Scientist Quits NIH Over Fetal Rules

Gary Hodgen, an ambitious specialist in fertility and pregnancy research, soon will be leaving the National Institutes of Health (NIH) to become scientific director of the Institute for Reproductive Medicine at the Eastern Virginia Medical School in Norfolk. His departure reflects his growing frustration with how rules restricting federal research on human fetuses are being interpreted, and the detrimental effect the rules may have on a wide variety of biomedical research. His leaving may also spell the end for much of NIH's intramural research on infertility and for several influential training programs.

Chief of the pregnancy research branch at NIH since 1978, Hodgen has worked on the Bethesda campus since he completed graduate work in 1969. He has nothing but high praise for the "nurturing atmosphere" of NIH, which he says has provided him with "truly exceptional opportunities." Nevertheless, current federal restrictions limiting government-funded research in reproductive medicine and NIH's narrow interpretation of them no longer make the Bethesda campus a conducive setting for his research.

Ten-year-old regulations governing federal support of in vitro fertilization, which are interpreted to encompass virtually all research on human embryos, specify that individual research proposals must be reviewed by a federally appointed ethics advisory board. But the appropriate board was disbanded in 1980, and thus no research in this area can be done until it is reinstated. (One or several such boards would deal with other categories of research—now also prohibited because review is impossible—involving children or prisoners.) Several months ago NIH sent a request for the board's reestablishment to the Department of Health and Human Services (HHS), and a set of options has been forwarded to HHS secretary Margaret Heckler. She has not yet ruled on the matter.

Jeffrey Fox

Gary Hodgen

The absence of an ethics advisory board is "frustrating some of our scientists who can't work on very important problems," says Mortimer Lipsett, director of the Institute of Child Health and Human Development where Hodgen has worked. Oddly enough, although antiabortion groups have been the strongest critics of in vitro fertilization, many of the scientific problems Lipsett alludes to can be construed as "pro-life" because they are aimed at improving an embryo's chances for survival. For example, one of Hodgen's research goals is to develop methods for diagnosing and correcting abnormalities in fetuses. Opponents have often discouraged research on embryos, arguing discovery of defects will lead to more abortions. Hodgen argues otherwise, saying: "We propose a middle ground. . . . If we had the knowledge and ability [to correct defects in fetuses], the mother might not want to elect abortion."

Despite this seeming congruence between Hodgen and critics of this research, the whole issue of in vitro fertilization and medical investigations on human embryos is being treated with extreme sensitivity by NIH. On several occasions, for example, permission for Hodgen to participate in scientific meetings dealing with these issues was withdrawn by NIH officials to avoid giving any impression that certain kinds of research were being advocated.

The most celebrated instance came in September 1982 when Hodgen was told not to attend a workshop being held—ironically now that he soon will be moving there—at Eastern Virginia Medical School. Hodgen says there were altogether three instances during his 14 years at NIH where administrators "infringed on his academic freedom" in this way. He was asked not to attend the 1982 conference to avoid "the appearance of conflict" with official policies, even though his work has adhered to those policies. Similarly, his scientific papers sometimes have been subjected to extra scrutiny and last-minute editing for reasons other than scientific clarity. "I have not felt this was censorship," Hodgen says, "but I think this is irregular . . . and has to do with perceived sensitivity" to the implications of his work.

By confining his studies to monkeys and other lower-order mammals, Hodgen has avoided any major confrontation with federal officials over the propriety of his research. But another frustration for him has been the impossibility at NIH of "translating" any of his results directly into clinical practice. Although NIH has a small program devoted to several aspects of human infertility, many issues simply cannot be addressed. For example, Lipsett points to the important medical problem in the United States of low birth weight, which in a broad sense contributes to the infertility picture because it affects infant mortality. Sheep studies indicate that amino acid supplements introduced directly into the amniotic fluid can allay this problem, but the technique cannot be applied to humans before proper studies are undertaken. However, appropriate studies cannot be done because there is no board to review proposals.

Hodgen's long-range interests include plans to study the feasibility of gene therapy in embryos, with the ultimate aim of preventing birth defects. His current proposals call for taking up this study in monkeys, but his ambition is to preside over the "confluence of reproductive and molecular biology in human medicine." This is a "big idea," he says, "We are far from realizing it. [But] I want to participate."

By not reinstating an ethics review board, the government has discouraged some scientists from seeking federal support for reproductive research and now has prompted Hodgen to leave NIH saying his "patience is worn out" waiting for such a change. It may prove a serious mistake to drive scientists such as Hodgen out of federal institutions, where research is done openly and its consequences may be debated while the work is progressing. When research must be done in the private sector, debate usually is postponed until results are announced.—**JEFFREY L. FOX**