A PROPOSAL TO MODIFY THE RESEARCH TAX CREDIT, AND H.R. 4138, TO PROVIDE THAT FEDERAL TAX REFUNDS WOULD BE OFFSET BY PAST-DUE STATE TAX OBLIGATIONS

HEARING

BEFORE THE

SUBCOMMITTEE ON SELECT REVENUE MEASURES

OF THE

COMMITTEE ON WAYS AND MEANS
HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

SECOND SESSION

OCTOBER 6, 1994

Serial 103–99

Printed for the use of the Committee on Ways and Means

U.S. GOVERNMENT PRINTING OFFICE

84–214 CC WASHINGTON : 1994

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402
ISBN 0-16-046313-0

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A PROPOSAL TO MODIFY THE RESEARCH TAX CREDIT, AND H.R. 4138, TO PROVIDE THAT FEDERAL TAX REFUNDS WOULD BE OFFSET BY PAST-DUE STATE TAX OBLIGATIONS

THURSDAY, OCTOBER 6, 1994

HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON SELECT REVENUE MEASURES,
Washington, D.C.

The subcommittee met, pursuant to call, at 3:07 p.m., in room B–318, Rayburn House Office Building, Hon. Charles B. Rangel (chairman of the subcommittee) presiding.

[The press release announcing the hearing follows:]

FOR IMMEDIATE RELEASE
THURSDAY, SEPTEMBER 29, 1994

PRESS RELEASE #25
SUBCOMMITTEE ON SELECT REVENUE MEASURES
COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES
1102 LONGWORTH HOUSE OFFICE BLDG.
WASHINGTON, D.C. 20515
(202) 225-1721

THE HONORABLE CHARLES B. RANGEL (D., N.Y.), CHAIRMAN, SUBCOMMITTEE ON SELECT REVENUE MEASURES, COMMITTEE ON WAYS AND MEANS, U.S. HOUSE OF REPRESENTATIVES, ANNOUNCES A PUBLIC HEARING ON TWO MISCELLANEOUS TAX ISSUES

The Honorable Charles B. Rangel (D., N.Y.), Chairman, Subcommittee on Select Revenue Measures, Committee on Ways and Means, U.S. House of Representatives, today announced a public hearing on two tax issues that have been referred to the Subcommittee. The hearing will be held on Thursday, October 6, 1994, at 3:00 p.m. in room B-318 Rayburn House Office Building.

The first issue is a proposal to modify the research tax credit specifically to cover the expenses of developing generic alternatives to brand-name products.

The second issue is H.R. 4138, a bill introduced by Mr. Jacobs (D., Ind.) and cosponsored by Messrs. Rangel (D., N.Y.), Stark (D., Calif.), Grandy (R., Iowa), McCrery (R., La.), and others, to provide that Federal tax refunds would be offset by past-due State tax obligations.

In announcing this hearing, Chairman Rangel stated: "The Subcommittee wishes to fulfill its responsibilities with respect to the issues that have been referred to it during the course of the 103rd Congress. To do this in the short time remaining before adjournment, it is appropriate to hold a hearing at this time on these two miscellaneous issues."

DETAILS FOR SUBMISSION OF REQUESTS TO BE HEARD:

Individuals and organizations interested in presenting oral testimony before the Subcommittee on either of the proposals specifically described herein must submit their requests to be heard by telephone to Harriett Lawler, Diane Kirkland, or Karen Ponzurick [(202) 225-1721] no later than noon on Tuesday, October 4, 1994, to be followed by a formal written request to Janice Mays, Chief Counsel and Staff Director, Committee on Ways and Means, U.S. House of Representatives, 1102 Longworth House Office Building, Washington, D.C. 20515. The Subcommittee staff will notify by telephone those scheduled to appear as soon as possible after the filing deadline. Any questions concerning a scheduled appearance should be directed to the Subcommittee [(202) 225-9710].

Persons and organizations having a common position are urged to make every effort to designate one spokesperson to represent them in order for the Subcommittee to hear as many points of view as possible. Time for oral presentations will be strictly limited with the understanding that a more detailed statement may be included in the printed record of the hearing. (See formatting requirements below.) This process will afford more time for Members to question witnesses. In addition, witnesses may be grouped as panelists with strict time limitations for each panelist.

In order to assure the most productive use of the limited amount of time available to question hearing witnesses, all witnesses scheduled to appear before the Subcommittee are required to submit 200 copies of their prepared statements to the Subcommittee office, room 1105 Longworth House Office Building, at least 24 hours in advance of their scheduled appearance. Failure to comply with this requirement may result in the witness being denied the opportunity to testify in person.

(MORE)

WRITTEN STATEMENTS IN LIEU OF PERSONAL APPEARANCE:

Persons interested in submitting written statements for the printed record should submit at least six (6) copies by the close of business on Friday, October 14, 1994, to Janice Mays, Chief Counsel and Staff Director, Committee on Ways and Means, U.S. House of Representatives, 1102 Longworth House Office Building, Washington, D.C. 20515.

FORMATTING REQUIREMENTS:

Each statement presented for printing to the Committee by a witness, any written statement or exhibit submitted for the printed record or any written comments in response to a request for written comments must conform to the guidelines listed below. Any statement or exhibit not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee:

1. All statements and any accompanying exhibits for printing must be typed in single space on legal-size paper and may not exceed a total of 10 pages.

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. Statements must contain the name and capacity in which the witness will appear or, for written comments, the name and capacity of the person submitting the statement, as well as any clients or persons, or any organization for whom the witness appears or for whom the statement is submitted.

4. A supplemental sheet must accompany each statement listing the name, full address, a telephone number where the witness or the designated representative may be reached and a topical outline or summary of the comments and recommendations in the full statement. This supplemental sheet will not be included in the printed record.

The above restrictions and limitations apply only to material submitted for printing. Statements and exhibits or supplementary material submitted solely for distribution to the Members, the press and the public during the course of a public hearing may be submitted in other forms.

***

*****

Chairman RANGEL. The subcommittee will come to order.

We welcome you this afternoon to the Select Revenue Measures Committee.

The first proposal is a proposal to modify the research tax credit to specify what covers the expense of developing generic alternatives to brand name products. This was discussed in the full committee in the consideration of health reform and was referred by the Chairman to the subcommittee for more careful review.

The second is H.R. 4138. This was introduced by my friend, the subcommittee chairman of Social Security, Andy Jacobs. And I am cosponsor with several other of my colleagues on the committee.

This bill would allow that Federal tax refunds could be offset by State tax obligations with some type of an agreement. Many States want this. The subcommittee wants to know how the administration feels and whether or not it can administer this or whether it supports it.

Mr. Jacobs.

Mr. JACOBS. Mr. Chairman, I could do no better with regard to this reciprocity proposal than to quote the great David M. Shoups, the Commandant of the Marine Corps at one time, who said: "We are here to help each other." He added, "and have a little fun." I don't know if you can do that in the tax area, but that is what the bill is all about—the State government and the Federal Government.

The Chairman knows I am a former police officer, and we had three departments in the same territorial jurisdiction, and when we cooperated we got more bad guys than when we didn't. And I suppose if we cooperate in this area, we will get more bad guys who don't believe in being good citizens and paying their legal taxes than otherwise.

So I express my profound thanks to the chairman for having this hearing and cosponsoring the bill.

Chairman RANGEL. Thank you. Mr. Payne.

Mr. PAYNE. Thank you very much, Mr. Chairman. I want to thank you, too, for holding this hearing.

The first item that you talked about having to do with generic drugs and the applicability of R&E tax credit is one that we discussed in full committee as we were working on health care and decided that it would be appropriate to hold this hearing to learn more before we moved further into that issue. And so I appreciate very much the witnesses who are here today to talk about that with us and look forward to their testimony. Thank you.

Chairman RANGEL. I yield to the ranking member, Mr. Hancock, for any opening statement that he might make at this time or maybe later during the hearings.

Mr. HANCOCK. I have no statement to make.

Chairman RANGEL. All right. Then we will start with the Department of the Treasury. We have before us Mr. Kohl once again.

You are not restricted to your statement. By unanimous consent it will be entered into the record, and you can share your views with us in any manner in which you feel comfortable.

STATEMENT OF GLEN A. KOHL, TAX LEGISLATIVE COUNSEL, U.S. DEPARTMENT OF THE TREASURY

Mr. KOHL. Thank you, Mr. Chairman and distinguished members of the committee. I will read a brief, shorter script and then take any questions.

Thank you for the opportunity to present the views of the Treasury Department on these two issues.

The first issue concerns the research tax credit. This raises the question of whether the development of generic drugs should qualify for the credit. My written testimony indicates that we oppose the proposed amendment on the grounds that we don't think generic drugs should get a special rule. We don't favor singling out one particular product for special treatment.

Under current law, a tax credit is given to taxpayers who increase their research spending. The issue regarding generic drugs is an issue relating to definition. Current law says the credit does not apply to products when the taxpayer has duplicated an existing product by looking at the product itself or plans, blueprints, specifications or other publicly available information about the product.

The current controversy began when the IRS issued a private ruling to a particular taxpayer and held that because of the duplication rule, the company wasn't entitled to the research credit. The question raised by this proposal in our minds is whether there should be a special rule to the effect that generic drugs are not duplicated. We believe all products should be equally subject to the duplication rule and the determination should be made on a case-by-case basis, taking into account all the relevant facts and circumstances of each case. For these reasons, we oppose the proposed amendment.

Concerning H.R. 4138, the bill introduced by Mr. Jacobs and cosponsored by many members of the committee, including Chairman Rangel, Congressman Stark and Mr. McDermott, this bill would provide for the ability to offset Federal tax refunds for past-due State tax obligations. We support the goals of H.R. 4138 and recommend certain modifications to its provisions. The Treasury Department would appreciate the opportunity to work with the committee to further develop this legislation.

By way of background, I should mention that the IRS currently has in place a refund offset program for delinquent Federal tax liabilities, other Federal obligations—such as student loans—and past-due child support. The taxpayer is entitled to receive a refund only to the extent the tax overpayment exceeds these delinquent amounts. There are various procedural safeguards in place to ensure that the taxpayers' rights are well protected.

The refund offset program has been very successful. The Federal Government has also benefitted by voluntary participation by numerous States in an IRS State income tax levy program, frequently referred to as SITLP. Under this program, States voluntarily agree to offset State tax refunds by past-due Federal tax debts.

The Federal Government derives significant benefit from this voluntary program. However, it cannot fully reciprocate under current law because the IRS is not authorized to offset Federal tax refunds for State tax obligations. H.R. 4138 would remove this obstacle. As I mentioned earlier, we support the removal of this obstacle.

With regards to H.R. 4138 in particular, we think there are some technical issues that have to be addressed. I will just highlight a few of them this afternoon that should be addressed, and we believe, can be readily addressed. They concern reciprocal agreements, priorities and various logistical problems of implementation.

In terms of reciprocal agreements, the issue is essentially that the bill does not require the States to reciprocate by offsetting State tax overpayments for delinquent Federal tax debts. And while the Treasury appreciates the voluntary compliance that we have had to date, we believe that the imposition of the legal obligation on the Federal Government should be matched by a similar obligation on the States.

In terms of priorities, we are concerned about one of the priorities in the bill, and that is, under the terms as it is currently written, State taxes would come before private non-AFDC child support obligations that are currently benefitting from the Federal reset program. We understand the rationale for the priorities in the bill and acknowledge that certain private non-AFDC child support payments right now come behind existing Federal Government obligations, but we believe, with respect to this new proposal, the States should come behind the existing program that exists for private, non-AFDC child support.

Basically, the reason is, to move States ahead would effectively put non-AFDC child support obligations in a worse position than they are now, and we don't think this harsh result is necessary. We think the goals of H.R. 4138 can be achieved without causing this harm.

Simply put, private child support obligations were in line first, and we don't think the States need to jump ahead of them to achieve their goals.

In terms of capabilities, the issue is just the IRS' ability to manage this new program. And, obviously, we consulted the IRS in connection with our testimony, and their biggest concern is the immense volume of this program. Adding all the States and the District of Columbia to the existing Federal refund offset program runs the risk of too much too fast.

The existing refund program has expanded gradually since it was introduced in 1981 to cover different types of debts, taxpayers and tax returns. This gradual enlargement has minimized disruptions in IRS systems, increased efficiencies and permitted necessary training of IRS and other agency personnel before the offsets are made. In short, we believe this gradual expansion has been crucial to the program's success.

The concern of too much too fast also relates to the effective date. The IRS estimates it would take approximately 2 years from enactment of legislation to draft regulations implementing the provision, preparing systems for the offsets, preparing preoffset testing and entering into memoranda of understanding with the States.

In order to achieve the goals of H.R. 4138 in an orderly manner we recommend the adoption of a phased-in approach in which the Secretary would be given the authority to phase in the program as the IRS' technological capabilities increase and the funds become available. Funding for the IRS' tax system modernization program will be helpful in handling this increased workload.

That concludes my remarks. Let me reiterate that the Treasury and the IRS would welcome working with the committee in developing a suitable refund offset program for State taxes, and I will be happy to answer any questions.

[The prepared statement follows:]

TESTIMONY OF GLEN A. KOHL
U.S. DEPARTMENT OF THE TREASURY, TAX LEGISLATIVE COUNSEL

Mr. Chairman and distinguished Members of the Subcommittee:

Good afternoon. I am pleased to have this opportunity to present the views of the Treasury Department with respect to two tax issues that have been referred to the Subcommittee.

The first issue is a proposal to modify the research tax credit to cover the expenses of developing generic drugs. The second is H.R. 4138, a bill introduced by Mr. Jacobs, and co-sponsored by many Members of the Committee, that would provide for the offset of Federal tax refunds to satisfy past-due State tax obligations.

I. RESEARCH TAX CREDIT FOR COSTS OF DEVELOPING GENERIC DRUGS

A. Current Law

Taxpayers are entitled to a tax credit for incremental "qualified research expenses" paid or incurred on or before June 30, 1995. The credit equals 20 percent of the amount by which the taxpayer's qualified research expenses for the taxable year exceed a base amount. The base amount is the product of the taxpayer's "fixed base percentage" and the average of the taxpayer's gross receipts for the four preceding years. The fixed base percentage is the ratio of the taxpayer's qualified research expenses to its gross receipts during the 1984-1988 period. The base amount cannot be less than 50 percent of the taxpayer's current-year qualified research expenditures.

Qualified research means research (1) with respect to which expenditures may be treated as expenses under section 174, (2) that is undertaken for the purpose of discovering technological information the application of which is intended to be useful in the development of a new or improved business component, and (3) substantially all of the activities of which constitute elements of a process of experimentation. Certain types of research are specifically excluded from qualified research. For example, qualified research does not include "research related to the reproduction of an existing business component (in whole or in part) from a physical examination of the business component itself or from plans, blueprints, detailed specifications, or publicly available information with respect to such business component." Code § 41(d)(4)(C).

In a recent technical advice memorandum, the Internal Revenue Service (the "IRS") held that the duplication exception of section 41(d)(4)(C) excludes from the definition of qualified

research costs incurred in the development of generic drugs. Private Letter Ruling 9346006 (August 13, 1993).

B. Description of Proposal

The terms of the proposed amendment provide that section 41(d)(4)(C) does not apply to research related to a business component that is an original alternative to achieve the equivalent result of a competitor's product. We understand that the purpose of the amendment would be to reverse the result reached in the technical advice memorandum, so that qualified research would include research to develop a generic drug product. The amendment is apparently not intended to change the applicable legal standards, but rather effectively to establish a per se rule under which the costs of developing generic drugs would automatically qualify for the research tax credit.

C. Administration Position

We oppose the proposed amendment. Generic drugs should not be granted a special per se rule under which the costs of their development automatically qualify for the research credit. The proposal illustrates the tension between the competing goals of encouraging innovation and encouraging competition. Once an innovative product is developed, the public has an interest in encouraging the development of competing products because market competition generally results in lower costs to consumers. Market competition in the pharmaceutical industry may be of particular concern because it serves the goal of containing health care costs. Measures that encourage the development of alternatives to innovative products, however, tend to reduce the benefits that accrue to the innovator, and thus discourage innovation. The proposed amendment would favor product competition over product innovation. The legislative history of the research credit, however, indicates that the credit is directed at encouraging innovation more than competition. Congress enacted the credit to overcome the reluctance of many businesses "to allocate scarce investment funds" to risky research programs. The possibility that competitors will learn from innovations and develop products in response is a principal reason why the rewards of research do not accrue entirely to the innovator.

For the reasons described above, the rationale for the research credit does not support subsidizing the development of competing products that reduce the rewards of innovation. Nevertheless, the credit has never been expressly limited to research resulting in innovative products that advance the general state of technology. Such a limitation would be difficult to apply, because it would put the IRS in the position of evaluating the extent of technological advancement achieved in the development of various products. Thus, the costs of developing a product that is new for a particular taxpayer can qualify for the credit even though other taxpayers already offer similar products. The only express limitation that applies to competing products is the exclusion for products developed by duplication.

The proposed amendment would effectively provide a per se rule under which the development of generic drugs would not constitute duplication. Thus, the proposal would allow the development of generic drugs to qualify automatically for the research tax credit. We believe it is inappropriate to adopt a per se rule that provides favorable treatment for a particular product. Instead, the question of whether the development of generic drugs is qualified research or non-qualified duplication should be resolved on a case-by-base basis, using the same standards that apply to other products and taking into account all of the relevant facts and circumstances of each case.

II. OFFSET OF FEDERAL TAX REFUNDS TO SATISFY STATE TAX OBLIGATIONS

A. Administration Position

We support the goals of H.R. 4138 and recommend certain modifications to its provisions. The Treasury Department would appreciate the opportunity to work with the Committee to further develop this legislation.

B. Background

The IRS currently has in place a four-tiered refund offset program. Under this program, the IRS offsets Federal income tax overpayments by the taxpayer's (1) delinquent Federal tax liabilities, (2) past-due child support obligations which have been assigned to a State under the Social Security Act ("AFDC child support"), (3) delinquent non-tax debts owed to other Federal agencies (e.g., student loans), and (4) past-due child support obligations which have not been assigned to a State ("non-AFDC child support"). A taxpayer is entitled to receive a Federal tax refund (or to apply a refundable amount to a tax liability for the subsequent year) only to the extent that the tax overpayment exceeds these delinquent amounts.

The refund offset program has been very successful and is growing. In calendar year 1993, for example, approximately $1.16 billion in past-due amounts were collected by the IRS as a result of offsets for delinquent child support and non-tax debts to Federal agencies. The programs accounting for the biggest shares of these offsets were student loans ($473 million) and AFDC child support ($449 million). Offsets of Federal tax refunds for 1994 are even larger, approximating $1.35 billion for the first three quarters of 1994.

The Cash Management Improvement Act Amendments of 1992 made participation by Federal agencies in the IRS refund offset program mandatory. As a result of this change and system adaptations, agency participation in the offset program has dramatically increased, contributing to the increase in collections. In 1995, the IRS expects to extend the program to cover past-due corporate debts owed to the Federal government and to include certain Federal corporate income tax returns.

The Federal government also has benefitted by voluntary participation by numerous States in the IRS State Income Tax Levy Program ("SITLP"). Under this program, States agree to offset State tax overpayments by past-due Federal tax debts. Although the IRS has the authority to levy manually on these overpayments, an automated offset program is much more efficient and effective. Twenty-nine States and the District of Columbia currently participate in SITLP. According to IRS figures, the SITLP program generated approximately $61 million in additional Federal tax revenues for calendar year 1993.

C. H.R. 4138

The Treasury Department, including the IRS, is committed to increasing cooperation between Federal and State tax authorities with a view to promoting compliance, enhancing efficiencies, and reducing taxpayer burdens. Since 1991, when the Office of FedState Relations was created in the IRS National Office, the IRS has initiated hundreds of cooperative ventures with the States. These ventures include the exchange of information by the IRS to States concerning audit disputes; matching of information returns so that these matches do not have to be performed at the State level; and IRS extracts from business, individual, and information return master files to assist the States in administering their tax laws. In addition, joint audit and collection activities are taking place to streamline

compliance and enforcement efforts and to alleviate burdens on taxpayers.

H.R. 4138 would extend the Federal refund offset program to provide for the offset of Federal tax overpayments to satisfy past-due, legally enforceable State tax liabilities.

As mentioned earlier, we support the goals of H.R. 4138, although the bill raises a number of issues that we believe need to be addressed before it is enacted. I would like to highlight four issues this afternoon. They concern (1) reciprocal agreements, (2) the scope of the proposal, (3) priorities for Federal offsets, and (4) the effective date. We would appreciate the opportunity to work with the Committee to resolve these and other issues of a more technical nature (including, for example, issues relating to disclosure of confidential tax return information).

The Treasury Department is sensitive to the potential impact of additional offsets on a taxpayer's willingness to voluntarily comply with the tax laws. We believe, however, that H.R. 4138, as modified pursuant to our suggestions, reasonably balances this concern with the benefits that would result from a State tax refund offset program.

1. Reciprocal agreements

The bill does not require that States reciprocate by offsetting State tax overpayments by delinquent Federal tax debts. We believe that it is appropriate that the IRS be permitted to require States to respond in kind. Reciprocal State participation is consistent with the IRS goal of improved Federal-State cooperation in matters of tax administration and will also contribute to additional Federal tax revenues.

2. Scope of H.R. 4138

The bill requires the IRS to offset any Federal tax overpayment by any past-due, legally enforceable State tax obligation. The bill defines a "State tax" expansively to include "any local tax administered by the chief tax administration agency of the State." The inclusion of all such local taxes in an expanded Federal offset program could be unduly burdensome.

The existing Federal refund offset program has been expanded gradually since it was introduced in 1981 to cover different types of debts, taxpayers, and tax returns. This has minimized disruptions of IRS systems, increased efficiencies, and permitted necessary training of IRS and other agency personnel before the offsets are made. In short, it has been a key to the program's success.

As the IRS moves forward with its Tax Systems Modernization and revitalized business vision, all aspects of the offset program will be incorporated into a streamlined, efficient electronic data interchange system. In order to accomplish this transition smoothly, we recommend a phased-in approach if H.R. 4138 or a similar bill is enacted, particularly in view of the added complications potentially arising from the participation of up to fifty States and the District of Columbia. Under such an approach, offsets would initially be made on Federal individual income tax returns for delinquent State individual income taxes and the IRS would be granted the authority to expand the program by regulations into other areas as its technological capabilities increase and resources become available.

3. Priorities

We also are concerned about the bill's rules for establishing priorities among competing claims for offsets of Federal overpayments. Under H.R. 4138, an offset for a past-due legally enforceable State tax obligation would be made after any offsets for past-due AFDC child support and debts owed to Federal agencies, but before any offset for past-due non-AFDC child support.

The Treasury Department believes that offsets for past-due State tax obligations should only be made after offsets for all child support payments (AFDC and non-AFDC), as well as after offsets for delinquent Federal debts.

4. Effective date

The bill would apply to Federal tax refunds payable after December 31, 1994. The IRS estimates that it would take approximately two years from enactment to draft regulations implementing the provision, prepare its systems for the offsets, perform pre-offset testing, and enter into memoranda of understandings with the States.

Treasury believes it is imperative that any such legislation reasonably accommodate IRS constraints. Accordingly, we recommend that the Secretary be given authority to prescribe specific implementation dates for different types of offsets by regulation.

* * *

This concludes my prepared remarks. I would be happy to answer any questions you have at this time.

Chairman RANGEL. Let's see if we can first deal with the research tax credit deduction. Mr. Payne.

Mr. PAYNE. Thank you, Mr. Chairman.

Mr. Kohl, I just had a couple of questions for you. Let me understand your position or the position of the Treasury. Is it your position or the position of the Treasury that the R&E credit is available only for research on products that are new to the marketplace?

Mr. KOHL. No, that is not our position. I guess what I would like to do is say that in this area, there is a tension between encouraging innovation and encouraging competition. Once an innovative product has been developed, the public obviously has a strong interest in it being copied and being widely available with prices reduced.

The question here is, what is the policy of the R&D credit? Is it innovation? Is it wide availability? The thrust of the R&D credit is one that favors innovation.

Now, in terms of your question, that doesn't mean that the R&D credit applies only to products that are "new to the world," to use the phrase. To say new to the world would put the IRS in the position of evaluating how great a new invention is and is this thing great or not. And the IRS cannot be in that position.

The current law doesn't go that far. All the law says along those lines is you can't duplicate. But, as a general matter, if you are not within the duplication rule, there is not a requirement that you be new to the world.

Mr. PAYNE. So then is it the position of the Treasury that a generic drug is simply a duplication of a brand name drug?

Mr. KOHL. We think that for a generic drug you have to look at the facts and circumstances. Obviously, on some level, a generic drug is a duplication. As a medical matter, it is a copy. As a legal matter, pharmacists can substitute the generic if they want to. So, on one level, generic drugs are copies.

The question is, for the purposes of the R&D credit, are generic drugs duplicates? And the duplication inquiry is a facts and circumstances inquiry. We have to look and see exactly what process that was undertaken in developing the drug. And it could be determined on a case-by-case basis.

The Treasury Department is not weighing in now and saying that generic drugs are or are not entitled to the credit. All we are saying is that the rules the Congress has enacted in the past should apply to the facts involved in developing a generic drug.

And we don't feel this issue of when you cross the line from inappropriate duplication to just looking around and studying and doing your own development work is unique to generic drugs. The issue can exist regarding any product. And we are just saying we don't support a special rule that says, OK, generic drugs, you are in because then the line will form: "What about this and what about that." And we think the current rule is fine.

Chairman RANGEL. Will the gentleman yield?

Mr. PAYNE. Sure.

Chairman RANGEL. The IRS allows for research to be deducted for generic drugs. When you challenge research being deducted you challenge a tax credit being given. How do you distinguish deductibility and tax credit for a duplicate drug?

Mr. KOHL. Let me answer that on a policy ground and a technical ground.

The technical ground is that the duplication exception exists only for the purposes of the credit. It is just not in the law for the purposes of the R&D deduction. So it is not just a hurdle that you have to go over for the R&D deduction.

Now, on a policy matter, why is the R&D deduction looser than the credit? Well, the answer is the R&D deduction is not only intended to encourage research, it also addresses merely a timing issue.

Many of the costs that are deductible as R&D would be either capitalizable and depreciable over time or they would be currently-deductible business expenses. The R&D deduction just resolves matters of timing. The credit is an extra bonus. And, because of that, Congress in 1986 tightened up the restrictions applicable to the credit and put in a duplication exception.

Mr. PAYNE. Let me ask one other way to try to clarify this at least for me. If a generic drug is not a duplicate of a brand name product and it cannot be manufactured by decomposing a brand name drug or publicly available information, then it would in fact be available for the R&E credit; is that correct?

Mr. KOHL. Congressman, we understand that the IRS, at least in many of the cases, has not challenged the credit, other than on the duplication grounds. So the answer is if my sense of how these cases is correct—that if the duplication issue were resolved favorably then, yes, the credit would be available.

Mr. PAYNE. I have no other questions. Thank you, Mr. Chairman.

Chairman RANGEL. Are there members seeking recognition for the purpose of seeking clarifications of the IRS position as relates to the tax credit for generic drugs?

Let me ask this. Mr. Kohl, is this unique in the pharmaceutical industry? Do we have this problem or this question raised in other areas that you know of?

Mr. KOHL. I don't know of it raising to this high level of visibility.

Chairman RANGEL. What low-level visibility things?

Mr. KOHL. The issue of duplication when you look at a competitor's product and you develop something to compete with it can exist in any industry. And this——

Chairman RANGEL. Do you know of any which the credit has been challenged on a question of generic——

Mr. KOHL. I am not aware of any, Mr. Chairman.

Chairman RANGEL. OK. Now we have heard the Secretary on the question of the Jacobs bill. Mr. Jacobs no longer—is there anyone that would like to—while we are waiting to see whether Mr. Jacobs is here, is it your testimony that if there is a quid pro quo, if the States allow the Feds to come in and attach State taxes or State refunds, then you have no problem with the administration of the Federal Government being able to do the same thing?

Mr. KOHL. Correct.

Chairman RANGEL. OK. Are there any members that have any questions with the Secretary on that issue? Well, I am certain that Mr. Jacobs will be pleased to——

Mr. MCCRERY. Mr. Chairman, do I interpret that to mean that the IRS is in support of this bill?

Mr. KOHL. Yes, we are. As I said, we are in support of the bill. There are numerous technical and minor modifications that we feel have to be made, but, yes, we are in support of it.

Mr. MCCRERY. Good. Thank you.

Chairman RANGEL. Thank you very much. And we will see you when we come back on November 29.

Mr. KOHL. I look forward to it.

Chairman RANGEL. The next panel, the Federation of Tax Administrators, New York State Department of Taxation and Finance. An old friend of this committee, the Joint Tax Committee and the State of New York and the president of the Federation of Tax Administrators.

And we are very anxious to hear your views. Your testimony will be restricted to the income tax refund issue; is that correct?

STATEMENT OF JAMES W. WETZLER, PRESIDENT, FEDERATION OF TAX ADMINISTRATORS, AND COMMISSIONER, NEW YORK STATE DEPARTMENT OF TAXATION AND FINANCE, ALBANY, N.Y.

Mr. WETZLER. Thank you, Mr. Chairman. It is good to be back.

I am here representing both New York State, where I serve as tax commissioner, and the Federation of Tax Administrators. The Federation represents the State tax administration agencies of all 50 States, the District of Columbia and the city of New York.

Presently, the Internal Revenue Service has the legal authority to levy on State tax refunds to obtain payment of Federal tax debts, and States do not have such right with respect to Federal tax refunds on account of the supremacy clause of the Constitution.

Thirty-one States and the District of Columbia have voluntarily agreed to allow the IRS to participate in their automated refund offset programs. The use of an automated program greatly simplifies the Service's use of its authority. In 1993, we understand these offsets amounted to $61 million. So it is a significant source of debt collection for the Service.

H.R. 4138 would authorize the Service to enter into agreements with States under which it would offset State tax debts against Federal refunds. State debts would be offset only after offset of other governmental debts such as overdue student loans, Federal tax debts, and assigned child support, and States would be required to meet various procedural requirements to ensure fairness to taxpayers.

I noticed that the Treasury recommended that we come not just after assigned child support but also after the unassigned child support.

I think the rationale behind Mr. Jacobs' bill is that government offsets should come before private offsets which is, I think, the reason why he put us ahead of the unassigned child support, which is going to go to a private person.

On the other hand, I would understand it if the committee made a judgment that we are less attractive than single parents and should come after they do. We would not object to that judgment.

Some of the procedural requirements to ensure fairness include the fact that a State would have to notify taxpayers that it is proposing to offset their debts. It would have to give the taxpayers 60 days to present evidence that the debt is not owed or is not legally enforceable, and the State would be required to consider that evidence.

Offset would only occur after taxpayers have exhausted all administrative and judicial remedies to protest the tax assessment.

We are only talking about debts where the taxpayer has no further right of administrative or judicial review, where everybody is certain that the debt is actually owed. That is what we are talking about. We are not talking about things that are in the appeals process or where the taxpayer has not yet exhausted his or her remedies.

The law would apply to local taxes administered by the chief State tax administration agency, such as the New York City income tax.

Now, I note that Treasury in its testimony expressed some concern about this part of the bill and suggested the program start with State income taxes. I think we would recommend that it might be OK to start with income taxes, but I think you want to include local income taxes administered by the State as is the case in New York State and New York City.

When we give a tax refund, it is a refund of both the State and city taxes, and the IRS will offset Federal debts against that entire refund, not just against the State part of the refund. And I think as we work with Treasury we will be able to convince them that it will be a simpler program if they don't attempt to distinguish between State versus city income taxes in a program that is administered just by the State administration agency. And so we will have to work with them further, I think, on that particular point.

The bill would authorize the Service to charge States a fee to cover the costs of the offset program as is now done for Federal agencies whose debts are the offset by the Service.

[The prepared statement follows:]

STATEMENT OF JAMES W. WETZLER
NEW YORK STATE COMMISSIONER OF TAXATION & FINANCE
ON H.R. 4138,
BEFORE THE SUBCOMMITTEE ON SELECT REVENUE MEASURES
HOUSE COMMITTEE ON WAYS & MEANS

October 6, 1994

Thank you for the opportunity to testify in support of H.R. 4138. I am here representing both the State of New York and the Federation of Tax Administrators (FTA), of which I serve as President. The FTA represents state tax administration agencies of the 50 states, the District of Columbia and the City of New York.

Presently, the Internal Revenue Service has the legal authority to levy on state tax refunds to obtain payment of federal tax debts. States have no such right with respect to federal tax refunds. Thirty-one states and the District of Columbia have voluntarily agreed to allow the IRS to participate in their automated refund offset programs, which greatly simplifies the Service's use of its authority to levy. In 1993, these offsets amounted to about $61 million.

H.R. 4138 would authorize the IRS to enter into agreements with states under which it would offset state tax debts against federal tax refunds. State debts would be offset only after the offset of other governmental debts such as overdue student loans, federal tax debts, and assigned child support, and states would be required to meet various procedural requirements to ensure fairness to taxpayers. For example, a state would have to notify taxpayers that it is proposing to offset their debts, give them 60 days to present evidence that the debt is not owed or not legally enforceable and consider such evidence. Offsets would only occur after taxpayers have exhausted all administrative and judicial remedies to protest the tax assessment giving rise to the debt. The law would apply to local taxes administered by the chief state tax administration agency, like the New York City income tax. The bill would authorize the Service to charge states a fee to cover the costs of the offset program, as is done to federal agencies whose debts are offset by the IRS.

We strongly support enactment of H.R. 4138. To the extent that refund offsets are an effective debt collection tool, there is no reason why the state-federal program should not be fully reciprocal. The principal policy issue surrounding refund offsets has been whether they affect voluntary compliance with the tax law. If they do, the Service should stop offsetting its debts against state refunds; if not, it should allow reciprocal offset of state debts against federal refunds. By making permanent the federal refund offset programs for child support and student loans, Congress has made the policy judgment that offsets are a cost-effective way to collect debts and do not hurt voluntary compliance. We agree, and we are not asking the Service to refrain from participating in our offset programs. We only want it to reciprocate, as provided in H.R. 4138.

Enactment of H.R. 4138 will encourage all states with personal income taxes to participate in the federal offset program. We understand that the Joint Tax Committee estimates that this increased participation will raise $9 million in revenue over the upcoming five years. That is another reason to enact the bill.

We greatly appreciate the work of Congressman Jacobs in drafting and sponsoring H.R. 4138, as well as the support for the bill by the Treasury Department, especially the Internal Revenue Service. We appreciate the time they have devoted to crafting a bill that is acceptable to them. Federal-State cooperation in tax administration is increasing rapidly, and enactment of this bill would be a welcome step towards increased interdependence.

Chairman RANGEL. The administration already supports your position. Maybe you might want to pause and see if some of the members might have problems with this legislation, because I think so far you have it. I mean——

Mr. WETZLER. Well, I will try not to talk you out of it.

Chairman RANGEL. There may be members that have questions. Certainly Andy Jacobs is a strong advocate. And we have any number of cosponsors and the administration thinks it makes sense and certainly you and your organization will have the talents to work out those administrative glitches if they exist.

Mr. WETZLER. One further point, the Joint Tax Committee, we understand, estimates that the bill will raise $9 million over a 5-year period. That is one more reason to pass the bill.

Chairman RANGEL. We can't move fast enough to pick that up. Anyone seeking recognition? Mr. Hancock.

Mr. HANCOCK. Does this apply to both individual income tax refunds and corporate tax refunds?

Mr. WETZLER. The bill would apply to all internal revenue taxes. As a practical matter, the existing offset programs only apply to personal income taxes, and so we are really not envisioning an initial program beyond the personal income tax.

If at some point the IRS were to start getting interested in levying on other kinds of tax refunds, then we might want to look at a reciprocal program there. But while the bill applies more broadly, I think all the IRS and the States are thinking about for the foreseeable future is a program involving personal income tax refunds.

Mr. HANCOCK. Does it apply to all personal income tax returns? Are there any exceptions like the one Federal employees have that their checks can't be garnished?

Mr. WETZLER. The IRS currently levies on all of our State tax refunds. And under the bill, as I understand it, there would be offsets for potentially all Federal income tax refunds.

Mr. HANCOCK. But does it exclude, like certain laws currently exclude, Federal employees from garnishment, Federal employees would also be included?

Mr. WETZLER. They would be covered by the bill, yes.

Chairman RANGEL. Any other members?

Thank you so much.

Mr. MCCRERY. Mr. Chairman, I am curious. I am a cosponsor of the bill. I think it is a good bill, but I am curious. How did Joint Tax come up with a $9 million gain in revenue as a result of this bill?

Mr. WETZLER. Their thinking is that, currently, while the IRS has the authority to levy on all income tax refunds, as a practical matter they only do it when States voluntarily allow them to participate in automated offset programs. Currently, 31 States do that out of the 46 States that have a personal income tax. I think the assumption is that with the reciprocal program, all 46 States that have personal income taxes will want the IRS to participate in the offset program. So the expansion to the extra 15 States is, I think, where the extra revenue comes.

Chairman RANGEL. Mr. Hancock.

Mr. HANCOCK. For instance, there are certain levies now that can be assessed against a tax refund like child support and what have you. Would this proposal give the State debt priority?

Mr. WETZLER. Under Mr. Jacobs' bill we would come behind all of the offsets for debts owed to governments but ahead of collection of child support from parents who are delinquent in their child support.

One of the suggestions Treasury made is that we should come last, behind the child support. And, as I indicated, we don't object to that placement.

Mr. HANCOCK. But in the bill currently, though, you would be ahead of child support?

Mr. WETZLER. We would be behind the child support assigned to the social service agency. As I understand the law, some child support gets assigned to the social service agency that administers the AFDC program. Other child support goes directly to the parent who is owed the child support, and we would come in between. We would come after the child support assigned to the social services agency but ahead of the child support going directly to the parent who is owed the child support. And Treasury would like us to come behind both kinds of child support.

Mr. HANCOCK. The State gets this money before the mother does or the other way around?

Mr. WETZLER. In Mr. Jacobs' bill we would come ahead of the custodial parent, and we would not object to being placed dead last.

Mr. HANCOCK. That is where you ought to be.

Mr. WETZLER. We recognize the relative attractiveness of our position.

Chairman RANGEL. We thank you once again for sharing your views with the committee. It looks like it makes good sense. And as soon as we get a vehicle, I am certain that Mr. Jacobs will be raising this again. Thank you.

The last panel restricts itself to the question of research credit deductibility. And we have another old friend, counsel to the Joint Tax Committee, Harry Gutman, former counsel, of course. He represents the Generic Pharmaceutical Industry Association, the National Association of Pharmaceutical Manufacturers and the National Pharmaceutical Alliance. With him is Kenneth Sawyer, CEO of Par Pharmaceuticals in Spring Valley, N.Y.; and Diana Sloane, the vice president of regulatory affairs of Par Pharmaceuticals.

Chairman RANGEL. Mr. Gutman, we welcome you to the committee. You have heard the testimony of the administration. You have heard the questions of Mr. Payne. We have your testimony. It would be entered into the record by unanimous consent. And you can present your views in any manner you feel comfortable. And we welcome your associates here to our subcommittee.

STATEMENT OF HARRY L. GUTMAN, COUNSEL, ON BEHALF OF GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION, NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS, AND NATIONAL PHARMACEUTICAL ALLIANCE; ACCOMPANIED BY KENNETH I. SAWYER, CHAIRMAN AND CHIEF EXECUTIVE OFFICER, PAR PHARMACEUTICALS, SPRING VALLEY, N.Y.; AND DIANA SLOANE, VICE PRESIDENT, REGULATORY AFFAIRS, PAR PHARMACEUTICALS

Mr. GUTMAN. Thank you, Mr. Chairman.

Before I begin my statement I would like to thank you and the members of the subcommittee for holding this hearing and taking the time out of your busy schedules at the end of this session to examine an issue that is of great significance to the generic drug industry.

I am pleased that my statement will be included in the record. Mr. Sawyer also has a statement that I ask also be included in the record. My statement makes all the technical points that I want to make, and those points are summarized in the statement summary which you and the members of the subcommittee have before you.

I just want to make a few general points at this stage. And, hopefully, you can address a number of questions to Ms. Sloane and Mr. Sawyer who are accompanying me.

First, I don't view this proposal as modifying the scope of the R&E credit. Rather, I view it as a clarification that is necessary because of the position the Internal Revenue Service is taking.

The research and experimentation credit is meant to induce research that will result in increased productivity and improved products.

There is no suggestion, for example, that the creation of an artificial diamond with the principal ingredient of carbon would fail to qualify for the credit because it duplicates what a natural diamond does. The research that leads to a successful generic drug is the same type of research, duplication of the results for a different formulation results in a new product and is, I think, precisely what Congress intended to encourage when it enacted the credit.

Chairman RANGEL. Before we get too far with that argument, you are willing to concede that if indeed this duplication is not a new product but merely the same product with the same ingredients, then your argument would be different, right?

Mr. GUTMAN. Under the statute, that is exactly right. Under the statute, if it were possible to reproduce the product——

Chairman RANGEL. In other words, that is the same—but you know that the artificial diamond is not a diamond.

Mr. GUTMAN. But it has the same function.

Chairman RANGEL. Forget the function. I am saying that if indeed you end up with a diamond and it is the same thing, except we are talking about a brand name, then you are not going to use the same argument.

Mr. GUTMAN. I would not use that argument.

I am disturbed by the analysis of the IRS in these matters. And I was gratified that the Treasury appears to take a different view. What a generic drug does is duplicate the result of a target drug. In all other respects it is new. And I see nothing in the statute that prohibits duplication of results where there is a new formulation to

achieve that result, nor is there any written indication that Congress intended that result, nor I believe does the Treasury think that Congress intended that result, if I understand Mr. Kohl's testimony properly.

And I guess my point would be that it would be very helpful if the Treasury would let the IRS know what the Treasury's position is with respect to this.

I am accompanied by two individuals who can speak to two relevant issues: First, whether the credit is an incentive for the industry; and the second is whether the production of a generic drug is possible from an examination of existing public data or simply by decomposing an existing target drug. I urge you to satisfy yourself on these issues.

As I said in my written statement, if the IRS took the time, listened and made an effort to understand the process of producing a generic drug, I believe it would conclude, as Congress has in connection with the FDC Act and the FDA with regard to approval requirements, that a generic drug is a new product and the research to produce it is creditable. We would not object to a case-by-case resolution if we were comfortable that the IRS would apply the law recognizing how generic drugs are produced.

In particular, the Internal Revenue Service would have to acknowledge, as the Treasury has today, that there is no merit to its assertion which it made in the technical advice memorandum that has been received by one taxpayer, "that Congress considers generic drugs to be duplications of listed drugs." That is the IRS' position, and that sounds an awful lot like a per se rule to me.

We would welcome the opportunity to demonstrate to the IRS that the way generic drugs are produced is not within the duplication language of the statute. And if that were the outcome of the hearing and the Internal Revenue Service were willing to listen and pay attention to the submissions made with respect to how generic drugs are actually produced, we would be very happy.

I thank you, Mr. Chairman.

[The prepared statement and attachments follow:]

STATEMENT OF

HARRY L. GUTMAN

On behalf of the Generic Pharmaceutical Industry Association, the National Association of Pharmaceutical Manufacturers, and the National Pharmaceutical Alliance

BEFORE THE

Subcommittee on Select Revenue Measures
Committee on Ways and Means
U.S. House of Representatives

October 6, 1994

Mr. Chairman and Members of the Subcommittee:

My name is Hank Gutman. I am a partner in the law firm of King & Spalding. I am pleased to appear before the Subcommittee today on behalf of the Generic Pharmaceutical Industry Association, the National Association of Pharmaceutical Manufacturers, and the National Pharmaceutical Alliance in support of the proposal to clarify the application of the research and experimentation tax credit ("the R&E credit") to expenses of developing generic alternatives to brand name products. I am accompanied by Kenneth I. Sawyer, President and CEO of Par Pharmaceutical, Inc. of Spring Valley, New York, and Diana Sloane, Vice President of Regulatory Affairs for Par Pharmaceutical, Inc.

I shall present the technical position of the organizations on whose behalf I am appearing. Mr. Sawyer will address the issue of the economic incentive provided by the credit. Ms. Sloane will answer any questions you may have with respect to the technical process of developing generic drugs. I urge the Subcommittee to satisfy itself with respect to these issues. In particular, it is our view that if the Internal Revenue Service ("IRS") fully understood the development process for generic drugs it would conclude, as we have, that the expenses incurred therewith are eligible for the R&E credit under current law.

Before I begin my analysis, I would like to thank the Chairman and the Members of the Subcommittee for holding this hearing and taking time from their busy schedules at the end of the legislative session to examine an issue of great significance to generic drug manufacturers.

In my statement, I shall first describe the issue that the proposal addresses. I shall then describe the process of developing and securing regulatory approval for a generic drug. Third, I shall discuss current law governing the allowance of the R&E credit, as well as the congressional intent in enacting that legislation, and demonstrate that the process of creating a generic drug falls squarely within the ambit of expenses that Congress intended to qualify for the R&E credit. Finally, I shall describe the alternatives available to the Subcommittee.

THE ISSUE

In a number of audits of generic drug companies, and in a technical advice memorandum, the IRS has taken the position that developers of generic drugs are per se ineligible to claim the R&E credit for their premarketing development costs and costs to secure Food and Drug Administration ("FDA") marketing approval of their products as new drugs. In many cases the IRS has conceded that the expenses of developing a generic drug product constitute qualified research under statutory tests other than Internal Revenue Code Section 41(d)(4)(C), which excludes from the credit expenses related to the reproduction of an existing business

component from a physical examination of the business component itself or from plans, blueprints, details, specifications, or publicly available information.[1/] However, the IRS has concluded that Section 41(d)(4)(C) applies to these expenses.

We believe this conclusion is unwarranted under the statute and is contrary to Congressional intent. First, as discussed more fully below, a generic drug is not developed from a physical examination of a target drug or from publicly available information. Thus, the process of development of a generic drug does not satisfy the literal language of the exclusion. Second, the legislative history of Section 41(d)(4)(C) makes clear that "reproduction" means reverse engineering of an existing product, not development of an alternative by original research and experimentation. Again, as described in more detail below, the process of developing a generic drug product does not in any sense constitute "reverse engineering."

The problem would disappear if the IRS would change its position. In lieu of that, clarification of Congressional intent that the credit is intended to apply to these expenses is necessary and appropriate.

DEVELOPING AND SECURING REGULATORY APPROVAL FOR A GENERIC DRUG

A generic drug product is a new drug that can achieve the same therapeutic results as a brand name drug product and that can be substituted in prescriptions for the brand name product. What is new is the manufacturing and delivery process and the research and experimentation of a generic drug manufacturer focuses on that.

A generic drug is developed by original research that delivers a known active ingredient using a newly developed and unique combination and ratio of inactive ingredients with the active ingredient. The identity, type, nature, characteristics and sources of each inactive ingredient must be intensively researched and evaluated because each ingredient must serve a specific purpose in the final formulation. Variations in combinations and identity of inactive ingredients with the active ingredient affect performance. The quantity and ratio of the inactive ingredients must be developed in combination with the active ingredient in the generic manufacturer's own formulation to achieve a successful generic drug product. Every aspect of the formulation of any drug product requires a delicate balance to achieve the desired result. Moreover, in addition to its own formulation, the generic drug manufacturer creates a new manufacturing process. Exhibit A describes the process in more detail.

A generic drug is, by definition, a new drug under the Food, Drug and Cosmetic Act (the "FDC Act"). 21 U.S.C. § 321(p)(1) (1988). It is a violation of the FDC Act to market a new drug in interstate commerce unless the FDA has approved a new drug application for the drug. 21 U.S.C. §§ 355(a), 331(d).

A generic drug may be approved through one of two types of new drug applications. The only difference between FDA approval standards for the two types of new drug applications, (1) full new drug applications ("NDA") and (2) abbreviated new drug applications ("ANDA"), is that ANDAs require bioequivalence data rather than clinical studies. Compare 21 U.S.C. § 355(b)(1)(A)-(F) with 21 U.S.C. § 355(j)(2)(A)(i)-(vi). Although an ANDA need not contain information on safety and effectiveness investigations, it is required to contain data demonstrating

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1/ Section references are to the Internal Revenue Code unless otherwise noted.

bioequivalence to a "listed" drug, i.e., a drug previously approved in a full NDA. If a generic drug company's initial tests do not demonstrate bioequivalence, the company must alter its formulation and retest. The cycle of testing and revising the formulation is followed until (1) the tests indicate that the two products are bioequivalent within a range of plus or minus 10% to 20% with respect to the rate and extent of absorption or (2) the company fails to achieve its objective abandons its effort.

An ANDA must contain the same types of information concerning components, composition, manufacturing methods, samples, and labeling, as a NDA. 21 U.S.C. § 355(j)(2)(A)(i)-(vi) (1988). Because the FDA considers each new drug as a unique product, an ANDA is not required to compare its qualitative and quantitative formulation and manufacturing process with that of the listed drug's manufacturer. See 21 U.S.C. § 355(j)(3) (1988). Each new drug's performance depends on product-specific variables, including chemistry, manufacturing, and control factors that are specific to the manufacturer and its product.

For each new product it attempts to develop, a generic drug manufacturer goes through a process of experimentation to discover chemical properties of the active ingredient, the dosage form technologies, combinations of inactive ingredients with the active ingredient, enclosures, and the equipment and manufacturing techniques that will produce a product that satisfies the ANDA performance test.

CURRENT LAW AND CONGRESSIONAL INTENT

Section 41(a), originally enacted as Section 44F in 1981, allows a tax credit for incremental "qualified research" expenses. Section 41(d)(4)(C), enacted in 1986, excludes from the definition of qualified research "any research related to the reproduction of an existing business component (in whole or in part) from a physical examination of the business component itself or from plans, blueprints, detailed specifications, or publicly available information with respect to such business component." The Treasury has yet to issue Regulations interpreting Section 41(d)(4)(C).

In many cases the IRS has conceded that, but for Section 41(d)(4)(C), the expenses of developing a generic drug would constitute qualified research expenses. However, it takes the position that Congress intended generic drugs submitted for approval under the ANDA procedure to be "duplicative" of existing drugs and therefore ineligible for the credit under Section 41(4)(C).

A generic drug is not a "duplicate" of an existing drug. The FDA has supplied a statement explaining the FDA's requirements for approving a generic drug and the agency's interpretation of the status of generic drugs under the FDC Act. The statement, which was supplied by Roger L. Williams, M.D., Director, Office of Generic Drugs, Center for Drug Evaluation and Research, is attached as Exhibit B. In it, Dr. Williams states, "Because a generic drug's performance depends on product specific variables, the FDA considers each generic drug as a distinct product. ... A generic drug is, therefore, not the same drug as the one approved in the NDA." Exhibit B, p. 2 (emphasis supplied).

Second, the activities listed in Section 41(d)(1)(4) are Congress' express illustrations of situations in which the credit will not be allowed because the research is not research in the experimental sense. A generic drug company's research activities are clearly experimental.

Thus, the scope of the exclusion of research related to reproduction of an existing business component from an examination is the critical question. Although the heading of Section 41(d)(4)(C) is "Duplication of Existing Business Component," as

noted above the exclusion is for "research related to the reproduction of an existing business component (in whole or in part) from a physical examination of the business component itself or from plans, blueprints, detailed specifications, or publicly available information with respect to such business component." Because a generic drug company conducts its own original research to produce its own new business components, and does not copy existing products by cloning or reverse engineering, its research activities are eligible for the Section 41 credit under current law.

The legislative history on this issue specifically states, "The exclusion for duplication does not apply merely because the taxpayer examines a competitor's product in developing a different component through a process of otherwise qualified experimentation requiring the testing of viable alternatives and based on the knowledge gained from such tests." H. Rep. No. 841, 99th Cong., 2nd Sess. (1986), at II-75 (report of the Conference Committee on the Tax Reform Act of 1986, Pub. L. No. 99-514) [hereinafter "1986 Conference Report"]. The clear implication is that a taxpayer who examines a competitor's product that achieves a particular result and then, through experimentation, develops its own original product that duplicates the result achieved by the competitor's product, is entitled to the Section 41 credit. The inactive formula and the manufacturing process developed in connection with a generic drug are clearly new and different business components under the statute.

As explained in the 1986 Conference Report, duplication means producing something that exactly corresponds in composition and structure to an original. The House Ways and Means Committee Report explanation of the Section 41 changes in P.L. 99-514 (H.R. Rep. No. 426, 99th Cong., 1st Sess. (1985)) defines duplication as "The reproduction of an existing business item of another person from a physical examination of the item itself or from plans, blueprints, detailed specifications, or publicly available information with respect to such item." Such duplication is referred to as "reverse engineering" in the 1986 Conference Report at II-75, restating the language from the Ways and Means Committee report cited above. A generic drug invention is not a duplicate or a reproduction, but is a new and different product; the new product duplicates results, but the product itself is not a duplicate or a reproduction.

The conclusion that generic drug research should be entitled to the credit is reinforced by the numerous references to drug products in the legislative histories of Section 41 and Section 174. In particular, the legislative history of Section 41 is crystal clear: "[C]osts of experiments undertaken by chemists or physicians in developing and testing a new drug are eligible for the credit because the researchers are engaged in scientific experimentation."

Moreover, it is also clear from various amendments to the FDC Act and from legislative history that Congress intended to encourage the development of generic drug products. For example, in 1984, Congress estimated that the availability of generic equivalents to brand name drug products approved after 1962 would save American consumers $920 million over 12 years. H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 1, at 17 (1984). Older Americans, in particular, would benefit, since they use almost 25% of all prescription drugs. Id. In addition, the federal government would save millions of dollars from the increased availability of generic drug products, since it purchases drugs through the Medicaid program and in veterans' and military hospitals. Id. at 17, 19. State governments would also save on drugs purchased through Medicaid. Id.

The availability of high quality, low cost alternatives to brand name drug products is desirable from both an economic and a public health standpoint. A generic drug product is usually sold

for a lower price than a brand name product. As mentioned above, the lower level of costs of research for generic drug developers compared to the development of a brand name drug results in lower credit compared to the major pharmaceutical houses, but it does not mean that the credit is not a major incentive for research.

The research required to develop a generic drug product consists of experiments related to the physical content, form and production process of the new drug, and, once a model has been developed, studies that compare the model's bioavailability with the bioavailability of the target brand name product. These studies are necessary in order to obtain FDA approval to market the generic drug product. 21 U.S.C. § 355(j)(2)(A)(iv) (1988). This process is less expensive, however, than the process would be if it also included the clinical studies necessary to show that a drug product is both safe and effective for the purpose for which it will be marketed. H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 1, at 19.

The potential for lower cost prescription drug products was one of the major factors that Congress discussed in connection with 1962 amendments to the Food, Drug, and Cosmetic Act. Drug Amendment of 1962, Pub. L. No. 87-781. The FDA established a procedure for submitting abbreviated new drug applications (ANDAs) for new generic versions of brand name products initially approved before enactment of the 1962 Amendment. See 21 C.F.R. 314.56 (removed by 57 Fed. Reg. 17950, 17963 (April 28, 1992)). In a further effort to expand the use of lower cost generic drug products and increase competition within the pharmaceutical industry, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984. Pub. L. No. 98-417. This Act amended the Food, Drug, and Cosmetic Act by adding an ANDA procedure for generic equivalents to any FDA-approved drug product for which a valid patent was not in force. 21 U.S.C. § 355(j).

Congress clearly intended to encourage the development of generic drug products by enacting special FDA procedures. Excluding the costs of such development from eligibility for research-related tax benefits would flatly contradict that intent. Allowing research credits for brand name drug product development while denying such credits for generic drug product development would decrease the competitiveness of generic drug products, discourage the development of generic products, and increase the costs of generic products. Congress certainly did not intend the application of the R&E credit to produce such results.

CONCLUSION

This statement reads somewhat like a brief. It is not the conventional way to present testimony to your Subcommittee. However, that approach was necessary to demonstrate that the expenses of developing generic drugs are eligible for the R&E credit under current law.

It is frustrating to have to come before the Subcommittee and suggest that clarifying legislation is necessary so that the IRS will interpret a statute in accordance with Congressional intent. Indeed, the generic drug industry believes the result sought in the clarifying amendment would ultimately be achieved through costly, time consuming litigation. Clearly these costs can be totally avoided if the IRS were to change its position. If it does not, non-retroactive, clarifying legislation will resolve the issue for the future. Litigation may have to decide the issue for the past.

EXHIBIT A

DEVELOPMENT OF GENERIC DRUGS

The development of a generic drug product is a very complex and intricate undertaking which requires a great deal of time, effort and research by skilled professionals. The company knows that a trade-name product can achieve certain therapeutic results, but must research and experiment to create its own product that will achieve those results. The products ultimately created are entirely new products created through a process of experimentation and research

Although the products created by generic drug manufacturers achieve the same results as trade-name drug products that have been patented, the generic drug products are entirely new. The patents do not contain information that would permit a generic drug manufacturer to duplicate patented drug products even if the generic drug manufacturer wished to do so. Such patents reveal only the active ingredients and do not reveal any of the many other variables discussed below. Moreover, patent file information generally does not reflect the product that actually goes to market. As a result, it can be misleading, and reviewing such information could result in confusion. Consequently, the staff of many companies do not even read patents.

The Goals. The goal of generic drug manufacturers is to design a particular dosage form (using a known active ingredient in a specific strength) which meets the same Food and Drug Administration ("FDA") standards of quality and efficacy as an already approved drug product (trade-name product)

For solid oral (and suspension liquid) products, the standard used is a demonstration that the generic drug product is bioequivalent to the trade-name product. This means the generic product must not differ significantly from the trade-name product in bioavailability, i.e., the rate and extent to which active drug ingredients with a given physiological effect are physically absorbed. Bioequivalence is demonstrated by comparing measured parameters from a controlled human bioavailability study and/or by comparing analytical test results such as dissolution profiles.

Bioavailability does not have to be demonstrated for injectable solutions. However, the FDA requirements and scrutiny of the formulation, purity and processing of generic injectable products are even more stringent than the bioequivalence standards for solids and suspension products. Generic firms must meet all FDA standards when developing generic products of acceptable quality.

The knowledge and experience of skilled research personnel are the keys to the development of a quality bioequivalent generic drug product. Any number of factors can affect the final safety, quality or performance of a generic product and each of the factors must be considered and addressed in the initial development of the generic product. The following summary describes in detail the many variables that must be researched to create new products that will produce known therapeutic results.

Evaluating and Selecting the Active Ingredient. The active ingredient is one of the primary factors which needs to be researched and evaluated even before a formula is developed. While the strength of the active ingredient has been established by the trade-name product, the nature of the active ingredient used for a generic product must be considered at the outset. Trade-name drug companies often synthesize their own active ingredients, but generic drug companies generally purchase active ingredients from outside sources. The particle size of the raw material may also substantially affect the absorption of the drug in the body. Consideration must also be given to the different available crystalline or polymorphic forms of the active

ingredient because the form may also have a great effect on the absorption and bioavailability of the drug and on the solubility of the drug in a final injectable solution.

Most bioavailability studies that fail do so because the generic formulation does not achieve the same maximum concentration of a drug in the blood at a certain time as the trade-name drug. A great deal of research is required to attain comparable concentration for two products in a bioavailability study. Lack of research into the characteristics of the active ingredient could very well be a substantial contributing factor in these study failures.

Developing the Formulation of the Drug Product. Once a suitable active ingredient has been selected, the company must formulate the generic drug product. The exact combination and ratio of inactive ingredients (excipients) with the active drug is very critical to the final manufacture, stability and bioavailability of a drug product. Just as with the active ingredient, the identity, type, nature, characteristics and sources of each inactive ingredient must be intensively researched and evaluated because each ingredient must serve a specific purpose in the final formulation. In addition, the quantity and ratio of the inactive ingredients must be developed exactly because the formulation of any drug product is a delicate balance of materials which is not easily achieved. For example, 1% of a specific inactive pharmaceutical material in a formulation can act as a lubricant to aid in manufacturing a product, but 3% of the same material can destroy the dissolution performance of the same product. The quantity of each ingredient must be painstakingly researched and evaluated to achieve the optimum balance in order to obtain the physical and chemical characteristics needed for the generic product.

A solid oral generic product must differ from the approved trade-name product in appearance (size, shape, coating, color, and so on). Changing the color, coating, size, shape, or other aspect of a product in any way can change the rate at which, and the extent to which, the active ingredients are released and absorbed (too high bioavailability) or it can decrease these functions (too low bioavailability). Consequently, changing trade-dress variables requires experimentation to determine what combination of new variables will produce the target biovailability.

Selecting Techniques for Manafacturing Dosage Form. The development work is not complete after the research of the initial formulation. The manufacturing procedure by which a product dosage form is made must be determined. Here, issues such as the type of machinery to be used, the mixing times needed, the use of milling or screening steps and the amount of compression force used come into play. Just as different sources or types of ingredients affect a formulation, different types of blenders or length of mixing times can substantially affect the final product. The dissolution and bioavailability of a product can be affected significantly by different types or rates of mixing, as well as by varying compression forces. For example, if there is too much compression force, the tablet will not dissolve, but if there is not enough compression force, the tablet will not hold together.

The use (of lack of) milling/screening steps in a manufacturing procedure is also a factor which must be considered because the particle size of the active and inactive ingredients in the final dosage form can be affected by these steps. As noted above, particle size of the active ingredients can be a very significant factor affecting the bioavailability of many drug products.

The effect of manufacturing conditions on a product's bioavailability must be considered in the context of developing a practical manufacturing procedure which can be used repeatedly on a large scale after the generic product receives FDA approval. Additionally, a balance must be developed for each manufacturing

factor for each individual formulation. The processing of injectable products requires significant effort and evaluation to establish accurate "in process" limits and validate the process. The FDA requires that the process of manufacturing injectable products and each system be validated before approval. The information required is quite extensive and must address not only the consistency and quality of the process and product but must also validate the sterility of the product and the sterilization process. The research and experimentation necessary to obtain this information is required for each new generic injectable product prior to approval.

Thus, extensive research and experimentation by experienced research personnel is required for each and every type of formulation in order to properly develop a reasonable manufacturing procedure for each successful generic drug product.

Developing Methods of Testing and Conducting Tests.

The analytical laboratory contributes substantially to the development of each product. Early in the process, the analytical laboratory must work closely on the development of the formulation, identifying any potential drug-excipient interactions and assessing the effect of each type and form of ingredient on the stability and analytical performance of the formulation. Experiments and assay procedures must be developed for use in such evaluations. Approval standards for a generic drug product require that the assay method be specific to the particular formulation developed. Such methods require research and development by the generic firm. The FDA requires extensive validation of these methods to demonstrate that the method is specific, reproducible and consistent with the particular formulations. Extensive research and testing using a characteristic number of batches of both the trade-name product and the developed generic product is required in order to satisfactorily show that the methods developed demonstrate the bioequivalence of the two drug products.

To obtain FDA approval to market an oral solid generic drug product, the company must demonstrate to the FDA that its product is bioequivalent to a trade-name product. To demonstrate this bioequivalence, the company conducts comparative bioavailability studies through an outside testing laboratory. It provides the testing laboratory with samples of its own proposed formulation and with purchased sample of the trade-name product. The laboratory administers these products to a group of subjects: one half of the group receives the trade-name product and one half receives the company's formulation. The laboratory then tests for bioavailability, for example by drawing blood samples at certain intervals. At a later time, the test is performed again on the same subjects: those who originally received the trade-name product are given the company's formulation, and vice versa. Bioavailability tests are conducted again, and the results are compared statistically between the company's product and the trade-name product.

Summary. Generic drug manufacturers perform extensive research and development to create new drug products. Of course, as in almost all research, the manufacturer has specific objectives or goals. The goal is to create new products that achieve the therapeutic results of trade-name drug products already on the market. The guidelines for the approval of a generic drug product require extensive demonstration that such a product is bioequivalent to the target trade-name product. This demonstration includes (a) accumulating extensive data necessary to demonstrate the purity of injectable products and to validate the manufacturing process or (b) demonstrating the bioavailability of solid oral products and suspensions.

The requirements for demonstrating that the bioavailability of a generic product matches the bioavailability of a trade-name product are very narrow and specific. In other words, very little

deviation is allowed. These stringent standards are made even more narrow by the inherent variability of the human body. Therefore, the development of a generic drug product involves research into and consideration of a combination of factors which affect the final bioavailability of the drug product.

This synopsis briefly summarizes the issues a generic research and development team must address and resolve through extensive experimentation and research in order to create a successful generic drug product. Research and experimentation is necessary for selection of variables, including active and inactive ingredients, the manufacturing equipment and procedures, and the analytical methodology to be used. Each variable must be carefully developed and evaluated to achieve the optimum effect on the physical and analytical performance, quality and stability of the generic drug product. Each combination of variables creates a potential for variation in the performance of the final product. The fact that there are a number of trade-name products off patent for which generic counterparts are not available demonstrates the difficulty in selecting and combining variables. Despite their research and experimentation, generic firms have not been able to develop the exact combination of variables to create successful generic substitutes for such products.

EXHIBIT B

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 25 1982

Mr. Thomas Scarlett
Ryan, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, DC 20005

Dear Mr. Scarlett:

Based upon your letter of November 17, 1982, we understand that the Internal Revenue Service has raised certain issues concerning the "creditability" of the costs associated with the development of generic drugs. The following statement explains the Food and Drug Administration's ("FDA's") requirements for approving a generic drug and the agency's interpretation of the status of generic drugs under the Federal Food, Drug, and Cosmetic Act ("FDC Act"). The statement is not intended to address the relationship between the FDA's process for reviewing and approving generic drugs and the IRS's tax issues.

Broadly speaking, there are two types of approval applications for prescription drugs. A "full" new drug application ("NDA"), contains safety, clinical effectiveness, and bioavailability data, as well as information about the chemistry of the proposed product, its method of formulation, and the manufacturing procedures that will be used to make it. An "abbreviated" NDA ("ANDA") omits the safety and clinical effectiveness data, but contains "bioequivalence" data to show that the drug is present in the blood at the same level as a drug approved in an NDA. An ANDA also contains the same types of chemistry, formulation, and manufacturing information as a full NDA.

A drug approved in an ANDA is commonly called a generic drug. It contains the identical active ingredient as the NDA drug to which it is compared in the bioequivalence test(s). It must also have the same dosage form, the same dosage strength, the same route of administration, and the same labeling. The most important point of similarity is that the generic drug must be shown to be bioequivalent to the NDA drug. How a generic drug company achieves that objective varies within a range of options determined by the chemical properties of the active ingredient, the available dosage form technologies, the methods for combining the active ingredient with inactive ingredients to yield the desired drug release characteristics, and the equipment and manufacturing procedures to be used to process the ingredients and make the finished dosage form.

Because a generic drug's performance depends on product-specific variables, the FDA considers each generic drug as a distinct product. No drug may be marketed unless it is shown to be safe and effective for its intended use. An NDA drug is shown to be safe and effective by pre-clinical and clinical data and also by data relating to the chemistry, manufacturing, and control factors mentioned above. The evidence for the safety and effectiveness of a generic drug consists of a showing of bioequivalence to the NDA drug and by data about the chemistry, manufacturing, and control factors that are specific to the generic manufacturer and to its particular formulation of the drug.

A generic drug is, therefore, not the same drug as the one approved in the NDA. The ANDA applicant may use any appropriate technology to design and manufacture the finished dosage form so it is bioequivalent to the comparison drug, including different inactive ingredients and manufacturing procedures, different types of dosage form materials, different dosage forms (if the FDA grants permission), and different methods of producing the active ingredient (e.g., synthesizing it as opposed to deriving it from a natural source). Because these differences may affect the performance of the generic drug product, the FDA requires the ANDA to contain, in addition to a showing of bioequivalence, evidence that the manufacturer has correctly formulated, and characterized the active and inactive ingredient and that it has the manufacturing procedures, and the knowledge of how to use them, to make the generic drug product so that it performs acceptably when used in patients. Not only must the generic product deliver the active ingredient "bioequivalently" to the comparison product, but it must also be an acceptable drug product in its own right based on the FDA's approval criteria for product-specific performance characteristics.

In developing a generic drug product, a manufacturer does not have access to the NDA or ANDA submissions of other companies that have obtained FDA approval to market a product containing a particular active ingredient (unless the owner of a submission has legally authorized such access). Moreover, although some data from NDA and ANDA submissions are available under the Freedom of Information Act, specific information about the chemistry and formulation of a product and about manufacturing methods are considered proprietary. For this reason, a generic drug manufacturer must generate its own technical information in order to develop a finished product to be used in bioequivalence tests. Therefore, although the goal is to make a generic drug product that is as close as possible to the NDA product in its performance in delivering the active ingredient, the generic product is "new" in the sense that it is the result of the generic manufacturer's knowledge and skill in devising its own original specifications and procedures for the purpose of making a product that will behave the same as the comparison drug product. Any similarity in methodology would be the result of chance operating on a finite number of possibilities, rather than replicating the NDA owner's work.

In fact, FDA considers every generic prescription drug product to be a "new drug" as that term is used in the FDC Act. The FDC Act used the word "new" to refer to any drug product that is not generally recognized as safe and effective. (See sections 201(p) and 505 of the FDC Act.) This means that, as a legal matter, each generic drug product must be approved in its own "new drug application", even though it has the same active ingredient and is otherwise similar to a product that has already been approved. The reason for this legal requirement is actually scientific, i.e., no two prescription drug products can be assumed to be the same only on similarities in the active ingredient, dosage form, and strength. Rather they are different products that must be shown to reach the same performance objective. A generic drug product is, therefore, "new" in the FDC Act sense. It is also different from the comparison drug product in that its similarity in the delivery of the active ingredient is the result of product-specific and manufacturer-specific decisions by the generic drug company. In other words, each approved generic drug product is unique.

If further information on the points explained above would be useful, please let me know.

Sincerely,

Roger L. Williams

Roger L. Williams, M.D.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

Chairman RANGEL. Mr. Sawyer, your statement will be in the record. Do you have any comments?

STATEMENT OF KENNETH I. SAWYER

Mr. SAWYER. I would like to put some magnitude of the problem in front of you so that you appreciate where we dwell in the generic drug industry.

It is a very small industry, probably at the manufacturing level $4 or $5 billion total at this time. An R&D tax credit to an individual company in an amount let's say of $200,000 could well generate $20 or $30 million in terms of public savings just off of that $200,000. A $200,000 credit to a generic drug manufacturing firm in any given year makes the difference between perhaps developing a new drug product or not.

Those are the magnitudes of the kind of numbers we deal in. Once we produce a generic drug successfully by producing a new drug and getting a new drug approval, after all the clinical testing and the like and demonstrating it to the FDA, then in almost perpetuity, an annuity goes forward saving the public the difference in the price between the brand and the many generic versions that may appear on the market. And that is indeed a perpetuity—an annuity, rather. So please comprehend that. That we are talking about very small dollars making a huge difference to individual generic drug companies.

Second, because of the way that generic drug companies tend to be treated; in particular I mean this, that on those matters of crucial importance where we should be distinguished from the PMA innovator companies, for example, rebates, Federal Medicaid or rebate programs, we are lumped together and carry the same burden which we cannot afford to do compared to the innovative companies.

On the other hand, on those matters where we should be treated the same, namely R&D tax credits, and traditionally have always been treated the same, for some reason we are now being segregated out of that pool. We tend to be kept in the bottom of the barrel, depending on which side of the issue. And no doubt it is because of the smallness of our industry and our inability to devote large-scale dollars to educating and presenting our position.

And, finally, I would say this. In addressing the comments in a case-by-case methodology for determining the issue, we have in a particular case demonstrated to the IRS, I think unequivocally, that in any particular case of developing a solid product, an oral tablet form product, it is in no way a duplication. It is theoretically impossible. On a case-by-case basis, we have spent more in demonstrating that issue in any one particular case than we would ever have received for the R&D tax credit to begin with.

So we can't afford to go forward and fight this on every single case-by-case basis. Which indeed at end of the day is a uniform position. And that is you cannot—you cannot duplicate the branded or innovative product or another generic version because it is unavailable by science to do that. You can't feed it into a computer and say tell us how it is made. Tell us what the process is or tell us what the active ingredients and inactive ingredients are and when they went in and how long it is stirred for.

All we can do is in in vitro and human testing demonstrate that we can produce in your bloodstream the same therapeutic result of another product. It is not duplication in any sense.

Thank you.

[The prepared statement follows:]

Statement of

Kenneth I. Sawyer
Chairman and Chief Executive Officer
Pharmaceutical Resources, Inc.

Before the

Subcommittee on Select Revenue Measures
Committee on Ways and Means
U.S. House of Representatives

October 6, 1994

I am Kenneth I. Sawyer. I am Chairman and CEO of Pharmaceutical Resources, Inc. and its generic drug manufacturing subsidiary, Par Pharmaceutical, Inc. It is a pleasure to appear before you today to describe why I believe there is a compelling public benefit to maintaining the availability of the research and experimentation tax credit to support the design, development and testing of new generic medicines.

I have been asked to address the issue of the importance of the credit to my company and industry. First, it is important to understand the important role that generic drugs play in benefitting the consumer and in reducing overall health care costs.

Generic medicines are therapeutically equivalent versions of off-patent brand name drugs that are approved by FDA. Developing a generic drug product involves essentially the same research and experimentation process as developing a method for synthesizing the active ingredient that goes into the drug. Starting with the active ingredient, the generic manufacturer tries to develop a new method of synthesizing the finished dosage form from the active ingredient, inactive ingredients, manufacturing procedures, equipment settings, and the like. This process is the same as developing the active ingredient itself from precursor substances, using a variety of chemical manipulations. The process can be difficult and time-consuming or it can be easy but, in either case, the process involves research and experimentation. The associated costs will vary with the magnitude of the challenge. Hence, with respect to any tax credit, there is no windfall involved. Like the research and experimentation credit that has been available to brand name drug development, this process is equally deserving of that incentive.

The share of prescriptions filled generically has risen from about 15 percent in 1983 to almost 40 percent in 1993, and is expected to rise sharply by the year 2000 as many popular brand-name drugs lose their patent protection.

Generic drugs reduce overall health care costs significantly and save money for both government and consumers. Prices of generic drugs may range from 30 to 90 percent below their brand name equivalent. This fiercely competitive industry is the only segment of the health care industry that actually has reduced prices in the last decade.

While the competitiveness of the generic drug industry has benefitted consumers, it brings with it considerable challenges to individual companies and to the industry as a whole. As price competition grows, profit margins shrink. It has been estimated that generic drugs produce only 2 to 3 percent net income as a percentage of sales as compared to a 15 percent comparable figure from brand name drugs.

The net effect has been a rapidly changed industry. Some firms have withdrawn. Others have formed strategic alliances or have been acquired by brand name companies eager to offset the impact of generic competition.

The generic drug industry has also been severely impacted by government programs intended to address the problem of increased prices of brand name drugs. Failing to recognize the inherent differences between the business aspects of brand name and generic drug manufacturing and failing to appreciate the counterproductive impact on consumers, both the federal government and many states have imposed rebate requirements for Medicaid or other government sponsored drug benefit programs. The negative impact of the cumulative effect of these rebates that function much like a gross sales tax cannot be overstated.

The important message from this background is that while generic drugs provide enormous consumer and public benefit, they do so with considerable business risk. Even otherwise small fluctuations in the cost of doing business might have dramatic consequences to a generic drug company operating on the smallest of margins. So too is it with the applicability of the research and experimentation tax credit. While the credits have not been large in actual amounts, the impact of their loss could be very significant to an individual company - mine included - and consequently to the industry, and to consumers.

I would like to suggest one other important public policy consideration that argues strongly for the maintenance of the credit. I mentioned earlier that developing a generic drug product involves essentially the same research and experimentation process as that involved in brand name drug development. This process is critical to establishing the safety and effectiveness of all drugs. Public policy should encourage full research on all drugs - both generic and brand name so that the public can have confidence in their quality. The availability of the research and experimentation credit is one such public policy. Its loss may discourage companies from undertaking the rigorous research needed to develop these products.

Government policies should support and encourage the generic drug companies and industry that provide enormous benefits to the health care system and to consumers by making available low cost, quality prescription drugs. Ensuring the availability of the research and experimentation tax credit is a critical element of those government policies.

Chairman RANGEL. Well, you certainly have complicated this for me. Do you agree with the Gutman argument about this diamond and synthetic diamond theory, that we are not dealing with diamonds, you are dealing with a new product that serves the same purpose?

Mr. SAWYER. In about 90 percent, I can adopt the Gutman theory.

Chairman RANGEL. Let's talk something—let's talk aspirin. If aspirin is out there and they have brand names for it, we normally believe that these drugstore names—we call that generic. And so, therefore, you don't get the brand name. You get generic.

Are you testifying that, in your opinion, the generic thing is a new—and it is not aspirin. It is just a new product that serves the same purpose as aspirin?

Mr. SAWYER. It is a new product that has some form of aspirin in it. But it is not Bayer aspirin, for example, with a different label.

And if you take a prescription drug—Valium was a branded prescription drug that people know about. The generic chemical compound is diazepam. What our goal is is to formulate and to develop a diazepam product containing an active ingredient called diazepam, which comes from a different source than a branded diazepam would——

Chairman RANGEL. Let's start again now. If there is a brand name and everyone knows exactly what it is and people go after that brand name and then you come up with a substitute for the brand name, you are not dealing with the ingredients of that brand name and juggling it around and coming back and calling it generic and a new product? You are coming up with a new product?

Ms. SLOANE. No, you are not necessarily dealing with the same ingredients. What you are dealing with is the same active ingredient in the same strength and the same dosage form.

Chairman RANGEL. Why is it that the brand name people think that you are doing them so much damage when really, from what you are saying, you are dealing with another remedy for an ailment. You are not duplicating the brand name product.

Ms. SLOANE. Well, I really can't answer as to why they think we are doing any damage.

Mr. GUTMAN. I think the reason they think that the generic drugs are doing damage is that, in fact, the generic drugs are able to produce the same therapeutic results. It is a bioequivalence. They can produce precisely the same result as a brand name drug, and they can generally do it at a lesser cost. And so when the generic drug is produced and sells at a lesser cost, that obviously is going to cut into the profit margins of the brand name drugs. That is where the damage is being done.

But the bioequivalence of result is conceded. Indeed it has to be in order to get regulatory approval, but the chemical composition of the drug is different.

Chairman RANGEL. Why would they call themselves generic? Why wouldn't they want to be an exciting, new brand name drug instead of just being an ordinary drug that is not a duplicate?

Mr. SAWYER. We do that so that we can sell our product at a price that is 30 percent of the price of the brand.

Ms. SLOANE. And it also has to do with the way the approval process goes through the FDA. Brand name drugs are typically approved via full new drug application which involves the clinical studies and a show of effectiveness and safety.

Because a generic drug is coming on the market after a brand name and after patent expiration, we don't have to go back and prove the safety of the active ingredient. Basically, what we do have to prove is that our product, which is a new product and a unique formulation, has the same effectiveness as the brand name drug. And, therefore, we go through an abbreviated new drug application.

Chairman RANGEL. So basically what you are saying is you don't trail the ailment and try to find a remedy for the ailment, you follow the brand name drug and then you coattail on their research so that you don't have to go through that process and see whether you can juggle it around a little bit and produce it for less?

Ms. SLOANE. We enter into the research process further on down the line. We do not do the research to develop an active ingredient, as you say, to treat the ailment. We develop a new dosage form that contains the active ingredient which has been already proven to be effective. Which is why we enter later on.

Chairman RANGEL. So if a brand name finds a cure for malaria, you don't deal with malaria. You find out what did they find out and then you see whether you can do it differently and produce it cheaper?

Ms. SLOANE. Exactly.

Mr. SAWYER. Nor do we seek the credit for anything that has already been done.

Chairman RANGEL. So you seek the money for the difference.

Mr. SAWYER. We seek the credit for our part.

Chairman RANGEL. You could have answered why brand name people don't like you.

Ms. SLOANE. We don't want to get into that.

Mr. PAYNE. I had a couple of questions.

Mr. Sawyer, you mentioned that you had been treated the same, and now you are treated differently. Does that mean that the R&E credit was available to you and for some reason now it no longer is?

Mr. SAWYER. Yes, sir. Traditionally, to my knowledge, since the R&D tax credit has been available for these kinds of purposes, generic drug companies have all taken advantage of the R&D tax credit. Along about 2 years ago, the IRS took the position in two or three cases where for the first time they took the position that the R&D tax credit was not available simply because you are generic and if you are generic, you can't be R&D.

And then it finally evolved to the issue of are you indeed reverse engineering or duplicating? And, at that point, the IRS said yes, and that is why we are trying to convince the Treasury to talk to the IRS.

Mr. PAYNE. But now the Treasury has just testified that they think each of these ought to be looked at on their own merits, is that not what the Internal Revenue Service is saying?

Mr. SAWYER. No. The IRS has taken a blanket approach and said that the generic drug industry—generic drugs by definition, if it is

in generic version, are not entitled to research and development tax credit. That is why we are so happy to hear the Treasury speak today.

Mr. PAYNE. One question for Ms. Sloane having to do with the way you develop a generic product. Is a sufficient amount of information publicly available for you to develop a generic product?

Ms. SLOANE. In terms of the brand product you are talking? A sufficient amount of information about a brand product?

Mr. PAYNE. Is it publicly available in order for you to take that information?

Ms. SLOANE. No. The extent of what is available in terms of a brand product is basically in the package insert. There may be a listing of an active ingredient in their product. That listing is standardly somewhat vague as well as incomplete.

There is—a lot of time there is a trailer that there are other inactive ingredients. It doesn't tell you the quantities or ratios of inactive ingredients that make up the formulation, and that is a critical aspect that we need to develop on our own.

That is about the only information that is available from a brand name product other than getting a sample of it. And we do our own testing on the brand product in terms of dissolution testing. That is our benchmark against what we develop. Because the theory is how the brand product dissolves is how it will behave in the body, and that is what we need to match.

We are attempting to develop a product which matches that same performance of the brand name product so we use the brand product as a benchmark in terms of examining anything else on the brand name product.

We obviously take a look at the physical examination of it in terms of size, shape and color, since we don't want to infringe upon any of that. So you really—for a generic drug product, you have to be a different size, shape or color than the brand product totally.

And what we do is we start with the active ingredient in the same dosage formula we are going for in the same strength and dosage form. From then on, we have to develop our own formula and manufacturing process to create a product which has the same dissolution performance and, hopefully, the same performance in the body as the brand name product.

But there are a lot of variables. We do not have any information on the brand product in terms of how their manufacturing process is, the order of addition, the—the quantities of the different inactive ingredients.

And there have been a number of times where we have gone to develop a product and we do not even have the same inactive ingredients because, based on our scientific experience, we have made the decision that different inactive ingredients will consistently produce the same performance as the brand name products.

Mr. PAYNE. Are these over-the-counter products or prescription?

Ms. SLOANE. No. Prescription.

Chairman RANGEL. Mr. McCrery.

Mr. MCCRERY. Thank you, Mr. Chairman.

You know, the reason we give R&D tax credits is to encourage research that will benefit society, that will have spillover benefits to society. And I understand that the research that you do is im-

portant in getting to a final product that you can put on the market at a lower cost and that is a benefit to society. What other benefits might we get from your research?

Mr. SAWYER. An interesting one is this, that the innovative product often in our history was developed in the 1960s. A lot has changed since the 1960s. And indeed FDA's regulations and attitudes toward development of a particular drug product has become much more stringent, the kinds of tests that have to be run today.

So in our developing a product later on in life, always more efficiently, and certainly huge consumer savings, we learn a lot about upgrading the entire science of pharmaceutical development.

We have, as I say, 20 or 25 years later have to approach it from a totally clean slate, and in that process we learn an awful lot about drug development. There is a turnover in house. All to the end of when the consumer is standing at the pharmacy counter and has five drugs that they need, they can afford to buy all five one way or the other instead of not buying any. And that is the end goal here.

Mr. MCCRERY. Well, let me ask you this. If a company that developed the brand name product say back in the 1960s now does additional research to find a more efficient way or a better way to package that active ingredient, would they get a tax credit for that additional research?

Mr. SAWYER. It is an interesting question. The answer is not in my view, because they are indeed starting with their product, reverse engineering it to find some better way to do it. So, in my view, they would not qualify.

However, I would point out—and I think Hank could verify—that in the committee reports to the R&D tax credit, the notion of an innovative drug product that is manufactured, let's say, in Germany and then domesticated by essentially the filing of paperwork in the United States and maybe some support testing that explicitly rates the R&D tax credit, whereas what we do does not according to the IRS. If that is not paradoxical and mind boggling, I don't know what is.

Mr. MCCRERY. Say that again.

Mr. GUTMAN. If you are a U.S. drug manufacturer and all you do is literally copy a drug that has been developed abroad, you are eligible for the R&D credit. It is a glitch in the way that the law works.

Mr. MCCRERY. But your company can do that as well?

Mr. SAWYER. No, sir, because, again, you need to distinguish between the innovator. The innovator is maybe a multinational, and they produce the exact product in Germany, and they want to bring it into the United States. They simply domesticate it. They explicitly deserve R&D tax credit. It is eligible.

On the other hand, since we are generic to begin with, the IRS says we don't care where you make it, you are not eligible.

Mr. MCCRERY. Wait 1 minute. This may be a way that we could find some money, Mr. Chairman. You mean a company in Germany develops a drug in Germany——

Mr. GUTMAN. And they bring it in and file the papers.

Mr. MCCRERY [continuing]. And all they do is bring it in and go through the procedures to get it qualified. Then they can get a ret-

roactive tax credit on the research that they have done in Germany?

Mr. GUTMAN. That is what the committee reports say. It could pay for this if it had a cost.

Mr. SAWYER. This may be the last time I testify.

Ms. SLOANE. In such a case they have the formula and the manufacturing procedures from their overseas partners which is something that we don't have, which is something that we have to develop in developing a generic drug product.

Chairman RANGEL. You got a revenue raiser here.

Mr. MCCRERY. It is certainly something that we could look at.

Anyway, I want to restate the question which I think is important and get you to distinguish for me why we should give you a tax credit but not the company that developed the innovative drug. If they go through additional research and development to "improve" their drug or to create an advanced formula or whatever, they don't get the R&E tax credit. If you went through that similar exercise you would get the tax credit.

Mr. GUTMAN. Let me answer at least one piece of that in terms of the economic rewards that the target drug company has. The target drug company has, as it should, patent protection during the period that the patent exists. Now, I think it is a nice question as to whether, at the end of that period, the improvement that the target drug company has made would qualify for the credit, and at least it is hard for me to categorically say it should or it shouldn't.

I think in some sense it is very much like the issue that is faced by the generics in terms of have they done something that has created—that has, in fact, constituted an improvement and something that was not—as a statutory matter, something that was not available simply from an examination of the product itself or from publicly available blueprints, records or other information.

Mr. MCCRERY. OK. Thank you, Mr. Chairman.

Chairman RANGEL. Mr. Neal.

Mr. NEAL. I have no questions, Mr. Chairman.

Chairman RANGEL. Well, let me thank you for clarifying an issue, and don't worry about that money. We checked with staff, and it is not that clear so we are not going to spend that yet. But let me thank you for sharing your views with us.

Before we adjourn, I see a group of young people in the back. Do you represent any particular school?

Mr. JAFARI. I am from the American University, studying for an economics class.

Chairman RANGEL. All of you are from American University? We welcome you.

And the committee will stand adjourned.

[Whereupon, at 4:04 p.m., the hearing was adjourned.]

[Submissions for the record follow:]

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CORRECTED

STATEMENT FOR THE RECORD
SUBMITTED BY COOPERS AND LYBRAND, L.L.P.

HOUSE WAYS AND MEANS SUBCOMMITTEE ON SELECT REVENUE MEASURES
HEARING ON PROPOSALS TO ALLOW RESEARCH TAX CREDIT FOR EXPENSES OF
DEVELOPING GENERIC PRODUCTS

OCTOBER 6, 1994

Mr. Chairman and members of the Subcommittee, Coopers & Lybrand appreciates this opportunity to submit testimony on behalf of the Firm and certain of our clients on the qualification for the research and experimental (R&E) credit of research and experimental expenses relating to generic products.

Our purpose in preparing testimony for this hearing is to raise two concerns with regard to legislative proposals "to modify the research tax credit to cover expenses of developing generic alternatives to brand name products." We are concerned, first of all, because we feel that such expenses already can qualify as "research expenses" under the R&E credit provisions of the tax code. And, secondly, we are concerned that if legislation eventually were enacted to "modify the research tax credit" provisions to cover such expenses, an inference could be drawn that such expenses incurred before date of enactment of the modification would not qualify for the credit. Our testimony will deal with both of these issues in the context of the generic drug industry with which we have the most relevant experience. We do think similar issues arise in other industries and products.

We appreciate this opportunity to express our opinion that expenses incurred by generic drug manufacturers in the development of generic drugs can be "qualified research expenses" and, as such, qualify for the R&E credit under Section 41 of the Internal Revenue Code (IRC). We are well aware that the IRS recently took the position in a technical advice memorandum (TAM 9346006) that a generic drug manufacturer could not claim the R&E credit for costs incurred to develop generic drugs for approval as new products by the Food and Drug Administration (FDA).

The IRS position is based on the assumption that the production of generic drugs is no more than the "duplication of [an existing] business component" and, as such, falls within the statutory exclusion from the definition of "qualified research" under IRC Section 41(d)(4)(C). We take issue with this IRS interpretation of the "duplication" exclusion. In our opinion, such a presumption not only is unreasonable but also is wholly without basis in Section 41.

It is our position that the research and experimentation necessary to develop, test, produce and market new generic drug products represent "qualified research expenses" under IRC Sections 41(b) and (d). We also believe that the expenses incurred in the development of generic drugs should not be presumed to be the result of the simple duplication or reproduction of an existing business component. Finally, we believe that for important public policy reasons, supported by Section 41's legislative history, these expenses are eligible for the R&E credit.

But, because of the IRS position, it may be necessary for Congress to clarify their intent that research and experimental costs relating to generic drugs can qualify under Section 41 as "qualified research expenses". Hopefully, this could be accomplished simply by appropriate members of Congress persuading IRS officials that the result reached in the 1993 TAM on generic drugs is contrary to the congressional intent behind Section 41 and that the result reached in the TAM should not be adopted as a general rule of construction relating to generic drugs. Whether R&E on generic drugs qualifies for the Section 41 credit should be decided on a case-by-case basis -- as is the case with the development of any other product.

Additionally, we would ask that it be made clear that any legislative deliberations or actions on this issue not be construed to prejudice past R&E efforts relating to generic drugs. Many generic drug manufacturers have relied in good faith on the availability of the R&E credit for their research and experimental costs. If they are now told that they cannot qualify for the credit simply because they manufacture generic drugs, many companies will find their past business decisions were based on rules that can be retroactively rewritten.

THE DEVELOPMENT PROCESS FOR GENERIC DRUGS

Generic drug manufacturers develop, test, produce and market drugs with the bioequivalence of brand name drugs. First, these manufacturers identify brand name drugs ("listed" or target drugs) for which they seek to develop lower-cost, generic drug substitutes. After the target drug is identified, the manufacturer begins the research and experimentation phase. The primary focus of this process is to develop a formula which successfully combines the target drug's active ingredient (which is already known to the generic drug manufacturer) with a newly devised combination of inactive ingredients (unknown to the generic drug manufacturer at the start of the research and experimentation phase) to create the generic alternative. Inactive ingredients provide the delivery mode for the active ingredient to enter the user's system. Development of the formula for combining active and inactive ingredients to produce a generic drug that produces approximately the same effect as the brand name drug is a trial-and-error process. Variations in the formula can produce unacceptable results in bioequivalance -- and thus rejection by the FDA -- of the new product. And, in some cases, the formulators fail in their efforts to develop generic drugs, either initially, upon reformulation, or in toto.

If a generic drug manufacturer succeeds in producing a bioequivalent to a brand name drug which can be manufactured economically, approval of the new drug is sought from the FDA. The manufacturer must show the FDA that the active ingredient, the route of administration, the dosage form, the strength and the conditions of use recommended in the labeling of the generic drug are the same as that for the brand name drug. In addition, good manufacturing practices must be followed and the quality of the drug in terms of its stability assured. Generic drug manufacturers also must show that the generic drug is bioequivalent to the brand name drug. FDA rejects generic drug alternatives that do not meet these requirements.

THE REQUIREMENTS OF SECTION 41(d)

Section 41(d) requires that "qualified research" --

> (1) meet the requirements for Section 174 research expenses and thus be incurred as development costs (in the experimental or laboratory sense) in the taxpayer's trade or business;
>
> (2) be undertaken to discover information which is technological in nature (i.e., relies on principles of the physical or biological sciences, engineering or computer sciences);
>
> (3) be intended to develop a new or improved business component for the taxpayer; and
>
> (4) be substantially constituted of elements of a process of experimentation for the purpose of developing a new or improved function, performance, or reliability or quality.

A generic drug manufacturer's research and experimental costs clearly can meet these requirements. They are incurred in the taxpayer's trade or business and are both developmental and experimental in nature. That is, they are incurred to discover information that will eliminate uncertainty (i.e., inactive ingredient formulations which will not meet FDA requirements) with respect to the development of the generic drug.

These R&E expenses also are incurred to discover information which is technological in nature in order to assure that no chemical reaction of active with inactive ingredients occurs. Furthermore, these expenditures are applied in the development of a new or improved business component of the taxpayer. A generic drug is a new drug, or product, and is recognized as such by the FDA. It is a new business component of both the generic drug manufacturer and the pharmaceutical industry at large. A generic drug differs in formulation, and price, from its brand name counterpart.

Finally, these expenses constitute elements of the requisite overall process of experimentation. The development of a generic drug requires that researchers determine a new formulation for an existing drug. While this process begins with an analysis of the brand name drug, it expands into ordinary and necessary laboratory research and experimentation. Scientists attempting to develop generic drugs must use trial-and-error to develop formulations, analytical methodologies, and manufacturing processes to produce the new drug. The development process for generic drugs is not always successful. For example, generic drug manufacturers have been unable to obtain FDA approval for a generic inhaler for asthma sufferers, or a generic alternative to Carafate, a drug used in the treatment of ulcers, and not absorbed systemically.

Generic drugs are "new" drugs for FDA purposes. Development of these new drugs requires much of the same laboratory experimentation that development of brand name drugs requires. A generic drug's Abbreviated New Drug Application to the FDA must show similarities to the brand name drug in dosage, strength and use, as well as bioequivalence to the brand name drug. Such similarities can only be achieved through qualified research and experimentation, and the expenses that are incurred during this process should be eligible for the R&E credit.

THE 'DUPLICATION' EXCLUSION

The "duplication" exclusion from qualified research expenses on which the IRS technical advice memorandum is based is in Section 41(d)(4)(C). The "duplication" exclusion removes from the definition of qualified research "any research related to the reproduction of an existing business component (in whole or in part) from a physical examination of the business component itself or from plans, blueprints, detailed specifications, or publicly available information with respect to such business component."

The legislative history of the duplication exclusion indicates it is intended to deny the R&E credit for expenses incurred for "reverse engineering" processes which are undertaken merely to duplicate or reproduce an existing product by physically examining the existing product. However, the legislative history clearly states that "the exclusion for duplication does not apply merely because the taxpayer examines a competitor's product in developing a different component through a process of otherwise qualified experimentation requiring the testing of viable alternatives and based on the knowledge gained from such tests." [House Report 99-841; Conference Report to accompany the Tax Reform Act of 1986 (H.R. 3838) at page II-75.]

With generic drugs, there is no duplication; there is no production of a second, identical product. Instead, after a generic drug has been developed there are two products: one is the brand name drug, the other is the generic alternative which is of a different chemical composition, although it produces substantially the same biological effect.

Scientists who work for generic drug manufacturers obviously examine brand name drugs in the course of development of generic alternatives. But their work to develop generic drugs clearly goes far beyond mere examination of the brand name drug. After a cursory examination of the brand name product, the primary focus of the process is development of a new combination of active and inactive ingredients which will produce the same biological result as the brand name drug. While the brand name drug provides a benchmark for these scientists, and its examination tells them a certain amount with respect to the active ingredient in the drug, mere examination and reverse engineering -- the costs of which are not eligible for the R&E credit -- do not provide a generic drug manufacturer with the information necessary to develop their own business component, the generic drug.

Generic drug manufacturers must determine the combination of inactive ingredients to include in the generic drug, and develop viable alternative formulations of those ingredients with the active ingredient before they can develop and manufacture a generic drug. In addition, researchers must develop physical characteristics and manufacturing techniques for the generic drug. This process requires all the traditional steps in the scientific method, including testing and retesting until failures are replaced by a new product or by a decision to abandon the effort. Thus, while knowledge gained from the testing of the brand name drug is certainly used in the development of a generic alternative, only through the process of qualified research and experimentation can a generic drug actually be developed.

ECONOMIC BENEFITS TO THE DEVELOPMENT OF GENERIC DRUGS

The distinct advantage of generic drugs over brand name products is cost. The consumer's price for generic drugs typically is no more than 50% of the price for brand name alternatives. This economic savings to prescription drug users is due in large part to the reduced cost of producing generic drugs. Scientists working for generic drug manufacturers carefully develop generic drug formulations to minimize the costs of inactive ingredients and the manufacturing process. The development of these drugs should be encouraged by government at all levels. Indeed, the House Committee Report to the Tax Reform Act of 1986 stated "activities relating to a new or improved function, performance, reliability, quality or **significantly reduced costs**, or such similar factors as set forth in Treasury regulations, may constitute qualified experimentation". (emphasis added) (House Report 99-426 page 181) At a time when health care costs have risen to such a level that national health care reform is the leading domestic issue in America, the development of generic drugs is critical and should not be discouraged through the disallowance of the research and experimental credit for qualified research expenses incurred toward the development of generic drugs.

CONCLUSION

In summary, we believe that the expenses incurred by generic drug manufacturers in the development of generic alternatives can meet the test of "qualified research expenses" under current law. A TAM is not law. It is issued without benefit of public comment or reasoned discourse. The issues in the particular TAM at the center of discussion today have not been litigated. Whatever this Committee does in this area must be done with care and sensitivity to these facts and must not prejudge the matter.

Further, we would point out that there is evidence in the legislative history of the credit that would suggest Congress intends the credit to be available for products that can meet the appropriate standards. We would hope that the Department of Treasury will revisit this issue and reach a satisfactory resolution without waiting for a legislative solution, as we strongly believe they can under the law and legislative history, and without the expenditure of vast sums by taxpayers and the government to litigate the matter.

However, if such resolution is not forthcoming from Treasury, we urge the Congress to act soon. We would hope that next year might be the time for enactment of a long overdue **permanent R&E credit**. That would be an opportunity for the Congress to clarify its intent on this issue if such action is necessary. Uncertainty is the enemy of sound tax law as a general matter and in the case of a provision intended as an incentive for certain behavior, like the research credit, uncertainty undermines the very purpose of the provision. For other sound policy reasons, encouraging the development of generic drugs is an important objective that should not be impeded.

MARK O. DECKER, PRESIDENT
NATIONAL ASSOCIATION OF REAL ESTATE INVESTMENT TRUSTS

Dear Ms. Mays:

The National Association of Real Estate Investment Trusts® ("NAREIT") represents over 230 real estate investment trusts ("REITs") whose combined market capitalization exceeds $40 billion , and more than 1400 non-REIT professionals involved in the REIT industry. Health care REITs are a significant segment of the REIT industry.

Health care REITs are REITs that either own health care properties that are leased to unrelated operating companies, or make mortgages to such operating companies. Health care REITs play an important economic role in both the health care and REIT industries. For example, REITs have invested more than $5 billion in health care properties, either as owners or lenders. This amount represents approximately 9% of the real estate investment by all REITs. These properties range from nursing homes and extended care facilities to acute care facilities.

Ways and Means Committee Press Release # 23 indicates that the Subcommittee on Select Revenue Measures will hold a public hearing in September on miscellaneous tax issues relating to health care reform. NAREIT has advocated several tax simplification changes relating to health care REITs that could allow such REITs to better finance health care operations. We would like the Subcommittee to consider these proposals if you consider them relevant to the hearings. We do not request to testify at these hearings unless you think that it would be necessary for the Subcommittee to consider our proposals We would like this statement entered into the record of the hearing.

The balance of this letter describes the health care REIT tax proposals.

Present Law

A REIT is permitted to conduct a trade or business using property acquired through foreclosure for 90 days after it acquired such property, provided the REIT makes a foreclosure property election. After the 90-day period, the REIT may no longer conduct such trade or business, except through an independent contractor from whom the REIT does not derive or receive any income. Property is eligible for a foreclosure election if a REIT acquired it through foreclosure on a loan or default on a lease, but not if a REIT acquired it because a lease expired.

If it makes the foreclosure property election in Code section 856(e)(5), a REIT may hold foreclosure property for resale to customers without being subject to the 100% penalty tax under the prohibited transaction rules. Non-qualifying income from foreclosure property generally is subject to the highest corporate tax rate (now 35%).

Under Code section 856(e)(4)(C), foreclosure property status is lost if, at some time after 90 days from the date such property is acquired, the property is used in a trade or business conducted by the REIT (other than through an independent contractor from whom the REIT does not derive any income).

Health care REITs face unique problems under the foreclosure property rules when the lessee/operator of a health care facility terminates its lease, either through expiration or default. Unlike most other forms of rental properties, if a health care property lease terminates, it is extremely difficult to close the facility because medical services to patients must be maintained. In fact, a variety of government regulations mandate measures to protect patients' welfare, which greatly restrict the ability to simply terminate the facility. In addition, because of the limited number of qualified health care providers, it can be very difficult to find a substitute provider that also will lease the property.

When a health care REIT acquires property either through a loan foreclosure, lease default, or lease expiration, the REIT must be able to ensure that the facility will remain open beyond the initial 90-day period. For many patients, especially those in rural areas, there may be no available alternative facilities in the locality. Frequently, if space is available in an alternative facility, such facility may not accept government-paid patients (i.e., Medicare, Medicaid or county assistance), which account for 70% of the residents in properties of health care REITs. Patients in facilities owned by health care REITs typically include the frail elderly, the chronically ill and the disabled who require long term care. They cannot, and should not, be evicted and forced to relocate away from supportive family and friends, which could jeopardize their health and cause treatment setbacks.

The 90-day time period during which a REIT is permitted to operate a facility is inadequate for the REIT to conclude a lease with a health care provider. Health care properties typically are acquired in a sale-leaseback transaction in which the original owner continues to operate the facility as a lessee. After this lessee vacates the property, it is very difficult to find a qualified health care provider that is willing to assume not only the operational responsibilities for the facility, but also the long-term financial risks associated with being a lessee. This is particularly true when the original lessee abandoned the facilities because of financial problems.

Regulatory requirements further complicate and delay the releasing process. Potential lessees may be required to obtain up to 30 separate licenses from separate government agencies before they can assume control of a facility.[1] In addition, many states impose certificate of need requirements when facility operators are changed. These proceedings can become adversarial and protracted.

Therefore, in order to keep a health care facility operational after the 90-day period has expired under the foreclosure property rules, a REIT must be able to hire a licensed health care provider that also qualifies as an independent contractor *from whom the REIT does not derive or receive any income or profits*. The limited pool of licensed providers that could qualify as independent contractors may be dramatically reduced, since many of these providers already lease other health care properties owned by the REIT. As existing lessees of the REIT, these providers generate income to the REIT, and thus may be viewed by the IRS as disqualified from serving as independent contractors.[2]

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[1] Fewer licenses are required for nursing homes than for acute care facilities. Changes in control also are complicated by the Medicare rule that only recognizes ownership transfers as of the end of a month.

[2] At least one REIT owns in excess of 160 health care properties that are leased to over 35 separate health care providers, none of which is able to qualify as an independent contractor under current foreclosure property rules.

The problems that arise from foreclosing on a defaulted lease or mortgage also exist in the case of a health care provider/lessee who abandons the facility upon the expiration of a lease. A final decision whether or not to renew the lease may not be made until expiration occurs, giving the REIT little or no lead time to find a substitute provider/lessee. Even if adequate notice is given to the REIT that the provider/lessee intends to quit the business, this notice does not increase the pool of health care providers that could qualify as independent contractors.

Proposal

NAREIT proposes that in the case of qualified health care properties, a health care provider should not be disqualified as an independent contractor for purposes of the foreclosure property rules solely because the REIT receives rental income from the provider with respect to one or more other properties. Qualified health care properties would be defined to include hospitals, nursing homes and other health care facilities, including related medical offices and parking facilities. In addition, the proposal would provide that a REIT could make a foreclosure property election with respect to lease expiration of a qualified health care property. The proposal would not extend the 90-day grace period.

This proposal would help ensure that important health care facilities are not forced to be closed because of a technical requirement in the Code. As with any properties that are subject to a foreclosure election, non-rental income realized by the REIT under this proposal would be subject to the highest corporate tax rate.

Statutory Language

1) Insert the following before the period at the end of the first sentence of section 856(e)(1):

> "or after there was a termination or expiration of a lease of a qualified health care property"

2) Insert the following phrase at the beginning of subparagraph (C) of section 856(e)(4):

> "except as provided in the following sentence,"

3) Add the following sentence at the end of subparagraph (C) of section 856(e)(4):

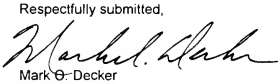
> "With respect to qualified health care property, such property will not cease to be foreclosure property solely because the trust derives or receives income that qualifies as `rents from real property' (as defined in subsection (d)) from such independent contractor with respect to other properties when the lease of a qualified health care property is foreclosed on, or is terminated or expires."

4) Add the following new paragraph (6) at the end of section 856(e):

> "**(6) Qualified Health Care Property** - For purposes of this subsection, the term "qualified health care property" means property that has been used as a health care facility (including hospitals, nursing homes, congregate care facilities, and other health care facilities), and for such other uses as may be necessary or incidental to such other related use, including medical offices and parking facilities."

Thank you for the opportunity to present our proposals. If you have any questions, please contact me or NAREIT's General Counsel, Tony Edwards.

Respectfully submitted,



Mark O. Decker
President
National Association of
Real Estate Investment Trusts®

cc: Tony M. Edwards

HEARING BEFORE THE
SUBCOMMITTEE ON SELECT REVENUE MEASURES
COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES

ON

MISCELLANEOUS TAX ISSUES

October 6, 1994

Written Statement
of
James R. Shanahan, Jr.
Price Waterhouse LLP

Introduction

I am pleased to submit this written statement concerning a proposal before the Select Revenue Measures Subcommittee to modify the research tax credit under Internal Revenue Code of 1986 (Code) section 41 "to cover the expenses of developing generic alternatives to brand-name products." The issue is important to the operation of the research credit rules, and I commend the members of the subcommittee for highlighting this matter.

The proposal addresses the IRS's ruling in Technical Advice Memorandum 9346006 (TAM) that the costs of developing a generic drug were ineligible for the research credit. The TAM is significant in that it represents the first IRS "guidance" on the 1986 Tax Reform Act's definitional amendments to the research tax credit. An IRS regulation project on these 1986 research credit changes was opened in 1990, but no rules have yet been proposed.

The TAM reflects an interpretation of the research credit's "duplication" exclusion that is inconsistent with the 1986 Act legislative history and sound tax policy principles. I believe that a legislative change is warranted unless the IRS formally modifies its position in the TAM in accordance with the comments below.

TAM 9346006

The taxpayer in the TAM, a manufacturer, claimed that certain costs incurred in conjunction with development of a generic drug were eligible for the research tax credit. The taxpayer had obtained approval of the generic drug from the Food and Drug Administration under a simplified procedure -- an "abbreviated new drug application" (ANDA) -- available in cases where the generic drug is shown to contain the same active ingredients as a previously approved "target" drug.

To develop the generic drug, the manufacturer had to discover a workable formulation of active and inactive ingredients, among other properties. While the active ingredients of a target drug are public information, the manufacturer at the outset did not know a workable formulation of the inactive ingredients. To arrive at a final formulation, the taxpayer engaged in analysis and experimentation with respect to alternative ingredients and testing and modification of the final drug.

The IRS ruled that none of the taxpayer's costs of developing the drug qualified for the research credit. In brief, the IRS found that the generic drug developed by the taxpayer represented "duplication" of the target drug, and that all research activities related to the duplication were excluded from credit eligibility. The IRS also ruled that the taxpayer could not "shrink back" to subsets of this project and evaluate whether portions may be eligible for the credit.

"Duplication" exclusion

The duplication exclusion under Code section 41(d)(4)(C) denies the research credit for "any research related to the reproduction of an existing business component (in whole or in part) of another person from a physical examination of the component itself or from plans, blueprints, detailed specifications, or publicly available information with respect to such business components." The 1986 Act legislative history refers to this type of activity as "reverse engineering."

In the TAM, the IRS appears to advance a *per se* rule that no costs associated with developing generic drugs can qualify for the research tax credit. "It is our view that Congress considers generic drugs submitted for approval under the ANDA procedure to be duplications of existing limited drugs," the TAM states. Further, "We believe the statutes and legislative histories . . . are evidence that a generic drug is a duplication of another taxpayer's business component."

The TAM thus focuses on the nature of the product, and whether it can be considered an improvement. My comments do not address the issue of whether, if the test advanced in the TAM were appropriate, the final generic drug should be viewed merely as a "reproduction" of an existing business component. Instead, I want to emphasize that a product-level focus is misguided. The question whether the duplication exclusion applies should turn not on perceptions of the end result of the research, but rather on whether the activities undertaken in reaching that result constitute elements of a process of experimentation.

Properly viewed, the duplication exclusion is part of a coherent set of rules defining research for purposes of the credit and merely details one type of activity that does not qualify for the credit because it does not involve a process of experimentation required by Code section 41(d). Thus, either the taxpayer's activities involve a process of experimentation or the taxpayer merely is undertaking duplication, adaptation, etc. In either case, the product being developed and its correlation to existing products is not relevant.

The IRS in the TAM does not contest the taxpayer's assertion that many of the activities undertaken in development of the generic drug are research or experimental in nature. Code section 41(d)(1)(C) describes "qualified research" as involving a "process of experimentation." The 1986 Act legislative history defines this term as follows:

> The term process of experimentation means a process involving the evaluation of more than one alternative designed to achieve a result where the means of achieving that result is uncertain at the outset. This may involve developing one or more hypotheses, testing and analyzing those hypotheses (through, for example, modeling or simulation), and refining or discarding the hypotheses as part of a sequential design process to develop the overall component.[1]

The taxpayer addressed in the TAM was uncertain at the outset how it would reach the desired result, and developed more than one potential formulation of the drug. The taxpayer tested the drug for compressibility and disintegration, among other properties. These types of activities are the antithesis of reverse engineering, and thus should qualify for the research tax credit. The research credit rules do not

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[1]H.R. Rep. No. 99-841, 99th Cong., 2d Sess. (Sept. 18, 1986) at II-72.

contemplate situations where a taxpayer's activities involve both experimentation and duplication.

The IRS's position in the TAM runs counter to the recently finalized regulations under Code section 174 governing the treatment of costs as deductible R&E expenditures. The final regulations state that the determination whether product development costs qualify as "research or experimental" is based on "the nature of the activities." Moreover, the regulations make clear that the nature of the product or improvement being developed and the level of technological advancement brought about by the research activities are not to be considered in determining if the costs for the activities are research or experimental expenditures.

If the IRS were to extend its holding in the TAM outside the sphere of generic drug manufacturing, IRS agents and taxpayers would be faced with a host of administrative difficulties and controversies in assessing the relative advances made by one product in relation to another. One would have to judge whether a new consumer product, for example, duplicates the function of an existing product. Questions also could arise over research undertaken to add to an existing product a function that already exists in a competitor's product. On the other hand, if the duplication exclusion is applied only to activities that are not part of a process of experimentation, these complexities do not arise.

For these reasons, the TAM should not be allowed to stand.

"Shrinking back"

The IRS in the TAM also addresses the "shrinking back" concept described in the 1986 Act's legislative history. Under this concept, the requirements for credit eligibility are applied first at the level of the entire product to be offered for sale by the taxpayer. If all the requirements are not met at that level, the test applies at the most significant subset of elements of the product. This shrinking back of the product continues until a subset of elements of the product that satisfies the requirements is reached.[2]

The IRS in the TAM rejected the taxpayer's argument that "shrinking back" was applicable in the case of the development of the generic drug. The IRS stated that

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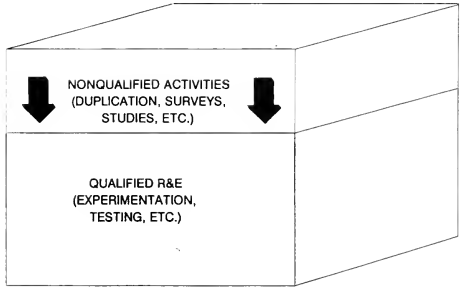
[2]H.R. Rep. No. 99-841, 99th Cong., 2d Sess. (Sept. 18, 1986) at II-72, 73.

"[i]f any duplication exists . . . no shrinking back is permitted to qualify various components or subsets of elements for the research credit." Thus, in the case of any given product, the IRS appears to be taking the position that the presence of any activities involving duplication will "taint" all activities involved in developing that product, even if the other activities are research or experimental in nature.

The "shrinking back" concept was specifically intended to avoid this result. If product development undertakings are viewed broadly, they all involve a mix of qualifying and non-qualifying activities. The "shrinking back" rule recognizes this fact and provides a mechanism for evaluating credit eligibility no matter how broadly a product development effort is initially defined.

The position taken by the IRS in the TAM could disqualify a substantial amount of experimentation that is currently undertaken from qualifying for the research credit. Where some, but not all, activities undertaken to develop a product involve duplication, the shrinking back concept should operate to qualify the taxpayer's true research activities, as illustrated below.

"Shrinking Back"



Conclusion

The IRS in the TAM takes an overly broad interpretation of the Code section 41(d)(4)(C) duplication exclusion. The IRS should clarify -- either in a reissued TAM, revenue ruling, or the forthcoming section 41 regulations -- that the nature of the activities undertaken, and not the final product itself, should control for purposes of determining whether duplication exists. The IRS should specifically clarify that the experimental activities undertaken by the generic drug manufacturer in the TAM are credit-eligible. Such action would obviate the otherwise serious need for the proposed legislative change being addressed in this hearing.

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ISBN 0-16-046313-0