

American Academy
of Pediatrics



DEDICATED TO THE HEALTH OF ALL CHILDREN™



ELIZABETH GLASER
PEDIATRIC AIDS
FOUNDATION

March 28, 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 American Academy of Pediatrics and the Elizabeth Glaser Pediatric AIDS Foundation, we write to express our enthusiastic support for H.R. 4274, 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. These studies have resulted in new dosing information, new indications of use, new safety information, and new data on effectiveness. Drugs studied under BPCA and PREA treat a wide range of diseases in children, including HIV/AIDS, cancer, diabetes, allergy and asthma.

Over 425 drug labels have been revised with important pediatric information as a result of these policies. Before BPCA and PREA, the vast majority of drugs—more than 80%—used in children were used off-label, without data on their safety or efficacy. Today that number has been reduced to

approximately 50%. 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, we are pleased to see 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 IOM and our respective organizations have called attention to the continued lack of pediatric data for certain pediatric age groups, particularly neonates. Your legislation will help increase the collection of pediatric data for this vital pediatric age group. 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,



Robert W. Block, MD, FAAP
President
American Academy of Pediatrics



Charles Lyons
President and Chief Executive Officer
Elizabeth Glaser Pediatric AIDS Foundation

- 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