Comments of Amy Allina
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at the Food and Drug Administration's Public Meeting
on Prescription Drug User Fee Act (PDUFA) Reauthorization
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The National Women's Health Network is a member-supported non-profit organization that advocates for national policies which protect and promote all women's health and that provides evidence-based, independent information to empower women to make fully informed health decisions. We have about 9,000 individual members and 300 organizational members nationwide.

Background

First I want to thank the FDA for inviting me to speak on the panel this morning. The Network has spoken at past meetings about PDUFA and has raised serious concerns about the program overall. Our greatest concerns about the PDUFA program relate to the ways in which we believe it has affected the FDA's relationship to the drug companies the agency is responsible for regulating. By establishing the user fee system and PDUFA performance goals created in consultation with industry, the Congress has undermined the agency's independence and the public's confidence in the quality of consumer protection that FDA offers.

The Network is a member two coalitions which share these concerns: the Patient & Consumer Coalition, an ad hoc coalition of patient and consumer advocacy organizations working to insure greater access to safe, effective affordable drugs and medical devices, and Prevention First, a coalition of independent health organizations.

The Public Health Impact of PDUFA

This panel has been asked to address the question "Has PDUFA supported FDA's mission to protect and promote public health?" The Network believes the answer to this question is no. In fact, we believe that on balance PDUFA has detracted from FDA's ability to fulfill its mission to protect and promote public health. While we do not dismiss the contribution made to the public health by faster approval of the few drugs which have represented genuine advances for consumers and the public health over the last several years, we believe this contribution has been outweighed by other effects of PDUFA.

Today, four years after the current PDUFA program was put in place, there is clear evidence that it has led to a reconfiguration of FDA's priorities and a reallocation of its resources to the detriment of the public health.

Reduced Resources for Public Health Protection

In the years since enactment of PDUFA, FDA's resources for functions outside of drug review have been reduced. This has impeded the agency's ability to meet its consumer safety protection responsibilities. The non-PDUFA programs which have been hurt include health fraud

performance goal of taking action against companies that fail to conduct such required research, enforcement of these approval conditions would improve.

With respect to review of direct-to-consumer advertisements, the agency reports that it is keeping up with timely review. However, in at least one case, it took several months for FDA to respond to a complaint filed about an ad which was eventually found to violate required standards of accuracy and balance. This delay meant that by the time the company was notified that FDA had found a problem with the advertisement, the ad had been running for several months and been seen by hundreds of thousands of consumers. Requiring that ads be reviewed within a specific time frame, soon after being aired or published, would improve accountability and encourage timely action in this area as well.

Similar performance goals for other consumer protection and public health promotion functions (such as plant inspection, fraud investigation, etc.) of the agency could be established.

We continue to be concerned about the inflexibility of the current drug review performance goals and the process by which they were established. However, we would like to work with FDA to create public health protection performance goals with appropriate flexibility and input from consumers and public health experts.

Conclusion

In conclusion, let me reiterate three key points:

- First, Congress's decision to fund FDA's drug review through user fees has undercut the agency's autonomy from the industry it regulates and undermined the agency's ability to fulfill its mission of protecting and promoting public health.

- Second, the fiscal demands of – and the establishment of performance goals for – faster drug review have drained resources from critical public health functions of the FDA and have inappropriately skewed the agency's priorities toward faster drug review at the expense of its ability to safeguard the public health through monitoring the safety of the nation's supply of drugs, medical devices, biologics and food.

- Finally, in reauthorizing PDUFA, Congress must address these problems by recommitting itself to funding FDA at levels that make it possible to fulfill its public health protection functions and by directing the agency to establish public health performance goals in consultation with public health experts and consumers so that faster drug review no longer trumps all other functions of the agency.