S. HRG. 105–524

LEGISLATIVE PROPOSAL TO INCREASE FUNDING FOR MEDICAL RESEARCH

HEARING

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED FIFTH CONGRESS

FIRST SESSION

SPECIAL HEARING

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LEGISLATIVE PROPOSAL TO INCREASE FUNDING FOR MEDICAL RESEARCH

TUESDAY, OCTOBER 21, 1997

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

The subcommittee met at 4:50 p.m., in room SD–138, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Gorton, and Harkin.

Also present: Senator Bennett.

NONDEPARTMENTAL WITNESSES

STATEMENT OF SCOTT HALLQUIST, SR., VICE PRESIDENT AND GENERAL COUNSEL, IMMUNEX INTERNATIONAL, INC.

OPENING REMARKS OF SENATOR ARLEN SPECTER

Senator SPECTER. We will now have a panel discussion examining a possible legislative proposal relating to medical research. Mr. Perry, Mr. Hallquist, Ms. Cioffi, Mr. Love, Mr. Clarkson, step forward, please.

This panel will examine the possibilities of increasing funding for medical research by having the Government extend the period of exclusivity for certain pharmaceutical products in exchange for the company providing a dedicated royalty income stream to NIH. This is obviously a complex issue which would involve greater rights of exclusivity, which would impede upon the issue of generics. And the question is what will the impact be on the consumer? What will the help be to aid medical research?

We will proceed at this time with our panel. First, we will hear from Mr. Hallquist, senior vice president and counsel of Immunex International, Inc., a research-based biopharmaceutical company headquartered in Seattle. Immunex markets products used in the treatment of cancer that temper the side effects of cancer therapy.

We'll set the clock again at 4 minutes and the floor is yours.

SUMMARY STATEMENT OF SCOTT HALLQUIST

Mr. HALLQUIST. Thank you, Mr. Chairman. Good afternoon, Mr. Chairman, Members of the subcommittee.

As you've introduced me, my name is Scott Hallquist and I'm the senior vice president and general counsel of Immunex Corp., a biopharmaceutical company based in Seattle, WA. I appreciate this

opportunity to present my company's views regarding the proposed data exclusivity demonstration. With me today are Ruth Berkowitz and Bob Altop of the economic research firm, National Economic Research Associates, or NERA, whose analysis forms the basis for my testimony.

I am summarizing my testimony and ask permission that the entire written statement be submitted to the record.

Senator SPECTER. All statements will be made a part of the record without further request and the summaries will be appreciated.

Mr. HALLQUIST. Thank you, Mr. Chairman.

Biopharmaceutical research is at the core of Immunex's mission. We have spent nearly a half a billion dollars on research on R&D since the company was founded 16 years ago. We understand the need for research and we applaud the committee's interest in providing additional research dollars for NIH, but we strongly believe that this proposed demonstration vehicle is a flawed piece of legislation that will not achieve the objectives of the committee.

We think it's the submarine that's going to put a torpedo into the Medicare budget several years down the road and needs to be very carefully analyzed in order to calculate what those added Medicare costs are going to be.

The proponents of the demonstration contend that 5 years of market exclusivity under Waxman-Hatch does not provide adequate incentive for companies to conduct research to develop new drugs. Waxman-Hatch was carefully crafted to balance the interests of patients, drug companies and others. Combined with the benefits of our patent system, these incentives have made the U.S. pharmaceutical industry today the world's leader by any token.

Whether the existing system provides sufficient incentives or whether it should be amended directly or indirectly are issues that require significant public debate and analysis. The appropriations process is not the right forum for that kind of critical decision.

This demonstration will not incentivize new research because it applies only to existing drugs, drugs that are already available, and it actually would deter research by innovative companies that want to develop new modes of administration, new formulations or new forms of drugs that are protected under this bill.

The other justification for this demonstration is that it will provide revenue for NIH. That's a laudable objective, but there is no free lunch. Let's look at Taxol, the primary drug beneficiary of this demonstration as a specific example. Taxol is the chemotherapy drug sold by Bristol-Myers Squibb and used to treat ovarian, breast and other cancers. The active ingredient in Taxol is a compound known as paclitaxel, which was discovered by the National Cancer Institute using taxpayer dollars.

As a result of the cooperative research and development agreement, Bristol-Myers Squibb was granted exclusive rights to develop Taxol using NCI's data. Upon approval, Bristol qualified for 5 years of exclusivity under Waxman-Hatch. Their exclusivity expires at the end of this year.

Under the Bristol monopoly, Taxol is a very expensive drug. A basic treatment can cost more than $2,000. The high price of Taxol and its 5 years of exclusivity were explicitly taken into account in

the negotiated agreement between Bristol and the Federal Government. This deal has paid off richly for Bristol. Its U.S. Taxol sales in 1996 alone exceeded $500 million. Immunex and several other companies in this country would like to develop competitive products to the paclitaxel product. Our competing product is already available in Canada. A breast cancer patient in the United States pays $183 for a bottle of Taxol. Her Canadian counterpart can buy our competing product for $100.

The NERA study, which we're providing as part of the record of this proceeding, compares—was actually developed to analyze the net Medicare and U.S. budget—or U.S. health care budget impact of extending the Taxol monopoly for just 2 years. Again, this particular proposal would extend it for 5 years. The bottom line numbers are an increased cost to the U.S. health care system of more than $1 billion for just a 2-year extension, of which $288 million is attributable to Medicare expense. So in other words, the increased costs to the health care system far outweighs the benefits that would be provided to NIH, however laudable by the 3-percent royalty that the companies are offering to pay.

PREPARED STATEMENT

There needs to be further analysis of such a sweeping piece of legislation that would essentially block people and disincentivize people from doing research and providing better drugs for patients. Thank you.

[The statement follows:]

PREPARED STATEMENT OF SCOTT HALLQUIST

Mr. Chairman and Members of the Subcommittee: On behalf of the employees and stockholders of Immunex Corporation, I am grateful to the Subcommittee for affording me the opportunity to present Immunex's views about the proposed demonstration project to fund biomedical research through extensions of market exclusivity for approved drugs. If implemented, this proposal would deprive our company of the ability to provide an important cancer drug to patients. Using this drug as an example, I will illustrate for the Subcommittee the punitive and anticompetitive impact of the proposed demonstration on private sector research, health care expenditures, the federal Medicare budget, and patient access to affordable drug therapies.

Immunex is a research-based biopharmaceutical company headquartered in Seattle, Washington. We have approximately 900 employees throughout the U.S. Our mission is to develop innovative treatments for patients with serious medical needs. Since the company was founded sixteen years ago, we have spent $483 million on research and development—approximately one-half of the company's revenues over that same period of time. In 1996, our total research investments exceeded $100 million.

Immunex markets seven products in the U.S. All are used in the treatment of cancer or to temper the side effects of cancer therapy. As one example, we received FDA approval to market a chemotherapy drug called Novantrone for the 80,000 men who suffer from advanced hormone refractory prostate cancer. Until Novantrone received clearance, there were few treatment options for these patients. In addition to the development of innovator drugs like Novantrone, Immunex has developed a generic form of paclitaxel, a chemotherapeutic agent used to treat metastatic ovarian and breast cancers that have not responded to first line therapies. We intend to market this drug as soon as the exclusivity period granted to Bristol-Myers Squibb for its brand, Taxol, expires.

Thus, we are able to consider the proposed demonstration project from a unique perspective—that of a company that is fiercely committed to research and development, that develops and markets innovator drugs, and that also has an interest in generics. In our view, the proposed demonstration runs counter to sound public policy and would not achieve its stated objectives.

Proponents of the demonstration offer two principal justifications: (1) five years of market exclusivity is not sufficient to provide adequate incentive for companies to conduct research to develop new drugs; and (2) the demonstration would provide a source of revenue needed to maintain support for NIH research. Unfortunately, the proposal fails on both counts.

Perhaps there should be a reexamination of the purpose and effect of the Waxman-Hatch market exclusivity law. But the appropriations process is not the proper forum for that debate. It requires the same level of scrutiny and consideration that was applied when the law was first adopted. This is particularly true in light of the anti-competitive nature of the demonstration and its likely adverse impact on patient access to lifesaving therapies. Moreover, the proposed demonstration does nothing to incentivize new drug development since it would extend, by up to five additional years, market exclusivity for existing drugs only. It actually would deter research to develop new formulations of drugs that qualify for the additional protections. Simply put, other companies that otherwise might produce new versions with fewer side effects, easier delivery systems, or greater efficacy would be unable to receive approval and would have no incentive to conduct the research necessary to achieve these kinds of breakthroughs. Depriving patients in this way goes well beyond current market exclusivity policy.

The projected revenue stream to NIH is another fallacy. As illustrated in the Taxol example below, the cost to the government of extending exclusivity periods under this demonstration would far exceed the projected $750 million of new revenue for NIH. It also is important to note that the proposed "royalty" would not be absorbed by the pharmaceutical companies but would be passed on to patients, private insurers, and government health care programs in the form of higher prices for drugs that are shielded from competition. A tax on sick and dying patients is an inappropriate and unnecessary way to fund biomedical research.

Conservatively, at least 21 drugs would receive protection under the demonstration. But one drug, Taxol, presents the most egregious case study on why the demonstration would be a horrible investment for taxpayers and a setback for cancer patients.

The active ingredient in Taxol is the anticancer compound paclitaxel. It was discovered, formulated, and introduced into human clinical trials by the National Cancer Institute using federal funding. As a result of a cooperative research and development agreement, or CRADA, Bristol-Myers Squibb was granted exclusive rights to the NCI paclitaxel research, continued the clinical trials of Taxol, and obtained FDA approval in December 1992. In return for its investment, Bristol received five years of marketing exclusivity under the Waxman-Hatch Act. This term of exclusivity is scheduled to expire on December 27, 1997.

Taxol is an expensive drug. A basic treatment costs a cancer patient more than $2,000. Taxol pricing was the subject of a negotiated agreement between NIH and Bristol following a House subcommittee hearing in 1991 at which a senior Bristol executive testified that the drug "is neither patented nor patentable; therefore, we do not have exclusive intellectual property rights to Taxol." Taxol's high price and five years of marketing exclusivity were part of the bargain that Bristol struck with the government.

The bargain paid off for Bristol. Bristol does not separately report U.S. Taxol sales, but the market research firm IMS America estimated U.S. Taxol sales for 1996 alone to total $519 million. Other firms have estimated them to be as high as $590 million. In August of this year, Bristol reported worldwide Taxol sales of $813 million and sales in the first half of 1997 of $444 million. Taxol is well on its way to becoming a billion dollar drug and certainly needs no additional legislative preference to ensure its success.

Four years ago, Immunex began working with paclitaxel. We have a supply arrangement with an innovative Colorado company, Hauser, Inc., that pioneered paclitaxel manufacturing processes when NCI research on paclitaxel first began. Immunex and Hauser each have invested heavily to prepare stockpiles of bulk drug for formulation and sale. Hauser also has developed a manufacturing process based on renewable biomass that can assure continued supplies of paclitaxel. In undertaking this effort, we relied upon the Waxman-Hatch law and have every intention of introducing on the market a competitive paclitaxel product in the U.S. upon the expiration of Bristol's initial exclusivity period for Taxol. Several other companies have expressed the same intent.

The positive impact of generic competition to Taxol is occurring in Canada where Immunex has introduced a competitive paclitaxel injection product. The prices for Taxol in Canada are already declining as the market adjusts to competition. Whereas a breast cancer patient in the U.S. pays $183 for a vial of Taxol, her Canadian

counterpart is able to obtain the competitive product for less than $100 (U.S. dollars).

NCI has indicated its expectation that generic competition for Taxol will occur upon the expiration of Bristol's initial term of exclusivity. In a letter to Senator Ben Nighthorse Campbell, dated February 26, 1997, Alan Rabson, Deputy Director of NCI, discussed the Bristol CRADA and stated, "* * * [N]ew anti-cancer indications for paclitaxel that hopefully will arise from research under the extended CRADA may increase market opportunities for generic manufacturers of paclitaxel once they are able to enter the market in January, 1998."

Nevertheless, Bristol continues to pursue efforts to obtain extensions of its Taxol exclusivity. At one point, Bristol was seeking a two-year extension. To better understand the economic impact of such an extension, Immunex commissioned a study by an independent economic research firm, National Economic Research Associates ("NERA"). NERA estimated that a two-year extension would cost the U.S. health care system in excess of $1 billion and would cost the Medicare program alone $288 million.

The proposed demonstration would provide not two, but five years of additional exclusivity to Bristol for Taxol. In exchange, NCI would receive a mere three percent royalty. Based upon the approximately $500 million in U.S. sales now recorded by Bristol, NCI would receive about $15 million in royalties in the first year. Comparing the estimated Medicare cost impact of a two-year extension with two years worth of royalty payments under the demonstration, taxpayers would spend an extra $10 on Medicare for every $1 invested in the demonstration. When one considers the over $1 billion in added costs to all federal health programs and private sector plans, the taxpayer cost balloons to nearly $30 for every one dollar spent with regard to Taxol alone. The numbers are even more astounding when all drugs covered by the demonstration are taken into account.

The sweeping protections granted to certain drugs under the proposal actually would deter other companies from researching and developing new formulations of paclitaxel or new methods of using and administering this anticancer compound, since any drug application relating to this active compound (even new drug applications directed to uses, indications, or formulations that are not researched or developed by Bristol or included in Taxol labeling) would be frozen for five years.

Thus, the proposed demonstration actually would cost the federal government billions of dollars that otherwise could have been dedicated, at least in part, to NIH research. It would discourage important research, deny patients access to lower-cost drugs, impose a hidden tax on the sick, and adversely impact companies that have made significant investments in researching new uses for drugs that are reaching the end of their exclusivity periods.

GENERICS

Senator SPECTER. Your company, Mr. Hallquist, is Immunex Corp. So you market generics as well as patented products?

Mr. HALLQUIST. Yes; Mr. Chairman, we have seven cancer drugs in the United States now.

Senator SPECTER. It would impact on your company by raising the prices, you are saying, and, therefore, raise the cost to Medicare center?

Mr. HALLQUIST. Well, essentially extending the period in which the first approved drug has exclusivity keeps us from——

Senator SPECTER. What I am looking for is just your company's approach on it. I understand your intention. I am just trying to understand your own position of interest.

Mr. HALLQUIST. We do research and we develop new drugs which qualify either for patent protection or if they have no patent protection for Waxman-Hatch. But since we have a family of cancer drugs, we're also interested in developing additional drugs to add to that portfolio and paclitaxel is one of those.

Senator SPECTER. Thank you very much.

STATEMENT OF DANIEL P. PERRY, EXECUTIVE DIRECTOR, ALLIANCE FOR AGING RESEARCH

Senator SPECTER. We turn now to Mr. Daniel Perry, founding executive director of the Alliance for Aging Research.

Mr. Perry, the floor is yours.

Mr. PERRY. Thank you, Mr. Chairman. Mr. Chairman, you have a copy——

Senator SPECTER. You may have been out of the room, but the lights will function on 4 minutes leaving us more time for dialog.

Mr. PERRY. Thank you.

You have a copy of my testimony, as do the members of the committee and the subcommittee. Rather than try to read that testimony or to summarize it, I would just like to underscore a couple of key points.

Senator SPECTER. That is fine.

Mr. PERRY. My organization is a not-for-profit advocacy organization that seeks to increase the priority of biomedical and scientific research in aging and chronic diseases of the elderly. Not surprisingly, we see that the greatest challenge to the United States and, indeed, to the world is the graying of nations.

It is the greatest medical, economic, social, and political challenge that we face. We believe that only by finding interventions and means to modify chronic, very costly long-term conditions that now accompany aging will we be able to navigate with success the aging of today's current unprecedentedly large populations of older people and the baby boom generation still to come.

It will only be if we can coax forward new innovations in diseases such as Alzheimer's, osteoporosis, stroke, diabetes related to aging that we will be able to see the success of that generation. The Federal Government's responsibilities in this area are key to—in supporting the National Institutes of Health and research, the Veterans' Administration and elsewhere. As Mr. Chairman, you and others in this committee know all too well, the current appropriations process, in all due respect, is broken when it comes to being able to provide long-term insurance that we're going to be able to grow the enterprise of medical research in this country. We're faced with kind of a cruel zero sum game.

First of all, with the laudable effort to move toward a balanced budget but with firewalls and the shrinking discretionary funds, we find that medical research is pitted against education, job training, low income energy assistance, a zero sum kind of format. And even more cruel, we're in a situation where we are having to pit breast cancer research advocates against research for aids, diabetes against spinal cord injury, diseases of the young against Alzheimer's disease. We have heard the appropriators say to the health advocacy community help us find new streams of revenue, help us find public-private partnerships that can supplement what we are currently trying to do at NIH.

The Alliance for Aging Research has endorsed in recent months and years the Harkin-Specter legislation that would do this. We've endorsed Harkin-Hatfield, we have supported levy on tobacco taxes, on tobacco to increase funding for medical research. We have supported moving savings from Medicare into this area and a $1 per insurance policy in health. We have tried all sorts of ways and

today you have a proposal that I think has some unique attractiveness in that it underscores incentives for companies to invest private-sector money in research. It provides a direct royalty feedback to NIH, and it moves toward greater harmonization globally with our trading partners.

Biomedical research is already providing a huge payoff. We released a study from Duke University earlier this year that showed that already disability among the Americans aged 80 and older has declined some 15 percent from the early 1980's to the present. This has already saved the Medicare system between $25 and $44 billion, according to this study from Duke University.

PREPARED STATEMENT

The benefits for Medicare are enormous in the savings we will provide if older people stay out of nursing homes and stay out of the need for hospital care as long as possible. This is a mechanism that will underscore the current pipeline of research, both public and private. We think it deserves your consideration.

Senator SPECTER. Thank you very much, Mr. Perry. I am going to have to take a very brief absence to return a call. Senator Bennett will preside in the interim.

[The statement follows:]

PREPARED STATEMENT OF DANIEL PERRY

Mr. Chairman and Members of the Subcommittee: Thank you for the opportunity to testify before this subcommittee today. I am Daniel Perry, Executive Director of the Alliance for Aging Research, an independent, not-for-profit organization working to stimulate academic, government and private sector research into the chronic diseases of human aging. I am here today to discuss the general need for continued increases in biomedical research funding, and specifically to urge your careful consideration of a proposed Demonstration Project to Fund Biomedical Research at the National Institutes of Health.

The research that is carried out at virtually every institute within the NIH has the potential to shed light on the chronic diseases of aging. The benefit of biomedical research at the NIH—namely, the ability to achieve longer, healthier lives—accrues not only to older people, but to all Americans. The processes of aging increases the risk of heart disease, cancer, stroke, arthritis, osteoporosis, depression, diabetes, and Alzheimer's disease, to name but a few. The cost of treating those eight diseases alone is staggering, over $573 billion each year. Unless we discover better ways to treat, prevent or postpone these diseases, this figure will grow exponentially in the coming years, as our population grows older.

The growing tide of older adults is just now beginning its sharpest rise, as the members of the first wave of the "baby boom" generation are turning 50 years of age. In just fourteen years, these individuals will be collecting Medicare old age benefits from the federal government. The Health Care Financing Administration has projected that half of all health care dollars spent in the U.S. will soon be used for treating unsolved medical problems of the elderly. It is therefore imperative that resources be dedicated today to research and reduce the costs associated with the chronic diseases of aging.

Older Americans, aging Americans, their families, and the nation as a whole, are benefited by discoveries in health care that come from biomedical research. These innovations have the potential to decrease significantly the need for, and cost of, hospital and nursing home care. We are already seeing the payoff in Medicare spending of past investments in research. A study conducted by Duke University's Center for Demographic Studies, released earlier this year, found that chronic disability rates among older Americans declined nearly 15 percent from 1982 to 1994, resulting in savings for the Medicare program of between $25.4 billion and $33.3 billion. Finding ways to keep Americans healthy longer through medical research simply has to be central to our efforts to keep Medicare solvent. Even a brief delay in the incidence of age-related disability can translate into dramatic savings for our economy. We estimate that postponing physical dependency for older Americans by

just one month would save the nation $5 billion a year in health care and nursing home costs. Postponing the onset of Alzheimer's disease by five years would, in time, save $50 billion a year in health care costs. And a five-year delay in the onset of cardiovascular disease could save an estimated $69 billion a year.

The need for greater national biomedical research efforts cannot be denied. Unfortunately, severely limited and shrinking federal discretionary funding has left the American biomedical research enterprise in jeopardy on many fronts. While we appreciate Congressional support for increased NIH allocations, we also understand that competing interests, budget constraints, and the vagaries of the political process have left the NIH budget in jeopardy and have removed the certainty that NIH will be able to sustain ongoing high quality research.

At present, nearly 4 out of 5 peer-reviewed research projects deemed worthy of funding by the NIH are forced to go unfunded. No one can be satisfied when eighty percent of worthy research projects cannot be funded. Not only does this cheat the American public of the results of that research, the funding crisis for medical research undermines the pipeline of medical discoveries we will need in the future. Moreover, the biomedical research rate of inflation has reduced research funding in real terms, and has eroded the technology infrastructure required for groundbreaking research and discovery.

Mr. Chairman, no one knows better than you, Senator Harkin, and the other members of the subcommittee how very difficult it will be to increase direct federal funding for research in the coming years. There are simply no remaining non-Defense discretionary funds available to put into research. The commitment to eliminate the deficit leaves medical research funding in a cruel, double zero-sum game.

The first zero sum is within the context of the overall discretionary budget. Any increase in funding for research must come at the expense of some other worthy program. The second, and frankly, more cruel, zero-sum game is the way in which an increase in funding for research on any specific disease or disability has to come at the expense of another disease or disability. Pitting diabetes against spinal cord injury, AIDS against breast cancer, diseases which predominate in women against those which strike more men, is hardly a rational or desirable way to function. Clearly, the current means of funding medical research are broken and new ways must be found, especially if there is to be any hope of realizing the Senate's goal of doubling the amount spent by NIH over the next five years.

In light of the current situation, it is critical for Congress to explore creative and novel ways to increase funding, including added incentives for private sector contribution to biomedical research. The Alliance over the years has supported various efforts to get more dollars into research—such as an increase in tax on tobacco, or redirecting Medicare savings, or a per capita fee on health insurance premiums. The Demonstration Project to Fund Biomedical Research, which is the subject of today's hearing, is another example of an opportunity to boost research efforts which will benefit the public both today and in the future. The demonstration project's provision of limited extended periods of market exclusivity for eligible new drug products in exchange for royalty payments to further biomedical research at the NIH would provide substantial off-budget revenues to maintain the preeminence of American biomedical research and deserves your careful consideration.

The Demonstration Project to Fund Biomedical Research is a voluntary, time-limited demonstration project which would generate funds in excess of $750,000,000 over five years for increased NIH funding of peer-reviewed biomedical research on serious or life-threatening diseases and conditions. As cooperative partners, private industry would commit at least an equivalent amount of funds to private sector research and development efforts in these areas. Funds would be generated from the extension of new data exclusivity for previously approved drugs; the maximum possible extension would be five years. During the extended period, the pharmaceutical company would pay NIH a royalty on net U.S. sales of the product and be obligated to invest an equivalent amount in private sector research. No product would have more than 10 years of exclusivity.

It is important to note that this additional five years of exclusivity brings the United States up to the 10 year period of exclusivity already granted in countries such as France, Germany and Great Britain. Harmonizing the United States' provision of 5 years of new drug exclusivity with the European standard of 10 years is necessary to keep the United States competitive in biomedical research and to maintain the ability of Americans to access the most innovative research for the treatment of chronic disease.

As a demonstration project, authority for this program would expire in five years, at which time the benefits of this boost in research funding may already be evident.

As a nation, we have choices. We can choose to make an increased investment in finding new ways to prevent, cure and treat age-related diseases now, or we can

choose to wait and pay for an unparalleled increase in the cost of caring for our oldest citizens later. Clearly, the choice should be funding the needed research. But we must be realistic and acknowledge that we cannot rely solely on government financing for the effort.

In closing, let me reiterate the paramount importance of biomedical research to the health—both physical and economic—of our nation. Dramatically increased funding for the American biomedical research enterprise is good for the health of the American people, good for the future of the Medicare program, and good for the nation's economy. The challenge of funding biomedical research requires the need to pursue creative solutions, including the Demonstration Project before you today. Failing to adequately fund biomedical research will result in the continued precipitous rise in health care costs for the American people.

Thank you for the opportunity to testify before you today. I would be happy to respond to any questions which you may have.

LETTER FROM THE ALLIANCE FOR AGING RESEARCH

OCTOBER 21, 1997.

Hon. ARLEN SPECTER,
Chairman, Subcommittee on Labor-HHS-Education, Committee on Appropriations, U.S. Senate, Washington, DC.

DEAR SENATOR SPECTER: It is our understanding that the Alliance for Aging Research has suggested an innovative demonstration program to increase funding for the National Institutes of Health, a goal we all share.

As you well know, and in spite of your outstanding work on the subcommittee, nearly four of every five peer-reviewed, approved research projects at NIH remain unfunded. With the additional pressures placed on domestic discretionary spending by the Balanced Budget Act, there is clearly a need for creative and innovative sources of revenues for NIH that will permit research to continue to advance.

The Alliance's demonstration program would extend the period of data exclusivity for certain pharmaceutical products for up to five years in exchange for royalty payments to the NIH, as well as a requirement for an equal private investment in research. It is a concept with a great deal of merit.

Your leadership in the field of biomedical research funding has been critical in the progress we have made to date. We respectfully encourage you, through your subcommittee, to move forward on a proposal such as that advanced by the Alliance for Aging Research.

Alliance for Aging Research; Beckwith-Wiedemann Support Network; Charcot-Marie-Tooth Association; Cooley's Anemia Foundation; Cystic Fibrosis Foundation; Depression and Related Affective Disorders Association (DRADA); Dysautonomia Foundation, Inc.; International Patient Advocacy Association; International Rett Syndrome Association; Jeffrey Modell Foundation; Malignant Hyperthermia Association of the U.S. (M-HAUS); MPS Society, Inc.; National Osteoporosis Foundation; Purine Research Society; PXE International, Inc.

LETTER FROM DR. ROBERT L. COMIS

OCTOBER 20, 1997.

Hon. ARLEN SPECTER,
U.S. Senate,
Washington, DC.

DEAR SENATOR SPECTER: The undersigned organizations represent people with cancer and the health care professionals who treat them. We understand that you are conducting a hearing on a legislative proposal to increase research funding for the National Institutes of Health (NIH) through royalties paid in exchange for additional marketing exclusivity for certain products. We are writing to express our support for this provision.

If patients are to receive the benefit of basic biomedical discoveries, there must be.more innovative approaches to encourage both the public and private sectors to pursue greater clinical research opportunities. The legislative proposal would provide incentives for companies not only to contribute to NIH funding, but also to conduct their own privately sponsored research in the same therapeutic area as the drug receiving additional exclusivity.

Thus, the proposal fosters the sort of public-private collaboration that is most likely to advance both basic and clinical cancer research. In addition, enactment of this

legislative proposal would bring U.S. law into greater conformity with exclusivity provisions in Europe, where ten years of exclusivity are generally available, in contrast to five in this country.

While we support the package of incentives represented by this legislation, we believe that it would be greatly enhanced if there were a mechanism for ensuring that current levels of appropriated NIH research funding would be maintained so that the royalty payments supplement rather than simply replace public funds.

We appreciate your attention to this issue of great importance to people with cancer and look forward to your hearing and subsequent introduction of the legislation.

Sincerely,

National Coalition for Cancer Survivorship; Cancer Care, Inc.; Candlelighters Childhood Cancer Foundation; National Alliance of Breast Cancer Organizations (NABCO); US TOO International, Inc.; Y-ME National Breast Cancer Organization (Y-ME); American Society of Clinical Oncology; Alliance for Lung Cancer Advocacy, Support and Education; Oncology Nursing Society.

LETTER FROM EASTERN COOPERATIVE ONCOLOGY GROUP, GROUP CHAIR'S OFFICE, ALLEGHENY UNIVERSITY, CANCER CLINICAL TRIALS RESEARCH CENTER

PHILADELPHIA, PA, *October 14, 1997.*

Hon. ARLEN SPECTER,
U.S. Senate,
Washington, DC.

DEAR SENATOR SPECTER: As president of a not-for-profit foundation which represents the interests of the Eastern Cooperative Oncology Group (ECOG), a National Cancer Institute clinical teals cooperative group, and a practicing oncologist, I know first hand the vital role biomedical research plays in battling life-threatening disease. I am compelled to write at this time in support of the novel proposal for increasing NIH finding for biomedical research currently scheduled for hearings before the Senate Appropriations Labor, Health and Human Services Subcommittee on October 24, 1997.

Over the last few decades federal dollars have been shrinking, making it more and more difficult to carry out innovative cancer clinical teals. In ECOG, as well as other national cancer cooperative groups, funds are being stretched to encompass current projects and trials. This allows little remaining resources to devote to planning and execution of future trials. In fact, ECOG as well as the other U.S. cooperative groups are funded at only about 50 percent of the level approved by the peer review process. In order to survive, the nation's cancer cooperative groups need to find ways to increase and diversify their funding base, as does the entire research support structure of the NIH.

The proposed legislation would create a 5-year demonstration project in which pharmaceutical companies could agree to pay a royalty on U.S. sales of certain eligible products in exchange for an extension of up to 5 years of market exclusivity. The millions of dollars that would be generated by this proposal would make an enormous impact on the abilities of research organizations such as ECOG and other National Cancer Institute funded programs to find better, more effective cancer therapies. The developments made in research, as you may know, ultimately impact standard care nationwide, thereby affecting the lives of millions of Americans.

Assuming that such an innovative agreement can be made with industry, it will be extremely important for the bill to be written in such a way that the new dollars actually go to fund research, land not other endeavors.

Research is the key to improving patients' quality of life now and, ultimately, finding a cure for this disease. Without this type of creative funding the limited federal funds currently available will cause stagnation of treatment development and drastically affect patient care. I, therefore, strongly urge you land your colleagues in Congress to lend your support to this effort.

Sincerely,

ROBERT L. COMIS,
President, ECOG Foundation.

STATEMENT OF KENNETH W. CLARKSON, Ph.D., DIRECTOR, LAW AND ECONOMICS CENTER SCHOOL OF LAW AND BUSINESS, UNIVERSITY OF MIAMI

Senator BENNETT. Whom do we go to next, Mr. Chairman? Or do I get to decide that?

Senator SPECTER. Yes.

Senator BENNETT. Dr. Clarkson.

Mr. CLARKSON. Good afternoon, Mr. Chairman, as you're leaving, members of the subcommittee. Thank you for the opportunity to testify before the subcommittee today. My name is Ken Clarkson and I'm a professor of law and economics and director of the law and economics center at the University of Miami where my areas of research and publication focus on regulating markets, public policy legislation, among other topics.

I have conducted economic analyses of the pharmaceutical industry for over 20 years and have published extensively on the outcomes of alternative incentive systems, including the relationship of incentives, financing and outcomes for biomedical research. I also have a prepared statement which I will submit and at this time and I'd like to just briefly summarize.

Senator BENNETT. By all means.

Mr. CLARKSON. Clearly the central issue before the committee today is how to best achieve reductions in the rates of morbidity and mortality for the U.S. population in a fiscally responsible manner. It involves a tradeoff between the early introduction of lower prices and additional dollars for NIH, increased company R&D, higher information infusion rates and improved global incentives for American companies.

The demonstration project to fund biomedical research is a novel mechanism to create additional research and development efforts to address compelling health problems first, while establishing extension of exclusivity to induce continued R&D, the project provides off budget financing to the National Institutes of Health. This will help reduce the four out of five rejection rate at NIH.

Second, the demonstration project provides additional research dollars for completion of existing clinical trials.

Third, it also provides incentives for examining a wide spectrum of new indications, including potential spinoff treatments and compounds, optimizing dosing amounts and schedules, exploring the use with other compounds, investigating the application to pediatric populations, and developing improvements in drug formulation.

In the absence of incentives created by data exclusivity, it is highly unlikely that the appropriate commitment to conduct these activities will exist. When incentives are improved, as they were in the Patent Restoration Act, R&D by research intensive firms rose by 36 percent in the decade following the passage of that act.

While controversial, the exclusivity for AZT caused innovator companies to develop or discover other compounds, creating an environment where cocktail therapy is now possible. If AZT had been initially available as a generic, prices would have been lower and innovation limited. As a result, morbidity and mortality would have been higher.

The lower price of aspirin has significantly delayed research and development for an improved indication for the prevention of heart attacks, an example where the absence of exclusivity has limited infusion and innovation.

Fourth, the demonstration project creates proper incentives for more rapid information infusion and patient uptake.

And finally the demonstration project data corrects an international imbalance between the rewards for conducting the research and development in the United States versus major European countries.

PREPARED STATEMENT

In conclusion, the expected societal benefits of increased revenues to NIH, additional company R&D, more rapid information infusion and the correction of international R&D incentives compared to the projected limited cost savings generated by earlier introduction of generic goods is more than sufficient to undertake this demonstration project.

Thank you.

Senator BENNETT. Thank you.

[The statement follows:]

PREPARED STATEMENT OF KENNETH CLARKSON, PH.D.

Good afternoon Mr. Chairman, Members of the Subcommittee. Thank you for the opportunity to testify before this subcommittee today. My name is Kenneth Clarkson. I am Professor of Law and Economics and Director of the Law and Economics Center at the University of Miami, where my areas of research and publication focus on regulated markets and public policy legislation, among other topics. I have conducted economic analyses of the pharmaceutical industry for over twenty years, and have published extensively on the outcomes of alternative incentive systems, including the relationship of incentives, financing, and outcomes for biomedical research and development.

The proposal before the subcommittee today, the Demonstration Project to Fund Biomedical Research, relies upon the extension of market exclusivity for a limited number of pharmaceutical products to generate funds for both federal and private sector research on serious or life-threatening diseases. This is a novel mechanism by which to provide off-budget financing to the National Institutes of Health, our nation's premier biomedical research facility.

My objective today is twofold. First, I would like to help you understand that market exclusivity is a necessity for incentivizing further commitment of private research dollars for pharmaceutical products, and that our system's current provision of five years of exclusivity is insufficient to keep the American biomedical research industry globally competitive. Second, in your considered deliberations, I would like to ask that you weigh the future reductions in societal morbidity and mortality which will result from today's investments in biomedical research against the short term costs associated with prolonging the entrance of generic competitors into the market.

Today, it is estimated that the amount of research and development expense necessary to bring a significant new drug to market exceeds several hundred million dollars. Yet while this number continues to rise to reflect increasing research costs, the life cycle over which these costs can be recovered is shortening and new payor practices are preventing broader use and full price reimbursement for innovator drugs.

Financial constraints imposed by more restrictive reimbursement policies from both private and public insurance programs have diminished the ability of pharmaceutical innovators to recover the costs of research, development, and market information dissemination for their products. This has resulted in a slower rate of uptake for innovative drugs, as well as shrinking aggregate payments for those drugs. These factors, when combined with a too-short exclusivity period, tend to drive innovator prices higher during the shortened exclusivity period and create disincentives for further drug development. Thus, under today's conditions of discouraged use of innovator compounds, it is all the more imperative that pharmaceutical firms be encouraged to increase their expenditure on research and development, as well as on the market-expanding information diffusion efforts critical to spreading information—and costs—on innovative treatments as broadly and quickly as possible.

Extension of periods of market exclusivity, as under the proposed Demonstration Project, would help to counter the current condensed rush to recover costs and the abandonment of further research on these compounds that occurs at the end of the prevailing five year period of market exclusivity. Ultimately, under the Demonstra-

tion Project proposed today, providing market exclusivity successfully capitalizes on private industry to attain public goals of reducing morbidity and mortality as well as resolving budgetary inadequacy and uncertainty for the NIH. Increasing the period of market exclusivity to a maximum of ten years also corrects a competitive imbalance which exists, since the major European nations have concluded that ten years of data exclusivity are necessary to fully develop promising new drugs.

Extending the period of market exclusivity for drugs which would qualify under the Demonstration Project does raise the possibility of delayed lower prices for those drugs in the short run. However, any objective evaluation of the relative merits of extending market exclusivity for drugs must weigh the potential social benefits gained from continuing to incentivize development against the potential social loss due to higher product prices. Moreover, higher prices during exclusivity would provide increased royalty payments to NIH.

Allowing exclusivity on these drugs to expire threatens the funding and completion of their associated clinical trials and research programs, reduces the chance of gaining new understanding about efficient treatment methods or novel applications of these drugs, and prevents wider information dissemination concerning the drugs and their therapeutic areas of application. Loss of exclusivity strongly reduces the probability of further investment on compound development or information diffusion activities. Diffusion or dissemination of information broadens the exposure and use of a compound, thereby making it more available to help patients requiring treatment, and is more effectively accomplished by continued marketing expenditures. A strong correlation exists between a high level of pharmaceutical information diffusion and added social welfare.

With extended exclusivity, the benefits which would occur with further research on these drugs include widening the spectrum of indications in which these drugs are known to be effective, examining potential spin-off treatments and compounds, optimizing dosing amounts and schedules, exploring their sequential use with other compounds, investigating their application to pediatric populations, and permitting improvements in drug formulations. I hope you will consider each of these benefits and their potential contributions to societal welfare in your analysis of this proposal.

My experience in this field has led me to conclude that the economic incentive established by an extension of exclusivity is likely to generally produce societal benefits which outweigh the limited cost savings generated by earlier introduction of generic goods. The added benefit of off-budget financing for the NIH under this Demonstration Project shifts the balance even further in favor of exclusivity. Particularly in a time of governmental fiscal restraint, providing economic incentives to achieve social objectives is a prudent alternative to higher federal spending.

Thank you for your time, and I would be happy to answer any questions which you may have.

STATEMENT OF GINA CIOFFI, NATIONAL DIRECTOR, COOLEY'S ANEMIA FOUNDATION

Senator BENNETT. Ms. Cioffi.

Ms. CIOFFI. Thank you. My name is Gina Cioffi. I'm the national executive director of the Cooley's Anemia Foundation. The foundation has been working for more than 40 years to provide services to anemia patients, to provide educational prevention programs and fund medical research.

At the outset, I just want to thank the committee for their support for medical research, for innovative proposals, and count on our support for the proposal here today.

You're asked to consider extending the market exclusivity period of certain pharmaceutical products in a limited 5-year demonstration product. We believe it is an incredible proposal. We have 16 chapters throughout the country working to raise medical research dollars. They have dinners, they have fashion shows, they have done very, very well.

We have been able to increase this past year by 50 percent the amount per fellowship. We're proud of our success, but we're also limited in our resources and what we're able to do. We're a rare disease, we're a small patient population.

In June we had an international symposium. We know that there's a cure, that there's better treatment within our reach, but we need the money, and the money has got to come from somewhere, and this is an innovative proposal that we think will be very helpful.

A number of the pharmaceutical products involved are for conditions related to the blood. Many of our patients are dealing with the effects of infection by HIV, hepatitis C and other viruses. The deactivation of these viruses is important to us. We think that the infusion of research funds in a given area, as we all know, will lead to the discovery of new uses of an existing product or a new compound or sometimes something tangentially related.

For example, many of our patients would benefit immeasurably from development of a way to deactivate the viruses in the blood that they're receiving blood every 2 weeks.

At a meeting of the special emphasis panel last year, NIH cited five areas of high priority research. They include: The need for medication that can be taken orally to remove iron from their organs; development of a noninvasive way of measuring the iron in their body; development of medications to treat fetuses in utero; and development of appropriate hormonal therapies.

Our patients are suffering. They're in serious need of medications and treatments identified by NIH last year. An oral drug to help remove iron from their body would free them from 12 hours of daily painful drug infusion. Fetal and gene therapy treatments could help relieve a lifetime of suffering.

The potential for breakthrough exists, just not the money to make it happen. We understand that there's no guarantees that there will be a breakthrough that will help our patients as a result of this action, but we know that there could be.

With less than 25 percent of approved peer review research products receiving funding, every additional dollar that can be generated for research increases the possibility that someone will find the means to relieve the suffering of our patients.

Funding has to come from the Government acting through the NIH and it has to come also from the private sector. This proposal embodies both of these elements. With NIH and an equal investment in private research in the same therapeutic area, you're creating additional opportunity for discoveries that will cure disease, relieve symptoms and improve the lives of your constituents.

When a baby is born with Cooley's anemia, it has a life expectancy that's much more improved than 25 years ago; these children didn't live past 10 years old. But just over the horizon, we hope for a time that a baby can have the life expectancy of any other and to reach that point will require a commitment of research dollars.

PREPARED STATEMENT

And I just want to add that in terms of a generic drug, Desferal is the only drug available for our patients right now, and there hasn't been anybody stepping up to come up with a generic drug because we're such a small patient population so that's not an area where they can really avail themselves.

I just want to thank you all for your leadership and your vision and thank you for inviting me to be here today.

Senator BENNETT. Thank you.

Now Mr. Chairman, I must step out. We've heard from everyone but Mr. Love, but I should be back as shortly as you.

Senator SPECTER. OK. We will put Ms. Cioffi's prepared statement in the record at this point.

[The statement follows:]

PREPARED STATEMENT OF GINA CIOFFI

Mr. Chairman and Members of the Subcommittee, my name is Gina Cioffi and I am the National Executive Director of the Cooley's Anemia Foundation, which is headquartered in Flushing, New York.

At the outset, Mr. Chairman, I would like to thank you for the invitation to testify before your subcommittee this afternoon. But, even more importantly, I would like to thank you for your leadership in supporting biomedical research in our country. Your efforts related to the Senate's appropriations bill for the 1998 fiscal year in which you obtained a 7.5-percent rate of growth for NIH is truly extraordinary.

Likewise, Mr. Chairman, your active stewardship, along with Senator Harkin, of the Specter-Harkin Health Research Trust Fund, has firmly established your credentials as the leader of this body in supporting NIH and biomedical research. On behalf of my organization, and many others like us, I thank you for the vision and the leadership you have exhibited.

Cooley's anemia is a genetic blood disease. For our patients to survive, they are required to have their blood transfused red blood cells every ten to fourteen days. When a person has blood transfusions that frequently, there is a life-threatening side effect that develops silently and, initially, without symptoms. Iron accumulates in the liver, the heart, and in other internal organs. If no steps are taken to remove the iron, the patient will die.

Twenty-five years ago, a drug was developed which helps to remove the iron from the internal organs. That drug is called Desferal, and it remains today as the only effective treatment for this condition. But, there is a terrible downside to the use of Desferal. It is not a pill or a liquid that can be taken by mouth. It cannot even be given in the form of a shot, like insulin. Desferal must be infused.

Cooley's anemia patients have this drug infused into their bodies for ten to twelve hours a day, every day of their lives. It is painful; it is severely limiting; it is their only option.

It is that lack of options that brings us to the legislative proposal that is pending before the subcommittee this afternoon and that is the subject of this hearing.

Mr. Chairman, the subcommittee is being asked to consider the creation of a limited, five-year demonstration program. A pharmaceutical company could receive up to five years of new market exclusivity for a drug that has been previously approved by the FDA. In exchange for that provision, the company would be obligated to pay a three percent royalty on net U.S. sales of that product during the new exclusivity period to the National Institutes of Health. At the same time, it would also be required to invest not less than an equal amount in research and development efforts in the general therapeutic area of the eligible product.

It is my understanding, Mr. Chairman, that there are about sixty pharmaceutical products that would potentially be eligible to participate in this demonstration. It is my further understanding that this demonstration program will result in more than a half billion dollars in additional NIH funding over the next five years, with an equal amount of private investment.

A half dozen or more of the products that are eligible for coverage by this provision are related to blood and that has certainly caught our attention. The infusion of research funding in a given area, as we all know, often leads to the discovery of new uses for an existing product. Similarly, it can lead to the development of a completely new compound in an unexpected, but related area. That is why the Cooley's Anemia Foundation is supportive of this proposal.

Last year, the NIH convened a Special Emphasis Panel to determine the most promising areas of research for thalassemia, the formal name for Cooley's anemia. They identified five:

—Support for clinical trials of more effective iron chelators and measurement of patient compliance with drug therapy.
—To support clinical trials of fetal hemoglobin enhancing drugs.
—To support research on improved technology for non-invasive measurement of iron deposits in human tissue.
—To develop plans for research into the need for hormonal therapy and its long-term effects on patients with Cooley's anemia.

—To support clinical studies of the phenotype vs. genotype of beta-thalassemia intermedia.

Our patients are suffering, Mr. Chairman. There is a serious and critical need for the research and development that will result in the medications and treatments that the NIH identified last year. An oral drug to help remove iron from the body can free a patient from 12 hours of daily, painful infusions with Desferal. Fetal and gene therapy treatments hold the potential to relieve a lifetime of suffering. The potential for a breakthrough exists. What we are lacking today is sufficient resources to make it happen.

All of us that are involved in the voluntary health agency community understand how medical research works. We know that there are no guarantees that the adoption of this proposal, or any other, will guarantee a breakthrough that will assist the patients that we care so deeply about. However, we also recognize that there could be.

With 25 percent of approved, peer-reviewed research projects currently receiving funding (in spite of the outstanding work of this subcommittee), we know that every additional dollar that can be generated for research increases the possibility that someone will find the means to relieve the suffering of our patients.

We also understand that, in 1997, money has to come from more than one source. Public/private partnerships are the way things get done today. Funding has to come from the government, through the NIH, but it also has to come from private industry. By requiring the payment of a royalty to the NIH and equal investment in private research in the same therapeutic area, this proposal creates the environment within which there are additional opportunities for discoveries that will cure diseases, relieve symptoms, and improve the lives of your constituents.

Mr. Chairman, twenty-five years ago, a baby born with Cooley's anemia rarely lived much beyond ten years of age. Today, thanks to treatment improvements that have been made, life expectancy is much better. But, just over the horizon, we hope for a time when that baby can have the same life expectancy as any other child. In order to get to that point, however, will require a strong and unwavering commitment of research dollars.

Everyone in this room, Mr. Chairman, knows that you have made that commitment throughout your legislative career. The support of this proposal by the subcommittee will go a long way toward furthering that commitment, finding cures, and relieving human suffering. I respectfully urge you to move forward with it.

Again, Mr. Chairman, I want to thank you for the opportunity to address the subcommittee this afternoon. I would be pleased to try to respond to any questions you may have.

STATEMENT OF JAMES LOVE, DIRECTOR, CONSUMER PROJECT ON TECHNOLOGY, ON BEHALF OF THE CENTER FOR STUDY OF RESPONSIVE LAW, WASHINGTON, DC

Senator SPECTER. Mr. Love.

Mr. LOVE. Thank you very much. I passed out my statement kind of late. I hope you all got it. I'm not going to read my statement but, rather, summarize a few points.

First of all, as I understand the proposal that is being considered today, there's this idea that linking these R&D percentage royalties or commitments on behalf of pharmaceutical companies on the one hand to increase biomedical research with an extension of their exclusive rights to data on the other hand, and I think it's appropriate for the committee to hear praise about one-half of the plan and to reject the other half.

That is to say, I think there's a lot of interest and I think it's very innovative, the idea that you would impose obligations on companies to sell drugs and reinvest in research and development in the United States and impose research royalties to help fund biomedical research by the NIH. That's a completely separate issue which should be severed and considered on its own merits, wholly apart from whether you decide to extend rights in data.

Now, the health registration issue has to be looked at in the sense it's not the only way innovation in drugs is growing, pro-

tected. Companies that invent drugs or invent uses for drugs get patents on drugs. And companies which bring drugs to market which have small client populations are protected under exclusive provisions of the Organ Drug Act.

What's left over is drugs where the company does not claim to be the inventor, drugs which are not for small client populations, in fact for big client populations where there are over 200,000 patients in the United States. And often, in the case of the drug that was discussed earlier, they're Government-funded drugs.

That's precisely why there are no intellectual property rights assigned to the drugs or why the issue of data exclusivity becomes the only way that the company marketing the drug can prevent competition from bringing the price down to a more affordable level.

Now, it's a shame that Bristol-Myers Squibb is not on this panel to explain to the committee why, after making a billion dollars in this next year on a drug invented by the Government, for which it charges a very high amount, a very extremely high markup over its own cost of manufacturing, producing the drug, how it can justify a continued monopoly beyond the 5 years that it's had which has generated literally billions for the company.

Now, I attached to my testimony a copy of a bill from a patient who contacted me about Taxol. This is a woman with breast cancer. This is for one office visit. It was $4,200 for an injection of Taxol and carboplatin. The Taxol injection alone for a single office visit was $2,324.70. Her husband contacted me. They're uninsured and she had to get these treatments about once every 3 weeks or once a month for a really long time. People, women that take Taxol for breast cancer can easily run up $50,000 in bills at current prices.

Now, Bristol-Myers Squibb was able to acquire Taxol from Hauser Chemical, which was the Government's own contractor, for 25 cents a milligram in bulk quantities, costs about 15 cents to finish it. They sell it for almost $5 a milligram. This patient paid nearly $9 a milligram.

My time's up. I just think to close, one thing I want to mention is that we have worked—we're very active right now in discussions with South Africa, The Netherlands, Canada, and other countries which are trying to get Taxol on the market. In discussions with U.S. trade negotiators over what norms are for the protection of clinical trial data, and the alternatives, even the current 5-year Waxman-Hatch provision, which many people in the public health community and the world health community believe are excessive and do not represent appropriate international norms, let alone in 10 years, which is the maximum in the countries currently provided.

PREPARED STATEMENT

There is no reason why U.S. consumers should be paying far more for a drug like Taxol, which was invented in the United States, than other consumers throughout the world, and the only reason we're here is because companies want to make these big profits on Government-funded drugs.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF JAMES P. LOVE

Thank you for the opportunity to testify today on proposals dealing with data exclusivity and funding of biomedical research. My name is James Love. I am the Director of the Consumer Project on Technology (CPT), which is a non-profit organization created by Ralph Nader. CPT is engaged in a wide range of projects involving intellectual property and pharmaceutical drugs. Much of this work is accessible through our home page on the Internet is http://www.cptech.org (no period).

CPT shares the view of Representative Henry Waxman that the proposal to tie a 10 year extension of market exclusivity to a 3-percent royalty for biomedical research is an outrageous and cynical proposal to exploit patients, under the color of addressing an important public health need.

Pharmaceutical drugs marketed in the United States benefit from several different forms of protection from competition. A firm that invents a drug or a use for a drug can obtain a 20 year patent, not including patent extensions. The U.S. Orphan Drug Act provides an even broader form of market exclusivity for a very large class pharmaceutical drugs. After a series of amendments which liberalized the definition of an Orphan Drug, firms can now obtain seven years of market exclusivity when the client population for a drug is less than 200,000 patients for any single indication. The subject of this hearing is the 1984 Waxman-Hatch act provision concerning the use of health registration data.[1]

The current provisions regarding health registration data prevent a new entrant from relying upon the evidence already presented to the FDA to establish whether a drug is safe and effective, for five years, without the permission of the "owner" of those research data. After five years, a generic drug manufacturer can "rely upon" these data to support an application to market a generic version of a drug. Of course, this is only important in those cases where the drug is not already protected by a patent or by the Orphan Drugs Act.

When we talk about drugs which are not protected by patent, we are often talking about drugs which were invented by the U.S. Government, such as Taxol, an unpatented cancer drug invented by the National Institutes of Health (NIH).[2] When we talk about drugs not protected by the Orphan Drug Act, we are talking about drugs which have large client populations.

Many health care experts believe the current five years of market exclusivity for health registration data is excessive, and perhaps even unnecessary, given the opportunities for market protection which are available under patent and Orphan Drug laws. However, if one assumes that unpatented drugs deserve special protections from competition, the current open ended protections are excessive. The best evidence of this is the current situation with Taxol, the unpatented drug invented by the NIH, and marketed by Bristol-Myers Squibb (BMS).

From the very beginning, BMS was able to acquire Taxol in bulk from Hauser Chemical, the former NIH contractor, for $.25 per milligram. Industry experts say that bulk Taxol can be prepared for human use for less than $.15 per milligram, for a total finished cost of less than $.4. BMS says it sells Taxol in wholesale markets for $4.87 per milligram. I am attaching a bill to an uninsured breast cancer patient. The patient was asked to pay $2,324.70 for nine 30 mg vials of Taxol, or $8.61 per milligram. The cost of the entire office visit, including $1,171 for an injection of Carboplatin, another NIH funded cancer drug now sold by BMS, was $4,200. Breast cancer patients are often expected to repeat these treatments every three weeks or so for 18 months or more, making the total cost of the treatment a great burden.

BMS's Taxol sales are expected to be about $1 billion this year, making the drug an enormous profit center for the company.

Following a 1991 CRADA between NIH and BMS, NIH agreed to give BMS exclusive rights to use NIH funded research on Taxol for commercial purposes. The initial CRADA did not require BMS to provide the government with any royalties. This agreement has been amended several times, and NIH has also licensed a number of Taxol related parents to BMS, including controversial patents on the doses used to treat cancer patients. BMS hopes to use these additional NIH patents on recommended doses to argue that generic entrants will infringe on the BMS "use" patents for Taxol, triggering automatic delays in the introduction of generic versions of Taxol.

BMS's role in the events leading up to the FDA marketing approval for Taxol was quite modest, as reported in BMS's own histories of the development of Taxol.

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[1] 21 U.S.C. Sec. 355(c)(3)(D)(ii) (1996).

[2] At the National Cancer Institute.

For example, in an April 8, 1997 "Application for Exclusive License to NIH Taxol-Related Patent Portfolio," BMS describes its pre-NDA role as taking over the production and manufacture of Taxol used in the NIH sponsored clinical trials, and the collection of data for the NDA application. BMS originally offered to provide NCI with 17 kilo's of Taxol for use in government sponsored clinical trials, and to investigate methods for harvesting and manufacturing Taxol. The amount of money actually spent by BMS on Taxol prior to FDA marketing approval was very modest. After the drug was approved for marketing, BMS has increased its investments in a variety of technologies which relate to the manufacture of the drug, which is a normal cost of businesses, and it supported a variety of clinical trials, either by providing NIH with Taxol for trials that would be "owned by" BMS, or by conducting its own trials.

In one case BMS rushed an application to the FDA to qualify Taxol as an Orphan Drug, for treating Karposi's sarcoma, after BMS determined that another firm was about to seek marketing approval for its own version of Taxol, on the basis of its tests on Karposi sarcoma patients. As a consequence, BMS was able to use the Orphan Drug Act to block the introduction of a competitor's versions of Taxol, even though Taxol could not qualify as an Orphan Drug for breast cancer, the most common prescribed use for Taxol.

CPT recommends that Congress reexamine current 5-year period of health registration data exclusivity, to determine if a lesser level of protection is appropriate, given the consequences to consumers of high drug prices. It is important to appreciate the fact that this is only an issue for drugs not protected by patent or by the Orphan Drug Act. When drugs are not protected by patent, it is because the company does not own the rights to the discovery of the drug, or the key inventions relating to uses of the drug. What is at stake is a "sweat of the brow" claim to protection from unfair competition.

Since exclusive rights to data can be an enormous barrier to entry, as evidenced by the Taxol case, CPT recommends congress introduce safeguards to protect consumers, such as a sunset provision after a drug grosses a target of gross sales, or a provision for compulsory licenses of the data, to protect consumers from monopoly power. This is particularly appropriate given the fact that in most cases, unpatented drug discoveries were invented by the government, or the invention was funded by a government grant.

We are supportive of the suggestion that Congress impose R&D royalty obligations on pharmaceutical companies, in order to promote a higher level of biomedical research in the United States. We have recommended this approach elsewhere. However, there is no need to tie this proposal to a higher monopoly profits on unpatented pharmaceutical drugs. The proposal for matching contributions for R&D has merit. because society benefits from a mix of public and private R&D investments.

Since January, 1997, CPT has been involved in several disputes involving health registration data as a barrier to entry for pharmaceutical drugs. Bristol-Myers Squibb is lobbying the United States government to take trade sanctions against South Africa, Canada, Australia, Argentina, the Netherlands and other countries which have approved generic versions of Taxol, the NIH developed cancer drug currently sold by Bristol-Myers Squibb. The United States government is taking the position in International trade negotiations that Article 39.3 of the TRIPS agreement requires countries to provide 5 years of data exclusivity, such as is currently the case in the United States, under the Waxman-Hatch Act. The TRIPS language follows:

SECTION 7: PROTECTION OF UNDISCLOSED INFORMATION

Article 39—

1. In the course of ensuring effective protection against unfair competition as provided in Article 10 bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices (see footnote 10) so long as such information:

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) has commercial value because it is secret; and

(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

We are telling foreign governments and the USTR that the U.S. law is too protective of the pharmaceutical industry, and that compromises, as were suggested above, are more appropriate international norms.

TAXOL ISSUE

Senator SPECTER. Ms. Cioffi, Dr. Clarkson, would you care to respond to the Taxol issue?

Ms. CIOFFI. The iron overload for our patients, that our patients suffer from, they have iron overload and they have as a result a lot of secondary conditions, diabetes, heart disease, hepatitis, all kinds of things besides the primary condition. So——

Senator SPECTER. The question is why should exclusivity be granted to Taxol which is so expensive when it is a Government-originated drug. Dr. Clarkson?

Mr. CLARKSON. That's a more difficult question than I think the first one you posed. Let me just make a couple of comments. One, there was reference to a NERA study that I believe points to something like $1 billion cost over several years.

If you look behind the numbers, the way they were generated, about $3 out of every $4 are attributed to new patients coming into the system, as opposed to higher prices. So the overall effect really is something in the neighborhood of $1 out of every $4 in terms of higher prices.

And that also gives you some good information about what are the consequences of extended exclusivity? Because behind those dollars is essentially an increased effort to find new populations, a much higher rate of diffusion of information.

Senator SPECTER. Is it your contention that the increase in exclusivity will enable the companies to spend more money on more research to find better products?

Mr. CLARKSON. Absolutely, and also to find more patients.

Senator SPECTER. Mr. Perry, you represent the people who are in the aging population and you are supporting this legislative concept. What is the impact on your clientele with respect to higher costs when the generics would be past this extended period of exclusivity?

Mr. PERRY. I don't think there's any question that we're talking about a conflict of values. There is a value for early access to less expensive generic drugs. There is also a value both to today's elderly and those tomorrow to see an investment in research so that we have better treatments, better means to prevent, postpone the diseases of aging tomorrow. From our perspective, the benefits that will come from helping people avoid Alzheimer's disease and Parkinson's and stroke or greatly diminish those in the future far outweighs the near-term benefit for lower cost drugs.

Senator SPECTER. We are searching for ways to increase funding for NIH, and I do not accept what you said, Mr. Perry, that we can-

not find more money for NIH. This subcommittee found $952 million more this year for NIH. And my own sense is if we have a presentation from NIH as to what it will cost for all of the unawarded grants, we could find more money. We have a budget of one trillion, seven hundred billion dollars, and you can fit $900 million into that quite a few times.

The concern that I have is the tradeoff. I'm apprehensive about more money for NIH in exchange for a greater period of exclusivity. If the period of exclusivity is warranted because it will generate more research and find more products, help more people live longer lives, then I think that is a very powerful argument if that can be quantified, and I would be looking for that quantification to the extent it can be demonstrated.

When you start talking about the greater period of exclusivity in return for payment to NIH, then I wonder about the cost to the consumers and have a hard time with that kind of an exchange. We have to deal with the public interest when we consider the longer period of exclusivity, which means more research products with the higher cost on generics. That is the overall layout I have. To the extent you can address these factors, in advance of Senator Bennett's questions and Senator Harkin's questions, they will not like it but I will.

Senator Harkin?

Senator HARKIN. Mr. Chairman, thank you. Again, this is an intriguing proposal. I share the chairman's statement that we are trying to find new funding for NIH, trying to get the money we need for more biomedical research which in the long run is going to save us lives and save us money. I am sure you all agree with that. That seems to be like God, mother and apple pie. The question is where do we come up with the money?

This seems to be a novel approach. Although, again I agree with the chairman that we are here to represent the public interest in trying to figure out what all the varying balances are. I was intrigued by the testimony on Taxol, and what the taxpayers would have to pay over 5 additional years if the price were kept up rather than having market exclusivity expire at the end of this year. That testimony indicated we would wind up spending more than we would invest in NIH.

Is that correct? Is that what you are saying?

Mr. HALLQUIST. Yes, Senator.

Senator HARKIN. What assurances do we have that if the patent expires that the price really is going to come down?

Mr. HALLQUIST. I would submit almost any study that's done of the price erosion of branded pharmaceuticals after generics are introduced, almost in every case—in fact, I can't think of a single case that has ever been cited to me where the price hasn't gone down and it hasn't gone down precipitously. Typically the price will decline by more than 50 percent within the first 3 months after the introduction of generic competitors.

Senator HARKIN. But your company is what, Immunex?

Mr. HALLQUIST. Immunex Corp.

Senator HARKIN. And you have developed or you have gotten the ingredient in Taxol that is the anticancer agent. I forget what the name of it is.

Mr. HALLQUIST. Senator, we use the same supplier that originally supplied NCI and supplied Bristol. We picked up the supply contract after Bristol let it lapse, and so we have a very high quality product. My chairman has authorized me to offer a royalty to NIH directly if we're allowed to sell our product.

Senator HARKIN. How much?

Mr. HALLQUIST. I think we can do better than 3 percent, I'll put it that way. But we've been relying upon the Waxman-Hatch compromise, we've been relying on the dialog that Bristol had with the government several years ago and we just want our chance to compete.

Senator HARKIN. Mr. Love?

Mr. LOVE. If you want to selloff market exclusivity to one company so they can charge high prices to consumers to fund biomedical research, why not make it a competitive process? Why not put a notice in the Federal Register and say whoever will bid the highest amount of money will get the market exclusivity for this drug? And then you can fund medical research. That, and we can let the market determine what is the appropriate royalty, instead of having Bristol-Myers Squibb or somebody offer 3 percent.

Senator HARKIN. Dr. Clarkson?

Mr. CLARKSON. Let me try to put this a little bit more in perspective. In 1971, it was an NIH grant, I think, that helped isolate the paclitaxel drug, which is the basis for—or the same thing as Taxol. 20 years later, you still had a significant supply problem. And at this time, there was an arrangement made with NIH to develop an adequate supply to submit to NDA's and other commitments with respect to spending research dollars.

And what happened after that is that the agreement resulted in an expansion from about 15 trials up to over 500. It moved from a roughly 400, 500 patient population to several thousand, around 40,000. The dollars spent exceeded are over $500 million, as opposed to $170 million set forth in the contract, and they still have just touched the tip of the iceberg. There are three approved indications now. There are many more cancers out there. And no one can guarantee what the future is.

But if we compare the roughly 5 years that Taxol is under this agreement with the outcomes with the 20 years beforehand when everybody had access to that information, you get startling results. And that's why I think that it's important to look at what are the incentives of exclusivity? If you have exclusivity, you get action.

Senator HARKIN. I am not opposed to exclusivity and I see that being a necessary thing to do and to give certain exclusive rights for a certain period of time. What I am worried about is extending a period of time when other companies have relied upon the time and invested money and research, ready to bring a product out. All of a sudden the Congress says bang, no, you cannot. That is a concern of mine. I mean, companies relied upon this, I would think. I do not know anything about your company but I would think——

Mr. CLARKSON. I think that you're at the end of a cycle of discovery with respect to new indications and you've already identified the populations, I think that's a very real concern.

I'm an economist, and I support competition and I think competition ultimately is the best outcome. The question is when?

Senator HARKIN. I agree with that. I worry about when there has been a set time and the company has relied on it and they have put money into research and they are getting toward coming out with their generic product.

Senator SPECTER. Suppose we did it prospectively from this point forward?

Senator HARKIN. You could do it prospectively, I suppose, for anything in the future. Senator Bennett's future.

Excuse me, Mr. Perry, I wanted to ask him a question.

Senator SPECTER. Just one last one?

Senator HARKIN. Just one last one.

Mr. PERRY. This is—both the generic and the name brands industries is a highly regulated area. And the downside to finding legislation like this that would affect one company, I think, has to be considered against the public interest, not only in the short run but in the long run. And the long-term public interests that I believe members of this committee have very close to their hearts is the need for more research.

I'm looking right now at some of the strongest Representatives in the Congress, and I take second to no one in praising the work of this subcommittee in helping make sure the research is there. But from 1970, when 1 out of 2 NIH applications that were peer reviewed and passed peer review were funded, to 1997, when it's 2 out of 10 and we know the competitions within that limited funding pool for discretionary funding is going to lead to a smaller NIH in the out years than what we have today, and what a tragedy at a time when the innovations are waiting to be discovered and when the public health needs need those breakthroughs, and what a time to lose that momentum.

This is just one more—this demonstration project, which is time limited and voluntary, is one more lever under that big rock, Senator, one more effort to try to get it and see if it works in 5 years. And I think we'll be able to better weigh the impact on the legitimate interest of lower prices for consumers and the complementary interest of more research.

Senator SPECTER. Senator Bennett?

Senator BENNETT. Thank you, Mr. Chairman.

First, Mr. Hallquist, I do not in any sense accuse you of bad faith. I think you gave us your numbers in perfectly good faith. But I have and will make available to the committee for the record other numbers, and I think ultimately this means this thing is going to have to be scored by CBO. A former CBO employee was asked to score this, and he says that this proposal would yield for the Federal Government $824 million in royalty revenue, lose $254 million in Medicare costs for a net gain to the Government of over half a billion dollars, $570 million.

So I just put that on the table to indicate that we better be careful before we start making sweeping statements, let us get this thing properly scored.

Now, the other thing that I want to make clear from my understanding and let you comment, and correct me if I am wrong, I hear all of the conversation about research and focusing on NIH as if NIH is the only place where research is going to be done here. And as I understand this proposal, this is the way it works.

A company develops a drug for disease A and the clock starts ticking, the 5 years start running. And in that 5-year period, they discover, as they bring the drug to market, that it possibly has an application for B, C, D, and E, and they put some research dollars into that. Well, if they are putting the research dollars in in the first year, they will get a return for them because they have 4 years in which that research can come to fruition.

Say that they discover in the first year with their research that B, which they had not thought of, when the 5 years started running, does respond to the drug, maybe C will, and so they start to put some money in research for C, and then there are indications out of the market experience that D and E also will respond. But now the 5 years are gone and someone says look, if we put in another $100 million, $200 million, whatever, into research, we may have the application of this drug for D and E. But no, the 5 years are up. It is now going to go generic, at which point the company says we are going to stop all research on D and E and probably not even launch the research on C because it is not going to go forward.

So this is research that the company has to put up its own money to do. And it is an incentive not just to have royalty for—for NIH. Mr. Love, I agree with you if that were the only issue, we might as well put this up for bid. It is for the company itself to say we are going to put our own money at risk based on our own experience, and we think the payoff is sufficiently great that we will gamble the extra $100 or $200 million or whatever it is that we will do that for D and E.

And as I understand the process, what we are saying in this demonstration project is if a company is willing to pledge those additional moneys, the company does not just automatically pledge the royalty. The company has to pledge the research dollars, as well. If the company is willing to pledge the additional research dollars plus the royalty, it can get the extra 5 years. It is taking a gamble, because if in that 5-year period D and E don't pay off, they have lost the money that they put into research. But if D and E pays off, we have—you are an economist, Dr. Clarkson, we have a return on our investment from a public point of view that is really quite substantial.

Now, have I categorized correctly? I see some people shaking their heads no and some people shaking their heads yes.

Mr. CLARKSON. Yes.

Senator BENNETT. Can we get a response as to——

Mr. HALLQUIST. Senator, in the specific example you just cited, under U.S. patent law, the company doing the research on indications B, C, D, and E would be entitled to apply for method of use patents that would extend to 17 to 20 years covering that research and the benefits of that research provided that it was inventive. As Mr. Love pointed out, the specific legislation that's on the table today only covers this narrow spectrum of specialty favored drugs which don't qualify for patent protection and for which the 5 years of exclusivity has already expired.

So you know, you can't look at Waxman-Hatch as though it were the only form of exclusivity available to U.S. drug researchers and

manufacturers. There also is the patent system. There's also the orphan drug act. So it can't be looked at in a vacuum.

With respect to your comments on our financial analysis, we can only address Taxol, it's the biggest pig in the litter. It's a huge drug and the economics, to our mind, disfavor this proposal.

Senator BENNETT. The numbers I have were also based on Taxol.

Mr. HALLQUIST. I'd be happy to comment on it. Our analysis definitely does show that growth in the Taxol market for the precise reasons that Mr. Perry talked about, the U.S. population is getting grayer, older, and we have more cancer patients.

Senator BENNETT. Anyone else want to comment on—Mr. Love, you do?

Mr. LOVE. The situation described happened once before with the same company Bristol-Myers with another cancer drug that was a Government-funded drug. In the early 1980's, Syspat was the largest selling cancer drug in the world as Taxol is today. There used to be, you could only get 5 years of exclusivity even under a patent if it was from a university. And so when the 5 years ran out, Bristol-Myers Squibb came to the Government and they said we can't justify more research on Syspat unless you extend our monopoly another 5 years. And it was like five or six companies which asked the Government to let them sell Syspat, too, and compete against Bristol-Myers and drive the price down.

So Bristol-Myers made a proposal that they would pay $35 million to fund cancer research that was supervised by the NIH. This is back in the early 1980's and they—and that they would lower the price of the drug 30 percent, which was the other part of the proposal, maybe they forgot about this time around.

In any event, though, what happened is one of the companies that came said, lookit, if this is about money for research, if that's all we're talking about, you name the number, we'll make the contribution. It's just like that gentleman there said, he said if you want research on biomedical research, tell all the new entrants that they pay 5 percent, 10 percent. They don't really care what the number is as long as everybody pays the same percent. It could be a dollar amount per drug sold, it could be a percentage of revenue. The Government could take the money, put it in a foundation or give it to NIH or have the company set up its own research funds.

The point they were making is that it is a problem when you eliminate monopolies because all the R&D profits disappear because the generic competition prices moves prices down to cost. But if you want to preserve that cushion for R&D, you don't want to have one company have a monopoly. You can put, as Senators Harkin and Specter proposed in the past, some kind of guideline like a royalty or something like that that has to go into research. And that was proposed in the area of Syspat. The Government rejected that advice.

They gave the monopoly to Bristol-Myers, just like it's being proposed right here. It's just like a deja vu. And you know, so we've been down that road before. As a result, patients in the United States pay a lot more for Syspat than they do in other parts of the world.

Senator SPECTER. Anybody else want to respond to Senator Bennett? Because we want to wrap up here.

Senator BENNETT. Before, Mr. Love, you stopped the story, I was waiting for the punch line and you never gave it to me. Did in fact Bristol-Myers do more research and was there a medical benefit that came out of that deal?

Mr. LOVE. They did spend portions of the research, we have the documents that they submitted in terms of the reports. But later on in the Reagan administration, the reporting basically petered off, and the fellow that was supervising the research for Bristol-Myers Squibb, Dr. Wittest went to work for Bristol-Myers Squibb and helped organize their application for the Taxol patent. I mean Taxol CRADA. Dr. Wittest was an employee of Bristol-Myers Squibb and it was under his direction that they got the Taxol CRADA. Now Dr. Wittest is back with NIH.

Senator BENNETT. You were not answering my question.

Mr. LOVE. The answer is they did spend some money, but it was not as much money as the consumers paid to Bristol-Myers Squibb.

Senator BENNETT. You are still not answering my question. Was there a medical benefit that came out of the money that they spent?

Mr. LOVE. There was a medical benefit. It was not as big as what the consumer cost was, but there was indeed a medical benefit for medical research.

Senator SPECTER. Ms. Cioffi, you want to respond? Go ahead.

Ms. CIOFFI. Yes; just to take it away from Taxol and speak about my patient population for just a second, I would suspect that there's very much a medical benefit that was involved here, but I can speak from experience in a new drug for oral kelation that's through a company where they do have the exclusivity and they've been able to spend this extra time on the drug, to find out that the application of the drug is broader than what they suspected and will have more benefit for a larger patient population. So that's an experience that's worked really well in this kind of proposal.

The other thing is that for our small patient population, again, even after all the credits and that experience, you get to a point where a company is not going to invest in generic drugs for this small population. So I need any additional amount of research for our patients to cure this.

Mr. CLARKSON. Just a couple quick comments. One, a footnote. NERA also did a study on that earlier grant where they came to the opposite conclusion, they were supporting exclusivity, and I urge the committee to try to get a copy of that report.

I wish you could teach my class because you have it right. You're right on in terms of the sequencing. And since it is focusing on this particular drug, Taxol, I do think that with so many other cancers that still exist, there's research going on in small lung and several other activities that I suspect—I wouldn't be able to predict for any particular country, but I would suspect would be curtailed substantially if not eliminated.

Mr. PERRY. Senator Bennett, I believe the explanation that you gave is exactly correct. As I understand the proposal, it rewards in three ways. It strengthens patent and nonpatent incentives for research, provides a royalty mechanism back to NIH, and it requires the companies that opt for this to match that with an equal

amount of additional R&D and perhaps another—in other applications of the particular drugs.

It is a novel benefit that I think meets and perhaps in some ways exceeds some other ways that we're trying to find additional research. Let me remind the audience at least that the Senate is on record calling for a 100-percent increase in National Institutes of Health over the next 5 years. I think we're all going to put our shoulder to the wheel to see if we can't help achieve that. But unless we can find some creative public-private partnerships, instead of relying on the appropriations process and the non—and the nondefense discretionary fund which is so squeezed right now, I don't see how we're going to get there and I salute those of you that are helping us to get there.

Senator SPECTER. Thank you all very much. This is the beginning of a process on considering a very complex issue. Also, we will include the CBO cost estimate on this issue, when it is received, in the record at this point.

[The information follows:]

LETTER FROM JUNE E. O'NEILL

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, November 18, 1997.

Hon. ARLEN SPECTER,
Chairman, Subcommittee on Labor, Health and Human Services, and Education, Committee on Appropriations, U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: At the request of your staff, the Congressional Budget Office has prepared the enclosed cost estimate for a proposed demonstration project that would grant up to 10 years of additional market exclusivity for certain drugs and antibiotics in exchange for royalty payments to the Federal Government.

If you wish further details on these estimates, we will be pleased to provide them. The CBO staff contact is Anne Hunt, who can be reached at 226–9010.

Sincerely,

JUNE E. O'NEILL,
Director.

Enclosure.

CONGRESSIONAL BUDGET OFFICE—COST ESTIMATE—NOVEMBER 18, 1997

PROPOSED DEMONSTRATION PROJECT TO FUND BIOMEDICAL RESEARCH

Summary

CBO estimates that the proposed demonstration project would increase both federal outlays and federal revenues over the 1998–2002 period, with the increase in revenues exceeding the increase in outlays. During the 2003–2007 period, however, outlays would increase more than revenues, and the deficit would rise. Because the bill would affect direct spending and receipts, pay-as-you-go procedures would apply.

Beginning in 1999, the proposal would increase costs for Medicaid, the Federal Employees Health Benefits Program (FEHBP), and Medicare. Outlays would increase by $12 million in 1999 and $236 million over the 1998–2002 period. The proposal would increase revenues through collections of royalty payments, but it would reduce federal income and payroll tax revenues by raising the costs of employer-sponsored health insurance and correspondingly reducing the amount of taxable compensation. On balance, revenues would increase by $19 million in 1998 and $458 million over the 1998–2002 period.

The proposal contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act of 1995 (UMRA). However, extending market exclusivity for certain drugs would increase costs for state Medicaid programs, other programs that provide prescription assistance, and employee benefit programs at the state, local and tribal level.

The proposal would constitute a private-sector mandate as defined in UMRA because it would prohibit the production of generic versions of the brand-name drugs eligible to participate in the demonstration. CBO estimates that the cost of this mandate would surpass the $100 million statutory threshold established in UMRA.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of the proposed amendment is shown in the following table. The costs of this legislation fall within budget functions 550 (Health) and 570 (Medicare).

ESTIMATED BUDGETARY IMPACT OF PROPOSED AMENDMENT

[By fiscal year, in millions of dollars]

	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
Direct spending:										
Medicaid	.....	.....	1	28	123	185	191	206	199	190
FEHB	.....	.....	.....	1	3	8	13	20	27	34
Medicare	.....	12	21	24	24	25	12	2	.....	.....
Total	.....	12	22	52	151	219	216	228	226	224
Revenues:										
Royalty payments	19	34	59	177	219	203	224	202	207	53
Income and payroll taxes	.....	.....	.....	−6	−44	−76	−86	−91	−87	−88
Total	19	34	59	171	175	127	138	111	120	−35

Basis of estimate

The proposed demonstration project to fund biomedical research would grant up to 10 years of additional market exclusivity for certain drugs and antibiotics. In return for the extension of market exclusivity, manufacturers would make royalty payments to the federal government to help fund biomedical research—subject to authorization and appropriation—and agree to spend an equal amount on biomedical research.

Products eligible to be included in the program are those for which a new drug application (NDA) was filed and approved under sections 505(b)(1) or 507 of the Food Drug and Cosmetic Act (FD&CA) during the five years preceding enactment of the proposal. Manufacturers of these drugs could elect to participate in the demonstration project through the end of fiscal year 2002. For the purposes of this estimate, CBO assumes that a manufacturer would not elect to participate in the program until the patent on its product was about to expire.

The proposal would prohibit the Food and Drug Administration (FDA) from accepting, reviewing, or approving any application for a drug containing the active ingredient(s) of an eligible product. This prohibition would extend for ten years after the approval of the NDA filed under section 505(b)(1) or 507 of the FD&CA.

To obtain extended market exclusivity, the manufacturer of an eligible product would agree to pay the Secretary 3 percent of its net U.S. sales of the eligible products—including all forms and dosages—and to spend an equal amount of money on biomedical research. Subject to authorization and appropriation, the royalty payments would be available to the Secretary of Health and Human Services to fund biomedical research projects approved by the Director of the National Institutes of Health (NIH).

It is unclear how the proposal would affect abbreviated new drug applications (ANDAs) that have already been filed under the FD&CA and are pending FDA approval. The proposal does not address whether the FDA could continue reviewing these ANDAs or whether it would have to stop work on them until the end of the ten-year exclusivity period. It is clear, however, that manufacturers of generics who were preparing to submit ANDAs—but have not yet done so—would be penalized financially if the proposal were enacted.

Outlays

The award of additional years of market exclusivity would increase costs for Medicaid, FEHBP, and Medicare by delaying the availability of generic products. Medicaid currently has a very high generic substitution rate because the program requires pharmacists to dispense lower-cost generic products once they are available, unless

the prescribing physician specifies otherwise. Additionally, many states have laws permitting generic substitution with the patient's consent. Therefore, CBO assumes that Medicaid would usually substitute generic for brand-name products. Generic substitution would probably occur at a slower rate among health plans participating in FEHBP and in Medicare.

Under the proposal, spending for Medicaid, FEHBP, and Medicare would increase by $236 million over the 1998–2002 period. CBO estimated this increase in spending by comparing the level of spending that would occur in the absence of generic entry with projected spending under current law. To estimate payments by Medicaid, FEHBP, and Medicare under current law for the set of drugs that would be affected by the proposal, CBO adjusted 1995 spending to account for projected inflation and the reduction in prices that would occur as generic entry took place. Using information from *Approved Drug Products With Therapeutic Equivalence Evaluations* (the "Orange Book"), CBO determined when patents would expire under current law for affected drugs and calculated the incremental period of exclusivity. For Medicaid, the estimate takes into account rebates paid by manufacturers.

For Medicare, the estimate takes into account the change in payment rates under the Balanced Budget Act of 1997.

Revenues

The proposed demonstration project would affect revenues in two ways. First, it would increase revenues because of the royalty payments made by participating drug manufacturers. CBO estimates that these payments would total $19 million in 1998, and just over $500 million over the 1998–2002 period. For the purposes of this estimate, CBO assumed that a manufacturer would not choose to participate in the demonstration until the patent on its product was about to expire and that it would stop participating at the end of the exclusivity period. Because the federal government's collection of the royalties would stem from its sovereign powers, these funds would be classified as governmental receipts.

Second, the proposal would affect income and payroll tax revenues. By delaying generic entry for eligible drugs, it would increase the prices insurers paid for pharmaceuticals, leading to higher premiums for employer-sponsored health insurance. Correspondingly, the amount of employee compensation subject to income and payroll taxes would decrease. CBO estimates federal income and payroll tax revenues would fall by $50 million through 2002.

Pay-as-you-go considerations

The Balanced Budget and Emergency Deficit Control Act of 1985 sets up pay-as-you-go procedures for legislation affecting direct spending or receipts. Because the proposal would affect direct spending and receipts, pay-as-you-go procedures would apply. For purposes of enforcing pay-as-you-go procedures, only the effects in the budget year and the succeeding four years are counted.

Estimated impact on State, local, and tribal governments

The proposal would place no enforceable duty on state, local, or tribal governments, and thus it contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act of 1995. However, the delayed availability of generic drugs would result in increased costs for health care. State and local governments would thus face higher costs both in the Medicaid program and in their employee health insurance programs.

CBO estimates that the state government portion of Medicaid costs would increase by $114 million over 5 years. In addition, any state, local or tribal government that offers health insurance coverage to its employees would face increased pharmaceutical costs. Based on the number of these employees who receive pharmaceutical benefits, CBO estimates that governments would face additional costs of approximately $23 million over 5 years. Economists generally believe, and CBO's cost estimates have long assumed, that workers as a group bear most of the cost of employers' health insurance premiums. The primary reason for this conclusion is that the supply of labor is relatively insensitive to changes in take-home wages. Because most workers continue to work even if their take-home pay declines, employers have little trouble shifting most of the increase for health care costs to workers' wages or other fringe benefits. Consequently, after the first few years, state and local governments would likely shift these costs to their employees.

Also, some states provide assistance for low-income individuals who are not eligible for Medicaid. States that provide this type of prescription assistance would face additional costs for these programs. At this time, CBO does not have sufficient information on the number of states that provide this type of assistance and on the types of prescriptions covered to provide an estimate of these costs.

Estimated impact on the private sector

The proposal contains a private-sector mandate over the statutory threshold ($100 million in 1996, adjusted annually for inflation) in 2001 and 2002 because it would prohibit generic manufacturers from producing copies of certain brand-name drugs containing an active ingredient that was initially approved by the FDA during the last 5 years. CBO estimates that prohibition would cost the generic drug industry over $500 million in lost profits (after taxes) between 1998 and 2002. Also, many purchasers would pay more for certain prescription drugs because of the reduced competition from generic manufacturers. CBO estimates that those indirect costs to prescription drug purchasers would total $1 billion over the 1998 to 2002 period, net of the increased costs to the Medicare, Medicaid and FEHBP.

Estimate prepared by:

Federal Cost Estimate: Anne Hunt (226–9010).
Impact on State, Local, and Tribal Governments: Leo Lex (225–3220).
Impact on the Private Sector: Anna Cook (226–2940).
Estimate approved by: Paul N. Van de Water, Assistant Director for Budget Analysis Division.

ADDITIONAL SUBMITTED STATEMENTS

Senator SPECTER. But this is the start of a debate which I think we will have. And these figures are not immutable as to 3 percent, et cetera, et cetera. This is something that we are searching for in trying to find more research dollars. We thank you for coming. And if you take a look at those questions, we would appreciate it.

For the record, we are inserting statements from Senator Wellstone, Senator Durbin and a statement of Congressmen Waxman, Brown, Deutsch, and Stark. We will also include a statement from the National Alternative Fuels Association.

[The statements follow:]

LETTER FROM SENATOR PAUL WELLSTONE

U.S. SENATE,
Washington, DC, October 20, 1997.

Hon. ARLEN SPECTER,
Chairman, Subcommittee on Labor, Health and Human Services, and Education and Related Agencies, Washington, DC.

Dear Senator ARLEN SPECTER: I am writing to express my concern about the proposal to include language concerning patent extensions for certain drug products in the Labor HHS appropriations conference. As you know, I have worked diligently in the past to retain the provisions that are in the 1984 Hatch-Waxman Act. That Act provides an equitable process for providing patent extensions when they are warranted.

The proposal that has been brought forth would grant branded pharmaceutical companies unearned, windfall profits at the expense of American consumers. Drugs such as Claritin, which has had an increase in U.S. sales of over 50 percent in the past 2 years, would receive this benefit. The manufacturer of this drug is expected to see even higher sales in the next few years than the $1.2 billion it saw in 1996. It is likely that a generic equivalent of this drug will be ready to go to market at the time the drug is due to come off patent in 2002. The availability of the generic will greatly decrease the cost of this drug to consumers, who rely on the product for treatment of allergies. This is important not only for consumers, but for health plans that pay for drug benefits for their members.

It is interesting that the latest proposal includes an attempt to decrease the controversy surrounding patent extensions by creating a demonstration project that would require that a manufacturer pay a 3 percent royalty to the Secretary in exchange for a patent extension, in order to fund research. While it is certainly beneficial to increase health research funding, I am not convinced that this method is the appropriate one. The proposed strategy appears to be a buy-off, with significant implications for consumers and others who pay for health care.

In addition, I am concerned about changing provisions of the Hatch-Waxman Act without fully understanding the implications of doing so. Major changes such as the one that is proposed should be fully vetted with those affected by them.

I am hopeful that you will understand the need to proceed cautiously with any attempt at patent extensions, and will make certain that any proposals to do so are fully and properly vetted.

Sincerely,

PAUL WELLSTONE,
U.S. Senator.

PREPARED STATEMENT OF SENATOR RICHARD J. DURBIN

Mr. Chairman, I want to thank the Subcommittee for this opportunity to submit testimony on this new proposal for NIH funding which is tied to extending prescription drug market exclusivity.

I have long been a supporter of increased NIH funding. I have also cosponsored bills to set up a trust fund for the National Institutes of Health (NIH) to supplement their appropriations. However this proposal under consideration today will be costly to those that its proponents claim to help, namely patients.

This proposal is extremely misleading. It masquerades as a means of supplementing NIH resources to increase research for new cures. As currently drafted the three percent royalty could merely substitute for current NIH funding. This proposal is really nothing short of a highly profitable quid pro quo for the drug companies who will reap billions of dollars in additional revenue by shutting out of the market new, cheaper generic drugs.

Unlike the Orphan Drug Act, this increased market exclusivity is not tied to developing new drugs. Instead extended exclusivity goes to companies that already have drugs on the market. This proposal in fact stifles the production of new second generation drugs that would be more affordable to patients.

This proposal could conservatively cost American consumers $10 billion in higher drug costs, based on the proponent's own estimates that it will increase revenue to NIH by $750 million over five years. For one drug alone, Taxol, this special interest provision would cost consumers $1.3 billion, including $288 million for Medicare for the period of 1999–2005. Up to 350 drugs potentially are eligible for this special treatment. Consumers of some of the drugs targeted for this lucrative patent extension include breast cancer patients, AIDS patients and seniors. They would be forced to pay billions in higher prices while taxpayers will pay more in Medicare and Medicaid costs.

While the proposal calls for the drug companies who would benefit from the measure to pay a percentage for NIH research, the expense to patients and taxpayers and the companies' windfall profits would far exceed any corporate payout to the government. It is also highly likely that the companies will pass the price of the royalty on to patients in the form of higher prices for these drugs. The cost to the federal government of this provision is likely to be far greater than the $750 million that proponents estimate will be added to NIH's budget. CBO is currently analyzing the cost to the government of this proposal.

This morning I was joined by U.S. Rep. Henry Waxman and consumer and patient groups at a Capitol Hill news conference, to discuss the possibility that this provision might find its way into the Labor-HHS spending bill. The Consumer Federation of America, AARP, Public Citizen and the Women's Health Network spoke out strongly about how harmful it would be to consumers to give certain drug companies an extra five to ten years of patent exclusivity.

Similar to the secret $50 billion windfall for the tobacco industry that was snuck in to the tax cut bill, this proposal is another "moonlight mackerel" being floated on Capitol Hill that could cost consumers and taxpayers billions of dollars, and it similarly, to paraphrase John Randolph, "shines and stinks like rotten mackerel by moonlight."

Special interest groups will always try to sneak in a backdoor deal and call it a benefit. But not all benefits are public benefits. The odor emanating from this provision can't be masked by a flower for the NIH. I urge the committee to reject this proposal and protect consumers from unnecessarily inflated drug costs.

PREPARED STATEMENTS OF REPRESENTATIVES HENRY A. WAXMAN, SHERROD BROWN, PETER DEUTSCH, AND FORTNEY PETE STARK

Mr. Chairman, we thank the Subcommittee for the opportunity to submit testimony on the subject of NIH funding and proposals to extend prescription drug market exclusivity.

For many years, the Congress has increased this Nation's investment in biomedical research out of recognition of the important benefits it creates for ourselves and the entire world. Most remarkably, Congress has sustained this real growth in the budget of the National Institutes of Health (NIH) in an era of shrinking federal resources. That is a striking testament to the importance we in the House and the Senate attach to basic research.

The proposal which is subject to this hearing has been clothed in the appearance of sustaining this worthy cause. It purports to provide additional resources to the NIH. It is being sold as a panacea to the difficult choices the Congress has had to make to sustain our country's scientific crusade against diseases like AIDS, cancer, diabetes and heart disease.

In reality, this is a stark special interest deal which only serves the financial interests of a small number of prescription drug companies. The funds which this deal would generate for research would not appear painlessly and miraculously from the air. They would be taken directly from the pockets of American consumers and taxpayers.

This special interest deal is breathtaking in its audacity. It boils down to a simple but profitable quid pro quo for the beneficiary companies—"give us up to 10 years of market exclusivity and we will give the U.S. government a 3-percent payoff." If this deal were to be enacted by the Congress, a handful of brand name drug companies would bar competition through lucrative market exclusivities, continue to charge exorbitant prices for drugs which will have already enjoyed full patent terms and exclusivities under existing law, and simply pass on the cost of the 3 percent government "payoff" directly to consumers.

This special interest proposal is offensive to simple equity for a variety of reasons. First, it would delay access to affordable generic drugs and force consumers to subsidize higher prices on products which have already received the full extent of patent protections and market exclusivities which are already available under current law. Since this deal would include any drug approved in the past 5 years and any future drug approved in the next 5 years, the direct costs to consumers, health payers, hospitals and HMO's would be unimaginably high. Companies which have spent years to prepare competitive generic drugs, and even secured tentative FDA approval, by complying with current law would be barred overnight by this proposal from the market for another 5 or 10 years, forcing them without warning to shutter plants, lay off workers and break contracts.

Second, American consumers would be forced to pay twice for this special interest subsidy. Taxpayers pay for the Federal government's health care programs, such as Medicare, Medicaid, veteran's health programs, the Public and Indian Health Services, and Federal Employee Health Benefit programs. The government would be forced to pay much higher prices for the drugs which qualify for this special interest deal, undoubtedly costing taxpayers billions of dollars over and above their direct drug costs. Our colleague, Congressman Pete Stark, ranking member of the House Ways and Means Subcommittee on Health, has requested that the Congressional Budget Office (CBO) examine these questions. We all look forward with great interest to CBO's findings.

Third, this proposal is a fraudulent effort to soften the choices the Congress must always make in allocating Federal resources. We would simply caution our colleagues that there is no such thing as a free lunch. Proponents of this measure claim that NIH could obtain $750 million without dipping any deeper into the Federal budget. This conveniently ignores the additional costs to Federal health programs generated by this proposal, but even more egregiously dispenses with the cold reality that it would be consumers who pay out of pocket for their drugs, especially older Americans, who would bear the brunt of the $750 million bill for this special interest proposal.

Congress should indeed explore imaginative ideas for expanding our country's biomedical research effort, not schemes sponsored by the prescription drug industry and intended to protect the market shares of drugs such as Bristol-Myers Squibb's cancer drug taxol, Glaxo's migraine drug Imitrex and HIV therapy Epivir, and Parke-Davis' Alzheimer's drug Cognex.

Finally, as Congressman Waxman is one of the coauthors of the 1984 Waxman-Hatch Act, we are deeply disturbed by the implications of this special interest proposal for the interests of consumers. This proposal would completely overturn the delicate balance of equities in the 1984 Act, without any careful or systematic regard for the implications for all of the commercial interests at stake, as well as the public welfare. Our colleagues Senator Hatch and Congressman Waxman have publicly stated on numerous occasions that any revisions to the 1984 Act must be made in the same spirit and to the same effect as the original statute. For this reason

alone, we would strongly oppose this proposal and seek its defeat in the House of Representatives.

There have been numerous efforts in recent years to obtain special patent extensions and special extensions of market exclusivity in direct contravention of the Waxman-Hatch Act and its underlying purpose. Some of these efforts have literally taken place in the dead of night. For example, one patent extension was smuggled into the conference report of the 1997 Kennedy-Kassebaum Health Care Reform Act. Only the strenuous, last minute efforts of Congressmen Stark and Waxman, and Senators Kennedy and Wellstone, prevented it from becoming law.

We urge our colleagues in the Senate to reject any notion of adopting this special interest proposal. Biomedical research may be expensive, but it is among the most valuable activities undertaken by the government and should be defended and protected on this basis. We should strenuously resist efforts by certain industries to "piggyback" their own interests on the cause of biomedical research.

PREPARED STATEMENT OF R. DOUGLAS CHIAPPETTA, PRESIDENT, NATIONAL ALTERNATIVE FUELS ASSOCIATION

Chairman Specter and Members of the Senate Appropriations Health Subcommittee, my name is R. Douglas Chiappetta, President of the National Alternative Fuels Association (NAFA). Thank you for the opportunity to testify on the proposal to expand pharmaceutical patents (for up to 5 years). As noted, pharmaceutical companies are proposing to pay the Federal Government to extend their market monopolies on best-selling brand name drugs. In return for these extensions, (a percentage of) company monies would be used for national research on cancer, heart disease, AIDS and other diseases.

Although NAFA is not a patient advocacy organization representing beneficiaries to this proposal, we applaud any effort to expand the Federal Government's commitment to reducing and eradicating life threatening illnesses. However, we believe our membership would be adversely impacted by the enactment of this proposal in its present form.

For the record, the National Alternative Fuels Association was founded in 1992 to support public policy and federal legislation resulting in the advancement of pollution reducing technologies. Our membership comprises concerned citizens, research scientists and entrepreneurial alternative fuel manufacturers, committed to preserving and enhancing the earth's air quality through expanded use of alternative fuel technologies.

Earlier this year, NAFA discussed (related) patent term extension concerns with staff to Senator Orrin Hatch, prime sponsor of omnibus patent legislation (S. 507) currently pending before the full Senate. (We have also convened discussions [on this issue] with some of the pharmaceutical companies in attendance at this hearing).

NAFA supports "a level playing field" for alternative fuel manufacturers struggling with federal patent laws and environmental regulations in their attempts to enter the commercial fuel additive market in the United States. It is my understanding that alternative fuel manufacturers (like other patentees) are protected for a period of 20 years from the filing of a patent application. However, due to regulatory delays, pharmaceuticals are accorded extensions to their patent monopoly.

Alternative fuel companies are subjected to EPA regulatory and other delays which are perhaps much more onerous then pharmaceuticals, but are not accorded extensions. Several of our members (with promising air pollution abating alternative fuel technologies) will not be able to introduce pollution reducing technologies if federal legislation or regulation is not adopted to remedy this problem.

NAFA has submitted (to Senator Hatch) draft legislation to address this matter. We are advocating amending Section 155 of Title 35 of the U.S. Code to insure extended patent protection for alternative fuel manufacturers subjected to regulatory review by the Federal Environmental Protection Agency pursuant to the Federal Clean Air Act (including Sections 211(f) and 211(k), such that sufficient motivation exists to encourage implementation of pollution reducing fuel technologies.

Under this proposed amendment, Fuel manufacturers would, like pharmaceutical manufacturers, be granted extended patent protection to provide for the additional time to meet the requirements under EPA regulation. Alternative fuel manufacturers typically expend 4–15 years grappling for EPA regulatory approval [e.g. Section 211(f), 211(k) of the Clean Air Act]. (Ethyl Corporation, for example, spent approximately 15 years in it's recent effort to obtain a Section 211(f) waiver for a fuel additive).

Although the enactment of this amendment will have a significant impact in "leveling the playing field" for alternative fuel manufacturers, its effect should not be overstated. Alternative fuel manufacturers will not begin to construct their physical plants until after final EPA approval is granted. Initial merchant facilities require a lead time (between 3–7 years) before a fuel can even enter commercial markets. Under this scenario, alternative fuel manufacturers find themselves with expired or substantially expired patent protection before they can generate revenues. Such facilities can only serve a fraction of the total market.

It is my understanding that pharmaceutical companies, once FDA approval is granted, require anywhere from no lead time to 12 months to bring a product or drug to the marketplace to meet total world wide demand. Thus, alternative fuel manufacturers are greatly handicapped under today's regulatory environment, perhaps much more so then pharmaceuticals.

The text of NAFA's proposal to Senate Hatch is as follows:

Amend U.S. Code Annotated (Title 35, Section 155). Section 155 (Patent term extension), the U.S. Code to read as follows: "Notwithstanding the provisions of section 154, the term of a patent which encompasses within its scope a composition of matter or a process for making or using such composition or a combination shall be extended for a period not less than the total time commencing with test relating to appropriate applications, until their ultimate EPA or FDA approval, or if such composition, [or] process or combination has been subjected to a regulatory review by the EPA, or Federal Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act, related legislation or regulation thereof said term shall be accordingly extended, or if review leads to the publication of regulation permitting the interstate distribution and sale of such composition or process and for which there has thereafter been a stay of regulation of approval imposed pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act which stay was in effect on January 1, 1981 by a length of time to be measured from the date such stay of regulation of approval was imposed until such proceedings are finally resolved and commercial marketing permitted."

NAFA invites Members of the Senate Appropriations Health Subcommittee to review this proposed legislation and consider drafting a letter of support (to Senator Hatch) in favor of this measure. As previously stated, expanded patent protection for alternative fuel technologies will usher in a new class of "clean fuel" technologies for the next century.

While NAFA does not take issue with the merits of the proposal under review today, we strongly believe that the adoption of a proposal this narrow in scope would afford pharmaceutical manufacturers similar (preferential) treatment, already provided through the signing of the "Hatch/Waxman Act". Moreover, congressional enactment of the aforementioned patent term extensions (to alternative fuel technologies) will not only improve our nation's air quality, but have its own corresponding impact on reducing and eradicating serious illnesses in the United States.

Mr. Chairman, thank you for the opportunity to present testimony on this critical issue before yourself and Members of the Appropriations Health Subcommittee. I will be happy to respond to any questions.

ADDITIONAL COMMITTEE QUESTIONS

Senator SPECTER. We have prepared some questions which we would invite any panelist to respond to for the record.

[The following questions were not asked at the hearing, but were submitted to the panelists for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SUBCOMMITTEE AND RESPONSES OF GINA CIOFFI

Question. Under the proposed 5-year demonstration project, pharmaceutical companies would receive an additional 5 years of data exclusivity on a product in exchange for agreeing to provide a 3-percent royalty payment to NIH on all net U.S. sales of the product during the 5-year extension period.

Why is this change in the law necessary? Who would be expected to benefit from this proposal? Who would be harmed?

Answer. The National Institutes of Health (NIH) is the premier biomedical research facility in the world. It has reached that status, in large part, as a result of the consistent and strong support it has received from the United States Congress, in general, and this subcommittee, in particular. However, even with that support, nearly four out of five approved research projects remain unfunded.

By changing the law in a manner consistent with this proposal, Congress will be generating additional funds for NIH which will be applied to research that will otherwise not be done. For any institute that is funding 20 or 21 or 22 percent of approved projects, who is to say that the research proposal that will result in the surprising breakthrough, or the unexpected—maybe even unrelated—discovery isn't just below the pay line. Maybe it is in the 23rd or 24th percentile.

Cooley's anemia is a unrelenting genetic disease that afflicts children from birth, robs them of their childhoods, takes away their ability to live a "normal" life, and occupies much of theirs and their family's time. It requires an daily, 12-hour infusion of a drug called Desferal to help remove the iron that accumulates in the organs as a result of the 30–35 blood transfusions that patients receive every year.

There has not been a new drug to treat this disease, or its symptoms, in a generation. Research is ongoing, but it is slow, it is under-funded, and every day another patient dies without ever having obtained the benefit of it. It is those little patients, having Desferal pumped into their bodies, who would benefit from the proposal. And, if I may be so bold, Mr. Chairman, the question is not who would be harmed by the proposal. The question to be considered by the subcommittee is, "Who is being harmed by not adopting the proposal?"

Question. Opponents of this proposal argue that it would increase costs to consumers and state and federal governments by keeping cheaper generic substitutes off the market.

How would consumers benefit from this proposal?

Answer. Consumers of pharmaceutical products would benefit from the investment in research that would result both for the NIH and in private industry as a result of this proposal. That investment may result in a breakthrough in cancer research, or Parkinson's disease, or Alzheimer's disease, or Cooley's anemia. The breakthrough might come in the form of a new product, a new use for an existing product, the discovery of the perfect vector for gene therapy, or in some other way.

Opponents who suggest that consumers' interests lie solely in obtaining pharmaceutical products at the lowest possible prices do a terrible disservice to millions of Americans who are suffering from disease and disorders. To carry that argument through to its logical conclusion, one would have to argue for no market exclusivity and, in fact, no patents. But, then there would be no pharmaceuticals, for who would do the research?

Question. Proponents of this proposal argue that the current 5-year period of data exclusivity is insufficient to keep America's biomedical research global industry globally competitive.

Do you agree or disagree with this statement and why?

Answer. I agree. There are a number of European countries that currently provide ten years of market exclusivity. Given the global nature of companies today, there is nothing that would stop a major company from moving its production off-shore. In fact, many of the large companies operating in the United States today are not even American companies. They are British, or Swiss, or German, or some other nationality. To keep our industry strong, our research well funded and our people supplied with the best products that are available, it is important that the United States remain a global leader in drug research and development.

CONCLUSION OF HEARING

Senator SPECTER. Thank you all very much for being here, that concludes our hearing. The subcommittee will stand in recess subject to the call of the Chair.

[Whereupon, at 5:50 p.m., Tuesday, October 21, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

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