derive a significant portion of their income from the production of traditionally bred tomatoes." It is a familiar—and potentially potent—set up.

Well, Fred—his number is (904) 592-6506—turns out to be the Florida chairman of the American Agriculture Movement, a lobbying group for small farmers. Fred feels "the small family farmers don't get what they should out of these things. It all goes to the big men." That's you, Roger. "A housewife ought to know that these are generic (sic) tomatoes and these are regular home-grown tomatoes like we've been growing all along." Fred may not know you intend to voluntarily label you tomatoes. Maybe you should tell him.

Tommy's another story. A retired tomato farmer whose three boys have taken over the farm, which is big enough to employ some 60 to 70 migrant workers for harvesting, Tommy Jackson says he talked on the phone to somebody up north from FET—he thinks it might have been JR—"less time than you've been talking to me." He continued: "You know how you get led by other indivduals, especially if you're busy and don't have time to figure out what they're asking you?" Well, there you go, Roger. That pretty much says it, doesn't it? One more thing. Tommy Jackson is also ready to plant genetically engineered tomatoes. "If I had to put on the box it was genetically improved, I don't see anything wrong with that," he says. "Why, if I was allowed access to it, I think I could compete with anybody." If you wondered, "it" means seeds for Flavr-Savr tomatoes. The coin of economic self interest has two sides—and you are sitting on one of them, Roger. I'd say Tommy Jackson, (904) 592-9530, was giving you the green light.

There may be others. Why don't you try John Stone, (904) 592-6701, and Jerry Howell, (904) 593-6198, too? They were the two other tomato farmers whose names JR's staff signed to his FDA petition and who apparently believe the "health and safety of the American public are at grave risk because genetically engineered foods may soon enter the consumer marketplace." Anyway, that's the statement they endorsed. So did Tommy.

Then you can start in on the chefs.

With reporting by Don Marti, assistant editor at ECO Magazine (Mount Kisco, NY).

BIOMEDICAL-POLICY EARTHQUAKE

AIDS-VACCINE BATTLE

WASHINGTON, D.C.—In a series of extraordinary developments, a candidate AIDS vaccine being developed by MicroGeneSys (Meriden, CT) has catapulted not only into the front runner's position in the race to a full-scale clinical trial but also into the epicenter of major biomedical-policy earthquake. The lobbying strategy followed by MicroGeneSys could backfire, however, if one plausible scenario develops—namely, that several competing AIDS vaccines are added to the large-scale trial now being contemplated.

The structure of the MicroGeneSys candidate vaccine, known as gp160, is based on a key glycoprotein in the coat of HIV. It is made by means of a baculovirus-based production system. Ordinarily, such viruses infect insects.

Public awareness of gp160 soared—and controversy flared—recently when Congress designated special funds of $20 million to support a clinical trial testing this vaccine. The funds, designated in the Department of Defense (DoD, Washington, DC) appropriations bill for a program directed by the Walter Reed Army Institute of Research (Washington, DC), were earmarked in part as a result of a lobbying campaign directed toward key members of Congress.

"In advocating a phase III efficacy test for gp160, Congress is recognizing the need to move forward promptly on treatments for AIDS and that the gp160 vaccine is the most-studied vaccine treatment now undergoing research," says Frank Volvovitz, the chief executive officer of MicroGeneSys. He also hints that his company's vaccine has not been given fair treatment by other scientists.

Diverse critics

The outburst against this lobbying-based approach to gain federal funds for a vaccine trial comes from a diverse corps of critics. For example, leading AIDS researchers from around the country, as well as key officials at the National Institutes of Health (NIH, Bethesda, MD) and the Food and Drug Administration (FDA, Bethesda, MD), have cried foul. In general, they argue that qualified experts—not lobbyists or members of Congress—should be deciding such complex public-health questions as how to evaluate vaccines for combating AIDS.

In addition, influential AIDS activists complicate the picture still further. Indeed, some argue in favor of gp160, saying that federal officials are dithering, while others, who welcome accelerated movement toward clinical trials, insist that the choice of experimental vaccines cannot be left to congressional whim or the self interest of vaccine producers.

Though members of Congress left a critical opening for NIH and FDA officials to have a say on gp160, the opening carries some peculiar features. An amendment to the appropriations bill stipulates that, besides DoD officials, appropriate authorities from NIH and FDA will need to confer before the clinical trial begins. However, the amendment is written in terms best appreciated by lawyers—explicitly stating that the trial will not go ahead unless officials from all three agencies concur on that decision. In other words, three dissenting opinions are required to block the trials.

In practical terms, however, that particular tactic may not work. FDA Commissioner David Kessler, for one, says unequivocally that his agency "will not abrogate its fundamental responsibilities" to assess gp160. Thus, regardless of language in the DoD appropriations bill, FDA officials could unilaterally block a clinical trial if, for example, they conclude that gp160's safety is not adequately demonstrated.

More comprehensive trial

These moves and countermoves swirled about as NIH and FDA officials convened the first of several meetings to consider gp160's test worthiness. "Your task is to inject scientific judgment where it is lacking and to provide an objective assessment of gp160 and of any other candidate vaccines," NIH director Bernadine Healy told an ad hoc advisory panel. "From the most cynical point of view, it would appear that Congress has signed an uninformed consent form for patients with AIDS. However, Congress's motivation is the desire to find a cure for this devastating disease."

After its first meeting, the panel reached no conclusions and framed no recommendations. However, it reviewed several other experimental AIDS vaccines in various phases of testing. In so doing, the panel learned that none of the subunit products so far has been proved unsafe. Neither has any emerged clearly as effective, in large part because early tests simply are not designed for that purpose.

In the face of that scientific uncertainty, an unlikely scenario may be taking shape as a way of finessing some of the current controversy. Conceivably, the panel could endorse a more comprehensive clinical trial than was envisioned in the DoD appropriations bill, one that would compare several vaccine candidates, including MicroGeneSys's gp160, across a large group of HIV-infected individuals. **—Jeffrey L. Fox**