

"Riding the Green Wave: Financial Conflicts of Interest in Industry-Sponsored Clinical Research"

Patricia M. Tereskerz, 2007, 227 pages, University Publishing Group, \$24.99

Review by Norman M. Goldfarb

"Riding the Green Wave: Financial Conflicts of Interest in Industry-Sponsored Clinical Research" provides an in-depth discussion of the topic for academics who must deal with the financial conflicts of interest inherent in industry-sponsored research.

The author is unambiguous in her distaste for financial conflicts of interest because "medical

researchers are sentries at the portals of life and death....The mere presence of a conflict of interest, whether acted upon or not, in all likelihood always injures the integrity of clinical research and researchers." In this light, industry-sponsored research in academia is problematic at best.

The book includes ten chapters:

- An Overview of Clinical Research Funding and Conflicts of Interest: Defining a Financial Conflict of Interest
- How Financial Conflicts of Interest in Clinical Research Evolved: A Recent Passage through Time
- The Fallout: Realizing the Effects of Financial Conflicts of Interest in Clinical Research
- Policies and Regulations on Conflicts of Interest in Research
- Beyond Federal Regulations: Legal Ramifications of Financial Conflicts of Interest in Clinical Research
- A Recent Clinical Trial Involving Financial Conflicts of Interest: Applying Traditional Legal Theories
- Is There a Constitutional Right to be Treated with Dignity within the Context of Medical Experimentation?
- Financial Conflicts of Interest and Potential Statutory or Regulatory Violations
- The Other Side of the Coin: Potential Liability for Overly Restrictive Employment Policies
- Developing a New Model: Preserving Scientific Objectivity, Trust, and the Informed Choices of Human Subjects

It would appear that an individual investigator who enrolls five subjects can do little to influence the results of a large multicenter study. However, the conflict can act in more mysterious ways. For example:

- Should a key opinion leader (and well-paid consultant) lend his or her name and reputation to a ghost-written publication?
- It is well-established that clinical research sponsored by pharmaceutical companies tends to yield results that favor the sponsor's products. If this

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- favoritism results from biased design, e.g., the dosage of an active comparative product, should the academic researcher decline to participate?
- If a clinical study constitutes no more than industrial product testing, is it appropriate for the academic researcher to participate if the sole purpose is to help his or her department meet its revenue goals?
 - While one investigator may not make a difference, one-hundred investigators acting under the same influences can make a large difference. What is the responsibility of each individual when others are standing in line to take his or her place in the study?
 - When an investigator submits a proposal for an investigator-initiated study to a sponsor, is it possible that consulting relationships and other financial influences unconsciously influence the study design?

The book relates a story of financial conflict of interest from the dawn of clinical research in the United States. In 1798, Benjamin Waterhouse, one of three full-time professors at Harvard Medical School, obtained a copy of Edward Jenner's treatise on cowpox vaccination to prevent smallpox infections. In 1800, he successfully tested the vaccine and then created a commercial monopoly on its use. In this and other disputes, he so enraged the other two professors that he was expelled from the Harvard faculty in 1812.

The book points out that, while insurance salespeople and mortgage brokers are legally required to disclose the amount of commission they will earn on your transaction, clinical research investigators are under no such obligation to subjects in their trials. If there is a disclosure, it is only that the sponsor is paying the site to conduct the research. While the FDA collects financial disclosures with new drug applications, the Agency holds the information in confidence, so monitoring and analysis by the public is not possible.

The author proposes a solution to the financial conflict-of-interest morass. This review cannot do justice to her proposal, but it involves an independent research brokerage that would serve as middleman between industry and academia. Competing investigators would propose trial designs to accomplish the sponsor's research purposes and have complete control over resulting publications. Competing investigators would disclose their financial entanglements for consideration in the selection process. As the author notes, "There appear to be few incentives for industry, investigators, and research institutions to support this model." Nevertheless, the alternative appears to be business as usual with a bit of fine-tuning.

The book does not cover other conflicts of interest that are endemic to academic institutions such as institutional politics and the imperative to publish or perish. These conflicts may be even more corrupting than filthy lucre.

The book is available in bookstores.

Reviewer

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