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**AAP Commends U.S. Senate Passage of Final Legislation
to Renew and Strengthen Pediatric Drugs, Devices Laws**

Washington, DC—The American Academy of Pediatrics (AAP) applauds the U.S. Senate for passing the *Food and Drug Administration Safety and Innovation Act* (S. 3187) today by a vote of 92-4. With this vote, the bill now goes to the President for his signature.

The legislation, which would reauthorize Food and Drug Administration (FDA) user fee programs, renews and strengthens three essential laws to improve the safety and effectiveness of pediatric drugs and medical devices used in children: the *Best Pharmaceuticals for Children Act* (BPCA), the *Pediatric Research Equity Act* (PREA), and the *Pediatric Medical Device Safety and Improvement Act*.

“Children are not small adults,” said AAP President Robert W. Block, MD, FAAP. “They have unique needs for drugs and devices, and the *Food and Drug Administration Safety and Innovation Act* makes giant strides toward improving our ability to meet these needs.”

The bill, a compromise between different House- and Senate-passed bills, contains strong provisions for children. The legislation will speed pediatric drug information to patients and providers by encouraging earlier pediatric study planning by drug manufacturers and giving the FDA new authority to ensure PREA requirements are met on time. It also improves the transparency of data from pediatric studies conducted prior to 2007. By making BPCA and PREA permanent, the bill ensures that children will have a permanent seat at the table for drug research and development.

In an historic advancement for neonatal drug studies, this legislation requires FDA to hire a neonatologist to work in its Office of Pediatric Therapeutics and be part of its Pediatric Review Committee, which will provide FDA with needed expertise to appropriately apply BPCA and PREA drug study provisions to neonates. The bill also requires BPCA requests for pediatric drug studies to include neonatal populations unless FDA offers a rationale for not doing so.

The *Food and Drug Administration Safety and Innovation Act* also reauthorizes the Pediatric Device Consortia Program, an innovative and effective program to help stimulate the development of medical and surgical devices for children, and preserves the successful pediatric incentive for humanitarian use devices.

“Congress’s swift passage of FDA user fee legislation reflects a commitment among our nation’s leaders to ensure that therapeutics are safe and effective for children,” said Dr. Block. “This compromise agreement would not have been possible without the bipartisan leadership of U.S. Representatives Upton, Rogers (R-Mich.), Eshoo, Markey, Waxman, Pitts and Pallone and U.S. Senators Harkin, Enzi, Reed, Alexander, Murray, and Roberts. The AAP looks forward to seeing this bill signed into law.”

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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. (www.aap.org)