NIHRAC MEETING

PANEL CONSIDERS BROADENING ITS MANDATE

WASHINGTON, D.C.—During its October meeting, the Recombinant DNA Advisory Committee (NIHRAC) of the National Institutes of Health (NIH, Bethesda, MD) tentatively recommended changing an essential definition that determines the scope of the committee's activities. The change would significantly extend the current guidelines to include non-recombinant DNA manipulations—not now covered under the precepts scrupulously developed during the last decade. The committee recommends that NIH hold hearings around the country; the outcome could help determine whether NIHRAC expands or, instead, contracts and eventually dissolves.

Early this year, the National Wildlife Federation (NWF, Washington, DC) proposed expanding the scope of the NIH Guidelines for Research Involving Recombinant DNA Molecules (*Bio/Technology* **7**:205, Mar. '89). Since the Guidelines were developed in 1976, many new gene transfer techniques have developed other than those strictly involving recombinant DNA molecules. NWF said the new techniques and the organisms they produce "may pose human health and environmental risks."

The ticklish issue of expanding the scope of the Guidelines was referred to a subcommittee. After deliberating, the group agreed to "present alternatives, not recommendations," subcommittee chair Monica Riley of the Marine Biological Laboratory (Woods Hole, MA) told the full committee.

The subcommittee considered whether "any new biohazards" would likely arise merely from using new techniques for introducing DNA into cells, and the "implicit conclusion is...in the negative," Riley says. Numerous studies, including the recently released report, "Field Testing of Genetically Modified Organisms: Framework for Decisions" of the National Academy of Sciences (see "In the News", this issue), conclude that "it is not the process of making recombinant organisms that confers hazard," she says. The report itself notes that new techniques to manipulate genes, "although powerful," are not "intrinsically dangerous."

Nonetheless, members of the subcommittee felt that some new techniques, particularly the polymerase chain reaction for amplifying specific gene segments, are so powerful and so widely used that they cannot be ignored. "We must be cognizant of concerns that new techniques not fall through the cracks," says NIHRAC *ad hoc* consultant Anne Vidaver from the University of Nebraska (Lincoln). Moreover, such techniques could enable some researchers to circumvent the NIH Guidelines.

Henry Miller of the Food and Drug Administration (Bethesda, MD) asserts that expanding the guidelines perpetuates an "illogical universe" in which the public is sent a false message of danger. "Perhaps it is time to consider...phasing out the guidelines," he says. The committee, sensitive to the political and scientific role it has played, seems in no hurry to take Miller's advice, however. Thus it gingerly recommends changing the definition of scope to include "molecules constructed inside living cells by joining enriched segments of DNA or their synthetic equivalents with intracellular DNA." If the recommended change is broadly accepted, "we'll cross the Rubicon from 'gene splicing' to 'new stuff,'" says NIHRAC member Paul Neiman of the Fred Hutchinson Cancer Center (Seattle, WA). "It's an excellent opportunity to see ...[whether] we belong in the Smithsonian as a historical artifact."

In other efforts to fend off such a consignment, the committee has been providing a public forum for evaluating human gene transfer and therapy experiments (*Bio/Technology* **6**:1279, Nov. '88). In October, the committee approved refinements in its "Points to Consider" document advising investigators on the conduct of clinical experiments involving changes in human genes.

The first such clinical experiment, which is being conducted by NIH researchers French Anderson, Steven Rosenberg, and their collaborators, involves use of retroviral genetic material to mark cells of patients with advanced cancer. So far, five patients have entered the trial, and it is going "extremely well," Anderson told the committee. In the two patients tested so far, the marker remains detectable (except during brief periods when malignant cell remission occurs), there are "no side effects of any type related to gene marking...[and] all safety studies are negative."

—Jeffrey L. Fox