In Eleventh Hour Action, Lawmakers Advance FDA User Fee Reauthorization

At last! After nearly a year of committee hearings and political maneuvering, Congress finally has approved legislation to reauthorize FDA's user fee programs for brand and generic drugs, biosimilars, and medical devices. The current programs expire with the close of fiscal year 2022 on September 30. Reauthorization will enable FDA to continue collecting application and facility user fees from industry for fiscal years 2023 through 2027, a 5-year period that begins October 1. Because roughly 60% of FDA's $2 billion annual budget for drug-related work comes from user fees, failure to reauthorize the programs would have had a severe impact on the Agency.

As we reported in the September 12 edition of *Rx Policy Post*, Capitol Hill insiders were predicting earlier this month that user fee legislation would be attached to a must-pass temporary spending bill (called a continuing resolution, or CR), necessary to avoid a government shutdown at the close of fiscal 2022. That's exactly what happened. Last week, an agreement was reached between the leadership of the Senate Health, Education, Labor, and Pensions (HELP) Committee and the House Energy and Commerce (E&C) Committee to add user fee reauthorization to a CR that will fund government operations through December 16. (While the House has approved its appropriation bills for next year, the Senate has not yet voted on its funding measures.)

The delay in reauthorizing the user fee programs was caused by the Senate's inability to agree on a final bill. Although a majority of the HELP Committee approved reauthorization via the "Food and Drug Administration Safety and Landmark Advancements Act" (S. 4348), Ranking Member Sen. Richard Burr (R-NC) objected to several policy riders in the that bill and offered an alternative bill -- the Food and Drug Administration Simple Reauthorization Act, S. 4535. (See our story in the September 12, 2022, edition of *Rx Policy Post.*)

Last week, HELP Committee chair Sen. Patty Murray (D-WA) and Burr agreed to attach a relatively clean reauthorization bill to the CR. The House overwhelmingly passed its user fee bill, the "Food and Drugs Amendments of 2022" (HR 7667), back in June. Differences between the Senate and House legislation will now have to be hammered out. The reconciliation should be completed this week and a final bill sent to President Biden for his signature.