agency for the entire PHS) hopes to create a new panel that would do for xenotransplantation what NIH's Recombinant DNA Advisory Committee does for gene therapy: it would review proposed clinical trials in public and encourage broad public participation in its deliberations but have no regulatory authority.

However, plans for the arrangement are provisional because the number of advisory committees the Executive Branch of the federal government can have is limited by law, and that limit has been reached.

The uncertain future of the proposed advisory panel aside, not everyone at the recent meeting was persuaded that it is prudent to allow clinical trials to take place while knowledge about the potential risks of cross-species transplants is so fragmentary that they might endanger public health.

The most vocal of the doubters was Fritz Bach, M.D., of Harvard University in Boston. He and Harvey Fineberg, M.D., Ph.D., the University's Provost, are the leaders of a group of nine scientists that in the Jan. 22 issue of Nature and the February issue of Nature Medicine called for a broad public debate on the matter and a moratorium on the trials in the meantime.

"Yes, the meeting at NIH was an open meeting," Bach said in a later interview. "But many who were there had a financial or career interest in making xenotransplantation pay off: either that or they were patient advo-

Cross-species Transplants May Pose Risk to Livestock

Stewart Jessamine, M.B., Ch.B., D.P.H., came halfway around the world to represent his country at January's conference on xenotransplantation at the National Institutes of Health.

An official at New Zealand's Ministry of Health, in Wellington, Jessamine was an invited speaker at the meeting because in 1996 a handful of diabetic New Zealanders were experimentally treated with porcine pancreatic islet cells before there was published information that would have alerted him and his colleagues to the controversial aspects of cross-species therapies.

Since then, some guidelines have been published and Jessamine reported that he is now able to turn to agencies like the U.S. Food and Drug Administration for technical expertise that is lacking in his nation of 3.5 million people.

New Zealand's health ministry has been asked to approve another clinical study involving viable animal tissue and it needs outside help to evaluate the request. However, Jessamine was at pains to add that "when developing public policy in xenotransplantation, we consider not only the scientific evidence, but also the cultural safety of the procedure."

In New Zealand, he said, cultural safety includes the participation of the 15% to 20% of the population that is Maori in health policy decisions. But it also includes anticipating possible problems for a country whose economy heavily depends on the export of meat, hides, wool, and other animal products.

In that regard, Jessamine said that he had been struck by the "very little research" that has been done on whether the ability of viruses carried by xenografts to jump species barriers, and so infect people, may also work in reverse. In that case, the alien viruses might — through mutations or other unanticipated changes — spread from a transplant recipient not into the human population (though, perhaps there, too) but back into livestock.

"I am not saying that this scenario could or would come to pass," Jessamine said in an interview. "But neither," he said, "is it wholly implausible: the more so, because most of our citizens who would be candidates for cross-species trials either live on ranches and farms or have close ties to them."

Although Jessamine was the conference's only speaker from a small country, there was a clear recognition by many at the meeting that New Zealand's concerns are not unique and that cross-species transplants merit attention from governments throughout the world.

It is for that reason that the agencies of the U.S. Public Health Service are consulting with their counterparts in France, Canada, England, and at the World Health Organization, which is based in Geneva, Switzerland. And it is also for that reason that, just as xenotransplantation policy will continue to evolve in the United States, so will it do so elsewhere.

— Judith Randal

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cates who are excited about its therapeutic prospects.

“I speak for all of us (who have appealed for the moratorium) in saying that I have the greatest sympathy for patients,” Bach added. “We realize many of them might be helped by living materials from other species. But when few people outside the scientific community have even heard of xenotransplantation, this sort of meeting — and there have been several — is not our idea of a genuine forum for public debate.”

Virologist Jonathan Allan, D.V.M., of the Southwest Foundation for Biomedical Research in San Antonio, was similarly troubled, but for a somewhat different reason. His concern is that the PHS has not put baboons and other non-human primates off limits as donors for clinical xenotransplantation trials.

The PHS position is that a ban is unnecessary because the FDA guidelines say that only animals free of diseases known to infect humans can be used as donors and that the chance that nonhuman primates can qualify is remote.

But Allan noted that the agency allowed an AIDS patient to be given baboon bone marrow in 1995 (the graft didn’t take), which might make it hard to turn down a similar trial in the future. He also fears repetitions of the privately done 1984 surgery in which a baboon heart was transplanted into an infant whose own heart was defective.

Allan said at the meeting that he was “absolutely baffled” by what he regards as a dangerous loophole because the possibility of transplants from non-human primates infecting people with a persistent retroviral illness — for which there would be no treatment and which might spread into the community — cannot be ruled out. “You are playing Russian roulette,” he warned.

“The point is,” he later explained, “that baboons represent an inherent risk that’s far greater than any risks from pigs. Any viruses in transplants from nonhuman primates are much more likely to be infectious (in people) and we already know that the DNA of baboons harbors at least two retroviruses. . . . So there’s reason to think that leaving the door open to the use of nonhuman primates as donors is poor policy.”

Only time will tell whether Allan’s fears or, for that matter, any fears about xenotransplantation are justified. What is clear for the moment is a point that was made by William Raub, Ph.D., Deputy Assistant Secretary for Science Policy at the Department of Health and Human Services.

Asked in an interview whether the potential benefits and risks of xenotransplantation merit the sort of high profile attention now being focused on human cloning, Raub answered in the affirmative. “Of the two,” he said, “xenotransplantation is the more imminent.”

—Judith Randal

President Proposes NCI Budget Increase

As the first step in the Clinton Administration’s initiative to increase cancer research funding by $4.7 billion by 2003, the president last month asked Congress to increase the National Cancer Institute budget in 1999 by 9% or $229 million. The president’s budget for NCI in 1999 would be $2,776.3 billion. The 1998 estimate is $2,547.3 billion.

Vice President Al Gore had announced earlier the proposal to increase total spending by the National Institutes of Health for cancer research from $2,914 billion in fiscal year 1998 to $4.8 billion in 2003, a 65% increase. All but 10% of the additional cancer research funds would go to NCI. (See News, Feb. 18, 1998.)

The president proposed that the NIH appropriation increase 8.4%, or $1,150.2 billion, between 1998 and 1999. In 1998, the NIH budget estimate is $13,647.8 billion. The proposal for 1999 is $14,798.0 billion.

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The president’s 1999 proposed NCI budget would increase the amount for research project grants from $1,223.8 billion to $1,335.0 billion, representing 48.1% of the total NCI budget. Funding for the NCI intramural program would be $442.9 million, or 16% of the total NCI budget.