Regulating Medical Research

Thursday, August 2, 2001; Page A18

THE HARSH disciplinary shot leveled at Johns Hopkins University last month by the federal government, which shut down all of the institution's federally funded human subject research for several days, brought cries of protest from both inside and outside the university. Johns Hopkins defenders noted that the university had already dealt candidly with the death of a healthy 24-year-old volunteer in an asthma experiment; they suggested that a zealous new enforcement agency, created just last year to protect human research subjects, had chosen to make an example of Johns Hopkins to establish its own bona fides. Researchers at other universities worried too, saying that the more demanding standard the government now appears to be seeking for university-based research could saddle scientists with unmanageable compliance costs and cut research productivity.

The concern is not frivolous; tighter regulation always carries costs. But the attempt to protect human research subjects more aggressively is not, as claimed, a sudden ratcheting up of formal requirements where a more relaxed approach has sufficed. On the contrary, the change comes after years of warnings that an overburdened system was failing to keep up with the pace and pressures of modern medical research.

Research involving human beings is subject to elaborate regulations if federal money is involved. But the Food and Drug Administration, in monitoring drug trials, checks documentation after the fact rather than monitoring trials in progress -- so it is ill-suited to catching problems that might pose a danger to the patients involved. The latter job is handled by institutions' own internal review boards. But reports by the inspector general of Health and Human Services in 1998 and 2000 described these review boards as dangerously overwhelmed with work, pressured to cut corners and running the risk of a tragedy like the one that befell 24-year-old volunteer Ellen Roche at Johns Hopkins in June. They urged that the boards get more support and more training, especially in conflicts of interest. They also urged the creation of the new watchdog agency that spotlighted Johns Hopkins. While much of Johns Hopkins' research resumed after a few days of negotiations, the conditions of that resumption reflect those same concerns: Regulators criticized the boards' record-keeping and will require most experiments to go through the vetting process again.

For research to be properly monitored, most universities need at least to double the number of review board personnel. Putting more data online could streamline work for them and for researchers checking the scientific background of substances under consideration for use. No system will catch every error, nor necessarily could have in the Roche case. But complaints about the burden of regulation ring hollow -- especially when someone has died.

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