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WOULD WE BE RIGHT TO TRY "RIGHT TO TRY"?

José Miola & Bernadette J. Richards[†]

ABSTRACT

In both the United Kingdom and United States of America legislation has been proposed or enacted which claims to provide patients with a 'right' of access to experimental drugs and treatments where there is no other hope. In this paper we will explore this narrative and consider the steps taken in the United States to shift to a more rights driven legal framework. The paper will critically assess the United States model and the similarly framed 'Saatchi' model in the United Kingdom; demonstrating that, despite the rights-based narrative, these laws do not represent a significant change in access to treatment for patients. Rather, the reality is that this 'right to try' paradigm represents a patient advocate narrative that is deeply flawed. It fails to implement any meaningful change, exposes vulnerable patients to risk of harm and, potentially, delays safe development of potentially life-saving treatment regimes.

CONTENTS

INTRODUCTION

The traditional doctor-patient relationship grew out of the paternalistic Hippocratic tradition.[1] It was an unequal interaction with

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1. *See, e.g.,* Edmund D. Pellegrino, *Toward an Expanded Medical Ethics: The Hippocratic Ethic Revisited, in* CROSS-CULTURAL PERSPECTIVES ON MEDICAL ETHICS 25 (Robert M. Veatch, ed., 1989); JOSÉ MIOLA, MEDICAL ETHICS AND MEDICAL LAW: A SYMBIOTIC RELATIONSHIP 23 (2007).

the all-knowing doctor sharing their knowledge and expertise with less-educated or uninformed patients.[2] A patients' best interests were determined wholly by the doctor who was responsible for all clinical decisions, and healthcare was something done to the vulnerable patient who was a passive participant in the treatment process.[3] Gradually over time this traditional paradigm has shifted with the patient becoming an active participant in the clinical relationship which is now most commonly defined as a partnership.[4] In some circumstances the pendulum has continued to swing through the partnership model to a rights-based narrative, with some asserting that the patient voice should be stronger, that the existing regulatory control over access to emerging treatment is inappropriate and that patients have a right to access treatments that would otherwise be withheld from them.[5] The patients have now shifted from being passive recipients of treatment to being characterized as "consumer exercising choice."[6] This exemplifies our new, patient-facing medical law.

This rights-based dialogue has driven the development, and in the United States successful introduction, of so-called 'right to try' laws.[7] The narrative around these laws is that patients have a right to access even unproven drugs and forms of treatment, and that the existing

2. Pellegrino, *supra* note 1, at 27. *See* Richard L. Street et al., *Beliefs About Control in the Physician-patient Relationship,* 18(8) J. GEN. INTERN MED. 609 (2003).

3. *See* MIOLA, *supra* note 1, at ch. 2.

4. Such a model is evident in the landmark ruling of the Supreme Court of the United Kingdom in Montgomery v. Lanarkshire Health Board [2015] UKSC 11, [81] (appeal taken from Scot.). *See also* Community Research, *Doctors' Attitude to Consent and Shared Decision-Making: Full Research Report for the GMC* 11-13 (2017), https://www.gmc-uk.org/media/documents/Doctors_attitudes_to_consent_and_shared_decision_making_ FINAL_research_report.pdf_72137875.pdf.

5. H. Fernandez Lynch et al., *Promoting Patient Interests in Implementing the Federal Right to Try Act*, 320(9) JAMA 869 (2018).

6. Indeed, this language of patients' rights can be said to be the key message of the decision in Montgomery. *Montgomery* UKSC 11, at [75]. *See* R. HEYWOOD & J. MIOLA., *The Changing Face of Pre-Operative Medical Disclosure: Placing the Patient at the Heart of the Matter,* 133 LQR 296 (2017). *But see* Jonathan Montgomery, *Law and the demoralization of medicine*, 26 (2) LEGAL STUDIES 185, 187-88 (2006), *and* Jonathan Montgomery & Elsa Montgomery, Montgomery *on informed consent: an inexpert decision?*, 42 J. MED. ETHICS 89, 90-91 (2016).

7. For the federal version, *see* Trickett Wendler, Frank Mongiello, Jordan McLinn and Matthew Bellina Right to Try Act 2017, S. 204, 115th Cong. (2017). For a full, updated list of states' laws *see Right To Try In Your State*, GOLDWATER INST., http://righttotry.org/in-your-state/ [https://perma.cc/2FPA-2D94].

framework represents an unacceptable denial of hope.[8] The focus of these laws is therefore on restoring 'patient rights' and the assertion that the State and regulatory bodies are withholding access, and therefore hope, from desperate patients. This represents a significant shift from a protectionist model whereby new medical treatments must work through carefully constructed stages of testing to ensure that they are safe to a demand and supply model (the patient can assert a right to take risks that, in the previous, principled approach, the State asserted were unacceptable.[9] In this paper we will explore this narrative and consider the steps taken in the United States to shift to a more rights-driven legal framework. The paper will critically assess the United States model and the similarly-framed 'Saatchi' model in the United Kingdom; demonstrating that, despite the rights-based narrative, these laws do not represent a significant change in access to treatment for patients. Rather, the reality is that this 'right to try' paradigm represents a patient-advocate narrative that is deeply flawed. It fails to implement any meaningful change, exposes vulnerable patients to risk of harm and, potentially, delays safe development of potentially life-saving treatment regimes. In short, the 'right to try' movement is inappropriately named and should instead be given the far less catchy, but more accurate label: 'right to ask to try an unproven and potentially dangerous form of treatment.'

I. WHAT ARE 'RIGHT TO TRY' LAWS?

Right to try laws are a legislative trend that has swept through America. Over 40 states have already passed such laws, with others having introduced them into their state legislatures and going through the process of doing so.[10] 8 In addition, a federal right to try law was passed in May 2018, and signed into law by President Trump later that year, which means that patients in states without the legislation can obtain access to its benefits.[11] There is insufficient space to consider the precise history of right to try laws in the US,[12] but it suffices to say

8. *See Federal Right To Try: Questions And Answers*, GOLDWATER INST., https://righttotry.org/rtt-faq/ [https://perma.cc/7T7W-35RB], the website created and maintained by the Goldwater Institute, the thinktank responsible for creating the initial 'off the shelf' legislation.

9. It should, however, be noted that this is a false narrative. *See* José Miola, *Bye Bye Bolitho: The Curious Case of the Medical Innovation Bill*, 15 J. MED. L. INT. 124 (2015); *see also* R. Dresser, *The "Right to Try" Investigational Drugs: Science and Stories in the Access Debate*, 93 TEX. L. REV. 1631 (2015) (regarding the position in the US).

10. GOLDWATER INST., *supra* note 7.

11. *See* Lynch et al., *supra* note 5.

12. For a history of the Right to Try movement in the United States, *see* Erin Mershon, *How the 'right-to-try' movement muscled its way into Washington*, STAT (Mar. 7, 2018), https://www.statnews.com/

that the laws began life as 'off the shelf' legislation created by the right wing, libertarian think-tank The Goldwater Institute (the Institute).[13] The Institute refers to itself as aiming "to defend and strengthen the freedom guaranteed to all Americans . . . [and] a national leader for constitutionally limited government."[14] This focus on limiting the role of government has led some to argue that the real purpose behind the legislation is a desire to weaken the Food and Drug Administration's control over drug licensing, replacing it with a free market system.[15] This is, however, denied by the Institute.[16] In any event, right to try laws are advertised as solving the problem of a lack of access to experimental drugs by patients with terminal illness.[17] They claim to give hope where previous regulatory regimes actively deny it.[18] This is made clear on the right to try website:

> Right to Try is needed because:
> - Dying people don't have access to promising treatments once clinical trials are over, even if they have been successful

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2018/03/07/right-to-try-movement-washington/ [https://perma.cc/N344-WU5T]. Also influential was support from the Abigail Alliance, an organization set up to lobby in support of the cancer sufferer receiving experimental but unlicensed drugs. For a more recent consideration of the background to the law and the different imperatives, *see* FOLKERS ET AL., *Federal Right to Try: Where is it Going?,* 49(2) HASTINGS CTR. REP. 26 (2019).

13. *See Do Dying Patients Have a Right to Try Experimental Drugs? Libertarians Say Yes,* GOLDWATER INST. (Aug. 21, 2014), http://righttotry.org/do-dying-patients-have-a-right-to-try-experimental-drugs-libertarians-say-yes/ [https://perma.cc/4H8X-QNAC].

14. Jennifer Tiedemann, *Patient with Aggressive Brain Cancer Treated under Right to Try*, GOLDWATER INST. (Jan. 9, 2019), https://goldwaterinstitute.org/article/patient-with-aggressive-brain-cancer-receives-treatment-under-right-to-try-law/ [https://perma.cc/FQC2-R4WE].

15. *See* Rita Rubin, *Experts Critical of America's Right to Try Drugs Laws*, 386 LANCET 1325, 1325 (2015); Alison Bateman-House, L. Kimberley, B. Redman, N. Dubler & A. Caplan, *Right to Try Laws: Hope, Hype and Unintended Consequences*, ANNALS OF INTERNAL MEDICINE 796 (2015).

16. *Goldwater Institute Responds to FDA Statement on Right to Try,* GOLDWATER INST. (Nov. 8, 2018), https://goldwaterinstitute.org/article/goldwater-institute-responds-to-fda-statement-on-right-to-try/ [https://perma.cc/YDP8-Q7WW].

17. *5 Reasons for Right to Try*, GOLDWATER INST. (Sept. 28, 2017), https://righttotry.org/5-reasons-for-right-to-try/ [https://perma.cc/L9CK-CCVH].

18. MARK FLATTEN, *Dead on Arrival: Federal "Compassionate Use" Leaves Little Hope for Dying Patients,* GOLDWATER INST. (Feb. 24, 2016), http://righttotry.org/dead-on-arrival/ [https://perma.cc/7VA6-B2BM].

- The FDA compassionate use process doesn't help enough people
- It takes too long for promising treatments to be approved
- You shouldn't have to ask the government for permission to try to save your own life[19]

The above bullet points illustrate both the allusions to a lack of access as the problem that is to be fixed by the legislation, as well as the assertion, consistent with the Institute's ideology, that government involvement is a hindrance rather than a help. It might be expected, given both this and an assumption of nominative determinism in the legislation title, that right to try laws would provide both a *right* to patients to try experimental drugs and access to those drugs. Or, in other words, right to try laws impose a duty on manufacturers and regulators to allow their use. Unfortunately, neither is the case. Rather, right to try laws merely provide a set of circumstances where access to drugs that have passed phase I clinical trials *might* be provided. They are that:

- Patients must be terminally ill and unable to get to a clinical trial
- The patient's physician recommends the drug
- The patient signs informed consent form
- The manufacturer chooses to provide the drug
- The patient pays for the drug if the manufacturer chooses to charge for it.

And if a patient chooses to access these drugs then:

- The patient may not sue the doctor or drug manufacturer in negligence in relation to the decision to provide the drug.[20]

The assertion of a right is most commonly unfettered, therefore the concept of a 'right to try' appears at first blush to empower a patient, in all circumstances, to access identified drugs or treatment. However, it is evident from the above that, rather than enshrining an unfettered *right* to try and therefore access promising treatment, there is much that is conditional. The patient may only use the legislation if she is terminally ill[21]rather than, for example, if she feels subjectively that her condition is unbearable. The physician acts as a gatekeeper – contrary

19. Goldwater Inst., *supra* note 17.

20. *See* Dresser, *supra* note 9; Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, Pub. L. No. 115-176, S. 204, 115th Cong. (2018).

21. *See* 21 C.F.R. 312.81.

to the tenets of a truly free market as supposedly encouraged by the Institute. Meanwhile, the manufacturer may choose whether to provide the drug at all, and also whether to charge for it. Therefore, a patient who is any one of not terminally ill, lacking the support of her doctor or poor will not have a 'right' to try anything at all. Even if she is none of those things, the ultimate arbiter is the drug manufacturer. There is no imperative imposed on manufacturers to provide access to the drug and if they choose to provide access, then they may charge as much for that access as they wish.[22] Also worthy of note is the fact that the legislation, hailed as a champion of individual patient rights, serves to remove a significant patient right of redress. If the drug is provided with the requested treatment, the patient automatically relinquishes the right to sue in negligence if they believe that it should not have been prescribed to them. Therefore, not only does the law fail to enshrine a right to access treatment, it actively diminishes other, well-established rights.

In England and Wales, there was an attempt (from 2014-2016) to introduce what was badged as a British version of a right to try.[23] Lord Saatchi's ultimately unsuccessful Medical Innovation Bill (MIB) had a prominent social media profile, and its Twitter feed on several occasions sought to ally itself with its US counterpart by including the hashtag 'righttotry' at the end of tweets.[24] However, Lord Saatchi's Bill was not a mere copy of the Goldwater legislation, and had personal tragedy as its genesis, [25] Lord Saatchi's wife died of cancer, and he determined that the key barrier to medical innovation (and thus a cure for cancer) was a fear of litigation.[26] The removal of this fear was thus the only aim of the MIB.[27] Nevertheless the MIB's authors, like proponents of right to try, sold their proposed legislation on the promise of increased access

22. *See* FDA FACT SHEET, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/media/133864/download [https://perma.cc/HMW2-XATR].

23. *See Medical Innovation Bill [HL] 2014-2015,* UK PARLIAMENT, https://services.parliament.uk/bills/2014-15/medicalinnovation.html [https://perma.cc/3H7G-BXRW] (charting the Bill's progress and amendments).

24. Miola, *supra* note 9, at 125; José Miola, *Postscript to the Medical Innovation Bill: Clearing Up Loose Ends*, 11(1) L. INNOVATION & TECH. 17, 26 (2019).

25. Bernadette Richards, *Medical innovation laws: an unnecessary innovation*, 40 AUS. HEALTH REV. 282, 283 (2016).

26. Maurice Saatchi, *Lord Saatchi Bill: We must liberate doctors to innovate*, TELEGRAPH (Jan. 26, 2014, 8:27 PM), https://www.telegraph.co.uk/news/health/saatchi-bill/10598161/Lord-Saatchi-Bill-We-must-liberate-doctors-to-innovate.html [https://perma.cc/74ZH-P8MP].

27. Richards, *supra* note 25, at 285.

to experimental drugs and treatments.[28] Take, for example, these quotes from the MIB's 'official media partner',[29] the *Daily Telegraph* (one of England's best selling broadsheet newspapers): "[the MIB is a] Bill which *would empower* patients and doctors to try out new innovative treatments";[30] "[a] *new law to allow patients to try* untested medicines will protect them and nurture medical innovation";[31] "Doctors *could be allowed* to experiment on dying patients with novel treatments under a new Bill . . . which looks set to become law".[32] Some other media outlets went even further, suggesting explicitly that access would be improved. City AM, for example, described the MIB as "[a] Bill proposed by Lord Saatchi to give dying cancer patients access to unlicensed drugs".[33]

It may therefore surprise readers to know that the MIB would have done nothing of the sort. It would not have been limited to terminally ill patients – indeed, it would have applied to any and all conditions excluding only those undertaken for a purely cosmetic purpose,[34] and at no point did it contain any attempt to increase access to drugs and treatments.[35] Rather, the MIB only ever contained two clauses: one relating to a database of innovative treatments and another, which was the focus of the Bill, was the exemption from the usual application of the law of negligence that legally indemnified a doctor providing an

28. Miola, *supra* note 9, at 140.

29. This was revealed in a briefing note to the House of Lords. *See* MAURICE SAATCHI, *Medical Innovation Bill: Session 2014-15 Briefing Note* 1, 10 (June 10, 2014), http://medicalinnovationbill.co.uk/wp-content/uploads/2014/05/Medical-Innovation-Bill-Briefing-Note-10th-June-2014.pdf [https://perma.cc/SH4N-6HXD]. *See* Miola, *supra* note 9, at 125.

30. *Lord Saatchi Launches the Consultation on his Medical Innovation Bill – Live'*, DAILY TELEGRAPH (Feb. 24, 2014), https://www.telegraph.co.uk/news/health/saatchi-bill/10657747/Lord-Saatchi-launches-the-consultation-on-his-medical-innovation-bill-live.html [https://perma.cc/CVH6-VGEJ] (emphasis added).

31. C. HOPE, *Leading Doctors Join With Patients to Back Lord Saatchi's Medical Innovation Bill,* DAILY TELEGRAPH (June 26, 2014) (emphasis added) [https://perma.cc/L5DM-LLHK].

32. S. KNAPTON, *Huge Response to Lord Saatchi's Medical Innovation Bill,* DAILY TELEGRAPH (June 1, 2014) (emphasis added) [https://perma.cc/5P5X-SVC3].

33. Guy Bentley, *Government Support for Saatchi Bill Could Mean Dying Patients are Given Untested Drugs by March*, CITYAM (Oct. 20, 2014), http://www.cityam.com/1413795751/government-support-saatchi-bill-could- see-dying-patients-given-untested-drugs-march [https://perma.cc/LWE6-XP22].

34. Medical Innovation Bill 2015, HL Bill [162] cl. 1(7) (UK).

35. A reading of the wording of the Bill demonstrates that there is simply no clause that provides for this. *See* Medical Innovation Bill 2014, HC Bill [162] (UK).

innovative drug or procedure if she followed the process contained in the Bill.[36] It was therefore framed as a regulatory symbol of hope through access to potentially life saving treatment but the focus was on the protection of doctors from negligence actions. As with the right to try laws, the practical application of the proposed law was in fact a limitation of a well-established and clearly framed protection under the guise of enhancing individual access to unproven treatment.

Right to try laws and the MIB seek to address the same apparent problem[37] but come from very different starting points. For Lord Saatchi, the tragic death of his wife from cancer made him determined to loosen what he saw as the shackles that fear of the law put on doctors.[38] Meanwhile, the Goldwater Institute's starting point was a view that limited government was to be encouraged, and that it is the right of individuals rather than government to determine what treatments they should be able to access.[39] Moreover, the substance of the two pieces of legislation are different, with right to try concentrating on the qualifying conditions for access, and the MIB on the law of negligence. Yet, despite this, they share two things in common: first, both ask the patient to engage in a bargain that swaps (theoretical) access to experimental drugs for the legal protection of appropriate provision of treatment and oversight of the doctor's duty of care to look after the best interests of the patient. Second, both right to try and the MIB seek to appoint apparent informed consent as the primary mechanism for protecting patient safety – something that we will argue is particularly problematic, not least given the discrepancy between how both pieces of legislation were sold and what they *actually* provide. It is to these two issues that we now turn.

II. THE 'BARGAIN'

It is curious that laws built on the rhetoric of 'patient rights' have, as a foundational requirement, the relinquishment of a well-established legal protection. Both right to try laws and the MIB seek to entice the patient into a bargain: in return for access to the experimental

36. *See* Miola, *supra* note 24, at 19 (discussing the inclusion of a database for innovative treatments); Miola, *supra* note 9, at 128 (noting that the Bill was designed to protect doctors' "responsible innovation" from negligence).

37. *See Right to Try,* U.S. FOOD & DRUG ADMIN., https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try#:~:text=The%20Right%20to%20Try%20Act%20permits%2Fallows%20eligible%20patients%20to,life%2D threatening%20disease%20or%20condition [https://perma.cc/WC9E-Y25N].

38. *See* Saatchi, *supra* note 26.

39. *See, e.g.,* GOLDWATER INST., *supra* note 16.

treatment, they must agree to forego the right to seek legal redress in relation to the decision to provide the drug.[40] The rationale behind this bargain is not difficult to explain. For advocates of right to try, the mantra of individual choice and personal responsibility makes such a deal attractive – 'you pays your money, you takes your choice'.[41] Meanwhile, for Lord Saatchi the *entire point* of the MIB was the removal of the fear of litigation from doctors in order to encourage them to innovate. It is therefore inevitable that the ability of the patient to seek civil redress for harm caused by inappropriate or careless treatment would have to be compromised or removed entirely in certain circumstances, as without the removal of the right to sue the fear of litigation would persist. There is no ability to interrogate or challenge the advice given by the treating doctor in the identification of the unproven treatment or support of the patient in seeking that treatment. This leaves open potentially unprofessional conduct, questions of conflict of interest or simply careless treatment.

This bargain is, of course, presented as a part of a package that is, ultimately, of benefit to the patient, consistent with the presentation of both pieces of legislation as enhancing patients' rights and ability to access experimental drugs and treatments. The wall of protection thrown up around the treatment team is underplayed, if not completely ignored. The purported value to patients of this bargain is predicated upon the promises of access to drugs and treatments that would otherwise be unavailable. But these promises are not met by the Bills themselves which, on the most generous interpretation, offer little more than a right to ask for access to a drug or treatment, so long as certain pre-requisites are met. This therefore falls short of an unfettered right of access. Indeed the 'rights' based laws offer no new right, there is no obligation imposed on drug manufacturers to provide the drug, on doctors to make the patient aware of the drugs, or on insurance companies to provide insurance for the use of these drugs. On that basis, we are compelled to ask: are these are actually *good* or *bad* bargains? Or, to put it another way, does the harm of foregoing the benefit of *post hoc* protection balance out against the benefit of the ability to seek access to drugs or treatments that are unproven, could cause further harm and are uninsured. The benefits to the patient are difficult to identify; not only is the access to the drugs only a *potential* access, the benefit of the drugs themselves is, at best, a *potential* benefit, sitting alongside *potential* harm. The patient is granted nothing more

40. It should be noted that this does not extend to the *administration* of the medication. If, for example, the wrong dosage was given or it was injected in the wrong place then the patient would still be able to sue. *See* Bolam v. Friern Hospital Management Committee [1957] 1WLR 583 (U.K.).

41. Taken from Aldous Huxley's foreword to the 1946 edition of *Brave New World*; *see* H. Bloom, BLOOM'S MODERN CRITICAL VIEWS: ALDOUS HUXLEY 100 (Infobase Publishing, 2010).

than a roll of the dice. Framed in this way, it looks to be a very poor bargain indeed.

This assertion becomes clearer when we consider the specific provisions, and practical application of the two regimes under consideration here. Turning first to the right to try movement. It will be remembered that it sells itself as an antidote to an FDA process that is apparently onerous, slow, and does not help enough people.[42] The strong implication is that right to try would solve these problems. However, comparing the FDA regime to right to try does not make it evident how right to try would actually help. First, right to try promises access to drugs that have passed phase I clinical trials,[43] while the FDA compassionate use program allows access to drugs *before* they have passed Phase I – an earlier point in the process.[44] Secondly, the implication that the FDA is denying access to drugs is not supported by the facts. As the FDA themselves report, their compassionate use program has approved *99%* of requests.[45] The 2018 Program Report was the result of an independent assessment with the "key goals" to "better understand the expanded access program's performance and identify ways to improve it."[46]

Whilst this serves as an acknowledgement that the program could be improved, it also shows that what is not lacking is *will* on the part of the FDA, and that it will continue to be receptive to reform of its program rather than its marginalization. Significantly, the focus of the FDA program is to "ensure patients continue to receive timely and medically appropriate access to investigational medical products through the EA program" and to balance the input of the wide variety of stakeholders (including healthcare providers, patients, drug and

42. *See* Lynch et al., *supra* note 5.

43. *See Right to Try,* U.S. FOOD & DRUG ADMIN., https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try#:~:text=The%20Right%20to%20Try%20Act%20permits%2Fallows%20eligible%20patients%20to,life%2D threatening%20disease%20or%20condition [https://perma.cc/G57Z-7QFE].

44. Dresser, *supra* note 9.

45. *Statement from FDA Commissioner Scott Gottlieb M.D. on New Efforts to Strengthen FDA's Expanded Access Program,* U.S. FOOD & DRUG ADMIN. (Nov. 8, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625397.htm [https://perma.cc/QTY2-KAQJ]. *See also Expanded Access Program Report 2018*, U.S. FOOD & DRUG ADMIN. 1, 2 (May 2018), https://www.fda.gov/media/119971/download (covering an independent assessment of the scheme which reported that over a 5-year period approximately 9,000 applications were processed with an approval rate of 99%) [https://perma.cc/3WA3-TAUA].

46. *Expanded Access Program Report 2018*, U.S. FOOD & DRUG ADMIN. 1, 2 (May 2018).

device manufacturers).[47] The FDA is demonstrating a wider focus than that of the crafters of the right to try laws who have created an unequal bargain. An important participant in the right to try bargain is the drug manufacturing industry, and whilst it is not something that the authors of right to try can be blamed for as they will not have known in advance, there is a significant gap in their proposed bargain. The legislated bargain relies on the support of drug manufacturers; indeed, a successful bargain relies on the manufacturers coming to the table, but as yet, they have failed to do so. This was clearly explained by a representative of Merck and Co in the following terms: "While well intentioned, current 'Right to Try' legislation is not in the best interests of patients and is unlikely to help us bring forward innovative, safe and effective medicines to all patients as quickly as possible."[48]

They are not alone, with some citing a fear that allowing their products to be used in right to try requests may hinder attempts to obtain full FDA funding.[49] It is also of note that patient groups have not supported the passage of the law. For example, Folkers et al. reported that over eighty patient groups signed on to various letters to members of Congress asking them to oppose right to try, whilst only seventeen groups signed a letter addressed to the Senate on August 2, 2017, to encourage passage of a federal bill.[50]

The bargain offered by right to try cannot be said to be a good one, and in some respects the law is best described as aspirational. It empowers drug companies to make drugs available but there is no mandate, and, as we have seen, the companies have expressed reservations about the law.[51] The most notable failing of the bargain is that the benefit offered is illusory: the law does not seem to offer any appreciable advantages over the FDA program and, crucially, it removes a significant right of redress from patients, as *the FDA program does not entail the loss of the right to sue* while right to try legislation does. In other words, despite the rights-based rhetoric, using right to try rather than the FDA program would give patients *fewer* rights rather than more, for no appreciable increase in their chances of access.

Lord Saatchi's MIB would have fared equally badly. The driving force behind the Bill – and the only factor identified as a barrier to doctors innovating – was doctors' apparent fear of the law of negligence.

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47. *Id.* at 3.

48. Shannon Firth, *Will "Right to Try" Bill Actually Help Anyone?,* MED. PG. TODAY (Aug. 11, 2017), https://www.medpagetoday.com/publichealthpolicy/fdageneral/67222 [https://perma.cc/2H5Q-GJ35].

49. *Id.*

50. Folkers et al., *Federal Right to Try: Where is it Going?,* 49(2) HASTINGS CTR. REP. 26, 30 (2019).

51. Firth, *supra* note 48.

The MIB's bargain therefore swapped the patient's right to sue in negligence (hence removing the fear from doctors) for the promised access to unidentified drugs and treatments, or at the very least a change in culture that would encourage such access to be granted. Yet the very premise that doctors were prevented from innovating due to a fear of litigation was an *assumption* that was not supported by the evidence.[52] When the Department of Health issued its consultation on the MIB, it asked whether it was the experience of respondees that innovation was being stifled by a fear of litigation.[53] The responses were chastening for supporters of Lord Saatchi's Bill, as only one small organization responded that there was such a fear.[54] Against this, all of the key stakeholders responded that no such fear existed. As one of us has previously noted:

> In other words, neither the doctors' trade union (the BMA), or either of the medical defence bodies (MDU and MPS), who doctors might be expected to consult *first* if worried about litigation, found any evidence of a fear of litigation deterring innovative treatment nor has the NHS body that would deal with such claims if they were to arise (the NHSLA). As demonstrated above, neither did the research bodies such as Cancer Research UK and the Association of Medical Research Charities.[55]

Also coming out in opposition were the GMC,[56] the medical regulator in the UK,[57] and the Association of Personal Injury Lawyers.[58] The MIB therefore managed to achieve something rare: it united doctors (medical defense bodies), lawyers (both claimant - and defense - focused), and research charities; but not in the way that its authors would have hoped. Patients were being asked to waive their right to sue in negligence in return for the promised removal of a fear that none of the key stakeholders agreed was there in the first place. And the

52. *See* Miola, *supra* note 9, at 131–32.

53. DEPARTMENT OF HEALTH, REPORT ON THE CONSULTATION ON THE MEDICAL INNOVATION BILL (2014).

54. The organization was BASO-ACS (British Association of Surgical Oncologists – Association for Cancer Surgery). *See* DEPARTMENT OF HEALTH, REPORT ON THE CONSULTATION ON THE MEDICAL INNOVATION BILL 11 (2014).

55. Miola, *supra* note 9, at 132.

56. *Id.* at 136 (noting that the GMC referred to the Bill as "unnecessary and undesirable").

57. *See generally* Medical Act 1983, c. 54 (UK).

58. Medical Innovation Bill Threatens to "Erode Patient Safety," APIL (Apr. 25, 2014), https://www.apil.org.uk/press-release/Medical-Innovation-Bill-threatens-to-erode-patient-safety [https://perma.cc/6PUJ-SU9E].

identified benefit? *Potential* access to *potential* treatment that was unproven and unsupported. A poor bargain indeed.

Let us be very clear about right to try laws and the MIB: they do not succeed, even on their own terms, if their purpose is to provide enhanced rights for patients. Neither provides access to any drugs or devices that doctors could not otherwise use (the MIB makes no mention of access, and right to try laws promise access at a point *later* than the FDA expanded use program) Neither allows a medical practitioner to do anything that she could not otherwise do. Finally, and perhaps crucially, neither provides any funding – something that *was* identified as a barrier to providing innovative treatments – that was not there before.[59] Moreover, they are specifically sold on a false promise of increased access to drugs and treatments that they cannot deliver.

For these reasons, the bargains that they invite patients to engage in are to all intents and purposes bogus. They are based on illusory benefits that come at an unacceptable cost. In the case of right to try, patients are asked to forego their right to sue in return for a program that is less advantageous than the existing one. The access to drugs is later than the FDA program would allow, has a less protective system of oversight and would struggle to meet the 99% approval rate of the existing program.[60] Equally, the MIB asks patients to swap their right to sue in return for the removal of a fear of litigation that there is little indication exists (and, where it does, could be mitigated by better education for doctors rather than a removal of the rights of patients). Patients, who are told that these laws would *add to* their rights, would actually see them *eroded* for no good reason.

But there is one way in which this approach does make sense. If we recategorize patients as "consumers exercising choices,"[61] and tell them that "adults who are capable of understanding that medical treatment is uncertain of success and may involve risks, *accepting responsibility for the taking of risks affecting their own lives, and living with the consequences of their choices*,"[62] we can ask them to trade the control for responsibility. The natural *quid pro quo* to making one's own decisions is that the decision-maker has both ownership of the decision and responsibility for its consequences. Readers with a background in English medical law will recognize the above quotes as coming from the landmark UK Supreme Court case of *Montgomery.* v *Lanarkshire*

59. *See* Miola, *supra* note 9, at 128.

60. *See Expanded Access (Compassionate Use) Submission Data,* U.S. FOOD & DRUG ADMIN., https://www.fda.gov/news-events/expanded-access/expanded-access-compassionate-use-submission-data [https://perma.cc/L8XN-65WY].

61. *Montgomery* UKSC 11, at [75] (quoting Lord Kerr and Lord Reed).

62. *Id.* at [81] (emphasis added).

Health Board.[63] This was a case about informed consent, and it is no surprise that another aspect of what right to try and the MIB seek to do is to replace negligence with informed consent as the mechanism for patient protection. The latter is far more in keeping with a view of patients as making and owning their own decisions in a market – certainly consistent with the Goldwater Institute's view of the world; and equally so with Lord Saatchi's vision of patients making their own choices and allowing innovating doctors the freedom to thrive without fear of legal censure.

All of this, of course, begs the question of whether informed consent is up to the task that it is has been set by these laws. We consider this later in this paper, but before that we focus on some other problems inherent in their approach.

III. SO WHAT'S THE PROBLEM

The introduction of new drugs and devices into standard care occurs within a carefully constructed, protective framework.[64] This is usually through clinical trials, where there is a framework that balances a breadth of interests and has as its foundational principle protection of the vulnerable patient and support for responsible clinical innovation.[65] This requires a high level of regulation but the regulation is not, as some would assert, driven by market forces.[66] Rather it has as its primary purpose protection of both the public health system and individual patient health care and both of these, of necessity, involves control over access to drugs and treatment until they are deemed safe.[67] This crucial characteristic of the regulatory scheme was highlighted in the US in the *Abigail Alliance* decision, when the Court drew attention to the fact that the rights based arguments overlook the significant

63. *Id.*

64. This is overseen by the FDA in the US and the Medicines and Healthcare Products Regulatory Industry (MHRA) in the UK and the Therapeutic Goods Administration (TGA) in Australia. *See* SHWETA HANDOO ET AL., *A comprehensive study on regulatory requirements for development and filing of generic drugs globally*, INT. J. PHARM. INVESTIG. 2(3):99-105 (2012).

65. In the UK, there is a new regularly framework starting in 2021, replacing the Medicines for Human Use (Clinical Trials) Regulations 2004. Bukky Balogun, Elizabeth Rough & Sarah Barber, *Research Briefing: Medicines and Medical Devices Bill 2019-21*, HOUSE OF COMMONS LIBRARY (Jan. 27, 2021), https://commonslibrary.parliament.uk/research-briefings/cbp-8699/ [https://perma.cc/WCW9-X6MN].

66. *See, e.g.*, Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 495 F.3d 695 (D.C. Cir. 2007).

67. *See generally* HAZEL BIGGS, HEALTHCARE RESEARCH ETHICS AND LAW 5-15 (Abingdon, Cavendish, 2010).

'history of regulating the *safety* of drugs' and suggested that the focus on accessibility and effectiveness of particular forms of treatment 'ignores one simple fact: it is unlawful for the Alliance to procure experimental drugs not only because they have not been proven effective, but because they have not been proven safe'.[68]

As a background note, the Abigail Alliance, like the MIB, grew out of personal tragedy, Abigail Burroughs suffered from neck cancer and was ineligible to enter a clinical trial, the Alliance was formed and her case brought to court. The Alliance challenged the established clinical trial framework and argued for more expanded access on the basis that the existing process was "inadequate to meet the needs of its terminally ill patients."[69] The Alliance also argued that they had a constitutional right of autonomy and self-defense where the Alliance asserted *inter alia* that the control exercised by the FDA and other regulators was driven by market imperatives and was not about protection of patients. The court ultimately rejected this argument. The introduction of the right to try laws and the MIB echoes the arguments raised by the Abigail Alliance (and ultimately rejected by the court), and represents a significant shift in the nature of the dialogue with the focus on an assertion of individual rights as opposed to collective interests. It cannot be denied that the motivation behind this regulatory initiative is positive, since it is about supporting individuals suffering from terrible diseases who feel disempowered by their poor health. But asserting a right to try unproven drugs and overriding the protective framework without careful review of either efficacy or safety, (as is provided by the expanded access program), is exposing those patients to unnecessary risk of further harm.[70] The rights-based dialogue has gained traction because of a natural sympathy for those who are unwell, and a perception that everything can be cured.[71] This is a poor foundation for major legal review as it represents a misconception, as a right to try experimental drugs or treatments will not automatically lead to good health. Unfortunately, the belief in the efficacy of these drugs is, at best, overly optimistic and at worst, dangerously naïve.[72]

The narrative behind the introduction of these laws appeals to public sympathy and employs emotive language. When Lord Saatchi introduced the MIB he did not engage with clinical benefits or broader public health interests. Rather, he relied on dark tales of cancer sufferers

68. *Abigail Alliance*, 495 F.3d at 703.

69. *Id.* at 699.

70. This was the crux of the opposition to Lord Saatchi's Medical Innovation Bill in the UK. In a letter of opposition, the Academy of Medical Royal Colleges warned that people could "risk untested treatments." Miola, *supra* note 24, at 24.

71. Dresser, *supra* note 9.

72. *Id.*

living through scenes "that would not be permitted in a Hollywood horror movie"[73] and the description of those "condemned [to death] by cancer" as suffering "a worse fate than the worst mass murderer[s], [w]hile they await execution, they are tortured."[74] And the Right to Try laws are built on stories of tragedy and 'avoidable' death. The right to try website has headline photos of children and teenagers who have had to leave the country to gain access to potentially life saving treatment or are fighting to save their own lives with the assistance of right to try laws.[75] Under the heading 'Why we Needed Right to Try' is the publication 'Dead on Arrival' which, amongst other things, tells the incredibly sad tale of Nick Auden, a 41-year-old who died in 2013 after trying unsuccessfully to enroll in clinical trials and access drugs under the expanded access scheme.[76] His story is undeniably a tragic one, but the center piece of the narrative is the refusal by Merck and Bristol-Myers Squibb to support his expanded access application, the implication being that right to try laws would have enabled access and potentially saved his life.[77] However, this is misleading because, as we have seen in the preceding discussion, the law does not impose a duty on companies to provide access to their drugs, and Merck representatives have not been supportive of the laws and argue that they fail to protect the best interests of the patients.[78] Given this, it is wrong to assert that right to try would have helped that patient.

The starting point of the introduction of right to try laws can therefore be seen as well-intentioned but misguided. There are two other potential problems with these laws which are worth considering. The first is that they fail in their primary goal, which is to protect the patient, and the second is the potential negative effect on the ongoing development of promising drugs -through the slowing down of clinical trials and negative market impacts on companies developing a drug. Each of these additional concerns will be addressed in turn.

IV. FAILS IN PRIMARY GOAL: PROTECTION OF THE PATIENT (THE (IN)ADEQUACY OF INFORMED CONSENT)

As mentioned above, the right to try narrative rests firmly on patient rights and an apparent protection of their interests, but it does

73. 742 Parl Deb HL (5th ser.) (2013) col. 757 (UK).

74. 754 Parl Deb HL (5th ser.) (2014) col. 1450 (UK).

75. *See righttotry*, GOLDWATER INST., http://righttotry.org/ [https://perma.cc/XGF6-GWEY].

76. *Dead On Arrival: Federal "Compassionate Use" Leaves Little Hope for Dying Patients*, GOLDWATER INST. (Feb. 24, 2016), http://righttotry.org/dead-on-arrival/ [https://perma.cc/VL44-A6CG].

77. *Id.*

78. Firth, *supra* note 48.

this through a removal of the foundational right to bring an action in negligence.[79] The authors of the law might argue that this does not reduce the overall protection of patients as it replaces this right, which otherwise undermines the doctor-patient relationship, with other protections.[80] A common feature of right to try laws and the MIB is this replacement of negligence (reviewing the *doctor's* decision) with informed consent (executing the *patient's* wishes) as the primary mechanism for protecting patient safety. However, changing the focus in this way fails to appropriately protect the patient as it overlooks the unequal nature of the doctor-patient relationship, the vulnerability of the patient, and the potential for interests other than those of the patient to insert themselves into the decision taken by the patient and doctor to proceed with the provision of innovative treatment. In short, whilst informed consent is an important patient right, it cannot adequately protect the patient in these highly complex situations. Before we consider this in more depth, it is worth restating that current English law on informed consent, as determined by the Supreme Court's decision in *Montgomery*, is very much consistent with the 'patient choice' ethos inherent in right to try and the MIB.[81] As we note above, the Supreme Court spoke of patients as "consumers exercising choices."[82] It is also worth quoting more fully the other declaration of intent that we noted above as it gives a flavor of the philosophy of the law as seen by the judges:

> [S]ocial and legal developments . . . point away from a model of the relationship between the doctor and the patient based upon medical paternalism. They also point away from a model based upon a view of the patient as being entirely dependent on information provided by the doctor. What they point towards is an approach to the law which, instead of treating patients as placing themselves in the hands of their doctors *(and then being prone to sue their doctors in the event of a disappointing outcome)*, treats them so far as possible as adults who are capable of understanding that medical treatment is uncertain of success and may involve risks, *accepting responsibility for the taking of*

79. *See* Lynch et al., *supra* note 5.

80. Indeed, Lord Saatchi has argued that the MIB would both protect patients and encourage innovation. *Doctors need more freedom to innovate, say Peers*, *Democracy Live*, BBC NEWS (June 27, 2014), http://www.bbc.co.uk/democracylive/house-of-commons-28055648 [https://perma.cc/WK78-62GD].

81. *Montgomery* UKSC 11, at [75].

82. *Id.*

> *risks affecting their own lives, and living with the consequences of their choices.*[83]

Of course, this only functions properly if the law is able to protect patients to make such choices meaningful and based on the information that they need. In this section, we argue that informed consent is not able to achieve this itself, and that it leaves patients exposed to 'bad actors.'[84] Indeed, when we say that we want to encourage innovation, what we really mean is that we want to encourage *responsible* innovation while simultaneously discouraging *irresponsible* innovation. It is worth noting here that the language we are using is the same as the original MIB with s1(1) providing that 'The purpose of this Act is to encourage responsible innovation,' the key point of differentiation being that we do not agree with the underlying premise of how this is to be achieved. We agree that the critical distinction between responsible and irresponsible innovation should be supported by the law and requires a level of regulatory oversight, but informed consent is not a sufficiently sharp tool for making this distinction. This is for several reasons.

To begin with, it is almost trite to say that informed consent depends on information.[85] The doctor must provide the patient with *sufficient relevant* information for her to make an autonomous decision.[86] But this means that the patient's decision will depend at least in part on what information is given, and how it is presented. A doctor who is an enthusiastic adopter or supporter of a specific innovation can easily become, intentionally or unintentionally, an advocate for it.[87] When asked by the patient whether *they* would take the offered treatment the doctor will often provide answers in the affirmative, and this, along with their general support for the treatment, will go some way to persuading or reassuring the patient that the treatment is worthwhile.[88] While this can, in theory, be addressed by the law, there is little in the cases that relates to tone, and *Montgomery*

83. *Id.* at [81] (emphasis added).

84. A point made by Lord Brennan in the House of Lords. *See* 27 JUNE 2014, Parl Deb HL (2014) col. 1479 (UK) [https://perma.cc/4ZB7-3FJK]. *See also* D. HILLS, *The Saatchi Medical Innovation Bill Will Put Patients at the mercy of Quacks,* THE GUARDIAN (May 22, 2014) [https://perma.cc/CX23-CBNS].

85. *See, e.g.,* A. Maclean, *Autonomy, Consent and Persuasion,* 13(4) EUROPEAN J. OF HEALTH L. 321 (2006).

86. *Montgomery* UKSC 11, at [109].

87. *See* Maclean, *supra* note 85, at 322. For an example of the difficulties involved in the mechanics of communication *see* Al Hamwi v. Johnson & Another, EWHC 206 (2005) (critiqued in J. MIOLA, *Autonomy Rules OK?,* 14(1) MED. L. REV. 108 (2006)).

88. *See* Maclean, *supra* note 85, at 330.

itself is noticeably vague on the issue of the mechanics of communication.[89] Yet this might well be absolutely crucial, as there are two other factors in relation to these patients that makes them more than usually vulnerable to such persuasion.

The first is that these are patients whose very position will mean that they may well need little persuading.[90] To qualify for right to try, patients must be terminally ill, while the MIB was (erroneously) advertised as relating most specifically for patients with rare cancers.[91] Put bluntly, the idea is that these are patients for whom there is no other hope: the standard treatment will be or have been ineffective, and the experimental treatment is therefore the only hope that they have left.[92] They are likely to be extremely receptive to *any* suggestion that offers the chance of a cure, alleviation of symptoms or at least a slowing down of the progress of their disease.[93] They will not hear the absence of proof, rather they will focus solely on the unsubstantiated promise of hope.

This is exacerbated by the second factor: the way in which the debate surrounding right to try laws are framed so that the discourse emphasizes good outcomes while minimizing the risk of adverse outcomes.[94] Rebecca Dresser has examined this in the context of right to try in the US, and found this to be the case.[95] As she notes, sometimes data surrounding success rates can become drowned out by anecdotes and distressing stories:

> In defense of access oversight, scientists, FDA officials, and policy experts cite data on investigational-drug risks and low success rates, as well as the need for a rigorous drug-evaluation system. But in the access debate, data and abstract policy considerations go only so far. Access advocates use a different strategy, one that highlights individual patients' stories. To support their cause, access advocates offer heartrending accounts of terminally ill patients seeking investigational drugs and deceased patients who

89. Heywood & Miola, *supra* note 6.

90. Dresser, *supra* note 9.

91. Miola, *supra* note 24, at 24.

92. As noted above, the narrative constructed by both Right to Try and the MIB is based on such cases.

93. *See* D. Christian Addicott, *Regulating Research on the Terminally Ill: A Proposal for Heightened Safeguards*, 15(2) J. CONTEMP. HEALTH L. & POL'Y 479, 503 (1999).

94. It should be noted that the latter are statistically more likely, particularly at the phase I trial stage of development. *See* Dresser, *supra* note 9, at 1631.

95. *Id.* at 1632.

> were denied such drugs. These stories strongly influence legislative and public opinion on the access question.[96]

Dresser goes on to demonstrate how advocates of right to try laws used such stories to emphasize the 'need' for the legislation.[97] In the UK, supporters of the MIB did the same.[98] However, Dresser also demonstrates that both doctors and non-doctors can be incredibly optimistic about how likely experimental drugs are to work, and that the voices of those who have had adverse reactions to experimental drugs are "drowned out."[99] In other words, the discourse surrounding the provision of experimental drugs *distorts* rather than *clarifies* the true situation. Patients are encouraged by advocates of such laws to overestimate the chances of success, and the voices of those whose quality of life has been made worse, or who have died horrendous deaths or had their lives shortened rather than lengthened are marginalized or silenced in our clamor to believe in the positive.[100] Patients are encouraged to believe that a drug in a phase I clinical trial is tomorrow's treatment today, rather than the reality, which is that it is far more likely not to be found safe and/or effective than it is to ever be licensed.[101] This leads directly to the next identified concern which is the negative impact that premature access to unproven treatments can have on well-established development regimes.

V. UNDERMINING MEDICAL ADVANCEMENT

The current process of bringing drugs into the clinical setting is a carefully constructed clinical trial regime and involves staged and closely monitored testing of the unproven drug.[102] It is not a speedy

96. *Id.*

97. *Id.* at 1632–33.

98. *See, e.g.*, Laura Milne, *Mum pleads for law to be changed to save her son*, EXPRESS (June 24, 2014), https://www.express.co.uk/life-style/health/484374/Leon-Arnold-DMD-Duchenne-muscular-dystrophy [https://perma.cc/NL2W-GCMU].

99. DRESSER, *supra* note 9, at 1651.

100. *Id.* at 1654–55.

101. *Id.* at 1634–35 (she cites figures that put the figure at only 1 in 6 drugs).

102. For an example from Australia, see *Australian clinical trial handbook*, AUSTRALIAN GOV'T DEP'T OF HEALTH: THERAPEUTIC GOODS ADMIN. 42 (Nov. 2020), https://www.tga.gov.au/sites/default/files/australian-clinical-trial-handbook.pdf [https://perma.cc/4PD5-T8EQ]. For an overview of the system in the USA, as coordinated by the FDA, *see Step 3: Clinical Research,* U.S. FOOD & DRUG ADMIN., https://www.fda.gov/patients/drug-development-process/step-3-clinical-research [https://perma.cc/P7C2-S76U]. At the time of writing the UK is still subject to the EU's Clinical Trials Regulations, governed by the Medicines and Healthcare Products Regulatory Agency. *See Clinical trials*

process but is designed to minimize risk with a focus on balancing the interests of participants in the trial, those who are currently suffering from the targeted illness, those who will suffer from it in the future and broad public health considerations.[103] It is a complex equation that simply cannot please everyone or meet all identified needs but it is best characterized as an appropriately protective regime.[104] Clinical trials often have restricted enrolment requirements and do not guarantee access to trial drugs with the design often involving a placebo arm.[105] Therefore, if an apparently promising form of treatment is made available outside of the clinical trial framework it will be a preferable path for those who focus on the hope provided by access to the new regime (as opposed to the exposure to risk) and they will opt for this path as opposed to the clinical trial one.

An example of how this can harm both patients and the clinical trial process overall can be found in the cautionary tale of access to aHSCT-HDIT (autologous hematopoietic stem cell transplant) treatment for breast cancer in the 1980s and 90s in the United States. The facts here are fairly straightforward (and are drawn from the detailed account provided by Rettig et al, 2007.)[106] The treatment emerged in the late 1980s and was 'catapulted' into widespread use before careful evaluation. Insurers characterized the treatment as experimental and declined to provide coverage, in response to this a number of enterprising patients and physicians then took the insurers

in human medicines, EUROPEAN MEDICINES AGENCY, https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials-human-medicines [https://perma.cc/6A7D-N8L6].

103. *See Clinical trials in human medicines*, EUROPEAN MEDICINES AGENCY, https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials-human-medicines [https://perma.cc/6A7D-N8L6].

104. *See, e.g.*, *Abigail Alliance*, 495 F.3d at 695 (explaining that the effect of this protection is a denial of access because the drugs have not been proven safe).

105. S*ee, e.g.*, AUSTRALIAN GOV'T DEP'T OF HEALTH¸ *supra* note 102, at 42–44. For an overview of the system in the USA, as coordinated by the FDA, *see Step 3: Clinical Research,* U.S. FOOD & DRUG ADMIN., https://www.fda.gov/patients/drug-development-process/step-3-clinical-research [https://perma.cc/P7C2-S76U]. *See EMEA/CPMP Position Statement on the use of Placebo in Clinical Trials with Regard to the Revised Declaration of Helsinki,* THE EUROPEAN AGENCY FOR THE EVALUATION OF MEDICINAL PRODUCTS (June 28, 2001), https://www.ema.europa.eu/en/documents/position/emea-position-statement-use-placebo-clinical-trials-regard-revised-declaration-helsinki_en.pdf [https://perma.cc/6A7D-N8L6].

106. *See* RICHARD A. RETTIG ET AL., FALSE HOPE: BONE MARROW TRANSPLANTATION FOR BREAST CANCER, 3 (2007).

to court arguing that the treatment was not experimental and sought a court order that the appropriate cover be provided.[107]

Rettig et al reported that there were 75 unique reported cases and one clear factor prevails; sympathy for these critically ill patients. A review of some of the legal decisions reveals that it was often this sympathy that swayed the decision- making and there was an urge to save patients.[108] It then became a self- perpetuating situation with the courts being persuaded by the apparent widespread adoption of the treatment being used as evidence of its acceptance and efficacy.[109] It took on the character of a self-fulfilling prophecy, but there was a complete absence of scientific evidence and support. The prophecy was false. But the widespread patient advocacy combined with the dire health of the applicants swayed the courts, despite scientific and medical challenges to the efficacy of the treatment.[110] During this time the relevant clinical trials were suffering with patients declining to enroll in the trial because the treatment was otherwise widely available.[111] Ultimately the trials were completed and they universally demonstrated that the treatment did not result in an increased chance of survival.[112] The only trial that had demonstrated a benefit was subsequently audited and found to be fraudulent.[113]

An in-depth examination of this story is well beyond the scope of this paper (and is provided elsewhere[114]), however it is worth noting as it presents a cautionary tale of widespread access without full and thorough research. Vulnerable patients bought into what proved to be false hope and energies that could have been directed in a more beneficial manner were focused on flawed treatment. Moreover, given the perception that the treatment offered hope, many patients were drawn to it and declined to participate in the established trial which meant that the trial process was slowed, those patients were all acting on perception of hope as opposed to evidence based treatment and positive harm was suffered by some vulnerable patients.[115]

A further cautionary tale can be found in premature access to an undeveloped drug in response to a potential global pandemic. An

107. *Id.* at 3, 11-14.

108. *Id.* at 82, 101-02.

109. *Id.* at 108.

110. *Id.*

111. *Id.* at 216-17.

112. *Id.* at 241.

113. *Id.* at 243-45.

114. *See id.*

115. *Id.* at 286.

example was provided by Dresser[116] and Bateman- House[117] in consideration of the response to the Ebola crisis. Both explained that the negative publicity surrounding early access to a developing treatment could cause a drug company to cease development and withdraw it from the trial process, thus limiting future development.[118] The drug discussed by Bateman-House was the experimental drug Brincidofovir which was administered to Thomas Duncan who was suffering from Ebola.[119] Unfortunately, either the drug did not work or he was too far progressed with his illness but he died and there was significant backlash against the company, and a subsequent drop in the stock price.[120] The company withstood the financial threat but Bateman- House raised the question of what would have happened if the negative impact had caused the company to fail.[121] A promising drug would have ceased its development and the potential for broader benefit lost.

A more generalized argument about the wider implications of right to try laws was made during the debate surrounding the MIB in the UK by medical research charities. This is that, where there are rare diseases, patients opting for treatment under the 'innovative treatment' pathway instead of joining a trial may make such trials unviable due to a lack of participants.[122] It should be noted at this point that this criticism applies specifically to the MIB, as qualification for the US Right to Try laws is dependent on it not being possible to join a clinical trial.[123] There was no such protection of trial viability in the MIB. This is perhaps surprising, as the Goldwater Institute's philosophy of the focus on the individual and freedom from state interference might be thought to preclude a duty to help the collective rather than oneself – which is ultimately what a clinical trial does. In other words, we should be clear that, at least in the British version of the law, there would be potential negative effects on the ability of researchers to recruit sufficient participants for clinical trials to be run in relation to rare

116. DRESSER, *supra* note 9, at 1632.

117. Alison Bateman-House, *Drug Development, Compassionate Use, and Adverse Events: A Cautionary Tale*, BIOETHICS.NET, http://www.bioethics.net/2015/03/drug-development-compassionate-use-and-adverse-events-a-cautionary-tale/[https://perma.cc/WR65-BS8E].

118. *Id.*

119. *Id.*

120. *Id.*

121. *Id.*

122. Miola, *supra* note 24, at 24.

123. *See Right to Try,* U.S. FOOD & DRUG ADMIN., https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options [https://perma.cc/B96V-59GR].

diseases. Tragically, the more rare the disease the more likely it is that this might come to pass and the lack of sufferers will already make it difficult to recruit for a trial, which ironically pushes patients towards 'innovative treatment' rather than a trial.

But we should also be clear about the corollary of this, as argued above. What we and the research charities are implicitly acknowledging is that we support encouraging patients to participate in trials rather than receive the more direct benefit of innovative treatment as a patient rather than a research participant. We should also be honest and admit that this would ask the patient to do something that is potentially not in their interests. This is for two reasons. First, in the trial the participant may be placed in the control group, if there is one. Second, the purpose of treatment as a patient is to directly benefit the patient. In a clinical trial, the purpose is instead to gather information.[124] A benefit to the participants may accrue, but it is not the primary aim, which is to gather data – although of course the clinical trials framework requires that patients are not harmed, and if their condition deteriorates they will be removed from the trial and treated.[125] Moreover, researchers are of course actively looking and hoping for improvement in the patient's condition.[126] That is not to say that innovative treatments will necessarily be better, and the reality is that outcomes will not always be positive– as Keren-Paz notes, there is often a lag between innovative treatments being tried to their being perfected, so one should prefer not to be among the first patients to receive them.[127] Nevertheless, at least the aim and intention would be to treat the patient, which is not the case in a clinical trial. This may be little more than a symbolic difference in almost all cases, since as mentioned above the *hope* with

124. For an example of human research guidelines from Australia, see NAT'L HEALTH & MED. RES. COUNCIL, NATIONAL STATEMENT ON ETHICAL CONDUCT IN HUMAN RESEARCH, https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018 (last updated 2018). For the UK equivalent, see *Research Ethics Service & Research Ethics Committees*, NAT'L HEALTH SVC. HEALTH RES. AUTH., https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/ [https://perma.cc/DXD3-8QYH].

125. *See Good practice in research and Consent to research*, GEN. MED. COUNCIL (2020), https://www.gmc-uk.org/-/media/documents/Good_practice_in_research_and_consent_to_research.pdf_58834843.pdf [https://perma.cc/R9BP-NWFW].

126. *See generally id.* (noting that research is important for improving health, but that researchers must prioritize the safety and wellbeing of participants over research outcomes).

127. T. KEREN-PAZ, *No Fault (Strict) Liability for Injuries from Innovative Treatments: Fairness or Also Efficiency?,* 11(1) *L., Innovation & Tech.* 55 (2019).

a trial is that the participant's condition will improve, but with innovative treatment the focus is *solely* on the patient, and there is no trial framework or wider aim to cause tensions.

CONCLUSION

We have argued that the right to try narrative (both in relation to the US's right to try laws and the MIB in the UK), fail to stand up to scrutiny. The claims made regarding access do not match the reality, and the bargain that patients are asked to engage in is deeply flawed. Patients are asked to forgo a well-established right to seek legal redress in the form of negligence, but gain little more than potential in return. This does not mean that we perceive negligence law to be faultless, but what we do demand is that any system that is proposed for replacing it should be shown to be *better*, and in neither right to try legislation nor the MIB can this been said to be the case. We have also identified that the notion of shifting the law's patient protection mechanism from negligence to informed consent is ineffective and can only result in a watering down of the law's ability to respond adequately to *irresponsible* innovation. If the crux of the law should be the encouragement of *responsible* innovation combined with the discouragement of *irresponsible* innovation, then these laws can be seen to fail on both counts.

Indeed, a further, unintended consequence of the removal of the ability of injured patients to sue in negligence is that the law's role as a deterrent to bad actors is compromised. Medical practitioners who are either 'snake oil salesmen' or, perhaps even more concerningly, too inexperienced or insufficiently skilled to see the flaws in their thinking also gain immunity from being sued.

We have also demonstrated that such laws contain other dangers, from the threat to the viability of clinical trials in rare diseases, to the aHSCT-HDIT example, where an ineffective treatment became widely available. Patients do not gain anything from such treatments, and lose the opportunity to try something else that might work. We are all agreed that there must be some method of allowing accelerated access to innovative drugs and treatments for patients who have no other hope, indeed regulatory bodies actively encourage and support such access. However, right to try laws are clearly not the best way and serve to undermine existing pathways. We suspect that the real answer may be more mundane: there is little evidence that either the FDA scheme in the US or the accelerated access schemes in the UK suffer from a lack of *desire* to make drugs available. It may well be that with better funding more patients can be helped. Yet whether or not that is the case, the removal of the right to sue in negligence in return for no greater access than afforded by these schemes (as is the reality of right to try laws and the MIB, rather than the narrative) not only takes us no further forward, but is likely to make matters worse. A final

cautionary note to sound is that the naming of these schemes is actively misleading. Neither of the regulatory frameworks presents a meaningful right to try anything. They both stop well short of empowering patients, and the 'bargains' that they seek to strike with patients can only be described as bad.