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House Advances Bipartisan FDA User Fee Agreements; Senate Faces Narrow Timeline to Act

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On July 12, the House passed a five-year reauthorization of four different user fee agreements that account for over a quarter of the Food and Drug Administration's (FDA) overall funding. The legislation, titled "The Food and Drug Reauthorization Act of 2017," would update and reauthorize the 2012 Prescription Drug User Fee Act (PDUFA), Medical Device User Fee Amendments (MDUFA), Generic Drug User Fee Amendments (GDUFA) and Biosimilar Use Fee Act (BsUFA), which all expire at the end of the fiscal year (September 30, 2017). The user fee agreements govern FDA's authority to collect fees from drug and device manufacturers to fund the agency's drug approval process. The FDA Reauthorization Act of 2017 now heads to the Senate, which is not expected to act on this issue until the fall.

The bipartisan user fee reauthorization package reflects over a year of work in Congress and closely follows agreements reached last year between the Obama Administration FDA and the drug and device industries. Notably, the House-passed reauthorization package does not include a proposal from President Trump's FY18 budget proposal requesting that Congress increase industry fees to fund 100 percent of costs for premarket review and approval activities for the FDA user fee programs. The White House issued a statement following the House vote on the FDA Reauthorization Act, urging Congress again to require drug and device companies to pay for the full cost of their FDA reviews. This policy would represent a significant shift from the Obama Administration user fee agreements with industry, but thus far, lawmakers have shown little appetite for including it in the final package.

Besides reauthorizing the user fee programs, the FDA Reauthorization Act of 2017 contains a number of new directives for the FDA, including provisions requiring speedier reviews of some generic drugs and changes in how the agency will conduct medical device inspections. FDA will also be directed to work on expanding clinical trial criteria so more patients can be eligible for experimental medications.

Takeaway: Congress is unlikely to renegotiate the five-year user fee agreements this year to accommodate the White House's request. Senate HELP Committee Chairman Lamar Alexander (R-TN) has stated that the Trump Administration's request "can be considered the next time the FDA negotiates the user fee agreements with the manufacturers of drugs and devices, but it is way too late to have an impact on this year's agreements." The Senate is expected to pass the user fee reauthorization package before September 30, when the current authorization expires.