

House Passes H.R. 2900, the FDA Amendments Act of 2007; Legislation Improves Drug Safety, Reauthorizes FDA's User Fee Programs

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NEWS RELEASE

Committee on Energy and Commerce

Rep. John D. Dingell, Chairman

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Washington D.C. - The U.S. House of Representatives today passed H.R. 2900, also known as the "FDA Amendments Act of 2007", by a vote of 403-16. The legislation originated with the Committee on Energy and Commerce's Subcommittee on Health. It improves current drug safety provisions, encourages greater transparency and timeliness in the drug review process, and reauthorizes the Food and Drug Administration's essential user fee programs.

"This bipartisan legislation provides FDA with the resources it needs to fulfill its mission of protecting the health of American consumers," said Rep. John D. Dingell (D-MI), Chairman of the Committee on Energy and Commerce. "By approving this comprehensive bill, Congress is striking the proper balance between new drug safety measures and consumer needs."

"Today, the House paved the way for restoring public confidence in the FDA by giving it the tools it needs to safeguard the public health," said Rep. Frank Pallone (D-NJ), Chairman of the Health Subcommittee. "We have produced a bipartisan bill that gives FDA the authority and resources it needs to ensure American consumers have timely access to safe and effective prescription drugs and medical devices."

Additional information on H.R. 2900, as well as the floor statement Rep. Dingell delivered today in support of this legislation, is available at: <http://energycommerce.house.gov>.

Highlights of H.R. 2900, "The FDA Amendments Act of 2007" are as follows:

Drug Safety Enhancement

Until today, FDA focused solely on a drug's safety before it was approved. This legislation establishes a new program within the FDA to monitor the safety of drugs after they have been approved and marketed. Under these drug safety provisions, drugs on the market would be subject to new FDA surveillance and safety requirements.

The bill also includes other measures to enhance drug safety, including increasing the penalties for drug companies that violate safety standards and imposing strict conflict-of-interest provisions to ensure FDA is not making decisions based on the personal financial interests of those serving on advisory panels.

User-Fee Reauthorization

PDUFA

The bill reauthorizes for five years the Prescription Drug User Fee Act (PDUFA) — the law that allows the FDA to charge fees to drug companies to expedite the agency's review of drug approval applications. It increases the user fees, which will be used to increase staffing and provide faster approval of drugs. It also contains provisions that permit appropriators to provide additional funding for the drug safety program that would allow the fees to be reduced by a corresponding amount.

MDUFMA

The bill also reauthorizes for five years the Medical Device User Fee and Modernization Act, which allows the FDA to charge user fees for the review of medical device approval. It is estimated that the FDA will collect \$287 million in fees from medical device companies over five years, just over a fifth of the total cost to the FDA to review new devices.

Penalties for Misleading Advertising

In an effort to promote drug safety, the bill also assesses a maximum penalty of \$250,000 for a first offense of a "false or misleading ad" in direct-to-consumer advertising for prescription drugs. There would be a penalty of up to \$500,000 per day for subsequent offenses in any three-year period.

Pediatric Drug and Devices Development

Finally, the bill includes several provisions to encourage the development of pediatric drugs and devices. For example, it reauthorizes for five years FDA's authority to require drugmakers to include assessments for pediatric use along with applications for new drugs or new uses for drugs. These provisions are intended to make more new drugs available to children, who typically represent a much smaller pool of likely consumers than adults. The bill also reauthorizes for five years FDA's authority to give drugmakers who find new pediatric uses for a medication an additional six months of marketing exclusivity for the drug as an incentive to research new treatments for children.

The bill will now be conferenced with S. 1082, the FDA Revitalization Act.

Prepared by the Committee on Energy and Commerce

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