

Floor Statement of the Honorable John D. Dingell in support of H.R. 2900

Statement of Congressman John D. Dingell, Chairman
Committee on Energy and Commerce

FLOOR STATEMENT
ON H.R. 2900, THE "FOOD AND DRUG ADMINISTRATION
AMENDMENTS ACT OF 2007"
July 11, 2007

Mr. Speaker, I rise to express my strong support for H.R. 2900, the "Food and Drug Administration Amendments Act of 2007". This is significant legislation and, in the best traditions of the Committee on Energy and Commerce, it is bipartisan. I commend the Members of the Committee for their hard work on this bill.

I wish to inform my colleagues that the bill text before the House today contains three useful changes from the bill that was reported by the Committee:

There is a new section on citizen petitions that is designed to prevent or minimize delays to the introduction of generic drugs. In addition to being good policy, it also reduces Federal expenditures and completely offsets the costs of H.R. 2900 so that the bill we consider today meets applicable budget pay-as-you-go standards.

Other changes are two clarifications: (1) that the Secretary is not authorized to order changes in the marketing plans of product sponsors; and (2) that PDUFA fees can be used to carry out the bill's postmarket safety activities under the risk evaluation and mitigation strategies authorized by the bill, known as REMS.

H.R. 2900 has nine distinct titles. Title I reauthorizes the Prescription Drug User Fee Act. It significantly boosts resources to have new drugs and biologic products reviewed in a thorough yet timely manner, and gives greater attention and resources to postmarket drug safety activities.

Title II reauthorizes the Medical Device User Fee and Modernization Act, providing increased user fee resources for the review of medical devices. The fee structure is broadened to both stabilize revenue and decrease the cost of application fees.

Title III is the Pediatric Medical Device Safety and Improvement Act of 2007, which will foster the development of medical devices for use by children. This fills an important gap in therapies for one of our most vulnerable and important patient groups. I commend Representatives Markey and Rogers for their efforts on this title.

Titles IV and V address the need for drugs that are tested and labeled for use by children.

Title IV reauthorizes the Pediatric Research Equity Act. This title will provide the FDA permanent authority to test and label drugs for pediatric patients.

Title V reauthorizes the Best Pharmaceuticals for Children Act, providing incentive for testing and labeling drugs for pediatric patients. Together these two pediatric drug programs achieve a common purpose—better therapies for our children. I want to recognize the efforts of Representative Eshoo on both titles.

Titles VI, VII, VIII, and IX represent the drug safety component of this bill.

Title VI establishes the Reagan-Udall Foundation for the Food and Drug Administration, which will foster private-public partnerships for the purpose of advancing FDA's mission to modernize product development, accelerate innovation, and enhance product safety. Representatives Engel and Giffords are commended for their work on this title.

Title VII addresses concerns about conflicts of interest among those who serve on the expert advisory panels that play a crucial role in FDA's work.

Title VIII establishes a clinical trials registry and database. This title will expand the amount of information available to patients, scientists, and other stakeholders regarding clinical trials.

Finally, Title IX represents a major enhancement of the safety of America's drug system through an active postmarket surveillance program, with the goal of reducing the likelihood of another Vioxx situation, when reported adverse effects went unheard. Representatives Waxman and Markey made important contributions to this legislation.

I wish to thank the Committee's Ranking Member, Mr. Barton, and Ranking Member Deal of the Subcommittee on Health. They worked with us throughout this process and brought forth good suggestions that made this a better bill. For that, I commend them for their hard work.

Finally, I wish to recognize the Chairman of the Subcommittee on Health, Mr. Pallone. His steady hand and hard work brought forth a very strong bill out of Subcommittee, and I applaud his exemplary leadership.

Mr. Speaker, this legislation strikes the proper balance between new drug safety measures and ensuring consumers have access to innovative prescription pharmaceuticals without undue delay.

I urge my colleagues to support H.R. 2900 and ask for a favorable vote on this important legislation.

Prepared by the Committee on Energy and Commerce
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