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EXTENSION OF REMARKS

BILL	DATE	PAGE(S)
H.R. 3605	July 19, 1983	E3581

REMARKS:
Introduced by Mr. Waxman

DRUG PRICE COMPETITION ACT

HON. HENRY A. WAXMAN

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Tuesday, July 19, 1983

● Mr. WAXMAN. Mr. Speaker, I have introduced today H.R. 3605, the Drug Price Competition Act. This legislation will make available lower cost generic drugs by allowing the Food and Drug Administration (FDA) to approve generic versions of drugs approved after 1962. Under current law, FDA generally allows generic versions only of drugs approved before 1962. The bill applies the same procedures used by FDA to approve generic versions of drugs approved before 1962 to those approved after 1962.

The Federal Food, Drug, and Cosmetic Act requires that all new drugs, including generics, be approved before they are marketed. For pioneer drugs, a manufacturer must conduct clinical tests and submit results in a new drug application (NDA) which show the product to be safe and effective.

As a result of the 1962 Drug Amendments, FDA established a policy permitting the approval of a generic drug equivalent to a pioneer drug on the basis of an abbreviated new drug application (ANDA). Under the ANDA process, a manufacturer must show that the generic is the same as the pioneer drug and that it will be properly manufactured and labeled. The generic manufacturer need not conduct human clinical trials. Such retesting is unnecessary and wasteful because FDA has already determined that the drug is safe and effective. In fact, such retesting may be unethical because it requires that some sick patients take placebos and be denied treatment known to be effective.

Unfortunately, FDA applies this ANDA policy only to drugs approved before 1962. There is no ANDA procedure for approving generic equivalents of post-1962 drugs. Although FDA has permitted the use of "paper NDA's"—that rely on published scientific reports, instead of clinical trials, to support findings of safety and efficacy—this procedure is inadequate because satisfactory reports are not available for most post-1962 drugs.

H.R. 3605 extends FDA's existing ANDA policy to permit the approval of generic versions of drugs approved after 1962. This change does not, in any way, infringe upon the patent of a pioneer drug. Generic drug makers will not be able to market their product until after the patent on the pioneer drug has expired.

Mr. Speaker, approximately 84 percent of our citizens pay their drug bill without any form of government subsidy. This is particularly hard on senior citizens, who are the largest consumers of medication, but are also those least able to afford the high price of drugs. Lower cost drugs can make a big difference in the health care costs paid by older Americans. This is because generic drugs, which are equivalent to the brand name version, are 300 to 1,500 percent cheaper.

The Subcommittee on Health and the Environment will hold a hearing on this legislation on Monday, July 25, 1983.●