

Chairman Dingell at the Subcommittee on Health Hearing entitled "Reauthorization of the Prescription Drug User Fee Act"

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

SUBCOMMITTEE ON HEALTH
HEARING ENTITLED REAUTHORIZATION OF THE PRESCRIPTION DRUG USER FEE ACT
April 17, 2007

Mr. Chairman, thank you for holding this important hearing. We are here to discuss the reauthorization of a very important piece of legislation, the Prescription Drug User Fee Act. Originally passed in 1992, this program has provided valuable resources to the Food and Drug Administration to allow timely approval of safe and effective new prescription pharmaceuticals and biologics. Each reauthorization has strengthened the program, and we find ourselves with the opportunity to make further enhancements.

As we consider PDUFA reauthorization, we must be mindful of two fundamental goals: gaining quicker access to life-saving products for patients; and ensuring that the products that do come to market are safe and effective.

For a cancer patient, access to a life-saving product in 6 months as opposed to 18 months, may be the difference between life and death. Similarly, for that same cancer patient, access to a drug that is neither safe nor effective may be the difference between life and death.

We are going to work to find a balance between those two concerns. We owe it to countless Americans who depend on the development of safe, effective, and accessible drugs and biologics.

We recognize the time sensitivity of this reauthorization. We must act in a timely manner to prevent a possible exodus of scientists and other very experienced medical officers at the FDA whose positions are funded by user fees. With this in mind, Chairman Pallone and I have sent a letter to the Commissioner of the Food and Drug Administration asking for a date certain by which the agency will begin issuing RIF notices. Coincidentally, the due date for this answer happens to be today. I hope our witness from the FDA will address this issue in her testimony.

I appreciate this hearing and the work that user fee stakeholders have put into this proposal. I look forward to the testimony of witnesses and the input of our Members as we discuss the PDUFA reauthorization.

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