

# **What The Doctor Didn't Say**

## The Hidden Truth About Medical Research

A book review by Perry Mill

Authors: Jerry Menikoff with Edward P. Richards

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The authors of this bound-to-be controversial book examine whether participation in medical research is beneficial to research subjects, and they conclude that for the most part it is not. Written largely from a legal perspective, the authors, both law professors, contend that medical research subjects need to be, but are often not, informed that by participating in research studies, their own health is of secondary importance compared to the health betterment of future cohorts of patients.

Menikoff and Richards find even the “gold standard” of informed consent for prospective medical research subjects to be inadequate. They argue that this deficiency is paternalistic and often deceptive. They also cite several examples, of risks and harms inflicted on naïve research subjects; as well as the illusory benefits (i.e., only a 50 percent chance of being allocated to the treatment group) of randomized, controlled medical research studies.

The authors point out the inadequacy and inconsistency of laws, regulations, incentives, and their application, which govern the enrollment in medical research studies, of individuals with diminished capacity.

Written in the context of American tort law and experience, which is widely recognized as being more litigious than the Canadian experience, the authors point to the limited legal protections afforded research subjects as compared with non-research patients, whose clinicians must meet a legal standard of care for them. In emphasizing the problems with informed consent in research studies, the authors also accept at face value the effectiveness of, and minimize or completely ignore the real difficulties in, gaining patients' understanding of the risks inherent in standard medical (i.e., non-research) care.

One of the recurring themes in “What the Doctor Didn't Say” is that medical research subjects are rarely, if ever, informed by researchers that they may be eligible to acquire “experimental” therapies outside of research studies (e.g., “off-label” medications). Making research subjects more aware of this possibility, however, can and would impede researchers from being able to recruit enough subjects for their studies.

Menikoff and Richards conclude their extensively-referenced and thought-provoking text with an example of a contentious and ethically-questionable approach to address the simultaneous “loophole” for patients and barrier for researchers, mentioned above: an imposition by health-care providers of limits on the kinds of treatments individuals can get *outside* of research studies. Such an approach may well reduce disincentives to

participating in medical research, whose inherent goal is to benefit all of society, but it would simultaneously conflict with the fiduciary duties clinicians have to care for their patients.

This dilemma raises difficult questions in the book's final chapter, regarding who gets to impose these limits, what authority they could claim in doing so, what the ethical implications would be for the clinician-client relationship, and how to legitimize restricting access to new therapies outside of research studies in a society, which values both individual choice and the public interest.

"What The Doctor Didn't Say" would be an excellent read for those involved in research and others who are interested in the question of who benefits from medical research and who does not.