GENE THERAPY

Varmus Proposes to Scrap the RAC

Harold Varmus, director of the National Institutes of Health (NIH), has decided that the government's method of reviewing gene therapy needs to be drastically simplified. In a policy to be announced this week, Varmus is suggesting that it is time to "dissolve" the NIH's Recombinant DNA Advisory Committee (RAC) and end the practice of subjecting each proposed new clinical gene therapy trial to public review. RAC—which includes lawyers, ethicists, public representatives, and clinicians—has served for 8 years as the final gauntlet that gene therapists must clear before getting approval to start a clinical trial.

Instead, Varmus would like to leave detailed safety analyses to others—including the closed-door reviews of the Food and Drug Administration—while focusing NIH's attention on big issues. He hopes to appoint a small group of experts to meet several times a year to advise NIH on gene therapy. In addition, Varmus says, NIH should sponsor regular public workshops examining such questions as whether it's wise to treat fetuses with gene therapy or to use HIV as a therapeutic "vector." Varmus unveiled his plans on 9 May at a meeting of gene therapy researchers in Hilton Head, South Carolina; later he confirmed them in a phone interview with *Science*.

RAC's impending demise has drawn criticism from some prominent gene therapists and current RAC members. But Varmus says that while the panel "did serve some function" in the early days—assuring the public that risks of genetically engineered products were well understood—he believes that it has outlived its usefulness. The two most recent RAC meetings (scheduled for March and June) were canceled because no novel experiments were submitted for approval. In any case, Varmus said, RAC had begun to exhibit a taste for trivia: It often got bogged down in debates over the wording of patient consent forms. "I don't think we can any longer justify the need for an NIH-based approval process," he argues, adding, "I'm not sure it was ever appropriate."

Varmus notes that in proposing to do away with RAC, he is following the recommendations of two expert advisory groups he commissioned last year. Both of them suggested that NIH should treat gene therapy no differently from other types of biomedical research. Indeed, some panelists said the fuss over gene therapy had given the public an overblown idea of its efficacy (*Science*, 15 December 1995, p. 1751). In addition, NIH is tightening up its coordination of intramural research on gene therapy, as the panels recommended, and encouraging studies on basic vector biology.

The announcement that RAC may soon disappear did "not elicit any cries of protest" from the gene therapists at Hilton Head, says Nelson Wivel, the virologist who serves as RAC's executive director. He was in the audience during Varmus's speech and sensed that the clinicians were "not unhappy to hear that they would have fewer hoops to jump through." Wivel is casting his own vote against RAC, in a way. Six weeks ago, he announced that he will be leaving RAC's staff and quitting the government (he also serves as chief of NIH's office of recombinant DNA activities). On 1 July, Wivel will become deputy to one of the best known gene therapists in academic medicine, James Wilson of the University of Pennsylvania.

RICK KOZAK

Broad view. Varmus says NIH should look at issues, not protocol.

Varmus's announcement did spark some dissent, however. W. French Anderson, a former NIH gene therapist now at the University of Southern California, calls the proposed closing of RAC "shortsighted, inappropriate, and wrong." Anderson says RAC's public reviews have "provided the public with confidence that genetic research is being done in an open and appropriate way." While Anderson agrees with Varmus that RAC should not focus on "routine protocols," he thinks it should review and pass judgment on the use of "significant new technologies."

Hematologist Brian Smith of Yale University, a current RAC member, favors efforts to simplify the process. But, echoing Anderson, he argues that Varmus's proposed public workshops ought to focus on actual—not hypothetical—proposals. Smith says, "When you talk about science, you talk about a specific experiment." The RAC "has served its function well because it is so specific," Smith believes, suggesting that it should play the role of a Supreme Court, taking up only exceptional cases. Abbey Meyers—president of the National Organization for Rare Disorders, a RAC member, and a patients' rights advocate—worries that unethical practices will increase if gene therapists are not kept under close scrutiny.

Both skeptics and advocates will have a chance to pass judgment on Varmus's plan. According to staffers, NIH will publish a summary of it in the *Federal Register* this week and allow 15 days for discussion. Then, more likely than not, NIH will terminate RAC.

–Eliot Marshall

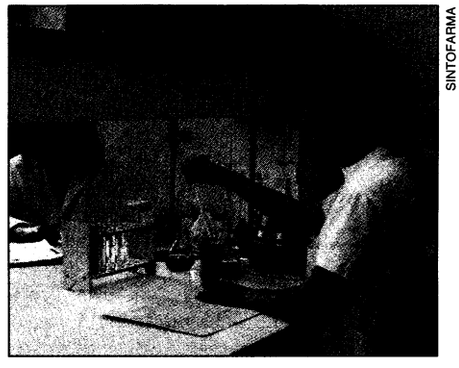
BRAZIL

Patent Law Closes Drug Loophole

SÃO PAULO—After a 5-year debate, Brazil has finally adopted a new patent law that extends intellectual property protection to foods and pharmaceuticals. The law, which was expected to be signed this week by President Fernando Henrique Cardoso, should put an end to the widespread practice in which Brazilian laboratories copy patented drugs and sell them freely in Brazil—the world's sixth largest market for pharmaceuticals. Supporters say the new law should stimulate outside investment as well as build up a homegrown drug industry. But critics contend that it is likely in the short run to have the opposite effect—to drive commercially useful research offshore or into the hands of multinational companies because of the absence of local capacity.

Passed by the legislature last month, the law aims to bring the country in line with international practices. It also relieves tension with the United States, which has been lobbying for stronger intellectual property rights. "Brazil has done the right thing," says a spokesperson for the Pharmaceutical Research Manufacturers of America. "We see it as a model for the rest of Latin America and the world."

While Cordoso says that the law is a step away from a "colonialistic mentality," many groups fought the measure on the grounds that the low level of R&D spending by Brazilian firms will give foreign-owned companies a chance to lock up all commercially valuable research. "We are not competitive," says Sara Kanter, technical director of the Association of the National Pharmaceutical Laboratories in São Paulo. "Our industry is still in the copy-and-innovate phase, and our market share does not allow us to have capital enough to invest in research." She predicts that the law will lead to "90% of the Brazilian academic research [in the field] being absorbed by multinational companies."



SINTOFARMA

Private property. New law ends a drug company's freedom to pirate patented products.