

Statement of the Honorable Anna G. Eshoo
Energy and Commerce Committee, Subcommittee on Health
April 18, 2012

Thank you, Mr. Chairman for holding this hearing on the reauthorization of the Medical Device and Prescription Drug User Fees at FDA. These are critically important programs that have provided essential resources to the Agency and improved the approval processes.

I have introduced, along with Reps. Mike Rogers and Ed Markey, a bipartisan bill to reauthorize both the Pediatric Research Equity Act (PREA) and Best Pharmaceutical for Children Act (BPCA), and I'm pleased to see it incorporated into the Chairman's latest draft of the PDUFA reauthorization. As the original author and champion of BPCA and PREA, I'm proud of the work we've done to improve the programs for pediatric medicine and the progress being made as a result of these laws.

As I've stated many times at this Committee: Children are not just small adults. Their bodies react differently to medications and their size can cause them to experience different side-effects. Without clinical data, children may be given the wrong dosage or may receive treatment that is ineffective for their age and size... and the results can be dire—toxicity, drug resistance, longer illnesses, needless pain and suffering, and higher costs to the healthcare system.

In the past five years alone, at least 130 products (80 under PREA and 50 under BPCA) have been studied for use in children. While it's clear that these programs are working to expand the number of treatment options for children, a lack of parity exists between the number of drugs studied for adults and the number studied for children.

Our bipartisan reauthorization makes significant improvements to the laws:

- Provides FDA the necessary enforcement tools to ensure that companies complete their required pediatric studies under PREA on time.
- Increases transparency on the status of pediatric clinical trials required under PREA.
- Ensures the timely submission of a company's "Pediatric Study Plan," a blueprint for how a company plans to study their drug in children.
- Ensures that neonatologists are involved in the process of reviewing and planning pediatric clinical trials.

Reauthorizing BPCA and PREA will move us closer to the goal of having all drugs include pediatric labeling. Children deserve access to the same safe drugs that adults do. We still have room to improve in important areas like pediatric oncology, and I'm working with my colleagues to ensure that FDA has the tools they need to engage companies in the appropriate studies.

Our legislation has the support of The American Academy of Pediatrics, BIO, PhRMA, the Elizabeth Glaser Pediatric AIDS Foundation, the March of Dimes, the Arthritis Foundation, the

Children's Defense Fund, and 16 other patient organizations.

I urge the Committee to make these programs a priority and I look forward to seeing them reauthorized this year.