



**EXECUTIVE OFFICE OF THE PRESIDENT  
OFFICE OF MANAGEMENT AND BUDGET  
WASHINGTON, D.C. 20503**

July 12, 2017  
(House)

## **STATEMENT OF ADMINISTRATION POLICY**

### **H.R. 2430 – FDA Reauthorization Act of 2017**

(Rep. Walden, R-OR, and three cosponsors)

The Administration is committed to expanding access to safe and affordable drugs and medical devices through timely reauthorization of the Prescription Drug User Fee Act, the Medical Device User Fee Amendments, the Generic Drug User Fee Amendments, and the Biosimilar User Fee Act.

H.R. 2430 would reauthorize these four Food and Drug Administration (FDA) user fee programs, under which companies that develop drugs and medical devices partially pay for FDA's premarket review of their products. H.R. 2430 also includes a number of provisions to improve FDA's drug review process, including greater use of real-world evidence and enhancing drug development tools such as biomarker development. FDA's review activities are critical to promoting rapid access to innovative therapies and driving competition toward better healthcare results and lower prices for American consumers. Improvements in FDA's premarket review process, funded by these user fee programs, have encouraged drug and device makers to expand research and development, leading to advances in medical technology that have saved and improved countless lives.

The President's Budget promotes faster economic growth by lowering taxes and strategically devoting resources to urgent priorities. To better support FDA's lifesaving mission while carefully spending taxpayer dollars, the President's Budget asks companies that benefit directly from FDA's premarket review of medical products to finance 100 percent of FDA's premarket review. In its current form, H.R. 2430 would require significant investment of taxpayer resources in FDA's medical product review programs. The Administration urges the Congress to provide for 100 percent user fee funding within the reauthorized programs. In an era of renewed fiscal restraint, industries that benefit directly from FDA's work should pay for it.

The Administration is also concerned with certain other provisions in the bill, such as those providing additional market exclusivity to manufacturers, which could make exclusivity unpredictable and decrease competition. The Administration is committed to promoting the availability of generics in an efficient and effective manner that avoids unintended, adverse consequences. In addition, there are a number of important technical changes that the Administration seeks to make to the bill, including adjusting the foreign drug facility inspection fee.

The Administration supports the goals of H.R. 2430 and looks forward to working with the Congress to expand access to affordable, lifesaving drugs and medical devices in a thoughtful manner that protects taxpayer resources, promotes competition, improves healthcare outcomes, and stimulates scientific innovation and medical advances.

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