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From the Editor

Medicine in an Age of Science

The theme editor introduces a special issue examining the balance between medical research, patient safety, and medical ethics.

At few other times in a long and illustrious history stretching back to Hippocrates has it been so exciting to be a physician. At the beginning of a new millennium heralded by the sequencing of the human genome, the promise of medical breakthroughs built upon a foundation of translational research shines brightly indeed. Yet the unprecedented pace of discovery in the biological sciences and the tremendous potential for advancement in the treatment of such scourges as cancer, neurodegenerative disease, and HIV do not come without a cost. For while the developments of the laboratory have given clinicians the expanded arsenal with which to attack the very DNA of a tumor or the enzymes of a retrovirus, they have also constructed a chasm between experimental science and effective clinical care that can only be bridged by a chain of human research subjects.

How do we respect the most universally recognized creed of the physician—first do no harm—when our ability to advance as a profession depends on at least some of our patients undergoing treatments that are not yet known to be efficacious and may in fact turn out to be quite harmful? How do we best regulate the design, operation, and reporting of clinical trials so that the ethical and professional demands of both science and medicine are satisfied? How do we define what constitutes "medical research" and how is the next generation of physicians, today's medical students and residents, educated to understand this process? How do we face the repercussions of a situation in which both patient and physician are willing to extend the accepted boundaries of medical care in pursuit of a second chance at life for the former? How do we sustain the integrity of the research relationship when vast sums of money are at stake? In short, how do we protect the patient when the patient is also a human research subject?

The November issue of *Virtual Mentor* centers around this theme of protecting the patient and presents a series of articles which expand upon some of the questions at the heart of this discussion. In the first case commentaries, David Alberts and Lucy Godley tackle the challenge of clinical trials as an option for patients with a terminal illness, those individuals simultaneously having the most to lose and the most to gain by participating in an experimental protocol. In the next pair of commentaries, Charles Weijer and Karen Kreiner weigh in on a different dilemma: how to consider experimental therapies for a patient with a disease for which successful treatments are already available. In the final clinical case, Vijaya Arekapudi comments on the rarely discussed middle ground—the actual process of conducting the clinical trial rather than its design or analysis—when things don't go as planned.

Following the clinical cases, the next set of articles begin to construct the social, legal, and policy framework of human subjects research. In their journal discussions, Alison Bickford and Abe Schwab shed light on 2 cornerstone topics: academic-industry partnerships and clinical equipoise, respectively. These analyses complement the related issues addressed in the 2 Policy Forum articles and the Medicine and Society piece. The risks and benefits in creating a clinical trials registry are expanded by Christian Krautkramer and Shane Green, while Daniel Carpenter takes up a related theme in his analysis of the FDA as the primary regulatory body for human subjects experimentation in the United States. Michael Berens and Gary Marchant consider the corollary social, legal, and scientific questions raised by advances in scientific technology; a legal analysis is further extended in Laura Lin and Bryan Liang's discussion of the *Wright v. Fred Hutchinson* case.

Finally, in keeping with its interdisciplinary tradition, this issue of *Virtual Mentor* also includes several pieces that speak to the humanities. Stephen Leapman and Sharon Moe reflect on past developments and the need for future

advances in the way in which medical students and then residents are trained to sustain and support medical research. Dr. Victoria Maizes and Dr. Randy Horwitz expand our consideration of medical research to encompass complementary and alternative medicine. Helle Mathiasen harnesses the power of literature, in this case a fictionalized account of a 19th–century Japanese surgeon who experiments on members of his own family, to express the complex connectedness of humanity. Yet perhaps most compelling is the story that is also autobiography. In a fitting conclusion for this particular issue of *Virtual Mentor,* Tricia Higgins reminds us of medicine's true central figure: the patient.

Together, these articles challenge us to consider anew the tenets of bioethics as applied to medical research while simultaneously moving inward to identify the unique role of the physician as a liaison between a patient and her disease. The ability of the physician to serve in this capacity depends on our ability to first identify, then seek to understand, and finally begin to address the questions arising from the paradigm of modern medicine. If the history of medicine makes one fact painfully obvious it is that no achievement, no matter how remarkable, occurs in a vacuum. The shadows cast by the physicians of the Third Reich or by those conducting a small study in the backwoods of Tuskegee County, Alabama, provide a stark reminder of the consequences of allowing the quest for knowledge to trump personal integrity. Advances in medical science are hurtling us at record speed towards the future of medicine; the time to address the challenges of bioethics and professional responsibility raised by human subjects research is today, not tomorrow.

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