

economy than in most other industrialized nations. U.S. growth, unemployment, and inflation are still determined mainly by domestic decisions on interest rates, budget deficits, and the like. And, according to most economists, technological change has a bigger impact on wage stagnation and job loss than do trade and foreign investment.

None of these perspectives on globalization is entirely correct, but each has some merit. Globalization clearly offers great opportunities to the U.S. economy. Firms capable of exploiting new foreign markets can bring valuable returns to their employees and investors. By keeping prices down and increasing purchasing options, import competition can benefit consumers and manufacturers. But developments that offer opportunities to some Americans pose challenges to others. Even though technology may be a bigger threat to U.S. wages and jobs, lower-skilled workers, in particular, face tough competition from countries where labor costs are much lower.

U.S. POLICY

The United States cannot stop globalization; the economic forces behind it are simply too strong. Nor could we withdraw from the world economy. The challenge for the U.S. is to position itself to benefit from the major changes now sweeping over the international economic system so that we raise the living standards of U.S. residents overall. We need to seize the opportunities created by globalization while responding to its costs.

That means, first of all, that we need to maintain our leadership on trade and continue to work to improve the international economic system. All nations will benefit from policies of openness and engagement, the kind of international economic system the U.S. has worked hard to establish for half a century. Such policies will create new markets for our products and enhance international stability and cooperation. By renewing fast-track trade negotiating authority, Congress can give the President the critical tool he needs to open foreign markets and prevent other countries from reaching trade agreements that harm our interests.

At the same time, we need to do a better job of helping lower-skilled workers acquire the education and training they need to get the higher-paying, higher-skilled jobs that our economy is creating. We provide too little support to workers who lose their jobs due to trade. Federal and state worker education and training programs are underfunded and uneven in quality. Efforts to reform these programs have stalled several times in recent years. With the federal budget climate improved, it makes sense to try again.

CONCLUSION

Our number one concern in this increasingly globalized economy is jobs—good and secure jobs for Americans. We need to pursue policies that promote economic growth and improve living standards for all Americans. We need to redouble our efforts to better prepare workers for the new jobs our economy is creating.

INTRODUCTION OF THE POLICE AND FIREMAN'S ADDITIONAL COMPENSATION ACT OF 1997

HON. CONSTANCE A. MORELLA

OF MARYLAND

IN THE HOUSE OF REPRESENTATIVES

Wednesday, October 29, 1997

Mrs. MORELLA. Mr. Speaker, I rise today to introduce the Police and Fireman's Additional

Compensation Act of 1997. This legislation would provide added pay for members of the Metropolitan Police and Fire Department of the District of Columbia, and to the U.S. Secret Service's Uniformed Division and the Park Police who carry out certain technical or hazardous duties.

This bill also would include the additional compensation paid for service longevity into retirement calculations for police and firefighters, and is a commonsense and budget-conscious way to encourage the retirements of police and firefighters who are at the top of their respective pay scales and seniority levels.

Under this legislation, members of the U.S. Secret Service Uniformed Division who travel to a foreign country in which a state of war or civil unrest exists would receive an extra \$100 a day in addition to his/her basic compensation and travel expenses.

The Police and Fireman's Additional Compensation Act of 1997 would save taxpayer dollars by encouraging the retirements of senior police and firefighters who have reached the top of the pay scale. At the same time, the bill provides needed compensation to those who risk their lives to protect and preserve our communities. These brave men and women provide the highest quality of service to our citizens; providing them with added compensation is an appropriate way in which to send a message that we appreciate the difficult work that they do.

LOOK OUT CONSUMERS: PHARMACEUTICAL RIP-OFF BEING PROPOSED

HON. FORTNEY PETE STARK

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Wednesday, October 29, 1997

Mr. STARK. Mr. Speaker, following is the testimony of Immunex Corp. from an October 21, 1997 hearing before the Senate Appropriations Subcommittee on Labor-HHS-Education.

It describes why a proposal by a number of drug manufacturers to extend the patent exclusivity on their drugs is a bad deal for consumers and America. Everyone is for increased research on the cure to illnesses—but charging sick people more for existing medicines while the corporations pocket most of the monopoly windfall for profits is a lousy deal.

The end of a Congress is a dangerous time, when last minute sweetheart deals get added to "must pass" legislation. The last time a pharmaceutical company tried this was an anonymous amendment to the Kennedy-Kassebaum law to provide special patent protection to Lodine. the result was a national outcry and special action to strip the "gift" out of the bill.

Keep your eyes open everyone—we may be facing the same robbery attempt again.

STATEMENT BY SCOTT HALLQUIST, SENIOR VICE PRESIDENT AND GENERAL COUNSEL IMMUNEX CORPORATION, BEFORE THE SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, COMMITTEE ON APPROPRIATIONS, U.S. SENATE

October 21, 1997.

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.

WORKERS COMPENSATION REFORM

HON. DENNIS J. KUCINICH

OF OHIO

IN THE HOUSE OF REPRESENTATIVES

Wednesday, October 29, 1997

Mr. KUCINICH. Mr. Speaker, there is a national campaign in our country to weaken the social safety net that has protected our citizens for 6 decades. The latest focal point for that campaign is my home State of Ohio.

Last spring, the Ohio State legislature passed, and the Governor signed, a very damaging piece of legislation that seriously undermines the workers compensation system. Under the guise of workers compensation reform, this law would make it very difficult for workers to receive compensation for legitimate workplace injuries such as carpal tunnel syndrome. It makes a number of extreme changes in workers compensation that would block injured workers from receiving medical care and benefits. Working families would suffer so that Ohio employers can save \$200 million per year in payments to injured workers.

Mr. Speaker, the citizens of Ohio have said enough is enough. More than 400,000 voters signed petitions to place Issue 2 on the November ballot. Issue 2 would protect the rights and benefits of injured workers by overturning this destruction of Ohio's workers compensation system.

This is truly a battle of titans. On the one side is a \$10 million advertising blitz financed by big business. On the other side is a coalition of injured workers, senior citizens, churches, public interest organizations, and unions. The entire Nation is watching this vote. The rights and benefits of injured workers hang in the balance.

TRIBUTE TO CWO3 NELSON CANALES

HON. SOLOMON P. ORTIZ

OF TEXAS

IN THE HOUSE OF REPRESENTATIVES

Wednesday, October 29, 1997

Mr. ORTIZ. Mr. Speaker, I rise today to pay tribute to CWO Three Nelson Canales, a father, a soldier, and a patriot. Following his family's long and distinguished tradition of serving the Nation through the armed services, Mr. Canales joined and served in distinguished fashion with the U.S. Army for 8 years as an officer, and most recently as an aviation maintenance officer with the Army National Guard, National Guard Bureau, in Washington, DC.

Chief Warrant Officer Three Canales, the son of retired U.S. Army Sergeant 1st Class Adolfo Canales, was born on October 13, 1960, in San Juan, PR. He graduated from the Interamerican University in San Juan, PR, attending as a U.S. Army ROTC scholarship recipient. Serving in the U.S. Army from 1983 to 1991, Chief Warrant Officer Three Canales graduated from flight school in 1985 followed by multiple tours: first serving with the Attack Battalion, next the 1st Infantry Division, followed by the 82d Medical Detachment (Air Ambulance), next the chief protocol-Republic of Honduras (U.S. Embassy/JTF), and his last assignment was with the U.S. Military Intelligence Battalion as a special electronic mission aircraft pilot for the RC-12 reconnaissance aircraft. After completing his service in the U.S. Army, Chief Warrant Officer Three Canales joined the Tennessee Army National Guard in 1992.

When the nation is in need, it is a great relief to know that there are men and women, like Chief Warrant Officer Three Canales and his family, who will respond to the call of duty. On behalf of a grateful nation, let us all join his wife Kimberly and their daughters Leah Beth and Anna Kris, to pay tribute to a man