Bloomberg Law®

FDA Package on User Fees, Baby Formula Advances to Full Senate (1)

By Celine Castronuovo and Alex Ruoff

June 14, 2022, 5:21 PM; Updated: June 14, 2022, 6:07 PM

- Committee votes 13-9 on revamping fast-track drug pathway
- Bipartisan bill seeks to boost infant formula oversight

A key Senate committee overseeing the FDA advanced a proposal to reauthorize the industry user fees that help fund the agency, paving the way for a vote in the full chamber.

The Senate Health, Education, Labor, and Pensions Committee Tuesday voted 13-9 in support of sweeping bipartisan legislation (S. 4348) that would revamp the Food and Drug Administration's accelerated approval pathway and boost oversight on lab-developed tests. The committee adopted a substitute amendment that includes several measures to improve infant formula oversight after a recall at an Abbott facility propelled a nationwide shortage.

"This is the most important, comprehensive FDA legislation to come out of this committee in many years," Senate HELP Committee Chair Patty Murray (D-Wash.) said ahead of the vote. "Overall this legislation will make for a stronger FDA, with more resources to carry out its work, more authority to oversee products families entrust their health to every day, and more accountability to guarantee FDA is fulfilling its mission, and putting patients and families first," she said.

Manufacturers would be required to notify the FDA within five business days of an infant formula supply chain disruption under the legislation. It would also establish the Office of Critical Foods within the Center for Food Safety and Applied Nutrition. Infant formula and medical foods would fall under this office's oversight.

Murray said Tuesday that she's "absolutely going to keep pushing to hold the FDA and industry accountable so we can get answers on the formula crisis and make sure this never happens again."

The user fee package now heads to the full Senate. The House voted 392-28 under suspension of the rules to pass its own version of the user fee legislation (H.R. 7667) on June 8.

House Energy and Commerce Committee Chair Frank Pallone, Jr. (D-N.J.) told Bloomberg Law Tuesday that he and the other committee leaders won't face much difficulty in combining the two versions. "I don't think it'd be a formal conference, but we'll work out any differences," he said.

Congress must pass user fee legislation for the next five fiscal years before the current agreements between the FDA and drug and device industries expire Sept. 30.

Pediatric Cancer Research

Murray hinted Tuesday that a pediatric cancer research bill not included in the latest package could still make its way into a final version.

The bill, called the Give Kids a Chance Act (H.R. 6972), is in the House package, and would authorize the FDA to require companies investigating a drug combination for an adult cancer to also launch a pediatric study plan if there are molecular similarities. Sens. Marco Rubio (R-Fla.) and Michael Bennet (D-Colo.) introduced a Senate version of Give Kids a Chance in May.

Murray said Tuesday that she hopes "to continue working with Senator Bennet and Senator Rubio on their proposal for cutting-edge pediatric cancer treatments."

Rubio's office said Monday that it is working to get the bill added to the user fee package "once it reaches the Senate floor."

Approvals, Diagnostics

The committee on Tuesday adopted several amendments on infant formula, including one from Sen. Mitt Romney (R-Utah) that would require the FDA to notify Congress within 24 hours of initiating a formula recall. The agency would have to include in its notification a summary of the FDA determination ▶

on an adulterated or misbranded product, and when the FDA was first made aware of the situation surrounding the recall.

The Senate proposal includes several provisions from the House version, including allowing the FDA to remove from the market any drugs that obtained accelerated approval if they fail to show a clinical benefit. It also states that the FDA may require post-market studies to already be underway before approval is granted.

The committee adopted an amendment from Sen. John Hickenlooper (D-Colo.) to increase transparency around fast-track approval determinations. The measure calls for the FDA to include with each new decision a summary of the basis for approval, whether an advisory committee meeting was held, and an explanation on why the specific surrogate endpoint is reasonably likely to predict a clinical benefit.

The bill also seeks to improve how the FDA regulates diagnostic tests by creating a new category of medical products called in vitro clinical tests. This measure, which isn't in the House package, would allow the FDA to oversee tests regardless of whether they came from clinical laboratories or from commercial companies.

Drug Importation

The latest Senate proposal would require the FDA to develop regulations that would facilitate the importation from Canada of certain prescription drugs for personal use. This provision is not included in the House-passed package.

The HELP committee voted 15-7 to table an amendment from Sen. Bernie Sanders (I-Vt.) that would have also allowed drug importations from the UK, and eventually, other countries with safety and approval standards similar to the FDA. It would have also permitted importation by wholesalers, licensed US pharmacies, and individuals. The provision in the committee package requires that states or tribes sponsor importation plans.

Ranking Member Richard Burr (R-N.C.), who was one of the nine "no" votes, told Bloomberg Law ahead of the vote that he would oppose the full package if Sanders' importation amendment was included. He added that the committee's import provisions are based on an FDA rule finalized during the Trump administration as part of the agency's efforts to reduce costs for American consumers seeking eligible prescription drugs from Canada. The agency has since released guidance for small entities wanting to participate in drug importation programs.

Senate HELP members adopted by voice vote an amendment from Sen. Mike Braun (R-Ind.) that would allow for the FDA to approve plans for post-market changes to a medical device during its pre-market submission phase. Existing FDA regulations require that medical device manufacturers submit a supplemental application or premarket notification for any changes to a product after it's cleared or approved.

The option for pre-determined plans "saves the FDA resources, and makes additional FDA review unnecessary when the device is updated in the future," Braun said when introducing the amendment Tuesday.

(Updated with Burr's vote in the 20th paragraph. A previous version corrected the vote count with an update from the committee's clerk.) ●

To contact the reporters on this story: Celine Castronuovo at *ccastronuovo@bloombergindustry.com;* Alex Ruoff in Washington at *aruoff@bgov.com*

To contact the editor responsible for this story: Alexis Kramer at *akramer@bloomberglaw.com*

Documents

Bill
S. 4348

Related Articles

Baby Formula Shortage Reporting Added to Senate FDA Fee Plan (2)
June 13, 2022, 12:06 PM

House Passes FDA Package Reauthorizing Drug, Device User Fees)
June 8, 2022, 8:31 PM

Fast Drug Approvals Would Get Revamp in Senate's FDA Fee Bill
May 27, 2022, 3:07 PM

Topics

medical device approval process
pharmaceutical research and development
product recalls
in vitro diagnostic devices
health product safety
classification of medical devices
children's product safety
drug approval process
federal health care legislation