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A new right for American patients: The Right to Try

May 25, 2018

On May 22, 2018, the U.S. House of Representatives passed Senate Bill 204, commonly known as the "Right to Try Act of 2017" by a vote of 250-169. The bill gives certain patients with life-threatening conditions the right to seek treatment with investigational drugs that are still in clinical trials, while bypassing the Food and Drug Administration's (FDA or the Agency) existing requirements for the Expanded Access program as well as other clinical trial regulations. The legislation has been sent to President Trump, who is expected to sign it.

We should note at the outset that nothing in the legislation forces companies to make their investigational drugs available in response to requests made under the Right to Try Act. Even so, with the passage of this law, companies may face enormous pressure to do so. In addition, we think the new legislation poses a number of other challenging questions for the biopharmaceutical industry, including:

- Will companies continue to use FDA's existing Expanded Access framework over the Right to Try pathway?
  - Companies may determine that there are certain benefits in having the Agency involved in the decision to make the company's investigational drugs available to patients for treatment use.
- Will companies take advantage of the provision in the new law that appears to permit certain cost recovery for making drugs available under Right to Try?
  - The new law contains a brief reference to compliance with 21 CFR 312.8(d)(1), which explicitly permits – in certain cases – the recovery of specific costs related to investigational drugs used for treatment purposes.
- Will parties who make use of the Right to Try pathway forego Institutional Review Board (IRB) review, as appears to be allowed by the law?
  - The legislation specifically exempts compliance with 21 CFR Part 56, the Agency's IRB regulations.
- Will the passage of the Right to Try law prompt companies to revise their policies on making their investigational drugs available on a compassionate use basis?
  - As we previously reported, the 21st Century Cures Act (enacted December 2016) required that any manufacturer or distributor of an investigational drug must

provide a public and readily available policy on evaluating requests for expanded access. We recommend that companies review their existing expanded access/compassionate use policies to determine if changes are needed. For example, it may be hard to justify a refusal to grant a Right to Try request in the absence of a clear public statement that explains how a company may handle these requests.

- What will companies include in their annual reports required under the Right to Try law?
  - Among the provisions in the bill, S.204 requires drug manufacturers or sponsors who provide access to investigational drugs through the new alternative pathway to submit an annual report of those uses – including any adverse reactions caused by the drug – to the U.S. Department of Health and Human Services. The department will make a summary of these reports publicly available on its website.

Additional Background

Although "right to try" laws exist in 40 states, their impact thus far has been minimal according to advocates of the federal initiative.

Meanwhile, FDA has already been moving in the direction of reducing the regulatory burden on experimental treatments, as we discussed here in February. FDA has long had in place "Expanded Access" regulations that make it possible for patients and doctors to obtain access to unapproved drugs. FDA has made substantial changes to this program in recent years to help streamline the process and respond to requests from patients and doctors more quickly, and has recently reported that it now authorizes over 99 percent of its requests for compassionate use. Furthermore, there is language in the 21st Century Cures Act that directs FDA to take greater steps in accepting real-world evidence and patient reported data, which could potentially be generated in right-to-try or expanded access programs.

Analysis

FDA Commissioner Scott Gottlieb, M.D. tweeted May 22 that he was "ready to implement [the Act] in a way that achieves Congress' intent to promote access and protect patients." Yet, there are many reasons why the pharmaceutical industry may want to be cautious about providing access to experimental drugs through the new program. More than 100 advocacy groups wrote in opposition to the bill, as did Democratic House Whip Steny Hoyer in the Daily Whip, expressing concern that these medicines give "false hopes" to patients.

There have also been concerns raised about how FDA might assess the data generated from the new Right to Try program and whether that data can be used to support or inhibit new drug approvals. Accordingly, the bill limits the circumstances in which FDA may use clinical outcome data derived from the program to delay or adversely affect the review and approval of the drug to situations in which the drug's sponsors request the use, or in which FDA determines that the clinical outcome data is critical to determining the safety of the eligible investigational drug.

Pharmaceutical companies face other key challenges, such as how they could respond to competitive threats posed by unscrupulous companies taking advantage of the Right to Try law. Companies will want to consider the potential strategic benefits in providing drugs on a Right to Try basis, while at the same time assessing the possibility of liability for making drug available under this new program.

If you have any questions about the new Right to Try law, please contact one of the authors of this alert or the Hogan Lovells lawyer with whom you regularly work.

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