Worthwhile or Window Dressing?

Right to Try Legislation

By Donna L. Fisher, Samuel J. Abate, Jr., and Melissa Hatch O'Donnell

"Right to Try" legislation, which enables terminally ill patients or patients with a "life threatening disease or condition" to seek access to investigative drugs with little to no oversight from the FDA, has been enacted in 38 states as of the end of 2017. A similar bill passed the U.S. Senate by unanimous consent on August 3, 2017, and other bills are under consideration in the House. Right to Try champions contend that the legislation protects the fundamental right of people to try to preserve their own lives and promises to reduce bureaucratic wait times and paperwork. Its opponents counter that the FDA already has an effective system in place, the expanded access program—sometimes called "compassionate use" or "preapproval access"—which helps patients gain access to investigational products; that Right to Try legislation is unlikely to persuade manufacturers to provide investigational drugs outside clinical trials; and that reducing FDA's role could endanger patients and invite abuse.

This article reviews the existing regulatory program for terminally ill patients to access investigational drugs and the Right to Try initiative, and probes the legislation's purposes, mechanics, and consequences. The article concludes that the recent reforms to the FDA's expanded access program—which may themselves have been a



■ Donna L. Fisher and Samuel J. Abate, Jr., are partners, and Melissa Hatch O'Donnell is an associate, in Pepper Hamilton LLP's Health Sciences Department, a team of 110 attorneys who collaborate across disciplines to solve complex legal challenges confronting clients throughout the health sciences spectrum.

response to the push for Right to Try legislation—may already have achieved the improvements that Right to Try legislation is capable of achieving. Nonetheless, because many people believe that the FDA's current role encroaches (however minimally) on patients' "fundamental right" to fight to save their lives, federal Right to Try legislation may well become law.

Regulatory Background

Section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA) generally prohibits interstate distribution of any new drug unless the Secretary of Health and Human Services (HHS) and, by delegation, the FDA approve an application supported by substantial evidence of the drug's safety and efficacy, or otherwise authorize use of the investigational drug through a clinical trial or expanded access program. *See* 21 U.S.C. §355(a), (b) and (d). After completing toxicity studies on animals, a drug manufacturer must submit an investigational new drug application (IND) to the FDA and successfully complete three phases of human clinical trials before submitting the IND for FDA approval. Phase I trials test the safety of the drug on 20–80 healthy volunteers and last for several months. Phase II trials assess the drug's safety and efficacy on a few dozen to hundreds of volunteers with the target disease or condition and last several months to two years. Phase III trials gather more information on safety and efficacy, based on the experiences of several hundreds to thousands of volunteers with the target disease or condition, and last one to four years. Of the compounds that enter Phase I, only 9.6 percent are ultimately approved for marketing. *See* U.S. Government Accountability Office, Investigational New Drugs: *FDA Has Taken Steps to Improve the Expanded Access Program but Should Further Clarify How Adverse Events Data Are Used*, at 5–7 (July 2017) [*hereinafter* GAO Report].

On different occasions, seriously ill patients have brought lawsuits to curtail the FDA's authority to bar their access to investigational drugs. For example, in 1975, terminally ill cancer patients and their spouses brought an action to enjoin the government from interfering with the interstate shipment and sale of the unapproved drug Laetrile. *United States v. Rutherford*, 442 U.S. 544 (1979). The Supreme Court rejected the claim, noting that the FDCA makes no special provision or exception for drugs to treat terminally ill patients. Further, the Court held that "effective" does not necessarily denote a capacity to cure, and a drug can be unsafe for terminally ill patients if its potential for inflicting harm is not offset by the possibility of therapeutic benefit. *Id.* at 551–57; *see also Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007) (finding no constitutional right of access to experimental drugs).

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FDA's Expanded Access Program

While the FDA was successful in defending court challenges to its restriction of drugs to terminally ill patients, the agency created an exception during the AIDS epidemic. In the 1980s, AIDS spread rapidly; in 1987, only 15 percent of those diagnosed with the disease were left alive after five years. Gina Kolata, *15 percent of People With AIDS Survive 5 Years*, NY Times, Nov. 19, 1987. The ruthless disease caused alarm and desperation in part because of the length of time required to bring a drug to market and because of the lack of access to experimental drugs. *See* Christina Corieri, *Everyone Deserves the Right to Try: Empowering the Terminally Ill to Take Control of Their Treatment*, Goldwater Institute Policy Report No. 266, 8 (Feb. 11, 2014) [*hereinafter* Goldwater Policy Report]. Against this backdrop, public pressure spurred the FDA in 1987 to develop formalized programs allowing patients to access investigational new drugs.

FDA's expanded access program facilitates availability of investigational drugs while protecting safety and avoiding interference with drug development. U.S. Food & Drug Admin., *Expanded Access to Investigational Drugs for Treatment Use – Questions and Answers: Guidance for Industry*, at 2–3 (Oct. 2017) [*hereinafter* FDA Q&A]. Under FDA regulations, expanded access may be sought for (1) individual patients, including for emergency use; (2) intermediate-size patient populations; and (3) widespread treatment through an IND or treatment protocol. *See* 21 CFR 312.310, 21 CFR 312.315 and 21 CFR 312.320, respectively. Almost 96 percent of requests are for single patients; however, because intermediate-size and treatment requests grant access to groups of patients, more patients may have gained expanded access through these types of requests. GAO Report at 17. For each category, expanded access may be sought through an additional protocol in an existing IND or a new IND submission, and expanded access protocols may only be used if the sponsor of the existing IND (typically a commercial entity developing the drug for marketing) is also the sponsor of the expanded access. When the IND sponsor declines to sponsor the expanded access, a new expanded access IND must be submitted by a licensed physician. In the past few years, the FDA has revised the program, most significantly by drastically reducing the time necessary to complete an individual application.

Currently, the expanded access program has flexibility in processing time. If a patient must be treated within a limited number of hours or days, a sponsor may request and receive authorization for emergency access by telephone. From fiscal years 2012 to 2015, the FDA's median response time on the more than 2,300 emergency expanded access IND requests that were submitted was less than one day. GAO Report at 19. In these cases, the sponsor must submit a new written IND within 15 working days of the authorization. Where expanded access is sought via an individual or an intermediate-size patient population expanded access *protocol* (rather than an IND), treatment can begin as soon as the submission is made. In

all other cases, treatment may begin thirty days after the date the FDA receives the early-access application, unless the FDA gives earlier permission or the IND is put on clinical hold. From 2012 to 2015, the FDA took a median of between three and nineteen days to review individual (non-emergency) IND requests and thirty days to review intermediate-size and treatment IND requests. *Id.* at 20.

Expanded access for all categories may be available only if all of the following conditions are met:

- The drug sponsor agrees to the use.
- The investigators treating a patient or patients with an investigational product obtain informed consent, ensuring that the patient knows that he or she will be treated with an investigational product and that there may be uncertainty about the safety and efficacy of the product. FDA Q&A at Q7. Seventy percent of drugs that are offered via expanded access are never approved by FDA because later clinical testing proves that they are unsafe or ineffective. Preliminary Transcript of Hearing of House of Representatives Subcommittee on Health at 68:14–17 (Oct. 3, 2017). [*hereinafter* Oct. 3, 2017, Hearing Trans.].
- FDA determines that the patient or patients have a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition. 21 CFR 312.305(a)(1); 21 CFR 312.310(a)(2).
- The patient's physician (in the case of expanded access for an individual) and the FDA determine that the potential patient benefit justifies the potential risks of the treatment use, and those potential risks are not unreasonable in the context of the disease or condition to be treated. 21 CFR 312.305(a)(2); 21 CFR 312.310(a)(1).
- The FDA determines that providing the investigational product will not interfere with clinical investigations to support marketing approval or otherwise compromise the potential development of the expanded access use. 21 CFR 312.305(a)(3).This means that generally patients must be ineligible or otherwise unable (*e.g.*, geographically unable to access a study site) to enter clinical trials to be eligible to receive expanded access.
- Except for emergency-access expanded use, an investigator treating a patient with an investigational drug under expanded access obtains review and approval by an institutional review board (IRB) before treatment may begin. FDA Q&A at Q6. (An IRB must be notified of *emergency* expanded access within five working days of emergency use. *Id.*) However, the FDA has recently streamlined the IRB review process for expanded access protocols for individual patients, including allowing just one IRB member—the chair or another appropriate person—to concur with the expanded access use upon the request of the treating physician. *See id.*; Witness Statement of Scott Gottlieb, M.D., Commissioner, U.S. Food & Drug Admin., Testimony Before the Subcommittee on Health: Examining Patient Access to Investigational Drugs, 8 (Oct. 3, 2017) [*hereinafter* Oct. 3, 2017, Gottlieb Statement].

As noted above, federal regulations require the FDA to weigh potential risks and benefits when evaluating an application for expanded access. The FDA must determine that there is sufficient evidence of safety and effectiveness to support the proposed use. Indeed, the FDA's Q&A on expanded access states that the FDA may deny a request for individual patient expanded access when previous requests for the same drug for the same or similar use have been permitted because, for example, the latter patient has a different stage of the disease, different tumor type or a comorbid condition, or the FDA has become aware of new safety signals or information about effectiveness. FDA Q&A at Q12. The FDA also may deny a request for individual patient access when it believes that the patient may be able to enroll in a clinical trial. *Id.*at Q11.

In practice, however, the FDA rarely denies applications for expanded access. From 2012 to 2015, FDA reviewed 5,753 expanded access requests and allowed 5,697 (99 percent) to proceed. GAO Report at 17. "[I]n the rare cases when FDA did not allow a request to proceed, the most common reasons were incomplete applications, unsafe dosing, the requested drug's demonstrated lack of efficacy for its intended use, the availability of adequate alternative therapies, and inadequate information provided in the application on which to base a decision." *Id.* The FDA also made meaningful changes to 10 percent of applications to enhance patient safety by, for example, adjusting dosing amounts, increasing safety monitoring, and bolstering informed consent. Oct. 3, 2017, Gottlieb Statement at 4.

Shortcomings in the Existing Framework

Right to Try proponents and the FDA recognize that, despite recent revisions, there are still obstacles to obtaining a drug through the expanded access program. The FDA cannot compel a sponsor drug company to provide expanded access to a drug. Therefore, patients' access to investigational drugs is dependent on the sponsor's agreement to provide the drug. The number of patients who seek permission from drug sponsors/manufacturers to submit an expanded access request is unknown. However, in a survey of nine manufacturers, each reported receiving 39 to about 800 single-patient IND requests. GAO Report at 16.These manufacturers also reported that, when considering expanded access requests, they weighed the following (in addition to the public backlash that might accompany denying the request):

- The risk of reducing participation in clinical trials by approving expanded access requests, particularly because expanded access recipients are sure to receive the drug while clinical trial participants may receive a placebo
- The risk that adverse events experienced by expanded access patients might compromise the drug development process
- The requested drug's availability
- The financial and administrative resources required to fulfill the requests.

Id. at 22.

FDA Commissioner Gottlieb explained in an October 3, 2017 hearing that he believes the most significant obstacle to expanded access is preapproval supply limitations because most drug companies run sufficient batches only for the clinical trial, and that supply does not go through the good manufacturing standards that commercially available drugs do. Oct. 3, 2017, Hearing Trans. at 43:17–19, 50:22–

51:11. He also testified that the risk that adverse events experienced by expanded access patients will affect the FDA's clinical approval process is slight. Recently, the FDA analyzed a decade of data and found no instance in which information gleaned from an expanded access program was used to deny approval of the drug, although in one instance, information gleaned from the program was incorporated into drug labeling, and in another instance, expanded access data helped lead to a drug's approval. *Id*. at 33:15–25.

Commissioner Gottlieb and others charge that another shortcoming of the FDA's expanded access program is that too few people know about it. In response to this criticism, HHS and the FDA recently enacted a number of reforms aimed at making the program more transparent and accessible, including (1) releasing guidance explaining expanded access and when and how to submit a request; (2) requiring drug sponsors to submit information about their expanded access policies to *ClinicalTrials.gov*; and (3) launching the Expanded Access Navigator, an online tool providing information on investigational oncology therapies and expanded access to those drugs, which the FDA plans to broaden to address other therapeutic areas. Oct. 3, 2017, Gottlieb Statement at 6–7. It is unclear whether these reforms will be successful in increasing awareness and use of the FDA's expanded access program.

The Goldwater Institute, the most vocal proponent of Right to Try legislation, argued in a 2014 report that, regardless of its expanded access program, "FDA persists in burdening a person's right to save his own life by preventing access to investigational medicines in three distinct ways." Goldwater Policy Report at 11. First, the Goldwater report argued, the FDA requirement that physicians seeking expanded access for a patient complete an IND "creates a serious impediment that discourages doctors from applying." *Id*. at 11–14. (However, since the Goldwater report, the FDA has streamlined the single-patient IND application, reducing the time it takes to complete to roughly forty-five minutes and decreasing the number of required attachments from eight to one. Oct. 3, 2017, Gottlieb Statement at 5–6.) Second, the Goldwater report charged that the FDA's expansive veto power, while rarely invoked, lacks humanity, and, third, that the IRB review requirement is inequitable because patients in rural areas or those who otherwise lack access to large medical institutions will lack the opportunity to obtain expanded access. Goldwater Policy Report at 14–18.

Additionally, proponents of Right to Try legislation often make more visceral arguments, invoking the plight of patients and their families and arguing that the burdens imposed on a terminal patient who exercises the fundamental right to fight to save his or her own life are a violation of personal liberty. Proponents argue that the "lengthy and bureaucratic" FDA approval process consumes more time than many terminally ill patients have left to live. 163 Cong. Rec. H2004 (daily ed. March 9, 2017) (statement of Rep. Biggs). They also note—pointing to recent reforms—that the FDA's expanded access "program was not put into high gear [until] federal legislation [was] looming." Oct. 3, 2017, Hearing Trans. at 21:22–24. Moreover, some proponents question the FDA's role with respect to drug trials generally, charging that the agency is prone to exercising excess caution when reviewing investigational drugs, and that the FDA should not have the power to require premarket testing for efficacy. *See* Goldwater Policy Report at 6, 19. Thus, a key rationale for Right to Try legislation is the perception that the government should not "play a role in deciding how someone deals with treatment at the end of life." 163 Cong. Rec. H8382 (daily ed. Nov. 1, 2017) (statement of Rep. Biggs).

Right to Try Legislation

Thirty-eight states (as of the end of 2017) have enacted Right to Try legislation, often following the contours of the Goldwater Institute's 2014 model legislation. In addition, in 2017, the U.S. Senate passed by unanimous consent a Right to Try bill, S. 204, the *Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017*. The Senate bill and H.R. 1020, the *Compassionate Freedom of Choice Act of 2017*, as well as several House bills related to S. 204, as of the beginning of 2018, were under review in the House. *See Right to Try Act of 2017*, H.R. 878, 115th Cong. (2017-2018); *Right to Try Act*, H.R. 2368, 115th Cong. (2017-2018). Momentum may grow after President Trump urged Congress to pass Right to Try legislation in his first State of the Union Address. Notably, FDA Commissioner Gottlieb has not opposed the federal bills, although he has offered some technical suggestions and voiced skepticism that the law will change drug manufacturers' decision-making.

The Right to Try state laws and federal bills share some features. They restrict the state and federal governments, respectively, from preventing the manufacture, importation, distribution, or sale of an investigational drug under certain circumstances, eliminating any FDA involvement in case-by-case decisions other than a core requirement that the considered treatment has gone through Phase I clinical trials. Most restrict Right to Try access to those with a "terminal illness," although S. 204 defines eligible patients as those having a "life-threatening disease or condition." Generally, the state laws and federal bills require patients to give written, informed consent and impose some requirement that patients consider or exhaust alternative therapies.

Like the FDA's expanded access program, state Right to Try laws and the federal bills do not require a manufacturer to make available an investigational product to anyone, nor do they mandate insurance coverage. However, the legislation attempts to encourage physicians and manufacturers to participate. For example, the legislation generally grants some protection to those involved in facilitating Right to Try access by limiting liability for resulting harms, and often permits manufacturers to recover some costs or profit from Right to Try users. For example, the Pennsylvania Right to Try law allows manufacturers to require a patient to pay manufacturing costs, S. 204 allows manufacturers to charge "direct costs," and H.R. 1020 has no apparent restriction on manufacturers' ability to charge high prices for experimental drugs. In the federal bills, another proffered inducement to manufacturers to provide the requested treatment is a restriction that prevents the FDA from considering clinical outcomes associated with Right to Try uses to delay or affect adversely the review or approval of the drug, with limited exceptions (in the Senate bill only) related to safety.

Right to Try Initiatives' Shortcomings

The primary arguments against Right to Try legislation are that it offers false hope to patients because pharmaceutical companies are unlikely to agree to allow increased access to investigational medicines, it jeopardizes patient safety by cutting FDA out of the process, and it invites abuse.

First, many are skeptical that state Right to Try laws and the federal Right to Try bills will accomplish anything because they cannot compel manufacturers to provide the drug, and the incentives may not overcome the obstacles that dissuade manufacturers from providing access to investigational drugs. *See, e.g.,* Oct. 3, 2017, Hearing Trans. at 43:9–19 (Com. Gottlieb testimony). As stated above, the bills all confer some form of immunity to protect manufacturers. For example, S. 204 provides that manufacturers of Right to Try products cannot be subject to liability for any harms, and physicians that recommend and facilitate Right to Try access cannot be subject to liability unless their misconduct was reckless or willful, or an intentional tort. Additionally, some of the legislation includes some restriction on using any clinical outcomes as a basis for not approving the drug. But, there are additional obstacles for manufacturers. In opposition to the Right to Try initiatives, some pharmaceutical companies have expressed concern that Right to Try legislation will exacerbate existing pressures for companies to grant access to investigational medicines—despite limited financial resources that should be put toward getting clinical approval quickly and despite the fear that adverse events could cause other patients to decline to participate in clinical trials—or otherwise slow the clinical development process. *See generally* Witness Statement of Kenneth I. Moch, President & CEO, Cognition Therapeutics, Inc., before the Subcommittee on Health: Examining Patient Access to Investigational Drugs (Oct. 3, 2017) [hereinafter Oct. 3, 2017, Moch Statement]; Kenneth I. Moch, *Ethical Crossroads: Expanded Access, Patient Advocacy, and the #SaveJosh Social Media Campaign*, 1 Medicine Access @Point of Care e119, e126 (2017) [*hereinafter* Moch, *Ethical Crossroads*]. These companies fear that, particularly "[i]n the era of Facebook and Twitter… the moral and ethical issues created by these situations are complicated by a hyper-intimacy that increases the intensity and scrutiny under which these issues must be addressed." Oct. 3, 2017, Moch Statement at 8. A difficult decision under any circumstance, requiring a company to weigh multiple factors, is made more difficult when done in the social media era.

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Additionally, manufacturers may prefer the safety of the regulatory framework of the expanded access program. As one former chief executive officer of a small biotechnology company wrote, "No ethical company that I know of would ever release an experimental medicine outside of the FDA's regulatory process" because a "basic mantra is that 'all drugs have side effects'" and the safety of an experimental medicine is not known after Phase I testing. Oct. 3, 2017, Moch Statement at 6; Moch, *Ethical Crossroads* at e126. It is unclear whether the federal bills' limitations on liability adequately address this perception. As discussed above, manufacturers often decline to provide investigational drugs through the current expanded access program, even though the program does not seem to expose companies to significant legal risks. Research by NYU Langone Health found no instances in which a drug company, doctor, or hospital was sued with regard to expanded access. Witness Statement of Alison Bateman-House, PhD, MPH, MA, Assistant Professor, Div. of Medical Ethics Dep't of Population Health, NYU Langone Health, Before the Subcommittee on Health: Examining Patient Access to Investigational Drugs (Oct. 3, 2017), 4.

Moreover, Right to Try opponents argue that *state* Right to Try laws are futile, as evidenced by the lack of persons availing themselves of those laws. Dr. Alison Bateman-House, assistant professor at NYU Langone Health, testified that, despite her best efforts, she has been able to find only two doctors who admit to giving treatments to patients under Right to Try (both located in Texas, and one of which had treated seventy-eight patients with an experimental radioisotope as of a Senate hearing in 2016). Oct. 3, 2017, Hearing Trans. at 133:13–17; Video, U.S. Senate Committee on Homeland Security & Governmental Affairs, Exploring a Right to Try for Terminally Ill Patients (Sept. 22, 2016). That may well be because, despite the existence of a Right to Try law in a patient's state, manufacturers are still subject to the FDCA, which mandates that "no person shall introduce or deliver for introduction into interstate commerce any new drug," unless FDA has approved an application for the product or otherwise authorized its use. *See* 21 U.S.C. §355(a). So the provision of a drug pursuant to a state Right to Try law, without compliance with the expanded access regulations as well, would be a violation of the FDCA.

Further, the state Right to Try laws may be impliedly preempted by the FDCA. A state law is impliedly preempted under the Supremacy Clause, U.S. Const. Art. VI, cl.2, under the doctrine of field preemption if a "scheme of federal regulation [is]… so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." *Amgen Inc. v. Sandoz, Inc.*, 877 F.3d 1315, 1326 (Fed. Cir. 2017). It is impliedly preempted under the doctrine of conflict preemption if there is an "actual conflict with federal law," such as where the state law "stands as an obstacle to the accomplishment and execution of the full

purposes and objectives of Congress." *Id.*; *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995). Here, a court may find that Congress adopted a complex statutory scheme that establishes the exclusive process for gaining approval to distribute or market a drug, and therefore state Right to Try laws are preempted under the field preemption doctrine. Further, the state laws may also be preempted under the conflict preemption doctrine because a drug manufacturer cannot, without FDA approval, provide a terminally ill patient with a drug that has passed only Phase I of FDA trials and, at the same time, comply with federal regulations that require more testing, and the state laws may pose an obstacle to the purposes and objectives of Congress when it authorized the FDA to limit access to investigational cures.

Opponents of Right to Try legislation fear that cutting the FDA out of the process jeopardizes patient safety. They note that "the current regulatory system for medical products and research in the United States was created as a result of serious patient harm and exploitation that occurred early in the 20th Century" and cite the example of thalidomide in the early 1960s—when thousands of babies in Europe, Canada, and the Middle East were born with birth defects, while infants in the United States were mostly spared when the FDA denied approval for the drug. Letter to Reps. Greg Walden & Frank Pallone (Sept. 19, 2017). Opponents note that the FDA mandates changes to 10 percent of applications, often on the basis of information concerning ongoing clinical testing in possession of the FDA that is not available to physicians, and that, by not allowing the FDA to make use of adverse event data related to Right to Try patients except in extreme circumstances, Right to Try legislation might endanger future patients. *See, e.g.,* Steven Joffee & Holly Fernandez Lynch, *Federal Right to Try Legislation – Threatening the FDA's Public Health Mission*, New Engl. J. Med., Jan. 10, 2018, at 2; Letter from Treatment Action Group to the Rep. Michael C. Burgess, MD & Rep. Gene Green, 3 (Oct. 3, 2017) [*hereinafter* TAG Letter].

The potential for adverse outcomes resulting from the FDA's reduced role is expanded with respect to the Senate bill, which makes patients who face a "life threatening disease or condition" eligible for the program, in contrast to most state bills, which require a "terminal illness." Sponsors of S. 204 explained that the legislation is designed to benefit patients like a boy with Duchenne Muscular Dystrophy, who has "a terminal disease by anyone's standards, but not one that will likely take his life within six months, one year, or even two." Letter from Sen. Joe Donnelly, *et al.* to Rep. Greg Walden, *et al.*, at 2 (Oct. 2, 2017). However, "life threatening disease or condition" could include very common chronic illnesses like advanced diabetes and class two heart failure, and therefore that language might significantly expand the scope of Right to Try. Oct. 3, 2017, Hearing Trans.at 35:1-20, 41:4-19.

Finally, also citing safety issues, opponents of Right to Try legislation fear that it invites abuse because the legislation allows "manufacturers to circumvent stringent regulatory approval requirements [and] instead focus on commercializing… products to desperate patients." TAG Letter, at 2-3. This concern is especially pronounced because the broad immunity conferred by federal Right to Try legislation would make liability unlikely. *Id.* In addition, Right to Try laws may invite poor decision-making by desperate, terminally ill patients and their families because they leave patients in danger of losing access to home health care, hospice care, and insurance coverage if they try an experimental product, which under the House Right to Try bill could itself cost any amount.

Conclusion

The questions facing Congress and the executive branch as they consider federal Right to Try legislation are whether recent and potential revisions to the FDA's expanded access program adequately address the concerns of terminally ill patients and their families, and whether Right to Try legislation can safely fill any gap. Recent FDA amendments have cut down on paperwork, and the 2017 GAO report has made clear that the FDA approves 99 percent of expanded access applications. FDA initiatives and tools like the new Expanded Access Navigator can help to promote patient awareness. Accepting some advocates' contention that the recent improvements were prompted by the Right to Try initiative, evidenced by a temporal relationship at the least, the movement may well have achieved much of what it is capable of achieving.

Should the focus on the expanded access program continue, however, manufacturers and regulators may continue to collaborate on further refinements that might increase access and make that access more equitable. For example, manufacturers and others have sought assistance in structuring objective methods for reviewing expanded access requests. Moch, *Ethical Crossroads* at e128. These structures may increase the availability of experimental drugs by assisting companies to move beyond a "yes to all" or "no to all" framework.

Beyond developing objective guidelines for manufacturers for responding to expanded access requests, the FDA likely cannot significantly improve incentives for manufacturers to grant early access in the existing program. Right to Try legislation attempts to ameliorate some manufacturer concerns—for example, by limiting liability for harms resulting from Right to Try uses of clinical drugs and restricting use of clinical outcomes as a basis for denying approval by the FDA—but it is unclear whether these measures are sufficient. Further, within the existing framework, the FDA cannot ameliorate the more visceral concern of some patients and their families: that by standing in the way (however nominally) of a potentially life-saving drug, the FDA is encroaching on patients' "fundamental right" to fight to save their lives.

Regardless of the merits of the FDA's existing program, this last concern—coupled with Right to Try's significant support and momentum—may be enough to push federal Right to Try legislation into law in 2018.

Postscript: The initiative has been moved to the legislative forefront. On March 21, 2018, the House of Representatives passed H.R. 5247, a new Right to Try bill first introduced in mid-March. As of March 23, 2018, the Senate had failed to pass H.R. 5247. The house bill partially addresses some concerns with S. 204 by narrowing the limitations of liability for medical providers and manufacturers/sponsors and providing that eligible patients must have a disease or condition in which there is a reasonable likelihood of death within a matter of months, or one that would result in significant irreversibly morbidity and is likely to lead to severely premature death.