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Navigating Liabilities Around the Right to Try Act

SCOPE AND MEANING

"Right to Try" legislation provides patients access to cutting edge therapies that haven't been formally approved by the FDA. This legislation has been passed at the state level in 41 states and Congress just passed legislation at the Federal level as an alternative to the Compassionate Use program currently in place.

Key Dates:

- House of Representatives passed HR 5247 on March 21, 2018 sending it to the Senate for consideration.
- May 22, the Senate passed the bill, and it was then sent to the President's desk for his signature.
- May 30, President Trump signed the bill into law.

OVERVIEW

FDCA (21 U.S.C. 360bbb et seq.) is amended by inserting after section 561A (21 U.S.C. 360bbb – 0) **section 561B Investigational Drugs For Use By Eligible Patients**. Under the terms of the bill, patients with an acute terminal prognosis or other terminal illness would be able to access drugs that have completed phase one clinical trials under existing FDA rules (CFR 312.21). The bill's process offers an alternative pathway for access to such treatments, in addition to current Expanded Access options favored by FDA regulations. Those that back the legislation emphasize that the bill includes "other" protections (e.g. FDA reporting and an active application (filed under section 505(b) of the FDCA or section 351(a) of the PHSA) by the company in order to receive the protection from liability the bill provides drug makers that participate. Unlike the prior version, the hurdles and application process would seem to focus its benefits on individuals without other medical options. The bill as passed and signed into law relies on existing federal regulations for illness eligible for the program[1].

In order to qualify, patients with a life-threatening condition must exhaust approved treatment options. In such cases, the FDA can't use any negative data with respect to the drug's clinical outcome to delay or adversely affect the review and approval for use under "Right to Try" unless it is critical in determining the safety of the product. The manufacturers and prescribers may be protected from liability if they meet certain requirements under the bill but there is still the potential for private actions under any State or Federal product liability, tort, consumer protection, or warranty law that may undermine the manufacturer or prescriber's protection. Patients no longer need to petition the FDA for approval to try an unapproved drug under the new "Right To Try" bill. The patient's physician may contact the drug company and if an agreement is reached, the patient can be granted access to the drug[2].

The "Right to Try" Act defines patients with a health condition that are life threatening with reasonable likelihood of death within months as subjects[3]. Unlike provisions for access to medicine via Compassionate Use, the "Right to Try" Act only requires patients to have conditions with "reasonable likelihood that death will occur within a matter of months."

The other major change from the prior version of the legislation involves preemption of tort liability which under the previous bill referenced any immunity for manufacturers participating in the program as predicated on "compliance."

Let's take a deeper look at key changes that were made to the bill that the President signed:

DRUG USAGE AND SAFETY

First, the bill only applies to conditions with "reasonable likelihood that death will occur within a matter of months," which is a change from the prior version that it applied to any "life threatening condition." The next important required provision is that the drugs that are to be "tried" are those that (1) have passed phase I clinical trials and (2) are still under development and undergoing further clinical trials. Opponents of the bill argue that Phase I trials are not designed to determine if a drug has any efficacy and, as such, may be unsafe which goes to the effect on how the FDA will safeguard the health of the public and that "Right to Try" removes the FDA from reviewing applications submitted by drug sponsors[4]. Opponents also argue that the FDA already has expanded access to investigational drugs outside of human clinical trials. These opponents point out that "Expanded Access with the FDA continues to perform its function as the gatekeeper for use of investigational drugs – and with those threatened to be sued continuing to have insurance and retaining the defense that the FDA as the safety net approved the use of the drug[5]" Opponents further cite FDA data which suggests that about 99% of submitted applications for expanded access to almost 9,000 investigational drugs were allowed to proceed over a one-year period, according to an FDA research study published by the journal of Therapeutic Innovation & Regulatory Science in 2016[6]. This then leads to the next important issue involving pharma, physician and hospital protection.[7]

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LIABILITY SHIELD

The "No Liability" section of the bill is found on page 9. This section improves on the prior version. The prior version stated that preemption of tort litigation was premised on a manufacturer's compliance with certain requirements of the program, which some lawyers believe is a weak standard for preemption protection and can easily be plead around by counsel. The new version is quite specific and the language/intent is clear that no manufacturer or sponsor will be liable. The liability section of the bill gives the same immunity from tort to both "Right To Try" and for participation in the FDA "Compassionate Use" program.

PRE-EMPTION FROM LITIGATION

The "Act" now specifies that "no manufacturer or sponsor of an investigational drug shall be liable for any alleged act or omission related to the provision of such drug to a single patient or small group of patients for treatment used in accordance with subsection (b) or (c) of section 561 or the provision of an eligible investigational drug to an eligible patient in accordance with this section, including with respect to the provision of any investigational drug under section 561 or an eligible investigational drug under this section, the reporting of safety information, from clinical trials or any other source…"

This verbiage says "no manufacturer… shall be liable" thus eliminating the compliance pre requisite to pre-emption. It also affirms the same immunity from tort will apply both to right to try and to participation in an FDA sanctioned compassionate use program (FDCA section 561 (b-c)) which levels the playing field with regard to manufacturers' exposure under either program[8].

There is an absolute prohibition on liability for non-participation by the manufacturer which is strengthened compared to the prior bill. In so doing, a manufacturer who elects not to provide the drug shall not be liable for determining not to provide access to an investigational drug under the "Act" or for discontinuing such access it may have initially provided[9].

PRIVATE ACTION – STATE OR FEDERAL

This provision is based on the premise that certain actions at a State level or any theory that might not be pre-empted to begin with may not be pre-empted. For example, in certain states, a lack of "informed consent" may be construed as "battery" and would not be pre-empted to begin with.[10] Other examples might include a sponsor misrepresenting findings of Phase 1 clinical trial (e.g., the sponsoring manufacturer hides info that demonstrates a lack of efficacy in the drug)… so the "Act" allows some redress by any person to bring a private action for Intentional conduct.

ADVERSE EVENT REPORTING

Another change is a general prohibition on the FDA using adverse events to interfere with the approval process of eligible investigational drugs. This section is found on pages 8-9 of the "Act." The summary by the manufacturer must include the number of requests granted, the number of patients treated, the therapeutic area of the drug made available and any known or suspected serious adverse events (SARs) pursuant to 21 CFR, section 312.32. While this section aims to smooth out the approval process under the Act, it does contain an exception if the safety information is critical in determining the safety of the product.

WILL YOUR LIABILITY POLICY RESPOND TO A "CLAIM" OR "SUIT"?

When we consider the insurance implications, it will be necessary to look at individual policy wordings. Will the investigational drug meet the policy definition of an insured product? A clinical trial is frequently defined to mean "testing of material upon or within human beings to establish effectiveness or safety of such material." It includes providing information necessary to obtain informed consent by the subject and such other activities in connection with testing. Under the "Right to Try" Act, those qualified may receive the investigational product without participating in a formal clinical trial, and with few exceptions, the FDA can't use any negative data from existing clinical trials unless it is critical in determining the safety of the product. So typical policy provisions for human clinical trials would not seem relevant.

For those companies who are at a "clinical only" stage, such requests under the "Act" necessitate a review of coverage in force, and for those carrying only clinical trials insurance, consideration to expand liability protection to insure Product Liability. This will address situations where clinical trials insurance limitations could prevent coverage for bodily injury allegations arising from a qualified investigational product, supplied to qualifying patients under the "Act."

According to Commercial Insurers who offered feedback after passage of the "Act," human clinical trial insurance provisions may not apply. Their response points the policyholder to the definition of Products and Product Hazard to determine how the liability policy will respond. Of course it remains important to ask whether there is an exclusion regarding the investigational drug being an unapproved drug. While most "Unapproved Goods or Products exclusions contained in a typical Product Liability policy focus on whether such products are/have been declared "unsafe" by a regulatory authority, it is important to examine such exclusions to determine if they might be applied.

Since the Act provides the drug company license to participate or to withdraw their investigational drug from the program, will a typical product liability policy allow coverage for claims or suits due to inventory shortage or failure to supply? Or will intentional act or expected or intended exclusions leave the manufacturer vulnerable? Finally, will blanket preemption really shield a manufacturer's liability or will private actions leave a wedge that the plaintiff bar will use to trigger product liability policies? How will blanket preemption affect the underwriting process? Such questions ultimately determine an underwriter's willingness to offer coverage and will impact both affordability and coverage limits that they are willing to supply.

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[1] H.R. 5247. 115th Congress 2D Session, March 1, 2018

[2] Ibid

[3] Ibid

[4] The Hill, Richard L. Plotkin. "Right to try" continues to be a sham. 3-12-2018

[5] Ibid

[6] HHS Manuscript, Jarow, Lemery, Bugin and Lowy. "Ten-Year Experience for the Center for Drug Evaluation and Research, Part 2: FDA's Role in Ensuring Patient Safety," circa 2016 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5443559/

[7] Bateman-House, A; et al. "Right to Try Laws: Hope, Hype, and Unintended Consequences" September 17, 2016.

[8] Drug & Device Law, Federal Right to Try Legislation – Is It Any Better – 2018 Edition. Bexis, March 23, 2018

[9] H.R. 5247. 115th Congress 2D Session, March 1, 2018

[10] Ibid

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