

Hatch Batters NCI with Straus Case . . .

The showpiece of the Senate's attack on the National Cancer Institute was the Marc Straus case

Amid great fanfare, the chairman of the Senate Labor and Human Resources Committee pounded his gavel on 2 June to open a hearing on the National Cancer Institute. According to committee aides, the hearing—culminating a 3-month investigation—would unveil examples of gross contract abuses at the cancer institute that has spent billions of dollars during the past decade since the war on cancer was declared.

But when all was said and done, the hearing did not match its advance billing. Before a packed room flooded with television camera lights, the new Republican committee chairman, Orrin G. Hatch of Utah, covered old ground, citing cases of contract abuse that have already been well investigated by the government.

“Just what was new? It was a rehash,” said an aide to Senator Edward

At the hearing, Hatch reviewed several government reports on contracting abuse that were completed as long as 3 years ago by the General Accounting Office and auditors from what was then the Department of Health, Education, and Welfare. The two most well-known examples were investigations of alleged abuses at the Eppley Institute, and the NCI bioassay program and its prime contractor, Tracor-Jitco. In both cases, which predate DeVita's tenure as director, the GAO found that monitoring of the contractors was lax.

For the bulk of the hearing, Republican committee members and Democrat Howard M. Metzenbaum of Ohio rebuked DeVita for failing to place a hold on a \$910,000 grant to a researcher who allegedly falsified clinical data. The physician in question, Marc J. Straus, has been accused by several former co-

submit a statement. His lawyer, Andrew Good of Boston, sent a telegram to Hatch the day of the hearing, charging that he was “unfairly misstating the facts” and “exploiting these shameful lies.” Straus contends that he was framed.

DeVita commented, “Although I'm uncomfortable about the possibility of wasting taxpayers' money, I'm equally uncomfortable about drawing conclusions about his guilt or innocence before an investigation is complete.”

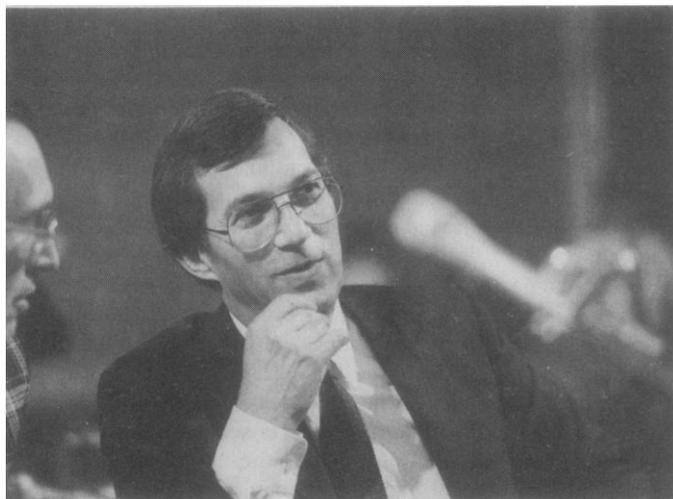
Metzenbaum fired back, “You're not in a position to play judge and jury. As an administrator, [you] let this guy prove his own innocence.”

Kennedy, who left early after haggling with Hatch over the parliamentary format of the hearing, does not favor placing a moratorium on a researcher's grant once it has been funded, according to a Kennedy aide. The senator, however, does agree with other committee members that a grant application should not be renewed when the researcher is under investigation.

DeVita conceded that he should have ordered an investigation earlier and also notified the National Cancer Advisory Board about the allegations against Straus when they were considering his application. The board has the authority to approve or deny grants.

Although most committee members seem to favor suspending a researcher's grant when serious allegations are raised, DeVita was uneasy about a broader principle. He said after the hearing, “I understand the senator's point of view, but what if Joe Baloney has to stop research and let go of his technicians? What if we find out it was a crank call? It's too late to put the pieces together. I'm worried about someone's livelihood.”

The Straus case seemed a poor example of mismanagement for Hatch to hang his hat on given all the uncertainty surrounding it. In any event, it appears that Hatch should have been more careful about discussing the case publicly. Because the committee released internal FDA documents on the case, it may have jeopardized the FDA's investigation. “If there is any criminal action to be found, it's severely compromised,” according to Alan Lisook, head of FDA's division of scientific investigations. In addition,



Marjorie Sun

Vincent T. DeVita, Jr.
Defended NCI

M. Kennedy (D-Mass.), the ranking minority member. Unfortunately, what appeared to get lost in the heated rhetoric of the hearing was a concern by government auditors who testified that NCI surveillance of contracts was slipshod and in serious need of reform. They did not, however, report any new cases of waste or abuse.

NCI director Vincent T. DeVita, Jr., acknowledged that the institute “has had a troubled history” in managing its contracts. But he argued that changes that he has initiated since he took office 16 months ago, should remedy many of the problems of the past.

workers at Boston University of fudging data while he was a researcher there. DeVita defended his judgment, saying he was reluctant to withhold the grant that is already being funded because the charges are yet unproved.

Although Straus is still under investigation by the National Institutes of Health and the Food and Drug Administration, committee Republicans and Metzenbaum appeared to be impressed by allegations against him that were reported in the *Boston Globe* and by preliminary information from NIH and FDA investigators. Straus was not asked by the committee either to testify or to

Lisook is upset that patients' names were not deleted from the FDA documents.

At one point during the Straus discussion, Hatch and Metzenbaum assailed DeVita as "blasé" about his administrative leadership. Hatch said, "You're not running some kiddie game here. You don't seem to know how to manage." Kennedy later came to DeVita's defense. A Kennedy aide said that Kennedy believes DeVita is "first rate. The hearing was unfair and an inappropriate attack on DeVita based on a single example."

Hatch chaired only the first portion of the hearing and then departed, leaving the hearing in the hands of Senator Paula Hawkins, the chairman of the subcommittee on investigations and oversight which held a hearing on NCI 2 weeks ago. With Hawkins the only committee member present, and the television lights

now gone, a significant part of the hearing received little attention. Auditors from the Department of Health and Human Services submitted a detailed report completed 9 months after DeVita took office, which specified serious weaknesses in NCI's monitoring of contracts and recommended a long list of ways to correct the deficiencies. Although only about half DeVita's reforms have been put into action, it appears that Hatch missed an opportunity to compare DeVita's changes to those recommended by HHS. During his opening statement DeVita tried to explain some of the reforms now in place. But what the committee seemed more interested in was a sense of commitment from DeVita, not the details. "I mean business," he told the committee, referring to a pledge for tougher management. Metzenbaum said, "That's the first time you haven't used buzz words."

Despite the hostile questioning by Hatch and others, it is clear that DeVita still has strong bipartisan backing including Kennedy and the new assistant secretary of health, Edward N. Brandt, Jr.

The cancer institute has undergone increasing scrutiny during the past 3 years. After the war on cancer was declared, the agency enjoyed an enviable relation with Congress which left it largely autonomous. But in 1978, when the GAO reports uncovered glaring examples of abuse, the relation was not so rosy. Congress continued to increase its oversight of the institute, and NCI apparently will have to continue living under its more watchful eye. Hawkins says she is giving the institute 90 days to implement changes in its management practices. If she's not satisfied, Hawkins says she may hold another hearing.

—MARJORIE SUN

. . . But Straus Defends Himself in Boston

After 3 years of silence, Straus came forward to proclaim himself victim of a conspiracy

Boston. After 3 years of silence, Marc J. Straus, a clinical cancer researcher who resigned in 1978 from the University Hospital of Boston University (BU) amid allegations of data falsification and patient abuse, has declared himself innocent of any wrongdoing and filed a \$33-million conspiracy suit against five members of his former BU research team who originally brought allegations against him.

Appearing at a special hearing of the President's commission for the study of ethical problems in medicine and biomedical and behavioral research, Straus said the allegations were "absolutely false" and that for 3 years he had been denied a fair review by his scientific peers. "I have seen discriminatory and selective prosecution, threatened kangaroo proceedings, supposed investigations conducted by persons without specialized training in oncology, slanted Senate hearings, and more," he said. The Straus affair is the subject of ongoing investigations by the Food and Drug Administration and the National Institutes of Health.

Just before the opening of the 5 June hearing Straus had his lawyer file the suit in U.S. district court. The suit, which

contains ten counts of individual malice and one of conspiracy, alleges that two doctors and three nurses on his staff falsified data, abused patients, and conspired to blame these acts on Straus, resulting in the loss of his job and research funding. Contacted by phone in Florida, one of the defendants in the suit, registered nurse Stephanie Richards, said: "I'm not worried. It's his prerogative to sue anybody he wants, but no court is going to find us guilty. There was

had built a million-dollar clinical research empire. That empire, however, was alleged to have been partly based on falsified data, which, according to several team members, had been doctored on the specific orders of Straus and also because of "general anxiety" that a shortage of statistically acceptable patients might threaten future funding for many of their clinical research programs. Because of the muddle of faked and real data, some team members feared that

An uncontested fact is that data falsification did occur.

no conspiracy, just a common concern about patient safety."

An uncontested fact amid the tangle of allegations is that some members of the Straus team did falsify data. The question is why.

As recounted in a series of articles in the *Boston Globe*, Straus at the time of the incident was a young, ambitious cancer specialist who in a few years at BU

wrong treatments were being administered. On Friday 2 June 1978 Greg Medis, a physician on the Straus team who 5 months earlier had begun a 2-year fellowship, resigned in protest. This resignation sparked the decision by several other team members to make an issue of Straus's practices. At the beginning of the next week, Medis and four other team members went to officials at BU's