

Medical-Research Official Cites Ethics Woes

By PHILIP J. HILTS

BETHESDA, Md., Aug. 16 — The chief federal official overseeing the safety and ethics of experiments with human subjects said today that conflicts of interest in medical research were so troublesome that "the system may have gotten entirely out of control" and might have to be reorganized.

The remarks by the official, Dr. Greg Koski, director-designate of the Office for Human Research Protections, concluded a two-day government-sponsored conference here on conflicts of interest in medical research. Speakers at the conference presented evidence that questionable financial ties between industry and researchers who test drugs or medical devices were more widespread than previously believed.

These were Dr. Koski's first public remarks since his appointment by Donna E. Shalala, the secretary of health and human services. As such, they were particularly significant, because his predecessor, Gary B. Ellis, was removed from office after

'The system may have gotten entirely out of control.'

shutting down human-experimentation programs at a series of major universities and medical centers for violations of federal ethics rules. Patient-advocacy groups have speculated that perhaps Dr. Koski was put in the job to take a softer line.

But his comments today signaled if anything a tougher stance. He said confidence in researchers to conduct human experiments had so eroded "that we must take steps to re-establish the public's trust in the goodness of our endeavors."

The problems pointed out by critics of the current ethics system, he said, are "very real, very serious and a threat to our entire endeavor."

Dr. Koski, a cardiac anesthesiologist at Harvard University and Mas-

sachusetts General Hospital, said he would not offer specific proposals till after he took office in September. But in response to a challenge here from Marcia Angell, former editor of *The New England Journal of Medicine*, he did say that researchers should not conduct studies on products of companies in which they own shares. Such arrangements are currently allowed, and even encouraged by many universities, which also frequently have an interest in the company and so stand to profit if the tested product proves successful.

Dr. Koski said he had been thinking hard about ways to reorganize the ethics system. "It may not be possible to drive that old Edsel much farther," he said.

On the question of the eight major universities and hospitals whose research has been shut down for ethics violations, including failure to fully disclose to the experiments' subjects the risks they faced, Dr. Koski said that anyone who did not comply with ethics rules was showing a lack of regard for the patients.

"Compliance," he said, "is one way we demonstrate our respect for the subjects. And failure to comply is a symptom of an institution's unwillingness to accept responsibility" in its work.

He stopped in his talk to re-emphasize that point. "I want to make it unmistakably clear," he said, "that institutions and individuals who fail to accept this responsibility should not be permitted to engage in this endeavor" of human experimentation. One reason, he said, is that when one institution so fails, the entire research enterprise suffers with the stigma.

But Dr. Koski said that his goal would be more than mere compliance with the current standards, that he wanted to urge research centers to work at "the highest standard of ethical responsibility."

He lauded the American Society of Gene Therapy for "just saying no" with its recently established policy that researchers should be free of significant financial involvement with the companies that sponsor their studies. He challenged other academic and industry groups, specifically the Biotechnology Industry Organization, to make similar declarations on financial conflicts.

Dr. Koski said he would use the information from the conference here to start developing a new conflict-of-interest policy by the government. He said disclosure of a scientist's conflict, as is currently required, would no longer be enough; new restrictions will be necessary, he maintained.

THE NEW YORK TIMES NATIONAL THURSDAY, AUGUST 17, 2000