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 (''NREA''). 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 that 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

who has served this nation admirably and continues to do so with distinction.

A TRIBUTE TO DAVID B. BURKE

HON. WILLIAM O. LIPINSKI

OF ILLINOIS

IN THE HOUSE OF REPRESENTATIVES

Wednesday, October 29, 1997

Mr. LIPINSKI. Mr. Speaker, I rise today to pay tribute to an outstanding scout, David B. Burke, in achieving the rank of Eagle Scout.

The Boy Scouts of America, Troop 358, will present David B. Burke with the Eagle Scout Award at St. Christopher's Gym in Midlothian, IL, on Sunday, November 2, 1997, in the presence of his fellow troop members, his parents, family, and friends.

The Eagle Scout Award stands for honor, which is the foundation of all character. It stands for loyalty and without loyalty, all character lacks direction. Finally, the award displays courage, which gives character force and strength.

Mr. Speaker, I congratulate David and his parents for the many years of participating in the Scouting Program that has proven to develop a solid foundation for many of our youths, all over this fine country of the United States.

EPA AIR REGULATIONS: BAD SCIENCE COMBINED WITH BAD TIMING

HON. WILLIAM M. THOMAS

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Wednesday, October 29, 1997

Mr. THOMAS. Mr. Speaker, I rise to oppose the new EPA particulate matter standards issued this summer, and I call on my colleagues to support H.R. 1984, which will delay these standards until data can be collected to support a balanced and rationale decision.

Particulate matter or PM is very fine particles of dust or smoke which are created from various sources such as engines, crop burnings, dirt, or simple household dust. Farming can generate PM simply when tractors cross dry soil or by burning crops after harvest. One business in my district must routinely sweep the roads in its plant at the demand of regulators in order to minimize PM from being thrown up when vehicles pass, despite the fact that the plant is situated in the middle or arid, dusty land where the wind blows dirt around everyday. I often hear from my constituents that they would not mind the effort and cost if government requirements made sense and solve a problem. Often, as here, they do not.

EPA frequently relies upon inadequate research to support its decisions as is the case of its new PM standards. In this instance EPA bases its decision on a very limited number of studies disregarding the ones that disagree with its decision. EPA makes sweeping statements that PM causes premature deaths, but none of the studies actually monitored the affected people for a link to PM. Factors like smoking history, physical fitness, and alternative causes of death were not taken into account by any study relied upon by EPA. Many current scientific studies say poverty and cockroach allergens, not manmade pollutants, have been the major cause of asthma. EPA's data is simply inadequate.

Moreover, EPA poorly estimates the cost of these new standards. The EPA originally said $3 billion per year. Now that the regulations are promulgated, it claims $37 billion is more accurate—$37 billion every year. A George Mason University study says $80 billion is more likely for full compliance with PM. The EPA freely admits that no technology today exists to accomplish the mandate of the new standards, but it blithely believes that setting unrealistic goals is the way to force businesses to come up with new antipollution technology. On behalf of farmers in my district, however, I want to ask EPA what technology it expects farmers to use to stop the wind from blowing dirt around. We already limit agricultural burns and plowing/harvesting practices.

Imposing onerous and flawed EPA standards on an already burdened public is wrong. I support clean air and the need for air regulations, even when it raises the price of goods and services in our economy. Clean air is a good that Americans want and are ready to pay for, but they want value for their dollar. I urge this Congress to reject these new EPA PM 2.5 regulations until more scientific data is available, data that is not rushed along by lawsuits, but is collected and analyzed in a careful, professional manner.

NATIONAL NARCOTICS LEADERSHIP ACT AMENDMENTS OF 1997

SPEECH OF

HON. THOMAS M. BARRETT

OF WISCONSIN

IN THE HOUSE OF REPRESENTATIVES

Tuesday, October 21, 1997

Mr. BARRETT of Wisconsin. Mr. Speaker, I am opposed to H.R. 2610, the National Narcotics Leadership Act, in its current form. This bill would reauthorize the Office of National Drug Control Policy [ONDCP]. It was considered by the Government Reform and Oversight Committee on October 7, 1996. No hearings were held on this legislation and there was no subcommittee consideration of the bill. A number of amendments were offered by Democratic members. The bill was considered under suspension of the rules on Tuesday, October 21, 1997, over the objections of myself and Representative HENRY A. WAXMAN, ranking minority member of the Government Reform and Oversight Committee.

The cornerstone of H.R. 2610 is a series of targets for reducing drug use. We support the concept of setting targets for reductions in drug use by adults and children. These targets should be aggressive, but they should also be realistic and based on the best available evidence and expert opinion.

Unfortunately, the targets in H.R. 2610 do not appear to meet these tests. Rather, they appear to lack a substantive basis and to be politically designed for failure. According to the President's Office of National Drug Control Policy [ONDCP], ''the unrealistic targets set forth in H.R. 2610 could hurt our efforts against drug use when the public, seeing the inevitable failure to meet these goals, becomes convinced the effort is lost.'' Since our Committee held no hearings on H.R. 2610, there is no record to support the targets established in the legislation.

The target for teenage drug use in H.R. 2610 illustrates the problems in the legislation. Teenage drug use is an extraordinarily serious problem. Drug use by teenagers has increased by 50 percent since 1992. Clearly, we need a focused national effort to reduce teen drug use dramatically. H.R. 2610, however, requires the executive branch to reduce teenage drug use by 90 percent by 2001. To achieve these reductions, ONDCP would have to reduce drug use by teenagers to just 3 percent of the teenage population in just four years—a level that is 67 percent below the lowest level of teen drug use achieved at any time since 1976, when records were first kept. There is simply no evidence that these reductions are achievable in just 4 years.

Another serious problem is that H.R. 2610 ignores the two substances most commonly abused by children—tobacco and alcohol. An effective drug control strategy has to include tobacco and alcohol because these are ''gateway'' substances to drug use. Statistics show that children who drink and smoke are 30 times more likely to use cocaine or heroin than children who don't. Unfortunately, the Republican members of the committee unanimously voted against establishing targets for reducing teenage use of tobacco and alcohol. This vote was especially ironic given that the Speaker criticizes the President's initiatives to reduce teen tobacco use on the grounds that these initiatives are too narrowly focused and don't prevent substance abuse on a broader basis.

There are a number of other problems with H.R. 2610. The bill authorizes ONDCP for only 2 years, making it impossible for the agency to plan to meet the 4-year targets in the legislation. General McCaffrey has requested a twelve-year reauthorization. A 2-year reauthorization is especially troubling since the targets established by the bill are for 2001. It makes little sense to sunset ONDCP when it is only halfway to reaching the goals contained in the bill. It will only cause confusion and hamper ONDCP's effectiveness. A 2-year reauthorization will also set up ONDCP for yet another reauthorization fight on the eve of a Presidential election, further politicizing the issue.

H.R. 2610 also prohibits the use of High Intensity Drug Trafficking Area [HIDTA] funds for drug treatment programs. Under the HIDTA program, the Director of ONDCP has the authority to designate High Intensity Drug Trafficking Areas, and to reassign Federal personnel to work together with local, State, and Federal drug control agencies. HIDTA's have a law enforcement focus, but a few have successfully used HIDTA funding to coordinate treatment activities as part of an overall counter-drug effort. This is entirely appropriate, as the local authorities have determined that without coordinating drug treatment and law enforcement activities, we will continue to recycle drug offenders in unacceptable numbers.

I would like to include with my statement the President's Statement of Administration Policy on H.R. 2610, and a letter from General Barry McCaffrey, Director of the Office of National Drug Control Policy, to the minority leader, Rep. GEPHARDT, further elaborating on his opposition to this legislation.