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BOOK REVIEW

Who's watching the watchers?

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Janice Parente, *Ethics on Trial: Protecting Humans in Canada's Broken Research System*. Dundurn Press, 2025. 240 pages. ISBN: 9781459755970 (paperback); 9781459755994 (ePub)

Everyone wants to be the next global biopharmaceutical hub. Chasing high-value jobs and economic spillover benefits, governments increasingly view the function of regulatory bodies as facilitating economic development as much as protecting public safety and well-being. Canada, amongst other countries, has employed expedited and flexible drug approval pathways, predictable approval timelines, and pre-submission consultations with sponsors to help industry navigate the regulatory process. This aspect of the "industrial medical complex" has been the subject of considerable discussion.

But there is another uncomfortable regulatory conflict of interest in Canada's biopharmaceutical sector; one that has received much less attention. This is the subject of Janice Parente's book. Researchers in Canada, as in most jurisdictions, must receive ethics approval to engage in projects that involve human research subjects. If a researcher is situated within a university or health authority, then those respective institutions will expect researchers to receive approval through their in-house Research Ethics Boards (REBs). These REBs, in turn, are guided by expectations outlined by Canada's key funding agencies in the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans. As universities and health authorities are sensitive to liability, they generally (but, as the author states, not always) endeavour to ensure a suitable level of protection for research participants.

Yet private companies do not always rely on partnerships with universities or health authorities. They may bypass these institutions and recruit subjects through individual physicians, other healthcare providers, or even non-health-oriented institutions such as schools. In such cases, they will use a private Contract Research Organisation (CRO). CROs can perform discrete functions, including the administrative logistics of clinical trials (such as study protocols and regulatory submissions), recruitment, and data analytics. They will often have an in-house REB that will provide assurance that a study meets the appropriate ethical requirements. Larger (usually multinational) CROs may also subcontract services to site management organisations.

The nub of the problem is in not clearly spelling out exactly what constitutes "appropriate" ethical requirements. REBs must have sufficient expertise to evaluate study protocols, but — much like physicians — the assumption is often that their professional judgement of what proper ethical parameters are is sufficient. Yet private CROs have a clear commercial interest in facilitating the interests of their clients. As Parente graphically documents, companies will naturally gravitate towards CROs with more lenient REBs that will provide a stamp of approval on practices that are preferred by the company. The more ethically stringent an REB, the less commercially attractive it may be. And, to paraphrase Upton Sinclair, it is difficult for an organisation to see ethical problems, when their profits depend on their not seeing them.[1]

So, the simple existence of "REB approval" for studies should not provide much reassurance. The deeper issue that Parente highlights is the question of who, precisely, watches the watchers. If REBs constitute the ethical safeguards that underpin our trust in medical research, then who oversees the REBs to ensure they are doing their job properly? And the unsettling answer that Parente gives — especially for private REBs is: no one.

Ethics on Trial is not an academic treatise; it is an unapologetic *j'accuse* targeting a regulatory state that seems disinterested in fully regulating the protection of research participants. What makes this book compelling is that the author was herself the head of a Canadian CRO. This gave her tremendous insight into the limitations of the governance protocol for research ethics, but — paradoxically — it seemed also to undermine her ability to change the system. Based on her professional experience in the bioethics industry, Parente's book is actually two quite distinct stories.

The first narrative documents in granular detail ways in which the ethics approval system allowed research participants to be subjected to serious harms, and the reason why these practices were permitted. This section raises issues not uncommon in the literature on bioethics: what, exactly, *is* "informed" and "free" consent? What constitutes a "harm"? What kind of risks must be identified? Does withholding data behind a wall of "commercially sensitive information" itself undermine informed consent? What are, or are not, "acceptable practices", and according to what standards? How long can research subjects be

confined? How extensive should screening be? Should research participants be paid for their involvement and, if so, how high should these payments be allowed to go, and at what point in the process should participants receive their remuneration? What standards should govern recruitment advertising?

These are real issues, and they highlight the difficulty in establishing concrete standards that can be applied across different contexts. But "difficult" is not a synonym for "impossible", and the second part of the book sets out the author's attempt to establish a framework for the formal oversight of REBs in Canada. The obvious strategy for oversight is formal accreditation, which includes a protocol for auditing, resources for training and administration, and clear lines of iterative communication between parties. All organisations with "protection programs" should be accredited, and this requirement must be embedded in governmental laws, regulations, and policies at the appropriate levels. The standards would have to be developed by a professional standards development organisation, and consistent funding streams would have to be established.

Parente documents the attempts made in Canada between 2005 and 2013 to develop a governance system for human research. These undertakings were ultimately unsuccessful. So, following her experience in accrediting her company with the American Accreditation Program, she began in 2017 to establish a private non-profit organisation, Human Research Accreditation Canada (HRA Canada), as well as a body (Human Research Standards Organization) accredited by the Standards Council of Canada to develop standards for human research in 2020.

What is remarkable in this narrative is the extent of the pushback against such an endeavour. Parente documents, with palpable frustration, the consistent refusal by public organisations to sanction or get involved with this regulatory exercise. Material from multiple freedom-of-information requests illustrate not only the disinterest on the part of key stakeholders, but also their suspicion and dismissal of the project itself. There was, unsurprisingly, disinterest from the *private* CRO industry: why agree to a system of accreditation that would limit their freedom to provide services palatable to their clients? The deeper mystery was why at least two key national organisations dedicated to ethical research would show a gamut of negative responses from disinterest to hostility.

Readers may feel that the speculative explanation for this behaviour has not been sufficiently analysed. The question of why such resistance existed amongst the bodies most responsible for the governance of bioethical standards is a critical one, and merits more probing.

There are at least three possible explanations, none of which excludes any other. The first — no surprise to anyone working in government (and the one Parente suggests) — is jurisdictional turf protection. The Secretariat on Responsible Conduct of Research and the Canadian Association of Research Ethics Boards were the two organisations best placed, and least willing, to participate. Neither body claimed any jurisdiction over private REBs, and yet they were antagonistic towards any attempt to impose accountability on these private bodies. Why? Because if the new HRA Canada organisation were given authority over REB protocols per se, including researchers funded by the three national research agencies, these organisations would see their authority over public REBs diminished.

Another possibility is the covert influence of the very stakeholder that would be most affected by a stricter regulatory protocol: the biopharmaceutical industry, which benefited under the status quo from the ability to shop around for the most amenable REBs. Interestingly, the pharmaceutical industry figures very little in the second part of Parente's narrative. It is possible that they were not a player in this drama at all; although, with so much at stake, it does not seem likely they would remain complacent regarding a tighter research ethics protocol, especially given the behaviour documented in the first part of the book. This industry is adept at working under the radar (through, for example, lobbying stakeholders or funding third-party advocacy groups), and it would have been interesting to know whether and how they could have influenced public stakeholders in this instance.

The third explanation is the most singular. This is the possibility that the role and function of Parente's new body was simply not clearly understood. Parente documents numerous instances of hostility focused on the "private" nature of the organisation: one correspondence stated that "we have some concerns with a 'for profit' organisation coming forward and declaring their standard to be the national standard"; another noted that "from what I can see, is that they want to make this a profitable initiative … Personally, I think that they want to privatize the whole ethics review/monitoring process". In the Canadian healthcare environment, "public" and "private" are drawn sharply in black and white; what isn't public is automatically suspect. The function of independent non-profits is often poorly understood despite the widespread presence of Accreditation Canada in ensuring standards at most healthcare facilities across the country. Indeed, the point of making accreditation agencies private non-profits is so that they are beyond the interference of partisan government interests. The very fact that HRA Canada was not a public body was enough to indict it and lead ill-informed interests to accuse it of perpetuating precisely the problems it was seeking to solve. In sum, the case for a disquieting phenomenon — one that remains largely invisible to the wider public — is well-made, but the explanation for it is more indeterminate.

Nonetheless, this is a useful and accessible work for those interested in establishing a formal protocol for the governance of research subjects, even if the institutional

context differs considerably across jurisdictions. Interestingly, Canada's highly decentralised federal system, often an impediment to national policy development, also facilitates more points of access for new endeavours. Despite being snubbed by national organisations and some of the larger provinces, HRA Canada has been embraced more enthusiastically by smaller provinces. Reflecting the competition between nation-states, Canadian provinces too are increasingly competing amongst themselves to host clinical trials, and the ability to boast accredited research standards may be seen as a competitive advantage. Whether the shining promise of biopharmaceuticals as a pathway to economic development is well-considered remains to be seen; but there would be some comfort in knowing that this strategy cannot capitalise on the predation of the most vulnerable.

Note:

[1] In his memoir of the 1934 California gubernatorial campaign, Sinclair wrote that "It is difficult to get a man to understand something, when his salary depends upon his not understanding it!" He was reflecting on why it was that mainstream commercial newspapers could not (or would not) grasp the systemic failures of a profit-only oriented growth strategy.

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