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EXTENSION OF REMARKS

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REMARKS:
by Mr. Hollenbeck

THE PATENT TERM RESTORATION ACT OF 1982

SPEECH OF

HON. HAROLD C. HOLLENBECK

OF NEW JERSEY

IN THE HOUSE OF REPRESENTATIVES

Monday, September 13, 1982

● Mr. HOLLENBECK. Mr. Speaker, I rise in support of H.R. 6444, the Patent Term Restoration Act of 1982.

Mr. Speaker H.R. 6444 is a balanced bill which will assure more rapid technological innovation in the pharmaceutical and chemical industries resulting in a stronger economy and the development of less costly and more competitive new therapies and chemicals. At the same time, the interests of consumers have been adequately protected under the legislation.

The purpose of the Patent Term Restoration Act is to prevent the regulatory practices of the Federal Government from damaging the flow of new prescription drugs to the American people. The bill will allow manufacturers of pharmaceuticals requiring Federal regulatory approval prior to release, to reclaim patent protection for the period of time required for mandated testing and processing up to a maximum of 7 years.

Under present law, a research intensive pharmaceutical firm which submits a new drug to the Food and Drug Administration (FDA) for approval faces the prospect of losing much of the useful life of its patent protection while the drug undergoes the approval process. As the complexity and length of the approval process at FDA has increased over time, the average useful life of a standard 17-year patent has declined from about 14 years in 1966 to 7.4 years in 1980. At the same time, the cost of developing drugs has risen from an average of about $6 million in 1960 to a staggering $70 million today. This is not a good situation, especially when the drug industry is on the brink of major new medical breakthroughs.

The intent of this legislation is to place pharmaceutical firms on an equal footing with the rest of American industry, who face no regulatory hurdles before they can introduce new products. Drug manufacturers have come up with a number of effective pain relievers over the years. Now it is the Congress turn to deliver a pain reliever to them, in the form of long needed changes in the patent laws. I urge the bill's adoption.●