

Chairman Dingell at the Committee on Energy and Commerce markup on health legislation

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

COMMITTEE ON ENERGY AND COMMERCE MARKUP ON PDUFA, MDUFA, AND OTHER FDA LEGISLATION June 21, 2007

Today we will consider nine pieces of legislation that will help ensure timely access to safe and effective prescription drugs and medical devices; support innovative treatments and safety for our children; and protect the integrity of the drug approval process at the Food and Drug Administration.

I begin by recognizing the hard work of Subcommittee Chairman Pallone, who has labored tirelessly to bring forth an impressive package of bills.

I also commend Ranking Members Barton and Deal for the collegial manner in which we have worked on these matters, consistent with the best traditions of this Committee.

The Prescription Drug User Fee Amendments of 2007 (PDUFA) reauthorizes prescription drug user fee program through Fiscal Year 2012. The Committee Print increases the total annual user fees collected to \$392.8 million for Fiscal Year 2008 for enhancements to pre-market review, post-market safety, and the financial footing of the program. It provides an additional \$225 million in user fees over 5 years for post-market safety. PDUFA also establishes a new user fee program for direct-to-consumer advertising, and increases transparency in the PDUFA negotiation process by including consumer and patient advocates.

We have heard from many stakeholders that FDA needs more resources to perform its responsibilities, and I agree. This legislation provides FDA with the necessary user fees to provide timely review of new drug applications, biologic license applications, and pre-market approvals for devices.

The Medical Device User Fee Amendments of 2007 (MDUFA) reauthorizes the medical device user fee program through Fiscal Year 2012. The Committee Print increases user fee revenue and includes two new user fees: an annual establishment registration fee and an annual fee for filing periodic reports. Among other things, the Committee Print authorizes additional appropriations for post-market device safety.

Several of our Members deserve recognition for their efforts on the legislation before us today.

I want to thank Rep. Markey for his leadership on the Pediatric Medical Device Safety and Improvement Act of 2007. This bill offers incentives for medical devices specifically designed to meet the needs of pediatric patients.

Ms. Eshoo deserves credit for her leadership on the Pediatric Research Equity Act (PREA) and the Best Pharmaceuticals for Children Act (BPCA). These programs will ensure that children are protected when it comes to the

drugs that they take.

I also want to thank Reps. Engel and Giffords for their leadership on the Reagan-Udall Foundation at FDA, which will advance the Critical Path Initiative to identify unmet needs in the sciences of developing, manufacturing, and evaluating the safety and effectiveness of diagnostics, devices, biologics, and drugs.

Finally, let me thank Reps. Waxman and Markey for their leadership on our drug safety legislation, specifically, the Committee Prints on Conflicts of Interest, Clinical Trials, and Risk Evaluation and Mitigation Strategies (REMS). We have been alarmed by recent occurrences at FDA regarding the safety of prescription drugs.

The Members and staff of this Committee are to be commended for their diligent work as we continue to move forward these important legislative proposals.

- 30 -

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