

April 5, 2012

The Honorable Mike Rogers
U.S. House of Representatives
Washington, DC 20215

The Honorable Anna Eshoo
U.S. House of Representatives
Washington, DC 20215

The Honorable Ed Markey
U.S. House of Representatives
Washington, DC 20215

Dear Representatives Rogers, Eshoo and Markey:

On behalf of the undersigned organizations, we write to express our enthusiastic support for the *BPCA and PREA Reauthorization Act of 2012* which reauthorizes and improves two essential laws to improve drugs for children, the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA).

As you know, children are not just small adults. Drugs work differently in children than in adults and must be studied specifically for their use. BPCA and PREA, two laws that you have fought hard to create and strengthen over many years, have encouraged and required the study of drugs in children. Under PREA, drug companies have been required to study adult drug indications in children, and the incentive under BPCA has been a successful mechanism to encourage drug companies to conduct Food and Drug Administration (FDA)-requested pediatric studies—especially for off-label drug uses—in return for an additional six months of marketing exclusivity.

We have seen how BPCA and PREA have positively changed pediatric practice because all studies result in labeling changes that provide valuable new pediatric information. Over 425 drug labels have been revised with important pediatric information as a result of these policies. Drugs studied under BPCA and PREA treat a wide range of diseases in children, including HIV/AIDS, cancer, diabetes, allergy and asthma. While there has been significant success, more progress is needed, and these laws must be reauthorized and strengthened.

Your legislation is critical because it both renews these important laws and makes several important policy improvements that are consistent with the recommendations made by the Institute of Medicine (IOM) in its recent *Safe and Effective Medicines for Children* report. For instance, the bill will improve the timing and quality of pediatric research by moving pediatric study planning earlier in the drug development process. It also gives the FDA new tools to ensure that studies required under PREA are completed by their due dates unless there is an appropriate reason for delay. The bill also calls needed attention and focus to the lack of pediatric data for certain pediatric age groups, particularly neonates. We also appreciate that this legislation reauthorizes the important BPCA program at the National

Institutes of Health that provides for pediatric studies of older drugs that no longer qualify for pediatric exclusivity or fall under the requirements of PREA.

We look forward to working with you to ensure the passage of this legislation. Thank you for your dedication to the health and well-being of children.

Sincerely,

Academic Pediatric Association
AIDS Alliance for Children, Youth, and Families
American Academy of Child and Adolescent Psychiatry
American Academy of Pediatrics
American Pediatric Society
American Psychiatric Association
American Society of Pediatric Nephrology
American Thoracic Society
Arthritis Foundation
Association of Medical School Pediatric Department Chairs
Child Neurology Society
Children's Defense Fund
Children's Hospital Association
Elizabeth Glaser Pediatric AIDS Foundation
March of Dimes
National Association of Pediatric Nurse Practitioners
National Organization for Rare Disorders
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition
Pediatric Pharmacy Advocacy Group
Society for Adolescent Health and Medicine
Society for Pediatric Research

cc. The Honorable Fred Upton, Chairman, Committee on Energy and Commerce
The Honorable Henry Waxman, Ranking Member, Committee on Energy and Commerce
The Honorable Joe Pitts, Chairman, Committee on Energy and Commerce, Subcommittee on Health
The Honorable Frank Pallone, Ranking Member, Committee on Energy and Commerce, Subcommittee on Health