U.S. Congress Reauthorizes Food and Drug Administration User Fee Programs, Acts on Other FDA Measures

After more than two years of negotiations and just before the summer recess, the Senate voted to reauthorize the Food and Drug Administration’s (FDA) drug and medical device user-fee programs. The President is expected to sign the bill, despite initial criticism from the White House. The Senate also approved a number of freestanding bills, suggesting that FDA will remain a focus when Congress returns next month.

Entitled the FDA Reauthorization Act of 2017, the legislation (H.R. 2430) was approved by the House in July and the Senate on August 3 in a near-unanimous vote (94-1), reflecting strong bipartisan support. Sen. Bernie Sanders, I-Vt., cast the only vote against the bill. This is the sixth renewal of the oldest user-fee program, the Prescription Drug User Fee Act (PDUFA). The Medical Device User Fee Act (MDUFA) is on its fourth iteration, and the Generic Drug User Fee Amendments (GDUFA) and the Biosimilar User Fee Act (BsUFA) are in their second cycles.

FDA is supported by a combination of user fees and congressional appropriations, and the user-fee programs are typically renegotiated with industry every five years. Because the current user-fee programs expire on September 30, FDA leadership had planned to send layoff notices to thousands of employees if the bill was not passed by August 1. In an email to agency staff last month, FDA Commissioner Scott Gottlieb moved the deadline forward to September 30.

According to a statement by the Senate Health, Education, Labor and Pensions Committee, manufacturers of drugs and medical devices provide more than a quarter of all FDA funding through user fees. The Congressional Budget Office report on the earlier Senate version of the bill had estimated that the programs would assess fees totaling as much as $9 billion for 2018–22.

An attempt to attach Sen. Ron Johnson’s (R-Wis.) “right-to-try” legislation (S. 204) to the user-fee legislation ensnared the Senate in debate. Ultimately, Johnson’s legislation was passed separately, allowing the user-fee bill to move forward. Similar “right-to-try” legislation (H.R. 878) was introduced in the House earlier this year. Advocates are pushing for the House to take up the measure soon but Speaker Ryan’s office and the Energy and Commerce Committee have not publicly announced any plans.

Two other FDA-related bills also passed the Senate by unanimous consent on the same day. Both still require approval by the House. One bill, referred to as “Jessie’s Law” (S. 2866), would make it easier for doctors to review a patient’s medical records for substance abuse. The bill, sponsored by both West Virginia senators,
would allow such upon oral consent from the patient or the patient’s family, dropping the requirement for written consent.

Another bill (S. 1052), requires FDA to introduce patient-experience information into its drug approval process. Sponsored by Sens. Amy Klobuchar (D-Minn.) and Roger Wicker (R-Miss.), the measure adds patient-experience information developed by the sponsor or another party to FDA’s existing risk-benefit assessment framework. FDA recently announced a public workshop on risk-benefit analysis, the second of the two workshops FDA had to hold under PDUFA V.

These legislative developments come on the heels of the Office of Management and Budget’s (OMB) issuance of a list of “inactive” regulatory actions, notifying the public that the Executive Branch has decided not to move forward with certain actions undertaken by previous administrations. “Inactive” FDA regulatory efforts on the list include key issues such as over-the-counter drug reviews for sunscreens, laxatives, and analgesics; establishing good manufacturing practices for dietary supplements; providing guidelines for direct-to-consumer prescription drug advertisements; and issuing regulations on drug compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act.

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