

**Opening Statement
Chairman Fred Upton
Subcommittee on Health Hearing
Thursday, February 9, 2012**

(As Submitted for the Record)

Today's hearing on the proposed generic drug and biosimilars user fees and drug shortages is an important part of our broader effort to address FDA drug and device approvals as we work to extend and expand user fee programs well before the September deadline.

The new generic drug user fee and biosimilars user fee would bring resources to FDA to help the predictability, consistency, and transparency of FDA regulation.

Currently, there are approximately 2,500 applications in the generic drug backlog, and it takes about 31 months to get a generic drug application in that backlog reviewed. This backlog is preventing important generics from getting to the market, putting additional financial strain on our nation's patients. Under this proposed user fee agreement, the generic backlog would be effectively eliminated in five years and future applications will be reviewed on a timely basis. I believe the proposed generic drug user fee and associated goals would bring tremendous improvements, and the generic drug industry and FDA deserve credit for their hard work in coming to this agreement.

The biosimilars user fee would bring resources the agency needs to help bring predictability to FDA's review of biosimilars applications. This predictability will help innovation in this burgeoning area.

This hearing also will focus on drug shortages, and I appreciate the chairman's continued leadership on this issue. Building on the hearing this subcommittee had in September, the discussion today will bring additional ideas on how Congress can help. Drug shortages are hurting patients across the country, and I look forward to working on a bipartisan basis to help alleviate the problem. Mr. Walden, Dr. Gingrey, Mr. Bass and Mr. Latta have been particularly engaged on our side of the aisle, and I know Ms. DeGette and others have been active as well.