October 3, 2022
September 30, 2022

Congress Enacts Clean Reauthorization of FDA User Fees, Leaving Uncertain Future for Important Policy Reforms

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On September 30, 2022, Congress passed a short-term continuing resolution ("CR"), H.R. 6833, as a temporary stopgap measure to continue funding the U.S. government past the end of the fiscal year. Among other provisions, the CR extends the authority of the Food and Drug Administration ("FDA") to collect user fees for prescription and generic drugs, biosimilars, and medical devices through the end of fiscal year 2027. Because these user fee programs have been authorized only for five-year periods, it has become customary for the "must-pass" reauthorization bills to include a range of FDA-related policy riders. Unlike prior reauthorization cycles, however, this time Congress was unable to reach a consensus regarding the riders to include as part of reauthorization legislation.

To avoid potential pink slips and layoffs of FDA personnel whose jobs depend on funding from industry user fees, Congress incorporated a "clean" user fee package into the CR without *any* policy reforms. Members of Congress have expressed a commitment to continue negotiations on bipartisan legislation to be enacted before the CR expires on December 16, 2022, but it remains to be seen whether much-talked-about reforms to FDA's regulation of in vitro diagnostics and laboratory-developed tests ("LDTs"), dietary supplements, and cosmetics, among others, will be enacted in the near term.

This Alert summarizes these developments and the reforms that so far have been left on the cutting room floor.

The Clean Reauthorization

Initial progress on user fee legislation in Congress in early summer suggested that a reauthorization package including policy reforms might be enacted well in advance of the end of the fiscal year. On June 8, the House of Representatives passed their version of user fee legislation—H.R. 7667, the Food and Drug Amendments of 2022—with bipartisan support. On June 14, the Senate Health, Education, Labor and Pensions ("HELP") Committee advanced the Senate's counterpart legislation—S. 4348, the Food and Drug Administration Safety and Landmark Advancements Act of 2022—out of committee.

However, substantial differences between the reforms included in the House and Senate bills complicated negotiations and slowed progress. In particular, the Senate bill included potentially landmark reforms to FDA's regulation of in vitro diagnostics and LDTs, dietary supplements, and cosmetics, whereas the House bill included none of these reforms. After members of the House and Senate were unable to negotiate a suitable resolution to these differences, Congress ultimately elected to pass a clean reauthorization as part of the CR to continue funding the government.

The CR reauthorizes the various user fees that help fund FDA's review and oversight of prescription drugs, generic drugs, medical devices, and biosimilars through October 1, 2027. In addition, it reauthorizes eight other programs and provisions, such as the Best Pharmaceuticals for Children Program and certain grants for orphan drugs, but only through December 16, 2022 (the end date of the CR). Absent from the CR are any of the policy riders included in either the initial House or Senate bills.

Key Policies and Reforms Left Out of the Reauthorization

Below is a brief summary of the most significant policy riders left out of the CR that will likely receive renewed attention as members of Congress come back to the negotiating table in an attempt to move forward with further legislation later this year.

- **New Regulatory Framework for In Vitro Diagnostics and LDTs.** S. 4348 includes the Verifying Accurate Leading-edge IVCT Development Act of 2022, or VALID Act. Statutory reform to FDA's oversight of LDTs has been a long-debated issue in Congress, and versions of the VALID Act have previously been introduced in Congress without gaining much traction, as summarized in a prior Ropes & Gray Alert. If enacted, the VALID Act would create a new regulatory framework for "in vitro clinical tests" ("IVCTs"), which include both LDTs and in vitro diagnostic tests. This framework would establish, among other things, notification and listing requirements for IVCT developers, as well as premarket review requirements (including a technology certification pathway), labeling requirements, test design and quality requirements, and reporting requirements for corrections, removals, and adverse events.

- **Modernization of Cosmetics Regulation.** S. 4348 includes provisions to strengthen FDA's oversight over cosmetic products via a comprehensive regulatory scheme that would require, among other things, facility registration and product and ingredient listing with FDA, serious adverse event reporting to FDA, compliance with certain labeling requirements, and maintenance of records that adequately substantiate product safety. FDA also would be charged with establishing cosmetic good manufacturing practices.

- **Listing Requirements for Dietary Supplements.** S. 4348 includes provisions to establish product listing requirements for dietary supplements. Specifically, these provisions would require manufacturers, distributors, and packers whose name appears on the label of a dietary supplement marketed in the U.S. (or the U.S. agent for any such foreign entity) to list product information with FDA, including the supplement's ingredients, any required warnings, notice and safe handling statements, allergen statements, and any health claims or structure/function claims.

- **Reforms to Improve Diversity in Clinical Studies.** H.R. 7667 would require sponsors of certain drug and device clinical studies to submit diversity action plans to FDA. It also would require FDA to issue guidance on the format and content required in such action plans, evaluate whether additions or modifications to FDA's authority are needed to mandate post-approval studies or post-market surveillance where insufficient data was collected for underrepresented groups in pre-market studies, convene public workshops to solicit input on increasing the enrollment of historically underrepresented populations in clinical trials, and report annually to Congress on progress to increase diversity in clinical studies.

- **Reforms to Accelerated Approval.** Both H.R. 7667 and S. 4348 include proposals to modernize the framework for accelerated approval of drugs. Both proposals would provide that post-approval studies must be agreed to by the time of accelerated approval and that FDA may require post-approval studies of such drugs to be underway prior to approval. In addition, both proposals would amend the procedures by which FDA can withdraw an accelerated approval.

- **Reforms in Response to Infant Formula Crisis.** In response to this year's infant formula crisis, S. 4348 would implement various reforms designed to better prepare the U.S. to address similar issues in the future. The bill would, among other things, establish within FDA's Center for Food Safety and Applied Nutrition a new Office of Critical Foods to oversee, coordinate and facilitate activities related to infant formula and certain medical foods. The bill also would shorten the premarket submission requirement for new infant formulas from 90 to 30

days, require manufacturers to notify FDA of product discontinuance or supply interruption within five business days, and relax certain foreign import rules.

Looking Ahead to Further Negotiations

Although the CR reauthorized FDA's key user fee programs for a full five years through the end of fiscal year 2027, its reauthorization of certain other provisions only through December 16, 2022 all but guarantees that members of Congress will try to negotiate additional legislation that includes at least some FDA-related policy riders. Senate HELP Committee Chair Senator Patty Murray (D-WA) and Ranking Member Senator Richard Burr (R-NC) released a joint statement that there is more work ahead this Congress and there is bipartisan agreement to continue to work towards "bipartisan legislation in a robust end of year package." However, it remains to be seen which policy riders, if any, will ultimately be included in an end-of-year omnibus appropriations bill when the temporary CR expires or whether certain reforms will need to be pursued anew in a future legislative session. With midterm elections scheduled for November 2022, followed by a "lame duck" session, there will likely be a narrow legislative window for Congress to act on potentially significant FDA reform measures.

Ropes & Gray will continue to monitor legislative developments in this area. If you have any questions, please contact any member of Ropes & Gray's FDA regulatory practice or your usual Ropes & Gray advisor.