

Chairman Dingell at the Subcommittee on Health "Legislative Hearing on Discussion Drafts of Prescription Drug User Fee Act Reauthorization, Medical Device User Fee and Modernization Act Reauthorization, Drug Safety, and Certain Pediatric Pharmaceutical and Device Legislation"

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

SUBCOMMITTEE ON HEALTH HEARING ENTITLED
"LEGISLATIVE HEARING ON DISCUSSION DRAFTS OF PRESCRIPTION DRUG USER FEE ACT
REAUTHORIZATION, MEDICAL DEVICE USER FEE AND MODERNIZATION ACT REAUTHORIZATION, DRUG
SAFETY, AND CERTAIN PEDIATRIC PHARMACEUTICAL AND DEVICE LEGISLATION"
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Mr. Chairman, thank you for your leadership on these issues and for the opportunity to begin consideration of the staff discussion drafts released by your Subcommittee last week. This hearing is an important step in crafting legislation that will affect millions of Americans, young and old, who need a medical device or take a prescription medication.

Many of these programs will expire at the end of the fiscal year, less than four months from now. It is this Committee's responsibility to ensure that these programs are reauthorized in a timely manner to avoid any personnel disruptions at the Food and Drug Administration. Hardworking, skilled employees at FDA are looking to us to do our job, so they can continue to do theirs.

As we begin this process of reauthorization, we must work towards strengthening the safety and effectiveness of the Nation's supply of drug and device therapies. We must strike the correct balance between allowing patients timely access to new therapies, while ensuring that those therapies that enter the marketplace are monitored for safety. We must enhance the post-market surveillance of both devices and pharmaceuticals so that if another "Vioxx" situation should occur, it is caught quickly.

Another important issue that the discussion drafts focus upon is the need for greater resources at FDA. We have heard about this need from a wide range of stakeholders. I agree. This legislation should provide FDA the necessary user fees to provide timely review of new drug applications, biologic license applications, and premarket approvals for devices. Equally important, we must work to ensure that Congress appropriates the funds authorized for FDA.

This Subcommittee has held a number of hearings this year on many of the issues contained in the discussion drafts. Those hearings have been very helpful in preparing us to work on these legislative matters. Again, I thank the Chairman for holding this hearing on the discussion drafts, and look forward to the testimony of the witnesses.

Prepared by the Committee on Energy and Commerce
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