



Congressman Henry A. Waxman's Washington Reporter Special Edition on Drugs

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Waxman Moves To Cut Cost of Prescription Drugs



TV actor Jack Klugman joins Rep. Henry A. Waxman at an emergency press conference called to avert a veto by President Reagan of the Orphan Drug Act in December 1982. The bill was signed into law on January 4, 1983.

PROGRESS ON DRUGS FOR RARE DISEASES

Only a year and a half has passed since the enactment of the Waxman Orphan Drug Act. Yet in this short time, major breakthroughs have been made in the war against rare diseases.

Before the passage of the Orphan Drug Act, people who suffer from such serious rare diseases as Parkinson's Disease, Cystic Fibrosis, and Multiple Sclerosis had no hope that a cure or treatment would be discovered. Developing a new drug can take decades and cost millions of dollars. Drug companies were simply unwilling to do the work necessary when the number of customers for the new drug would inevitably be small. The Orphan Drug Act created incentives for private research and a program for government research aimed specifically at drugs for diseases ignored by existing programs.

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Huge Savings for Consumers

If legislation initiated by Rep. Waxman and now pending in the House of Representatives becomes law, the price of key prescription drugs developed over the last 20 years will go down between 30 and 90 percent. Among the drugs that would be affected by the Waxman bill are the country's two most popular prescription medications, Inderal and Dyazide. Both of these drugs are very expensive and often taken indefinitely by people suffering from chronic heart problems or hypertension. Among the other costly and widely used drugs which would be affected are Motrin, Lasix, Indocin, and Valium.

Elderly to Benefit Most

Those who would benefit most from the reduced drug prices are senior citizens in poor health. Senior citizens account for almost 25% of all prescription drug sales. As Medicare pays for prescription drugs only while in the hospital, drug costs are a major burden on older people.

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HEROIN FOR CANCER PATIENTS

Research Study Proposed

Earlier this year I introduced the "Compassionate Pain Relief Act." This bill seeks to set up a 4-year research program to provide terminally ill cancer patients with heroin to relieve their pain.

Heroin will only be given in a hospital setting. It will be available only to those patients whose doctors request it. It will be available only to individuals who are suffering severe pain and are receiving little or no relief from the remedies for intractable pain now available. Distribution of heroin will be under the strict supervision of the General Accounting Office, the Food and Drug Administration and the participating hospitals.

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Dear Congressman Waxman:

I am writing for myself and the numerous other people involved in the National Organization for Rare Disorders. We want to express to you formally the deep feelings so many of us have expressed to you informally over the past several years.

Your willingness to dedicate so much of your time to the so-called "lost cause" of finding cures for rare diseases has changed the lives of thousands of people across America. Patients and their families feel for the first time that there is hope. We know for the first time that a prominent member of Congress has our problems at the very top of his agenda.

Above all, we are indebted to you for your willingness to face any obstacle—no matter how intimidating. Very few members of Congress ever challenge the White House, members of the opposition party, or powerful members of their own party as you did in fighting for the Orphan Drug Act.

In just a year and a half, we have all seen tangible results from your legislation. Even those who have not yet gained practical benefits from your bill have at least emerged from the nightmare in which absolutely no one anywhere was doing anything to relieve their suffering or save them from a painful and premature death.

For your compassion, determination and consummate political skill, we are eternally grateful. May God bless you and your family with the most precious gift of all: good health.

With warmest good wishes,

Abbey S. Meyers
 Director, Government & Industry
 Liaison Committee

Dedicated to Helping People with Orphan Diseases

Honorary National Chairman
 Jack Klugman

Representing*:

- The Alexander Medical Foundation
 - American Neurology Association
 - Atrophologic Lateral Sclerosis Society of America
 - Center for Neurologic Study
 - Conata de Lange Syndrome Association
 - Cystic Fibrosis Foundation
 - Cystic Fibrosis Foundation
 - Dysautonomia Foundation, Inc.
 - Dysgraphic Epileptics Guild Research Association
 - Epilepsy Foundation of America
 - Frederich's Ataxia Group in America, Inc.
 - Gaucher's Disease Registry
 - Guthrie-Born Syndrome Support Group
 - Huntington's Disease Foundation of America
 - International Joseph Diseases Foundation
 - Myoclonus Families United
 - National Association for Sickle Cell Disease
 - National Ataxia Foundation
 - National Head Injury Foundation
 - National Huntington's Disease Association
 - National Multiple Sclerosis Society
 - National Neurofibromatosis Foundation
 - National Tuberculous Sclerosis Association
 - Page's Disease Foundation
 - Parkinson's Disease Foundation
 - Parkinson's Educational Program • USA (PEP • USA)
 - Prader-Willi Syndrome Association
 - Tourette Syndrome Association, Inc.
 - United Parkinson Foundation
 - Wilson's Disease Association
- *Associations are joining enthusiastically, for nearest listing contact the NORD office

Rare Diseases (Continued from page 1)

Spirited Race to Find New Drugs

As a result of the Orphan Drug Act, 8 new drugs have been approved, 38 are under development, and 30 more are being considered for testing. (This includes pentamidine, a drug which may benefit AIDS patients.) Small, independent investigators previously denied funding have now been awarded almost \$2 million for the development of 12 drugs to treat rare diseases.

Efforts Coordinated Nationwide

As a result of the Orphan Drug Act, a new government agency—the Orphan Products Board—has been established. The Board monitors and coordinates all research on rare diseases sponsored by government agencies. Substantial headway has been made toward the creation of an all-encompassing national clearing-

house to facilitate the exchange of information among doctors, patients, research laboratories, and drug companies involved in the war against rare diseases.

Suffering Patients No Longer Forgotten

Patients suffering from painful, debilitating and even life-threatening ailments are no longer ignored. Their spirits have been lifted by the knowledge that every day top-notch researchers in both the public and private sectors are bringing their full talents and energies to bear on the scientific challenge of unusual ailments. Previously within the framework of profit-making drug companies, rare diseases went unnoticed. The Orphan Drug Act of 1983 created a whole new context in which human suffering takes precedence over short-term corporate budgets.

DRUGS AND THE ELDERLY

We all benefit from the miracle of modern drugs. However, some people need to be more careful about medicines than others. The older people become, the more likely they are to have drug-related difficulties. Older people buy one-fourth of all the drugs sold each year. Some may get confused about which medicines to take and when to take them. Others may have a different reaction to certain drugs than younger people. Some physicians might not be fully aware of these problems.

There have been several recent efforts to help older people take medications safely. The National Institute on Drug Abuse has pointed out four things people can do:

GIVE AND GET CLEAR INFORMATION WHEN YOU VISIT THE DOCTOR

Giving clear information may be hard sometimes,

ALCOHOL: THE MOST DANGEROUS DRUG OF ALL

Public health officials agree that alcohol—not heroin, PCP, or cocaine—is the most dangerous drug in our society. Alcohol, a powerful central nervous system depressant, affects the entire human body.

In a move strongly supported by Rep. Henry A. Waxman, Congress recently enacted legislation to encourage all states to raise the minimum drinking age to 21. The goal is to reduce sharply the number of young drivers with easy access to alcoholic beverages.

Alcoholism Takes a Terrible Toll

The costs to our nation of alcohol abuse extend far beyond traffic deaths and injuries. Alcoholism plays a major role in crimes of violence, unemployment, child abuse, industrial accidents, and birth defects.

Is Hospitalization Needed?

Alcoholism is now recognized as a medical problem which can be treated effectively. There is, however, a spirited debate as to what forms of treatment are most effective.

Heavy television advertising has made most Americans aware of the many hospitals offering in-patient treatment of alcoholism. Such treatment can cost \$700 a day and take between 1 and 4 weeks.

Self-help groups—such as Alcoholics Anonymous—and non-hospital-based programs provide help to alcoholics at a cost as much as 6 to 10 times lower than that charged by hospitals.

Medical Aid Required?

Hospital detoxification and rehabilitation programs offer an array of medical services not always available in community programs. However, relatively few alcoholics require intensive medical care. Such care is needed primarily by patients whose alcoholism is compounded by other serious health problems.

The Congressional Office of Technology Assessment concluded from its recent study of alcoholism treatment that “. . . there is little conclusive evidence that any treatment or treatment setting is better than any other.”

The key point to remember is that individuals and our society as a whole can successfully combat alcohol abuse. For more information on obtaining treatment for alcoholism, here are two local non-profit groups you can contact:

National Council on Alcoholism

Los Angeles County, Incorporated (213) 384-0403

Alcoholics Anonymous

Los Angeles Central Office (213) 387-8316

since many people are nervous or feel rushed when they go to see the doctor. It often helps to write down a list of questions and things you want the doctor to know. You should bring in all the medicines you are taking—even if that means filling a shopping bag. Try to remember any allergies or bad reactions you have had.

Getting clear information may require asking questions until you are **sure** you understand. Never hesitate to ask any questions on your mind. You need to know the name of the drugs, what they are for, how often and under what circumstances you should take them, and when they will expire. Sometimes people do not want to hear about what can go wrong, but it is very important to know what side effects to look for and what they might mean.

GET INFORMATION ABOUT MEDICINES FROM YOUR PHARMACIST

Pharmacists are experts on the effects of prescription and over-the-counter drugs. They can also help with special packaging, such as easy-to-open caps, and help you save money by buying generic drugs.

ORGANIZE A SYSTEM FOR TAKING YOUR MEDICINES

Some kind of system is necessary as many older people take many different drugs. Writing information down and making charts helps people make sure to take their medicines on time. Some people find it helpful to keep the drugs needed for each day in separate packets.

RECOGNIZE AND KNOW WHAT TO DO WHEN A MEDICINE CAUSES NEGATIVE SIDE EFFECTS

Drugs are very powerful chemicals and can cause problems as well as help with diseases and disorders. Certain individuals may be allergic or overly sensitive to some medicines that are perfectly safe for other people. When people have to take more than one medicine, the drugs may cancel out or strengthen the effect of each other. The combination may cause side effects that would not happen with one drug at a time.

To keep down the chances of a negative drug interaction, it is essential for the doctor to know about all the medicines that the patient is taking—both prescription and over-the-counter. Patients need to be on the lookout for possible side effects.

Certain symptoms are often warning signs of dangerous drug reactions. These include rashes, mental confusion, chronic tiredness, stomach problems, and weight loss. An especially serious side effect is difficulty in breathing. People who are taking medications should take such complaints or any other new symptoms seriously, and tell their doctor about them right away.

By following these tips on drugs, older people can enjoy the benefits of modern medicine while reducing the chances of developing health problems caused by drugs.

The material in this article was drawn from “Using Your Medicines Wisely: A Guide For The Elderly.” The complete booklet has more information and shows how to make lists and keep good records. If you would like a free copy, write to:

NATIONAL CLEARINGHOUSE FOR DRUG ABUSE INFORMATION

Room 10A-43 Parklawn Building

5600 Fishers Lane

Rockville, Maryland 20857

(301) 443-6500

Refer to DHHS Publication No. (ADM) 82-705

Prescription Drugs (Continued from page 1)

Bill Breaks Drug Industry Monopolies

The exorbitant cost of many drugs is a result of the fact that even though the patent on the drug has expired, under current federal drug law, generic versions of many drugs are prohibited. Only one company is allowed to make the drug. The Waxman bill would result in spirited competition among various companies for sale of more than 150 popular drugs now off patent and each marketed by a single firm.

Huge Savings for the Federal Government

A nationwide reduction in the prices of costly and widely used drugs would benefit all American taxpayers. The Federal Government—through the Veterans Administration hospitals, Medicare, Public Health Service, and other government programs—stands to save more than \$100 million a year on prescription drugs. Lower prices for popular drugs would allow the Federal Government to reduce greatly its spending for drugs.

Safety and Effectiveness Guaranteed

The Waxman bill requires the generic equivalents (copies) of well-known, brand name drugs to be the same as the brand name drug and to meet all the standards set by the Food and Drug Administration. Despite the much lower price of generics, the products are just as helpful and safe as the more costly brand name product.

New Funds for Drug Research

Finally, the complete revision of the drug patent laws that the Waxman bill would bring about would result in much more money for the development of new drugs. The bill provides special patent considerations to encourage basic drug research.

Heroin (Continued from page 1)

Heroin Stronger Than Morphine

Anyone who has watched a loved one die in utter agony knows that this bill is badly needed. Heroin is more than 2½ times as strong as morphine. During the last weeks and days of life, some cancer patients receive no relief from any of the drugs now used.

At the end of four years, we would then judge whether the program deserved to be extended, expanded or terminated.

The bill would do absolutely nothing to weaken current laws against the manufacture, possession, sale and use of heroin for non-medical purposes. Neither would it make heroin available to any hospital or doctor not participating in this tightly regulated research program.

Heroin is used extensively in England by physicians and hospice programs to relieve cancer pain. Work at the Georgetown Medical Center in Washington, D.C. confirms that heroin is one of the most effective drugs now available for the control of cancer pain. Until we have something better to offer, we have a moral obligation to make heroin available to those whose suffering cannot be reduced by any other means.

NEW PAIN KILLER STIRS CONTROVERSY

Ibuprofen, a pain killer available for the last 10 years by prescription only, is now being sold over-the-counter under two brand names—Advil and Nuprin. The over-the-counter version is only half the strength of the prescription tablets.

Dispute Over Warnings

Despite the drug's good record as a prescription remedy, some health professionals fear that it will be misused by consumers unaware of its dangers.

Though both Advil and Nuprin are 100% aspirin free, both are extremely dangerous for people allergic to aspirin. Up to 90% of the people who cannot safely take aspirin will suffer dangerous negative reactions from the new drugs. People who have suffered bad reactions from **any** pain killer should consult their doctor **before** taking Advil or Nuprin.

Deepest fears have been expressed by kidney specialists and other doctors who treat serious internal diseases. People with liver ailments, high blood pressure, or kidney disease may risk kidney failure by taking the new drugs.

Are Warnings Adequate?

The drug manufacturers include clear warnings of side effects both on the containers and in the ads.

Critics fear that few consumers will read the small print on the package, study magazine ads thoroughly, or catch the brief warnings on TV and radio ads.

Kidney Danger Emphasized

UCLA kidney specialist Dr. Leslie Dornfeld has warned that anyone with certain kidney problems might be taking a great risk in using ibuprofen. Dornfeld noted that kidney problems are common among older people and diabetics. He also noted that people taking diuretics (used to treat high blood pressure and premenstrual symptoms) may damage their kidneys by taking ibuprofen.

While Dornfeld approved of the sale of Advil and Nuprin, he concluded that these are "good drugs, but we've got to warn people about all the potential risks."

What doctors fear most is habitual use of over-the-counter ibuprofen products by people who should not be taking the products at all.

Advil and Nuprin are expected to win a major share of the annual \$1.4 billion market for over-the-counter remedies for minor pains, inflammation of arthritis, headaches, pain and fever of common colds and flu.

Spokesmen for the company producing the new drugs point to the popularity of ibuprofen as a prescription remedy sold under the trade names of Motrin and Rufen. Critics retort that users of these drugs all had the benefit of a doctor's judgment before taking the medication.

Is the Drug Right For You?

The 10 year record of ibuprofen in the United States indicates that the drug is both safe and effective for **some** people. It will take a careful reading of the drug information circular and, perhaps, a chat with your doctor to find out for sure if it is the right drug for **you**.