

## Key Committee Passes Eshoo Bills Improving Pediatric Drug-Testing Laws

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Washington, D.C. — The House Energy and Commerce Committee unanimously approved legislation based on a bill introduced by Rep. Anna G. Eshoo, D-Palo Alto, to reauthorize the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA). Eshoo's legislation makes significant improvements to these successful programs, increasing the quality and quantity of lifesaving pharmaceutical therapies available to children.

"The timely reauthorization of these laws will benefit our nation's children by increasing access to drugs that are clinically proven to be safe and effective for them," Eshoo said.

Eshoo, a senior member of the Energy and Commerce Health Subcommittee, has championed these programs for nearly a decade.

According to the American Academy of Pediatrics, only 25% of drugs used in children have been appropriately tested for use in pediatric populations. By necessity, pediatricians have to prescribe drugs for "off-label" use, meaning most drugs prescribed to children have not been studied in appropriate FDA-approved pediatric clinical trials. In some tragic cases, children have died or suffered serious injury as a result of taking drugs that are safe for adult use but have had different results on children. Reauthorizing BPCA and PREA will increase the number of drugs tested and labeled for children.

"Children are not small adults," Eshoo said. "They have specific medical needs that have to be considered when drugs are used."

Congress responded to these problems in 1997 with the initial passage of BPCA, and again in 2003 with enactment of PREA. Specifically, BPCA provides a voluntary incentive for drug manufacturers to conduct clinical trials in children. PREA gives FDA the authority to require pediatric studies of drugs. These two laws have established a "carrot and stick" approach to pediatric drug testing that has been extraordinarily successful.

The reauthorization legislation will increase the availability of pediatric information to doctors, parents, and researchers. Transparency and accountability of pediatric drug testing programs at FDA will be improved, and post-market surveillance of pediatric drugs enhanced. The legislation also makes permanent the FDA's authority to require pediatric studies of drugs.

The legislation incorporates recommendations of public health professionals at the Government Accountability Office (GAO) and the Food and Drug Administration (FDA). Leading child care advocates, including the American Academy of Pediatrics (AAP) and the Elizabeth Glaser Pediatric AIDS Foundation, strongly endorse the legislation.

Seven other bills were also considered at Thursday's Full Committee markup, all aimed at improving the safety and efficacy of pharmaceuticals, biologics and medical devices. The bills are scheduled to be considered by the full House before July 4th.