

American Academy of Pediatrics



DEDICATED TO THE HEALTH OF ALL CHILDREN™

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**Press Statement on
U.S. SENATE PASSING PEDIATRIC DRUG AND DEVICE BILLS
By
Jay E. Berkelhamer, MD, FAAP, president, American Academy of Pediatrics**

“The U.S. Senate today passed its Food and Drug Administration Revitalization Act, which contained three pediatric provisions supported by the American Academy of Pediatrics (AAP). We appreciate the support of so many senators who clearly want to see additional improvements in the medications prescribed to children and in the development of medical devices designed specifically for use in children. In particular, we thank Senators Dodd and Clinton for their sponsorship.

“The U.S. House of Representatives must now take action on these pediatric issues. We encourage them to do so as soon as possible. The Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA), two laws to test medicines and label them for use in children, will expire by Sept. 30, 2007 if not renewed by Congress. The Pediatric Medical Device Safety and Improvement Act is a new AAP-backed bill that will provide incentives for developing pediatric medical and surgical devices.

“The AAP will mobilize its membership to guide the House in its action on these issues. However, there is one change we continue to pursue. The Senate approved an expiration date in 5 years for PREA, now known as the Pediatric Research Improvement Act (PRIA). The AAP calls on the House to make PRIA permanent. We want the same standard for children that adults get: permanent Food and Drug Administration authority that drugs used in adults be tested for their use. There is no expiration date for determining the safety of medicines in adults. We expect no less for our children.”

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The American Academy of Pediatrics is an organization of 60,000 primary care pediatricians, pediatric medical subspecialists and pediatric surgical specialists dedicated to the health, safety and well being of infants, children, adolescents and young adults.