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Subject to Review

Obama Admin. Proposes New Regs for Human Subjects Research

In July 2011, the U.S. Department of Health and Human Services (HHS) announced its proposal to change the rules that govern research involving human subjects. These rules are much more far-reaching than they might initially seem, affecting a broad array of important projects—and for that reason, as well as our interest in dealing ethically with human subjects, our country has a great deal invested in seeing that we get the new rules right. Unfortunately, HHS's past history in this area, as well as a review of the draft rules, raises the concern that the new rules may actually serve to harm, rather than help, research.

Medical innovation, which is vitally important to both our economy and the state of our health, depends on researchers' ability to experiment and test new ideas with a reasonable degree of freedom from bureaucratic interference. Take, for instance, the case of Peter Pronovost, a young doctor at Johns Hopkins who in 2006 published the results of his study testing a straightforward idea for reducing infections caused by medical procedures. There are a number of things that doctors and nurses should do every time they perform a procedure, such as washing hands and putting a sterile drape over the patient before inserting an IV line. But Pronovost had noticed that even experienced health care professionals sometimes fail to take these most basic steps.

His idea, then, was simple: create a five-step checklist of basic precautions that doctors and nurses must take to limit the spread of infections, even and especially those basic steps that could sometimes be forgotten. Pronovost created a program to test the checklist idea in intensive care units in Michigan, and found that infection rates fell dramatically—for some infections, to zero. While this may not sound like a major scientific advance, it has the potential to provide huge benefits in terms of reducing the persistent problem of hospital-acquired infections, which cost over $11 billion and cause over 90,000 deaths every year. (Indeed, the eighteen-month Michigan study alone is estimated to have saved 1,500 lives.)

Unfortunately, at this point a little-known part of HHS called the Office of Human Research Protections (OHRP) stepped in, ruled that Pronovost's research constituted a human research study, and shut the program down. OHRP was founded, as its officials are wont to point out, to ensure that abominable studies like the Tuskegee syphilis experiments never occur again. Today, however, that type of study is extremely unlikely to occur, and OHRP too often gets in the way of truly life-saving and groundbreaking research.

In this particular case, though, higher powers intervened. In December 2007, the *New York Times* ran an op-ed by Atul Gawande criticizing OHRP's shortsightedness, raising the public profile of the issue, embarrassing the HHS leadership (of which I was then a part), and inducing it to intercede and allow the research to proceed. If the *Times* had not published the Gawande piece, the case might not have attained the notoriety it did, and the lifesaving checklist might never have been put into wider effect. The lesson for HHS's new rules is that their focus needs to be on allowing innovative new research to go forward without undue bureaucratic hassles, and without concerns that the media will have to raise a shout in order for it to proceed.

Unfortunately, the Obama administration does not have the best record on producing regulation designed to reduce bureaucratic oversight. One example is the universally panned new rules proposed in the spring of 2011 for the regulation of accountable care organizations. ACOs might be a good idea in theory: they are networks of health-care providers that can reduce costs by efficiently managing patients' care. But the statute allows HHS to force beneficiaries into ACOs without their knowledge or consent, and the rules regulating ACO operations that the Obama administration proposed in early 2011 were confusing, heavy-handed, and onerous.

The Obama administration has long claimed that it will seek to reduce unnecessary regulation. But even so, the proposed rules for human subjects research would in some areas add new regulations. One proposed change would greatly expand the domain of the rules themselves, so that they would apply to all studies conducted at institutions that receive funding from

medically-related federal agencies. So for example, as noted in another *Times* article, "if a university gets financing from the National Institutes of Health, then even a study at that university paid for by a drug company would be covered by the rules." But the Food and Drug Administration already has jurisdiction over drug company research used to get drugs approved, so this new rule would just add another bureaucratic hurdle to what is already a lengthy process.

Another new rule requires a patient's written consent for the research use of his or her tissue samples, also known as biospecimens. This rule could reduce the number of biospecimens available to researchers; securing consent is better done when the sample is originally collected, and so better left between patients and hospitals.

And another proposed new rule will likely send chills down the spines of researchers who are used to dealing with the federal government: "To strengthen the enforcement mechanisms…we are considering providing for periodic random retrospective audits, and additional enforcement tools."

Fortunately, the proposed set of rules is only a concept paper, and interested parties have until October 26, 2011 to provide comments before HHS produces a draft rule. In addition, there is broad recognition that the rules need to be revised to reflect modern technological advances, and that some of the proposed ideas sound like worthy ones. These include initiatives to consolidate multiple Institutional Review Boards into one board of record, to limit continuing review of human subjects, and to allow minimally risky studies to proceed without bureaucratic rigmarole—all of which are important and overdue improvements. The hope should be that, in the final version of the rules, the preponderance of the changes will be these kinds of improvements, and the Obama administration will sublimate its congenital impulse to regulate and will instead focus on the promotion of innovative and lifesaving medical improvements.

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