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Includes Eshoo Legislation to Improve Pediatric Drug-testing Laws

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WASHINGTON, D.C. - The House of Representatives voted 403 to 16 today to approve H.R. 2900, the Food and Drug Administration (FDA) Amendments Act of 2007, a bill to reauthorize and reform vital FDA functions such as drug and medical device approval and safety monitoring.

The bill includes provisions 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.

"Simply put, 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.

H.R. 2900 also reauthorizes the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee Act (MDUFMA), both of which have been successful in speeding up FDA approval of new drugs, biologics and medical devices. The legislation also implements new post-market safety requirements for drugs that may cause serious side effects in certain populations, and establishes a national clinical trials database.

The Senate passed similar legislation earlier this year. Differences between the bills will need to be resolved through a Conference Committee.

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