Insight

UFA! That's a Lot of User Fees!

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2012 has only just begun, but Congress, FDA and several healthcare industries will soon be busy with ironing out the details of new user fee acts (UFAs) and the reauthorization of expiring UFAs. Below, is a brief description of potential obstacles that each UFA may face. Be sure to stay tuned to our Upcoming in Congress page for the latest in Congressional hearings regarding user fees.

Medical Device User Fee Act III (MDUFA III)

Perhaps the most contentious of the UFAs, MUDFA III would go into effect on October 1, 2012 if reauthorized by Congress. However, the medical device industry and FDA disagree on several points including the proposed increase in fees and changes to performance goals. Industry is particularly disgruntled by the significant increase in the total time required for a device to receive approval through the 510(k) premarket review process.

Prescription Drug User Fee Act V (PDUFA V)

Once reauthorized by Congress, PDUFA V will go into effect on October 1, 2012. Besides fee increases for inflation, workload adjustments, and standardized method for Risk Evaluation and Mitigation Strategies, PDUFA V will contain few additional changes.

Generic Drug User Fee Act (GDUFA)

GDUFA will be similar to PDUFA and will outline goals for the timely review of generic drugs as well as a fee structure which manufacturers will pay to have their drugs reviewed

by the FDA. FDA and industry have largely agreed on GDUFA legislation.

Biosimilar and Interchangeable Products User Fee Act

The Biologics Price Competition and Innovation Act of 2009, a part of the Affordable Care Act, directed FDA to create a user fee program to review biosimilars, the generic versions of biologic drugs. Biosimilars are considerably more complex than normal generic drugs, which is why a separate user fee program is needed. FDA and related industry experts are currently in discussions to draft legislation for the UFA.