Gene panel reprieved after public outcry . . .

Washington. Harold Varmus, director of the US National Institutes of Health (NIH), last week announced a compromise on the future of NIH's Recombinant DNA Advisory Committee (RAC). The committee's role as a public forum for discussion of issues relating to gene therapy will be preserved, although its responsibility for approving specific protocols will be scrapped.

The proposal, outlined in the *Federal Register* on 22 November, reverses Varmus's earlier call for the abolition of the RAC, whose members include scientists, lawyers, ethicists and consumers (see *Nature* **381**, 635 & **382**, 197; 1996). The committee — reduced in number from 25 to 15 — would meet to discuss protocols that a majority of its members agree are novel enough to justify public discourse. But it would no longer vote to approve or block protocols.

That responsibility would rest solely with the Food and Drug Administration (FDA). The new procedure would also eliminate the role of Varmus, who currently receives approved protocols from the RAC and gives (or occasionally withholds) his approval before sending them to FDA.

The announcement in the *Federal Register* hints at the outcry that followed Varmus' initial proposal in July to eliminate the RAC, a 22-year-old committee which has provided a public forum for debating issues raised by recombinant DNA technology. The modifications come "in response to public opinion" and the view that the RAC has "historical importance" as a platform for discussion of gene therapy, the proposal says.

"My goal was to expand public discussion about gene therapy now and in the future, avoid duplication with the FDA, and maintain the public database," says Varmus. "This proposal accomplishes those goals and responds to public interest in retaining NIH oversight of human gene therapy".

The NIH received 71 communications in response to its initial proposal, published in July; opponents of RAC's elimination outnumbered supporters by two to one. Support came mainly from biotechnology and pharmaceutical firms.

The new proposal, which the RAC itself will respond to at a meeting on 9 December, departs significantly from the earlier one, which would have replaced the RAC with a smaller committee charged primarily with convening gene-therapy policy conferences on novel topics.

Abbey Meyers, president of the National Association for Rare Disorders and a member of RAC, calls the new proposal "wonderful". She says that Varmus has "accomplished his purpose" — to avoid adding NIH's stamp of approval to mediocre proposals approved by the RAC, which is charged with judging not scientific quality but ethics.

In contrast, Paul Berg, the biochemist at Stanford University whose concerns in the 1970s were largely responsible for the creation of the RAC, called the revised proposal "an intermediate step" towards abolition. Berg believes that the RAC has outlived its usefulness.

But W. French Anderson, the molecular geneticist at the University of Southern California who pioneered *ex vivo* human gene therapy in 1990, calls the new proposal an "excellent compromise". He wants the panel to continue to vote on the protocols it reviews, because, even though such votes lack any authority, they will have influence.

Another RAC member, Robertson Parkman, a paediatric immunologist at the Children's Hospital in Los Angeles, says that whether the restructured committee takes votes is "irrelevant". The main need, he says, is to have "the pros and cons discussed in a public fashion". But he points out that the current proposal does not specify the threshold of novelty at which a protocol would trigger a majority of RAC members to call for a public discussion.

The revised proposal — provisional until Varmus issues a final version after the next RAC meeting — retains the proposed gene-therapy policy conferences. These will be convened to coincide with RAC meetings and co-chaired by RAC members. The conferences are intended to deal with novel and controversial issues such as *in utero* gene therapy and germ line therapy. Comments on the revised proposal should be sent to the NIH Office of Recombinant DNA Activities by 2 December. **Meredith Wadman**

. . . as concern grows over screening

San Francisco. Companies marketing the first broad-based genetic tests available in the United States are raising unnecessary alarm and promising impossibilities, according to geneticists, bioethicists and others who took part in a forum on genetic testing last week.

"One of my fears is that we will commit so many egregious errors early on that the American public will decide that they do not want to have anything to do with this technology," said Francis Collins, director of the National Center for Human Genome Research at the National Institutes of Health (NIH). "We don't need a genetic thalidomide."

The forum was organized in San Francisco by the Stanford University Program in Genomic, Ethics, and Society. The centrepiece of the meeting was the presentation of guidelines developed by a 53-member panel convened by Stanford to study the introduction of genetic tests for mutations in *BRCA1* and *BRCA2*, which confer susceptibility to breast cancer.

In a keynote address, Collins criticized advertising by the Genetics and IVF Institute, based in Virginia, that appealed to Jewish women, regardless of family history, to be tested for the *185delAG* deletion. This mutation in *BRCA1* is found in about 1 per cent of women of Eastern European Jewish ancestry.

Neil Holtzman, chair of a joint NIH/Department of Energy Task Force on Genetic Testing, chastized companies for their advertising of genetic tests for breast cancer susceptibility. Among other problems, he claimed that Myriad Genetics, of Salt Lake City, Utah, and IVF overstate the risk of breast cancer among women with the *BRCA1* and *2* mutations by using data from the most dramatically affected families.

Participants at the meeting expressed alarm at statements made in a presentation by Mark Skolnick, executive vice-president of research for Myriad, about the company's decision to offer full sequence testing for mutations in *BRCA1* and *2*, at a price of $2,400.

Skolnick argued that claims by the Stanford group about the uncertainty of the tests' benefits were irresponsible and misleading. The Stanford guidelines say that there are no known methods for preventing breast or ovarian cancer that would particularly help women with the mutations; Skolnick said prophylactic surgery was an effective preventive measure that could be taken by women found to have a mutation in *BRCA1* or *2*.

The Stanford guidelines advise most women not to take the test, unless they have a strong family history of breast or ovarian cancer. They call on the Food and Drug Administration (FDA) to regulate all genetic tests and their marketing. The agency should develop new rules that require evidence of safety and efficacy — not only in a medical sense, but also psychologically and socially — before genetic tests enter the market, said Hank Greely, professor of law at Stanford and chair of the panel. **Sally Lehrman**

• Myriad Genetics announced on Monday that it had dropped plans to proceed with a public stock offering, on the grounds that "conditions are not favorable to going forward at this time".