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Federal "Right to Try Act" Becomes Law: What Your Risk Management Team Needs to Know

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On May 30, 2018, Congress enacted the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 (the "Act"). *See* Pub. L. No. 115-176, § 204, 132 Stat. 1372 (2018). The Act allows eligible terminally ill patients to access prescription drugs that have passed Phase 1 clinical trials but that the FDA has not yet approved for general use ("investigational drugs"). Forty states have adopted variations on "Right to Try" laws.[1] Yet state law protections and immunities offer little comfort to manufacturers, providers, and patients without a federal law counterpart.[2]

The new law aims to fill that void. It provides for broad-based civil tort immunity and prohibits the FDA from using adverse clinical outcomes to delay or deny drug approval. Though lauded by some as the saving grace for terminally ill patients, and derided by others as a threat to patient safety, one thing is certain: implementing the Act poses legal, ethical, and administrative challenges for pharmaceutical manufacturers and healthcare providers alike.

Key Provisions of the Act

Under the Act, patients can gain access to eligible investigational drugs if they (1) have "been diagnosed with a life-threatening disease or condition," (2) have "exhausted [FDA] approved treatment options and [are] unable to participate in a clinical trial," and (3) provide "written informed consent" to a treating physician. Pub. L. No. 115-176, § 204. Pharmaceutical manufacturers may choose to provide access to such investigational drugs, but are not required to do so.

Significantly, the Act insulates drug manufacturers and providers from liability for any claim arising from the provision of an investigational drug to an eligible patient, unless their actions constitute "reckless or willful misconduct, gross negligence, or an intentional tort under

1 As of May 30, 2018, these states include: Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, Wisconsin, and Wyoming. http://righttotry.org/in-your-state/.

2 Previously, courts adjudicating this issue held that terminally ill patients did not have a fundamental right to access experimental drugs. *See Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 701 (D.C. Cir. 2007) (*en banc*) (holding that terminally ill individuals do not have "a fundamental right to experimental drugs that have passed [initial phase] clinical testing"). The federal Right to Try Act renders decisions like *Alliance* moot. Legal challenges to the new law likely will center on the patient population included in the definition of "life threatening disease or condition" and informed consent requirements.

any applicable State law."[3] In addition, the FDA may not use clinical outcomes to delay or otherwise adversely affect approval of the investigational drug, unless the FDA determines that the use of such clinical outcome is "critical" to determining drug safety. *Id.*

Although these provisions remove many barriers to providing access to investigational drugs from the manufacturer's standpoint, manufacturers still have an obligation to report "serious adverse events" to the FDA in the form of an annual report. *Id.* In addition, the law leaves many important terms undefined, and several open questions remain. Before permitting eligible patients to access investigational drugs, manufacturers and providers should consider these incentives, risks, and open questions, among others, in their risk-benefit calculations.

Incentives to Providing Access

- **Good will and social capital**: Pharmaceutical manufacturers should consider the potential opportunities for good will among providers, patients, and the media that comes with providing access to investigational drugs.

- **Additional *in-vivo* data**: Use of investigational drugs will generate additional data on the safety and efficacy of the drug outside of the clinical trial setting. This data may inform decisions on drug improvement, dosing, and administration. In addition, the manufacturer can report positive patient outcomes to the FDA to consider in approving the drug for general use.[4]

- **Early brand visibility and recognition**: Providing investigational drugs to patients and healthcare providers may help prime patients, providers, and purchasers to buy the drug before general marketing efforts have begun, generating brand loyalty and a competitive advantage prior to market entry.

Risks to Consider

- **Tort litigation and preemption of state law**: The law does not expressly address preemption of state law tort claims arising from the provision and use of investigational drugs.[5] This is a significant concern for manufacturers and providers, due to the uncertainty of immunity from litigation in states where there is no concomitant Right to Try law.

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3 Pub. L. No. 115-176, § 204. The law provides comprehensive immunity from civil tort liability, stating, in relevant part:

> (b) NO LIABILITY —
> (1) ALLEGED ACTS OR OMISSIONS.—With respect to any alleged act or omission with respect to an eligible investigational drug provided to an eligible patient pursuant to section 561B of the Federal Food, Drug, and Cosmetic Act and in compliance with such section, no liability in a cause of action shall lie against—
> (A) a sponsor or manufacturer; or
> (B) a prescriber, dispenser, or other individual entity (other than a sponsor or manufacturer), unless the relevant conduct constitutes reckless or willful misconduct, gross negligence, or an intentional tort under any applicable State law.

Id.

4 While the Act prohibits use of clinical outcomes to adversely impact drug approval in most cases, FDA may consider clinical outcomes at the request of the drug's sponsor. PL 115-176 § 2(a).

5 The letter and legislative history of the law, however, tends to suggest implied preemption. *See* 164 Cong. Rec. H1738-05, 164 Cong. Rec. H1738-05, H1743.

- **Written informed consent requirement is vague**: The law does not define the term "written informed consent," leaving manufacturers and providers guessing as to the level of disclosure required.[6]

- **Bad press and reputational damage**: Investigational drug manufacturers and sponsors must report "known serious adverse events" to the FDA on an annual basis, and the FDA may publish the annual report on its website.

Open Questions

- **"Life threatening disease or condition" is broad**: The eligible patient population, as defined, may result in confusion and administrative challenges for manufacturers and providers and sweep in unintended patient populations.

- **Cost and insurance coverage**: Providing investigational drugs free or at cost may not be feasible, but market pricing could deny access to all but the wealthiest patients. In addition, the law provides no guidance on insurance coverage.

- **Physician oversight and input regarding use of investigational drugs**: The law is silent on dosing, administration, and monitoring requirements for investigational drugs, leaving providers exposed and without guidance.

- **Providers' obligation to report adverse events**: The law addresses reporting requirements for manufacturers and sponsors of investigational drugs, but it is unclear whether healthcare providers have any federal reporting obligations.

Conclusion

Pharmaceutical manufacturers and healthcare providers need to consider the ambiguities in the law and anticipate the ways in which they can materialize into real risks for the business and professionals before providing access to investigational drugs. Well-organized administration and thorough record keeping, as well as robust informed consent protocols will help the manufacturer or provider minimize the risks of increased use of investigational drugs, while capturing the benefits to the business and fulfilling the ultimate goal of expanding patients' access to life-saving treatment.

Questions or Information

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6 Compare to certain state Right to Try laws, such as the law in Connecticut, which provides a detailed description of informed consent requirements. *See* Conn. Pub. Acts No. 16-214, *available at* https://www.cga.ct.gov/2016/act/pa/pdf/2016PA-00214-R00SB-00371-PA.pdf.

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