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EXTENSIONS OF REMARKS

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REMARKS: REMARKS BY MR. WEISS

DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984

SPEECH OF

HON. TED WEISS

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

Thursday, September 6, 1984

The House in Committee of the Whole House on the State of the Union had under consideration the bill (H.R. 3605) to amend the Federal Food, Drug, and Cosmetic Act to authorize an abbreviated new drug application under section 505 of that act for generic new drugs equivalent to approved new drugs.

● Mr. WEISS. Mr. Chairman, in July of last year I joined Chairman WAXMAN as an original sponsor of H.R. 3605, a bill to provide expedited approval of generic equivalents of drugs originally approved after 1962.

Such an abbreviated approval process is already in place for drugs originally approved before 1962. But the lengthy and expensive application procedure required for generic copies of drugs approved after 1962 has made it economically impossible for many generic manufacturers to submit such applications. As a result, there are now about 150 drugs which are no longer protected by patents, but for which no generic equivalent exists.

By providing rapid approval of generic drugs already proven to be safe, H.R. 3605 promised to save consumers about $1 billion over the next decade in drug costs. However, it quickly became apparent that passage of H.R. 3605 was unlikely unless a compromise could be reached with major drug manufacturers. Therefore, Chairman WAXMAN engaged in extensive negotiations with representatives of the brand-name generic drug companies in order to craft a workable compromise that would satisfy all interested parties.

The compromise that was fashioned provided for both faster approval of generic drugs along with extended patent terms for companies that develop pioneer drugs. The drug companies have long promoted patent term extensions as a method of encouraging research and development into new drugs. They have argued that the extension of patent protection will compensate for the period of patent protection lost while the new product is awaiting approval.

While some of the senior citizen, labor and consumer groups that favor the abbreviated approval of generic drugs have in the past opposed patent term extension for new drugs, they were willing to endorse the compromise bill in order to achieve substantial savings for consumers on their drug costs. I shared their concern that increased profits for drug firms would not necessarily lead to increased research, but I joined them in support of this reasonable compromise, which satisfied most of the parties involved.

Unfortunately, a number of dissident brand-name drug manufacturers broke rank with their own industry association and began an all-out lobbying campaign to create additional and unnecessary benefits for drug manufacturers. In order to satisfy these powerful interests, it became necessary to upset the delicate balance of the previous compromise and to slant the bill in favor of major drug companies. Last-minute changes to the bill include a provision allowing a drug company holding multiple patents to decide which of the patents would be extended and a provision providing market exclusivity for some products that are not patentable.

I am disappointed that the dissident companies would seek to upset a well-reasoned and equitable compromise, and I am disturbed that these powerful interests must be accomodated before we can pass legislation benefitting the consumer. However, the savings to consumers under this bill remain intact. Senior citizens and others who are currently burdened by excessive drug costs will experience a considerable reduction in these costs in the near future. I believe that these benefits to the consumers outweigh the concern we may feel over excessive profits for drug manufacturers, and I urge my colleagues to join me in approving the amended version of H.R. 3605.●