COVER STORY

New Drug Law:

"Safe and effective drugs at the lowest possible cost"

President Ronald Reagan — September 24, 1984

President Reagan with Health and Human Services Secretary Margaret M. Heckler at the Rose Garden signing ceremony. Secretary Heckler called the Act *"a major gain for all older Americans."*

H. MELVIN LUKENS IV

When President Reagan signed the Drug Price Competition and Patent Term Restoration Act into law at a Rose Garden ceremony last fall, he enabled physicians to immediately cut in half the prescription bills of many of their patients and reassured them that the drug they prescribe generically will have the same therapeutic effect as its brand-name counterpart.

The new legislation—supported by both the Pharmaceutical Manufacturers Association and the Generic Pharmaceutical Industry Association—passed Congress with only one dissenting voice (Senator Howard Metzenbaum). It will double the number of generics now available to consumers, hospitals, and the government, and, in the next five years, will reduce the prices of almost 200 drugs, including many of the most frequently prescribed pharmaceuticals in America. As generic competition increases, the prices of these drugs will be reduced to approximately one-fifth their current cost. When these 200 generic drugs reach the marketplace, savings are estimated at a billion dollars a year.

The legislation also permits up to five years of patent extension for new drugs and some extended market life for products now being sold. In that

sense, it answers complaints by the brand-name companies that the federal approval process has curtailed patent life. Extensions will be granted for one-half the time lost in the IND, or investigational process, and all the time lost in the NDA, or approval process. But no patent extension will be granted for any drug which already has an exclusive market life of fourteen years. Drugs now in the FDA pipeline will be eligible for up to two years of added patent life.

In signing the legislation, President Reagan summed up its advantages: "When you add it all up, this bill will provide regulatory relief, increased competition, economy in government, and best of all, the American people will save money, and yet receive the best medicine that pharmaceutical science can provide."

The legislation was the work of what *The New York Times* called "unlikely political bedfellows": liberal Democratic Congressman Henry Waxman of California and conservative Republican Senator Orrin G. Hatch of Utah. They were supported by the AFL-CIO, organizations for senior citizens, consumer groups, and a bipartisan coalition of cosponsors that ranged from Senator Ted Kennedy to Senator Strom Thurmond, and from Congressmen Albert Gore, Jr., (now Senator) of Tennessee and Barney Frank of Massachusetts to Congressman Gingrich of Georgia, the leader of the new conservatives, and Florida Congressmen Bill McCollum and Clay Shaw. Senator Charles Mathias of Maryland and Congressman Mike Synar of Oklahoma, cosponsors of the patent restoration legislation, gave Hatch and Waxman the impetus they needed to forge what *Business Week* called "a drug compromise that benefits everyone."

PAUL HOSEFROS/NYT PICTURES

Rep. Henry A. Waxman and Sen. Orrin G. Hatch with the nightshirts they were given by the Generic Pharmaceutical Industry Association upon passage of the Drug Price Competition Act.

The legislation took special note of lingering doubts by some physicians that there might be a margin of difference between a product prescribed generically and the equivalent product prescribed by its brand name. The law converts what has been a proven approval process for pre-1962 generic drugs into a formal requirement for post-1962 generics. All generic products, under these approval requirements, must be "bioequivalent" to the brand-name reference drug. Bioavailability testing to measure the rate and extent of absorption of the drug is required to show that the generic drug will have the same therapeutic effect as the referenced brand. These standards have been used by FDA to approve some 4,000 versions of pre-1962 generic drugs. The agency reports no instance of therapeutic failure under its generic pharmaceutical approval standards.

To implement the new law, FDA has established an independent division for generic drugs which will be headed by a physician and research scientist, Dr. Marvin Seife. He has previously supervised the approval of pre-1962 generic counterparts. A generic drug bioequivalence review unit has been established under Dr. Shrikant Dighe of FDA's biopharmaceutics division.

Excerpts from Remarks of the President at Signing Ceremony, Drug Price Competition and Patent Term Restoration Act of 1984, September 24, 1984

"This legislation will speed up the process and reduce the approval time for generic versions of many prescription drugs, make the generic versions more widely available to consumers, and grant pharmaceutical companies new incentives to develop new drugs.

"Everyone wins, particularly our elderly Americans. Senior citizens require more medication than any other segment of our society. I speak with some authority on that.

"They use about twenty-five percent—we use about twenty-five percent of all the drugs sold. With this bill, elderly Americans will have access to safe and effective drugs at the lowest possible cost.

"The bill will promote medical breakthroughs and drug innovation by granting drug companies up to five more years of patent protection for new drugs. And this extension will help compensate for the years of patent life lost due to the time-consuming but essential testing required by the Food and Drug Administration.

"And I might add that the American people will benefit because the federal government, the largest single consumer of drugs, will be able to purchase generic drugs at significantly lower cost.

"... This bill will provide regulatory relief, increased competition, economy in government, and best of all, the American people will save money, and yet receive the best medicine that pharmaceutical science can provide."

Off-Patent Drugs With No Generic Competition

Brand Name	From	For	Patent Expires	'83 Sales (Millions)
Dyazide	SmithKline	Hypertension	1980	$230
Ativan	Amer. Home Prod.	Anxiety	1/3/84	75
Tolinase	Upjohn	Diabetes	11/13/79	70
Dalmane	Hoffmann-La Roche	Insomnia	1/17/84	55
Keflin	Eli Lilly	Infections	11/11/82	40
Norpace	G.D. Searle	Irregular Heartbeats	12/21/82	45
Minocin	Amer. Cyanamid	Infections	12/23/82	30
Tegretol	Ciba-Geigy	Seizure	8/9/77	30
Lidex	Syntex	Dermatitis	3/24/81	20
Reglan	A.H. Robins	Gastrointestinal Problems	11/23/82	45
Navane	Pfizer	Psychosis	3/21/84	25
Danocrine	Sterling Drug	Infertility	6/24/81	22
Meclomen	Warner-Lambert	Arthritis	4/11/84	25
Serax	Amer. Home Prod.	Anxiety	1/3/84	25
Oncovin	Eli Lilly	Cancer	9/7/82	16
Clomid	Dow Chemical	Infertility	11/24/76	13
Restoril	Sandoz	Insomnia	1/3/84	13
Atromid S	Amer. Home Prod.	Cholesterol	7/26/83	12
Calan	G.D. Searle	Angina	1983	25

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The FDA reports no instance of therapeutic failure under its generic pharmaceutical approval standards.

In a separate action, Congress unanimously approved $3.2 million and 73 new positions to expedite the generic approval process and to ensure that there will be no delays in approving new drugs.

The legislation was several years in the making. With the election of President Reagan, the Pharmaceutical Manufacturers Association began a campaign to extend patent terms by seven years, an effort which some believe was spurred by increasing generic competition. The generic market share has been growing at nearly three times the rate of the total pharmaceutical market.

The PMA claimed that effective patent life had been "cut in half" by government regulations after the 1962 Kefauver-Harris amendments to the Food, Drug, and Cosmetics Act required new drugs to be proven effective as well as safe. To support its claim, PMA presented an "independent" study from the Center for the Study of Drug Development, then located at the University of Rochester. Congress later learned that the study had been financed by PMA companies interested in patent extension.

Congressional studies and testimony also established that actual market life for leading pharmaceuticals, after FDA approval, ranged from 15 to 18 years, not the 7.5 years reported by the Rochester Center. In hearings before Congressman Gore, Peter Hutt, representing PMA, was asked to produce the raw data on which the Rochester claims had been based. He refused, claiming it would "only confuse" the Congress.

When Congressman Synar became the prime sponsor for the patent extension bill in 1983, he required that the raw data be provided before legislation was considered. The data was finally turned over and was analyzed by the Congress, but the conclusions were not released. *Generics* magazine has confirmed that the analysis revealed that exclusive market life for the most frequently prescribed pharmaceuticals averaged nearly 15 years, not the lower figure earlier submitted to the Congress.

Concurrent with the patent extension fight, the generic drug companies were complaining that there was virtually no scientific procedure for them to obtain FDA approval for generic versions of drugs which entered the market after 1962. The FDA confirmed to Congress that it did not have a workable procedure and volunteered the information that 150 off-patent drugs were being denied approval. FDA testified before Congress that legislation was needed to implement proven procedures for the approval of post-1962 drugs.

It was the resolution of these two issues which led to the Hatch-Waxman legislation and to the President's approval. ■

Some Drugs Losing Patent Protection Soon

Brand Name	From	For	Patent Expires	'83 Sales (Millions)
Inderal	Amer. Home Prod.	Hypertension	1984	$350
Aldomet	Merck	Hypertension	1984	280
Diabinese	Pfizer	Diabetes	1984	125
Valium	Hoffmann-La Roche	Anxiety	1985	250
Motrin	Upjohn	Arthritis	1985	185
Haldol	J&J	Anxiety	1986	60
Minipress	Pfizer	Hypertension	1986	80
Flexeril	Merck	Muscle Spasm	1986	45

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