Health Industry Alert

Akin Gump
STRAUSS HAUER & FELD LLP

FDA User Fee Reauthorization Gains Momentum with Senate HELP Committee Approval

June 24, 2022

There continues to be no shortage of FDA-related issues in front of Congress this summer. In recent days, the pace of Congressional action on reauthorizing FDA's user fee programs has significantly picked up with the Senate HELP Committee approving its package last week. The breadth of the FDA policy riders included in the Senate bill has only increased as this "must pass" reauthorization continues to advance through the legislative process. On June 8, the House of Representatives passed their FDA user fee reauthorization bill (H.R. 7667, the Food and Drug Amendments of 2022) by a bipartisan vote of 392 to 28. Less than a week later, on June 14, the Senate Health, Education, Labor and Pensions (HELP) Committee approved S. 4348, the Food and Drug Administration Safety and Landmark Advancements (FDASLA) Act, by a bipartisan vote of 13 to 9. The House and Senate will now begin informally reconciling their respective versions of this legislation into a final bill to be considered by both chambers.

The Senate user fee reauthorization legislation has evolved since the initial discussion draft was released by the Committee last month and has consistently been broader in scope than the House bill. This dynamic continued as the Senate HELP Committee marked up its FDA user fee reauthorization bill. In addition to changes to, and new, provisions that were included in the manager's amendment of the bill, additional provisions were also adopted as part of the Committee's markup of the manager's amendment of S. 4348. The Committee debated and voted on numerous amendments and the bill approved by the Committee now encompasses policy provisions related to brand and generic prescription drugs, biologics, medical devices, diagnostics, dietary supplements, cosmetics, and infant formula, among other topics.

This alert highlights some of the notable new provisions included in S. 4348 during the Senate HELP Committee markup.

Infant Formula

The manager's amendment added new provisions to FDASLA to improve the supply of infant formula in the United States. The manager's amendment would establish an Office of Critical Foods within FDA's Center for Food Safety and Applied Nutrition and set forth regulatory flexibilities in the event of a formula shortage or disruption. The bill

Contact Information

If you have any questions concerning this alert, please contact:

Nathan A. Brown
Partner
nabrown@akingump.com
Washington, D.C.
+1 202.887.4245

Anna K. Abram
Senior Advisor
aabram@akingump.com
Washington, D.C.
+1 202.887.4151

Craig B. Bleifer
Partner
cbleifer@akingump.com
New York
+1 212.872.8148

Sean Feely
Policy Advisor
sfeely@akingump.com
Washington, D.C.
+1 202.416.5537

would also require timely FDA communication with a manufacturer of infant formula following an FDA inspection of a facility engaged in the manufacturing of infant formula for consumption in the United States and FDA to prioritize and expedite an inspection or reinspection of an establishment that could help mitigate or prevent a shortage of an infant formula. The manager's amendment also directs the Secretary of the Department of Health and Human Services (HHS), in consultation with the Secretary of Agriculture, to develop a national strategy on infant formula to strengthen and protect the formula supply chain.

In addition to the provisions included in the manager's amendment, the Committee also adopted several amendments related to infant formula during the markup. An amendment offered by Sen. Mitt Romney (R-UT) would require FDA to notify Congress within 24 hours of initiating a recall of infant formula. Another amendment from Sen. Romney would require FDA, following an inspection of a formula manufacturer, to coordinate with the manufacturer on actions needed to address any deficiencies and restart production. Sen. Lisa Murkowski (R-AK) offered an amendment that would temporarily allow individuals to import up to a three-month supply of formula for personal use from Canada, the European Union, or any other country that HHS deems safe. The Committee also adopted another amendment from Sen. Murkowski that would temporarily allow FDA to waive certain requirements for the importation of specialty formula.

Prescription Drugs

The manager's amendment included a new section on importation of prescription drugs from Canada. Section 906 would require the Secretary of Health and Human Services (Secretary), after consultation with the United States Trade Representative and the Commissioner of Customs, to issue regulations to facilitate prescription drug importation programs subject to certain safety conditions and limitations. The section also would also allow the Secretary to issue regulations to permit the personal importation of prescription drugs subject to certain safety conditions and limitations. It would also clarify FDA's authority to terminate these programs under certain circumstances. The HELP Committee voted 15-7 to table an amendment from Sen. Bernie Sanders (I-VT) that would have permitted importation by individuals, pharmacies, and wholesalers from Canada and the United Kingdom, as well as other countries. However, the Committee approved another amendment from Sen. Sanders to require a Government Accountability Office (GAO) report on the number of Americans who die each year because they cannot afford their prescription medications.

Several amendments adopted at the markup are focused on accelerating the development and market entry of generic drugs. An amendment from Sen. Maggie Hassan (D-NH) would allow FDA to provide enhanced directional guidance to generic drug applicants on their proposed formulations. The Committee adopted an amendment from Sen. Tina Smith (D-MN) that aims to address exclusivity "parking" by generic first-filers, and an amendment from Sen. Tammy Baldwin (D-WI) that would streamline FDA's ability to deny citizen petitions intended to delay the approval of a generic drug application and require FDA to establish procedures for referring to the Federal Trade Commission any petition or supplement to a petition that the Secretary determines was submitted with the primary purpose of delaying approval of an application. The manager's amendment also added a new section which would allow

FDA to approve a generic drug in cases where the labeling for the reference product has been changed within the previous 90 days.

Sen. Jacky Rosen (D-NV) offered two amendments on nonprofit drug manufacturing that were added to FDASLA. The first would direct GAO to publish a study on nonprofit pharmaceutical manufacturing organizations and what impact they may have on drug costs and the mitigation of drug shortages. The second amendment would require FDA to hold a public meeting on nonprofit drug manufacturing.

Finally, the Committee also adopted an amendment from Sen. John Hickenlooper (D-CO) that would require FDA to provide a summary of the basis for approval for each new drug or biologic approved under the accelerated approval pathway.

Medical Devices

Several amendments related to medical devices were adopted by voice vote during the markup. An amendment from Sen. Mike Braun (R-IN) would give FDA the statutory authority to approve or clear medical devices submitted with a predetermined change control plan that describes planned changes that may be made to the device without requiring a supplemental application. The Committee agreed to another Braun amendment that would allow FDA to waive the annual medical device establishment registration fee for small businesses.

An amendment from Sen. Rosen (D-NV) would require FDA to update within two years its guidance on cybersecurity for medical devices. The language also would require a GAO report identifying challenges in cybersecurity for medical devices. Sen. Roger Marshall (R-KS) added an amendment that seeks to improve medical device adverse event reporting by allowing FDA to access certain underlying data.

Rare Disease Products

The manager's amendment added a new section related to rare disease products. Section 508 would require both GAO and FDA to report to Congress on the agency's policies, practices, and programs related to the review of applications for drugs and biological products intended to treat rare diseases and conditions. The Committee also adopted an amendment from Sen. Bob Casey (D-PA) that would require these reports to review FDA's consultations with rare disease patients and patient groups. Another amendment from Sen. Casey that was also adopted at the markup seeks to encourage FDA consultation with rare disease patients and patient groups during the pre-submission phase for rare disease products.

Sen. Baldwin offered an amendment to apply orphan drug exclusivity only to the same approved use or indication within a rare disease or condition by allowing FDA to approve the same drug from different manufacturers if the products are intended to treat different patient populations.

VALID Act

The HELP Committee also considered amendments to the VALID Act provisions of FDASLA. The Committee voted 12-10 to table an amendment from Sen. Tommy Tuberville (R-AL) that would have exempted academic medical centers from the *Verifying Accurate Leading-edge IVCT Development (VALID) Act*, which comprises

Title VIII, Subtitle C of FDASLA. The Committee did adopt, however, an amendment from Sen. Marshall (R-KS) to require a GAO report that examines the impact of the VALID Act on academic medical centers, hospital-based laboratories, and other health care practitioners.

Additional Amendments of Note

The Committee also adopted various amendments with respect to FDA and conflicts of interest.

Sen. Hassan offered several amendments related to FDA conflicts of interests; all of which were adopted by voice vote. These amendments would require FDA contractors to continually disclose conflicts of interest, bar individuals from consulting simultaneously for FDA and a company regulated by the agency, and require FDA to make public any waivers it has granted related to organizational conflicts of interest.

The Committee adopted an amendment from Sen. Rosen (D-NV) that would require FDA to update within two years its Women's Health Research Roadmap. Sen. Rosen pointed out at the markup that the Roadmap was first released in 2015 and has not been updated since.

The Committee further broadened the scope of its bill to include food packaging by adopting an amendment from Sen. Hassan that would prohibit food packaging containing per- and polyfluoroalkyl substances (PFAS) beginning on January 1, 2024.

Outlook & Next Steps

There is always a high degree of interest in the FDA user fee reauthorizations given the significance of these programs to patients, industry, and the agency, among other stakeholders. The interest in attaching FDA-related policy riders to this “must pass” legislative vehicle has only become more dynamic amidst the backdrop of the increasing bipartisan focus on the agency’s performance, accountability, and current authorities in fulfilling its public health mission. The FDA user fee reauthorization policy riders being considered by the House and Senate are not the only FDA issues Congress is working on—earlier this year the Senate HELP Committee advanced their bipartisan PREVENT Pandemics Act, which included FDA policy reforms, and may be folded into any final user fee reauthorization bill depending upon how the final bill comes together.

Now that the full House has passed its bill and the Senate HELP Committee has approved a Senate bill, the differences between these two bills will need to be reconciled and these efforts are expected to quickly commence. The “four corners” – the Chairs and Rankers of the Energy and Commerce Committee and Senate HELP Committee—are expected to reconcile a final bill to be considered by both the House and Senate and ultimately sent to the President’s desk for signature. In prior FDA user fee reauthorization cycles, Congress passed legislation ahead of the August recess, and well in advance of the end of the fiscal year to ensure no disruption to these FDA user fee programs. However, there is precedent for the user fee reauthorizations to go into September: in 2007 the reauthorization bill was enacted in late September, but ahead of the end of the fiscal year. Another practical consideration is that the number of legislative days in the House and Senate is decreasing ahead of the end of the

fiscal year (September 30), and any final bill needs to pass both the House and Senate prior to being sent to the President.

While the exact timing and policy contours for a final FDA user fee reauthorization bill remain very dynamic, the interest in FDA-related issues is only increasing, and the "UFA" clock is steadily ticking as the August recess and end of the fiscal year draws nearer. As the recent developments in the House and Senate underscore, it is clear that there is bipartisan interest in moving forward with reauthorization of these programs, and the Senate HELP Committee markup demonstrated that there is also a growing momentum for the potential for historic FDA policy reforms to be part of a final bill. However, how and exactly when the House and Senate policies are reconciled into a final bill remains to be seen, and these developments are certain to be closely followed given the significance for patients, consumers, the agency, industry, and public health.

akingump.com