RAC MEETING

HUMAN GENE THERAPY GUIDELINES PASS

BETHESDA, Md.—The National Institutes of Health's Recombinant DNA Advisory Committee (RAC) unanimously adopted its *Points to Consider in the Design and Submission of Human Somatic-Cell Gene Therapy Protocols* at the committee's regularly scheduled Sept. 23 meeting here.

The formal action followed months of discussion—most of it soul-searching by researchers. Leroy Walters reported that his working group on human gene therapy had received 14 letters of comment after the first-draft guidelines were published. And only three letters and a telephone call followed publication of the second draft presented to the RAC last May, he said. Walters is director of the Kennedy Institute's Center for Bioethics at Georgetown University (Washington, DC).

Under the newly adopted guidelines, gene therapy may be performed only on somatic cells. Researchers are asked to describe the precautions they will take to avoid involving germ-line tissue. The guidelines also presume that human genes will be manipulated only to correct diseases for which alternative treatments are unsatisfactory.

The RAC adopted 14 "minor technical changes" to the May version of the guidelines. Only two of these amendments—both couched in footnotes—might substantively change their impact on researchers. One footnote affirmed the Food and Drug Administration's jurisdiction over drug products intended for use in clinical trials on human patients. The other explicitly applies the guidelines to recombinant DNA and DNA derived therefrom—but pointedly omits recombinant RNA, which is technically outside RAC's charter. Since RNA viruses are likely to be the vectors used to transfer genetic material into subject cells, this presents certain problems: RAC's regulations would not apply directly to retroviruses.

Several RAC members, like Genentech vice president David W. Martin Jr., himself a gene-therapy researcher, expressed concern over this omission.

The guidelines require case-by-case RAC approval, following local Institutional Review Board endorsement and publication of experimental protocols in the *Federal Register*. The points to consider also prescribe exceedingly detailed descriptions of all facets of the treatment (the disease, the therapeutic gene, the insertion vector). Investigators are also asked for thorough assessments of preclinical and public-health risks, a full analysis of clinical procedures and patient monitoring, and for descriptions of investigators' qualifications and facilities. Sections of the guidelines reiterate requirements for informed consent and try to make researchers aware of the need for a balance between a patient's right to privacy and the necessity of accurate public information.

The real test of the *Points to Consider*, however, will not come until researchers finally submit an experimental protocol.

"The language," said RAC member Susan Gottesman of the National Cancer Institute, "is as good as we're going to get it until we get a proposal.... This is a working document."

Or, as RAC member L. Albert Daloz put it, "It's time to stop straining gnats. Let's get us a case we can get our teeth into."

—Douglas McCormick

RAC MEETING

NEW 'COORDINATED FRAMEWORK' FOR REGULATION

BETHESDA, Md.—When a White House official unveiled the latest wrinkle in the administration's plan for biotech regulation, reactions at the Sept. 23 Recombinant DNA Advisory Committee (RAC) meeting here were mixed.

Bernadine Healy, Deputy Director of the Office of Science and Technology Policy (OSTP), described what she called a better mechanism for coordinating science policy than the two-tiered structure set forth in the "Proposal for a Coordinated Framework for Regulation of Biotechnology" published in the Dec. 31, 1984 *Federal Register*. That plan called for a RAC-like umbrella Biotechnology Science Board to coordinate the activities of five recombinant advisory committees—one RAC for each of the five agencies that funds research or regulates products produced by biotechnology: the National Insitutes of Health (NIH), the National Science Foundation (NSF), the U.S. Department of Agriculture, the Food and Drug Administration, and the Environmental Protection Agency.

That plan drew considerable fire. Critics charged variously that the loose Biotechnology Science Board would be unable to preserve confidentiality; that it would be redundant, cumbersome, and unable to meet statutory timetables; and that as an advisory body, it could not enforce scientific standards on RACs more closely tied to the regulating and funding agencies.

The new proposal would preserve the separate agency RACs. Instead of a Biotechnology Science Board drawn from the ranks of scientists and the general public, however, the administration proposes an all-governmental body. This "Federal Coordinating Council for Science and Technology" (FCCST, pronounced "fix-it") would be part of OSTP and would be chaired alternately by the directors of NIH and NSF. The White House already runs nearly a dozen other coordinating councils.

The coordinating council would have five main functions: reviewing summaries of agency RAC reports to act as a sort of clearinghouse on scientific issues; to evaluate the agency review procedures; to evaluate broad scientific issues; to develop generic scientific guidelines; and (indirectly) to act as a forum for public concern.

While the original Biotechnology Science Board was proposed in large measure as the central forum for public debate, the public will be largely excluded from coordinating council deliberations. Public testimony would, however, be invited by the agency RACs and by "expert panels" assembled by the proposed coordinating council

RAC member Arthur Landy of Brown University noted that this structure seemed topsy-turvy, with public input only on the "narrow end," before the regulating agencies and their RACs, while there is no public input before the FCCST, which should be deciding on broad scientific policy. Healy responded that other FCCSTs are now used successfully to set policy in just such broad ethical areas.

Healy emphasized that the FCCST would serve as a scientific advisory body; regulatory decisions would be made by the regulating agencies based on their RAC and FCCST advice. And jurisdictional questions would be decided by another mechanism entirely.

—DMcC