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House Panel Advances FDA User FeeBill, Teeing Up Full Vote (1)

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- House votes 55-0 on billions in new funding for FDA
- Current user fee agreements expire Sept. 30

The House Energy and Commerce Committee on Wednesday approved a comprehensive package reauthorizing the user fees that help fund the FDA, a key step in moving the must-pass legislation to a vote in the full chamber.

Committee members voted 55-0 in support of legislation (H.R. 7667) that governs the fees the drug and device industries pay to the Food and Drug Administration to make improvements to its review and approval process. The latest agreement must be reauthorized before the current user fee agreements expire Sept. 30.

"This bill has been crafted with consensus in mind from the start, as it is critical we pass this on time,before FDA funding runs out," Energy and Commerce Committee Chair Frank Pallone, Jr. (D-N.J.) said ahead of the vote Wednesday.

The action comes a week after the House subcommittee on health voted 30-0 to advance the bill. User fees make up nearly half of the FDA's funding, and the latest agreement includes proposals to revamp the accelerated approval pathway and remove barriers to generic drug competition.

The approved package includes an amendment from retiring Rep. G.K. Butterfield (D-N.C.) based on his bill (H.R. 6972)—the Give Kids a Chance Act. The amendment, which was adopted unanimously in a voice vote, 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.

Pallone and other committee members thanked Butterfield for his work on the bill, which builds on the RACE for Children Act included in the 2017 reauthorization of the FDA user fee deals. Butterfield said ahead of the vote Wednesday that the latest legislation will "provide more hope" and give "more treatment and cures" for pediatric cancer patients.

Lawmakers also highlighted the need for strengthening the FDA's food division, especially with the recent infant formula shortage that have rattled parents nationwide.

Pallone said the user fee package "will extend an authority first provided in the 21st Century Cures Act that will allow FDA to retain top scientists and high-level professionals," for the Center for Food Safety and Applied Nutrition and other FDA product divisions.

The full House must now vote on the committee's package. Rep. Anna Eshoo (D-Calif.), chair of the health subcommittee, said Wednesday that the House is on track to pass the bill in the full chamber "with plenty of time" before the September timeline.

The Senate Health, Education, Labor, and Pensions Committee released Tuesday a discussion draft for its own version of the user fee package. The Senate proposal includes provisions expanding the FDA's authority over cosmetics, dietary supplements, and lab-developed tests. The senators will be accepting public feedback on the discussion draft through May 22.

House Package

The bipartisan House proposal, first unveiled May 4, would give the FDA the authority to remove from the market any drugs that obtained accelerated approval if they fail to show a clinical benefit. Both the FDA and lawmakers have pushed for legislative changes to minimize the amount of time between when a drug enters the market and the completion of studies demonstrating a clinical benefit.

The user fee package also would give the FDA powers to require drug and device companies to submit diversity action plans for their clinical trials. The package calls for improvements to the FDA's inspections program, including a pilot program to increase the use of unannounced surveillance inspections of foreign human drug facilities. ▶

It includes provisions to speed up the approval of generic drugs, including by letting the agency approve a generic drug even if the brand-name version's label changes during the review process—a tactic lawmakers have accused pharmaceutical companies of using to delay the market entry of lower-cost alternatives.

Proponents of allowing the FDA to pull certain accelerated approved drugs off the market say they are hopeful the Senate will include these provisions in their package. But Senate HELP Committee Ranking Member Richard Burr (R-N.C.) said Wednesday "that's an area we're going to have to work out with the House."

"I like the accelerated approval at the FDA," Burr said. "It's worked extremely well."

Advocacy group Doctors for America, co-founded by Surgeon General Vivek Murthy, visited Capitol Hill this week to lobby for additional changes to the user fee package, including a provision that would automatically have a drug's accelerated approval expire if follow-up studies don't show a clinical benefit.

Members of the group's FDA Task Force met with lawmakers to "discuss the value of a transparent FDA approval and review process, improving expedited review pathways to adhere to the highest evidentiary standards and the importance of codifying diversity standards within clinical trials," the group said in a press release.

Rep. Janice Schakowsky (D-Ill.) pushed for additional accelerated approval changes at Wednesday's hearing, namely that drugs or biologics being considered for fast-track approval by the FDA first be considered by an independent expert advisory committee. The pathway drew renewed scrutiny after Biogen's Alzheimer's drug Aduhelm received approval despite an outside panel of experts voting against it.

"We must ensure drugs and treatments are available fast," but "are also safe and effective," Schakowsky said.

The House package doesn't include provisions from the Senate's discussion draft that would change how the FDA regulates diagnostic tests. Those provisions are based on the VALID Act (H.R. 4128), which Reps. Diana DeGette (D-Colo.) and Rep. Larry Bucshon (R-Ind.) have been working on for years with Senate HELP Chair Patty Murray (D-Wash.) and Burr.

DeGette expressed disappointment the VALID Act wasn't included in the House version, but said she was"pleased to see the Senate take action to include the VALID Act as part of the Senate user fee package."

—With assistance from Zach C. Cohen
(Updated with additional reporting starting in the 8th paragraph.) ●

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