Testimony before the

Senate Committee on Health, Education, Labor and Pensions

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Chairman Harkin, Ranking Member Enzi, and members of this committee, thank you for the opportunity to testify about the importance of the user fee agreement legislation to patients and public health.

Based on data, science, and non-partisan research, the Pew Health Group works to reduce risks to the health, safety, and well-being of American consumers. Pew applies a rigorous, analytical approach to improve public policy, inform the public, and stimulate civic life.

Today, I would like to talk about how the user fee agreements can promote innovation, and help to ensure the safety and effectiveness of medical products ultimately with the goal of improving health. These agreements fund critical activities of the Food and Drug Administration (FDA), the federal public health agency that regulates important, life-sustaining products, such as drugs, vaccines, medical devices, biologics, and food, as well as other products people use daily, including cosmetics, vitamins, and, most recently, tobacco.

The user fee agreements promote innovation

Since 1992, user fee agreements have given FDA significant and sustained resources that allow the agency to review new products quickly. Preliminary findings of a study Pew has funded show that FDA reviews new drugs faster than its counterparts in the European Union and Canada.

The 1992 Prescription Drug User Fee Act also established an accelerated regulatory review process for drugs that offer major advances or provide treatment where no adequate therapy exists. FDA devotes extra time and resources to drugs with priority review status

This issue is particularly important to Pew's Antibiotics and Innovation Project, which is working to promote the development of new antibiotics needed to treat people suffering from serious and life-threatening infections. Since 2000, FDA granted priority review to four of the 11 new antibiotics (linezolid, daptomycin, tigecycline and fidaxomicin) that it approved, quickly bringing much needed treatments for pneumonia, serious skin infections, and *Clostridium difficile*-associated diarrhea to market.[1] According to the Centers for Disease Control and Prevention, *Clostridium difficile*, a bacterium that can cause life-threatening infections, sickened 339,000 hospital patients in 2009 and is responsible for 14,000 deaths per year.[2]

In 2002, Congress established a user fee program for medical devices. We are asking that Congress swiftly reauthorize this program as well.

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[1] http://www.accessdata.fda.gov/scripts/cder/drugsatfda/
[2] Vital Signs: Preventing Clostridium difficile Infections. MMRW. March 9, 2012 / 61(09);157-162 http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6109a3.htm?s_cid=mm6109a3_w

The fees FDA collects under MDUFA provide the agency with additional resources to review applications and add about 200 much-needed staff members to the agency's Center for Devices and Radiologic Health (CDRH). Under the proposed agreement, the total fees collected over the five year period to 2017 are expected to reach $595 million, a significant increase over the previous agreement. This will help create a more efficient center that is sufficiently resourced to better protect consumer safety and facilitate the introduction of innovative devices.

The need for additional resources to boost the agency's capacity is especially important at CDRH. An analysis commissioned by the Pew Health Group examined CDRH, the Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research and the Office of Regulatory Affairs. The report reveals that CDRH has the highest annual attrition rate of the four centers, with nearly 10 percent of the center's science, technology and engineering staff leaving in FY 2010. Resource issues may help explain the high attrition rates; less than half of CDRH employees surveyed agreed that their workload is reasonable and even fewer reported having sufficient resources to get their job done. For it to function as efficiently and effectively as possible, CDRH must have adequate funding.

Overall, the user fee programs have substantially sped up the review of new drug applications. In the decade after the first user fee agreement was passed, the median review time fell from 27.7 months to 13.8 months. Review times for drugs given priority status have also

fallen by half. Indeed, a standard review today is as fast as a priority review a decade ago (13.9 months).[3]

Review times are important insofar as they speed patients' access to potentially important products. The user fee agreements make review times a performance metric. However, it is critical to remember that true innovation is not just about getting products to market faster; it is about developing products that are safer or more effective than existing drugs and devices. While more challenging to measure than review times, improving health is the ultimate goal of the FDA.

The user fee agreements give FDA more resources to ensure drug safety

While user fees primarily support the review and approval of medical products, some funds are available to partially underwrite certain product safety activities. Five years ago, Congress created the risk evaluation and mitigation programs, known as REMS, as a new tool to help FDA and manufacturers manage the risks of drugs. The current user fee agreement directs resources towards ensuring the effectiveness of these important programs.

The new generic drug user fee agreement also contains important safety provisions. This landmark measure will enable FDA not only to review generic drug applications, but also to inspect overseas drug manufacturing facilities more regularly. Eighty percent of the ingredients

[3] http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/speedingaccesstoimportantnewtherapies/ucm128291.htm#compare

in our pharmaceuticals come from foreign suppliers.[4] Yet, while FDA inspects American manufacturers every two years, it lacks the resources to conduct effective inspections of facilities in places such as China and India. In fact, FDA inspects overseas facilities on average every nine years.[5] Addressing this disparity will help protect patients from substandard drugs and will provide a level playing field for generic drug makers that manufacture their products and source their ingredients domestically.

While GDUFA is a very important step forward in increasing drug safety, and PDUFA funds will help evaluate certain drug safety initiatives, we are disappointed that the draft MDUFA agreement does not allow FDA to apply user fees to fund some important medical device post-marketing surveillance activities. A robust post-market surveillance infrastructure is critical to ensure the safety of these products once they are on the market. Without adequate monitoring, it is difficult to identify devices on the marketplace with unexpected safety issues, which presents a threat to patient health. The user fee agreement should recognize that creating an effective post-marketing surveillance system is crucial to the willingness of the public and regulators to see devices come to market quickly, with less clinical data.

As a result, we urge Congress to allow FDA to apply user fees to certain device safety initiatives. PDUFA already provides funding for the agency's Sentinel Initiative, a proactive

[4] U.S. Government Accountability Office (March 1998). Food and Drug Administration: Improvements Needed in the Foreign Drug Inspection Program (Publication No. GAO/HEHS-98-21).
[5] : U.S. Government Accountability Office (September 2010). Drug Safety: FDA Has Conducted More Foreign Inspections and Begun to Improve Its Information on Foreign Establishments, but More Progress Is Needed (Publication No. GAO-10-961).

system for tracking drug adverse events. We believe this program should be expanded to include medical devices as well.

In closing, I would like to emphasize that as important as user fees are to the efficient function of FDA, they cannot be a substitute for adequate appropriated funding. User fees are not available for critical activities such as enforcing good manufacturing practices, most post-market safety activities, and for regulating non-drug products, such as food, which are not covered by user fee agreements. Furthermore, FDA is a public health agency that works to promote the health of all Americans. Because of the public interest in a well-performing FDA, the agency should receive public funds and be accountable to the public, not just to the industries it regulates.

If the user fee agreements expire, patients, public health, and industry will suffer. Given the broad support for these agreements from Democrats, Republicans, the business community, and consumers, we urge Congress to move quickly to pass these important bills to ensure that FDA has continued, sustained funding to carry out and expand its important public health mission.

Thank you and I look forward to answering any questions.