

House Approves Passage of Landmark FDA Reform Bill

September 19, 2007

House Approves Passage of Landmark FDA Reform Bill

Includes Eshoo Legislation to Improve Pediatric Drug-Testing Laws

September 19, 2007 | Video

WASHINGTON, D.C. - Today, Congresswoman Anna G. Eshoo, D-Palo Alto, voted for final passage of H.R. 3580, 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 House voted 405 to 7 to send the bill to the Senate.

H.R. 3580 includes provisions based on Eshoo's bill (H.R. 2589, Improving Pharmaceuticals for Children Act) 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 the quantity of lifesaving pharmaceutical therapies available to children.

"Children are not small adults. They have specific medical needs that have to be considered when drugs are used," Eshoo said. "This legislation will benefit our nation's children by increasing access to drugs that are clinically proven to be safe and effective for them."

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 and labeled for use in kids. By necessity, pediatricians often have to prescribe drugs for "off-label" use, because the drug has 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.

H.R. 3580 improves drug safety for children in two ways. First, under BPCA the bill provides an incentive of an extra six period of marketing exclusivity for a drug if the innovator company agrees to undertake comprehensive pediatric studies requested by the FDA. Second, under PREA, the FDA is granted authority to require studies when there is a demonstrated need. Also, PREA requires drug companies to submit a pediatric assessment each time they apply to market a new drug or change an existing drug's purpose.

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.

H.R. 3580 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.

{moseasymedia media=http://youtube.com/v/utl_LR0PgI0&rel=0}

##