On August 3, 2017, the Senate passed H.R. 2430, the FDA Reauthorization Act of 2017 (FDARA), which reauthorizes through fiscal year (FY) 2022 the FDA's critically important user fee programs. The bill was passed 94 to 1 without amendment. The House of Representatives previously passed the bill by voice vote. The current user fee programs were set to expire on at the end of FY 2017 (September 30, 2017). The bill is now headed to the President for signature.

The bipartisan bill reauthorizes the Prescription Drug User Fee Act (PDUFA), the Medical Device User Fee Amendments (MDUFA), the Generic Drug User Fee Amendments (GDUFA), and the Biosimilar User Fee Act (BsUFA). The user fees account for more than one-fourth of all FDA funding, or about $8 to $9 billion over a five-year period. Specifically, fees generated by PDUFA accounted for more than 70 percent of the brand drug review budget in FY 2016; fees generated by MDUFA accounted for 36 percent of the medical device review budget; fees generated by GDUFA accounted for more than 75 percent of the generic drug review budget; and fees generated by BsUFA accounted for 29 percent of the biosimilar review budget (see HELP committee advances FDA user fee agreements to Senate floor, May 12, 2017).

The reauthorization of the FDA's user fee programs will ensure the FDA has the tools needed to deliver safe and effective drugs, devices, and treatments, to patients more swiftly. "This bipartisan work has produced a big win for patients," said House Energy and Commerce Committee Chairman Greg Walden (R-OR). "FDARA will help bring lower-cost generic drug alternatives and biosimilars to market faster - increasing competition and lowering drug costs - and it will streamline the process for reviewing and approving new treatments and cures for patients, ultimately delivering new and innovative therapies, drugs, and devices to patients more quickly."

Other provisions of the bill. In addition to reauthorizing fees related to drugs, devices, generic drugs, and biosimilar products, the bill also contains provisions governing (1) pediatric drugs and devices; (2) other reauthorizations and improvements related to drugs; (3) device inspection and regulatory improvements; (4) improving generic drug access; and (5) reporting requirements. Some of these key provisions would:

- extend through FY 2022 and revise the National Institutes of Health (NIH) program to conduct pediatric studies of drugs;
- revise requirements for the FDA to report on pediatric use of medical devices;
- extend through FY 2022: (1) marketing exclusivity for certain chemical variants of approved drugs; (2) Critical Path Public-Private Partnerships; and (3) support to defray the costs of developing drugs, devices, and medical food for rare conditions; and
- revise provisions regarding FDA inspections of establishments that manufacture or process medical devices.

The bill would also require the FDA to:

- adopt uniform processes and standards for inspections of domestic and foreign medical device establishments;
- meet with applicants for approval of new drugs or biological products to discuss, upon request, the initial pediatric study plan for medication to treat serious conditions and to discuss deferral or waiver of pediatric assessments;
• prioritize review of, and act within eight months of submission on, generic drug applications for drugs for which there is a shortage or for which there are not more than three approved products and no blocking patents or exclusivities; and
• annually publish information regarding the past year’s inspections of drug or medical device facilities, including the amount of time between steps in the inspection process.

In addition, beginning FY 2024, the bill prohibits the use of user fees for maintenance, renovation, and repair of facilities; and acquisition, maintenance, and repair of materials and supplies that are not necessary scientific equipment.