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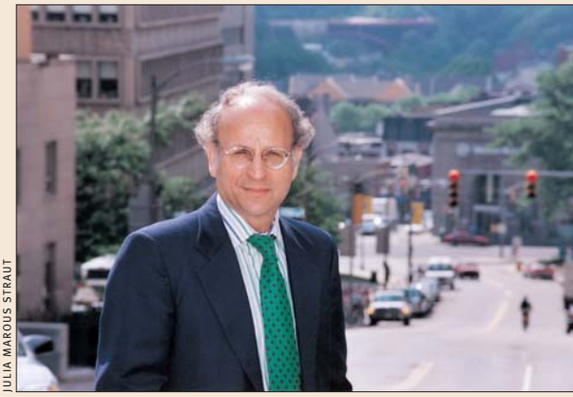
"If I didn't do it, who else would? There are a lot of people out there younger than me who need to know what [drugs] to take." These words were uttered a couple of years ago by Dorothy, a woman who participated in a clinical trial here for an osteoporosis drug; her participation was covered by this magazine. Dorothy's example makes me think of what Mason Cooley said about generosity—it knows how to count, but refrains. Patients volunteering for clinical trials truly are altruistic and courageous.



JULIA MAROUS STRAUT

Many such trials simply seek to establish the maximum tolerated dose of a new drug when the actual efficacy of that drug is not yet being tested. Other trials have a control arm, in which patients may be randomly assigned to receive the best known treatment for a disease. (Infrequently, the best known treatment may be no treatment, i.e., a placebo.) Patients in the "experimental" arm receive a new treatment that may be better, worse, or the same as the best known treatment. It is easy to understand the reluctance of patients to enroll in a trial. Cultural and social issues also influence such decisions, but whatever the explanation, we need more patient volunteers. The problem is compounded by the changing regulatory climate, notably the advent of HIPAA, which, though well-intentioned in its design to protect patient privacy and confidentiality, has further impeded our ability to recruit volunteers.

For the past several years, many have worried about the future of clinical research in this nation, especially regarding our ability to conduct adequate trials on the safety and efficacy of new drugs. In fact, clinical trials may have to be more extensive and lengthy than in the past—witness the unexpected side effects of Vioxx, detected only after huge numbers of patients had been treated for long periods of time. And while fewer patients are enrolling in clinical trials, fewer young physicians are preparing for careers in clinical research—just when the number of new therapies developed as a consequence of our rapid progress in the laboratory is nothing short of astonishing. I've discussed the dearth of clinician-scientists before on these pages. Among the powerful disincentives to young doctors embarking on this path is a lack of institutional support.

In October, I was invited by Dr. Elias Zerhouni, director of the National Institutes of Health, to spend a day brainstorming with him on innovative approaches for strengthening the nation's clinical research enterprise. Pitt is seen as an exemplar, given our long-term track record in conducting clinical trials. Further, we have a unique Office of Clinical Research that supports and integrates the efforts of all of our health science schools, an approach which is vital in this multidisciplinary and interdisciplinary era; a renowned Center for Clinical Research Education that is focused on preparing students, fellows, and junior faculty; and an Office of Academic Career Development that's concerned with every aspect of developing the next generation of investigators.

What else can academic medicine do to improve the climate for clinical research? As my colleagues consider whether to make institutional changes to address this pressing issue, I ask them again to consider Dorothy's example: If we don't do it, who else will?

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