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Since Stanford wouldn't agree to the clause, the contract was withdrawn from Stanford and awarded to St. Louis University Medical Center in Missouri; Stanford filed suit last October to get it back (see *Science,* 9 November 1990,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