be unified without losing their sovereignty,” said Alterowitz. “NPCC represents educators, survivors, researchers, physicians, and pharmaceuticals — all dedicated to the same objective.”

Earmarking research dollars for prostate cancer also has fueled debate. Some believe advocates should champion cancer research as a whole and avoid focusing on specific cancers.

“I think the subjectivity of a disease is critical to many people, especially if they are somehow touched by it. A prostate cancer patient, for instance, wants his disease to be cured and that’s the reason why he donates or becomes an activist,” said Alterowitz. “Even though he can generally understand cancer research, he will only speak with conviction and dedication to the specific need for prostate cancer research.”

— Sabine Steimle

**Gene Therapy Group Agrees to Smaller Size, Less Authority**

After a year on the sidelines, a federal oversight committee for gene therapy met again last month and wrestled not with its dissolution, as originally anticipated, but with what authority — if any — the committee has left.

Although members of the Recombinant DNA Advisory Committee voted to accept “in concept” a compromise proposal by National Institutes of Health Director Harold Varmus, M.D., to shrink rather than eliminate the 25-member group, there was a lengthy discussion over what the RAC’s new role will be.

According to a Nov. 22 Federal Register notice, the RAC will lose its formal voting approval over individual gene therapy protocols, but will continue public review of novel and controversial gene-splicing experiments. The RAC’s role in Varmus’ proposed gene therapy policy conferences on controversial topics, such as in-utero gene therapy, remained less clear.

Earlier in the meeting, Varmus suggested that RAC members propose topics for these genetic conferences, but that the conferences would be run by outside experts in the field under discussion. However, several RAC members suggested the RAC reassert its authority by setting the agenda for these conferences and linking them to its own meetings.

Fusing the two meetings from the “public’s perspective is the only approach that makes sense,” argued Doris Zallen, Ph.D., an associate professor of...
science studies and humanities at the Virginia Polytechnic Institute and State University, Blacksburg.

Karen Rothenberg, J.D., Marjorie Cook professor of law at the University of Maryland, agreed. "Maybe this is where we can exert [our] authority," noted Rothenberg, adding that if the RAC has no power of protocol approval and no power over these conferences, "why exist?"

Familiar Ring

For RAC members, this question had a familiar ring, as over the past few years the committee has often pondered its role. Gary Chase, Ph.D., professor and chair of the department of biomathematics and biostatistics, Georgetown University Medical Center, Washington, D.C., likened RAC’s plight to that of Little Red Riding Hood. "RAC [still] has its historic prestige. . . . We’re out of the woods, but we’ve been badly mauled," Chase said. "Once you take away our legal force, what is left?"

But both Varmus and Phil Noguchi, M.D., of the U.S. Food and Drug Administration’s Center for Biologics Evaluation and Research, argued that even without the power to approve or disapprove individual protocols, the RAC will continue to play a vital role in the fast-changing arena of gene therapy by focusing attention on public concerns.

“Our most powerful decision-making tool will be public discussion," said Noguchi. "When I hear RAC members say ‘let’s vote ourselves out of existence,’ I say ‘not now.’ " With in-utero gene therapy clearly on the horizon, Noguchi added, there is a growing need "to get more than a little ahead of the curve" with a public debate.

Because FDA, which has regulatory responsibility for gene therapy protocols, provides for limited public review, the perceived erosion of public participation sparked a lively debate earlier this year when Varmus proposed scuttling the existing RAC and replacing it with a small advisory group of six to 10 members [see News, Nov. 6, 1996, p. 1523].

During the 30-day comment period, considerable support was expressed for the present RAC, including that of several members of Congress. The NIH Office of Recombinant DNA Activities, which oversees the RAC, received 71 letters from consumer groups, industry representatives, and ethicists.

As part of the compromise solution, Varmus abandoned his plans to dismantle the RAC and decided to pare down its membership less sharply — from its full strength of 25 members to 15 members. For an advisory group, he said, 25 is a large number, and 15 seemed an adequate size for preserving the RAC’s diversity while fulfilling the mandate to downsize government.

Although he did not restore the RAC’s voting privilege, Varmus said he will continue to receive recommendations and advice from the oversight group on an informal basis. As one RAC member opined about the loss of stature, "this is a done deal" and RAC members need to acknowledge that "we’re no longer the only game in town." At the same time, however, he suggested, the RAC needs to make sure the public’s interests continue to be protected and that incremental steps are taken in such a rapidly growing field.

“Slow Down”

“This is a matter of public accountability,” agreed M. Therese Lysaught, Ph.D., an assistant professor in the department of religious studies, University of Dayton, Ohio. “We are still the vehicle through which the public can say ‘slow down.’ "

In addition to better defining its role in the days ahead, RAC members also addressed a number of other concerns. For the RAC to do its job effectively, for example, the group felt there should be a timely feedback mechanism in which RAC members would be notified by investigators of any protocol changes required by the FDA prior to approval. Other concerns were about the endpoints for RAC discussions and recommendations, the process of identifying gene therapy topics, and RAC’s future relationship with FDA.

Many of these issues were left for discussion at the March meeting, as was the RAC’s final approval of Varmus’ proposal. Although technically the NIH director could move ahead before then, it is considered unlikely he will do so.

— Susan Jenks