Pediatric Medication Studies

"The Success of BPCA has transformed the drug development process for kids. Our nation's most vulnerable citizens can now lead healthier, more productive lives as a result of new information about the safety and efficacy of drugs they use to treat and manage their diseases." (2007 BPCA Reauthorization, Senator Chris Dodd)

THE ISSUE: When it comes to biopharmaceutical research, children are not just small adults. Medications affect children's bodies differently than adults and may produce unique side effects. It is crucial that medications used in pediatric populations are studied specifically in children to ensure their safety and efficacy. The Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA) encourage and require the study of medications in children. PREA legally requires manufacturers to conduct a pediatric assessment of new medications and BPCA provides an incentive of six months of additional patent exclusivity for drug companies that conduct additional FDA requested pediatric studies. Data acquired from these studies are added to prescription labels to give providers and parents additional information on the safety and efficacy of these medications in children.

BPCA and PREA have a proven track record of success and have made medications for children safer. Thus far, BPCA and PREA studies have led to over 400 medication label revisions with important pediatric information (FDA, New Pediatric Labeling Information Database). Prior to BPCA and PREA, more than 80 percent of medications prescribed to children were prescribed off label, meaning the safety and efficacy of these medicines had not been tested specifically in children. Since the enactment of BPCA and PREA, approximately 50 percent of the medications used in children have now been tested for safety and efficacy (AAP, Reauthorizing BPCA and PREA: Building on a Record of Success, January 2012). However, both PREA and BPCA will sunset this fall. Congress should take action to strengthen and permanently extend both of these crucial programs.

THE SOLUTION: The BPCA and PREA Reauthorization Act of 2012 (H.R. 4274, S.2289) would permanently extend both programs and strengthen them by:

- Providing the FDA with the necessary enforcement tools to ensure that companies complete their required PREA studies in a timely manner;
- Ensuring the timely submission of a company's "Pediatric Study Plan", a blueprint for how a company plans to study their drug in children; and
- Increasing the transparency of the status of pediatric clinical trials required under PREA.

AACAP POSITION: AACAP urges you to support the **BPCA and PREA Reauthorization Act of 2012 (H.R. 4274, S.2289)**

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