POLITICS › NATIONAL POLITICS

"Right to Try" bill could face slower action in House

The bill, sponsored by Sen. Ron Johnson of Wisconsin, intends to help dying patients access experimental drugs

Darren Hauck, Getty Images

(L-R) Senator Russ Feingold (WI-D) and Republican candidate Ron Johnson discuss topics as they take part in the Senatorial debate held at Marquette University Law School Oct. 22, 2010 in Milwaukee, Wisconsin.

By **ANDREW SIDDONS** | CQ-Roll Call

PUBLISHED: August 16, 2017 at 12:03 pm | UPDATED: August 16, 2017 at 12:04 pm

WASHINGTON — A Senate-passed bill intended to help dying patients access experimental drugs will likely face lengthier deliberations in the House. While the Senate fast-tracked the bill on Aug. 3, the House will likely subject it to a hearing and markup before bringing it up to a vote, according to congressional aides and a lobbyist.

The bill would reduce some of the paperwork involved in getting access to experimental treatments, and would offer protections to the drug companies who choose to make drugs available outside of a clinical trial. It's the federal version of "Right to Try" measures that have been passed in 37 states with support from libertarian-leaning Republicans who say the Food and Drug Administration prevents dying patients from getting treatments.

The Senate bill's sponsor, Sen. Ron Johnson, threatened to slow down consideration of a separate bill to renew the FDA's fee-collection authority unless his bill was also brought to the floor. So the Senate passed the Wisconsin Republican's bill by unanimous consent in order to finish work on the FDA bill ahead of the August recess.

Johnson agreed to proceed to the FDA bill only after getting promises from House leaders that they would also pass the "Right to Try" legislation. A similar House bill led by GOP Reps. Andy Biggs of Arizona and Brian Fitzpatrick of Pennsylvania has more than 40 co-sponsors, including four Democrats. The House supporters will likely back passage of Johnson's bill.

But if the House Energy and Commerce Committee changes the bill in its expected markup, the Senate would have to vote again. That could stall the bill.

Energy and Commerce staffers are still reviewing the bill, and the committee has not yet scheduled a hearing or markup, according to a spokeswoman.

If the committee does not make changes, a House aide said, the bill would likely go to the floor under suspension of the rules.

After several iterations, the pharmaceutical industry said it does not oppose the bill — but they are not exactly endorsing it.

"We appreciated the opportunity to work with Senator Johnson and look forward to continuing to work with his office. The revised Right to Try legislation that passed the Senate includes important protections for patient safety and the clinical trial process," said Andrew Powaleny, a spokesman for the Pharmaceutical Research and Manufacturers of America, the industry's main trade group.

Currently, when a patient seeks access to an experimental drug, his or her physician must work with the drug company, the FDA and an institutional review board that signs off on drug testing to approve the treatment's use. When originally introduced in January, Johnson's bill would have taken the FDA and other government entities out of that process. It would have let the states define "terminal illness," potentially leading to dozens of different standards across the country about who would qualify for access. It also would have prevented the FDA from using outcomes associated with the experimental use when considering the drug's application.

The new bill, instead of leaving the definition of terminal illness to the states, says that eligible patients should have a "life-threatening disease or condition" as defined by current federal law. It also gives the FDA the right to use outcome data if the administration determines that it is critical to assessing the drug's safety — or if the drug company wants the outcomes used.

The drug companies would also have to provide the FDA with information about the experimental uses. Like the original bill, the new version shields companies against liability, but extends that protection to manufacturers who chose not to grant access to treatments. The bill would also limit the drugs that can be provided to those that have already completed the first phase of formal clinical trials, which are conducted to assess drug safety.

The bill does not compel any drug companies to provide experimental treatments, but its provisions are designed to ease their concerns when they do.

"Some companies are just not going to do this, and that's OK," said Starlee Coleman, a senior policy adviser at the Goldwater Institute, a conservative think tank and a major backer of the Right to Try effort. "But for companies that want to, and want to do it without a delay or red tape associated with the FDA process, they now hopefully will have that option."

Ultimately, the drug industry doesn't seem to think that the bill would do all that much, which is why they aren't opposing it.

"Drug companies assume that a federal law won't have a big effect on them, that things will remain kind of where they have always been," said James C. Shehan, a senior counsel for FDA practice at the law firm Lowenstein Sandler.

He said companies that have traditionally sought expanded access to treatments likely still would, and those that haven't probably wouldn't start. "Companies still have the final say on allowing expanded access, and they have different points of view on this in general and on specific individual requests that depend on many factors," he said, such as safety and availability of the drug.

Some skeptics of the bill think that if the FDA isn't involved, it could deter companies who are seeking the agency's guidance from participating. Coleman noted, however, companies that choose to seek the FDA's approval before participating in expanded access programs still could.

FDA's role

In July, the Government Accountability Office found that the main FDA-related barrier to expanded access was that companies weren't certain how the agency would use data about adverse outcomes. The FDA says that it is important to track adverse outcomes, but that its reviewers recognize that the patients using the drugs in this context are already at greater risk of death than the population typically being tested. Ultimately, the FDA agreed with the GAO that it could be clearer about how it uses outcome data.

Otherwise, the GAO report suggested the FDA isn't slowing down access to experimental treatments. From 2012 through 2015, out of 5,753 requests, the FDA approved 5,697 — a 99 percent approval rate. The FDA told GAO investigators that it typically responded to emergency requests within a day.

The agency also has worked to improve the process. In 2016, it released a new form for physicians to fill out that requires less than half as much information as was previously required and is designed to take 45 minutes to complete. In July, the Reagan-Udall Foundation, a nonprofit that receives money from the FDA and private industry to conduct research relevant to the FDA's mission, launched a website to help doctors and patients navigate the experimental treatment process.

Aside from the Right to Try bill, Congress has taken other steps to improve access to treatment. The recently passed FDA user fee bill, which President Donald Trump is expected to sign, requires the agency to convene a public meeting to assess barriers to clinical trial participation. Last year's "21st Century Cures" Act requires drug companies to make public their policies on expanded access.

TAGS: CONGRESS, DONALD TRUMP, FOOD AND DRUG ADMINISTRATION, HEALTH CARE, TERMINAL ILLNESS, WASHINGTON, WISCONSIN