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PRESIDENT KENNEDY SIGNS NEW DRUG AMENDMENTS



Observers are, from left to right, Senator Thomas J. Dodd, Dr. Frances Kelsey, Commissioner Larrick, Senator Philip A. Hart, Senator Hubert H. Humphrey, Senator Estes Kefauver, Senator Olin D. Johnston, Under Secretary Ivan Neustingen, Congressman Leo W. O'Brien, and Congressman Kenneth A. Roberts.

On signing the Amendments on October 10, the President made the following statement:

"I am pleased to approve this bill, which is designed to provide safer and more effective drugs to the American consumer. Enactment of this legislation will help give the American consumer the protection from unsafe and ineffective drugs. It will also insure that our pharmaceutical industry will be even better equipped to provide us with the best possible drugs to be found anywhere.

"The Congress is to be congratulated in moving so quickly. Fortunately, prior to the revelation of the dangers posed by drugs like thalidomide, the foundation for legislative action on drugs had been laid down in exhaustive

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October 10, 1962:

The Kefauver-Harris Drug Amendments are passed, prompted in part by public concern over birth defects caused by the drug thalidomide. Among the new requirements: proof of drug effectiveness as well as safety, controls over clinical trials, and better quality assurance practices in drug manufacturing.

Better quality assurance practice in drug manufacturing meant the development of Good Manufacturing Practice, which was implemented in 1963.

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FDA medical officer Frances Kelsey receives the President's Distinguished Federal Civilian Service Award from President John F. Kennedy at a White House ceremony in 1962. The award, the highest honor available to civilian government employees, was for Dr. Kelsey's work in blocking U.S. approval of the drug thalidomide in the 1960s. It's estimated that more than 10,000 children in 46 countries where the sleep aid had been approved were born with deformities as a consequence their mothers using the drug while the women were pregnant.