view clinical research protocols to make sure they conform to ethical guidelines governing research on human subjects. They have the authority to require changes in protocols or veto them if they don't pass muster.

Healy is not alone in wanting to beef up the IRB system. "The IRBs aren't nearly as sensitive to the changing morals of society as they should be," asserts Walter Rogan, an epidemiologist at the National Institute of Environmental Health Sciences and chair of its IRB. In particular, Rogan argues that some IRBs are only now beginning to realize how important it is to include women and minorities in study populations. Because of these perceived shortcomings, the director of NIH's Clinical Center, other institute directors, and NIH's bioethics office in the past have kept an eye out for potentially troublesome protocols. In fact, in the fall of 1991, then deputy director for intramural research Carl Kupfer singled out one project—an experiment that may one day lead to a visual prosthesis for the blind—for an extra review that could serve as a model for the sort of additional scrutiny the PIRCs will recommend (see box on p. 1820).

Liotta formalized this ad hoc screening in an August 1992 memo to the institutes' scientific directors, asking them to set up a PIRC in each institute. Liotta said the PIRCs (each composed of the institute's scientific director, clinical director, and a third scientist, preferably an official in NIH's extramural program) should double check the IRB minutes and pay close attention to research that involves "potentially vulnerable" subjects such as children, pregnant women, and prisoners. They should ensure that any collaborative research ventures are "fully documented and are deemed to be free of conflict of interest." And, finally, Liotta gave the panels a broad directive that some researchers find troublesome: The PIRCs should check that each protocol is "consistent with [the institute's] research objectives and is likely to yield knowledge of importance to the mission of NIH." Says one IRB chair: "That's vague...there's great concern in the scientific community over what that means."

Liotta said that the panels should direct specific problems with protocols to the IRB chairs, but protocols "of special interest" should be sent to him. Liotta would then decide whether to convene a "special review committee," including NIH policy experts and a couple of ad hoc members with relevant scientific backgrounds, to take a closer look. Sandler, who played a key role in designing the new system, says the committee has the authority to turn down protocols if necessary.

Most NIH officials contacted by *Science* are reserving judgment until the system has been in operation for some time. (Since the PIRCs were established last fall, they have flagged six protocols, all of which Liotta has approved without further review.) But there's some unease about the power of the Special Review Committee, says David Goldman, a geneticist at the National Institute on Alcohol Abuse and Alcoholism and chair of that institute's IRB. Says another IRB chair: "We didn't want [this extra layer of review]; it's a potentially dangerous layer of administrative coverage."

Investigators themselves also seem to have mixed feelings about the new system. "It's all pretty reasonable," says Frank Balis, a cancer researcher at the National Cancer Institute and previously a longtime IRB chair. "In a sense it's not the committee that's making those protocols political, it's the studies themselves," he says. But one investigator who's been through an extra review commissioned prior to this system—Conrad Kufta, principal investigator of the visual prosthesis protocol—feels differently. "There's a lot of controversy at the principal investigator level," he asserts. "We don't want to go through another layer of bureaucracy to get things done."

Some IRB chairs welcome the new system, however. "On the surface there's an air of political correctness," says Phillip Fox, a dental researcher who chairs the IRB for the National Institute on Aging. But, he says, "it doesn't hurt to have more people look at a protocol. In the climate of society today, the more examination the better."

**–Richard Stone**

AIDS VACCINES

# MicroGeneSys Withdraws From Trial

MicroGeneSys Inc., the controversial biotech firm that enraged AIDS researchers last fall when it successfully lobbied Congress for $20 million to test its therapeutic AIDS vaccine, once again has the scientific community up in arms. Ironically, this time the Meriden, Connecticut, company is being assailed for the opposite behavior: refusing, at the last minute, to allow its vaccine—VaxSyn—to be used in a long-planned, government-sponsored trial of therapeutic AIDS vaccines.

Why would the company take such different stances only a few months apart? MicroGeneSys president Franklin Volvovitz did not respond to repeated requests for an interview by *Science*, but the small biotech firm's corporate partner, Wyeth-Ayerst Research, said in a letter to the organizers of the planned trial that the protocol "does not address any specific issues directly relevant to the Clinical Plan for VaxSyn development and licensure," and cited "scientific considerations" as reasons for the withdrawal, including the timing of vaccine shots in the trial and the trial's clinical endpoints. Some angry researchers, however, don't think that's the whole story. They point out that the trial MicroGeneSys pulled out of would have involved a comparison of VaxSyn with vaccines made by two other companies: Chiron and Genentech. The trial the company lobbied for last fall, in contrast, would focus solely on the MicroGeneSys product.

HANK MORGAN

**Pulling out.** MicroGeneSys president Franklin Volvovitz.

Therapeutic AIDS vaccines aim to expand immune responses in already infected people, delaying or preventing the onset of disease. A half-dozen such vaccines are now being tested in human beings, and though it is not clear that any of them can delay the onset of AIDS, they appear to be safe—and some show hints of clinical promise.

The comparative trial MicroGeneSys bowed out of is being planned by the National Institute of Allergy and Infectious Diseases (NIAID) to find out which preparation is most likely to fulfill that promise. Though the MicroGeneSys, Chiron, and Genentech vaccines all contain genetically engineered versions of a protein that studs HIV's surface, the vaccines differ in the size of the protein they contain, the strains of HIV they rely on, and the way they are prepared. These differences might mean that one of them works better—or worse—than the rest.

John Moore, a researcher at New York's Aaron Diamond AIDS Research Center, contended in a letter published in the 11 February *Nature* that MicroGeneSys, unlike Chiron and Genentech, has engineered a protein that does not mimic the native HIV protein closely enough and thus has a "severely limited" ability to induce a "relevant" antibody response. "It's unfolded and has a shape nothing like the natural molecule," says Moore. "Some people would think that's a virtue. Most people would think of that as a crippling handicap." In the past, MicroGeneSys has argued that no one knows precisely what the relevant antibody

response is and noted that VaxSyn is capable of stimulating cell-mediated immunity, another critical line of immune-system defense.

NIAID had hoped to find out who's right in this set-to by comparing vaccines in a head-to-head trial. Working with representatives from each of the three companies, NIAID began designing the comparative trial last summer. In all, 120 HIV-infected people were to be enrolled at eight sites in a 9-month trial that would measure changes in the immune system and the amount of HIV found in blood.

As the plans for the trial developed, two events occurred that Robert Schooley, the principal investigator of the NIAID-sponsored trial, suspects led MicroGeneSys to jump ship. One is that in October, Congress listened to well-connected MicroGeneSys lobbyists and allocated $20 million to the Department of Defense for large-scale tests of VaxSyn. (It's still not clear whether that trial will proceed, but the law says a decision must be made by 6 April—see *Science*, 23 October 1992, p. 536 and 5 February, p. 752.) In addition, MicroGeneSys announced last month that Swedish researchers are launching a VaxSyn trial in 1000 HIV-infected people, which the company hopes will reveal the vaccine's clinical effectiveness as early as 1995. Because of these trials, MicroGeneSys has "very little to gain by comparing their vaccine to the others," argues Schooley, head of infectious diseases at the University of Colorado Health Sciences Center. As a result, Schooley says, he was not surprised when MicroGeneSys, through Wyeth-Ayerst, notified him on 2 March that they were pulling the plug on the comparative trial.

David Ho, head of Aaron Diamond and one of the researchers set to analyze samples from the trial, says, "I think [the MicroGeneSys] product is going to look worse by [the] standard, objective measurements" used in the comparative trial—and he thinks that's the reason MicroGeneSys withdrew. Not so, retorts Wyeth-Ayerst—which has a minority interest in the biotech firm and a licensing agreement to market VaxSyn. In a statement to *Science*, the company says "we have no objection to a comparison of VaxSyn" with similar products, and notes that VaxSyn is already part of a government-sponsored comparative study in infected children.

Schooley, in a sharply worded reply to Wyeth-Ayerst, called the company's scientific objections to the trial "relatively weak." He also criticized Wyeth-Ayerst for taking a short view of therapeutic HIV vaccines. "If they were in it for the long haul, they'd like to know as much as they could about their vaccine," he argues. And he says that if only one vaccine is tested and it doesn't work, the effect would be "like a blocking antibody to letting the field develop in a scientifically meaningful way."

Though the withdrawal of MicroGeneSys was a blow to the comparative trial's designers, the NIAID trial, now limited to two participants, remains on the drawing board and should begin within a few months.

**–Jon Cohen**

## Egineering Academy Elects New Members

Sixty-nine men and four women have been elected to membership in the National Academy of Engineering. They are:

**B. Jayant Baliga**, North Carolina State University; **Peter M. Banks**, University of Michigan; **Leslie A. Benmark**, E.I. du Pont de Nemours & Co.; **F. Peter Boer**, W.R. Grace & Co.; **Robert K. Brayton**, University of California, Berkeley; **Renso L. Caporali**, Grumman Corp.; **Philip R. Clark**, GPU Nuclear Corp.; **Harvey E. Cline**, GE Corporate Research and Development Center; **Jerome B. Cohen**, Northwestern University; **Jerome J. Cuomo**, IBM Thomas J. Watson Research Center; **Carl R. De Boor**, University of Wisconsin, Madison; **George E. Dieter Jr.**, University of Maryland, College Park; **Earl H. Dowell**, Duke University; **Stephen W. Drew**, Merck & Co. Inc.; **Charles B. Duke**, Xerox Corp.; **Francis G. Dwyer**, Mobile Research & Development Corp.; **Jerald L. Ericksen**, engineering consultant, Florence, OR; **Leroy M. Fingerson**, TSI Inc.; **Fred N. Finn**, consulting civil engineer, Monticello, IL; **Robert L. Fleischer**, GE Corporate Research and Development Center; **John W. Fondahl**, Stanford University; **William L. Friend**, Bechtel Group Inc.; **B. John Garrick**, Pickard, Lowe, and Garrick Inc.; **Ronald E. Goldsberry**, Ford Motor Co.; **Susan L. Graham**, University of California, Berkeley; **Walter Herrmann**, Sandia National Laboratories; **David W. Johnson Jr.**, AT&T Bell Laboratories; **Donald L. Johnson**, Grain Processing Corp.; **Donald B. Keck**, Corning Inc.; **Alexander M. Klibanov**, Massachusetts Institute of Technology; **Gerald L. Kulcinski**, University of Wisconsin, Madison.

**H.T. Kung**, Harvard University; **James L. Lammie**, Parsons Brinckerhoff Inc.; **Robert C. Lanphier III**, AGMED Inc.; **Richard C. Larson**, Massachusetts Institute of Technology; **W. John Lee**, Texas A&M University; **Sidney Leibovich**, Cornell University; **Thomas S. Maddock**, Boyle Engineering Corp.; **Jan D. Miller**, University of Utah; **Linn F. Mollenauer**, AT&T Bell Laboratories; **Manfred Morari**, California Institute of Technology; **E. Phillip Muntz**, University of Southern California; **Tak H. Ning**, IBM Thomas J. Watson Research Center; **James G. O'Connor**, United Technologies Corp.; **Thomas D. O'Rourke**, Cornell University; **David A. Patterson**, University of California, Berkeley.

**Irene C. Peden**, National Science Foundation; **Alan W. Pense**, Lehigh University; **Richard H. Petersen**, Virginia Air and Space Center; **Arun G. Phadke**, Virginia Polytechnic Institute and State University; **Frederick G. Pohland**, University of Pittsburgh; **James W. Poirot**, CH2M Hill Inc.; **William F. Powers**, Ford Motor Co.; **Donald W. Pritchard**, State University of New York, Stony Brook; **Fredric Raichlen**, California Institute of Technology; **Jose M. Roesset**, University of Texas, Austin; **Donald E. Ross**, Jaros, Baum & Bolles; **Nicholas Rott**, Stanford University; **Paul E. Rubbert**, Boeing Commercial Airplane Group; **William B. Russel**, Princeton University; **Albert B. Schultz**, University of Michigan.

**Deborah J. Seifert**, Allied-Signal Aerospace Co.; **Hsieh W. Shen**, University of California, Berkeley; **Robert J. Spinrad**, Xerox Corp.; **Alvin W. Trivelpiece**, Oak Ridge National Laboratory; **G. Keith Turnbull**, Aluminum Co. of America; **Charles M. Vest**, Massachusetts Institute of Technology; **C. Michael Walton**, University of Texas, Austin; **Joseph E. Warren**, Joseph E. Warren Inc.; **Watt W. Webb**, Cornell University; **Jack K. Wolf**, University of California, San Diego; **William A. Wulf**, University of Virginia; **William D. Young**, Genentech Inc.

Eight engineers have been elected as Foreign Associates: **Che-Min Cheng**, Institute of Mechanics, Beijing, China; **Kaare Hoeg**, Institute of Geology, University of Oslo, Norway; **Jiro Kondo**, president, Science Council of Japan, Tokyo; **Yuri A. Ossipyan**, Solid State Physics Institute, Russian Academy of Sciences, Moscow; **Roger W.H. Sargent**, Imperial College of Science and Technology, London; **Yasuharu Suematsu**, Tokyo Institute of Technology, Tokyo; **Hans-Juergen Warnecke**, Fraunhofer Institute for Manufacturing, Engineering, and Automation, University of Stuttgart, Germany; **Niklaus Wirth**, Swiss Federal Institute of Technology, Zurich, Switzerland.