New Biotech Review Board Planned

The creation of a Biotechnology Review Board that would cut across agency lines raises questions about the role of the NIH RAC

Plans to establish a federal Biotechnology Science Board that would have broad authority over research and development in genetic engineering are likely to vastly diminish the scope and clout of the National Institutes of Health longstanding Recombinant DNA Advisory Committee, known colloquially as the RAC. Under the proposed plan, the new Biotechnology Science Board (BSB) would be vested with oversight of genetic engineering in the Department of Agriculture, the Environmental Protection Agency, the Food and Drug Administration, the National Science Foundation, and the NIH. As a result, the NIH RAC, which has been viewed as something of a supreme court for genetic engineering, would be superseded by the new science board, which would be chartered in the Department of Health and Human Services and report to the assistant secretary for health.

If the BSB ends up being organized along the lines outlined in a memo obtained by *Science*, ultimate jurisdiction over experiments in the deliberate release of genetically modified organisms into the environment and over the first clinical trials of human gene therapy will be transferred from the RAC to the BSB. Although NIH officials have wanted to avoid regulating deliberate release experiments, which NIH director James B. Wyngaarden considers "application" rather than basic "research," the prospect of losing authority over human gene therapy experimentation has met with opposition from the handful of persons who are aware of recent developments regarding the Biotechnology Science Board. The new plan is being touted by FDA commissioner Frank Young, who is expected to move up to the post of assistant secretary for health any day.

In anticipation of the first experiments involving an attempt to cure an inherited disease by means of human gene therapy, about a year ago NIH formed the "Working Group on Human Gene Therapy" as a subcommittee of the RAC. Comprised of researchers, ethicists, lawyers, and public representatives, the working group developed a set of guidelines for scientists who might be among those to submit the first protocols for NIH approval. The first draft of "Points to Consider in the Design and Submission of Somatic-Cell Gene Therapy Protocols," was published in the *Federal Register* for public comment earlier this year (*Science*, 1 February, p. 493).

It is not clear just when the first protocol for a human experiment will be submitted but it is possible one could be ready in only a couple of months. Work by W. French Anderson and his colleagues at NIH and other institutions appears to be moving rapidly, for instance. New data from his team have been reported recently at several meetings. Within the past few months, the group has developed a new vector for carrying a therapeutic gene into a deficient cell that is more efficient and more stable that previous vectors. In addition, in just the past weeks, it looks as if there has been a succcessful experiment involving the in vitro "cure" of human cells taken from a young patient with adenosine deaminase or ADA deficiency—an immune disorder that leaves its victims without any immune defense. Early results indicate that, in the test tube, the patient's ADA-deficient cells have incorporated ADA from a viral vector carrying a cloned ADA gene. Experiments in nonhuman primates also are now under way, raising the possibility that if all goes well, an application for a human trial may not be far off.

> The RAC could become a scientific advisory body for NIH alone.

Whether a protocol could be held up pending establishment of the BSB is unclear. NIH was getting ready to publish a revised version of its gene therapy document last month when Wyngaarden was told by Young that republication should wait until the new science board is in existence so that it could review the NIH working group's work.

At the same time, it became apparent that in a power play between NIH and FDA, the FDA was moving deliberately to assert its own authority over human gene therapy. The issues came plainly to light on 1 August when the memo regarding the BSB was discussed at a Cabinet council meeting run by Bernadine Healy, deputy director of the White House Office of Science and Technology Policy. As drafted, the memo undercut what NIH had assumed to be its purview. First, it specifically stated that NIH could not publish the gene therapy points to consider without BSB review. Second, it said in black and white that NIH would have no role to play in review or approval of field trials or clinical trials of genetically engineered products if they also fall under the jurisdiction of some regulatory agency. Thus, anything that can be interpreted as falling under FDA regulations (such as gene therapy in which a modified gene would be inserted into a patient) is exempted from NIH's purview.

The NIH-FDA issue here is a subtle one. It has always been the case that FDA has jurisdiction over medical products and medical devices, but FDA exercises wide discretion in deciding the point at which to exert its authority. For instance, the drug agency often keeps at arms length from early clinical research in NIH-funded experiments that include no more than a few patients. In addition, FDA has opted not to regulate organ transplantation because, as Henry Miller, the agency's coordinator for biotechnology put it, organ transplantation "is regulated effectively by peer groups." At first, NIH officials presumed that this would be FDA's position regarding the initial attempts at gene therapy. Indeed, through publication of the first draft "points to consider" in the 22 January *Federal Register*, it looked as if FDA would behave as usual.

But human gene therapy is different. It is an emotional, controversial subject, despite the fact that most informed scientists, ethicists, and religious leaders agree that as long as one sticks to the therapy of somatic (as opposed to germline) cells for the treatment of often lethal diseases, gene therapy is in principle no different from other highly experimental medical procedures.

Differences of opinion among NIH officials and FDA staff, particularly Miller who is the FDA's liaison to the NIH RAC, have prompted a more assertive