an FTE ceiling for the Department of HHS. The Secretary can distribute the Department's ceiling among the agencies as she sees fit.

Well, let me put it this way. By early next week I will have something from the Secretary authorizing you to have additional FTE's. OK?

Dr. JACOBS. Sir, if I could elaborate on one other point. This was the reason I brought up the reauthorization of the NIH legislation. There is specific authority in there for us to hire clinical fellows, which I feel can be devoted solely to the notion of clinical investigation in the area of alternative medicine which would strengthen the activity in the area of field investigations. And those fellows are not counted against the FTE ceiling.

Senator HARKIN. As I said, I will get the Secretary to authorize that. I am sure she is more than willing to do that. I know she supports this. I would not want to put words in her mouth; she has her own department to run. But I am sure this is something she would be more than happy to do. And I want your assurance that when that comes through, you will be expeditious in getting these additional five scientific advisors.

And if you can get other clinical investigators, all the better. Sounds like you could use them.

Dr. JACOBS. Yes. Yes, sir.

Senator HARKIN. How much of your current budget is directed toward investigation and validation of alternative treatments?

Dr. JACOBS. Well, I would have to consider, obviously, the RFA program, the grant program, as part of the activities related to investigation and validation. It is a grant program. It may be viewed as being research, but it basically is clinical research.

Senator HARKIN. Wait a minute. Let me see if I understand this. We talked about investigation and validation. That, as I understand it to mean, was to use trained researchers—that is why we put the five in there, such as yourself or Dr. Eskinazi—to investigate and validate therapies and alternative treatments.

As I understand this grant proposal, these are grants to individual researchers to help them write grant proposals, to do research, but it is not to investigate and validate. Please clear up my thinking on this.

Dr. ESKINAZI. I would think that the RFA and the grant program, would certainly fall under the concept of investigation and validation. The program, the request for applications, as it is designed, is precisely to foster collaboration between practitioners of alternative medicine and conventional practitioners, or conventional researchers.

Senator HARKIN. I understand that.

Dr. ESKINAZI. We have, in effect, since we got approximately 500 responses, we have generated 500 types of teams who will be able then—and this is contained in the applications—who will get preliminary data as well. And this program is specifically designed or mostly designed for clinical investigations. So I find it difficult to divorce that from investigation and validation of alternative medicine.

Dr. JACOBS. Senator, I think there may be some confusion with regard to what we are trying to do with the RFA.

Senator HARKIN. Well, I think I am probably confused because I thought—let me just tell you what I conceive of as investigation and validation.

There are a lot of therapies. Take my bee pollen, for example. I think it is a good example. Does it work or not? It worked for me. Has it worked for anybody else, or did a gamma ray from outer space all of a sudden hit me and cure me? You know? I do not know. But an investigation and validation is to investigate some promising therapies that some people have said work, at least have some semblance of validity to them, to investigate them, to set up the protocols and to see if they really do something. It is a procedure. You investigate it, you set up protocols, you set up a definite way of treating people, certain groups, so that you have one test group, one placebo, all these things. And then you validate.

That is what I thought that meant.

Dr. JACOBS. Well, I think you are correct—

Senator HARKIN. Wait a second. I want to get this cleared up in my head because maybe I am not right.

Dr. JACOBS. Well, you are to a certain extent, if I may be so bold. In the example of bee pollen, we went to talk to the proponent of bee pollen.

Senator HARKIN. I saw that here.

Dr. JACOBS. And he explained to us that it is a miracle drug; it clears everything.

Senator HARKIN. He told me it cures everything, too.

Dr. JACOBS. In fact, when I was there I was suffering really badly from allergies. I can really relate to your story, what you were talking about. But I took his therapy and became nauseous and almost vomited, and I hate nausea. What saved my life, turned my life around, was nasal steroids which I have been using for the past 7 or 8 years. So I tried the bee pollen. It did not work for me.

What we will do essentially is make the investigation. How do we validate this? We put together a protocol with the assistance of someone at the University of Texas, and as they negotiate, the proponent and the researcher negotiate this, this is going to be conducted not by my office, although we will oversee the research being done, but the actual researcher will be somebody, a clinician who is credible and has the perfect credentials to make sure that when the results come out, that they are validated. That they are valid results.

I understand what you are saying, and that is precisely what we are trying to do, but I do not think we are doing in the way that you quite envisioned. Because we do have to worry about acceptable results to the rest of the medical community.

Senator HARKIN. Well, as long as it was done in a methodological manner, scientifically good, and you come up with results, why would they not be acceptable to the rest of the medical community? I do not understand.

Dr. JACOBS. I gave the example earlier in my oral testimony about the reports about the association between pancreatic cancer and coffee drinking. Clearly, if you have bias, negative bias, toward alternative medicine, you are going to run into trouble.

We are aware of a researcher who made an attempt with homeopathy with an excellent study put together on showing that home-

opathy treats childhood diarrhea successfully with statistically significant results. She was unable to get her paper published in pediatric literature because one out of the three reviewers stated that unless she could, and her colleagues could, explain how homeopathy works they would not pass on her paper. This is reviewer bias. It is seen in conventional medicine, but it is a particular problem when you have to deal with alternative medicine.

So I think the notion of setting up study protocols to investigate and really importantly validate these therapies is a very complicated issue. And we have to do it in the way that science accepts the ways in which these things are done; otherwise, the results are not going to be accepted.

Senator HARKIN. It just seems like 1 week does not go by that I do not open the paper and find another study on something.

Dr. JACOBS. Absolutely. It is confusing.

Senator HARKIN. They just come out all the time. But why do we have to be holier than Caesar's wife? What is that phrase? Why do we have to be purer than the rest of the scientific community in America?

Dr. JACOBS. Actually, we are not. And that was the point I was trying to make with Dr. Wennberg's studies and also with the work of the Agency for Health Care Policy and Research. As Berkley Bedell mentioned, outcomes research is one of these new studies. But what is interesting is that Wennberg showed that the difference for prostate surgery, the difference between watchful waiting versus having surgery—you are probably better off watchful waiting if the symptoms do not bother you for benign prostatic hypertrophy, which I think is an earth-shattering revelation in conventional medicine.

So, actually, these standards are no more strict in alternative medicine than they would be in conventional medicine.

Senator HARKIN. Well, I will get better on this investigation and validation protocols. But, the office has been in existence for 1 year and 8 months now. Has there been one investigation and validation protocol done?

Dr. JACOBS. Well, last fiscal year, fiscal year 1992, there were a number of studies that were funded out of the office through some of the other Institutes, and those studies are ongoing right now. They were peer reviewed through the other Institutes. Dr. Burzynski's work is also one of those that is being conducted right now.

Senator HARKIN. I understand that in 1992, of the \$2 million appropriation, \$500,000 was given to NCI?

Dr. JACOBS. Yes.

Senator HARKIN. To conduct an evaluation of Dr. Burzynski's treatment of cancer. And also, is this in addition, \$250,000 for the purchase of the medicine from Dr. Burzynski? What has happened to this money?

Dr. JACOBS. Yes; we are attempting to find out the status of the conducting of the research. As I understand it, the additional \$250,000 was put aside for the possibility of having to manufacture the antineoplastons in the event that Dr. Burzynski would be unable to supply it. We are currently working with the NCI right now

in terms of trying to sort out how we are going to deal with the additional funds.

Senator HARKIN. I guess on May 17, your office had correspondence with FDA.

Dr. JACOBS. Yes; I believe so.

Senator HARKIN. Did you write a letter to FDA?

Dr. ESKINAZI. Yes.

Senator HARKIN. Did you get an IND from FDA for this?

Dr. JACOBS. Yes.

Senator HARKIN. When did the \$500,000 go to NCI? That was in 1992.

Dr. JACOBS. Yes, sir; that was fiscal year 1992.

Senator HARKIN. How come nothing happened until May 17 to get to the FDA?

Dr. JACOBS. Well, they are in the process of doing the paperwork to file an IND for the study of the antineoplastons, and they have also solicited from their cancer community protocols for the evaluation of the antineoplastons, and that process has been ongoing for the past year.

Senator HARKIN. Well, I know it has been ongoing. I know it has been ongoing clear back to 1991. Right?

Dr. JACOBS. The May 17 letter to the FDA was related specifically to childhood brain tumors. Prior to that, the activity that the NCI is currently doing now with the antineoplastons is related specifically to adult brain tumors. So this is a new activity, or a new target population if you will, in the use of antineoplastons.

Senator HARKIN. I still want to know what happened to the original money. I do not know what happened to that.

Dr. JACOBS. The original money is with the NCI at the moment.

Senator HARKIN. And what are they doing?

Dr. JACOBS. They are setting up a multicenter study of antineoplastons in adult brain tumors.

Senator HARKIN. So they are not really investigating and validating Dr. Burzynski. That is what you are telling me.

Dr. JACOBS. Well, the use of multicenter studies in clinical trials is a method of investigating and validating.

Senator HARKIN. It may be one method.

Dr. JACOBS. Yes; OK.

Senator HARKIN. It may be their method.

Dr. JACOBS. That is true.

Senator HARKIN. It may not be the only method that could be used.

Dr. JACOBS. Yes, sir; that is true.

Senator HARKIN. Well, what I am wondering about is it just seems as if this money went into a black hole someplace, and that is what I am worried about. And if this is what is going to happen, I am going to have NCI up here. I want to find out what they are doing with that money. I will have Dr. Broder up here. I had him up before. Had I known this at the time I would have had him on the hot seat on this to figure out what is going on here with this money.

I guess what I am concerned about is, \$750,000 out of \$2 million, that is quite a big chunk of money that went out to conduct an evaluation; \$250,000 for the purchase of medicine. And I cannot

find out what has happened to the money. I can't find out what has happened to the medicine. Was the medicine purchased or not? I do not know. That was \$250,000. Now, that did not go to NCI, did it? Or did it.

Dr. JACOBS. It did go.

Senator HARKIN. All of it went to NCI.

Dr. JACOBS. Yes; it did all go to NCI.

Senator HARKIN. All right. All of it went to NCI.

Dr. JACOBS. As I understand it, sir, customarily, when they are testing a new drug, if it is a pharmaceutical manufacturer, for example, the manufacturer provides the drug at no charge to the Institute so that the Institute can conduct the proper investigation of the clinical benefit of the drug. And as I understand it, they are treating the investigation of antineoplastons in exactly the same way they would treat any other pharmaceutical.

Senator HARKIN. Do you know whether Dr. Burzynski is willing to give this drug to them for this? He is?

Dr. ESKINAZI. He has given the drug.

Senator HARKIN. If he has given the drug then why do we need \$250,000 for the purchase of medicine?

Dr. ESKINAZI. If I may answer, it is because NCI knew of Dr. Burzynski's difficulties, let us say, with the authorities and they were concerned that precisely what you heard today, the possibility that he may not be able to manufacture the drug any longer, might happen during the clinical trial. In which case, having the money, they could go to another manufacturer and ask for the drug to be manufactured.

Senator HARKIN. Is that what has happened? Not yet?

Dr. ESKINAZI. That was a reserve.

In terms of the trial itself, the work that has been done, or at least the attempt that has been done by the NCI, has been to work through the funded cancer centers. They have a number of cancer centers around the country, and when they accepted to run the trial on the antineoplastons, they requested the investigators in the cancer center to submit letters of intent or letters of interest in conducting such a trial and they proposed both adult and pediatric tumors. And apparently, only the adult tumors generated any interest.

At that point, then, they selected a couple of centers, already-funded centers, one being at Sloan Kettering and the other one at the Mayo Clinic, and they requested the investigators there to submit a project. So this project, at least from Sloan Kettering if I am not mistaken, has been submitted recently and has been forwarded to Dr. Burzynski for his comments. Dr. Burzynski had several comments about the project and I think that is the way it is at the present time.

In terms of the pediatric tumors, no one was interested. The investigators apparently were not interested, and this is why we have stepped in and have tried to do one of these field investigations, and we have started this.

So we have two different things. The one study that is being planned by the NCI through their cancer centers, and the field investigation that we are planning—what you call, investigation and validation I believe—through our office. The letter of May 17 that

you referred to is from our office to get an IND number for the pediatric tumors.

Senator HARKIN. I have this copy here from the National Cancer Institute dated October 1991 talking specifically—it does not mention his name but I am told it is Ryan, the young boy that was here today. A 10-year-old male—that there has been improvement. So, in October 1991, NCI had looked at this. And yet, then they come back and say there is no interest in looking at childhood tumors like this. That is what I do not understand.

Dr. JACOBS. As Daniel indicated, what they did was contact their funded pediatric cancer centers to see if there was any interest in using antineoplastons to treat childhood brain tumors, and there was no response. There was no interest on the part of—

Senator HARKIN. Of NCI.

Dr. JACOBS. No, no, no. Not of NCI, but the cancer centers around the country that were treating childhood brain tumors.

Senator HARKIN. There was no interest by them to look at this.

Dr. JACOBS. That is correct.

Senator HARKIN. But NCI had this information.

Dr. JACOBS. Yes.

Senator HARKIN. Did they ever give you this information?

Dr. JACOBS. I have discussed with them their site visit that they made to Dr. Burzynski. In fact, Daniel and I made a subsequent site visit to see Dr. Burzynski to just discuss some of his cases. And because of the fact that there was a lack of interest on the part of the pediatric cancer community, they felt that they were not inclined, if you will, to move any further.

Senator HARKIN. Well, you are a pediatrician. Would you be interested in this?

Dr. JACOBS. Yes; I would be. In fact, I will volunteer to tell you, Senator, that I have had a number of people who have called me. Obviously, as I indicated, a lot of patients call me, or families call me. And my response is this. I have to say at the beginning, I am a physician first, a bureaucrat somewhere down the line. But I have had mothers call me and talk about their childhood tumors and have been brought to the conclusion by themselves and by their oncologists that the patients have no options.

From a professional point of view it is very difficult for me to recommend an alternative therapist if they have not been validated, if you will. But as a human being, when somebody asks me, Joe, what would you do if it was your child, or if it was your brain tumor and you had no medical options available to you, my response is, I would probably be on the plane to Houston.

I think there is something there. I think, even the NCI feels intrigued enough that there is something there to at least put into the system, if you will, a clinical investigation through their standard centers. And that is probably one of the best places at least to have it tested to truly validate it. If cancers centers like at Dartmouth, Harvard, Stanford, Hopkins, the University of Maryland, or what have you, test the substance and it does show clinical regression, that is the best thing one can do. That is what I would like to see happen, is a good universal testing of this substance.

Senator HARKIN. I would, too. I just do not know why it has taken so long. I guess that is my frustration. I like everything you

are saying, but it always seems that it is prospective, it is going to happen sometime. And we have been waiting for this.

I am trying to figure out where I need to focus on this. Is it you or is it NCI? I am trying to figure out where the focus is going to be on this. And I am going to keep you both in my eyesight.

Dr. JACOBS. That is fair, sir.

Senator HARKIN. And I say this. I hope that you will exercise your authority as the head of this office, through letter of correspondence with Dr. Broder, the head of NCI, to ask him to please submit to you what they have done with this money, what they are doing and how they are going to proceed. And I see no reason why you cannot, since it is your money from your office given to them to do this, that you cannot start pushing him a little bit to get this process moving a little bit faster. So I hope that you will do that. There just seems to be a tremendous amount of delay there.

Well, that is enough on that. I am faced with a problem here. I would like to put more money into the office, but if you are telling me you cannot even hire scientific investigators, that you have got to exist with one secretary and three other people running an office out here when you have all these requests coming in, and you give money to NCI that goes into a black hole someplace and we never see it again and nothing happens, maybe I should just shut the whole thing down. I do not know, you see. Is that the kind of pressures I am under? I am not going to give in to that.

I am not saying it is you. Not from you. But whoever, NCI or whatever else is happening out there. I intend to see this office move forward, and I will do whatever it takes. And believe me, Secretary Shalala tried calling me this morning and I could not take her call because I had to be in this hearing. But we have established a good relationship and I am going to bring this to her attention and we are going to move ahead on this. I fully intend to move this office forward.

And I have given time. We put the office in the bill in October 1991. I know things do not happen overnight. I understand bureaucracies. I have been around this town a long time. So I waited all during 1992. And I will ask you publicly, have I ever bugged you? Have I ever called you on the phone? Have I called you one time on the phone, personally?

Dr. JACOBS. No; you have not.

Senator HARKIN. Not one time, have I?

Dr. JACOBS. No.

Senator HARKIN. That is because I figured, well, they hired someone good. I read about you. I never met you before. Have we ever met really, personally?

Dr. JACOBS. No; we have not.

Senator HARKIN. Never have, have we. I figured I am not into that. I will let them handle it, let them set it up. Evidently they interviewed people and they found who they thought was the best qualified to run that office. I figured I will let it go.

But there comes a point in time where I have to exercise my responsibilities to the taxpayers and to the members of this subcommittee who are interested in this and, I might say, other Senators who keep asking me, "What is happening, Harkin? You set up that office. Is it moving ahead? What are we doing?" And they

are getting requests from constituents and people like that. Senator Pell. I do not think there is a week goes by that he does not ask me, and I have to say, "Well, give us time. Give us time."

So we have had a year and a half now. We are going into the third year of this next year, and we have got to see some things start to happen. And to the extent that you want to get the scientific investigators onboard, to the extent that you want to push NCI, to the extent that you want the new director of NIH to focus on this, believe me, I am in your corner.

Dr. JACOBS. Thank you.

Senator HARKIN. You have an ally in me.

But to the extent that I suspect—no, I would not say suspect. To the extent that I have any information and belief that there is foot-dragging going on in this office, that you are not being aggressive enough in pursuing the mandate that we have given that office, then you will hear from me. You have not yet because I am willing to give time. I know these things take time. But we have had enough time now, and now we start to have to move ahead I think fairly aggressively.

And so, to the extent that you do the former you have an ally. To the extent that anything happens in the latter category, you will hear from me.

Dr. JACOBS. I hear you, Senator.

Senator HARKIN. Thank you very much, Dr. Jacobs. Anything else?

Dr. ESKINAZI. Yes; I think that I would like to make a final statement, or at least a short statement.

I think a lot of the frustration, I would say, that we have all experienced is very well summarized by Congressman Bedell, and he has given a good explanation of why this is the case. I used to work on head and neck tumors as a researcher, and one of the slides that I would present early on would be more people live from cancer than die from cancer, and I think that says it all.

We have heard a lot of optimism, and I have been actually extremely surprised by the number of people who have come forth and told us how optimistic and how enthusiastic they were about the fact that we exist and about the fact that they could finally come out of the closet. When I say people, I mean very well-established researchers in excellent institutions.

However, these people represent still a very, very small minority, and the inertia is still quite large. And for a small office like us, it is difficult to change things overnight.

Senator HARKIN. Yes; I understand that. And I do not want to be unfair. And you have raised something else. I did not mean to go on any longer than this. But we have another actor in this play, and it is called the FDA. I stated that earlier I think. And I will even be more forthcoming. I know that some of these people who are dealing in alternative medicine can be difficult to deal with. Those are my words. Difficult to deal with.

Dr. ESKINAZI. I must put myself in their camp. Dr. Jacobs has mentioned that I was trained in oral medicine and immunology. He has not mentioned that I have been extremely interested in homeopathy and that I have a license in acupuncture. I have been inter-

ested in alternative medicine not since I have joined the office in January, but since 1977.

So no one has been more frustrated than I have been over the years, and there is no foot-dragging in this office, I can guarantee you.

Senator HARKIN. I appreciate that. And I know that we have got some problems with FDA. And I have talked to some people out there that are afraid of FDA. I just know that they are afraid and they feel that if they do something they may wind up in jail. They may wind up with Lord knows what. I had no idea that the guy who gave me this [indicating the bee pollen capsules] could be prosecuted for saying that it could cure my allergies.

And again, I will be frank with you. I have only met this man, Mr. Brown, once. He was in my office. Quite frankly, I am like anyone else; I am pretty skeptical about a lot of things. And, of course, when he goes on saying all the wonderful things this can do, then it kind of goes overboard. But I can only say what happened to me. It did not work for you. There are a lot of drugs. I took Seldane for 3 years. It quit working for me but other people take it and it works fine.

But somehow, we have got to bring FDA into this thing, too, and get them to help us out.

Dr. JACOBS. Senator, I should add at this particular point, we meet with the FDA on a regular basis, at least on a monthly basis if not more frequently than that. And I have to say that my colleagues at the FDA have been extremely helpful so far in trying to assist us in some of these difficult policy issues.

The FDA has two heads; there is the evaluation side and there is the regulatory side. I do not anticipate major barriers in trying to evaluate some of these therapies. It is when the results come out and a desire is made on the part of the proponents to market these drugs; then that will be a different problem for the FDA.

On the evaluation side, it is not quite as bad. I have tried to—I have allowed myself to be interjected into the issue related to Dr. Burzynski and getting an IND for his antineoplastons with the HIV. The FDA staff people had told me exactly what to do to make sure that I have access to their documents, which just because I am a Federal employee does not mean I have automatic access. So they have been very helpful in trying to facilitate the involvement of the office in some of these IND applications.

I am not ready to necessarily jump in and file an IND for every person who comes in, because I suspect that when our grant program—when we start awarding grants and people are going to need INDs for herbal therapies or acupuncture, they may feel uncomfortable about giving an IND to this individual. I am afraid they are going to ask my office to file the IND on their behalf. You have a pretty good idea, I think some inkling of an idea, of the administrative problems I have right now. If I have the imperative of having to file an IND on behalf of 16 researchers, my hair is going to be a little bit grayer than it is now, sir.

Senator HARKIN. Well, if I can give you any help there, you have to let us know.

Dr. JACOBS. I appreciate that.

Senator HARKIN. And I think there is a possibility that we can. I just think you are going to need some more people. I hate to build bureaucracies, but I think this is one area where we need it. I mean, I cannot say that 10 people is a bureaucracy, for crying out loud.

Dr. JACOBS. I think the comment that Senator Mikulski made earlier is a very valid one in terms of, one of the things that we have tried to do is try to broker these relationships with other Institutes. They have a lot more staff, more money. I would like to be able to influence them in a positive way, in the way of alternative medicine.

Senator HARKIN. I agree. So would I.

Well, you are very kind and very patient to stay here this long. I look forward to working with you in the future. As I said, I will be having another hearing on this—I do not know if I can have it this summer but maybe by September with a followup hearing, at which time I will have FDA here. I will have a joint hearing perhaps with another Senator and we will have—or we will get the authorization to have FDA here under the auspices of the Agriculture Appropriations Subcommittee. And we will have them here, too, and we will take a further look at it. So we will get together at that time.

But again, keep pushing ahead.

Dr. JACOBS. Senator, thank you very much for your support.

Senator HARKIN. Thank you. Thank you, Dr. Jacobs, and thank you, Dr. Eskinazi. Thank you all for being here today. Again, I want to thank all of the witnesses who appeared before us today.

QUESTIONS SUBMITTED BY SENATOR GORTON

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to Dr. Jamison Starbuck for response subsequent to the hearing:]

Question. The role of nutrition and lifestyle change in the rise of chronic disease is well-established in the scientific literature, including former Surgeon General Koop's Report on Nutrition and Health in 1988. Many studies have called for increasing education of health professionals in these areas. Would you comment on the extent of training of naturopathic physicians in these areas, and the way in which this training is brought into practice?

Answer. Naturopathic medical students study approximately 140 hours of nutrition throughout their 4 years in medical school. Such training includes clinical nutrition, which is applied on a daily basis in practice after these students become physicians in private practice.

Every naturopathic physician utilizes nutrition in the practice of naturopathic medicine. Most naturopathic physicians ask patients to keep diet diaries, exploring a patient's daily nutritional intake; most naturopathic physicians test patients for food allergies, are aware of the complex interactions of foods and their effect on the health of an individual; naturopathic physicians are also able to use food and diet in a therapeutic manner.

Question. While this hearing relates to "alternative medicine", don't some individuals in the state of Washington consider naturopathic physicians as their primary care providers? To what extent do naturopathic patients use naturopathic services as they would a family doctor, and to what extent as an adjunct to conventional care?

Answer. Naturopathic physicians are primary care, family physicians who treat the whole range of disease from school physicals, routine Pap and pelvic exams through the treatment of chronic degenerative diseases such as diabetes and heart

disease. Many patients utilize naturopathic physicians as their "family physician" and use the services of MD's when the services of a specialist or a surgeon is required. Naturopathic physicians are trained in conventional diagnosis and are well able to know when a referral to another physician is appropriate.

Question. Would you please give a specific example of a way these diverse therapies in which a naturopathic physician is trained may be utilized for a given condition? Please describe at what times referral might be appropriate.

Answer. Otitis media is a common complaint for a significant portion of the American pediatric population. Naturopathic physicians commonly treat otitis media with great success. While many naturopathic physicians have the legislatively authorized ability to prescribe antibiotics, these are most often not necessary. A typical way to treat otitis media is to prescribe herbal ear drops for the local inflammation, a herbal internal remedy and a homeopathic remedy to enhance the function of the immune system, dietary modifications which eliminate antagonistic foods, and an examination of the underlying causes of disease, such as food allergy, environmental factors, exposure, etc.

Question. Has Mrs. Clinton's Task Force on National Health Care Reform responded positively to your requests that they consider naturopathic medicine as part of comprehensive health care reform?

Answer. Mrs. Clinton's Task Force has asked for input from the naturopathic profession. The American Association of Naturopathic Physicians has submitted a document to the Task Force, outlining our profession's structure and value to this nation's health care system. To date the AANP has not had further interaction with the Task Force.

CONCLUSION OF HEARING

Senator HARKIN. The subcommittee will stand in recess subject to the call of the Chair.

[Whereupon, at 4:45 p.m., Thursday, June 24, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]



Material Submitted Subsequent to Conclusion of Hearing

[CLERK'S NOTE.—The following statements and letters were received subsequent to the conclusion of the hearing. The statements will be inserted in the record at this point.]

(145)

STATEMENT OF JOSEPH M. HELMS, M.D., ON BEHALF OF THE
AMERICAN ACADEMY OF MEDICAL ACUPUNCTURE

Acupuncture is a relatively new medical discipline in the United States. The American public became aware of this traditional healing art only after 1972, when President Nixon established diplomatic connections with the People's Republic of China (PRC). The wave of media enthusiasm for things curious and Chinese included the practice of acupuncture, which was dramatically demonstrated as a technique for surgical analgesia in the urban hospitals and for primary treatment by the "barefoot doctors" in rural clinics.

This general fascination prompted funding for the preparation of several survey reports on health care and traditional medicine in the PRC.^{1,2} However, due to the absence of any acceptable scientific literature or easily comprehensible clinical texts, acupuncture was regarded with suspicion by the mainstream medical community. The National Institutes of Health (NIH) stopped funding acupuncture research in 1973, and shortly thereafter the Food and Drug Administration (FDA) designated acupuncture needles and stimulating devices as "investigational," and the American Medical Association (AMA) declared acupuncture to be an "experimental procedure." These appellations effectively dampened the exploration of acupuncture in medical research centers and the exploitation of acupuncture by conventional physicians, and have shaped the practice of acupuncture in this country since that time.

Despite official caveats of the FDA and AMA, the American curiosity was piqued by early media presentation of acupuncture. Lay practitioners from Asian urban centers started taking students in acupuncture and other Oriental medical disciplines. By the late 1970's this movement was formalized in several states by acts of legislation that licensed the practice of acupuncture by non-physicians. The fundamental curriculum of the non-physician acupuncture schools is the standardized communist Chinese approach referred to as "traditional Chinese medicine" (TCM). It is founded on the prescription of herbal formulae, whose effects are reinforced by acupuncture treatments.

Presently thirty states have legislation licensing non-physician practitioners of acupuncture, and many of the state acupuncture boards have neither physician members nor any responsibility to the medical boards. The political position of the national societies representing these practitioners is that acupuncture and TCM must be recognized as a separate but equal primary care option for the patient population of the United States, and must be delivered independent of regulation, supervision, or integration by the established Western medical system.³

MEDICAL ACUPUNCTURE

Although acupuncture has not been widely practiced in the United States during the twentieth century, it had a small role in American medicine during the nineteenth century. In 1892, Sir William Osler mentioned in the first edition of *The Principles and Practice of Medicine* that "for lumbago, acupuncture is, in acute cases, the most efficient treatment" and that for sciatica, "acupuncture may be used." In contrast, the practice of acupuncture in Europe has co-evolved with the practice of allopathic medicine through the nineteenth and twentieth centuries. This is because the early Dutch traders and Portuguese and French Jesuit missionaries to China and Japan in the seventeenth and eighteenth centuries returned to Europe with reports and books on the principles and practice of acupuncture. Translations of these texts provided an understanding of the tradition of acupuncture to medical and academic circles of that period.

The French colonization of Indochina in the nineteenth century exposed their military physicians to practitioners of acupuncture, and since the 1820's acupuncture has been taught and practiced within the mainstream of medical practice in France, Germany, and Italy. In most Western and Central European countries, acupuncture training is offered through the orthodox medical education system as well as through private societies, and acupuncture is practiced by five to ten percent of physicians.

In the United States in the late 1970's, physicians who had received either Oriental or European training in acupuncture started to structure teaching programs for other physicians. By the mid-1980's "medical acupuncture" emerged as a discipline of medicine practiced by doctors of medicine and osteopathy. Medical acupuncture distinguishes itself from TCM by its conscientious integration into the existing treatment models and practice specialties of conventional Western medicine. To date, the continuing education courses offered through medical schools (e.g., UCLA School of Medicine, New York University School of Medicine and Dentistry, Washington University School of Medicine) have trained approximately 3,000 physicians in the principles and practice of medical acupuncture.

In 1987 the American Academy of Medical Acupuncture (AAMA) was formed to represent the education and practice interests of well-trained physician acupuncturists. The AAMA has been active in developing basic and advanced education programs for physicians, public education and referral services, and addressing physicians' concerns of hospital privileges, malpractice insurance coverage, and third party insurance reimbursement. Currently, the AAMA has 600 members, all licensed M.D.'s and D.O.'s.

BASIC SCIENCE AND CLINICAL RESEARCH

Neurophysiologic studies into the nature of acute and chronic pain created a niche of respectability for acupuncture in conventional medicine when the endogenous opioid peptides were linked with the pain control effects of acupuncture. In the past fifteen years the neurochemical mechanisms of this analgesic aspect of acupuncture have been better defined than those of the most surgical anesthetics currently in use.⁴ Further basic science investigations have identified a collection physiological responses triggered by acupuncture that activate a general body response of homeostasis, that is, acupuncture stimulates an internal regulation that corrects for mild abnormalities and encourages a return to normal functioning.⁵

The clinical science of acupuncture has been less successful in convincing non-advocates of the value of acupuncture. A review of the clinical literature shows a compelling but not conclusive body of evidence supporting the anecdotal claims of acupuncture practitioners. Most of the foreign studies must be discarded because of methodologic flaws. Even the best of the domestic studies can be criticized on the strength of sample size. The problems of research design manifested in the acupuncture clinical literature are those inherent in investigator-driven clinical studies of any nature.⁶

Recent documentation in France and the United States has shown early data confirming the cost-effective aspects of acupuncture in a conventional medical practice setting. In France, the statistics of the insurance syndicate show that physicians who practice acupuncture half-time or more cost the system considerably less than non-acupuncture colleagues, in the categories of laboratory examinations, hospitalizations, and prescriptions for medication.⁷ In the United States, follow-up on patients receiving acupuncture in a managed care setting demonstrates a reduction of total clinic visits and telephone consultations, as well as diminished laboratory, hospitalization, and prescription costs.⁸

MEDICAL APPLICATIONS OF ACUPUNCTURE

While much of the clinical research in acupuncture, and the notoriety for the discipline in this country, involves pain management, acupuncture can serve as a primary or adjunct treatment modality for many problems of internal medicine and surgery. A recent review of the world clinical literature on successful applications of acupuncture, while not yielding statistically conclusive evidence of efficacy, gives a range of frequent uses (in diminishing order of publications):

- pain (chronic, perioperative, arthritic, malignant, headache, backache, extremity, dental)

- . organic lesions (cardiovascular, respiratory, gastrointestinal, skin, urological)
- . neurological (peripheral and central)
- . substance abuse (drugs, nicotine, food, alcohol)
- . gynecological
- . psychiatric (depression, anxiety)⁹

Acupuncture is a dimension of medicine that offers intervention early in the evolution of a problem, well before it becomes fixed in dense histopathology. In the clinical practice of most primary healthcare providers, fifty to eighty percent of new complaints in new or established patients fall into this pre-morbid category of early dysfunction, problems that escape the diagnostic categories and therapeutic modalities that are conventionally employed. Intervention at this stage requires less expensive procedures and medications, and renders patients healthier, happier, and more functional members of society. Physicians who understand its more subtle and supple aspects confirm that acupuncture provides refined but potent health maintenance and preventive medicine.

LEGITIMIZATION OF MEDICAL ACUPUNCTURE

In the past five years there has been much favorable popular media coverage of acupuncture that, coupled with equally favorable response to acupuncture by patients, has created an increased demand by patients upon their physicians to provide this service within the context of a private or managed clinical practice. As more physicians trained in this modality have incorporated it into their practices, the aura of mystery and unorthodox approach that once surrounded acupuncture has disappeared. Physician participation in medical acupuncture training programs continues to increase. Training of ancillary primary healthcare providers - nurse practitioners and physician assistants - in the basics of medical acupuncture is being considered as a means to fulfill the demand for acupuncture services in managed healthcare and community service environments.

Most of the physicians who participate in the medical acupuncture training programs through UCLA and NYU are family practitioners. The second most represented specialty is physiatry, and then pain management, which is composed of physiatrists, anesthesiologists, family physicians, surgeons, and psychiatrists. Following these specialties, others are represented equally: internal medicine, neurology, obstetrics and gynecology, and emergency medicine. Physician graduates of these programs are distributed equally in private practice, managed care, and hospital environments, and practice in all parts of the country.

Acupuncture is gradually being accepted and approved by other influential medical bodies, despite the lack of endorsement by the FDA and the AMA. The

American Osteopathic Association and the California Medical Association both endorse acupuncture as one technique among others for the treatment of acute and chronic pain problems. In 1986 the Office of Medical Applications of Research of the NIH held a Consensus Development Conference on the "Integrated Approach to the Management of Pain," at which time acupuncture was cited as a valuable non-pharmacological intervention. In its 1990 application to the American Board of Medical Specialties for authorizations to issue a Certificate of Special Qualification in Pain Management, the American Board of Anesthesiology included a requirement for pain management fellows to undergo training in the techniques of acupuncture. Citations and chapters in prominent physical medicine and rehabilitation^{10,11,12} and pain management^{13,14,15} textbooks have been in publication since 1985.

The World Health Organization (WHO), through the Division of Traditional Medicine, has convened scientific groups to standardize several specialized aspects of acupuncture. The World Federation of Acupuncture Societies, a WHO-guided organization, has established standards for training in acupuncture for both physician and non-physician practitioners. In October 1990 the WHO Executive Board recommended that member nations participate in preparing guidelines for the regulation of acupuncture by health authorities, for practice and safety in acupuncture, and for acupuncture research and clinical trials. At the World Health Assembly in January 1991 the U.S. Surgeon General, Dr. Antonia Novello, endorsed this proposal by saying: "Promotion of the ethical use of acupuncture by trained practitioners [is] a worthy goal."

CHALLENGES

Concurrent with patient and physician acceptance and the clinical success of acupuncture in the Western medical environment is an increasing demand that acupuncture practiced by M.D.'s and D.O.'s be acknowledged as a legitimate discipline in medicine. There is constant physician frustration because of reluctant third-party or managed healthcare insurance coverage for this service. The demand for legitimacy, whether made for insurance reimbursement, malpractice insurance coverage, or state medical society recognition, is consistently deflected by the obsolete shield of the FDA's "investigational" and AMA's "experimental" designations.

In order to change these designations, the officials of the FDA and the AMA insist on new drug style pharmaceutical research to demonstrate acupuncture's efficacy. There have been no independent fundings of acupuncture clinical studies adequate to structure trials of sufficient statistical power to convince the skeptics. There is no equivalent to the pharmaceutical industry in the world of medical acupuncture. It is apparent to interested clinical investigators that the participation of the NIH in funding

such research is indispensable to change the current impasse in the acceptance, integration, and full exploitation of this dimension of healthcare service.

The challenges facing medical acupuncture are threefold: clinical care, education, and research. It is important that ethical standards of practice be delineated for the physician acupuncturist community, and that the role for medical acupuncture in modern medicine be uniformly acknowledged. The challenge of educating physician colleagues is linked to that of clinical care. Information must be disseminated so that physicians can become more sensitive to medical arts that are complementary to allopathic pharmacosurgical medicine. The clinical research necessary to further the scientific evolution of medical acupuncture requires funding sources with the vision to expand beyond drug-based therapies.

When addressing clinical research in medical acupuncture, the first step is one of political and social exigency: to prove - using the existing drug models - the efficacy and safety of acupuncture for medical problems defined in allopathic terms. These initial studies should assist in changing the designations imposed by the FDA and AMA on the practice of acupuncture. The drug model of research, however, can investigate only limited characteristics of acupuncture therapy.

The next step in clinical research involves constructing new research and statistical methodologies to evaluate acupuncture in a state closer to its actual practice, so that it can be appreciated as a technique individualized for each patient, that it can be changed with each treatment, and that its efficacy can be evaluated on clinical information not usually considered in the allopathic process. In order to accomplish this goal a well-orchestrated program with adequate funding must be undertaken. The American Foundation of Medical Acupuncture, the sister research organization of the AAMA, has been evaluating research strategies as a service to the Office of Alternative Medicine, and is available as a resource for further collaboration.

As founding president of the American Academy of Medical Acupuncture, I encourage this Appropriations Subcommittee to pursue the goals identified by the WHO and endorsed by the Surgeon General, in the interest of improved and expanded cost-effective healthcare for the people of the United States. The Office of Alternative Medicine within the Office of the Director of the National Institutes of Health is the logical vehicle through which this pursuit can be undertaken. With collaboration on this project of mutual interest, medical acupuncture will ultimately attain its proper place in the armamentarium of effective medical techniques offered through the established healthcare delivery system.

Thank you for the opportunity to present this report for your consideration.

REFERENCES

1. Quinn, J.R., ed.: *Medicine and Public Health in the People's Republic of China*. National Institutes of Health, DHEW Publication No. (NIH) 72-67, 1972.
2. Chen, J.Y.T.: *Acupuncture Anesthesia in the People's Republic of China*. National Institutes of Health, DHEW Publication No. (NIH) 75-769, 1973.
3. The 1993 law enacted by the New Mexico Legislature mandates that all lay practitioners of acupuncture use the title "Doctor of Oriental Medicine (D.O.M.);" and serve as independent primary care practitioners.
4. Pomeranz, B.: Scientific basis of acupuncture. *In* Stux, G., Pomeranz, B.: *Acupuncture: Textbook and Atlas*. Heidelberg, Springer-Verlag, 1987, pp. 1-34.
5. Omura, Y.: Acupuncture and related unorthodox methods of diagnosis and treatment. *Acupuncture and Electro-Therapeut. Res., Int. J.* 4, 69-89, 1979.
6. American Foundation of Medical Acupuncture: *Biomedical Research on Acupuncture: An Agenda for the 1990's: Conference Summary*. Los Angeles, AAMA, 1993.
7. L'Association Française d'Acupuncture, Paris: Unpublished documents, 1993.
8. American Association of Medical Acupuncture, Los Angeles: Unpublished documents, 1993.
9. AAMA Conference Summary, *op. cit.*
10. Lee, M.H.M., Liao S.J.: Acupuncture in physiatry. *In* Krusen's Handbook of Physical Medicine and Rehabilitation. Edited by F.J. Kottke and J.F. Lehmann. Philadelphia, W.B. Saunders, 1990, pp. 402-432.
11. Walsh, N.E., Dumitru, D., *et al.*: Treatment of the patient with chronic pain. *In* Rehabilitation Medicine: Principles and Practice. Edited by J.A. DeLisa. Philadelphia, J.B. Lippincott, 1988, pp. 708-864.
12. Saal, J.A., Saal, J.S.: Later stage management of lumbar spine problems. *In* Physical Medicine and Rehabilitation Clinics of North America. Edited by G.H. Kraft. Philadelphia, W.B. Saunders, 1991, pp. 205-221.
13. Chapman, C.R., and Gunn, C.C.: Acupuncture. *In* The Management of Pain. Edited by J.J. Bonica. Philadelphia, Lea and Febiger, 1990, pp. 1805-1861.
14. Evans, D.: Acupuncture. *In* Practical Management of Pain. Edited by P.P. Raj. St. Louis, Mosby Yearbook, 1991, pp. 934-944.
15. Ng, L.K.Y., Katims, J.J., Lee, M.H.M.: Acupuncture: A neuromodulation technique for pain control. *In* Evaluation and Treatment of Chronic Pain. Edited by G.M. Aronoff. Baltimore, Williams & Wilkins, 1992, pp. 291-298.

STATEMENT OF THE AMERICAN CHIROPRACTIC ASSOCIATION

Thank you Mr. Chairman for this opportunity to submit the views of The American Chiropractic Association (ACA) on the issue of alternative medical practices and, in particular, the work of the United States Office of Alternative Medicine (OAM). Clearly, as more and more Americans utilize and depend on the services of non-medical alternatives for their health maintenance and the treatment of their health conditions, it is vital that we understand which alternatives are effective and safe and which are not. With your leadership, the OAM was created last year to help make these determinations.

As the world's largest chiropractic organization, the ACA and its 23,000 members are proud of their traditional role in leading efforts to foster public awareness and appreciation of the chiropractic profession and its contributions to our Nation's health care system. For years, the ACA has emphasized the critical role of research, practice parameters and quality guidelines as methods for fostering the profession's growth, increasing public confidence and meeting its responsibilities as a member of the broader health care community. As a result of these efforts, today the chiropractic profession enjoys widespread acceptance and is firmly planted in the mainstream of our nation's health care delivery system. Chiropractic is licensed in all fifty states and the District of Columbia; it is covered under most commercial health insurance policies and federal health care programs; it serves millions of patients annually; and it enjoys a nearly unrivaled record for safety and quality.¹

Despite these achievements, the profession continues to take aggressive steps to improve itself. Two years ago, with the moral and financial support of the ACA, the profession developed a comprehensive set of practice parameters for chiropractic. The resulting document -- known as the Mercy guidelines -- specifies recommended practices for the conditions D.C.s most commonly treat. The guidelines enjoy widespread support and have been endorsed by both the ACA and the Federation of State Chiropractic Licensing Boards. They are a testament to the profession's commitment to quality assurance and appropriateness of care. To our knowledge, our profession is among the first to establish such guidelines.

The Mercy guidelines are based on the most up-to-date clinical and scientific information available. Their publication represents a significant achievement when one considers that

¹ According to the Health Care Financing Administration, D.C.'s malpractice liability premium costs account for a mere 1.8% of their total operating costs -- one of the lowest percentages of any health care specialty.

it has been estimated that *as little as 15% of all medical interventions are supported by valid evidence, and that many have never been assessed at all.*^{2 3} In contrast to this, the chiropractic profession's treatment methods have been proven to be enormously successful in treating many health care conditions, especially those relating to back and lower-back pain.^{4 5 6 7 8}

Because of the profession's demonstrable strides in the area of clinical research and scientific validation, the ACA is deeply concerned with suggestions that chiropractic is an "unconventional" or "unproven" method of health care. To the degree that spinal manipulation, one of chiropractic's primary treatment modalities, is the focus of the OAM's research efforts, the notion that chiropractic is "unconventional" will be intimated. In this there is a great risk that the profession be categorized with other health care methodologies and professions being studied by OAM. Most other alternative practices possess much less public, scientific and clinical support than chiropractic, and it is our obligation to our patients that we draw that distinction.

We do not wish to belittle any other professions that will come under study at the OAM. While ~~computers, new techniques, and other methods~~ ^{SOME} have ~~been~~ ^{AND OTHERS WILL} doubtlessly ~~make~~ ^{AS A GROUP THEY} significant contributions to human health, ~~these professions~~ ^{AS A GROUP THEY} have reached ~~the~~ ^{NOT YET} level of ~~acceptance~~ ^{BROAD} acceptance achieved by the chiropractic profession. Considering the fact that an estimated 19 million patients visit D.C.s yearly, that 85% of major employers cover chiropractic services under their employee health plans and that most major federal, state and commercial health care programs cover chiropractic services, it becomes clear that chiropractic does not belong in the same category as these other professions.

² Smith R (1991) *Where is the Wisdom: The Poverty of Medical Evidence*, British Medical Journal, 303:798-799.

³ Rachlis N and Kuschner C (1989) *Second Opinion: What's Wrong with Canada's Health Care System and How to Fix It*, Collins, Toronto.

⁴ Stano M, et al (1992) *The Growing Role of Chiropractic in Health Care Delivery*, Journal of American Health Policy, Vol.2, No.6:39-45.

⁵ Shekelle P, et al (1992) *The Appropriateness of Spinal Manipulation for Low-Back Pain*, RAND Corporation.

⁶ Meade T, et al (1990) *Low Back Pain of Mechanical Origin: Randomized Comparison of Chiropractic and Hospital Outpatient Treatment*, BMJ 300: 1431-1437.

⁷ *Common Diagnostic and Therapeutic Procedures of the Lumbosacral Spine* (1991) Spine, Vol.16, No.10:1161-1167.

⁸ Jarvis K, et al (1991) *Cost Per Case Comparison of Back Injury Claims of Chiropractic Versus Medical management for Conditions with Identical Diagnostic Codes*, Journal of Occupational Medicine, Vol.33, No.8:847-852.

While we do not believe it is the intention of this subcommittee to "pigeon-hole" the chiropractic profession or to pronounce it and its treatments as "unconventional" or lacking empirical underpinnings, the ACA fears that some elements of the traditional medical community would view the creation of the OAM as an ideal opportunity to do so. As the subcommittee is all too aware, for years our profession was the target of an illegal conspiracy by organized medicine to boycott and "eliminate" chiropractic.⁹ Given that unfortunate history, one can understand our misgivings with any effort to define chiropractic as out of the mainstream. While we do not wish to appear "shrill" or "unrealistic", the ACA will resist efforts to isolate the profession in this manner. We hope that Congress and this subcommittee understand our position.

The federal government's policy should not be one aimed at confining the study of chiropractic methods to any single agency or relegating its research agenda to one specific bureaucratic office. To the contrary, the chiropractic profession should be fully represented within and integrated into the entire federal health care policy and research apparatus, from the National Institutes of Health to the Physician Payment Review Commission.

The ACA has worked diligently to win the chiropractic profession a place at the federal health care policy and research table. Unfortunately, by and large our efforts have been either resisted or ignored by the Department of Health and Human Services (HHS) and others within the federal health care policy structure. It was only through your efforts, Mr. Chairman, and those of many of your colleagues on this subcommittee, that the ACA was able to win authorization for the chiropractic profession's first-ever federal research grant program last year. Under Title VII of the Public Health Service Act of 1993, chiropractic colleges are now eligible for federal grants to conduct demonstration projects in collaboration with medical physicians to identify and provide effective treatments for spinal and lower-back conditions.

While implementation of that program is going smoothly, other ACA-supported congressional initiatives designed to help integrate the profession into the federal health care policy and research system are being stymied. Two years ago, the committee report accompanying the 1992 Senate appropriations bill (Senate Report 102-104) expressed the committee's concern that doctors of chiropractic (D.C.s) and other non-medical health care providers were not sufficiently represented within the HHS and other federal departments. As a result, the Committee directed HHS and the other federal agencies within its jurisdiction to "...include a significantly larger number of chiropractors and other health care providers on all current and future advisory boards, commissions, and peer review panels."

⁹ *Wilk v American Medical Association*, 895 F 2d 352 (cert. den. 110 S.Ct. 2621, June 11, 1990.)

To date, we are unaware of any efforts on the part of HHS to abide by this directive. One would imagine that if HHS was taking this directive seriously, it would have contacted ACA with requests for appropriate nominees for these positions. We have received no such requests however. As of today, only one D.C. of whom we are aware serves on an HHS advisory committee. Given the fact that the chiropractic profession boasts 45,000 practitioners and 19 million patients, it is absurd that it has been granted but a single seat within HHS's gigantic policy advisory system.

Therefore, while we applaud the creation of the OAM and the attention that its creation has brought to the issue of health care alternatives, the ACA cannot support efforts to relegate the chiropractic profession's research agenda and policy making contributions to this small, albeit important, office. Chiropractic is mainstream health care. It deserves to be granted a significant and fully integrated place within the federal government's health care policy making and research community.

At a time when the country debating the reform of our health care system to provide basic benefits to all Americans, chiropractic and its millions of adherents are legitimately concerned over implications that it is "unconventional" or "unproven". Chiropractic has stood the tests of time, public confidence and scientific validation as much as any medical specialty. We know that chiropractic, like all health care professions, must continually strive to improve and understand the methods that it employs. However, this understanding should be derived from research and study performed in the context of the larger health care environment of which chiropractic is, and has been, a part.

The ACA thanks the subcommittee for this opportunity to obligation its views.

STATEMENT OF JENNIFER JACOBS, M.D., ON BEHALF OF THE
EVERGREEN CLINIC

My name is Jennifer Jacobs. I am a family practice physician in private practice for fifteen years as well as a University of Washington trained epidemiologist. In my medical practice, I see people of all ages with all kinds of health problems. Allergies, arthritis, ear infections, depression, fatigue, skin problems- all of the common illnesses that are seen in a typical family practice- these are the daily problems which I deal with in my patients.

I use the same diagnostic and laboratory evaluations as other physicians in my field. The difference in my practice and that of my colleagues is that I use homeopathic medicines instead of the conventional pharmaceutical drugs that are commonly prescribed in this country. In 99% of the cases I treat, homeopathic medicines are all that I use. It is only the rare rapidly progressive infectious disease, such as pelvic inflammatory disease or meningitis, or life

threatening situation, such as an acute asthma attack, where I am forced at times to resort to conventional treatment.

There are also times when mechanical interventions are necessary in my patients- such as setting a bone fracture or emergency surgery for appendicitis. In these cases, however, I use homeopathic medicines to speed recovery, rather than pharmaceutical drugs. I practice in the Seattle metropolitan area with my husband, who is also a homeopathic physician. Our practice is very successful, with a three to six month waiting list for people who want to become patients at our clinic.

I became interested in homeopathic medicine during my residency, when I became dissatisfied with modern medicine. I felt that the drugs that I was prescribing to my patients were only covering their symptoms, but not curing the underlying problem. Many drugs had harmful side effects which necessitated further drugs to counteract the ill effects. Homeopathy appealed to me because it seemed to promote the body's own ability for self-healing, which I had felt modern medicine did not address.

(For a detailed discussion of the principles of homeopathy, its utilization worldwide, cost-effectiveness, and a review of the scientific research in homeopathy, please see the Addendum to the Testimony provided by James J. Carbone to the Senate Appropriations Subcommittee on Labor, Health and Human Services and Education on June 24, 1993.)

My experience after several years of homeopathic practice was that people seemed to get better with this treatment, without strong conventional drugs. I saw an improvement in the overall health and vitality of my patients, as well as their mental and emotional approach to life. However, when I shared this observation with other physicians and scientists, I was scoffed at, largely because of the lack of scientific proof of homeopathy's efficacy. I began to question the validity of my own experience- was what I was doing a delusion?

The main criticism of homeopathy was that there was no scientific research, yet no one in the field of research was interested in homeopathy and no one in homeopathy knew how to do research. I resolved to go to graduate school to learn research methodology, so that I could carry out rigorous scientific studies about the efficacy of homeopathy. In the Department of Epidemiology at the University of Washington, where I received a Masters of Public Health in 1990, I found many skeptics about my field of interest. Luckily, there were some open-minded faculty members who supported me in my goal of subjecting homeopathy to the rigors of strict scientific investigation. There were also those who wanted me out of the department, for fear my interest in homeopathy would reflect badly on them.

Since that time, I have conducted two double-blind placebo controlled clinical studies of the use of homeopathy in treating acute childhood diarrhea in Nicaragua. I am currently trying to obtain funding for a similar study of otitis media in the Seattle area. In the research world, I have encountered many obstacles because of homeopathy.

Funding, of course, is always an issue. Until the Office of Alternative Medicine was established, there was no interest from the NIH in funding research on alternative medicine. It was initially very difficult to get my projects approved by the university, largely because of lack of knowledge about homeopathy. Now that I am trying to get the results of my studies published, I am finding that many of the peer-reviewed medical journals are hesitant to become involved in the controversy that might arise from publication of a study about homeopathy.

The Office of Alternative Medicine (OAM) has been a godsend to me and others interested in alternative medicine research, because finally there is a place within the NIH that will encourage a serious investigation of these treatment modalities. Since the Eisenberg study showed that nearly one third of the population uses unconventional practices, the importance of research in these areas has become more obvious to the general medical and scientific community.

My biggest concern now about the OAM, is the serious lack of funding that exists for this office. The current level of \$2 million per year is not enough to carry out the large-scale clinical trials that need to be done in the various areas of alternative medicine- homeopathy, acupuncture, naturopathy, mind-body healing, etc. One good clinical trial can cost upwards of \$500,000. A large amount of the current budget is taken up by administrative tasks of the office- salaries, meetings, etc., leaving even less for research. The current level of funding is only 0.02% of the total NIH budget, which is gravely inadequate for an area of medicine that is used by 30% of our population.

I would also urge the office to focus its research efforts on rigorous, well-designed clinical studies that will stand up to the closest scrutiny by the general medical and scientific community. While field investigations and best-case series research are important to identify specific treatments for further study, they should not take the place of serious investigations that can lead to a body of published literature in alternative medicine. Because alternative medicine is so controversial, studies done in this area need to be better than most scientific studies in order to be properly accepted.

Encouragement of research on alternative medicine within the other Offices and Institutes within the NIH should also be done by the OAM. If a certain percentage of the budget for each institute was earmarked for studies in alternative medicine, it would provide much needed funding, as well as broaden the effort in this field. Since many alternative treatment modalities are used for menopausal symptoms and other women's health problems, consideration should be given to adding an arm for alternative treatment within the Women's Health Initiative.

Alternative medical systems need to be aggressively evaluated, both for scientific efficacy and cost-effectiveness. Inclusion of these methods into the health care system could lead to improved health, wellness, and

longevity, while reducing health care costs. Since most alternative practices are low-cost and low-tech, they are easily accessible to consumers. The skyrocketing costs of the conventional health care system along with the rising number of people seeking alternative health care suggest that there is something radically wrong with the dominant system of medicine in this country. At some point in evaluating health care reform, we must start to look at what kind of health care is being delivered, rather than just how health care is being delivered.

STATEMENT OF ED McCABE, ON BEHALF OF THE FOUNDATION FOR THE ADVANCEMENT OF OXYGEN THERAPIES

Senator Harkin and the assembled committee members,

On June 16, 1993 Statisticians from the Federal Center For Disease Control announced that in 1990 AIDS was the leading killer of men in the 25-44 year age range in New York, California, Florida, Massachusetts and New Jersey. It is the leading killer for these men in 64 cities as well. For women the same is true in nine cities. NIH's Dr. Sten Vermund wrote: "Adolescent and young adult HIV transmission guarantees the continuation of the epidemic." This was back in 1990. Epidemiologist Susan Chu, a contributing author, says the numbers have likely risen since then.

Successful Treatment for AIDS Ignored by the NIH

On June 16, 1993 A 6 year old girl, depressed because her mother is dying from AIDS, deliberately stood in front of a fast moving freight train in Dania, FL. Jacqueline "Jackie" Johnson had talked about wanting to be with her mommy in heaven.

- Reported in the Fort Lauderdale Sun-Sentinel

Reports like these are steadily increasing. The United States is facing the biggest health crisis in its history. This is not a time for politics as usual. Many of us have tried to end the suffering and inadness, but medical politics stand in the way. In light of the absolute health and societal crisis we are facing from AIDS, I ask the NIH and the FDA this open question;

There is a safe, inexpensive, and effective therapy that has been used for over 50 years by over 5,000 physicians around the world. There are over 6,000 medical references on it available in the worldwide medical literature, including recent articles in the U.S. and Canada. The Office of Unconventional Medicine heard testimony last June of 1992 stating 6 U.S. physicians had brought over 200 former AIDS patients to HIV negative using it. In August of 1992 the NIH Infectious Disease (AIDS) Institute - at the request of Senator Harkin - was physically presented with two former AIDS patients, their doctors, and historic state medical records showing that both had been converted to HIV negative and returned to full health using this therapy. The therapy practiced all over the world - yet ignored here in the U.S. - is medical ozone therapy. With all this promise and documented 50 year history, why do you continue to ignore ozone therapy?

Here are some of the proofs I offer you as to the help available RIGHT NOW to our society if only the NIH would stop ignoring this valuable area. Much of this has already been given to the NIH.

Ozone Medical References

1958 - 1973 Dr. Robert Mayer and Dr. Edmund J. Ryan were granted 8 ozone patents. 1950, 55, 58 patent # 3,063,904 granted Nov. 13, 1962: Polymeric Oxygen (Ozone) In Blood and Sera Treatment and the Product Thereof.

1966 June 20 Dr. Otto Warburg's booklet: The Prime Cause and Prevention of Cancer with two prefaces on prevention - revised lecture at the meeting of the Nobel Laureates on June 20, 1966 at Lindau, Lake Constance, Germany by Otto Warburg, Director, Max Planck Institute For Cell Physiology, Berlin Dahlemer; English Edition By Dean Burk, National Cancer Institute, Bethesda Maryland, USA 1967. "Lack of oxygen causes cells to turn cancerous."

Is ozone safe? In Germany 644 ozone therapists were surveyed and they reported 384,775 patients had received 5,579,238 ozone treatments. The side effect rate was only .0007% during 5 1/2 million dosages. Only 39 incidents of any side effects occurred. Ozone side effects are typically minor irritations that are caused by incorrect application and quickly disappear. This side effect rate is incredibly far, far, lower than U.S. drug therapy side effect rates wherein each year approximately 140,000 people die from prescription drug usage. That's two and a half times more Americans than were killed in Vietnam.

1980 August 22, SCIENCE vol 209 peer reviewed article "Ozone Selectively Inhibits Growth of Human Cancer Cells" "Exposure to ozone ... inhibited cancer cell growth more than 90 percent."

1983 June The chairman of neurosurgery at Jefferson Medical College in Philadelphia, Dr. Jewell Osterholm, announced that stroke damage can be reversed with spinal injections of an oxygen rich mixture. Experiments on lab cats showed the procedure does reverse stroke damage.

1983 Sweet, et al publishes in "Science," a peer reviewed scientific journal, their study "Ozone Selectively Inhibits Human Cancer Cell Growth." Ozone stops cancer, yet there is no response from mainstream medicine.

1983 May - PROCEEDINGS - SIXTH WORLD OZONE CONFERENCE Washington, D.C.

INTERNATIONAL MD'S LIST 33 MAJOR DISEASES SUCCESSFULLY TREATED WITH OZONE

"OZONE Removes viruses and bacteria from blood, human and stored..."

Successfully used on AIDS, Herpes, Hepatitis, Mononucleosis, Cirrhosis of the liver, Gangrene, Cardiovascular Disease, Arteriosclerosis, High Cholesterol, Cancerous Tumors, Lymphomas, Leukemia..Highly effective on Rheumatoid and other Arthritis, Allergies of all types...Improves Multiple Sclerosis, ameliorates Alzheimers Disease, Senility, and Parkinson's...Effective on Proctitis, Colitis, Prostrate, Candidiasis, Trichomoniasis, Cystitis... Externally, ozone is effective in treating Acne, burns, leg ulcers, open sores and wounds, Eczema, and fungus."

1986, Dec 30, Patent # 4,632,980 granted, now held by Medizone, NYC, NY.

"OZONE DECONTAMINATION OF BLOOD & BLOOD PRODUCTS" Medizone states all stored blood can be decontaminated with ozone, and all HIV can be eliminated. Medizone applies for human test approval. Despite 50 years of use on humans and flawless animal studies, FDA won't allow human testing.

1987 Dr. Horst Klef, Heidelberg, FRG, announces successful treatment of 3 AIDS patients brought from Stage 8 back to Stage 1 at his German clinic using autohemotherapy ozone/1 gram vitamin C therapies. States "You can kill the AIDS virus with ozone therapy... No side effects." 15 ARC patients exhibit "full remission." Gained weight, T cells went from 300 back up to 1500 (normal), gone back to work. "One patient was so weak he couldn't turn on the radio. After only 3 treatments, he walks to the bathroom unaided. Typical treatment twice a week (outdated), continues for 7 to 11 months.

1987 Dr. Hans Neiper, an ozone using doctor in Hanover, FRG, in an interview by videographer Jeff Harsh, talks about his colon cancer work. Although he can't divulge the name of his patients; "President Regan is a very nice man." And, "You wouldn't believe how many FDA officials or relatives or acquaintances of FDA officials come to see me as patients in Hanover. You wouldn't believe this, or directors of the American Medical Association, or American Cancer Association, or the presidents of orthodox cancer institutes. That's the fact."

1987

The Use Of Ozone In Medicine ""

Classic medical ozone textbook published by Karl F. Haug, Heidelberg, by Professor Siegfried Rilling, M.D. and Renate Viebahn, Ph.D., co-authors. 225 OZONE MEDICAL REFERENCES AND OVER 48 DISEASES COMMONLY TREATED WITH OZONE including: "Abscess, Acne, AIDS, Allergies, Anal Fissure, Antiviral effect, Cerebral sclerosis, Circulatory disturbances, Cirrhosis of the liver, Menopause, Constipation, Cystitis, Bedsores, Dermatology, Fistulae, Funguses, Furunculosis, Gangrene, Gastroenterology, Gerontology, Hepatitis, Herpes, High Cholesterol, Colitis, Neurology, Dental Medicine, Tumors, Cancer, Orthopedics, Osteomyelitis, Parkinson's, Rheumatism, Proctology, Gynecology, Radiology, Raynaud's disease, Scars, Inflammation of the vertebrae, Stomatitis, Joint dystrophy, Surgery, Phlebitis, Open sores, Urology, Vascular surgery, Wound Healing."

1987 Cuban (FDA equivalent) National Inst. For Scientific Research conducts ozone animal studies proving ozone is non-toxic, non-mutagenic, non-carcinogenesis. (Ozone won't cause toxicity, mutations or cancer)

1988 Dr. Gerard Sunnen wrote: "Ozone In Medicine"

Dr. Sunnen, at the Bellevue Medical Center in New York City, lists medical ozone as commonly being used worldwide on: "Herpes, AIDS, and Flu. Wounds, burns, staph infections, fungal and radiation injuries, and gangrene. Colitis, fistulae, hemorrhoids and anal infections. It promotes healing. Blood ozone treatments have been used to treat virus infections including: AIDS, hepatitis, flu, some cancers, diabetes and arteriosclerosis. Used in dental surgery, periodontal disease, mixed in water and swallowed for use on gastric cancer, and applied as a wash in intestinal or bladder inflammation. Mixed with olive oil it is used on fungal growths and skin ulcers. Ozone baths are used to irrigate the skin, to disinfect and treat eczema and skin ulcers. "All of the world's blood supplies may be made virus free (AIDS, etc.) by passing 40-50 mcg/ml of ozone through them."

1988 "OXYGEN THERAPIES" book self published by Ed McCabe lists 5 AIDS case histories showing successful treatment by ozone, and lay translation of paper based upon 74 medical references proving ozone's effectiveness in disease treatment. First widely distributed international lay press publication in history to describe effectiveness of every known oxygen therapy, those being commonly self administered, and those administered under a physician's care.

1989 FIRST MODERN U.S. HOSPITAL TEST OF OZONE ON HUMANS STOPPED

George Perez, M.D., Dir. of Virology at Saint Michaels Med Center, Newark, NJ commissioned to undertake a 30 day institutional review board supervised ozone/AIDS protocol. 5 Patients underwent 30 days of ozone treatments at Saint Michaels Hospital in Newark, New Jersey. At the start, one was so badly covered with herpes lesions he couldn't wear clothes. All had T-cell counts of below 200. By the end of the 30 days, herpes pt. skin healed, all had been released from the hospital. No adverse side effects were reported. T/4 counts remained stable or increased. Viral protein core (p24) counts decreased indicating mass virus destruction. Four MD's state ozone therapy is non toxic, and should be adopted. Due to political pressure, the tests were aborted.

1989 Nov Cuban MD's successfully treating sickle cell anemia, ankle ulcers, farm accidents, and ocular (RP, retinitis pigmentosa) disease with ozone.

1989 "Ozone In Medicine, Vol 3" Proceedings of The Ninth World Ozone Congress, New York, 1989, published by International Ozone Association of Zurich. 14 presentations of the medical therapeutic applications of medical ozone by bona fide international MD's and scientists.

1990 Dr. Michael Carpendale M.D. Veteran's Administration Hospital, San Francisco, & Joel Freeberg M.D., UC Medical School San Francisco, Bay Medical Research Foundation, San Francisco, privately publish a medical paper:

"Ozone Inactivates HIV At Noncytotoxic Concentrations

"HIV (p24) was reduced in all ozone treated cultures compared to controls."

1991 Susan M. Lark M.D. Los Altos, CA publishes clinical results paper entitled "Ozone and Its Uses In Medical Therapy" she states: After a decade of research with oxidative modalities, **"I have found ozone/oxygen therapy to be one of the most powerful and effective therapeutic modalities I have ever worked with."**

1991 Oct 1

PEER REVIEWED "JOURNAL OF THE AMERICAN SOCIETY OF HEMATOLOGY"

In a major breakthrough for U.S. medical thinking, three years after the study concluded, the ozone/HIV work of MD's Wells, Latiuo, Galvaclin, & Poiesz are published in a well respected U.S. peer reviewed medical journal. Their article: "Inactivation Of HIV Type 1 by Ozone In Vitro" appears in "Blood Journal," describing the research coordinated by Dr. Bernard Poiesz from Syracuse State University of New York Research Hospital. They performed 15 replications of an ozone study that interfaced ozone with HIV infected factor 8 blood. The ozone completely removed the HIV virus from the blood 97 to 100% of the time, yet was non-toxic to normal healthy blood components. Ed McCabe announced this study back in 1988, in his "Oxygen Therapies" book.

1991 A brave humanitarian U.S. MD (Dr. J.B., ret.) in a southern state comes forward with his secret clinical ozone/hyperbaric therapy results. All his testing was performed at a major hospital and within independent labs.

Out of 248 HIV POSITIVE patients he reported bringing 113 to HIV NEGATIVE, each within 60 Days, using ozone autohemotherapy immediately followed by hyperbaric therapy.

His reward? An armed S.W.A.T team invades his house and office, threatens his family, seizes his ozone machine, patient records and computer. The MD gave up medicine, & now grows tomatoes. None of his former patients or the hospital or the labs will come forward due to their fear of reprisals.

1991 2 more US MD's come forward with clinical ozone/DMSO results.

9 patients brought from HIV POSITIVE to HIV NEGATIVE, each within 30 days.

Neither will allow their names to be used. One had his house burnt down and he left the country.

1991 New York physician comes forward with clinical ozone results.

Staff member brought from HIV POSITIVE to HIV NEGATIVE T-cells go from 700 down to 150 as ozone kills off diseased cells, and then back up to 11,000 as the body replaced them with fresh new healthy cells. Tested PCR negative.

1991 Dec Dr. Robert Mayer joins the doctors reporting patients sero-converted to HIV NEGATIVE through use of ozone autochemotherapy.

1992 June Author Ed McCabe is invited to testify before the newly created National Institute of Health's Office of Unconventional Medicine. He testifies that "Due to the many interviews I have conducted, it is my opinion that the AIDS problem has been solved. If immunity from state, and federal, and agency, and medical board prosecution could be assured, these humanitarian doctors would gladly make available their knowledge for the public good. I stand ready to do the same. They don't even need your money, they'll fund it themselves. If we can get ozone doctors immunity from prosecution, within 90 days the only thing left to do would be to implement the existing solution."

1992 July Author of "Oxygen Therapies," Ed McCabe, went to Washington on July 22nd, 1992 after setting up private meetings with 2 U.S. Congressmen to coincide with the meeting that former Iowa Congressman Berkly Bedell and I had set up on the same day with U.S. Senator Tom Harkin.

Mr. Bedell and I decided to invite 2 doctors that had each brought a patient from HIV+ to HIV-. We also invited Jim Caplan, the man responsible for convincing the Cubans to approve medical ozone therapy for general use, and Dr. John Pittman, an ozone using doctor, and one of his recently denied treatment AIDS patients. Dr. Pittman's office was closed down by the North Carolina state medical board in the middle of successful clinical ozone trials due to "ozone not being FDA approved." We visited the Congressmen, were warmly received at each meeting, and ended up in turn at Senator Harkin's office for our meeting with him, where we were joined at this point by Dr. Michael Carpendale and his boss from the San Francisco Veterans Administration Hospital.

Senator Harkin immediately decided to set up a meeting between us and the NIH's (National Institute of Health) Institute of Allergy and Infectious Diseases Director Dr. Anthony Fauci. The AIDS problem is under this institute, and Dr. Fauci has been referred to as the U.S. Government's "AIDS Czar."

1992 Aug On August 20th we met in NIH's building 31 wing 7A room 24 with Dr. Fauci and his boss Deputy NIH Director Dr.

Moskowitz. Also present were Dr. Hill, Dr. Killan, and other legislative and legal aides. Mike Hall and Marina Metallios were there to observe for Senator Harkin's Office. About 30 people attended.

We presented our two ozone treated patients who no longer were HIV+, and no longer had fevers, swollen lymph nodes, diarrhea, pain, night sweats, weight loss, or any other manifestation of the AIDS/ARC disease. We handed Dr. Fauci and the others copies of their medical documentation, and they listened to doctor Carpendale and one other doctor and their former AIDS patients. Dr. Latino from Medizone spoke of the flawless ozone animal trials that had already been done by Medizone. Dr. Pittman and one of his patients made emotional pleas for the open medical use of ozone so he could finish his clinical ozone trials. I asked for the same, gave them a brief 50 year history of the effectiveness of medical ozone on hundreds of thousands of people in Europe, and cited ozone's perfect safety record in millions of dosages. We made a sound, experienced, documented, and reasonable case for the immediate investigation of ozone's effectiveness in treating AIDS successfully. I also asked if anything could be done to influence the FDA to halt its suppressions of ozone using M.D.'s. We were told that the NIH had no power over the FDA.

Comment: Picture this. Here's our small but dedicated group gathered at a round table with the U.S. Government's official AIDS policy makers. Around the outside of the table are aides, secretaries, assistants, and division chiefs. There were no big corporations funding us, as is usually the everyday case at these meetings. We all had to take time out from work and pay our own considerable travel, hotel, and meal expenses. We came from all over the country simply to help our fellow countrymen dying from AIDS. We were sitting right there at the table with two now perfectly healthy former AIDS patients testing HIV negative - one PCR (Polymerase Chain Reaction - a test for any of the seven nucleotides of the HIV virus itself) negative, and one Western Blot/Elisa (HIV antibody presence) negative. We were sitting there with the examples and their records showing complete eradication of all secondary diseases, their actual doctors, a politically harassed doctor and his patient who can't get the treatment, and several thick notebooks of ozone medical references from the U.S. and Europe. What answer did we get? "They are obviously so healthy they must not have ever had AIDS" and, "We see no reason to pursue this."

Analysis: Here's the problem with the current NIH reasoning:

1. Although they said they were unknowledgeable about the FDA's history of seizing ozone machines, harassing ozone using doctors, and forcing doctors to falsely claim ozone as worthless, they did hear me tell them of all this and how hard it was to get any doctors to show up at all to testify and present evidence to them. How can anyone conduct open trials on this beneficial treatment if the FDA will close them down as soon as they open the doors?

2. Why ignore the most significant facts proving complete eradication of all secondary diseases and symptoms? This is a far more compelling test of whether or not to immediately begin research into ozone, if those who suffer can have their suffering eliminated, whether or not they test "PCR negative." What about the quality of their life all by itself?

The way the Center For Disease Control has decided to officially classify if someone has AIDS or not tells the story. They look for the presence of several diseases all occurring at once. Both patients that we brought in had completely eliminated their secondary infections and any clinical symptoms. Therefore by definition, besides testing HIV negative, they no longer had AIDS according to CDC guidelines. The real live people proof and their medical records and blood tests were sitting right in front of the NIH employees - yet they could not see. Let's hope more practical thinking will win out in the end.

Just so you understand medical ozone in the proper treatment of AIDS, a few shots of medical ozone are not going to be magic bullets. Successful ozone AIDS treatment has always been 2 to 5 hours a day of many oxidative and other therapies for 15 to 30+ days in a row, depending upon the particular aggregate methods employed, which are always combined with lifestyle changes, proper diet, eliminative organ cleansing, and cultivating a spiritual or moral balance, and the inclusion of an immune system rebuilding regimen.

1992 Summer Dr. Frank Shallenberger M.D. takes five AIDS patients into a two week single shot per day two week ozone clinical trial. All five patients show dramatic clinical improvements after only two weeks. Dr. Shallenberger later used a test model polyatomic apheresis recirculating ozone generator in a last minute attempt to save an almost dead AIDS patient. The patient was only 92 pounds and covered with kaposi's sarcoma. Brought in on a stretcher, he had difficulty in breathing, yellow skin and dark yellow eyes. Normally a patient will be hooked to the machine for 35 minutes, but they decided that the situation was imminently dangerous if left alone, so they hooked him up and ozonated him for one hour and five minutes at 200 ml per minute. At the end of one and one half hours, the patient's skin was pink, his eyes white, his breathing normal, and he got up under his own power and walked away.

1992 Aug Drs. John Waldron and Phillip Tiemo continue their New York University study on ozone's effectiveness in killing viruses, after getting a 1.4 million dollar budget approved by the NYU Board. He reports 100% kill ratios on over 46 viral groupings. Showing any substance able to be 100% effective in viral kills while being harmless to blood components is startling news. Study using Polyatomic, Biozone, and Vacuzone ozone units.

1992 Sept - Dec. Dr. Michael Ingraham Nassau, Bahamas finished a three month study of the ozone unit sporadically treating 20 AIDS patients. 5 turned p24 negative.

1992 Sept Research and Development Bulletin No. 234 Science and Technology section of the Canadian Government's Supply and Services Dept publishes "Better Blood Sterilization With Ozone." "Under a \$303,943 contract with the Surgeon General Branch of Department of National Defence Headquarters, researchers from the National Reference Laboratory at the CRCS are investigating two ozone sterilization technologies to confirm their reported efficacy in deactivating a variety of potential viral contaminants in blood, including HIV-1 and hepatitis... In Europe an estimated 350,000 people were treated with ozone between 1980 and 1985. The University of Bonn reviewed these cases and reported virtually no side effects of ozone therapy when properly administered... 'The products of this research have worldwide applications,' says DND's Capt. Shannon. In the right concentration, ozone sounds almost too good to be true. We're trying not to be overly enthusiastic, but the data so far is very compelling."

1992 Dec. Aids Patient Care Magazine publishes in Vol. 6 No. 6 "Point Of View: A Case For Ozone Therapy" by Ed McCabe, a reprint of Mr. McCabe's testimony before the NIH Office of Unconventional Medicine. "I have interviewed six U.S. MD's who, independent of each other, have collectively reported bringing over 300 AIDS patients to HIV negative status (using Western Blot, ELISA, and PCR), including complete eradication of any secondary disease factors such as energy loss, weight loss, diarrhea, etc."

1993 Jan 9th Ed McCabe, during a lecture to the Human Ecology Action League in room 218 of the Hunter School of Health Sciences in New York City, presents to the media and those assembled 4 patients, three who were AIDS patients, and one cancer

patient who had ozone therapy. One of the AIDS patient was PCR negative, two were p24 and Western Blot negative, and the cancer patient had watched a tumor the size of a "kiwi fruit" (5.5cm mass) disappear from her liver. All cases had complete before and after medical documentation.

1993 Feb 6 Joe McCord at the Webb-Waring Institute for Biomedical Research in Denver shows the HIV virus suppresses the body's production of Super Oxide Dismutase, the enzyme "that keeps cells healthy, and keeps the HIV virus in check."

1993 Feb Brad Anderson, self treating 11 year AIDS patient using a combination of ozone, Homozone, and other oxidative and natural protocols appears on CBS TV's "48 Hours" AIDS program and declares "I'm going to live forever!"

1993 Mar 15th Dr. Frank Shallenberger, of Nevada, using Polyatomic ozone chairs for about six months - and getting great results with AIDS patients - stated if he "could get a patient to volunteer to be treated for 8 hours in the chair, he could probably be turned PCR negative." His clinic is raided by the FDA. FDA forces him to stop using the 2 Polyatomic ozone set-ups so no more AIDS patients can be treated by him. Despite the fact that he was getting great documented results.

1993 Dr. Benjamin Lau at Loma Linda CA University continues ongoing successful in vitro polyatomic blood studies proving the polyatomic method could purify whole donor blood. FDA raids him, but declares him "squeaky clean" because he isn't using it on people. Dr. Lau says the results are "very promising."

1993 Dr. Phillip Tierno at NYU Medical Center has achieved 100% bacterial, fungal, mold, yeast and viral kill in over 40 degenerative diseases using polyatomic apheresis and other ozone equipment during ongoing studies.

1993 June 2, 1993 **Headline: Medizone's Blood Decontamination Technology Proven Successful In Canadian Monkey Trial.**

Still trying to inch their way through the system, Medizone announces their successful trials on monkeys. This was one of the requirements imposed last August when McCabe/Bedell/Latino et. al. met with Dr. Fauci at the NIH. Dr. Fauci said "Why can't you do a simple monkey trial?" So Medizone did, and now they are announcing the successful completion of the first two phases of a Canadian research project overseen by scientists representing the Canadian Red Cross, Canadian Departments of Defense and Agriculture, Cornell University Veterinarian Medical College and Medizone Canada Ltd.

Two groups of monkeys were infused with plasma infected with highly virulent strains of Simian Immunodeficiency virus (monkey equivalent of HIV). The first group died within 12 days. The second group's infected plasma was first infused with ozone through Medizone's process. None of the second group showed any sign of infection.

Dr. Latino, Medizone's president stated; "These preliminary research results indicate the capability of Medizone's patented scientific and technological process to inactivate blood and blood products of certain viral contaminants, including the AIDS virus."

There is a lot more proof available if someone will only seriously research it.

Example: The Humares Medical Ozone Generator Manufacturing Company has a database of over 6,000 ozone medical references available. However, they must be translated from German into English. With so many Americans getting AIDS, The U.S. government must be able to access someone who can read German.

LETTER FROM DR. PHILIP MAFFETONE, ON BEHALF OF THE FOUNDATION FOR ALLIED CONSERVATIVE THERAPIES RESEARCH

15 June 1993

The Honorable Tom Harkin,
316 Hart Building,
Washington, DC, 20510

Dear Senator Harkin:

This serves as written testimony for your 24 June 1993 hearings on alternative medicine.

The many viable but separate health care interests competing for representation have served to fragment the discussion of health care policy. Unifying the most viable elements could produce a higher quality, cost effective system for all Americans.

Please allow me to outline some key points on health care and alternative therapies.

I am a trustee of the Foundation for Allied Conservative Therapies Research (FACTR) and the Chairman of the International College of Applied Kinesiology (ICAK), non-partisan clinical research and membership organizations comprised of MD's, chiropractors, osteopaths, dentists and other doctors who utilize alternative therapies.

The following three key points must be considered and *properly* represented in present discussions on alternative medicine:

1. Alternative therapies are best seen as a compliment to conventional medicine. This complimentary approach is the missing ingredient in efficient and real cost savings and truly comprehensive health care.
2. This solution is achievable with the unification of viable alternative therapies, rather than numerous, separate techniques. The groups I represent have spent the past thirty years working to understand how the alternative therapies can be drawn together, utilizing their core elements. We have turned these separate and competing therapies into a single unified whole, enabling one doctor to effectively administer a specific alternative therapy, or in many cases several therapies, based on the individual requirements of each patient.
3. The cost effectiveness of alternative care and the cost savings which result from a healthier population are significant and well established.

Increasing health and quality of life are crucial for lowering costs. Less sick time means a more productive work force. A healthier old age means more productive years and a shorter less expensive course of illness before death.

A recent *New England Journal of Medicine* article showed that 61 million Americans use alternative therapies — mostly educated, higher income, middle aged individuals. This large group of voters is very concerned about choice in health care. It should be noted that over 80% of the therapies mentioned in this survey, are utilized, taught and researched by the ICAK and FACTR.

We have been actively involved with NIH's Office of Alternative Medicine. While the research front is progressing well, (although the need for more research is still a priority) it is health policy that we must address.

We do not represent any one particular alternative group, rather we represent the unification of all viable alternative therapies. And because of our interdisciplinary approach using these methods, we also represent the tens of thousands of doctors who practice and the tens of millions of Americans who use these therapies. We believe that representation of our experience is crucial to the success of an efficient, cost effective, comprehensive health care plan.

I am frequently in Washington and would like to discuss these items further with you and assure proper representation in the present health policy planning process. You may contact me through my New York office at 914-628-5000 or fax at 914-628-3248 (Box 596 Baldwin Place, NY 10505).

STATEMENT OF PETER BARRY CHOWKA

For two decades, as a journalist and medical-political analyst, I have reported on leading edge issues and controversies in science and medicine, including alternative therapies. During the fall and winter of 1992-93, I served by invitation on two of the original program advisory writing panels of the National Institutes of Health's Office of Alternative Medicine (OAM) that met periodically in Bethesda, Maryland.

Recently, there has been an explosion of interest in alternative methods of healing -- among the general public, in the media, and in some elements of government. The study by David Eisenberg, M.D., and his colleagues in the New England Journal of Medicine (January 28, 1993) provides the most recent confirmation of this extraordinary interest. Indeed, it is

reasonable to assume that, if the playing field of science and medicine were more level or fair, we would now be witnessing a Renaissance of credible, nontoxic preventive and therapeutic modalities.

Unfortunately, the history of twentieth century medicine is replete with examples of official disinterest in -- and disfavor and marginalization of -- both traditional and innovative forms of nontoxic healing. If this situation is changing now, it is primarily because, as Linus Pauling, Ph.D., told me once, of public interest and pressure.

Although I've covered the work of medical professionals ranging from Nobel laureates to little-known clinicians working on the fringes, the most major impacts on the direction of medical policy I have witnessed have consistently come from so-called ordinary Americans. It is the non-professional private citizen, after all, who is subjected to steadily rising incidences and death rates from cancer, AIDS, and other degenerative diseases, and who experiences the most urgent need for real answers to these vexing medical problems. It is the American public whose sole agenda is finding information that might save lives. And it is this same constituency that, despite a legacy of official mis- and dis-information, is turning increasingly to alternative treatments as viable solutions.

It is, of course, private citizens who the Office of Alternative Medicine was set up to help, and non-professional people who have made significant contributions to earlier official inquiries in this field. In this regard, I am reminded of my late friend and colleague, Robert DeBragga. Bob survived for twelve years with an especially virulent form of lung cancer that his doctors predicted would kill him within twelve months of his diagnosis in 1978. He attributed his long-term survival to two primary alternative therapies, the protocols of William D. Kelley, D.D.S. and Emanuel Revici, M.D. -- both of which, it should be noted, remain on the American Cancer Society's prejudicial list of "unproven" or "questionable" methods.

During the decade that he lived and thrived after his original prognosis as terminal, Bob DeBragga became an effective counselor to thousands of cancer patients from all over North America. As a leading activist, he founded a high-profile national patients' rights advocacy organization, Project CURE. Working politically, Bob had as much positive impact as anyone on the protracted process that ultimately has resulted in promising developments like the Office of Alternative Medicine.

In 1980, Bob DeBragga correctly predicted that the numerous official barriers to alternative medicine would not begin to fall until the issues were brought to the attention of the U.S. Congress. And that is exactly what has occurred, with the interest and active involvement of Senator Tom Harkin.

The legacy of Bob DeBragga and others like him confirms that non-professionals must be a vital part of the ongoing process inside of the OAM. If private citizens are not included and their input given weight, this important official work could easily digress into yet another detached, irrelevant, academic exercise, with the immediate needs of millions of Americans (afflicted with cancer, AIDS, and other conditions) largely overlooked.

The considerable promise represented by alternative therapies cannot be discussed without citing some of the profound limitations of conventional medicine that have led people to embrace a variety of "unproven" options with such enthusiasm.

The official War on Cancer, for example, presents a stark case history in the politics and economics of medicine. Approximately \$1 trillion has been spent fighting cancer (conventional treatment and research) since the Federal Government and medical establishment declared "war" on the disease in 1971. Ignominiously, today cancer is more of a problem than ever before: It remains the #2 cause of death, and by the end of the decade it will become, according to official predictions, the leading cause of death. The age-adjusted, per capita rates at which Americans get and die from cancer are rising every year.

Recent studies in the scientific literature have identified the cancer war as a "qualified failure" (Bailar and Smith, New England Journal of Medicine, 1986). According to John Cairns, M.D. (Scientific American, 1985), chemotherapy drugs, the main orthodox therapy, help no more than five percent of patients who receive them. The prestigious British medical journal The Lancet (February 6, 1993), in announcing a forthcoming international scientific conference on breast cancer, acknowledged the "failures of primary therapy" and the "static overall mortality from carcinoma of the breast," and pondered editorially, "Have we lost our way?" The Lancet suggested that the time has arrived "to challenge dogma and redirect research efforts along more fruitful lines."

The peculiar irony here is that, as the cancer problem persists and worsens in spite of unprecedented spending, there exists a well-documented entrenched resistance to exploring and integrating independent, innovative ideas that might well offer solutions. While a few alternative therapies have succeeded in breaking through to public awareness and even become popular for a time (laetrile, vitamin C), they are the tip of the iceberg of many equally or more promising primary treatments that have been kept marginalized and officially unexamined. Moreover, there is considerable evidence that points to coordinated efforts, past and present, to suppress many alternative approaches.

Interestingly, unconventional cancer therapies, routinely lumped together and dismissed out of hand as quackery, comprise the only true alternatives to the three conventional cancer treatments (surgery, radiation, chemotherapy) that, despite profound limitations, have totally dominated the field of oncology since World War Two. Occasionally, aspects of these alternatives (limited dietary modification, for example) are accepted grudgingly by the mainstream. Meanwhile, a persistent minority of people with cancer actively seeks access to innovative alternatives beyond the nation's borders or discretely here at home.

A variety of independent national polls of public opinion conducted between 1985-90 (including AP/Media General, Harris, and Roper) confirm that a majority of adult Americans support more freedom of choice in deciding one's therapeutic options and medical pluralism. A recent Harris poll commissioned by the Department of Health and Human Services found that nine out of ten Americans who had used an alternative therapy (and 25 percent in that sample had) reported that they had been helped by the treatments, while only one in forty said that they had been harmed. This de facto endorsement of alternative healing contrasts with the crisis in confidence (including excessive litigation by patients and the widespread practice of defensive medicine) that is currently confronting the conventional medical system and creating added momentum for reform.

The unquestionable popularity of alternative medicine, the formation of the OAM, and other complementary developments are occurring within the broader context of the accelerating national interest in reforming the entire health care delivery system. In this sense, credible alternatives, which are both clinically effective and cost effective, can make -- indeed, have already made -- a major impact on a public and a system that are prepared for substantive, innovative change. It should be obvious that our nation needs more than "reforms" that amount to little more than the equivalent of rearranging deck chairs on the Titanic.

Regarding the Office of Alternative Medicine, which may be the best opportunity at hand for fast-tracking credible alternatives into the mainstream of medicine: It is important to keep in mind that the OAM was the end result of political pressure that originated with and reflected the public's serious interest in alternative healing. To be sure, the Office and its outside advisors include many people of experience, achievement, and commitment. But apparent already are a disturbing lack of urgency and an insufficient representation of many potentially interested parties, particularly people with cancer, AIDS, and other life-threatening and disabling conditions.

Some of the problems facing the OAM are not of the Office's own making, but many of them have seemed to originate there. There is little need, for example, to reinvent the wheel regarding alternative medicine. The OAM could have accomplished a lot already by collecting, analyzing, and disseminating some of the considerable information on credible alternatives that already exists. Such an approach would have resonated quickly with the American people, and earned for the Office a useful reservoir of public good will and support.

The OAM instead has made its main priority the funding of a small number of prospective studies, each at a small level of support. It is to be hoped that the well-documented limitations of relying on the peer review system to decide which research proposals deserve funding will be recognized and overcome. The Office might also still consider choosing a smaller number of promising primary alternative therapies to evaluate. The antineoplaston treatment of Stanislaw Burzynski, M.D., Ph.D., is one possibility. Another is the Hoxsey herbal cancer therapy, which presents not only a rich history but a massive data base of applied nontoxic clinical experience that spans many decades.

Whatever the ultimate direction and impact of the Office of Alternative Medicine (NIH), true health care reform that includes a leading role for alternative medicine is an idea whose time has surely come. From my experience as a journalist and a participant in the OAM process, I think that every American citizen owes a debt of gratitude to Senator Harkin and his colleagues in the United States Senate for bravely moving forward into this officially uncharted, usually controversial, but ultimately very promising terrain of alternative medicine.

BIOGRAPHICAL SKETCH OF PETER BARRY CHOWKA

As a writer, historian, investigative researcher, and political analyst, Peter Barry Chowka is regarded as one of America's most eminent medical/scientific journalists. During the past eighteen years, he has been widely published on numerous topics related to controversies in science, alternative therapies in medicine, and global environmental and political issues.

Peter has been a long-time contributing editor to over ten different publications in the United States, Europe, and Australia. In the late 1970s, Peter's investigations of the National Cancer Institute's cover-up of its own promising diet/cancer research figured in the U.S. Senate Nutrition Subcommittee's hearings on national cancer policy, and his article, "Lifting the Lid Off a Fifty-Year Cover-Up," was republished by the Subcommittee in its official hearing transcript.

In the 1980s, Peter's inquiries into the controversial Hoxsey herbal cancer therapy, published in Points of Departure (New American Library), New Age magazine, and Conquering Cancer (Time-Life Books), led to the production of the award-winning motion picture documentary Hoxsey: How Healing Becomes a Crime. The film was distributed worldwide and became the most frequently requested non-fiction program in the history of the Cinemax national cable television channel.

Peter has been a consultant, as well, to many television documentaries, including ABC's "The War on Cancer: Cure, Profit, or Politics?" (1981) and PBS' "The Cancer War" (1983). He has frequently been invited to appear on hundreds of local and national television and radio talk shows around North America. Many of these programs have taken the form of debates with leading scientists and physicians on a wide range of critical issues related to medical and scientific policy.

In 1990 Peter was asked to testify before an Office of Technology Assessment hearing on the subject of cancer. His input was included in the OTA's seminal report of that year, Unconventional Cancer Treatments. In 1992, Peter was invited to be a member of two program advisory panels organized by the recently established Office of Alternative Medicine of the National Institutes of Health.

**LETTER FROM HARI M. SHARMA, M.D., PROFESSOR OF
PATHOLOGY, OHIO STATE UNIVERSITY HOSPITALS**

Hon. Senator Thomas Harkin
Attn: Gladys Clearwaters
Appropriations Committee
86, Dirksen Senate Office Bldg.
Washington, D.C. 20510

June 25, 1993

Hon. Senator Harkin:

Regarding the Senate hearing on Alternative Health Care, I would like to call your attention to Maharishi Ayur-Ved, the traditional system of natural health care from India, which is strongly prevention-oriented. It is entirely complementary to contemporary medicine and is being increasingly utilized by physicians and the public. Scientific research and clinical experience indicate that it can make a significant contribution to whatever plan you decide to adopt and will help save billions of dollars.

Research shows that if widely implemented, Maharishi Ayur-Ved can produce substantial cost savings while also reducing the burden of disease and suffering. A long-term published study, one of over 500 scientific studies on the approaches of Maharishi Ayur-Ved, showed significantly lower medical care utilization on the order of 50 percent, including an 87 percent reduction for heart disease and a 55 percent reduction for cancer and other tumors. Other studies on Maharishi Ayur-Ved have yielded additional results in the areas of prevention of cancer and cardiovascular disease, aging, and immune disorders.

There is strong evidence that the reception of the general public to such an approach is already highly favorable. A Harvard Medical School study published in the New England Journal of Medicine in January, 1993, found an estimated 425 million visits were made in 1990 to alternative medicine providers, exceeding the number of visits to all U.S. primary care medical doctors.

Moreover, I and many other like-minded physicians are aware that contemporary medical practice alone cannot provide a solution. Our present medical system actually contributes to the crisis through costly and often questionable use of therapies and surgical procedures, toxic side effects, and most of all, inadequate preventive measures.

Maharishi Ayur-Ved takes into account the mental, physical, behavioral, and environmental determinants of disease. It offers a comprehensive approach to prevention that can make preventive health care effective at last. It also includes methods to treat chronic diseases where conventional approaches have only limited success. Its systematic therapeutic methodologies have been time-tested through thousands of years of clinical experience.

Among its many strategies, Maharishi Ayur-Ved incorporates the following:

- stress management programs, including the Transcendental Meditation technique,
- individualized behavioral, nutritional, and lifestyle approaches,
- physiological purification therapies,
- programs for neuromuscular and neurorespiratory integration,
- programs for collective health,
- natural herbal preparations that have the distinct advantage of lacking harmful side effects and can, therefore, be safely applied on a long-term basis.

The problems of health care go beyond the need to expand access and curtail escalating costs. Unless illness rates are reduced through effective prevention-oriented health care and education, any plan based on budget caps, managed care, or other economic measures must ultimately fail, as the demand for medical services will continue to rise.

I urge you and your staff to become familiar with Maharishi Ayur-Ved. I would like to join you in your efforts to solve the nation's health care crisis and request an opportunity to meet with you or your advisors to discuss the role that Maharishi Ayur-Ved can play.

With all best wishes for your success.

Sincerely,



Hari M. Sharma, M.D., FRCPC
Professor of Pathology
Director, Cancer Prevention
and Natural Products Research
Department of Pathology

**SUPPORTING STATEMENT OF DR. SEYMOUR BRENNER,
RADIATION ONCOLOGIST, FOR DR. EMANUEL REVICI**

Dr. Emanuel Revici prepared the statement which follows for a hearing before the Office of Professional Medical Conduct (Dept. of Health, NY), in December 1992. The OPMC had alleged inadequate record keeping, citing seven records of cancer patients. Because the OPMC made it clear that it would reject any testimony as irrelevant that discussed aspects of Revici's career other than the alleged defects in these seven records, he withdrew the statement without attempting to read it into the record.

The statement defends his practice of medicine, indicates the stakes for his patients and for the public in general in his case, and provides details of mainstream interest in his research and clinical findings. It quotes from documents, and has a solid documentary base where it refers to events and occasions without quoting sources.

Dr. Seymour Brenner, a board certified radiation oncologist, did a retrospective best case study of Revici's patients, presenting it at a fact-finding hearing on Revici conducted by then Congressman Guy Molinari in 1988. Molinari arranged for Brenner to meet with the former commissioner of the FDA, and the current director of the NCI, in efforts to obtain official approval to do a prospective trial of Revici's treatment with terminal cancer patients. In March, 1993, Dr. Joseph Jacobs, Director, Office of Alternative Medicine, met with Drs. Revici and Brenner and requested a protocol for testing.

STATEMENT OF DR. EMANUEL REVICI

Gentlemen, I am 96 years old, and I have been practicing medicine for 72 years. I have asked to enter information about my research and long service to patients into the record; I understand you have granted my request.

While I appreciate this opportunity, equally appreciative, I believe, are my patients, some 30 of whom submitted letters on my behalf today. All my patients are concerned about what could happen to them, should you recommend I cease practicing; for patients of mine unfortunately failing to benefit from conventional treatment, who are benefitting under my care, that possibility alone causes extreme anxiety and stress.

I should note in opening that on February 8, 1970, after I had been practicing 50 years, Dr. Walter T. Heldmann, then president of the Medical Society of the State of NY, sent me the following communication:

"It is with a great deal of pleasure that I transmit to you the attached citation commemorating your 50 years' dedication to medicine.

The commendations of the House of Delegates of the Medical Society of the State of New York at their 164th Annual Convention in New York City are manifest in their presentation of this citation.

May I add my personal congratulations and sincere compliments for your years of devoted service in the interest of the health and comfort of your fellow men.

With highest personal regards,"

How I passed from that happier moment in my life to this present inquiry regarding my professional conduct has more to do with the politics of medicine, in my opinion, than it does with how I've practiced medicine -- since the manner has remained constant from virtually the beginning of my practice. This story, however, is too complicated for telling here. But I trust you will gain insight as I recount high points in my career, then illustrate several difficulties I have encountered in publishing my research and obtaining impartial evaluations of my clinical results.

I earned admittance to the medical school of the University of Bucharest at the start of World War I, interrupted my studies to command a medical battalion at the front

during the war, graduated at the top of my class, and qualified for my license by examination in 1920. (I qualified for my license in NY in 1947, after residing in the US one year, passing the examination in my first try.)

In Europe in the 1930s, eminent authorities considered my therapeutic method revolutionary, calling me in to apply it in the most intractable cases. Moreover, I had invented a process for refining crude oil to lubricate airplane engines, and the patent royalties enabled me to concentrate on research and to travel to the scientific centers of Europe. I spent a number of months, for instance, carrying on my studies at the Pasteur Institute in Paris. My research centered then, as it always has, on the role lipids play in physiopathology.

From 1937 through 1938, the sub-director of the Pasteur Institute, Professor Mesnil, deposited in the National Academy of Science 5 papers of mine on the effects of lipids on pathological pain and the effects of lipids in cancer -- a prestigious way of registering innovation.

I had relocated with my wife and daughter to Paris in 1936 and no doubt would have stayed permanently, save for the German invasion of France at the outset of World War II. Being Jewish, it was dangerous for me to continue to reside in the French capitol under Nazi occupation, but I was reluctant to forsake the laboratory facilities at my disposal and the encouragement of some of the most respected medical figures in Europe; and I had friends in high places, among them the head of the police.

By March of 1941, the situation had grown too perilous. Warned by the chief of police one evening to leave immediately, that very night we fled to Nice. There, pursuing my studies at a local hospital, I secretly lent my medical services and skills to the French Resistance. Soon, though, this clandestine activity again endangered my family and me, obliging my companions among the leaders of the Resistance to resettle us in Mexico.

As it happened, my "temporary" resettlement in Mexico lasted for the duration of the war, and ended in my emigration to the US, and in my becoming a US citizen. The 4 years I lived in Mexico, specifically Mexico City, nonetheless proved rewarding. With financial assistance from a fellow exile who had served as chief European representative of the Dupont chemical company, I established a modern, well equipped clinic to study cancer and other chronic degenerative diseases. I named it (in English translation), the "Institute of Applied Biology." It primarily functioned as a means for applying laboratory research to clinical practice as rapidly as tests for safety and efficacy permitted.

A fair number of physicians from the US, hearing about our findings in cancer by early 1943, journeyed to Mexico City to observe our cases first hand.

These doctors came mainly from the newly founded M.D. Anderson Hospital in Houston, Texas, and from the McArdle Cancer Research Center at the University of Wisconsin. In their correspondence, they reported results worthy of further study (so, at least, they wrote privately).

Professor George Dick, dean of the medical school at Chicago University, invited me to his institution in 1946, offering me the finest scientific conditions. Not long after I arrived, he resigned and I found myself without support for the facilities I needed.

My entry in the US, by the way, was smoothed by Sumner Welles, assistant to President Franklin Roosevelt, who issued special visas for me and my family in recognition of my service with the French Resistance -- and the potential medical value of my scientific innovations.

In 1947, I accepted an invitation from doctors in private practice in New York City to open an experimental clinic, in which they would participate, backed by prominent civic leaders.

Thus I founded the second Institute of Applied Biology on American soil, with the same essential purpose; to apply breakthroughs in pure biology to patient care as rapidly as possible.

The 4½ decades which have followed have included numerous encouraging moments.

The US Navy, testing A-bombs off Bikini Atoll in the Pacific, invited me on 2 occasions (the last in 1948), to advance treatments I had devised to protect against or heal radiation injuries. I received top security clearances but declined, resolving to devote myself to cancer.

The New York Times published articles by foremost science columnists and reporters about my research and case results throughout the 1950s. I cite them individually.

In 1951, a Times science column described a paper I had co-authored on the effect of n-butanol on shock caused by severe burns, which one of my colleagues had delivered before the annual meeting of the American Association for the Advancement of Science.

In 1952, the Times featured a story on the Institute's pioneering research in the treatment of cancer with lipids. This article noted that Dr. John Masterson, former president of the Medical Society of the State of NY, and Dr. John Galbraith, past president of the Nassau County Medical Society (and later to be president of the state medical society, in 1962), served as directors of the Institute of Applied Biology.

In 1955, the Times reported on the purchase of Trafalgar Hospital in Manhattan as a treatment facility for the Institute.

In 1959, a report appeared in the Times about a paper co-authored by me on an index I had devised to measure adrenal response, read at the American Chemical Society's annual meeting.

The Society for Promoting International Scientific Relations awarded me its annual medal in 1961. At that time, this society's board of directors included 11 Nobel laureates!

A full-day hearing on my treatment for physical detoxification of narcotic addicts took place in Congress, before the House Select Committee on Crime, on April 28, 1971. Congressman Charles Rangel arranged this hearing, and he testified (in part):

"The results and what we witnessed with patients [were] so unbelievable that the doctor from Municipal Hospital has now gone back on a daily basis in order to continue with this chance to see the miraculous

results that have taken place. I personally have gone back on several occasions to the clinic. I have talked with patients, talked with youngsters that have given up on being decent human beings...talked with their parents and grandparents, many times in the presence of responsible state officials that have subscribed publicly to the methadone program and yet vigorously support the efforts that have been made by Dr. Revici."

Former Congressman Guy Molinari held a Congressional fact-finding hearing concerning my work and patients in New York City on March 18, 1988. A highlight of this hearing occurred when Dr. Seymour Brenner testified, presenting objective data on 10 of my patients in extraordinary long-term remission, and offering to conduct and fund personally a prospective evaluation of my therapy.

I prefer to cite just a few of the worst moments I've experienced during my years in New York, possibly the 2 most damaging and distressing times.

In 1961, in July, the D. Van Nostrand Company published my textbook, Research in Physiopathology as Basis of Guided Chemotherapy: With Special Application to Cancer. This publishing house (no longer in business), had brought out respected scientific volumes for more than a century. Its president at that time, Edward Crane, wrote to one of my principal financial supporters:

"I want to again assure you of our keen interest [in] what I think is an important and valuable book."

Earlier in 1961, however, in its journal for March/April, the American Cancer Society had published an article about me, stating that my therapy was "unproven"; this article killed sales, dooming almost the whole press run to destruction. (In the end, I believe they burned the unsold stock.)

In this textbook, among other subjects, I had written about abnormal trienic fatty acids produced by radiation burns, describing the action of prostaglandins decades before Bengt Samuelsson won the Nobel Prize for his description of prostaglandins in 1982.

I had written, too, about elements such as calcium, copper, and selenium in cancer; magnesium as a preventive and therapy for arterial disease; on lipids as anti-viral agents; on lipids as transporters of therapeutic compounds to lesions and as targeters of abnormal foci. These experimental and clinical findings represented just a small portion of the fruits of 4 decades of research by me and my associates in Europe and America.

Because of this action (and other opposition) by the American Cancer Society, my research results never circulated throughout the medical community. Today, few people appreciate the serious work I've accomplished in these areas.

Most important, should my studies be confirmed eventually, this action will have delayed understanding of certain disease processes and their remedies for years and years, perhaps denying thousands of patients effective treatment or relief.

In 1965, November, a group of 9 oncologists, calling themselves the "Clinical Appraisal Group," published a summary of their evaluation of my treatment in the Journal of the American Medical Association. I had requested this evaluation. (I had sought an evaluation of my therapy ever since I set foot in America!) My funding organization paid for it.

The CAG concluded that none of the patients they observed under my care derived any benefit from my therapy.

People who dislike what I do, or who have little idea how poorly the peer review process can work in the US, cite this report against me.

How many of them have the slightest idea of the crucial ways in which the CAG violated the protocols we had agreed to follow?

How many of these people know that only 2 of the 9 participants in this group actually observed patients directly? That the other 7 co-signed on the representations of the 2 who did observe cases? Such co-signing is considered tantamount to fraudulent scientific practice these days.

How many of the people who cite this summary realize it never was blinded to avoid evaluator bias? Or randomized? Or that patients who evidenced measurable remission were dropped from the final report, while others who failed to respond were added? This is a protocol breach no reputable scientist would countenance!

Hardly anyone knows that in the same month when the CAG first leaked its report, February, one of the preeminent cancer authorities in the world, Professor Joseph Maisin, past president and editor of the International Union Against Cancer, had written to me, providing details about a clinical trial he had run on 12 advanced patients, administering my medications himself. Maisin's letter describes exceptionally good results in 9 of these 12 cases -- 75 percent!

Professor Maisin informed me of exceptional results from my treatment in a series of letters written until 1971, when tragically he died from injuries sustained in an automobile accident.

Why have I remained in practice far beyond the age when most people retire? Why persist in carrying forward my studies, refining my treatments, instead of closing my office and advising my patients they must seek care from other providers?

Many of my patients come to me after unsuccessful mainstream treatment. My therapy places a number of them in remission, prolonging their lives beyond normal expectation. My therapy allows a more normal quality of life, because my lipidic agents manifest no significant side effects, building instead of compromising defense responses.

I worry greatly about these patients. Who will help them, if I am not there for them?

This year, more than half-a-million patients will succumb to cancer -- almost all of them perishing under conventional treatments. The National Cancer Institute, summarizing in a recent edition of its journal data for 15 years in the War Against Cancer, has admitted that overall incidence and mortality still are increasing. Yet every day in my

office, I see patients doing better with my therapy. Certainly not every one, but a significant proportion.

My own daily experience confirms what Maisin, and Brenner, and others through the years have corroborated; my treatments are effective, and sometimes when no other therapies are!

Why should I not remain in practice for patients who need or choose to entrust themselves to my care?

I never suffered a major medical negligence suit until the 1980s -- after 60 years as a clinician. Then 2 suits were filed against me, by the same attorney. To date, I've prevailed in the appellate court in each case. In the course of these cases, I have contributed to the creation of a new affirmative defense for physicians; Express Assumption of Risk.

In deciding the first case (Schneider v. Revici), the judges concluded:

"Appellees contend that it is against public policy for one expressly to assume the risk of medical malpractice and thereby dissolve the physician's duty to treat a patient according to community standards. We first note that the 'public policy' referred to...is defined solely by statute...and appellant points to no statute imposing limitations on such express agreements. Moreover, we see no reason why a patient should not be allowed to make an informed decision to go outside currently approved medical methods in search of an unconventional treatment. While a patient should be encouraged to exercise care for his own safety, we believe that an informed decision to avoid surgery and conventional chemotherapy is within the patient's right 'to determine what shall be done with his own body.'"

Where will my patients go, where will like-minded patients go, if I and physicians like me, who administer treatment "outside currently approved medical methods," are removed from practice?

I believe biological "dualism," a theory I conceived, and my methods for treating pathological conditions according to whether they test predominantly anabolic or catabolic, will gain acceptance as valid medical options.

I have devoted my professional life to examining evidence for dualism; developing analyses to determine why, how, and when pathological conditions change metabolic character as they progress and in response to treatment; compounding agents of opposite character to resolve or palliate diseases which kill or painfully afflict people.

I would not know how to stop myself now from inquiring into fundamental causes, how to stop myself from searching for new, more effective applications of biological dualism for the benefit of patients.

When I was 10 years old, I told my father I wanted to become a physician. My father was a physician.

He asked me, "Why do you want to go into this profession?"

I answered, "I want to help people."

My father asked further, "Is it because you think you also can make a good living from medicine?"

"No," I responded. "I want to help people -- only that."

My father said, "I'm glad you answered in this way. If you had told me that you also anticipated earning a lot of money, I would have been disappointed."

During the first decade of the Institute of Applied Biology in New York City, we never charged a patient one penny! In the early 1980s, a consultation with me still cost \$30. Even today, with expenses for attorneys and other emergencies, our fees are moderate; the total cost of treatment amounts to substantially less than patients pay for conventional cancer treatment. And I never turn away a patient who requires my assistance but cannot pay. Never when I started here in the US! Nor to this very day!

Thank you for your patience.

LETTER FROM SEYMOUR M. BRENNER, M.D., RADIATION
ONCOLOGIST

Hon. Guy V. Molinari
Naval Station of New York
Building 203
Staten Island, NY 10305

March 24, 1988

Dear Mr. Molinari:

I would like to take this opportunity to thank you for your interest and cooperation in what I consider a critical situation.

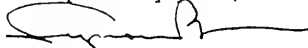
Certainly some of our major organizations and institutions such as American Cancer Society, American College of Surgeons and National Cancer Institute have stated that the understanding of cancer and the effectiveness of the treatment of this disease has improved. I personally feel we are going forward at a very slow rate. As a physician who has been in the field of cancer for approximately 35 years, I have a sense of desperation that I believe has stimulated me to investigate what we call "alternative" techniques of treating cancer. The American Cancer Society has predicted that there will be one million new cases of cancer in America in 1988. 500,000 of these patients are projected as succumbing to their disease ultimately. As you know, over 400,000 people are dying each year from this disease, with the numbers increasing on a yearly basis. Considering this very pessimistic prediction, I wonder why there is any hesitancy to enter into a carefully designed program to evaluate alternative methods for treating cancer. I wish to stress that I am not offering this program as an alternative to treating cancer. I wish to apply these alternative methods only in those patients who are considered hopeless where standard and accepted treatments are involved.

I therefore have established a panel of six physicians including myself, all of whom limit their practice to the treatment of cancer. The five other physicians have excellent qualifications and the respect of the medical community. These physicians are willing to volunteer their services once an approved study has been established. It is my intention to notify the medical community that we are prepared to accept patients that they choose and designate as hopeless to enter into our study. Their records would be submitted to our panel of experts. If this group of physicians agree that the situation is not amenable to standard therapy, then we will recommend that they be placed on an alternative method. It is my intention to begin this study utilizing Emanuel Revici, M.D.'s techniques. Essentially, we will take approximately 100 patients, place them on the study and at the end of six months and again at 12 months we will re-evaluate them. In that brief period we will be able to determine whether Dr. Revici's program really is effective. I cannot stress the potential of altering the prognosis of over 400,000 dying individuals by a brief, simple one year program.

I am enclosing a protocol which I intend to use for this examination. In addition, a separate list will be submitted defining some of the patient's Dr. Revici has treated in the past whom I consider examples of unexpected, exciting responses.

If any questions arise concerning this presentation please contact me at your convenience.

Respectfully yours,



Seymour M. Brenner, M.D.

PATIENT HISTORIES

Each patient whom I have described below has been treated and evaluated at a major and accepted institution throughout the country. I have copies of all the patient's records from the various institutions so that I have confirmed the diagnosis and stage of illness prior to the patient's visit to Dr. Revici. Each one of these cases certainly seems interesting, rewarding and difficult to explain. I do not believe any of these patient's would have survived if Dr. Revici had not treated them.

Patient #1 - 43 year old male was admitted to Memorial Hospital September 1980. He was found to have an invasive, high-grade, transitional cell carcinoma involving the bladder trigone on the left and the right lateral wall of the bladder. Pathological report on biopsy was, poorly differentiated epidermoid carcinoma involving the muscle. Cystectomy was recommended. Patient decided to go on Dr. Revici's therapy program which he did on October 27, 1980. The patient has had no other treatment and is currently without evidence of disease on cystoscopy performed in 1987.

Patient #2 - 29 year old female admitted to hospital on October 20, 1983, surgery was performed for a posterior fossa tumor which proved to be a chordoma. The tumor was incompletely resected and followed by a course of radiation therapy. The patient's condition progressively worsened between the time of surgery and for the next 12 months. She was confined to a wheelchair with progressively decreasing functional ability. The patient was seen by Dr. Revici on 5/1/84. Her condition has progressively improved. From wheelchair confined to minimal functional ability the patient is now essentially self-sufficient and is ambulating.

Patient #3 - 30 year old female was operated on in 1984 for an ovarian carcinoma and a bilateral salpingo-oophorectomy and hysterectomy. All gross tumor was removed. The patient was placed on chemotherapy which was continued for six months. In November, 1985 second surgery for pelvic tumefaction with omentum metastasis. Biopsy only, no definitive surgery was done. The pathology report was the same on both specimens which showed borderline serous papillary adenocarcinoma. Following the second operation the patient went on Dr. Revici's program in January 1986 and has remained in good health ever since.

Patient #4 - 50 year old female operated on in 1980, adenocarcinoma of the left lung, tumor unresectable. Tumor involved recurrent laryngeal nerve on the left side, received 7,000 rads of radiation to the lesion, 4,000 rads to the mediastinum 8/14/81. Following the completion of radiation therapy there was decrease in the tumor size with no evidence of extrathoracic metastases. No chemotherapy was given. The patient was seen for the first time in Dr. Revici's office 10/2/81. At that time the patient still had a hoarseness which was related to the recurrent laryngeal nerve tumefaction. In January of 1982 her voice apparently returned to normal. Currently, the patient is asymptomatic and her x-rays show progressive improvement of the mediastinal mass.

Patient #5 - 34 year old male who underwent above the knee amputation of the left leg for a giant cell tumor of the femur. In 1979 he had a right thoracotomy with removal of two nodules containing metastatic giant cell tumor from his lung. In August 1980 chest x-ray showed a new 1.5cm. pleural nodule in the left lung as well

as several smaller nodules in the right lung. An IVP showed a 10 x 13cm. renal mass. A smaller 2 x 2cm. renal mass was seen on the left side. In October 1980 the patient went on Dr. Revici's program. He gained 20 pounds in weight. A chest x-ray in 1981 showed no progression of his pleural nodules. IVP showed almost complete disappearance of the right renal mass. The left renal mass which was much smaller initially also decreased in size. The patient is currently well with no progressive disease.

Patient #6 - 40 year old female in 1981 was diagnosed as having oat-cell carcinoma of the lung with metastases to the ovary. Bilateral salpingo-oophorectomy and hysterectomy was performed along with an omentectomy. Chest x-ray showed a 2cm. lesion in the left apex. A mass was seen in the hilum of the liver. The liver was markedly enlarged. Started on chemotherapy on January 3, 1981. She received Mitomycin VP-16 and Cis-platinum. Apparently the patient had 3 cycles of this chemotherapy and discontinued the program and started on Dr. Revici's program on April 1981. The patient is currently in complete remission of her disease.

Patient #7 - 23 year old female diagnosed as having a meningioma extending into the left eye, the left orbit and the left maxillary sinus. Treated with radiation therapy alone to a dose of 5,000 rads. Treatments were completed February 1985. The patient started on treatments with Dr. Revici in March 1985. Significant persistent tumor on CT scan at that time. Patient is currently in good state of health 3 years later, although on NMR there is still measurable disease demonstrable.

Patient #8 - 60 year old male, diagnosis of squamous cell carcinoma of the lung, inoperable because of local extension, treated with radiation therapy, completed July 2, 1985. Patient seen for the first time with Dr. Revici 12/13/85. No further treatment other than Dr. Revici's treatment. Patient is currently feeling well without evidence of progression of his disease.

Patient #9 - 53 year old female in March 1985 diagnosis of adenocarcinoma of the lung, locally unresectable was established. Patient was referred for radiation therapy. Treatments were completed June 10, 1985. Patient was seen by Dr. Revici July 21, 1985. Her condition has continued to improve and the patient is currently well. This patient, as are the other patients with carcinoma of the lung not resectable, all received radiation therapy and all are doing well. Unresectable carcinomas of the lung have a poor prognosis for cure when treated with radiation therapy alone.

Patient #10 - 27 year old female was admitted to hospital in May of 1987. CT scan was done revealing a mass in the head. She was started on a course of Cobalt 60 Teletherapy. She was continued to a dose of 5,000 rads. In November of 1978 she was operated on. Residual necrotic tumor was found which was thought to be a Stage III astrocytoma. There was some dispute as to the diagnosis, in that some pathologists felt the tumor represented a glioblastoma. The patient was seen in Dr. Revici's office in June of 1979. The patient's condition has generally improved and she is essentially well at this time, some 9 years later.

○

BOSTON PUBLIC LIBRARY



3 9999 05981 797 1

ISBN 0-16-041294-3



90000



9 780160 412943