

"Medical Research for Hire: The Political Economy of Pharmaceutical Clinical Trials"

Jill A. Fisher, 2009, 257 pages, Rutgers University Press, \$24.95

Review by Norman M. Goldfarb

"Medical Research for Hire: The Political Economy of Pharmaceutical Clinical Trials" is a hard book for clinical research professionals to love, but it is worth reading because of the provocative issues it raises.

The book is unpalatable for six reasons:

- The book's principal thesis is that clinical research is fundamentally corrupted by financial motives, which cause all the players to rationalize their actions to justify exploitation of uninsured and impoverished study subjects that "neoliberalism" offers up as unwilling victims. For those unfamiliar with the liberal political lexicon, neoliberalism is the opposite of traditional liberalism; the neoliberal state "transfers responsibility to its citizens to provide for themselves," e.g., through welfare reform, and then gives them the freedom to get a job. The clinical research industry exploits structural aspects of society, such as poverty, lack of insurance, race and gender to enroll subjects in clinical trials with no real, autonomous ability to protect themselves. "Participation in clinical trials becomes almost a duty for those who have no other access to health care because it is available as a 'choice.'"
- The author builds her argument on interviews, averaging 40 minutes in length, with 10 physician-investigators, 18 study coordinators, three recruiters, nine site administrators, CRO representatives and monitors, and 14 study subjects. No demographics or quantitative data is provided. This type and amount of research is enough to generate interesting hypotheses, but not the solid conclusions the book presumes to draw. The author advances her argument with footnoted statements but says little about what the sources actually said and the soundness of their methods or conclusions. For example, the only data provided to support the conclusion that "pharmaceutical studies in the United States are overwhelmingly conducted on uninsured and impoverished citizens" is: "...one research team did collect data on the insurance status of their participants and found that uninsured individuals were seven times more likely than those with insurance to enroll in their cardiac drug studies." The author compromises the integrity of her argument with statements like, "Native Americans and Latinos also have been targeted for medical experimentation... One well-documented example occurred during the 1940s and 1950s when Navajos were employed to mine uranium that would be used in military research for bombs." And "...the blockbuster-seeking mentality... propels... developing largely 'me too' drugs."
- The book includes enough factual errors and misleading statements to impeach the author's objectivity and expertise about clinical research, for example: "Presently, there are only four SMOs operating in the United States"; "Study brokers — sometimes referred to as trial management organizations..."; "PDUFA requires that companies pay applications [sic] fees to subsidize the FDA clerks..."; "Private research [not "funded by federal money"] is not required to follow the federal requirements... Although the FDA has its own regulations for human subjects research... it only governs research directly leading to the marketing of products"; "...physician-investigators earn [i.e., profit, not revenue] an average of \$5,500 per

subject enrolled... Conducting clinical trials is remunerative"; "Most [physicians] offer nutraceuticals"; "...the system of monitoring as it is now organized by the clinical trials industry is technically voluntary." "The Fiddes case led to the amplification of monitors' duties to make fraud detection the primary objective of site visits."

- The text is peppered with jargon that may be common in bioethics seminars, but is foreign to most clinical research professionals: "decontextualized," "historical contingencies," "valence toward participation," "identity construction," "work intensification," "meta-level," "mobilizing informed consent," "reifies the logic," and "neoliberal audit culture." These terms mark the author as "other," but she must have found our jargon even more impenetrable.
- The book analyzes investigators, study coordinators, site monitors, and study subjects through the lens of gender analysis. (The author's previous faculty appointment was Assistant Professor of Women & Gender Studies Program.) For example: "That nurses and coordinators are women is not incidental to the devaluation of their work... there is a perception that any woman could replace them..."; "Their specialized knowledge and skills get overlooked because of their gendered position in the industry..."; "With women predominantly filling the ranks, monitoring, like coordinating, is feminized labor that the industry considers unskilled"; and "Male coordinators are more likely to be treated as physician's peers."
- After going to immense efforts to castigate the clinical research enterprise, the complete and entire remedy the book proposes is that "universal health care may be the best defense in creating an ethical system of research and development" and more discussion of the issues is necessary.

On the other hand, it is worth holding your nose through the misinformed and obnoxious passages to get to some really interesting perspectives on clinical research. The clinical research enterprise certainly has ethical challenges that deserve attention. Any of the following perspectives should provoke a spirited discussion among thoughtful clinical research professionals:

- "... the worst cases of abuses to human subjects occurred not because of the treatment of individuals but because of the treatment of groups."
- "By ignoring other types of vulnerability to research abuses, the regulation[s] effectively cast all other human subjects as equally 'autonomous' and able to protect themselves through the informed consent process... As a result, those who have important structural reasons for participating, such as poverty, lack of insurance, and/or illness, must protect themselves individually through the informed consent process..."
- "Physician-investigators, however, cannot counsel [obese or irritable bowel syndrome] study subjects to make these lifestyle changes unless they are explicitly included in the clinical trial protocols."
- "...the relationships that coordinators develop with patient-subjects to encourage them to enroll in drug studies also create conflict over determining to whom they have obligations, the pharmaceutical companies or the patient-subjects. Thus, the role imposed on coordinators as part of their job descriptions — producing data for the pharmaceutical industry — is not sufficient for most coordinators' professional identities. Instead, coordinators construct an alternative role that situates their work in terms of mediating the ethical conduct of drug studies through their care for patient-subjects... Rather than simply caring for the health of patients,...coordinators ensure the protection of subjects within the clinic."

- "...coordinators'... sense of altruism spills over to create an imperative that altruism should also be the motivation for patient-subjects to participate in medical research... coordinator's mobilization of altruism can lead to the further exploitation of disenfranchised groups."
- "...monitoring is a job for which women are better candidates than are men because it requires attention to details, intuition and interpersonal skills. Many in the clinical trials industry believe that women are better suited to the work than men because most men would view the tasks as too tedious or onerous... Women are better able to give [feedback about mistakes] in a less threatening and more diplomatic way... women monitors are said to place more emphasis on cooperation or teamwork... Women are better at not *appearing* to have more power."
- "Women are perceived as being compliant, docile patient-subjects who express more trust in their physicians and the research enterprise than do men... Clinical trials pose a risk to patient-subjects' time and energy, and this too is often a risk men are less likely to take than are women."
- "Most decisions about participating in clinical trials occur prior to the formal process of informed consent... The vast majority of potential subjects are generally uninterested in the information contained in consent forms... The act of consent can only occur in the context of choice, of having an option of not agreeing. But if one is desperately ill, very poor, or unable to access necessary healthcare, then one may feel no choice but to consent... Informed consent appears to work as intended by regulators only to discourage patients from participating in efficacy studies that carry extreme risk or inconvenience... In fact, informed consent is transformed into a tool to enhance the compliance and control of subjects for increased profit and decreased liability for the industry as a whole."
- "...coordinators understand the consent process as an effective mode of teaching patient-subjects the 'responsibility' associated with clinical trials... This helps to explain why sites often stress revisiting informed consent at each visit even when IRBs do not require it."
- "...treatment-naïve populations could be better understood as treatment-bereft..."

The book consists of nine chapters:

- Clinical Trials: Coming Soon to a Physician Near You
- Governing Human Subjects Research
- Pursuing Contract Research
- Coordinating Clinical Trials
- Monitoring the Clinical Trials Industry
- Recruiting Human Subjects
- Mobilizing Informed Consent
- Cultivating Pharmaceutical "Compliance"
- Changing Markets in Pharmaceutical Research

The book is available in bookstores.

Reviewer

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information, consulting and training services. Contact him at 1.650.465.0119 or ngoldfarb@firstclinical.com.