The Price for More Generic Drugs

When the Pharmaceutical Manufacturers Association (PMA) last year asked Congress for more patent protection of drugs, Representative Henry Waxman (D–Calif.) argued that the drug companies had not proved their case and successfully blocked the proposal. But Waxman, chairman of the House environment and health subcommittee, has now reversed his position. In order to pave the way for other drug legislation that Waxman badly wants passed, he has forged a bill with provisions that PMA has long pressed for. On 6 April, Waxman publicly announced for the first time the outlines of a compromise struck with PMA. The proposal, which is expected to be approved by Congress, contains the major objectives Waxman has previously sought, but it would also give PMA its central aim of increasing the patent life of new drugs. It appears Waxman is paying a substantial price to achieve his goal.

For several years, Waxman has advocated the need for generic drugs and pressed for legislation that would stimulate the generic drug industry. His proposals, however, have never gained much momentum. At the same time, competitiors of the generic companies—drug firms that conduct research and manufacture new drugs—pressed hard for a change in patent law that would correct what they say is an unfair situation. These companies, represented by PMA, argue that the effective marketing life of their products is considerably shortened because of federal regulatory review. PMA has therefore been arguing that the period of patent protection on drugs should be extended to compensate for the years lost in federal review, and it claims that the reform is needed to spur innovation (*Science*, 11 November 1983, p. 593).

Waxman has combined his wish list for generic drugs with PMA's desire for patent extension and, after 25 drafts, a proposed bill is now circulating for comment. Although PMA's board has objected to some of the details of the draft bill, PMA and the Generic Pharmaceutical Manufacturers Association both support Waxman's proposal in principle. The provisions also apply to veterinary drugs, pesticides, and other chemicals.

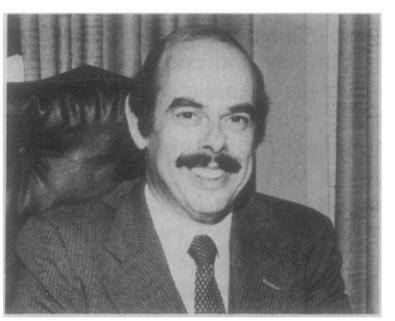
The proposal is very complex. Basically, it would lift a major restriction on the production of generic drugs that has severely handicapped the generic drug industry. It would accomplish this by allowing generic companies to manufacture drugs approved by FDA after 1962 and whose patents have now expired. PMA members would lose profits from the passage of this provision, but their loss would be offset by two major provisions in Waxman's plan that extend the marketing life of the drug. For top-selling drugs, each additional year of patent protection could translate into millions of dollars of extra revenue.

One provision would grant a 10-year exclusive marketing life to drugs approved by FDA after January 1982 but before the Waxman legislation is enacted. The other provision would extend the patent life of a drug based on its patent expiration date. Under a complicated formula, all new drugs, which have not yet been submitted to FDA for review, would be allowed up to five extra years of marketing life beyond the date when the patent expires. Drugs that are already undergoing FDA review would be eligible for a 2-year extension.

In some ways, Waxman's plan gives the drug companies more than PMA's own patent extension bill, which the Senate passed last year. The Senate version, for example, did not include the plan for an additional 10-year marketing life or the 2-year extension. Waxman's proposal, however, limits the marketing life of a patented drug to 14 years, a restriction that the Senate bill did not include.

Waxman has yet to publicly produce the evidence to support patent extension. Last fall, Waxman, joined by Representative Albert Gore (D–Tenn.) again insisted that PMA present raw data to allow Congress to determine for itself whether federal regulation significantly abbreviated the marketing life of a patented drug. After considerable delay, PMA submitted figures on more than 250 drugs to the legislators.

According to informed sources outside Waxman's subcommittee, the data, in fact, do not support PMA's contention. They say the figures showed that when a company wanted to push a drug through the regulatory process, the marketing life averaged 14 to 15 years. Both Gore and Waxman have refused to release the PMA data.



Henry Waxman

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Furthermore, a small survey conducted last fall by the General Accounting Office at the request of Gore, showed that the FDA did not unduly delay the approval of six drugs deemed new and important by the agency. In three cases, the companies themselves chose to delay the approval of the drugs for a variety of reasons, such as marketing strategy and scientific concerns.

Nevertheless, legislation—once the details are hammered out—is likely to be approved by Congress without much trouble. The legislation must pass muster with Robert Kastenmeier (D–Wis.), chairman of the House judiciary subcommittee with authority over patent issues. Although he has not taken an official position on the draft bill, Kastenmeier last year introduced his own version of a patent extension bill. The Senate and the Reagan Administration have consistently supported patent extension. And in an election year, the generic drug provisions can be touted as a consumer issue.

Waxman has needed a legislative vehicle to move his generic drug bill through Congress and found it in patent extension. Waxman's plan will result in lower prices for drugs whose patents have expired, but it will also increase the profit of the major drug companies. Says William Shultz of the Public Litigation Group, "Waxman has traded a short-term gain for a long-term loss."

—MARJORIE SUN