Free Speech and Clinical Trials

What happens when the publication requirements of a federal research contract collide with the Bill of Rights? It's not a question that comes up very often. But it did last week, when Stanford University won a lawsuit against the National Institutes of Health. Stanford had charged that federal research contracts restricting publication of research results are in violation of the First Amendment, and Judge Harold Greene, of the U.S. District Court in Washington, D.C., agreed. Greene ordered NIH to reinstate a $1.5-million contract it had denied Stanford when the university refused to agree to a requirement that it submit results of the study to NIH for approval before publication.

The decision isn't just an abstract delight for scholars of the Constitution. On the contrary, it could potentially affect a significant chunk of the more than $550 million in research contracts awarded by NIH each year. According to an NIH spokesman, there is no record of how many of those contain the approval requirement, but it is commonly used in multicenter clinical trials.

The dispute over the requirement began in June 1990, when the National Heart, Lung, and Blood Institute (NHLBI) awarded a contract to Stanford cardiac surgeon Philip Oyer for the testing, in 10 patients, of an artificial heart-assisting device called a left ventricular assist system. A similar contract was awarded at the same time to the University of Pittsburgh. But Stanford refused to agree to a clause in the contract requiring Oyer to apply for permission from the NHLBI contract officer before publishing any results of the study. According to Stanford lawyers, the clause violated not only Stanford's policy concerning freedom to publish, but also the First Amendment right to free speech.

Since Stanford wouldn't agree to the clause, the contract was withdrawn from Stanford and awarded to St. Louis University Medical Center in Missouri; Stanford filed suit last October to get it back (see *Science,* 9 November 1990, p. 746).

In his decision, Judge Greene compared the case to another First Amendment case involving the Department of Health and Human Services—Rust *v.* Sullivan—in which the Supreme Court recently ruled that the federal government could prevent physicians and counselors in federally supported family planning clinics from discussing abortion with their clients. But Greene found the restrictions in the Stanford case to be broader than those in Rust. "Unlike the health professionals in Rust," wrote Greene, "the Stanford researchers lack the option of speaking regarding artificial heart research" even on their own time, until it is approved by NIH. That degree of restriction is unconstitutional, the judge concluded.

How will the ruling affect the multicenter trials that are typically bound by the clause? NIH officials wouldn't comment on that question last week. When the suit was filed, however, NIH officials argued that without the clause, an unrepresentative part of the results of a clinical trial could be published independently—leading to confusion among both physicians and the public. But Stanford attorney Iris Brest argues that removal of the clause is unlikely to have damaging effects because researchers in multicenter trials tend to police themselves. "There is a very well-elaborated process," she says, by which results of such trials are coordinated.

Not all those familiar with such trials, though, say the picture is so simple. Epidemiologist Stephen Hulley of the University of California, San Francisco, who has participated in several trials funded by heart institute contracts, agrees with Brest that most researchers involved in such trials agree voluntarily to reach consensus before publication. But Hulley adds that health policy decisions "can be impeded by frivolous reporting." The clause, he says, may in some instances act as a failsafe to rein in individuals who might not be willing to go along with the group.

Whether that failsafe has truly gone by the boards won't be known until NIH decides if it's going to appeal the decision—a question that NIH spokesmen refused to comment on at the moment. If NIH decides not to appeal, or if it loses the appeal, then some other, more practical matters remain to be decided. Among them could be the fate of the contract with St. Louis University. Although some press reports last week suggested St. Louis might have to give up its grant, an NIH spokesman firmly denied the court's decision had any such implication. But what the ultimate implications of the decision are clearly remain to be worked out. ■ MARCIA BARINAGA

Emphasizing the Health in NIH

For much of its history, the National Institutes of Health has functioned like a collection of occasionally overlapping scientific fiefdoms, with each institute largely pursuing its own research agenda. Ending this Balkanization of biomedical research was high on the list of Bernadine Healy's priorities when she took up the reins as NIH director early this year, and it was clearly high on the agenda at a unique meeting of the agency's top brass last month.

On 10-11 September, the chiefs of the 15 institutes and five centers that make up NIH spent 20 hours in a retreat going over the rough outlines of a strategic plan, scheduled to be completed early next year. The blueprint is intended to set out some overarching research and policy themes for NIH and to tie its activities more firmly to public health goals. In addition, says Healy, one aim is to develop "a sense that we are a single corporate entity."

The job of coordinating the development of the plan has fallen to Jay Moskowitz, associate director for science policy and legislation, who has become one of Healy's top deputies. Moskowitz, who was the first director of the new National Institute on Deafness and Other Communication Disorders, says that Healy's corporate analogy is exactly appropriate to what NIH is up to, and it's a strategy that other large "mission" agencies have adopted. "We're developing a plan like NASA would," he says. Just as NASA sets large program goals—such as going to Mars or launching a space station—NIH will identify scientific topics crucial to the nation's health, and only then decide how much research support is needed to pursue them. This would inevitably affect NIH's traditional penchant for setting numerical targets for the grants the agency will give out, Moskowitz says. "You don't ask how many grants will come out of the space station," he notes.

The effort to emphasize the "Health" in NIH serves two purposes. First, it helps answer critics in other government agencies who complain that NIH is more concerned about the budgetary headaches of scientists than the health needs of the public. Second, it takes advantage of what NIH officials believe is a well-established willingness to spend tax dollars on health-related research—hence Moskowitz' statement that "we're not the National Institutes of Sci-

ence, we're science in the pursuit of health."

In addition to setting a corporate philosophy, the planning process is intended to establish some specific areas for emphasis. A small committee of senior NIH officials chaired by Moskowitz had come up with 12 science topics and 11 policy issues that served as focusing themes for the 2-day meeting. For each topic area, the individual institutes and centers were asked to suggest projects they are already funding that could be part of a larger, NIH-wide activity. This approach is "tremendously encouraging to the smaller institutes," says National Institute of Dental Research director Harald Loe, because it will provide an opportunity to engage in projects that they could never afford on their own. And Loe says it will also get them in on the early planning stages of projects, rather than being asked to piggyback some research on a protocol already developed by a different agency.

The strategic plan is scheduled for a formal unveiling on 5 February in Texas at a Southwest Foundation research symposium. So far, work is well advanced on the science topics, but is lagging on the policy topics. This isn't surprising, given the recent difficulty NIH has had grappling with issues like scientific misconduct, research on fetal tissue, and issues relating to human reproduction.

One issue still to be worked out is how to implement the plan. Work on this has just begun. Each institute will continue to receive a separate budget from Congress, so how can they be persuaded to participate in the cross-cutting activities?

Again, using the corporate analogy, Healy and Moskowitz see the meetings of institute directors acting like corporate board meetings where recalcitrant corporate divisions are brought into line by the will of the majority. Healy is convinced that the directors will not be alienated by this process. At last month's meeting, "[They] saw that their roles were not diminished by the process," she says, adding, "Everybody wants to be a part of NIH's future and they don't want to be left at the station when the train pulls out."

Sounds good, but will some Machiavellian institute head emerge to tilt the planning process to his or her own ends? So far the answer appears to be no, and the plan is moving forward according to schedule: After it has been shown to the scientific community at a series of meetings in February, it will be discussed with senior officials in the Administration and members of Congress. And insiders are already saying that just the act of developing the strategic plan represents a turning point in the direction and management of NIH. ■ JOSEPH PALCA

Glenn Uncovers the Great Pizza Scandal

Senator John Glenn (D–OH), like other people who followed the investigation of Stanford's accounting practices, has the impression that "our major universities are slipshod" and "lackadaisical in the management of their own affairs." So, as chairman of the Senate government affairs subcommittee, he commissioned a study to see if officials who oversee grants at the National Science Foundation (NSF) really know how scientists are using the money they receive—whether it is always put to worthy purposes or sometimes to frivolous uses.

Sen. John Glenn

After combing through the records of three big universities—Harvard and the universities of Chicago and Michigan—for 10 months, a team of accountants from the General Accounting Office (GAO) returned last week and spilled its findings before Glenn's subcommittee. There was palpable relief among the university administrators in the chamber as the auditors detailed their "revelations." It was hardly a catalogue of horrors:

■ Although rules forbid the use of research funds for entertainment or food, GAO found that grantees had spent about $5000 at the three universities for "pizzas, deli sandwiches, luncheons, and dinners"—apparently because they wrongly assumed that "working lunches" were billable.

■ A University of Chicago researcher paid for two $500 "thank-you" lunches for people who had helped him with his grant proposal; grant funds may not be used for this purpose.

■ Grants may be used only for air travel on U.S. airlines, but GAO investigators found that an administrator at Michigan used university funds to buy a $515 ticket on a foreign carrier, then compensated by charging an NSF grant $500 for office supplies.

■ Michigan billed an NSF grant for $4754 worth of fax and Xerox machine expenses that were not used specifically for research. These should have been billed as "indirect expenses."

"For the most part, we found no basis for questioning" the expenditures of NSF grantees, GAO's Judy England-Joseph testified. But the administrators' relief may have been premature. England-Joseph went on to say that government auditors have no reason to be confident that worse offenses are not hidden in the records. "NSF does not have a system in place to provide for adequate federal oversight of its grants," she said, and for this reason GAO cannot say whether the results of its audit were typical or not. The implication: More record-keeping and auditing may be needed. And, as it happens, that's just what universities are about to be faced with, as a result of reforms installed by the Office of Management and Budget (OMB) in 1990.

Until recently, all agencies of government have relied on universities to check abuses on grant expenditures through what is essentially a self-policing honor code. And while universities were supposed to submit biennial audit reports to the government, few did. In fact, Harvard, Michigan, and Chicago were among those who made no filings. Alexander Sharp, vice president for business at the University of Chicago, says this failing occurred not through sloth or sloppiness, but because "we never got the guidelines" from the government explaining how to do it.

Guidelines have now been formulated and put into effect under a new rule (OMB circular A-133), making it mandatory to file grant expenditure reports, prepared every other year by an outside auditor. The first are due this year. While this will be an improvement over past practices, NSF's inspector general, Linda Sundro, says her office won't be able to check the reports in detail, given the small size of the staff. Glenn, weighing the possibility of increasing the NSF inspection staff, said, "I don't want to set up a program that's going to require zillions of accountants accounting for every nickel," yet he doesn't want people thinking they can "dip into the federal money bag," either.

While university officials were concerned about the cost of OMB's new rules (Harvard may spend an extra $200,000, and Chicago, more than $50,000), they were pleased that the government still plans to rely largely on university staffs—with independent auditors—to police the faculty. ■ ELIOT MARSHALL