

BOOK REVIEW

The Law and Ethics of Medical Research: International Bioethics and Human Rights.

Aurora Plomer, Cavendish Publishing, 2005, 158 pp., £50.00, ISBN 1-85941-687-X

The relentless expansion of human activities from purely local to global (in objective and consequence) raises many new ethical and legal challenges. With respect to medical research, the effects of globalisation are manifold, and include, *inter alia*, the increased occurrence of:

- developed world actors conducting research in the developing world (on particularly vulnerable subjects);
- utilisation by developing world actors with short research histories, weak research infrastructures, and financially challenged and inequitable settings, of novel, expensive, and potentially harmful technologies; and
- research agendas, wherever formulated or pursued, being driven in large part by commercial and market considerations.

Within this environment, stakeholders must determine how best to govern the conduct of actors operating across borders and around the world. However, more fundamentally, they must come to grips with the question of the extent to which international governance is possible at all. The history of exploitation and abuse in international human subject research does much to underline this latter conundrum.

In *The Law and Ethics of Medical Research*, Aurora Plomer engages with this debate, focusing on the governance of human subject research and its evolution from a professionally-driven ethics model to an international human rights-driven legal model. Her primary claim is that the internationalisation of such research has increased the plurality of the ethical environment, thereby inhibiting the possibility of ethics instruments (with no direct legal force) effectively governing this field. As an alternative to this regime, she turns her attention to the instruments of the international human rights movement, primarily the European Convention on Human Rights (ECHR (1950)),¹ and the Council of Europe's Convention on Human Rights and Biomedicine² (CHRB (1997)). The former is legally enforceable by states and individuals and contains rights that are particularly relevant to medical practice and research (eg: rights to life, respect for private life, etc.), whereas the latter can serve as an interpretive aid for some of the rights contained in the former.³

¹ European Convention for the Protection of Human Rights and Fundamental Freedoms, 1950, Rome, ETS No. 005.

² Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, 1997, Oviedo, ETS No. 164.

³ And this argument finds some preliminary support in *Glass v. UK*, [2004] 1 F.L.R. 1019 (E.C.H.R.).

In Chapter 1, “From Bioethics to Human Rights in Biomedicine”, drawing largely on the Declaration of Helsinki, Plomer highlights the rise of “principlism” and the difficulty of arriving at universally accepted understandings of fundamental ethical principles. While accepting the potential for broad consensus around the core of certain principles, Plomer argues that there will (always) remain indeterminacy and conflict around their boundaries. Thus, philosophically-grounded ethical guidance has limited potential to achieve uniform international application. As a consequence, she suggests, it has gradually been replaced by legal regulation grounded in human rights. She concludes that this shift in emphasis from the ethical to the legal is significant insofar as legal instruments can be enforced in courts, themselves bound by agreed procedures and canons of interpretation.⁴ [p. 16] Given her thesis, and recent references to the Nuremberg Code in medical jurisprudence,⁵ I would have preferred that instrument as the starting point and some more consideration of its past use and potential importance in the new regime.

In Chapter 2, “Human Rights and Universal Principles”, against the background of the US radiation and other (obviously) morally suspect military-sponsored research trials, Plomer addresses the universality of ethical principles and legal rights by examining six ethical principles expounded by the US Advisory Committee on Human Radiation Experiments,⁶ on the one hand, and the various “legal” provisions of the CHRB (1997), on the other hand. [see pp. 27-35] This seems a curiously narrow basis for drawing any conclusions about the universalist claim or the convergence of understanding of ethical principles (either at their core or their peripheries); surely these examples, particularly that of the CHRB (1997), exemplifies a politically negotiated morality from which, in the absence of much greater reference to the constellation of relevant international instruments, very little can be concluded.⁷ Having said that, the chapter does make clear the need for flexible, enforceable, and overtly morally engaged international regulation in the human subject research arena.

The following three chapters consider three particularly controversial types of research and their interaction with international (and predominantly European) human rights instruments. In Chapter 3, “Non-Therapeutic Research: Domestic Remedies and Convention Rights”, Plomer tests the allegations surrounding the UK Porton Down chemical weapons experiments against existing legal remedies and judicial

⁴ Despite this shift, Plomer has not convinced me that the legal framework introduced by international human rights instruments is significantly more determinate (as far as its primary legal principles are concerned) than the ethical framework it is “replacing”.

⁵ In *Grimes v. Kennedy Krieger Institute* (2001), 782 A. 2d 807 (Maryland C.A.), it was applied, whereas in *Abdullahi v. Pfizer Inc.*, [2005] W.L. 1870811 (N.Y. Dist. Ct.), it was noted as being non-binding, but in both cases, it figured into the courts’ analysis.

⁶ Advisory Committee on Human Radiation Experiments, *The Human Radiation Experiments: The Final Report of the Advisory Committee on Human Radiation Experiments* (NY: OUP, 1996).

⁷ I believe that a more holistic evaluation, drawing on a more inclusive list of widely subscribed to instruments would strongly suggest that there are universally recognised values. Like Plomer, I recognise that differences in their interpretation, particularly at the boundaries, endure, and I am not so naïve as to believe that that will soon change. Stakeholders are self-interested, positions are entrenched, precarious power (im)balances are vigorously defended. As a realist, I believe that any attempt to draft a normative international rights instrument that is directive and enforceable is doomed to failure, at least in the short term. As such, the best we can hope for is a negotiated pseudo-moral order which might well be little more than a race to bottom.

decisions, and then offers some suggestions as to the potential effect of the ECHR (1950) as an interpretive tool. [pp. 60-64] In Chapter 4, “Embryonic Stem Cell Research: Human Dignity and the Right to Life” Plomer notes the divergence of ethical opinion on the status of the embryo, linking it to conflicting interpretations of human dignity, and states that:

... the unprecedented and massive increase in references to human dignity in the new human rights instruments in biomedicine does not conclusively dispel the uncertainty and controversy regarding the scope of application of the concept [p. 74]

She concludes that, despite continuing ethical discord, there is some evidence of legal convergence (in a number of jurisdictions) insofar as the embryo (the person in potentia) has no status at law that would trump the rights of the woman (the person in being). In Chapter 5, “The Rights of the Dead: Research on Human Tissue and Body Parts After Bristol and Alder Hey”, Plomer rehearses various moral arguments for respecting the dead and revisits the common law position of denying property in the body.⁸ She claims that neither the property nor the consent model are adequate to govern this field, rather suggesting that a human rights framework (ie: the ECHR (1950)) could be extended to protect the dead while recognising the legitimate public interest in some forms of interference with the corpse for publicly beneficial scientific purposes.⁹ [pp. 105-111]

Chapter 6, “Research in Developing Countries: New Ethics and New Threats to Human Rights”, notes the recent phenomenon of exporting human subject research to less developed countries, and highlights the difficulty of regulating same. Plomer states that:

... there are compelling reasons to doubt that the framework of guidance offered by the (Helsinki) guidelines may be sufficient to prevent abuse in practice. One major source of concern is the absence of overarching regulatory mechanisms to monitor and control adherence to the guidelines, even less to exact compliance and impose penalties for breach. The guidelines assume that Research Ethics Committees (RECs) may be entrusted with the task ... but ... in developing countries, where research infrastructures are practically non-existent, there are no RECs to review research protocols. [p. 126]

She then considers the potential impact of the ECHR (1950), interpreted in conformity with the CHRB (1997) and its relevant Protocols, on human subject research conducted in developing countries. Ultimately, she concludes that aggrieved participants hoping to vindicate their human rights through this instrument in the

⁸ A rule that is open to challenge, morally, legally and pragmatically: see S. Harmon, “A Penny For Your Thoughts, A Pound For Your Flesh: Implications of Recognizing Property in Human Body Parts” (2006) 7(4) Med. Law Int. 329-354.

⁹ Once again, I am left unconvinced by her argument insofar as I am not convinced that the human rights model, which is clearly associated with the concept of consent, is relevantly distinct from these models, particularly the consent model that she challenges.

European Court of Human Rights would have to overcome significant and in some cases fatal hurdles. [p. 134]

On the whole, Plomer's book is interesting, informative and generally well researched with respect to the main ethical and legal issues in this field, and, as such, it is a useful resource. However, it suffers from a number of shortcomings which detract from its overall effectiveness. Most importantly, it suffers from a startling lack of continuity from one chapter to the next; their sometimes abrupt end and a regrettable absence of conclusions means the sometimes disparate contents of the chapter are neither drawn together nor linked to the overall themes of the book. This hinders a robust comprehension and testing of her primary theses. Related to this is (1) the inconsistent deployment of relevant instruments and case studies, which make one think that this is not a unified text but rather a collection of articles,¹⁰ and (2) the troubling formatting (ie: the sometimes curious conception of section headings, which do not seem to transition smoothly or logically from one to another), which made understanding the argument more difficult than it should have been. Finally, and this may admittedly be a trifling complaint, the reference to Blackmun LJ and his "speech" in *Roe v. Wade*¹¹ was unfortunate. [p. 91] As an Associate Justice of the US Supreme Court, he is Blackmun J., and he rendered the "majority opinion" or "majority decision". Despite these reservations, I believe this is a worthy and stimulating read which draws profitably from the author's legal and philosophical experience, and it represents a useful tool for anyone who is interested in human subject research, bioethics and emerging biolaw.

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¹⁰ For example, I would have preferred a more consistent reference to and use of both the key instruments (eg: the Nuremberg Code, Helsinki Declaration, ECHR (1950), CHRB (1997)) and the core case studies (eg: US radiation trials, UK Porton Down trials, international Pfizer trials) throughout the book as a recurrent means of testing her claim that rights are more determinate than ethics.

¹¹ (1973), 410 U.S. 113.