Health Law & Business

FDA Lab Test Oversight at Risk of Getting Cut From Year-End Bill

By Celine Castronuovo and Alex Ruoff

Nov. 18, 2022, 1:08 PM

- Dispute over vetting clinical vs commercial diagnostic tests
- Accelerated approval changes have better chance, analysts say

Changes to how the Food and Drug Administration regulates diagnostic tests and other agency fixes could wind up on the chopping block as lawmakers seek compromise on measures to attach to an end-of-year spending package.

House and Senate negotiators are considering adding to a December omnibus bill provisions that were dropped earlier this year from a package (Public Law 117-167) reauthorizing industry user fees to the FDA. They're preparing policy riders narrower than previous agreements, aides familiar with the discussions say, likely jettisoning more controversial provisions such as the VALID Act, which would allow the FDA to oversee tests regardless of whether they came from clinical laboratories or from commercial companies.

Democrats intend to propose a full-year $1.7 trillion omnibus spending bill and pass it before Dec. 16, when current government funding is set to run out. Priorities including aid to Ukraine and additional Covid-19 response funds will likely leave off the table any potential riders that face resistance, biotechnology analysts and former FDA officials say.

Researchers work in a lab developing testing for Covid-19 at Hackensack Meridian Health Center for Discovery and Innovation in February 2020 as the pandemic spread.
Kena Betancur/Getty Images

“Anything that’s even a little controversial that has either FDA opposition or significant industry opposition will just drop,” said Marc Scheineson, a former FDA associate commissioner. “There’s no appetite for a big FDA reform deal,” added Scheineson, now co-head of Alston & Bird’s Food and Drug Law Team.

User fee reauthorization happens every five years, and lawmakers typically use it as a vehicle to pass additional legislation to boost FDA oversight or establish new regulatory authorities.

A shrunk-down version of the dozens of policy riders Congress has been considering would leave the medical product industry without long-sought clarity on the FDA’s authority over diagnostic tests, as well as other areas such as dietary supplements and cosmetics. It could also leave industry without incentives to conduct certain pediatric cancer research, and without other measures intended to facilitate greater patient access to novel medical products.

Read More: White House Seeks $37.7 Billion for Ukraine in Lame-Duck Session

‘As Much as Possible’

The top two members of the Senate HELP committee—Patty Murray (D-Wash.) and Richard Burr (R-N.C.)—said in interviews this week they’re working on user fee negotiations, but had no major updates since Congress’ post-midterm return.

The proposal to let the agency oversee tests from commercial as well as clinical laboratories, and other measures — such as expanded FDA oversight on infant formula — were attached to a Senate Health, Education, Labor, and Pensions Committee version (S. 4348) of the legislation. The House also passed its own version (H.R. 7667) in June with additional proposals, including provisions to improve diversity in clinical trials and boost pediatric cancer research.

Congress cleared a slimmed-down FDA reauthorization in the stopgap government funding bill in September. Murray and Burr, along with House Energy and Commerce Chair Frank Pallone (D-N.J.) and ranking member Cathy McMorris Rodgers (R-Wash.), said at the time they wanted to return to the bargaining table to get more riders through.

Murray remains committed to delivering the kinds of changes families need to see from FDA and from industry, a Democratic committee aide said in an email, without elaborating on specific provisions.

Pallone said this week he's pushing for lawmakers to adopt the House-passed version of the user fee package. "We're trying to get as much of it in as possible," he said in an interview.

Tests, Dietary Supplements

The FDA has defended its ability to regulate laboratory-developed tests. But the clinical lab industry opposes the VALID legislation (H.R. 4128), seeing it as double regulation. Laboratories must already comply with the Clinical Laboratory Improvement Amendments, which the Centers for Medicare & Medicaid Services administer.

Burr has been one of the main negotiators behind the VALID measure. His retirement after this session of Congress means he may "want a legacy and accomplish as much as he can," Scheineson said.

Earlier: Califf Hints at FDA Diagnostics Changes if Congress Fails to Act

Retiring members also don't want to stand in the way of a sweeping government spending package, said Howard Sklamberg, a former FDA associate commissioner.

"Is Sen. Burr willing to hold up an entire bill that's not just FDA?" Sklamberg, now a partner at Arnold & Porter, questioned. "It's one thing to hold up user fee legislation. It's another thing to hold up an omnibus."

Another proposal with industry resistance would apply to dietary supplements. The Senate HELP measure would have required manufacturers and distributors of dietary supplements to register their products with the FDA in order to better identify potentially harmful ingredients or health claims. Some industry trade groups have supported mandatory product listing for dietary supplements. Others, including the Natural Products Association, have called the proposal government overreach.

Sklamberg said he could see dietary supplements not making it into the year-end package, but that "there'll be continual efforts to get those enacted" in the future.

Accelerated Approval

Industry members and former FDA officials says provisions with little opposition have a better chance at ending up in a spending package. Among them: legislation to revamp the pathway to accelerate approval of new drugs that treat serious conditions and fill an unmet medical need.

The provisions aim to minimize the time between when a drug enters the market, and completion of studies demonstrating a clinical benefit. The FDA grants accelerated approval based on a surrogate marker, such as a laboratory measure, and requires companies to conduct postmarket studies to confirm the anticipated clinical benefit, like overall survival. The pathway came under scrutiny after the FDA's accelerated approval of Biogen Inc.'s Alzheimer's drug Aduhelm, which targeted a disease marker but had an unclear benefit for patients.

Proposals to streamline the postmarket requirements were included in both the House and Senate versions, but were scrapped after Burr and other Republicans pushed for a "clean" stopgap funding measure in September with few policy riders.

FDA Commissioner Robert Califf and other agency leaders have called for improvements to the approval pathway.

Read More: FDA Cancer Chief Wants Quicker Ways to Pull Failed Drugs

Drug companies need to "step up and take their drugs off the market as rapidly as possible" if a follow-up study shows their fast-tracked product doesn't work, Richard Pazdur, director of the FDA's Oncology Center of Excellence, said Thursday at the Friends of Cancer Research annual meeting.

Sklamberg said provisions such as accelerated approval and clinical trial diversity mandates—included in the House user fee package but not in the Senate's— have "a lot of bipartisan consensus on Capitol Hill," and have a better chance in a year-end package.

The Biotechnology Innovation Organization, which represents biotechnology industry members, is focused on any changes to accelerated approval.

"We just want to make sure that if there are modernizations done to accelerate approval, they're done in a way that allows the accelerated approval pathway to still do what Congress intended it to do in areas of unmet medical need," said Nick Shipley, the group's chief advocacy officer.

Uncertain Future

Policy analysts see two major options for those provisions left out— passing them as a standalone bill, or waiting five years for the next user-fee reauthorization.

Brett Guthrie (R-Ky.), ranking member of the House Energy and Commerce health panel, reintroduced a bill this week to help bring quicker insurance coverage for FDA-approved drugs and medical devices. The bill was included in the House-passed FDA user fee package, and the congressman hopes it can "become law as either a standalone bill or included in a bipartisan legislative package," his communications director S.K. Bowen said in an email.

The House user fee package also included the Give Kids a Chance Act (H.R. 6972), which 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 in what the drugs target. Nancy Goodman, founder and executive director of nonprofit group Kids v Cancer, helped craft the bill and said she's pushing to get it included in the year-end package.

"It's a scramble with so many priorities on the agenda," she said in an interview. "I hope that kids with cancer are not forgotten."

If the bill isn't included in the omnibus, "we're going to have to wait until next Congress" to "understand why this wasn't a priority for them, and what they need to have happen so that it does become a priority," Goodman said.

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

To contact the editors responsible for this story: Robin Meszoly at rmeszoly@bgov.com; Anna Yukhananov at ayukhananov@bloombergindustry.com