

Statement of the Honorable Anna G. Eshoo
House Committee on Energy and Commerce
Markup on the Prescription Drug User Fee Act and the Medical Device User Fee Act
May 10, 2012

MS: ESHOO: Mr. Chairman, thank you for holding this markup today on the reauthorization of the Prescription Drug User Fee Act and the Medical Device User Fee Act. These critically important laws have improved patient access to important therapies and our nation's regulatory system.

The Prescription Drug User Fee Act (PDUFA) was enacted in 1992 when drug review times were lagging and FDA simply couldn't keep up with the flood of new drug applications. Through user fees paid by applicants, PDUFA gave FDA the resources it needed to hire and support more staff. The program has been successful at reducing review-time backlogs and expediting safe and effective therapies to patients.

Along with faster drug approvals, Congress also recognized the need to study drugs in children. Children are not just small adults—drugs react differently in their bodies and must be studied accordingly. The Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA) are the result of this need. BPCA and PREA have vastly changed the medical landscape for those treating children and have resulted in new dosing information, new

indications of use, new safety information, and new data on effectiveness. The drugs studied under these programs treat a range of diseases in children, including cancer, HIV/AIDS, diabetes, allergy, and asthma.

As the original author of BPCA and PREA, I'm proud to report that hundreds of drug labels have been created specifically for children since the passage of these laws. Before BPCA and PREA, the vast majority of drugs (more than 80 percent) used in children were used off-label, without data for their safety and efficacy. Today that number has been reduced to 50 percent. While we still have a long way to go, we've made remarkable progress in the last decade.

In this year's reauthorization, it was important for us to look at areas in need of improvement. The bipartisan legislation gives FDA the tools it needs to ensure companies are thinking about pediatric populations as early as possible in the drug development process, and that they're able to enforce timelines that are routinely missed. The language encourages further study into untested age groups, like neonates, and clarifies the any confusion which some see as "loopholes" to allow companies to access the market exclusivity incentive without completing additional studies.

I would like to thank my colleagues, Rep. Mike Rogers and Rep. Edward Markey who worked tirelessly with me to improve these programs, and the American Academy of Pediatrics, along with 20 other pediatric advocacy groups, who provided expert guidance and recommendations throughout the process. Together we've improved BPCA and PREA to benefit medical care for children for generations to come.