

## Chairman Dingell, Subcommittee on Health Markup on PDUFA, MDUFMA, and other FDA Legislation

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

SUBCOMMITTEE ON HEALTH  
MARKUP ON LEGISLATION ON PDUFA, MDUFMA, AND OTHER FDA LEGISLATION  
June 19, 2007

Mr. Chairman, thank you for your calling this Subcommittee markup today. You have had a steady hand on this process since the first hearing a number of weeks ago. For that, I am very appreciative.

As I mentioned yesterday, we have an aggressive schedule outlined to move the user fee acts and other FDA-related legislation. To this end, we want to continue to work with our friends on the other side of the aisle, and will make sure we give them the opportunity to have meaningful input into this process.

For the past several days, Democratic and Republican Members and staff have been working cooperatively to reach agreement. In many areas, we have been successful and that is reflected in the many substitute amendments. In other areas, where we cannot agree on substantive issues, the Subcommittee will vote. It is in the best spirit and traditions of this Committee that we have worked on this legislation in a bipartisan fashion, and we will continue in that vein through both Subcommittee and full Committee markup.

Mr. Chairman, as I stated in our last hearing, it is this Committee's responsibility to ensure that user fee 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.

In the last few weeks, the Nation has learned of the safety problems with the diabetes drug, Avandia. With this markup, we have the opportunity to strengthen the safety and effectiveness of the Nation's drug and medical device therapies. In doing so, it is imperative that we strike the right balance between safety and innovation. Furthermore, we must work towards enhancing post market surveillance for both pharmaceuticals and devices.

Finally, we must ensure that as this markup goes forth, we craft legislation that will provide more resources to FDA in fulfilling its mission. We have heard about this need from many stakeholders, and from the FDA itself. I agree and urge all of my colleagues on this Subcommittee to craft legislation that provides FDA with the necessary resources to provide timely review of new drugs and devices. Just as important, the Congress must work to appropriate the funds authorized for FDA.

Again, I thank the Chairman for holding this markup, and look forward to working with all of the members of this Subcommittee towards reporting out a bipartisan bill to the full Committee.

- 30 -

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