

the Critical Path Initiative in 2004 to improve the efficiency and safety of drug and medical product development. This provision authorizes the FDA to enter into Critical Path Public-Private Partnerships with universities and non-profit organizations to modernize the process to develop prescription drugs and other medical products. These collaborations will help the FDA move drugs and medical devices through the approval process in a quicker, safer and more reliable manner at a lower cost.

Mr. Speaker, the Food and Drug Administration Amendments Act is only one important step in providing FDA with the necessary tools and resources to do its job. Congress must also significantly increase federal appropriations to FDA so that the agency is able to fulfill its most basic responsibilities. Such an increase will not only make foods, drugs and devices safer, but it will also lead to a stronger, more effective FDA that can restore public confidence, speed innovation and ensure that America remains competitive in foreign markets.

I believe H.R. 2900 will help ensure the timely access to safe and effective prescription drugs and medical devices as well as improve the integrity of the drug approval process at FDA. I urge my colleagues to support H.R. 2900.

Mr. GENE GREEN of Texas. Mr. Speaker, I rise in strong support of H.R. 2900, legislation to reauthorize important user fee programs at the Food and Drug Administration and enact critical drug safety reforms at the agency.

This legislation is the result of years of hard work by the Energy and Commerce Committee and particularly the Oversight and Investigations Subcommittee and the Health Subcommittee. I am proud to serve on both of these subcommittees. The Oversight and Investigations Subcommittee has worked on a bi-partisan basis to investigate the drug safety concerns brought to light by scandals associated with drugs such as Vioxx, Ketek and Selective Serotonin Reuptake Inhibitors, or SSRIs, which are typically used to treat depression. These investigations uncovered significant safety lapses at the FDA and shed a bright light on the FDA's bias toward drug approval with too little attention paid to post-market safety concerns.

The FDA Amendments Act of 2007 makes important changes at the FDA to place a greater emphasis on post-market surveillance within the agency. Specifically, this legislation would establish a Risk, Evaluation, and Mitigation Strategy whereby drugs approved by the agency are monitored throughout their lifecycle for adverse events or other signs of safety concerns. A critical aspect of this strategy is the additional authority this bill gives the Secretary of HHS to mandate that drug manufacturers conduct post-market studies.

Under this bill, the additional post-market activities extend to the user fee programs that help fund the drug approval process. Specifically, this bill directs drug manufacturers utilizing the FDA's drug approval process to dedicate an additional \$225 million over five years for post-market surveillance activities at the FDA. This additional funding represents an important investment by the pharmaceutical industry in the FDA's postmarket safety activities, while also ensuring that pre-market user fees are adequate to bring potentially life-saving medicines to market in a reasonable time.

This legislation also reauthorizes the Medical Device User Fee Act, as well as the Best Pharmaceuticals For Children Act and the Pediatric Research Equity Act. The unanimous support of the committee for this bill is a testament to the open process and bi-partisan nature in which the committee members and staff on both sides of the aisle conducted these negotiations.

I would like to thank our Chairman, Mr. DINGELL, and our Health Subcommittee Chairman, Mr. PALLONE, for their work on this important legislation, and encourage my colleagues to support this important bill. These necessary changes at the FDA will go a long way toward restoring the American public's confidence in the agency and its ability to ensure the safety of the nation's drug supply.

Ms. HOOLEY. Mr. Speaker, I am particularly pleased that H.R. 2900 includes a provision I authored and worked on with my colleague Mr. DOYLE from Pennsylvania that will require the FDA to establish a unique device identification (UDI) system for medical devices.

Currently, most medical devices cannot be tracked or identified in any systemic fashion. A UDI will enable the FDA to better pinpoint devices associated with adverse events and look for patterns across event reports. A more sophisticated reporting system will thus strengthen FDA's post-market surveillance capabilities.

A UDI system will not only provide FDA with the tools to discover warning signs of a defective device earlier, thus potentially saving lives, but will also improve the agency's ability to promptly respond to device recalls. I believe our current system for notifying patients in the event of a recall is deficient. When defective medical devices are recalled, the absence of a standard identification system hinders the FDA's ability to notify patients. These UDI provisions take an important step toward improving the ability of the FDA, device manufacturers, and physicians to quickly and effectively communicate risk information to patients.

Ms. ESHOO. Mr. Speaker, I rise in full support of H.R. 2900, the Food and Drug Administration Amendments Act of 2007. An extraordinary amount of time was put into negotiating this bill and the fact that it's coming to the floor without contention is a testament to the leadership of our Committee and Subcommittee Chairmen, Ranking Member, and Majority and Minority staffs.

The bill is important for ensuring the safety and efficacy of pharmaceuticals and medical devices available to the American public. It includes necessary funding for vital FDA functions, such as drug and device review and approval, and also enhances post-market surveillance activities for these products.

I want to focus my remarks on the sections of the bill that renew the Pediatric Research Equity Act (PREA), and the Best Pharmaceuticals for Children Act (BCPA). I championed the original enactments of these successful programs which have helped to increase the number of drugs tested and labeled for use in children, and I'm proud these programs will be renewed and further improved under this bill.

According to the American Academy of Pediatrics, only about 25% of drugs administered to children have been appropriately tested for use in kids. Pediatricians often have to prescribe drugs for "off-label" use, because the drug has not been studied in appropriate FDA-approved pediatric clinical trials. Children have

specific medical needs that have to be considered when drugs are used. Children have died or suffered serious side effects after taking drugs that were shown safe for use in adults but had different results in children.

I've worked with stakeholders on all sides of this issue to update BPCA and PREA to increase the amount and quality of pediatric information available to doctors, parents, and researchers. I've also enhanced labeling and post-market safety requirements. The bill also makes permanent the FDA's authority to require pediatric studies of drugs, which is consistent with its permanent authority to require studies of adult formulations. Together, these changes will help to generate important new information about the safety and efficacy of drugs prescribed to children.

A coalition of children's groups has endorsed H.R. 2900. The bill was unanimously passed out of the Energy and Commerce Committee before the July 4th Recess and I urge my colleagues to support it.

In closing I want to thank the staff members who have worked exceedingly hard to bring this bill to the Floor today: John Ford, Bobby Clark, Pete Goodloe and Jack Maniko of the Energy and Commerce Committee Majority staff, Ryan Long and John Little of the Minority staff, and Jennifer Nieto from my office.

I'm proud to be an original cosponsor of H.R. 2900 and I urge my colleagues to vote for it.

Mr. PALLONE. Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New Jersey (Mr. PALLONE) that the House suspend the rules and pass the bill, H.R. 2900, as amended.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. PALLONE. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX and the Chair's prior announcement, further proceedings on this question will be postponed.

REPORT ON RESOLUTION PROVIDING FOR CONSIDERATION OF H.R. 2956, RESPONSIBLE REDEPLOYMENT FROM IRAQ ACT

Mr. HASTINGS of Florida, from the Committee on Rules, submitted a privileged report (Rept. No. 110-226) on the resolution (H. Res. 533) providing for consideration of the bill (H.R. 2956) to require the Secretary of Defense to commence the reduction of the number of United States Armed Forces in Iraq to a limited presence by April 1, 2008, and for other purposes, which was referred to the House Calendar and ordered to be printed.

REPORT ON RESOLUTION PROVIDING FOR CONSIDERATION OF H.R. 1851, SECTION 8 VOUCHER REFORM ACT OF 2007

Mr. HASTINGS of Florida, from the Committee on Rules, submitted a privileged report (Rept. No. 110-227) on the