

# The 1962 Kefauver-Harris Drug Amendments: An Appreciation

Remarks at "Celebrating a Public Health Milestone"  
As given by Margaret A. Hamburg, M.D.  
Commissioner of Food and Drugs  
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Thank you, Virginia.

I want to add my personal welcome to our distinguished guests and to my FDA colleagues—those who are here in the room with us today and those who are following this ceremony online through the webcast. Thank you all for helping us commemorate the 50th anniversary of the Kefauver-Harris Amendments—or, as the law was officially titled, the Drug Amendments of 1962.

This law, which was passed unanimously by both houses of Congress on October 2, and signed by President Kennedy eight days later, richly deserves to be celebrated. It is one of the most seminal federal acts of in the last century.

It has ushered in a process of enormous importance for our agency, and it has helped advance the public health, our economy, and American leadership in pharmaceutical science and technology.

The story of how the Amendments became the law of the land goes back to 1956, when a German manufacturer introduced thalidomide, a sedative that rapidly became, throughout the world, a popular therapy for morning sickness in the first trimester in pregnancy. Within five years, the drug was used by thousands of future mothers in 46 countries—with disastrous consequences for their babies, who were either stillborn or, more frequently, born with deformed and truncated limbs.

The U.S. was spared this heartbreaking tragedy by FDA's drug reviewer Dr. Frances Kelsey, a physician and former teacher of pharmacology at the University of South Dakota. In 1960, during her very first month as FDA employee, Dr. Kelsey took the bold step of banning thalidomide from marketing while insisting on evidence of its safety.

And when a growing torrent of reports about malformed babies bore out her position, FDA drafted legislation for keeping Americans safe from harmful drugs. These measures were adopted by Senator Kefauver, a crusader for truthful marketing, and formed the basis for most of the drug-testing requirements of the Kefauver-Harris Amendments.

In retrospect, the enactment of the 1962 law can be seen as sequel to the 1938 Food, Drug and Cosmetic Act, which remains the basic statute of our agency. But while the FD&C Act

completely reformed the public health system by greatly expanding FDA's responsibilities and powers, it had serious shortcomings that stymied consumer protection.

One very serious drawback was a provision that allowed a manufacturer to start selling a drug if the seriously short-handed and underfunded FDA failed to act within 60 days to prevent the product's marketing.

Another weakness of the 1938 law was a lack of FDA authority to enforce good manufacturing practices.

And in the absence of meaningful FDA authorities to oversee manufacturing and marketing, manufacturers could make fantastic claims for the effectiveness of their drugs.

There were basically no protections for patients harmed by faulty medicines, and there was scant monitoring of the safety of drugs on the market.

The 1962 law took steps to counter all of these drawbacks, but it did much more than that. The public outrage over the dreadful fate of the "thalidomide babies" prompted Senator Kefauver, the chairman of the Senate Antitrust and Monopoly subcommittee, to add FDA's carefully designed drug safety measures to his pending bill to enforce truth in labeling and marketing of medicines.

The law that he sponsored jointly with Representative Oren Harris, the chairman of the House Committee on Interstate and Foreign Commerce, completely changed the FDA's regulatory environment.

The key force behind this transformation was a requirement that new drugs had to be proven effective in the crucible of rigorous scientific investigation—and be approved by FDA—before they could be marketed in the United States. In the highly specific language of the Amendments, the claim of a drug's effectiveness has to be shown through "adequate and well-controlled investigations" conducted by "experts qualified by scientific training and experience."

The resulting evidence has to be sufficient to convince these experts that, the law says, "the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling."

With the passage of the Amendments, FDA was no longer a helpless bystander while unproven medicines were streaming to pharmacies and patients' bedsides. FDA could now place a "clinical hold" on noncompliant drug trials; it could inspect drug facilities to enforce good manufacturing practices; it could insist on truthful advertising of prescription drugs.

Most importantly, the new powers in the 1962 law bolstered an FDA capacity that makes our agency pivotal and highly engaged, while advancing progress for the pharmaceutical industry and the public health. That capacity was the talent of FDA's highly skilled scientists, policy makers and regulators to initiate—and adapt to—change.

This core strength of our agency was promptly tested by the severe criticism with which drug manufacturers, the American Medical Association and others showered the Kefauver Harris Amendments. The drug testing in particular was opposed as too expensive and time consuming, and FDA's approval process was criticized as too slow and rigid. There were dire predictions of a shortage of new drugs and the demise of the pharmaceutical industry.

In fact, the effects of the 1962 law were just the opposite. FDA rose to the challenge by dramatically streamlining and upgrading its processes. Within a year after the passage of the Amendments, the agency issued Investigational Drug Regulation that firmly anchored drug development and evaluation in science. It was the critical step that helped create the science-based FDA of today.

From the end of the 1970s on, our drug experts developed a series of new processes—such as "fast track," "accelerated approval," "priority review," and "treatment IND"—that have significantly shortened review times and have made urgently needed medications available in the U.S. faster than anywhere else in the world. And in the last 20 years, FDA's innovations have completely transformed the way the agency operates.

New programs provide us with additional product review resources, and private-public partnerships help us develop novel scientific tools for drug evaluation. We operate an unprecedented system of monitoring approved drug performance in millions of patients. We protect the public health globally, and we do it more scientifically, and more efficiently than was ever thought possible.

There can be no doubt that the Kefauver-Harris Amendments, with their rigorously science-based standards, triggered vast progress for FDA and for the public we serve. And notably, despite initial skepticism, Kefauver-Harris has had much the same effect on the pharmaceutical industry. To comply with the challenging drug requirements that Dr. Kelsey helped shape, firms greatly upgraded their scientific know-how, equipment, strategies and processes.

Arguably, the 1962 law laid the foundation for today's modern pharmaceutical industry, which is one of the most advanced and prosperous sectors of our economy.

In 1962, President Kennedy awarded Dr. Kelsey the Distinguished Federal Civil Service Award for protecting our country from the thalidomide tragedy. This was quite a distinction and represents one of the greatest honors bestowed on our agency.

But today, 50 years later, we have still more reason to remember the events of 1962. Today, we must add our thanks to Congress for passing an act that made possible magnificent progress in fulfilling our mission to promote and protect the health of the public.