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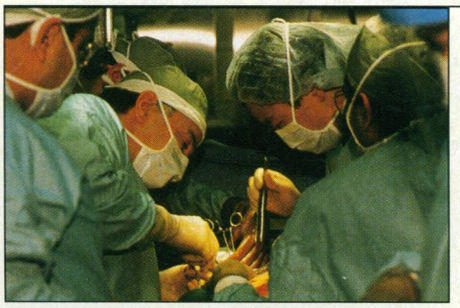
edited by JOCELYN KAISER



UNIV. OF PITTSBURGH MEDICAL CENTER

Gearing up? Guidelines may give green light for procedures such as this baboon–to–human liver transplantation.

Xenograft Guidelines Clearing Last Hurdles

Long-awaited safety guidelines on animal-to-human transplants are likely to be out from the Public Health Service this month, fueling debate about the risk that xenotransplants could lead to new infectious diseases in humans.

First proposed last summer by the Food and Drug Administration (FDA) (*Science*, 21 July 1995, p. 293), the guidelines offer 50 pages of often detailed advice to local research oversight panels on everything from procedures for breeding and screening disease-free donor animals to proposals for lifelong monitoring of recipients and storing data in a "central registry." Phil Noguchi, director of FDA's division of cell and gene therapy, says the guidelines are now undergoing final review and will likely be published this month in the *Federal Register*.

The suggested rules are endorsed by the National Institutes of Health and the Centers for Disease Control and Prevention (CDC). But it's not clear how closely clinicians will be required to follow them. The popularity of the procedure could be heavily influenced by the progress of Jeff Getty, the AIDS patient given a baboon bone marrow transplant in December to boost his declining immune system. The CDC is running retroviral detection tests on Getty's blood for potential baboon-borne infections, although so far he has shown no adverse effects from the transplant. Xenoexperimentation—such as temporary baboon–to–human heart transplants—could take off like "gangbusters," says one FDA official, or "proceed with great caution," depending on the test results.

Virologist Jonathan S. Allan of the Southwest Foundation for Biomedical Research in San Antonio is worried by the guidelines' emphasis on what he calls "containment, not prevention," and he's urging broader debate among researchers on the infectious disease risks of xenotransplants. But a more important measure, says one biotech industry insider, will be the public's response to the guidelines.

Congress Bans Embryo Study Funds

The spending bill that Congress passed last month to support the National Institutes of Health (NIH) through September had few provisions relating to biomedical research policy (*Science*, 12 January, p. 136). But last week one of these so-called "barnacles"—a ban on federal support for human embryo research—reappeared as part of a resolution to fund other agencies through 15 March.

The provision prohibits spending federal funds to create a human embryo for research purposes or on "research in which human embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than allowed for research on fetuses in utero" under existing laws. An embryo, the law says, is any organism "derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes."

The new language "leaves us pretty much where we were before—on hold," says NIH Director Harold Varmus. Eight groups have received grants to study the human fertilization process, but they are restricted to using animal material or halting their observations of human ova short of full fertilization. Varmus says NIH doesn't know how long this latest congressional ban will last. But in the meantime he hopes "to do a better job of educating the public" about the benefits of such research.

Hatfield Bill Boosts Clinical Research

Clinical researchers, unhappy with how the National Institutes of Health (NIH) has responded to their concerns about funding and training, have come up with a legislative solution to their problems. Last week Senator Mark Hatfield (R–OR) introduced the Clinical Research Enhancement Act of 1996 to address what Hatfield calls a threefold "crisis"—a shortage of clinical researchers, an inadequate infrastructure to train them, and "a declining fiscal investment in biomedical research overall."

The bill, endorsed by 75 professional societies and co-sponsored by Senator Edward Kennedy (D–MA), would direct NIH to spend more on young clinical investigators, clinical training programs, and extramural clinical centers. One key provision would create an advisory panel of 12 outside experts, chosen by the president and reporting through the White House's Office of Science and Technology Policy (OSTP), to survey all federal clinical programs. It also would examine the "compositions, functions, and outcomes" of all peer groups ranking federal biomedical research grants.

The Clinton Administration is lukewarm toward the idea. NIH already has a panel, created last year by Director Harold Varmus and headed by David Nathan of Boston's Dana-Farber Cancer Institute, that is monitoring clinical research at NIH. Varmus says the Nathan panel is "doing an excellent job." Hatfield's bill would extend the panel's life for 5 years and have it report to OSTP as well as NIH.

Prospects for the bill are uncertain. Hatfield staffers say it could be merged this year with a broader bill to reauthorize NIH in the Senate Committee on Labor and Human Resources.

Academia vs. DOE Labs: Who Does Better Science?

In funding R&D, a recent National Academy of Sciences (NAS) panel recommended, federal agencies should "favor" universities over national labs and other research institutions because the quality of the science is generally higher on campus (*Science*, 1 December 1995, p. 1430). But one widely used yardstick of merit suggests that the panel's assumption may not be correct.

The yardstick in this case is an index of publications maintained by the Institute for Scientific Information (ISI) in Philadelphia. ISI's David Pendlebury, his interest piqued by the NAS recommendation, compared citation rates for papers from 1990 to '94 in the physical sciences and engineering from 110 research-intensive U.S. universities with those from the Department of Energy's (DOE's) 10 multipurpose labs. The idea was to see what research scientists consider most relevant to their own work. The results? The average DOE paper received 6.41 cites, compared with 5.32 for those from academia. In addition, the DOE papers scored 14% more cites than the norm for all papers of a similar year, type, and publication; the academic papers scored only 7% above the norm.

Frank Press, chair of the NAS panel, isn't fazed by the ISI analysis; "we pointed out that some of the 700 federal labs do superb work and should not be weakened," he notes. DOE's multipurpose labs might be expected to perform better than federal labs as a whole, says NAS staffer Robert Cook-Deegan, who directed the study, because they're run by contractors and aren't bound by stultifying civil service rules. And citation analysis, he adds, ignores training and other contributions to the overall value of research. Pendlebury agrees, but he's concerned that the NAS panel deliberated without any quantitative review of output. "I just think that facts are helpful," he says.