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Reauthorization of FDA User Fee Legislation Critical to Ensuring Access to Cancer Treatments and Therapies

Bill Take Steps to Address Drug Shortage Issue

WASHINGTON – April 25, 2012 – Families affected by cancer are encouraged by efforts in the U.S. Congress to advance legislation this week that would reauthorize and expand the industry-supported user fee program that pays for the expeditious review of new pharmaceutical drugs and medical devices by the Food and Drug Administration (FDA). This legislation has the potential to make a significant difference in the lives of patients, providing them with timely access to cutting edge therapies.

"Industry user fees are critical to enable the Food and Drug Administration to speed approval of lifesaving cancer drugs and treatments," said Christopher W. Hansen, president of the American Cancer Society Cancer Action Network (ACS CAN), the advocacy affiliate of the American Cancer Society. "Renewing this important industry-government partnership is tantamount to ensuring that cancer patients, survivors and their families have access to the newest evidence-based treatments to help ultimately eliminate death and suffering related to this disease."

The Prescription Drug User Fee Act (PDUFA) allows the Food and Drug Administration (FDA) to collect fees from the pharmaceutical industry so the federal agency has the resources it needs to evaluate and approve new drugs in a timely fashion. First passed in 1992 and reauthorized every five years, the law has had a major impact on patients with life threatening and chronic diseases by helping them to access safe and effective medicines as quickly as possible. The 2012 reauthorization would further strengthen the program by including important provisions for cancer patients and survivors that incentivize innovation.

In recognition of the dramatically increased use of generic drugs, Congress is also for the first time recommending a similar Generic Drug User Fee program (GDUFA) that would collect fees from generic drug manufacturers for the specific purpose of accelerating review and approval of generic drugs.

Additionally, the user fee legislation contains new provisions aimed at mitigating the ongoing drug shortage problem in the United States, which has been experienced first-hand by cancer patients and survivors who needed drug therapies that were suddenly unavailable. The legislation directs manufacturers to provide FDA with early notification of a prospective discontinuation or interruption in the drug manufacturing process that could lead to a shortage of a particular drug. It also establishes an FDA task force to work with manufacturers and the Secretary of Health and Human Services to ensure the availability of alternative sources of drug supply in the case of an ongoing or prospective shortage.

“We commend Congress for addressing the drug shortage issue that has impacted cancer patients and their families acutely,” Hansen said. “ACS CAN together with the American Cancer Society has been working with the FDA and representatives of the pharmaceutical industry for many months to find a solution to this critical problem, and we believe proper notification and the creation of a task force along with the new generic drug user fee is a good start that will begin to alleviate some of the shortages now in effect.”

The user fee legislation also includes the reauthorization of the Medical Device User Fee Act (MDUFA), a program that since its inception has resulted in significant improvements in the device review program and saved countless number of lives of cancer patients. ACS CAN strongly supports a provision in the Senate Health, Education, Labor, and Pensions (HELP) version of the MDUFA legislation that would require the Secretary of HHS to determine whether warning labels for indoor tanning beds effectively inform consumers about their risks. In 2009, the International Agency for Research on Cancer rated indoor tanning equipment as definitely “carcinogenic to humans,” evidence that the public needs better information on the risks associated with this equipment.

Finally, Congress is considering permanent reauthorization of the Best Pharmaceuticals for Children Act (BPCA) and Pediatric Research Equity Act (PREA), two laws that have advanced pediatric research since they were first authorized in 2002 and 2003 respectively. Science has shown that children are not just small adults and drugs work differently based on the size and anatomy of an individual. The legislation strengthens the FDA’s authority to evaluate the effectiveness of drug therapies for children, requiring better communication between FDA and the drug manufacturer earlier in the drug approval process.

Collectively, the drug and device user fee acts have had a direct and significant impact on the lives of families affected by cancer since their enactment. ACS CAN supports timely reauthorization so cancer patients and survivors can continue to have access to lifesaving treatment.

ACS CAN, the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. ACS CAN works to encourage elected officials and candidates to make cancer a top national priority. ACS CAN gives ordinary people extraordinary power to fight cancer with the training and tools they need to make their voices heard. For more information, visit www.acscan.org.

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