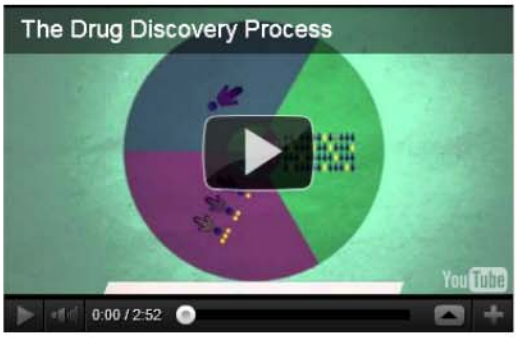
PhRMA Statement Regarding User Fee Act Reauthorization



Washington, D.C. (September 1, 2011) — Pharmaceutical Research and Manufacturers of America (PhRMA (http://www.phrma.org/about/about-phrma)) Senior Vice President for Scientific and Regulatory Affairs Dr. David E. Wheadon issued the following statement today on reauthorization of the Prescription Drug User Fee Act (PDUFA (http://en.wikipedia.org/wiki/Prescription_Drug_User_Fee_Act)):

"The PDUFA-V performance goals letter (http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf) that was published today is the result of lengthy technical negotiations between the biopharmaceutical industry and Food and Drug Administration (FDA (http://www.fda.gov)), and includes unprecedented input from other stakeholders, including patient and medical provider groups. The agreement represents a shared goal of benefitting patients by facilitating efficient and thorough drug review processes that should allow more timely access to safe and effective new medicines.

[Read Kate Connor's blog piece "One Step Forward In PDUFA Reauthorization (http://www.phrma.org/catalyst/one-step-forward-pdufa-reauthorization)."]

"If implemented as published, the PDUFA-V agreement will provide the FDA with much-needed resources and management tools to support patient safety and to promote innovation through increased transparency, predictability, and efficiency in FDA's science-based human drug review program.

"Our growing and evolving knowledge of science has led to recent breakthroughs in complex areas such as personalized medicine, biomarkers and treatments for rare diseases. The enhancements included in the PDUFA agreement, specifically the advancement of regulatory science at FDA, will more effectively support FDA's role in promoting innovative approaches to drug development.

"The PDUFA-V agreement will also establish an enhanced review model for novel medicines known as New Molecular Entities (NMEs), providing the FDA with meaningful management tools to support agency review of innovative new medicines. This enhanced review model targets completion of FDA assessments of efficacy and safety within the first review cycle and is intended to reduce the overall time until new medicines become available to patients, while maintaining FDA's gold standard of safety and efficacy. One aspect of this proposal which should facilitate this goal is increased scientific communication between FDA and sponsors prior to and throughout the review process.

"FDA's robust drug safety system would also be strengthened through provisions in the agreement that include greater standardization of and earlier consideration of risk evaluation and mitigation strategies (REMS) in the review process, support for the use of Sentinel as a tool for assessing post-market safety issues, methods for maximizing existing FDA tools for adverse event detection, and adoption of standardized approaches for electronic data submissions.

"Having successfully concluded the technical negotiation phase of the PDUFA-V reauthorization, PhRMA looks forward to continued collaboration with Congress, the Administration, and all other stakeholders as we work toward timely reauthorization of this important program."

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