UNIVERSITY OF LEICESTER

Curtailing Conscience: Values, Patient Autonomy and the Role of Regulation

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Claims of Conscience - Miola

- Not based on ‘professional judgment’
- The doctor must have the liberty to make her own decision

J. Miola, ’Making Decisions About Decision-Making: Conscience. Regulation and the Law’ (2015) 23(2) *Medical Law Review* 263

Claims of Conscience - Smith

- Values must be *moral* values
- No need for options: only authorship
- Must be inward-facing

S. Smith, 'Individualised Claims of Conscience: Clinical Judgment and Best Interests' (2016) 26(1) *Health Care Analysis* 81

‘Innovative’ Treatments

Simms v. *Simms* [2002] EWHC 2734 (Fam)

Medical Board of Australia v. *Boyd* [2013] WASAT 123

Paolo Macchiarini

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

From the Goldwater Institute Template …

"*A licensing board or disciplinary subcommittee shall not revoke, fail to renew, suspend, or take any action against a health care provider's license … based solely on the health care provider's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device*. An entity responsible for medicare certification shall not take action against a health care provider's medicare certification based solely on the health care provider's recommendation that a patient have access to an investigational drug, biological product, or device."

Disadvantages of ‘Right to Try’

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

Lord Blencathra's Plea:

- "I assure you, any study you undertake, any research you do, you will find there are tens of thousands of us, in particular those suffering the worst disease, who will volunteer to participate in clinical trials. And we don't want to wait five years while a pile of more mice and rats are experimented on. This rat is willing to become a guinea pig at very, very short notice"

  ('Saatchi Bill: Let Me be a Guinea Pig for New Drugs, Urges Peer', *Daily Telegraph*, 27th June 2014)

"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)

“No matter the quality of medicine practised, and no matter the doubts of doctors themselves about the appropriateness of their involvement, human life is increasingly medicalised. In part, this is the result of the growing professionalism of medicine, in part our responsibility for asking too much of doctors. In part, however, it is also because the buffer which might be expected to stand between medicalisation and human rights - namely the law - has proved unwilling, unable or inefficient when asked to adjudicate on or control issues which are at best tangentially medical.”

S. MacLean, *Old Law, New Medicine: Medical Ethics and Human Rights* (Pandora Publishing, 1999)

Conclusions

- We do not just want doctors to exercise conscience, we want them to exercise *good conscience*. This entails boundary setting by the law and professional regulators

- The danger of the fetishisation of autonomy is that it legitimises all ‘offers’ on the table, and prevents legal/regulatory oversight

- Indeed, RtT and the MIB actively sabotage such oversight and allow poor exercises of conscience

- We must therefore not just consider how to enable uses of conscience, but how to set boundaries even where uses of conscience are appropriate