Doctor vs. Scientist?

By LYNN A. JANSEN

Reflection on the ethics of clinical research has a history. The fact that physician-investigators have conducted much of the research on patient-subjects shapes this history and, not surprisingly, generates much concern about whether their dual roles are compatible. For example, can a physician-investigator who conducts a randomized controlled trial reconcile his therapeutic obligation to provide medical care for his patients with his research-based obligation to engage in sound scientific practice? The principle of clinical equipoise was advanced to allow physician-investigators to meet both therapeutic and research-based obligations.

But perhaps the ethics of clinical research needs to leave behind any concern with therapeutic norms. This is the course of action boldly recommended by Steven Joffe and Franklin Miller in their engaging paper "Bench to Bedside: Mapping the Terrain of Research Ethics." Rather than viewing clinical research on patient-subjects as sui generis, Joffe and Miller situate it in a spectrum of activities spanning from laboratory science to experiments on nonhuman animals to research on human subjects, whether they are sick or well. What unifies these disparate activities is the shared goal of advancing knowledge that aims to improve human health, and the set of norms, constitutive of sound scientific practice, that governs them. What differentiates them is the different "experimental materials" they employ—bacteria, rats, human beings, etc.—which are subject to less or more demanding ethical constraints depending on their moral status.

Joffe and Miller point out that the failure to distinguish clinical research from therapeutic medicine encourages the so-called therapeutic misconception. If physician-investigators consistently viewed themselves as scientists and not as physicians, then misunderstandings about the nature and purpose of clinical research would likely be reduced. However, they stop short of recommending a sharp institutional separation between therapeutic medicine and clinical research, suggesting instead that physician-investigators can avoid therapeutic obligations to patient-subjects by changing their self-conception. Arguably, this ignores the social dimension of role obligations. Joffe and Miller acknowledge that patient-subjects in clinical trials have "deep-seated expectations for optimum treatment." Physician involvement in these trials encourages these expectations. Indeed, the practice of research on patient-subjects likely depends on physician involvement, for physicians may be needed to recruit sick patients into clinical trials. If so, the entanglement of clinical research and therapeutic medicine is not a historical accident.

Joffe and Miller helpfully outline a number of ethical constraints on clinical research involving patient-subjects. These constraints are not themselves derived from a scientific orientation to clinical research. While consistent with scientific practice, they are imposed on it. In itself, this is no criticism. Joffe and Miller's proposal aims to free the ethics of clinical research from its historical preoccupation with therapeutic norms. Yet whether a thoroughly nontherapeutic approach can yield an adequate account of ethical constraints remains to be seen. The bench to bedside framework does not address the crucial problem of determining, in a reasonably precise and principled way, the level of acceptable risks of harm that can be imposed on patient-subjects in the course of clinical trials. Joffe and Miller do say that trials should not impose an "undue" level of risk on patient-subjects. But what is needed is an account of what would constitute an undue level of risk.

Without this, it is hard to assess the claim that the ethical constraints on research involving patient-subjects should avoid any therapeutic obligations. Joffe and Miller suggest that patient-subjects consult their own physicians prior to enrolling in a clinical trial. But if the physician is competent, she will recommend against participation in trials contrary to her patients' best medical interests. In effect, this looks like a therapeutic restriction on ethically acceptable recruitment practices. Some patient-subjects may desire to participate in the valuable activity of advancing scientific knowledge against the advice of their physicians. However, the vast majority of sick patient-subjects likely do not feel this way.

Joffe and Miller's imaginative proposal succeeds in showing that a purely scientific orientation to clinical research does not entail a morally anemic view of the investigator-subject relationship. But will the ethics of clinical research fare better if it eliminates all reference to the therapeutic obligations of physicians? An answer to this question requires a deeper engagement with substantive ethical theory. It cannot be answered by situating research on patient-subjects along a spectrum of biomedical scientific activities.

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