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Prologue: A case study in biomedical conflicts

THE VERITAS CASE: FICTION THAT RINGS A BIT TOO TRUE?

The following is the transcript of a fictitious radio news story.

This is Nina Totenberg for NPR News in Washington.

The death of a teenager at Rhode Island University Medical Center in Cranston last month is raising questions about conflicts of interest involving both the university and its faculty. The death is only the latest in a series of ethics problems that have plagued the prestigious medical center.

When the clinical trial for a new drug to treat cystic fibrosis began earlier this year, researchers had high hopes for its success. The drug had passed initial trial stages with flying colors, but something went terribly wrong, and within the first month of this first trial with cystic fibrosis patients, 13-year-old Brian Veritas was dead.

There was no doubt about the cause of death. According to hospital reports, it was complications from the drug. Moreover, young Brian's parents, Hazel and John Veritas, now contend that they were duped into allowing their son "to be a guinea pig" so that the university and its chief researcher, Dr. Howard Empathy, could become rich.

Dr. Empathy and university officials heatedly deny the charge, noting that the Veritas family was informed that the university and its principal investigator had a financial interest in the development of the drug.

The drug in question is patented under the name Fibergone. It has been in development for the last 5 years under a joint venture agreement between MiserTech Pharmaceuticals, Rhode Island University Medical Center, and Dr. Empathy, a renowned expert on cystic fibrosis. The joint venture followed basic research funded by the National Institutes of Health, which under long-standing policy will not fund commercial development of drugs.

Dr. Ron Honcho, dean of the medical school, said in an interview today that Dr. Empathy had followed the university's policy in disclosing both his and the university's financial interests to Mr. and Mrs. Veritas at the time they agreed to have their son participate in the trial.

Mrs. Veritas acknowledged that she knew the university and Dr. Empathy were working with MiserTech and that the company had funded the research to the tune of $17 million. But she said she had not understood that profits in the millions or even billions could accrue to both the university and Dr. Empathy if the drug were eventually approved for widespread use.

"I think they pushed the envelope so they could win the jackpot," said Douglas Torta, a lawyer retained by the Veritas family.

Dr. Empathy, reached at his vacation home in Hawaii last night, said his heart goes out to the Veritas family but that it was folly to suggest that any doctor would have anything to gain from risking a patient's life.

"It is the nature of the trial that things may not always go as one hopes," said Dr. Empathy. "This case is particularly tragic, but it proves that very point."

The death, he noted, sounds the death knell, for now, of a drug that he has worked on for years, and that the university and MiserTech have spent millions to develop. However, Dr. Empathy would not rule out a revised trial of the drug at a future date.

For years, critics of the medical school's conflict-of-interest rules have warned that mere disclosure is not enough to prevent research from being skewed by the profit motive.

In response to some of that criticism, the medical school last year adopted an internal policing policy under which an 11-member board of faculty members screens all arrangements with private industry for conflicts of interest. Unlike similar boards at some other medical schools, however, the board includes nobody outside the medical school, and critics note that eight of the board members have consulting arrangements with one or more of the nation's major drug companies.

The death of Brian Veritas comes at a time when the medical school and the hospital are under increasing scrutiny for other arrangements with private industry.

Earlier this year, an investigation conducted by NPR disclosed that all 53 of the fellowships at the medical center

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are funded by MiserTech Pharmaceuticals, Orthonomics Device Company, or the SurgiTech Medical Device Company. The investigation also revealed that these three companies had reached agreements with the medical center to use their products on a preferred basis.

Rhode Island University Medical Center President John Uptight said that "the arrangements benefit both patients and industry by keeping prices down under negotiated price agreements while at the same time funding education for medical specialists." In addition, he said that joint ventures with medical device and drug manufacturers provide needed funds to be plowed back into medical education while at the same time pioneering new devices and drugs to improve patient care.

Nina Totenberg, NPR News, Washington.

MANY QUESTIONS, THE SAME CENTRAL ISSUES

The preceding fictional piece (there is no such place as Rhode Island University Medical Center, by the way) is an example of what I call the "*Washington Post* rule," namely, "Is your arrangement something you can live with when it is emblazoned across the front page of the *Washington Post* or *New York Times* and cast in a less-than-flattering light?"

Many questions will be discussed at this conference, apart from the ones raised in my fictional piece. First, what are the repercussions of potential conflicts, not just for the academic institution but also for industry? On the more mundane front, do small gifts matter? Why does industry give gifts, be they free medication samples, free dinners, or free lunches? What, if any, educational gifts are appropriate for medical students, residents, or doctors, or for continuing medical education?

In a larger sense, though, every question boils down to the same core issues: How strict should ethics codes be? What kind of enforcement mechanisms should there be? Is mere disclosure enough? If not, how does an institution manage conflicts, since almost everyone in medicine has conflicts?

Indeed, in the world of academic medicine, every discipline is relatively small, with the best people most in demand to talk about and review the things they know best. These are the very people, of course, who have a conflict because they have done something important in their field.

Since almost no one in academic medicine is without conflicts, we should have plenty to discuss throughout today's conference.

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