

Support H.R. 5651 – The Food and Drug Administration Reform Act of 2012

The United States has led the global medical device and biopharmaceutical industries for decades. This leadership has made the U.S. the medical innovation capital of the world, bringing hundreds of thousands of high-paying jobs to our country and life-saving devices and drugs to our nation's patients. U.S. medical device-related employment totals over 2 million jobs, and these are good, rewarding jobs as employees in the device industry earn an average of \$60,000 per year. The U.S. biopharmaceutical industry is responsible for over 4 million U.S. jobs.

Unfortunately, our nation's device and biopharmaceutical leadership is under threat. The threat comes from Food and Drug Administration's (FDA) unpredictable, inconsistent, non-transparent and inefficient regulation of devices and drugs. Because of the lack of predictability, consistency, transparency and efficiency, U.S. device and drugs jobs have gone overseas and foreign patients, not U.S. patients, have been the first to benefit from U.S. innovation.^{1 2 3}

The significant policy reforms contained in H.R. 5651, coupled with the accountability and transparency measures in the user fee agreements, would address the lack of predictability, consistency, transparency and efficiency at FDA so we can ensure that the U.S. remains the world leader in medical innovation, device and drug jobs stay in the U.S., U.S. patients benefit first from new device and drugs, and FDA no longer wastes U.S. taxpayer and innovators' resources because of bureaucratic red tape. Further, the amended bill would reduce the deficit by \$370 million over ten years. Below is a summary of the bill, including its reform and accountability measures:

Title I- The Prescription Drug User Fee Act Reauthorization

Under the bill, the drug industry would pay over \$700 million in FY 2013 and higher amounts in the remaining four years. In exchange, FDA would commit to the following goals: (1) meeting performance goals regarding the timely review of drug applications; (2) increasing interaction between drug sponsors and FDA during the review process; (3) improving engagement with patients, including those with rare diseases; (4) providing more granular data from its review divisions to improve transparency, and (5) undertaking an independent assessment by a third party of FDA's performance in FDA's reviewing applications for novel drugs.

Title II- The Medical Device User Fee Act (MDUFA) Reauthorization

Industry would pay \$595 million in user fees for FY 2013-2017 in return for significant changes in FDA performance and accountability. The bill would authorize the following changes: FDA would report its total time for reviewing devices; the review process would include greater interaction between sponsors and the agency; an independent entity would review the device approval and clearance process; and FDA would have to implement a corrective action plan to address deficiencies found in the independent review.

Title III- Generic Drug User Fee Act (GDUFA) Authorization

The generic drug industry would pay approximately \$1.5 billion over five years in return for faster and more predictable

¹ Even the Administration's own Jobs Council believes that regulatory uncertainty at FDA has caused our medical innovation ecosystem to suffer. The Council commented: "[O]ur medical innovation ecosystem is in jeopardy. Investment in the life sciences area is declining at an alarming rate because of the escalating cost, time, and risk of developing new drugs and devices. While many factors have contributed to this decline . . . an important factor is the uncertain FDA regulatory environment." President's Council on Jobs and Competitiveness, Interim Report, *Building Confidence: Five Common-Sense Initiatives to Boost Jobs and Competitiveness*.

² A study by the California Healthcare Institute and The Boston Consulting Group found that in 2010, the European Union (EU) approved applications for new medical devices on average about 46.8 months faster than the U.S.

³ Last July, the Energy and Commerce Committee heard testimony from American patients who had to travel overseas to access U.S. innovation. One of these patients, Marti Conger, had to travel to England to get access to a device made by a company located 40 miles from her home in California.

review of generic drug applications and increased inspections of drug facilities. There are currently 3,000 generic applications in the backlog at FDA, and one of the goals of the GDUFA would be to eliminate this backlog in five years. These improvements brought by the new generic user fee would bring cheaper drugs to the market faster, saving patients and the federal government money.

Title IV- Biosimilars User Fee Act (BSUFA) Authorization

This new user fee would apply to products approved under the abbreviated approval pathway for biological products shown to be biosimilar to an FDA-licensed biologic. These funds will bring more certainty to the regulation of this new segment of the biopharmaceutical industry.

Title V: Best Pharmaceuticals for Children Act (BPCA) and Pediatric Research Equity Act (PREA)

The bill would permanently reauthorize these programs, which incent testing of prescription drugs in children to allow for the safe use of these products by children. BPCA has been very successful in spurring research in the pediatric population for rare conditions and encouraging companies to undertake research where there was no incentive to do so. For example, almost 50 percent of all of the oncology products that have received pediatric exclusivity since BPCA's enactment were for drugs for rare conditions. This success is not limited to oncology. According to GAO, BPCA has led to additional research into over 16 different broad categories of disease.

Title VI: FDA Administrative Reforms

Title VI would change FDA's guidance process to encourage public participation and Congressional oversight, and it would improve FDA's conflict of interest rules to ensure the agency and its advisory committees have access to the most knowledgeable scientific experts.

Title VII: Medical Device Regulatory Reforms

Title VII would significantly reform FDA's medical device review process to build additional certainty, predictability, transparency and efficiency into the process, including the following: (1) restore the Investigational Device Exemption (IDE) standard so innovators can bring clinical trials back to the United States and end inefficient double reviews of IDE applications, which wastes U.S. taxpayer and innovator resources; (2) require FDA to withdraw the 510(k) modifications guidance that would increase device submissions by 300 to 500%, which will save U.S. taxpayers resources and prevent a crippling of the device review process and innovation; (3) require FDA reviewers to provide the scientific and regulatory rationale for major decisions and allow an expedited appeal of those decisions to provide transparency and certainty to the review process; (4) streamline the de novo classification process for novel medical devices to save U.S. taxpayer and innovator resources; (5) reform the Humanitarian Device Exemption to incent the development of devices for adults with rare conditions; and (6) reaffirm the "least burdensome" provisions to ensure that device approvals and clearances are not held up by unnecessary information requests, saving U.S. taxpayer and innovators money.

Title VIII: Drug Regulatory Reforms

The legislation includes numerous provisions to improve the drug review process. One provision would increase access to the Accelerated Approval pathway so patients could access life-saving drugs faster. The legislation also includes incentives for the development of antibiotics to address the public health threat of antibiotic resistance. Finally, it includes provisions to protect patients through reforms that would allow FDA to deal with the increased globalization of drug manufacturing.

Title IX: Drug Shortages

Title IX would help patients, doctors, nurses, and hospitals handle the current drug shortages crisis. The legislation includes reforms that would require the FDA inform the public through a drug shortages list, alleviate current shortages by modifying current reporting requirements, expedite the review of manufacturing changes of drugs in need, and prevent a future crisis by authorizing GAO to examine the causes of the crisis and issue recommendations to prevent future shortages.