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NEWS AND COMMENT

NIH: Plan to Charge Research Patients Provokes Protest

Caspar Weinberger, Secretary of Health, Education, and Welfare (HEW), has decided that charging research patients at the National Institutes of Health (NIH) would be a good way for government to make a little extra money. His proposal, which is one of a long series of generally successful moves to reduce the federal commitment to biomedical research, has convinced many members of the NIH community that the Nixon Administration really is out to get them. Something of a "this is the last straw" atmosphere prevails among clinicians at the NIH campus in Bethesda.

Representative Paul G. Rogers (D–Fla.), chairman of the House subcommittee on health and environment, has accused Weinberger of wanting to "change the world's greatest clinical research center into a community hospital."

Since the inception of the NIH Clinical Center in 1953, its patients, who are said to give as much as they get when they check into the 300-bed research-only hospital, have always been treated free. NIH investigators fear that the move to charge patients will destroy the intellectually special environment of the center which, over the years, has earned an extraordinary reputation for excellence in clinical research. NIH is often the place that the latest results of laboratory research are first applied at the bedside. It is often there that new ideas for therapy are developed to the point at which they can be widely used to patients generally. And the explanation for this, NIH supporters argue, is that the Clinical Center is such an ideal place for doing the kind of front-line research that it does. Every patient the center gets is an experimental subject. It is argued that guinea pigs should not be charged for the privilege of contributing to the advancement of medicine.

Charles C. Edwards, assistant secretary for health at HEW, is one member of the Administration who is sympathetic to those who would leave the Clinical Center and its way of doing business in tact. In a 26 October memo, he told Weinberger that he "would recommend against" charging Clinical Center patients. Edwards surely echoed the thoughts of NIH investigators when he wrote:

> I think it is important to emphasize that the Clinical Center is not a typical health facility. While most hospitals exist to provide direct benefits to patients, the Clinical Center's only reason for existence is to increase biomedical knowledge through the support of clinical investigation. Center *research patients*, although they may be receiving useful treatment and the best of patient care, are also directly participating in diagnostic and therapeutic trials. *These patients are occasionally on placebos and undergo many diagnostic tests unrelated to normal treatment.* Many patients suffer from diseases which have no established treatment and are actually studied rather than treated. Generally, all Clinical Center patients give their time and cooperation by accepting research procedures which are often uncomfortable and restrictive. In my view . . . it is simply inappropriate to ask or request research patients for payment under such conditions.

The thing that makes this all so difficult for NIH investigators to take is that the financial stakes are so comparatively low, measured in almost any terms, compared to the intellectual and psychological stakes which, for them, are so high. The figure that is being bandied about as that which the government would earn if it started charging patients is $9 million, give or take a little. Researchers feel that it is unwise to jeopardize a program of proven value for a sum as modest as this. They are afraid that if they have to start charging, patients won't come in many instances, which would mean an end to the Clinical Center.

If a charge system were put into effect at the Clinical Center, most of the money would come from third-party payers—insurance companies, Blue Cross and Blue Shield, and the like. To get some rough information about the insurance coverage of patients in the Clinical Center, a survey was made of the 284 persons who were in the hospital last 6 September. Seventy-four percent carried either private or government insurance; the rest had no health insurance at all.

Weinberger is quoted as having said that there is no point in having the government spend money if insurance companies will. "Most people have some sort of hospitalization coverage and not to even investigate whether it is applicable at the center is ridiculous. There seems to be a great alarm that we would interfere with the research capabilities of the Clinical Center. I have no desire to do that. But I am impressed that a certain amount of insurance is being left with insurance companies when it could go to poor people. It's just as simple as that."

Needless to say, not everyone agrees with Weinberger on that.

During the last few years, it has become increasingly apparent that there are profound differences between the way the Nixon Administration and the scientific community views the world. And there is a feeling that their differing attitudes may be at the root of this current flap. As one NIH official said, "There is a real cultural gap between Weinberger and us."

NIH investigators are convinced that Weinberger simply does not understand how important their special population of patients is or why alterations in it could damage the entire Clinical Center program.

Clinical Center patients, drawn from all over the United States, are selected for admission solely on the basis of their potential for contributing to some medical research program. For example, cancer researchers have been interested in the effects of certain drugs on patients whose disease has just been diagnosed and who have not yet received any therapy. Letters go to doctors and hospitals across the country describing the type of patient needed for the study. Back at NIH, the cancer researchers wait, counting on the cooperation of their medical colleagues for referrals and the willingness of individual patients to subject themselves to experimentation. And, because finding a cancer patient whose condition has been diagnosed but never treated is no mean feat, the investigators need all the cooperation they can get.

This is true time and again, for virtually every clinical program NIH has. Patients are asked to leave home and, because many of them come from far away, their friends and relatives are never able to visit. They are often asked to stay in the hospital longer than they would be if they were treated at home. NIH clinicians believe there is no doubt that the fact that treatment is free is a very important inducement.

The fact that treatment is free, these investigators believe, is also an important element in guaranteeing that patients are selected only for their appropriateness to the study in question and not with regard to their ability to pay. Among other fears, the NIH doctors are worried that once patients are charged, there will be pressures to make the Clinical Center a self-sustaining operation. Next, there would be pressures to select patients on the basis of their insurance policies as well as their disease.

If that were to happen, NIH officials predict, the quality of research would suffer, as would NIH's ability to attract and retain first-rate research physicians. NIH attracts some of the best clinical investigators in the country precisely because it can offer them facilities and patients tailored to their research needs. That means that NIH physicians are only taking care of patients whose medical problems relate to the research that is going on. And those patients are more-or-less readily available because of the center's unique ability to draw from the national patient pool.

NIH scientists, anxious to defend their position, mention research that led to a cure for choriocarcinoma as an example.

A few years ago, concurrent studies of a rare—and now curable—cancer, choriocarcinoma or cancer of the placenta, were being carried out at the Clinical Center and at the Memorial Sloan-Kettering Cancer Center in New York. In the time that Sloan-Kettering doctors were able to find and study 10 women, NIH doctors had seen 200.

It is this kind of situation that induces top-flight researchers to stay at the Clinical Center where they are earning far less in salary than they would by taking a job with a university medical center. It is not unusual for an NIH physician to receive an offer from a good medical school for as much as $10,000 a year more than he is making. Thus far, it has also not been unusual for him to turn it down. NIH officials worry that if the environment of the Clinical Center is changed much, —if the patients stop coming—that kind of loyalty will become a thing of the past.

In addition to the problems that charging patients might cause to the research environment of the Clinical Center, the legality of charging may also prove to be a reason for reconsidering such a move. Richard J. Riseberg, legal adviser to NIH, looked into the matter at the request of NIH director Robert S. Stone. Edwards summarized Riseberg's findings in his memo to Weinberger. "In brief, the General Counsel states that there is no sound legal base for imposing a charge for care of Clinical Center patients."

Riseberg's analysis of the Public Health Service Act showed that:

> The study patient category is the *only* one in which the patient is *selected* by the service and for a purpose which is not primarily the therapeutic treatment of the individual but the furtherance of a general Service function. To the extent therefore that a service or benefit is involved, the basis of the relationship is that of service and benefit to the Government rather than the reverse.

Furthermore, the issue of whether third-party payers will pay if they asked to do so is not clear cut. In preliminary discussions, NIH took the matter up with Blue Cross and Blue Shield and with Maryland State Medicaid officers. They discovered that neither pays for patients involved in research. To further complicate the issue, there are indications that insurance company policy on this question varies from company to company and state to state. It poses administrative problems no one is anxious to face.

What happens now depends upon how much support NIH scientists can get for their position and how well they can justify it. Apparently they are going to have to convince their own, new director—Stone—of the adverse significance of the Weinberger proposal, as well as Weinberger himself. Stone, reportedly, has not taken as strong a position on this as his people would like him to. At least, they are not confident of his support at this stage. (It was not possible to reach Stone for comment before this issue went to press.)

So, NIH clinicians from each of the institutes are busy preparing impact statements and like documents to submit to Stone who will then, they hope, pass them on to the Secretary who has said he is willing to consider the question further.

In addition, some persons who are sympathetic to the researchers' point of view have taken the matter to Congress, particularly to Edward Kennedy (D–Mass.), chairman of the Senate's health subcommittee, and to Paul Rogers in the House. A spokesman for Kennedy says the Senator has not yet decided whether to intervene. Rogers says he will investigate the issue. In a 9 November letter to Weinberger, Rogers asked that implementation of the proposal to collect fees be delayed until his subcommittee can hold hearings to air the pros and cons. He is waiting for the Secretary's answer.

—BARBARA J. CULLITON