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## Fighting for the “Right To Try” Unapproved Drugs: Law as Persuasion

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Over the last several months, five states have passed “Right to Try” laws,<sup>1</sup> which are designed to allow terminally ill patients to obtain experimental drugs.<sup>2</sup> Often popularly known as “Dallas Buyers Club” laws,<sup>3</sup> Right to Try legislation appears to bypass the FDA’s safety procedures—procedures that supporters of Right to Try legislation believe too often prevent the terminally ill from accessing drugs that might save their lives.<sup>4</sup>

The reality of Right to Try laws, however, is very different. Media descriptions often do not even mention one of the most pressing questions surrounding these laws: do state laws on drug access meaningfully alter the legal regime governing experimental drugs?<sup>5</sup> Regardless of the substantive merits of allowing terminally ill patients to use experimental drugs, FDA regulations require

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1. Such laws have been passed in Colorado, Louisiana, Missouri, Michigan and Arizona. Right To Try Act, COLO. REV. STAT. ANN. § 25-45-101-06 (West 2014); Right To Try Act, 2014 LA. SESS. LAW SERV. ACT 346 (West); MO. ANN. STAT. § 191.480 (West 2014); Right To Try Act, MICH. COMP. LAWS ANN. § 333.26451 (West 2014); Terminal Patients’ Right To Try Act, ARIZ. REV. STAT. ANN. § 36-1311 (West 2014).
  2. By “experimental drugs,” I mean drugs as-yet unapproved for general sale by the FDA.
  3. See, e.g., Patti Parson, *Colorado First State to Pass ‘Right To Try,’ or the ‘Dallas Buyers’ Club’ Law*, PBS NEWSHOUR (May 19, 2014), <http://www.pbs.org/newshour/rundown/colorado-first-state-pass-right-try-dallas-buyers-club-law/> [<http://perma.cc/NU67-VQZ5>].
  4. Christina Corieri, *Everyone Deserves the Right To Try: Empowering the Terminally Ill To Take Control of Their Treatment*, GOLDWATER INST. 1-2 (Feb. 11, 2014), [http://goldwaterinstitute.org/sites/default/files/Right%20To%20Try\\_1.pdf](http://goldwaterinstitute.org/sites/default/files/Right%20To%20Try_1.pdf) [<http://perma.cc/LS5M-4Y5S>].
  5. Many news reports assume these laws will allow greater access to the relevant drugs, even though the assumption is dubious. See, e.g., John Tozzi, *Do Dying Patients Have a Right To Try Experimental Drugs? Libertarians Say Yes*, BLOOMBERG BUSINESSWEEK (Aug. 21, 2014), <http://www.businessweek.com/articles/2014-08-21/do-dying-patients-have-a-right-to-try-experimental-drugs-libertarians-say-yes> [<http://perma.cc/HEE2-QXYW>]; *‘Right To Try’ Law Gives Terminal Patients Access to Drugs Not Approved by FDA*, PBS NEWSHOUR (June 21, 2014), <http://www.pbs.org/newshour/bb/right-try-law-gives-terminal-patients-access-non-fda-approved-drugs> [<http://perma.cc/3QJ9-RKQE>].

drugs to be approved before they can be sold to consumers, and Right to Try laws do nothing to change that. So what is the purpose of these laws?

I suggest that Right to Try laws do not themselves meaningfully alter substantive law but instead serve a different function. By advocating for these reforms, the movement’s leaders<sup>6</sup> are seeking to persuade policy makers at other levels of government. Their aim is either to promote federal policy reform through the FDA or Congress, or to convince federal courts to recognize a Right to Try under the Constitution. The laws’ supporters are using state legislatures as forums to draw attention to and legitimate their cause. The Right to Try saga therefore demonstrates an important feature of American federalism: even when federal law ensures that states lack legal power to alter substantive law meaningfully, state actors can still use their legislative processes to promote their desired policies and constitutional interpretations at the federal level.

I proceed in three parts. Part I describes the content of the Right to Try laws and the context surrounding their passage. Part II argues that state Right to Try laws are unlikely to lead directly to wider access to drugs. Finally, Part III argues that Right to Try laws instead serve the purpose of persuading federal decision makers to reform federal law.

## I. THE RISE OF THE RIGHT TO TRY MOVEMENT

Existing Right to Try laws share several common characteristics. Most generally, they codify a position that the state government will not interfere with a terminally ill patient’s attempt to save her life.<sup>7</sup> The laws enact this general policy in two ways. First, they permit doctors to prescribe and drug companies to provide any drug, biological product, or medical device that might save an otherwise terminal patient, as long as it has passed the FDA’s Phase 1 testing and some minimal procedures are followed.<sup>8</sup> Under FDA regulations, such drugs would not otherwise be available to the general public for several years (though they are sometimes made available to terminal patients through the Admin-

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6. The organization at the forefront of the movement is the Goldwater Institute, a libertarian think tank that has recently begun pushing for these laws after unsuccessful litigation on the issue in the D.C. Circuit. *See infra* notes 16-23 and accompanying text.

7. *See* COLO. REV. STAT. ANN. § 25-45-104 (West 2014) (providing that manufacturers may sell experimental drugs to terminally ill patients, and insurers may cover such purchases); 2014 LA. SESS. LAW SERV. ACT 346 § 1300.384 (West) (same); MO. ANN. STAT. § 191.480 (West 2014) (same); MICH. COMP. LAWS ANN. § 333.26452-53 (West 2014) (same); ARIZ. REV. STAT. ANN. § 36-1311 (West 2014) (same).

8. *See* COLO. REV. STAT. ANN. § 25-45-104-05 (West 2014); 2014 LA. SESS. LAW SERV. ACT 346 § 1300.384 (West); MO. ANN. STAT. § 191.480 (West 2014); MICH. COMP. LAWS ANN. § 333.26452-53 (West 2014); ARIZ. REV. STAT. ANN. § 36-1311 (West 2014).

istration's "expanded access" program).<sup>9</sup> Second, Right to Try laws shield, at least to some extent, doctors and drug companies from state tort liability for providing experimental drugs.<sup>10</sup> However, these laws do not create any requirement or incentive for drug companies to provide the drugs or for insurance companies to cover them.

Advocacy organizations dedicated to the Right to Try have supported these recent laws. We can trace the genesis of the Right to Try movement back to Abigail Burroughs, who died of cancer in 2001.<sup>11</sup> Her doctors had advised her that an unapproved drug, Erbitux, might save her life.<sup>12</sup> Burroughs's family launched a media campaign to get her the drug, pressuring both the producers and Congress to allow her access.<sup>13</sup> She died without ever getting a chance to try it.<sup>14</sup>

Burroughs's father, Frank, then established the Abigail Alliance for Better Access to Developmental Drugs with the mission of facilitating access for future patients in Abigail's situation.<sup>15</sup> The Alliance's first major effort was to sue the FDA, claiming a constitutional due process right for terminally ill patients to access unapproved drugs.<sup>16</sup> In 2006, a divided three-judge panel of the D.C. Circuit found that the Constitution indeed provided this right.<sup>17</sup> The panel's decision would have constitutionalized the putative substance of the current Right to Try laws had the decision stood (at least in the District of Colum-

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9. See *IDE Early/Expanded Access*, FOOD & DRUG ADMIN (Jun. 27, 2014), <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm> [<http://perma.cc/ZYE-9739>].
  10. The statutes vary on the extent of the shield. The Colorado statute, for example, shields manufacturers and doctors unless "there was a failure to exercise reasonable care." COLO. REV. STAT. ANN. § 25-45-107 (West 2014). In contrast, the Missouri law shields providers "[e]xcept in the case of gross negligence or willful misconduct." MO. ANN. STAT. § 191.480 (West 2014).
  11. See Jann Bellamy, *The Illusions of "Right To Try" Laws*, SCI.-BASED MED. (Mar. 6 2014), <http://www.sciencebasedmedicine.org/the-illusions-of-right-to-try-laws> [<http://perma.cc/9J7U-AWKW>].
  12. See *Our Story*, ABIGAIL ALLIANCE, <http://www.abigail-alliance.org/story.php> [<http://perma.cc/XJV4-K7FG>].
  13. *Id.*
  14. Peter Hart, *Abigail Alliance Case Discussed: Balancing Study Drugs, Safety*, UNIV. TIMES. Feb. 19, 2009; <http://www.utimes.pitt.edu/?p=8605> [<http://perma.cc/Y58C-DLWV>] (noting that the FDA denied Burroughs's request for the drug).
  15. See *Our Story*, *supra* note 12.
  16. See Bellamy, *supra* note 11.
  17. *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach*, 445 F.3d 470 (D.C. Cir. 2006), *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007).

bia).<sup>18</sup> However, in 2007, the D.C. Circuit reheard the case en banc and reversed the panel.<sup>19</sup>

After a quiet interval of a few years, Right to Try backers turned their attention from federal courts to state legislatures. Recently, five states have adopted Right to Try laws with bipartisan support.<sup>20</sup> While the Alliance has long lobbied for Right to Try laws,<sup>21</sup> the Goldwater Institute, a libertarian think tank, has been the driving force behind this recent wave of legislation. The Institute wrote and publicized model legislation,<sup>22</sup> which the recent bills have largely followed, and it engaged in a broad campaign to establish the Right to Try in state legislatures.<sup>23</sup>

Right to Try’s supporters have successfully framed the laws as both a boon to personal liberty and a remedy for bureaucratic failure.<sup>24</sup> They state that the laws enshrine “the fundamental right of people to try to save their own lives”<sup>25</sup> and describe them as “*Dallas Buyers Club* laws” – that is, laws that might have prevented some of the horrors of the AIDS crisis as portrayed by the 2013 film.<sup>26</sup> The fact that laws have been passed in multiple states suggests that the-

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18. There is at least one important difference between what the plaintiffs asked for in *Abigail Alliance* and what the new laws aim to achieve: the litigation would have allowed for some continued oversight of the process by the FDA, while the new laws, at least superficially, cut out the FDA altogether. See Bellamy, *supra* note 11.

19. *Abigail Alliance*, 495 F.3d 695.

20. See *supra* notes 1, 3.

21. See Mary Lou Byrd, *The Right to Try*, WASH. FREE BEACON (Feb. 21, 2014), <http://freebeacon.com/issues/the-right-to-try> [<http://perma.cc/WU8F-4HD4>]; David Gorski, “*Right To Try*” Laws and Dallas Buyers’ Club: Great Movie, Terrible for Patients and Terrible Policy, SCI.-BASED MED. (Mar. 08, 2014), <http://www.sciencebasedmedicine.org/right-to-try-laws-and-dallas-buyers-club-great-movie-terrible-public-policy/#more-30518> [<http://perma.cc/EZD2-FV3E>].

22. Corieri, *supra* note 4.

23. See *id.*

24. *Id.*

25. *Id.*

26. *Dallas Buyers Club*, a popular film based on true events for which Matthew McConaughey won the Academy Award for Best Actor, portrayed an AIDS patient’s struggle to gain access to promising drugs that the FDA refused to approve. See Kyle Smith, *How the Oscar-Winning Libertarian Favorite “Dallas Buyers Club” Exposes the FDA*, FORBES (Mar. 05, 2014), <http://www.forbes.com/sites/kylesmith/2014/03/05/how-the-oscar-winning-libertarian-favorite-dallas-buyers-club-exposes-the-fda> [<http://perma.cc/R49U-8TRK>]. Backers of Right to Try laws see their project as allowing patients similarly situated to McConaughey’s character get access to the drugs they need without interference from the FDA. See Eleanor Clift, *The “Dallas Buyers Club” Bill*, DAILY BEAST (Mar. 4, 2014), <http://www.thedailybeast.com/articles/2014/03/04/the-dallas-buyers-club-bill.html> [<http://perma.cc/V8GH-MMSX>]; Kristen Wyatt, *Colorado’s ‘Right To Try’ Law Will Give Some Patients Access to Experimental Drugs*, HUFFINGTON POST (May 18, 2014),

se efforts have been by and large successful; it may be unpopular to argue that terminal patients shouldn't be allowed to try whatever drug their doctor thinks might work.

## II. WHY A STATE RIGHT TO TRY CREATES RIGHTS THAT CANNOT BE VINDICATED

Beneath the rhetoric, however, the force of these laws is much less certain. It is not clear that the states have power to legislate on this matter in the first place.<sup>27</sup>

The FDA requires patients seeking access to unapproved drugs to go through its expanded access program.<sup>28</sup> This process intends to ensure that the potential benefit to the patient from using a drug is not outweighed by the risks.<sup>29</sup> (Experimental drugs have potential downsides even for terminal patients, such as excessive pain or reduced lifespans.)<sup>30</sup> Absent approval through

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[http://www.huffingtonpost.com/2014/05/18/colorado-right-to-try-law-experimental-drugs\\_n\\_5347490.html](http://www.huffingtonpost.com/2014/05/18/colorado-right-to-try-law-experimental-drugs_n_5347490.html) [<http://perma.cc/J56E-DQ4F>].

27. There are also significant substantive debates over the movement's goals. One issue is that the Right to Try laws do little to motivate drug companies—which are arguably more difficult to convince than the FDA—to provide access to the drugs. *See, e.g.,* Wyatt, *supra* note 26 (“Gorski [a surgical oncologist and editor of the blog Science-Based Medicine] said a drug company ‘wouldn’t do anything to endanger a drug they’re potentially spending hundreds of millions of dollars to bring to market’ through elaborate FDA trials.”).
28. The expanded access program was actually largely created in response to the FDA’s errors during the AIDS crisis. *See Expanded Access and Expedited Approval of New Therapies Related to HIV/AIDS*, FOOD & DRUG ADMIN., <http://www.fda.gov/ForPatients/Illness/HIVAIDS/Treatment/ucm134331.htm> [<http://perma.cc/M3TB-66B8>] (“FDA has taken significant steps, primarily in response to the HIV/AIDS crises, toward making experimental drugs intended to treat life-threatening diseases more widely available to severely ill patients, as well as toward speeding the review and approval of the applications for these products.”).
29. *See Understanding Expanded Access/Compassionate Use*, FOOD & DRUG ADMIN., <http://www.fda.gov/ForPatients/Other/ExpandedAccess/default.htm> [<http://perma.cc/EEY8-YF3U>] (To grant access to the drug to a patient, the “FDA must . . . determine that: there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition[;] 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[;] providing the investigational drug will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access use[;] that the patient cannot obtain the drug under another . . . protocol.”).
30. *See* Darkshak M. Sanghavi, *The Pills of Last Resort: How Dying Patients Get Access to Experimental Drugs*, N.Y. TIMES MAG., Oct. 31, 2013, <http://www.nytimes.com/2013/11/03/magazine/how-dying-patients-get-access-to-experimental-drugs.html> [<http://perma.cc/8ZT4-DZ87>] (describing how the author’s terminally ill father petitioned his insurance company for off-label use of a drug, only for at-the-time unknown side effects to worsen his condition and hasten his death); *Understanding Expanded Access/Compassionate Use*, *supra* note 29 (“It is important to remember that the drug/device may have unexpected serious

the expanded access program, FDA regulations prevent access to drugs that have not completed all three stages of the FDA’s approval process.<sup>31</sup>

Numerous reports assert that Right to Try laws let patients “bypass” or “circumvent” the FDA expanded access process.<sup>32</sup> However, the laws do not explicitly “bypass” federal law; it is more accurate to describe them as establishing a “Right to Try” under state law, irrespective of federal law. Even if a law did attempt to “bypass” the expanded access process, that aspect of the law would be invalid, since it would contradict federal requirements.<sup>33</sup> Either way, the result is the same: FDA regulations still prevent drug companies from providing experimental drugs to terminal patients, and Right to Try laws do not protect companies or individuals from liability under federal law. A state Right to Try therefore does not meaningfully change the legal regime to which drug companies are subject and so is unlikely to bring unapproved drugs to more patients.<sup>34</sup>

That said, it is possible that some patients will obtain unapproved drugs as a direct result of these laws. The FDA has not taken an official position on Right to Try laws,<sup>35</sup> and it is possible that political pressures would prevent the

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side effects and that patients need to consider all the possible risks when seeking access to an investigational drug or device.”).

31. See *IDE Early/Expanded Access*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm> [<http://perma.cc/GUU7-JSRE>] (“An unapproved medical device may normally only be used on human subjects through an approved clinical study in which the subjects meet certain criteria and the device is only used in accordance with the approved protocol by a clinical investigator participating in the clinical trial.”). Similarly, drugs the FDA has not approved may not be marketed. See *Unapproved Prescription Drugs: Drugs Marketed in the United States That Do Not Have Required FDA Approval*, FOOD & DRUG ADMIN., <http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/enforcementactivitiesbyfda/selectedenforcementactionsonunapproveddrugs/default.htm> [<http://perma.cc/JCW4-4CDY>] (describing drugs sold without FDA approval as being “marketed illegally”); *How Can I Get Access to a Drug That Is in Testing but Has Not Yet Been Approved?*, FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194958.htm> [<http://perma.cc/8TMV-6NQY>] (describing exceptions to FDA approval requirements).
32. See, e.g., Wyatt, *supra* note 26; ‘Right To Try’ Law Gives Terminal Patients Access to Drugs Not Approved by FDA, PBS NEWSHOUR (June 21, 2014), <http://www.pbs.org/newshour/bb/right-try-law-gives-terminal-patients-access-non-fda-approved-drugs> [<http://perma.cc/ALF6-MGPX>].
33. It is well accepted that federal law trumps state law when they conflict. *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 41 (1824); ERWIN CHEMERINSKY, *CONSTITUTIONAL LAW* 402 (3d ed. 2013).
34. See Wyatt, *supra* note 26 (“The FDA regulates drug development, and this doesn’t do anything to change that,” said Dr. David Gorski, a surgical oncologist and editor of the blog Science Based Medicine.”).
35. See *FDA and Marijuana: Questions and Answers*, FOOD & DRUG ADMIN. (Jun. 20, 2014), <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm#Q10> [<http://perma>

agency from actively opposing the laws.<sup>36</sup> As the cases of marijuana legalization in Washington and Colorado have shown, the federal government may choose not to enforce federal law where a state has legalized a practice under its own laws.<sup>37</sup>

Access to experimental drugs, however, differs from marijuana legalization in at least one important respect. Marijuana producers have an obvious financial incentive to sell the drug to consumers.<sup>38</sup> In contrast, for Right to Try laws to help anyone, the drug companies must risk FDA enforcement and other issues for financial returns that are likely to be marginal. The number of patients seeking access to experimental drugs is necessarily small,<sup>39</sup> since participants must be terminally ill, unable to get into a nearby clinical trial, and unable to find a reasonable alternative – while also desiring to use a drug the FDA has not

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.cc/JB7K-KM6J] (“The FDA has not taken a position on any particular state ‘Right to Try’ bill. The FDA works with companies to provide patients access to experimental therapies through enrollment in clinical trials or through the expanded access provisions described in the FDA’s statute and regulations. The FDA may permit the use of an experimental therapy, but the sponsor company ultimately decides whether or not to provide experimental therapies to patients.”)

36. In all likelihood, a straightforward announcement that companies were still not permitted to provide drugs without the FDA’s consent would be sufficient to guarantee no rational company would do so: even the chair of Goldwater’s Right to Try National Advisory Council has acknowledged it would be a bad idea to disregard the clear statement of the FDA on this issue. NEURALSTEM: CEO BLOG (Jun. 6, 2014), <http://www.neuralstem.com/neuralstem-ceo-blog/216-fda-has-demonstrated-its-commitment-to-supporting-access-to-experimental-therapies-for-patients-living-with-serious-diseases#sthash.n1rnqlls.dpuf> [<http://perma.cc/HTX2-K98J>] (“No one is suggesting that this process take the place of the existing clinical trial process. And no company (though I can only speak for Neuralstem) will offer a drug if the FDA tells it not to.”). (Neuralstem’s CEO chairs the Goldwater Institute’s Right to Try National Advisory Council. *Neuralstem Flirting with Stem Cell Noncompliance in Colorado via Right To Try Law?*, KNOEPFLER LAB STEM CELL BLOG (Jun. 11, 2014), <http://www.ipscell.com/2014/06/neuralstem-flirting-with-stem-cell-noncompliance-in-colorado-via-right-to-try-law> [<http://perma.cc/FY8Z-5ZU9>].
37. See Ryan J. Reilly & Ryan Grim, *Eric Holder Says DOJ Will Let Washington, Colorado Marijuana Laws Go Into Effect*, HUFF. POST (Aug. 29, 2013), [http://www.huffingtonpost.com/2013/08/29/eric-holder-marijuana-washington-colorado-doj\\_n\\_3837034.html](http://www.huffingtonpost.com/2013/08/29/eric-holder-marijuana-washington-colorado-doj_n_3837034.html) [<http://perma.cc/7ZP9-FMXE>]. Alaska, Oregon and Washington, D.C. also recently legalized marijuana in their territory. See Dan Merica, *Oregon, Alaska and Washington, D.C. Legalize Marijuana*, CNN (Nov. 5, 2014), <http://www.cnn.com/2014/11/04/politics/marijuana-2014> [<http://perma.cc/F794-U3U8>].
38. See Christopher Ingraham, *Colorado Marijuana Tax Revenues Surge as Recreational Sales Surpass Medical*, WASH. POST: WONKBLOG (Sep. 11, 2014), <http://www.washingtonpost.com/blogs/wonkblog/wp/2014/09/11/colorado-marijuana-tax-revenues-surge-as-recreational-sales-surpass-medical-for-the-first-time> [<http://perma.cc/7VRB-9L7C>] (describing recreational marijuana sales of nearly \$30 million in Colorado between January and July 2014).
39. For example, in 2013, the FDA received fewer than 1,000 total requests for expanded access across all unapproved drugs. Kelly Servick, *‘Right To Try’ Laws Bypass FDA for Last-Ditch Treatments*, SCI. (June 20, 2014), <http://www.sciencemag.org/content/344/6190/1329.full> [<http://perma.cc/898D-F38D>].

yet deemed effective. This would limit the financial upside of providing unapproved drugs. Given that it takes, on average, ten years and roughly \$1 billion to complete the FDA approval process,<sup>40</sup> the money a company might make from such experimental sales would likely be nominal compared to the costs of development. Moreover, even without fear of FDA enforcement, drug companies are often reluctant to provide access to experimental drugs, reasoning that a bad outcome might damage a drug’s chances of being approved,<sup>41</sup> or that a company should focus its resources on the approval process.<sup>42</sup> While Right to Try laws shield pharmaceutical companies from state tort liability, limiting their exposure significantly, a careful lawyer would still almost certainly advise her client to go through the FDA process.

So long as the Right to Try remains a creature solely of state law, it will be unlikely to get many more drugs to patients. The most likely short-term outcome is that few, and perhaps no, drugs will be provided to patients that would not have been available otherwise.<sup>43</sup>

### III. THE STATE RIGHT TO TRY AS AN ATTEMPT TO PERSUADE

If this analysis is correct, do Right to Try laws simply lack a purpose? Some commentators have suggested this is the case,<sup>44</sup> but I don’t think so. As toothless as the current laws may be, their passage can support a campaign of persuasion that may ultimately lead to meaningful federal reform.

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40. See Tozzi, *supra* note 5.

41. See Servick, *supra* note 39; see also Brady Dennis & Ariana Eunjung Cha, ‘Right To Try’ Laws Spur Debate over Dying Patients’ Access to Experimental Drugs, WASH. POST, May 16, 2014, [http://www.washingtonpost.com/national/health-science/right-to-try-laws-spur-debate-over-dying-patients-access-to-experimental-drugs/2014/05/16/820e08c8-dcfa-11e3-b745-87d39690c5co\\_story.html](http://www.washingtonpost.com/national/health-science/right-to-try-laws-spur-debate-over-dying-patients-access-to-experimental-drugs/2014/05/16/820e08c8-dcfa-11e3-b745-87d39690c5co_story.html) [<http://perma.cc/A6XH-SD67>] (“Granting unwarranted expanded access requests not only places ‘an individual’s health ahead of the public’s health,’ [Sascha Haverfield, vice president of scientific and regulatory affairs at the Pharmaceutical Research and Manufacturers of America,] said, but it also could undermine the regulatory process and hinder a company’s ability to make new drugs available to a broader patient population.”).

42. See Servick, *supra* note 39.

43. As far as I am aware, the only drug company that has indicated it might provide its unapproved drugs as a result of these laws is Neuralstem, which is developing an ALS drug, and whose CEO chairs the Goldwater Institute’s Right to Try Advisory Council. *Neuralstem Flirting with Stem Cell Noncompliance in Colorado via Right To Try Law?*, KNOEPFLER LAB STEM CELL BLOG, *supra* note 36. However, even Neuralstem announced it would ultimately defer to the FDA. NEURALSTEM: CEO BLOG *supra* note 36.

44. See, e.g., Bellamy, *supra* note 11; Joan Korber-Walker, *HCR 2005—“Right To Try” Won’t Benefit Patients*, ARIZ. BIOINDUSTRY ASSOC. (Mar. 24, 2014), <http://www.azbio.org/hcr2005> [<http://perma.cc/RLQ2-WC5F>] (arguing against the passage of the Arizona law in part because of its ineffectiveness in the face of FDA regulations, and recommending advocating for changes to Congress and the FDA *instead* of passing state laws).



If a law is passed, it is natural to assume that its primary effect consists in the legal rights it creates or removes. When a legislature passes a law outlawing a particular drug, its undoubted purpose is to deter and punish those who use the drug. Under ordinary circumstances, it would be strange for a politician supporting a bill to say, “I believe this law will not meaningfully create or alter substantive law, but I think we should pass it anyway.”

However, within our federal system, with its multiple sources of law and separate legislative bodies, a state law can also serve to persuade federal decision makers. This is one of the assumptions behind the famous “laboratories of democracy” theory of federalism, which celebrates the way in which state-level legal experiments can become models for nationwide reforms.<sup>45</sup> Indeed, it is common for a policy movement to begin by seeking changes to state law on the road to its ultimate aim of changing federal law.<sup>46</sup> Such a strategy can have two benefits from a movement’s perspective: first, it can bring the desired policy to a segment of the population before the whole country is prepared to accept it (though not in the case of Right to Try). Second, and more relevant here, it draws greater national attention to the issue<sup>47</sup> and conveys the point that respectable public figures believe in the policy. In this sense, state laws can serve to legitimate a policy and help to develop its constituency, even if the laws themselves do not alter the current legal regime in a meaningful way.

State Right to Try laws primarily leverage this second benefit. The movement seeks to influence federal policymakers, from congressmen<sup>48</sup> to FDA regulators to federal judges. It increases the salience of the issue for the American

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45. See *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) (“It is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.”); see also *Cruzan ex rel. Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 292 (1990) (O’Connor, J., concurring); Kristin Madison, *Building a Better Laboratory: The Federal Role in Promoting Health System Experimentation*, 41 PEPP. L. REV. 765, 771 (2014) (describing the Patient Protection and Affordable Care Act as the product of such a “laboratory” in Massachusetts).

46. The gay rights movement can be interpreted to provide an example of this strategy. It began by achieving marriage equality in a small number of states, and has since moved on to great success in various state and federal courts, with the ultimate aim of convincing the U.S. Supreme Court to enshrine marriage equality as a constitutional principle. See George Chauncey, *The Long Road to Marriage Equality*, N.Y. TIMES, June 26, 2013, <http://www.nytimes.com/2013/06/27/opinion/the-long-road-to-marriage-equality.html> [http://perma.cc/87TG-LBKG].

47. For example, according to Google Trends, news headlines containing the “Right to Try” spiked dramatically in May 2014, when Colorado passed the first law of its kind. *Interest in Search Term “Right to Try” Over Time*, GOOGLE TRENDS, <http://www.google.com/trends/explore#q=%22right%20to%20try%22> [http://perma.cc/YU66-BHKV].

48. There is a Right to Try bill in Committee in the House even now, though there is no indication as yet that it will get a vote on the floor. See *Compassionate Freedom of Choice Act of 2014*, H.R. 4475, 113th Cong. (2014).

public<sup>49</sup> and may help to achieve what Jack Balkin calls putting a constitutional argument “on the wall”—that is, convincing elites that the position is legitimate.<sup>50</sup> Frank Burroughs himself, founder of the Abigail Alliance, has gestured at some of these goals: “[A lawsuit challenging state Right to Try laws] wouldn’t be all bad news because it would further elevate this issue in the public arena and put pressure on Congress and the FDA to make this change.”<sup>51</sup>

Therefore, while the current Right to Try laws do not create new rights, they are not necessarily futile. The movement behind them is leveraging a facet of American federalism: that state laws can be used to persuade federal actors. In the future, the Right to Try may become an entrenched legal right, and these laws, currently toothless, may very well have made the difference.

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49. See *supra* note 45 and accompanying text.

50. See Jack M. Balkin, *From Off the Wall to On the Wall: How the Mandate Challenge Went Mainstream*, ATLANTIC, June 4, 2012, <http://www.theatlantic.com/national/archive/2012/06/from-off-the-wall-to-on-the-wall-how-the-mandate-challenge-went-mainstream/258040> [<http://perma.cc/T449-4S97>].

51. See Michael Ollove, *Right-To-Try for the Terminally Ill*, USA TODAY, June 19, 2014, <http://www.usatoday.com/story/news/nation/2014/06/19/stateline-fda-terminal-illness-drugs/10836705> [<http://perma.cc/8ED2-4LCF>].