South Carolina Blocks Test of Rabies Vaccine

A plan to test a genetically engineered virus on raccoons in the wild is on hold at least until next spring

CEDAR AND MURPHY ISLANDS are slivers of placid wooded land off the coast of South Carolina, but they have become the center of a dispute that has been simmering between scientists and state officials over a proposal to conduct a novel biotechnology experiment.

For nearly 2 years, researchers at Philadelphia's Wistar Institute of Anatomy and Biology have been trying to win federal and state approval to test a genetically engineered rabies vaccine on the islands' resident raccoons. The researchers believe the vaccine could be a potent weapon in controlling rabies worldwide.

They thought they were close to reaching final approval this spring when the test passed muster with the U.S. Department of Agriculture and the South Carolina Wildlife and Marine Resources Department. But on 15 June, the South Carolina health department, Wistar's last regulatory hurdle, rejected the institute's request. Health officials left open the possibility that Wistar could conduct the test next spring, but they have demanded more proof that the vaccine is safe. Wistar scientists contend that the health department is essentially demanding the impossible: that the experiment pose zero risk.

The disagreement and the reasons behind it provide yet another example of how proposals for small-scale outdoor experiments with genetically engineered organisms stir anxiety—often out of all proportion to the scientific risks involved—in local authorities and how scientists can inadvertently exacerbate these emotions in the quest for regulatory approval.

Wistar scientists created the rabies vaccine by snipping the gene for a glycoprotein from the rabies virus and inserting it into a weakened strain of vaccinia virus: the old smallpox vaccine. They intend to spike smelly fish bait with the vaccine and leave it on the island for the raccoons to eat. The vaccine is being manufactured by the French company, Rhône Merieux, one of the



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world's largest makers of animal biologics. Wistar would make \$10,000 a year plus perhaps a nickel per dose in royalties, says associate director Warren Cheston.

With encouraging lab results in hand, Wistar scientists now need to evaluate the vaccine in the wild. Cedar and Murphy Islands provide an ideal spot. The surrounding water provides a natural barrier to prevent raccoons from migrating into or out of the test area. The islands are free of rabid raccoons and endangered species. They are seldom used for recreation and are accessible only by boat.

But because the vaccine had already been the focus of some bad publicity, Wistar officials anticipated difficulties in getting approval for its test. Three years ago, Argentine officials accused Wistar scientists of testing the vaccine on local cattle without notifying government authorities, and they claimed the institute failed to take adequate health precautions with the animal caretakers (Science, 28 Nov. 1986, p. 1068). Although Wistar researchers argue that they got a bum rap, they knew they would have to minimize the impact of that incident on South Carolina authorities. So Wistar hired the public relations firm Hill and Knowlton to help pave the way—a move that was to backfire in some respects.

State health department officials concluded that the vaccine cannot cause rabies in

animals or humans. But they raised another concern: could the vaccinia virus itself pose a danger to humans? When the original live smallpox vaccine was administered decades ago, a relatively small number of people developed serious neurological problems. Although Wistar is using a different and more attenuated vaccinia strain, South Carolina officials have made suggestions that the institute should test the vaccine on primates before proceeding with the field trial.

Wistar scientists argue that the strain they are using is attenuated even more by the gene insertion. Furthermore, the chances of human exposure to the vaccine during the test on the island are very slight. Even USDA deputy director of veterinary biologics David A. Espeseth seems to disagree with the state officials. Espeseth said in an interview that it would be unusual, if not unprecedented, to test an animal vaccine on primates to evaluate its safety to humans

To South Carolina officials, Wistar's hiring of a public relations firm was a handicap. Says Jarrett: "We wanted to know

about the science. But Wistar scientists hired a PR firm to handle the approval politically rather than working scientist to scientist. We got phone call after phone call from politically influential people to approve this." Wistar officials counter that the state health authorities have never made it clear what would satisfy their concerns. Charles Rupprecht, head of Wistar's rabies vaccine unit, says that state health officials are "focusing on science fiction, the things that sell movies. We're trying to work through that."

Brown also noted that although Rhône Merieux said it would assume liability for the field test, the company's insurance policy expired 3 months ago. "It's not the type of thing that builds confidence," he says." (The policy has been renewed.)

Is Wistar dead in the water? Hedging its bets, Wistar applied to Virginia at the same time it applied to South Carolina to conduct the test on one of its islands. A decision by Virginia officials is expected this summer. Cheston says although the institute is disappointed by the South Carolina health department's decision, it will keep trying to satisfy officials there.

Jarrett comments, "We'd like to take part in solving what's a worldwide problem, but I don't know what the risk is of vaccinia. There was a lot of PR effort without resolving the technical problems."

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