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Innovative Treatments, The Spaces In Between and ‘Bad Bargains’

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What is ‘Right to Try’?

- ‘Dallas Buyers’ Club’ Laws
- Created by the Goldwater Institute as ‘off the shelf’ legislation
- Bypasses FDA after Phase 1 testing complete

Features of ‘Right to Try’ Legislation

- Patient must be terminally ill and unable to get to a clinical trial
- Physician Recommends
- Patient signs informed consent form
- Manufacturer *chooses* to provide
- Manufacturer *may* charge
- Professional barred from disciplinary action
- Many states also remove at least some civil liability – House Bill removes all

See R. Dresser, ‘The “Right to Try” Investigational Drugs: Science and Stories in the Access Debate’ (2015) 93 *Texas Law Review* 1631

Disadvantages of ‘Right to Try’

- Vulnerability of this particular patient group
- ‘Choice’ in US makes it easier for patients to engage quacks
- Lack of civil liability makes it more difficult to seek redress
- ‘Voices’ all point in one direction
- No requirement to report results

Merck and Co:

"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"

(S. Firth, 'Will "Right to Try" Bill Actually Help Anyone?', 11th MedPage Today, 11 August 2017)

“[w]e don’t support right to try legislation … because ignore key patient protections without actually improving patient access to investigational drugs outside of clinical trials”
(American Society of Clinical Oncology, April 2017)

“The Bill will encourage irresponsible experimentation. Families, already at heightened susceptibility to the promise of miracle cures because of the illnesses of their children or loved ones, will be prey to at worst quackery and at best to the possibly strongly held but inadequately justified convictions of medical practitioners who do not know how, or do not wish, to test treatments objectively … [it] poses a real danger to the safety of infants, children and young people.”
(Royal College of Paediatrics and Child Health, October 2015: https://www.rcpch.ac.uk/news/access-medical-treatments-stop-bill-now)

Montgomery v *Lanarkshire Health Board* [2015] UKSC 11

"patients are now widely regarded as persons holding rights, rather than as the passive recipients of the care of the medical profession. They are also widely treated as consumers exercising choices: a viewpoint which has underpinned some of the developments in the provision of healthcare services"

Montgomery v *Lanarkshire Health Board* [2015] UKSC 11

"The social and legal developments which we have mentioned point away from a model of the relationship between the doctor and the patient based upon medical paternalism. … 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 risks affecting their own lives, and living with the consequences of their choices*."
(*per* Lords Reed and Kerr)

Conclusions

- Wishful Thinking and the Transition from Research to Treatment
- The ‘Bad Bargain’
- ‘Shamans of the Liminal’
- Law’s Duty to Respond/Protect