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Taking the Long View: *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision Making*

Mary Donnelly and Barry Lyons

Introduction

David Rothman's *Strangers at the Bedside* is a carefully constructed origin story of (to borrow the book's subtitle) 'how law and bioethics transformed medical decision making' in the United States of America (US).¹ Rothman traces the complex and frequently contentious relationship between 'insiders' (doctors) and 'outsiders' (bioethicists, lawyers, judges, politicians) during a crucial period of transformation, and seeks to locate the shifting position of the patient² within this. By doing this, he helps to explain why autonomy became the dominant legal principle in medical decision-making and why consent became the foundational norm in health research and treatment, while also revealing the contingencies of these outcomes. This chapter draws on conversations between an insider (Lyons - a clinician) and an outsider (Donnelly - a legal academic) to make the case that from both perspectives, *Strangers* should be considered a leading work in health law and ethics beyond the US.

The Work

No profession has had as much cultural authority or autonomy of action in twentieth-century America as medicine. Yet, in recent years, an extraordinary irony has occurred. As medical knowledge has accumulated to previously unimaginable proportions, and as medical technology has developed an astounding ability to prolong life, doctors are no longer in complete control of the clinical decision-making process. Intruding themselves into the decision-making are families, hospital administrators, ethics committees, court representatives, lawyers, judges, regulatory committees, legislators, and bioethicists.³

Strangers is an account of how this transformation came about. Rothman, an outsider (a social historian), was brought in to Columbia University's Medical School in 1982 'to bring the methods and materials of the social sciences and the humanities' into the medical curriculum.⁴ In writing *Strangers*, Rothman sought an understanding of how outsiders came into medicine; how an insular, self-contained, and almost entirely responsible-to-self only profession had undergone the kind of extraordinary change required to permit the admission of strangers to the bedside.⁵

¹ David J Rothman, *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision Making* (Basic Books 1991).

² We are conscious that 'patient' is a troubled term but are using it here because this is the term which Rothman adopts. We also use the term doctors, again to reflect Rothman who uses the term physician too.

³ Kenneth M Ludmerer, 'Watching the doctors: A review of *Strangers at the Bedside*' (1992) 20 *Reviews in American History* 386, 386.

⁴ Rothman (n 1) 5.

⁵ Albert R Jonsen, 'The birth of bioethics' (1993) 23 *Hastings Center Report* S1, 11.

Although not in any sense strictly historical, *Strangers* is concerned primarily with the decade 1966-1976, which Rothman has identified as the ‘critical period of change’ in medical decision-making in the US.⁶ The period of the account is bookended by ‘a whistle-blower and a scandal’⁷ at one end (the publication of Henry Beecher’s incendiary article on ‘Ethics and Clinical Research’ in the *New England Journal of Medicine (NEJM)* in 1966,⁸ which precipitated the Belmont Report),⁹ and an influential legal case at the other (the decision of the Supreme Court of New Jersey in *Re Quinlan* in 1976), which categorically placed medical decision-making within the purview of the law.¹⁰ Rothman also acknowledged earlier events as being an important part of the story, particularly the establishment of a committee in Seattle whose duty it was to select patients for entry into the recently opened haemodialysis programme.¹¹ As Albert Jonsen has said, the authorities of the past, namely physicians, seemed an inadequate group to fairly select candidates for access to a very limited medical resource.¹² Thus, a radical new solution was arrived at:

a group of physicians, in unprecedented fashion, turned over to a lay committee life-or-death decisions prospectively and on a case-by-case basis. A prerogative that had once been the exclusive preserve of the doctor was delegated to community representatives.¹³

The motif of the ‘stranger’ runs through Rothman’s narrative, where it plays a dual role. The term is used to describe both the *why* of the shift (doctors becoming strangers to their patients), and the *how* (the interpolation of strangers in the form of lawyers, bioethicists and others into the doctor/patient relationship). Rothman argued that *Re Quinlan* marked the culmination of the move away from absolute medical paternalism to a new model reflecting an enhanced respect for patient autonomy.¹⁴ He did not simply describe this change, he also interrogated it. As he acknowledged, ‘[t]o present the history of a change is inevitably to raise questions on the merits of the change’.¹⁵ To the contemporary reader, Rothman’s ruminations on the merits of change are, perhaps, as interesting as his account of why and how the change occurred.

The Causes of Estrangement

Rothman pinpointed World War II (WWII) as a pivotal point in the changing of the doctor-patient relationship and set out two particular issues as being fundamental to creating the context. First, a loss of public trust following particularly egregious and unethical conduct on the part of some physician-researchers, and, second, the more phenomenological separation of doctors and patients due to economic circumstances, medical sub-specialisation, and the increasing interposition of diagnostic technology between the two. Prior to WWII, on Rothman’s account, doctors and patients were part of the same communities,¹⁶ a close knowledge of the patient and their circumstances was the best (and often the only) weapon in

⁶ Rothman (n 1) 3.

⁷ *ibid* 15.

⁸ Henry Beecher, ‘Ethics and clinical research’ (1966) 74 *NEJM* 1354.

⁹ National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report* (Department of Health, Education and Welfare 1978).

¹⁰ 70 NJ 10, 355 A.2d 647 (NJ 1976).

¹¹ Rothman (n 1) 150-51.

¹² Jonsen (n 5).

¹³ Rothman (n 1) 150-51.

¹⁴ *ibid* 222.

¹⁵ *ibid* 13.

¹⁶ *ibid* 111-26.

the diagnostic armoury,¹⁷ hospitals were divided on ethnic and religious grounds,¹⁸ and most medical research was a ‘cottage industry’.¹⁹ There were class differences in how patients and doctors interacted,²⁰ but Rothman made a reasonable case that even the socially disadvantaged engaged with neighbourhood doctors, albeit in a less steady way than the more affluent.²¹

In respect of the first of Rothman’s theses, WWII saw medical research transformed into a national programme aimed at finding ways to reduce the impact of health problems on efficiency in combat, losing ‘its intimate and directly therapeutic character’ and assuming profoundly utilitarian foundations in the process.²² The heavily controlled environments of prisons and asylums, orphanages and other institutions made them ideal locations in which to conduct research, with enrolment in research trials viewed as ‘allowing’ inmates to make a contribution to the war effort. As Rothman described it, in a world where soldiers were sent off to die in battle, the sacrifices and hardships endured by research subjects were easily justified in the interests of the greater good: ‘the effort to conquer disease entitled them [researchers] to choose the martyrs to scientific progress’.²³

The innovation and energy of the war years carried forward into a post-war ‘gilded age of research’,²⁴ underpinned by the same utilitarian justifications as those which had been widely accepted in wartime. Concerns about consent and voluntariness came a poor second to the tremendous potential for scientific advancement.²⁵ And, thus, the stage was set for Beecher’s account of 22 profoundly unethical research trials.²⁶ Not only had basic consent requirements been ignored by physician-researchers, but substantial harms had been inflicted on highly vulnerable populations (women, racial minorities, and those who were impoverished, incarcerated and intellectually impaired),²⁷ who had served as ‘cannon fodder for battles in a war against disease’.²⁸ Despite protestations from some (medical) quarters,²⁹ it was clear that this was not an odd or isolated occurrence. The conflict of interest between the medical researcher and the subject of research had been laid bare, and any preconception that medical researchers were simply doctors acting in the best interests of their patients was decisively dispelled.³⁰

Rothman’s focus on Beecher’s article meant that medical research dominates the early part of *Strangers*. To the contemporary reader this may seem odd. However, it reflected the dual role of hospital clinicians of the day (acting as both researcher and physician). It also acknowledged that the pre-eminent ‘theory’ of North American clinical ethics (principlism)³¹

¹⁷ *ibid* 17.

¹⁸ *ibid* 123-24.

¹⁹ *ibid* 18.

²⁰ *ibid* 115-16.

²¹ *ibid* 116-17.

²² *ibid* 30-31.

²³ *ibid* 50.

²⁴ *ibid* 51.

²⁵ *ibid* 51.

²⁶ Beecher (n 8).

²⁷ Rothman (n 1) 74-78. The research studies are not named in Beecher’s article, although the relevant details were provided to the *NEJM* editors for verification. They are listed in Appendix A to *Strangers*.

²⁸ Rothman (n 1) 80.

²⁹ *ibid* 85.

³⁰ *ibid* 88-89.

³¹ Principlism views medical ethics as grounded in four fundamental principles: respect for autonomy, beneficence, non-maleficence and justice, see Tom L Beauchamp and James F Childress, *Principles of*

was derived from a national inquiry into unethical research established during the timeline of *Strangers*.³²

It was only in Chapter 6, that Rothman finally turned his attention to estrangement at the bedside and identified a range of causes for the growing separation. First, there was the ‘precipitous rise in physicians’ incomes’ in the period from 1945, which helped to ‘foster a belief that doctors had become more concerned with their pocketbooks than their patients’.³³ Secondly, a variety of structural factors had led both hospitals and doctors to become increasingly removed from their communities.³⁴ Medical specialisation and sub-specialisation had become the norm, creating doctors ‘trained so intensely in the functioning of a particular organ or system that they might well lose sight of the patient’s presence’,³⁵ sometimes caricatured as ‘the kidney in bed 10’. Religion and ethnicity no longer determined hiring practices even in ostensibly sectarian hospitals,³⁶ and local and community hospitals were no longer economically viable.³⁷ The pace and rhythm of medical practice had changed too; diagnostic information was more likely to be gained from new technologies than from detailed case histories or physical examination.³⁸

Interpolating Strangers

Henry Beecher was the consummate ‘insider’; he was Chair of the Department of Anaesthesia in Harvard who turned whistle-blower. While, in the first instance, his *NEJM* article was aimed at medical professionals, he also notified the press of its forthcoming publication.³⁹ As told by Rothman, the effect of this intervention was to make ‘the invisible visible’⁴⁰ to a range of outsiders including journalists, politicians and the general public, who did not like what they saw, finding ‘harm where investigators perceived the opportunity for progress’.⁴¹ New rules came quickly, and by August 1966 the Food and Drug Administration had issued a comprehensive new policy on consent.⁴² Perhaps more significantly, philosophers and lawyers started to take an interest in the operation of human experimentation too, ‘at first hesitantly and with apparent humility, later, in a more aggressive and confrontational style’.⁴³ Within a short time, inter-disciplinary publications on human experimentation were becoming established,⁴⁴ and outsiders were becoming essential (and active) participants in Institutional Research Boards.

The interpolation of outsiders into the clinical relationship took a more circuitous route. Rothman identified three critical flashpoints. The first was the possibility of organ transplantation. While this development offered extraordinary life-saving potential, the

Biomedical Ethics (8th edn, Oxford University Press 2019). **Beauchamp and Childress’s book is discussed in Stephen Smith’s chapter in this collection.**

³² National Commission (n 9).

³³ *ibid* 108.

³⁴ *ibid* 128.

³⁵ *ibid* 129.

³⁶ *ibid* 129-30.

³⁷ *ibid* 130-31.

³⁸ *ibid* 131-32.

³⁹ *ibid* 74.

⁴⁰ *ibid* 1.

⁴¹ *ibid* 94.

⁴² *ibid* 93.

⁴³ *ibid* 95.

⁴⁴ See, for example, the special issue: ‘Ethical aspects of experimentation with human subjects’ (1969) 98 *Daedalus*.

established principles of clinical ethics no longer offered guidance here.⁴⁵ The basic principle of beneficence could not justify removing a kidney from a living donor to benefit a third party, the allocation of scarce organs required choices to be made among potential recipients, and post-mortem organ acquisition and subsequent transplantation raised questions about the definition of death ‘in the most dramatic way’.⁴⁶ The second flashpoint related to end-of-life practices in neonatal nurseries, where decisions were routinely made not to treat and/or not to provide hydration or nutrition to newborn infants with disabilities, usually by the doctor acting alone.⁴⁷ These practices were opened to public view (by an insider whistle-blower) at around the same time as the Supreme Court was expanding the scope of family privacy through *Roe v Wade*,⁴⁸ and the disability rights movement was mobilising and beginning to have a decisive impact on public policy.⁴⁹ Doctors therefore found themselves caught in the crossfire of debates around abortion and disability.⁵⁰ As the transformative period identified by Rothman advanced, it became increasingly the case that ‘[p]hysicians who were strangers could not be trusted to exercise discretion over weighty matters of life and death’.⁵¹ Thus, the involvement of outsiders was becoming an inevitability.

The final, and Rothman would suggest determinative, flashpoint also related to withdrawal of life-sustaining interventions and came in the decision in *Re Quinlan*.⁵² Any student of health law can recount how the Supreme Court of New Jersey authorised the withdrawal of ventilation from a young woman (Karen Quinlan) who was in a persistent vegetative state (PVS), and held that her constitutional right to privacy should be protected by permitting her guardian and family ‘to render their best judgment ... as to whether she would exercise it in these circumstances.’⁵³ Many (perhaps most) students do not go beyond this. Rothman, however, presented *Re Quinlan* as the ultimate battle for authority in US medical decision-making.⁵⁴ Although Quinlan’s treating doctor cited a ‘moral problem’ in refusing her parents’ request,⁵⁵ the Court saw, instead, a concern with malpractice or even criminal sanction, which could only be addressed by looking beyond the medical profession for guidance.⁵⁶ One option put forward by the Court was the establishment of hospital ethics committees.⁵⁷ Another was the ongoing involvement of the courts. In fact, as Rothman described, *Re Quinlan* ‘served as a bridge for lawyers and judges to cross over into medicine’.⁵⁸ This crossing was well and truly completed when, some months after *Re Quinlan*, the Supreme Judicial Court of Massachusetts found that courts were not just an appropriate but the required locus for decision-making in some end-of-life situations.⁵⁹

The Context

⁴⁵ Rothman (n 1) 154-56.

⁴⁶ *ibid* 156.

⁴⁷ *ibid* 197.

⁴⁸ 410 US 113 (1973).

⁴⁹ Rothman (n 1) 205-6.

⁵⁰ *ibid* 220.

⁵¹ *ibid* 109.

⁵² 70 NJ 10, 355 A.2d 647 (NJ 1976).

⁵³ Rothman (n 1) 41-42.

⁵⁴ *ibid* 222-28.

⁵⁵ *ibid* 224.

⁵⁶ *ibid* 226.

⁵⁷ *ibid* 227-28.

⁵⁸ *ibid* 233.

⁵⁹ *Superintendent of Belchertown v Saikevicz* 373 Mass 728, 370 N.E. 2d 417 (1976).

Strangers was published in 1991, some 15 years after the end of the transformative period Rothman described in it and this gap allowed him time to absorb the implications of the 'critical period of change' which he analyses.⁶⁰ The book includes an epilogue in which Rothman reflected on developments in the intervening years. By this time, he, while not a true 'insider', had (as Professor of Social Medicine) nonetheless a first-hand perspective on the operation of contemporary medicine. This may explain a degree of ambivalence about the changes wrought in the decade examined.

Rothman's own academic history had seen him engage with some of the most egregious harms which elements in the medical profession, as well as the broader state, had imposed on the mentally ill or disabled.⁶¹ It is no surprise, therefore, that, as he acknowledged at the outset, his 'own predilection strongly favoured bringing rules to medicine'.⁶² Looking back, however, he was more sceptical about what had been achieved. By the time *Strangers* was written, the AIDS crisis was devastating the gay community, and the contemporary concern was no longer how to protect vulnerable patients from unregulated researchers but how to ensure that dying patients could access possibly life-saving drug trials.⁶³ Courts, lawyers and hospital ethics committees were decisively now a part of medical decision making. While recognising that the patient's voice was generally better heard, Rothman was not oblivious to the cost of this. In a quote which invites repetition, he said that '[t]o make certain that the patient's voice would be heard and respected demanded the support of a chorus, and as sometimes happens, the chorus can overwhelm the soloist'.⁶⁴ Thus, *Strangers* is not an account of unadulterated progress, but a more subtle meditation on the costs and benefits of change.

The decision of the United States Supreme Court in *Re Cruzan*,⁶⁵ which shortly preceded the publication of *Strangers*, is addressed briefly in the epilogue. This decision turned out to be pivotal to the future relationship between law and medicine in ways which Rothman could not have foreseen. The Supreme Court affirmed both a constitutional right to refuse medical treatment, including artificial hydration and nutrition (ANH),⁶⁶ and the applicability of substituted judgement (decision-making based on what the patient would have wanted) where a person lacked capacity to make decisions for themselves. The Court also affirmed the right of each State to determine the applicable standard for the operation of substituted judgement.⁶⁷ In so doing, it allowed for new inconsistencies to enter into end-of-life decision making. Nancy Cruzan (and her family), who lived in Missouri, were required to show 'clear and comprehensive evidence' that she would have wanted to have life-sustaining treatment withdrawn.⁶⁸ However, if she had lived in neighbouring Illinois, where the usual civil standard applied, treatment could have been withdrawn on the basis of her parents' evidence

⁶⁰ Rothman (n 1) 3.

⁶¹ See David J Rothman, *The Discovery of the Asylum: Social Order and Discovery in the New Republic* (Little, Brown 1971); David J Rothman, *Conscience and Convenience: The Asylum and its Alternatives in Progressive America* (Little, Brown 1980); David J Rothman and Shelia M Rothman, *The Willowbrook Wars* (Harper & Row 1984).

⁶² Rothman (n 1) 9.

⁶³ *ibid* 252.

⁶⁴ *ibid* 261.

⁶⁵ 497 US 261 (1990).

⁶⁶ *ibid* 279.

⁶⁷ *ibid* 281.

⁶⁸ This was the most demanding civil standard under US law and in effect, other than in exceptional circumstances, required that the patient had made some form of written advance directive: Mary Donnelly, *Healthcare Decision-Making and the Law: Autonomy, Capacity and the Limits of Liberalism* (Cambridge University Press 2010) 187.

of ‘a somewhat serious conversation’ in which she had expressed this wish. Thus, *Re Cruzan* made it clear that inconsistency was not just a feature of medical decision-making but was also present in the new world of judicial decision-making in end-of-life contexts.

If neither doctors nor lawyers could deliver consistent, reliable responses, the need for legislative intervention was obvious.⁶⁹ The first legislation was at a federal level through the Patient Self-Determination Act 1990, which required hospitals and other facilities covered by Medicare and Medicaid to draw patients’ attention to their right to make an advance directive. The second was the Uniform Health-Care Decisions Act 1994, the key principles of which were widely adopted across individual states (albeit with considerable variability at a level of detail).⁷⁰ The 1994 Act outlines models for advance directives and enduring powers of attorney. Most significantly, where these options are not availed of, it provides for surrogate decision-making, setting out an automatic order in which surrogates are appointed, presuming that they are ‘reasonably available’.⁷¹ The practical effect was to remove end-of-life decision-making from the courts and return it to the private sphere. However, now, legal authority very clearly resided with the patient’s family and not with the medical profession or, indeed, the hospital ethics board. While there have been a small number of controversies before the courts, most notably the highly publicised (and politicised) case of Terri Schiavo,⁷² by and large the (re)privatisation of end-of-life decision-making seems to have been accepted.⁷³

Moving outwards from the US, the publication of *Strangers* coincided with a transition in the relationship between insiders and outsiders in other jurisdictions, although this played out in different ways. In the United Kingdom (UK), the tensions recounted by Rothman did not emerge to anything like the same degree. There was an early aggressive legal intervention through the prosecution of consultant paediatrician Dr Leonard Arthur for murder, following his prescription of ‘nursing care only’ for a baby born with Down Syndrome, at the request of the baby’s parents.⁷⁴ As with the US, the case came to the attention of authorities through the action of insider whistle-blowers, in this case nurses who were affiliated to the ‘Life’ organisation. During the trial, the prosecution conceded that Dr Arthur had acted with the highest of motives and he was unanimously acquitted by the jury after just two hours deliberation. The criminal law has not been used again in this context. However, doctors or, more specifically, NHS health authorities,⁷⁵ began to seek the involvement of the courts in making decisions in contentious situations.⁷⁶

⁶⁹ See *ibid* 188-89.

⁷⁰ See Charles P Sabatino, ‘The evolution of health care advance planning law and policy’ (2010) 88 *Milbank Q* 211.

⁷¹ Uniform Health-Care Decisions Act 1994, s. 5(c).

⁷² For a summary, see Donnelly (n 68) 189-90.

⁷³ See Carl E Schneider, ‘Hard cases and the politics of righteousness’ (2005) 35 *Hastings Center Rep* 24.

⁷⁴ See the summary of the case in Diana Brahams and Malcolm Brahams, ‘The Arthur Case: A Proposal for Legislation’ (1983) 9 *JME* 12. doi: 10.1136/jme.9.1.12.

⁷⁵ Arguably, the two pivotal cases in establishing this practice were *Re B (A Minor) (Wardship: Medical Treatment)* [1981] 1 WLR 1421, CA, where the NHS health authority sought the guidance of the court on the provision of a life-saving operation for a baby with Down Syndrome against parental wishes, and *Re F (Mental Patient: Sterilisation)* [1990] 2 AC 1, HL, where the NHS health authority sought court authorisation for the non-consensual sterilisation of an adult woman with a learning disability.

⁷⁶ For a fascinating account of the impact of the contemporary political context on this approach, see Ruth Chadwick and Duncan Wilson, ‘The Emergence and Development of Bioethics in the UK’ (2018) 26 *Med L Rev* 183, 192.

Thus, the predominant role of the courts, rather than the legislature or clinical ethics committees, was established. To a large extent, this has remained the position. While there has been some legislative intervention in ‘new’ areas,⁷⁷ and the development and consolidation of the broader ‘ethics industry’,⁷⁸ for the most part, the courts have remained the locus for the determination of difficult cases. Some institutions, including, most notably, Great Ormond Street Children’s Hospital, have established clinical ethics committees,⁷⁹ and several academics continue to call for greater use of such bodies.⁸⁰ However, the operation of such committees has more recently come under critical scrutiny by the courts, indicating ongoing uncertainties about the role of legal procedural entitlements in their operations.⁸¹

The transition in Ireland has more closely resembled the tense stand-off between insiders and outsiders described in *Strangers*. These tensions came to the fore in *In re a Ward of Court*,⁸² a case with some similarities to *Re Quinlan*. The ward had been in a ‘near PVS’ for over 23 years when her mother (with the agreement of other family members) applied to the High Court to have ANH removed. The application was opposed by the ward’s medical and nursing staff, with the institution where the ward resided stating that withdrawal would be contrary to their ethics and philosophy.⁸³ The Supreme Court (acting as ‘prudent, good and loving parent’) ultimately determined that the withdrawal of ANH was both in accordance with the ward’s constitutional rights and in her best interests.⁸⁴ The Court did not, however, order either the institution or the health professionals to withdraw ANH. Nonetheless, the Irish Medical Council (the regulatory body for the medical profession) saw fit to intervene and immediately issued a statement that doctors were not permitted to withdraw fluids and nutrition in any form.⁸⁵ Thus, any doctor giving effect to the Court’s decision would immediately be brought into conflict with the ethical standards of their profession and the fitness to practice process.

Although the actions of the Irish Medical Council set the stage for a constitutional crisis, this did not materialise. With the assistance of an anonymous doctor, the ward was removed by her family from the institution and died at home shortly afterwards. Reflecting its (extraordinary) confidence in its own status, the Council continued to advance its position for several more years, maintaining an ongoing tension between the Supreme Court’s authority (and the individual’s constitutional rights) and the stance of medical orthodoxy.⁸⁶ By the early 2000s, the Irish Medical Council had re-formulated its ethical guidance in line with the

⁷⁷ Most notably, the Human Fertilisation and Embryology Act 1990.

⁷⁸ See Duncan Wilson, *The Making of British Bioethics* (Manchester University Press 2014) ch. 6.

⁷⁹ For a list of such committees, see the Clinical Ethics Network website: <https://www.ukcen.net/committees/member_list> accessed 19 August 2022.

⁸⁰ See, for example, Richard Huxtable, *Law, Ethics and Compromise at the Limits of Life: To Treat or Not to Treat?* (Routledge 2012); Dominic Wilkinson and Julian Savulescu, *Ethics, Conflict and Medical Treatment for Children: From Disagreement to Dissensus* (Elsevier 2019).

⁸¹ See *In re the Matter of X* [2020] EWHC 1958 (Fam) [21] – [23].

⁸² [1996] 2 IR 73.

⁸³ *ibid* 99.

⁸⁴ *ibid* 169.

⁸⁵ Gerard Bury, ‘Regulating the medical profession in Ireland: Medical regulation, medical dilemmas and making decisions ...’ Paper delivered to the Citizens’ Assembly, 5 February 2017 <<https://2016-2018.citizensassembly.ie/en/Meetings/Gerard-Bury-Paper.pdf>> accessed 19 August 2022. At the time, the Irish Medical Council was medically dominated, with only four of 25 members coming from the lay community.

⁸⁶ See Medical Practitioners Act 1978, s 9.

legal and constitutional position.⁸⁷ However, the intervening tension between divergent legal and regulatory actors was unsettling for ordinary health professionals.

The Significance

If we judge significance by the range and number of book reviews, *Strangers* was regarded as a significant contribution to scholarship in its day. As might be expected, it was widely (and generally favourably) reviewed in US-based medical/scientific history journals,⁸⁸ as well as some generalist historical journals.⁸⁹ It was also reviewed in US-based bioethics,⁹⁰ legal,⁹¹ medical,⁹² policy⁹³ and sociology⁹⁴ journals, and, unusually for an academic book, by leading newspapers and periodicals.⁹⁵ There are notably fewer reviews to be found in journals which are not based in the US,⁹⁶ although *Strangers* is subjected to a delightfully acidic review by Roger Cooter in the UK-based *Social History of Medicine*.⁹⁷

Cooter's merciless exposure of some of the limitations of *Strangers* is a good place to start if we broaden our understanding of significance. Cooter argued persuasively that Rothman favoured the individual story over more structural elements. He refuted the causal significance which Rothman affords to Beecher's *NEJM* article, arguing that the evidence presented 'does little to legitimate this star billing'.⁹⁸ Relatedly, Cooter took Rothman to task for his 'manifestly non-sociological' approach,⁹⁹ and for his failure to provide 'any political and structural analysis of the post-war medical profession'.¹⁰⁰

Cooter's most substantial concern was less with the book itself and more with the impact of the book in copper-fastening the role of ethics (and philosophy) as the dominant discipline in responding to the ongoing challenges of medical practice. He argued that 'Rothman's account of the rise of bioethics only generates, in effect, the "bioethicists' tale"'.¹⁰¹ Thus, for Cooter, *Strangers* played a substantial role in the construction of bioethics. As he described, '[b]y producing a history of bioethics [Rothman] has legitimated the enterprise of bioethics as

⁸⁷ For a contemporary iteration see Medical Council, *Guide for Professional Conduct and Ethics for Medical Practitioners (Amended)* (8th edn, Medical Council 2019) para. 45.2.

⁸⁸ For example, Susan E Lederer, 'Review of *Strangers at the Bedside*' (1992) 83 *ISIS* 519; Robert Baker, 'David J Rothman, *Strangers at the Bedside*' (1993) 37 *Med Hist* 113.

⁸⁹ For example, Greg Gramelspacher, (1992) 79 *Journal of American History* 346; Ronald L Numbers, 'Review of *Strangers at the Bedside*' (1992) 97 *The American Historical Review* 633.

⁹⁰ For example, Dan W Brock, 'The birth of bioethics' (1992) 22 *Hastings Center Report* 41.

⁹¹ For example, Sandra H Johnson, 'Strangers at the Bedside' (1993) 33 *Jurimetrics* 341; Edward P Richards, 'The role of the horrible in understanding medicine: A meditation on David Rothman's *Strangers at the Bedside*' (1992) 60 *University of Missouri-Kansas City. Law Review* 729.

⁹² For example, Stanley B Troup, 'Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision Making' (1991) 266 *JAMA* 851.

⁹³ For example, George G Reader, (1992) 13 *Journal of Public Health Policy* 120; Carole Levine, 'How bioethics made strangers bedfellows' (1992) 70 *The Milbank Quarterly* 227.

⁹⁴ For example, Charles L Bosk, 'Whose bedside is it anyway?' (1991) 20 *Contemporary Sociology* 831.

⁹⁵ For example, Perri Class, 'Diagnosing Doctors' New Dilemmas: *Strangers at the Bedside*' *LA Times* (Los Angeles, 26 May 1991).

⁹⁶ Specialist medical/health law journals were still in their infancy, with the *Medical Law Review*, for example, launched in 1993.

⁹⁷ Roger Cooter, 'The Resistible Rise of Medical Ethics' (1995) 8 *Social History of Medicine* 257.

⁹⁸ *ibid* 267.

⁹⁹ *ibid*.

¹⁰⁰ *ibid* 268.

¹⁰¹ *ibid* 269.

historically distinct and worthy of humanistic study'.¹⁰² Although Cooter did not intend this as a compliment, it is difficult to imagine a stronger statement in support of the case for the significance of *Strangers*. Rothman himself was by no means unaware of the consequences of the individualism of the bioethical approach which elevates the 'microissue – what should a doctor do about this baby? – not the macroissue – Are expenditures on the neonatal nursery the best use of social resources?'.¹⁰³ However, ultimately for Rothman, the rise of bioethics happened because of ethicists' (and lawyers') 'strong commitment to individual rights', something which allied them with patients and their families who 'like the Quinlans, had confronted unyielding medical authority'.¹⁰⁴

Cooter's review essay was focused on the role (and rise) of bioethics, and he did not address the role of law. Rothman is not a lawyer, and one would not read *Strangers* for its doctrinal insights. Instead, the relevance of *Strangers* for lawyers lies in the social and historical context which it provides for legal norms. This was significant when *Strangers* was published, and it remains significant today. This is because of the role which narratives play in the law's normative universe. As Robert Cover has described, '[n]o set of legal institutions or prescriptions exists apart from the narratives that locate it and give it meaning'.¹⁰⁵ Law is more than a set of rules (although some doctors may sometimes perceive it to be just this); if law is to have normative force, its requirements must 'be located in discourse – to be supplied with history and destiny, beginning and end, explanation and purpose'.¹⁰⁶ By presenting a foundational narrative, *Strangers* provided a lens through to view (and critique) legal frameworks.

The Legacy

In a memorial piece published almost three decades after the publication of *Strangers*, Barron Lerner wrote that '[o]ne of the joys of historical scholarship is how historians eventually themselves become part of the history'.¹⁰⁷ *Strangers* is now decidedly a part of history and unlikely to feature in the readings of many younger health law scholars. The book's legacy is not that it told the 'truth' of 'how law and ethics transformed medical decision making' in the US, still less the rest of the world. The story could have been told differently, with different entry and exit points, and different points of emphasis. Instead, the book's legacy might be seen as more methodological, and questioning, in nature.¹⁰⁸ First, and most obviously, it provides a prototype for historical analyses of the three-way relationship between medicine, ethics and law in other jurisdictions. Duncan Wilson's book, *The Making of British Bioethics*,¹⁰⁹ presents a very different picture to that of *Strangers*, although the core focus of the investigation is similar – how did bioethics assume its current position in British discourse, and (to a lesser extent) what role did the law play in this? It is perhaps a bit more of a stretch to see the ongoing strong critiques of the elevation of ethics (and informed

¹⁰² *ibid.*

¹⁰³ Rothman (n 1) 221. See also Rothman's account of Renee Fox's critique of individualist bioethics at 242-43.

¹⁰⁴ *ibid* 243.

¹⁰⁵ Robert M Cover, 'The Supreme Court 1982 Term, Foreword: Nomos and Narrative' (1983) 98 *Harv L Rev* 4, 4.

¹⁰⁶ *ibid* 5.

¹⁰⁷ Barron Lerner, 'Fox, Bosk, and Rothman: An appreciation of three scholars of medicine', The Hastings Center, <<https://www.thehastingscenter.org/fox-bosk-and-rothman-an-appreciation-of-three-scholars-of-medicine/>> accessed 19 August 2022.

¹⁰⁸ Matters of methodology are discussed in the chapters by Louise Austin, Sara Fovargue and Stephen Smith in this collection.

¹⁰⁹ Wilson (n 77).

consent) within healthcare as part of Rothman's legacy. Nonetheless, it could be argued that by telling 'the bioethicists tale', Rothman provided at least part of the grounding for these critiques.¹¹⁰ Certainly, the absence of this grounding can be felt in jurisdictions like Ireland where there has not (yet) been a similar foundational analysis.

Secondly, *Strangers* provides a foundation for the refutation of ahistorical, first principles reasoning in contemporary legal and ethical discourse. As one of us has argued in a critique of the approach of the Presidential Commission inquiry on research in Guatemala, 'if we create a facile narrative by designating actions simply as bad in themselves then we stand to lose an understanding of why events unfolded as they did'.¹¹¹ The problem with historical amnesia is not just that it produces an incomplete picture of a set of events, it also limits the capacity to develop appropriate strategies to deal with contemporary problems.¹¹²

Thirdly, reflecting Rothman's rejection of simple narratives and neat conclusions,¹¹³ perhaps the most important legacy of *Strangers* is the continuation of the broader conversation which it started around the delicate balance between ethics, law and medicine. In the epilogue, Rothman rejected the notion that the intrusion of outsiders had been an unalloyed good. Given this, it seems apposite to ask 'what benefits has the increased (and increasing) engagement of law and bioethics with medical practice wrought?' Certainly, one can point to individual cases and to statutory public inquiries that have revealed (sometimes truly awful) medical failings and made particular recommendations.¹¹⁴ But in the context of the many millions of interactions between doctors and the public who seek their services, the extent to which legal and bioethical engagement has resulted in a substantial improvement in the lot of patients remains open to debate. It is a depressing reality that notwithstanding that the (political) mantra of accountability¹¹⁵ has led to a whole series of regulatory interventions,¹¹⁶ patients appear to be no better protected or safer in hospitals today than they were when *Strangers* was published.¹¹⁷

In 1976, in a report on *Ethical Problems in the Delivery of Health Services* to the US Department of Health, Education, and Welfare, the sociologist David Mechanic outlined what he saw as the central concerns in protecting patients in the delivery of health care:

Given the vast differences in knowledge between the typical physician and patient and the exaggerated dependency associated with illness, patients are in a position in which

¹¹⁰ For example Roger Cooter, 'Into the whale: Bioethics in history and discourse' (2010) 23 *Social History of Medicine* 662, 664.

¹¹¹ Barry Lyons, 'History, ethics and the Presidential Commission on Research in Guatemala' (2014) 7 *Public Health Ethics* 211, 222.

¹¹² *ibid* 222.

¹¹³ Rothman (n 1) 13, 261.

¹¹⁴ For example, *Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol* CM 5207 II (HMSO 2001); *The Royal Liverpool Children's Inquiry Report* HC 12-11 (HMSO 2001).

¹¹⁵ See Chadwick and Wilson (n 75).

¹¹⁶ These include setting up specialist investigatory bodies, analysing and reporting on multiple adverse events and professional transgressions, legislation, litigation, regulatory sanction and the occasional criminal prosecution of medical professionals.

¹¹⁷ Troyen A Brennan et al, 'Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I' (1991) 324 *NEJM* 370; Christopher P Landrigan et al, 'Temporal trends in rates of patient harm resulting from medical care' (2010) 363 *NEJM* 2124; Warren Connolly et al, 'The Irish National Adverse Event Study-2 (INAES-2): longitudinal trends in adverse event rates in the Irish healthcare system' (2021) 30 *BMJ Quality & Safety* 547.

they must trust the wisdom and integrity of those who care for them. There are many potential violations of such trust, but to enumerate them or attempt to devise specific rules to prevent them is largely an exercise in futility. Most rules are easily subverted in practice; when regulations are imposed, efforts are devoted often to meeting their bureaucratic requirements without major impact on behavior; and the proliferation of regulation itself adversely affects morale and practice.¹¹⁸

This statement remains relevant today. As outlined by Robert Francis QC following the public inquiry into Mid Staffordshire NHS Foundation Trust in 2013, healthcare systems regulators exist because of repeated episodes of organisational failure and dismal stewardship, and professional regulators endure because of similar failures by doctors, nurses and other professionals to perform their duties to the required standards, sometimes to the extent that they are guilty of failing ‘to protect patients from unacceptable risks of harm and from unacceptable, and in some cases inhumane, treatment’.¹¹⁹ But this form of legal or regulatory ‘existence’ seems inherently problematic. Surely the value of the inculcation of law, bioethics and regulation into the medical world should have been the setting of robust standards and the establishment of clear frameworks that protected patients up front, rather than the establishment of inquiries and required compensation when they were harmed.

In reviewing law’s engagement with medicine, Charles Foster and José Miola have suggested that the relationship between law and medical ethics (which they take to mean the rules set down by the medical profession to regulate, and thus reflect, the corporate morality of the profession) has been dysfunctional:

the law has failed in its duty to create a coherent foundation from which [ethical] ... decision-making might properly be regulated, and this has resulted in a haphazard legal framework that contains no consistency.¹²⁰

Foster and Miola contend that, as a consequence, law has failed to advance the rights of patients, seeking rather (or achieving regardless of intent) the circumscription of medical power. Their conclusion is that law needs to step up and use its established structures, procedures, and powers to greater effect. But the historic incoherence arising from the stated dysfunction has hardly been helpful to either health professionals or patients.

Akin to Foster and Miola, Jonathan Montgomery appears less than sanguine about law’s influence on medical practice ‘seen through a glass darkly’,¹²¹ concluding that ‘the attempt to set and police moral standards for medicine from outside through the law ... failed to demonstrate much impact’.¹²² While, he states, the development of health care law was not primarily driven by the principles of medical ethics, ‘it was consciously formed in such a way as to enable them to flourish’.¹²³ Law seemed to place its trust in doctors and professional

¹¹⁸ David Mechanic, ‘Ethical problems in the delivery of health services: A Report to the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research’ in *Appendix to Ethical Guidelines for the Delivery of Health Services* by DHEW (U.S. Department of Health, Education, and Welfare DHEW Publication No. (OS) 78-OON, 1978).

¹¹⁹ *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry* (HC 947, 2013) Executive Summary 8.

¹²⁰ Charles Foster and José Miola, ‘Who’s in charge? The relationship between medical law, medical ethics and medical morality’ (2015) 23 *Med L Rev* 505, 505.

¹²¹ Jonathan Montgomery, ‘Law and the demoralisation of medicine’ (2006) 26 *LS* 185, 207.

¹²² *ibid* 209.

¹²³ *ibid* 207.

good faith, rather than telling doctors what to do through explicit rule making. The merit of this approach was that it appeared to provide a vaguely normative framework that, in principle at least, encouraged health professionals to work towards a high standard of ethics. The problem was that the law lacked the capacity, or reach, to ensure that adherence to articulated new norms actually happened.

Montgomery's concern lies primarily in what he terms the de-moralisation of medicine in the face of the increasing incorporation of market values, echoing Margaret Brazier's worries about the marketisation of medicine where '[p]atients become consumers purchasing the service of their choice'.¹²⁴ This leads us to Foster and Miola's question: 'what should be the role of the law in overseeing and intervening in issues of ethical significance?'.¹²⁵ In partial response, we return to *Strangers* and to Rothman's final challenge. The epilogue concludes, '[i]n the end, patients may well continue to experience medicine as modern, powerful and impersonal, a more or less efficient interaction between strangers'.¹²⁶ This may be the world thrust upon patients through global market forces, or, indeed, the world that increasing numbers of health consumers choose for themselves. It may be that many in the public are increasingly comfortable with medicine as a more transactional encounter provided by competent strangers, rather than a personal service delivered by professionals with whom they have an enduring and intimate relationship. While we are not advocating for such a model, it is clear that the Covid-19 pandemic has prompted new and remote ways in which patients and doctors have interacted with seemingly high levels of efficiency, efficacy and satisfaction.¹²⁷ This, along with artificial intelligence,¹²⁸ machine-learning,¹²⁹ and robotic surgery,¹³⁰ points to further changes in the relationship between doctors and the public.¹³¹

In the end, we can see *Strangers* as an origin story of the incursion of lawyers and bioethicists into the world of medicine. In it, Rothman asked important questions of what these actors have achieved, invited us to ponder their contemporary role, and to critically evaluate the capacity of bioethics and law to make a future meaningful contribution to the rights, health and security of the public in their interactions with healthcare. These remain crucial matters today.

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¹²⁴ Margaret Brazier, 'Do no harm – Do patients have responsibilities too?' (2006) 65 *CLJ* 397, 415.

¹²⁵ Foster and Miola (n 120) 506.

¹²⁶ Rothman (n 1) 262.

¹²⁷ For a review see, for example, Thomas McMaster et al, 'Current and future use of telemedicine in surgical clinics during and beyond COVID-19: A narrative review' (2021) 66 *Annals of Medicine and Surgery* 102378.

¹²⁸ Kevin B Johnson et al, 'Precision medicine, AI, and the future of personalized health care' (2021) 14 *Clinical and Translational Science* 86.

¹²⁹ Amol Verma et al, 'Implementing machine learning in medicine' (2021) 193 *CMAJ* E1351.

¹³⁰ G Gitas et al, 'Robotic surgery in gynecology: is the future already here?' (2022) *Minimally Invasive Therapy & Allied Technologies*, advance access.

¹³¹ Stephen J Swensen et al, 'Cottage industry to postindustrial care - the revolution in health care delivery' (2010) 362 *NEJM* e12.

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