

BIOETHICS  
Prof. Mayo

**The Seattle Times**



## Editorials & Opinion

Saturday, March 17, 2001, 04:00 p.m. Pacific

Guest columnists

### **The ethical dilemmas of drugs, money, medicine**

by Thomas Bodenheimer and Ronald Collins  
Special to The Times

This week, The Seattle Times reported on a serious medical problem. The article by Duff Wilson and David Heath ("[The Blood-Cancer Experiment](#)") claims that patients involved in a Protocol 126 experiment were given experimental cancer drugs and died unnecessarily. Moreover, research scientists at the Hutchinson Cancer Research Center, where the drug trials were carried out, allegedly had a personal financial interest in giving patients those drugs.

The Wilson-Heath article raises important professional, ethical, legal, and policy issues that must be addressed.

The Hutchinson incident is not unprecedented. For example, in 1999, [Jesse Gelsinger](#), a healthy 18-year-old, died of an experimental drug at the University of Pennsylvania. The principal research scientist had positioned himself to profit if the toxic drug had worked. The Gelsinger family was not fully aware of that conflict of interest and had not been adequately told of all the drug's dangers.

On a related front, last November, the Los Angeles Times reported that a Loma Linda University experiment used humans to test the effects of pills laced with an industrial pollutant. Among other things, what those involved in the experiment, funded in part by Lockheed Martin, did not know was that when they "voluntarily" agreed to be guinea pigs, Lockheed was being sued over the safety of the very product being tested.

In all of this, one key problem is that too often, too little is divulged. Researchers do not regularly divulge their financial ties to drug companies when asking patients to enroll in drug trials. Similarly, drug companies do not routinely divulge everything the public and physicians need to know about company-funded drug research.

Financial conflict of interest in clinical drug trials is a significant problem in the United States. It affects millions of people - those who are subjects in drug trials and those who use the drugs once they enter the market.

Predictably, company-funded research tends to favor company products. For example, a 1998 report in the *New England Journal of Medicine* revealed that 96 percent of medical journal authors whose research was favorable to certain cardiac drugs had financial ties to the drugs' manufacturers. By contrast, only 37 percent of authors of studies critical of those drugs had such financial ties. And according to a 1996 study published in the *Annals of Internal Medicine*, an amazing 98 percent of company-sponsored drug studies published between 1980 and 1989 in peer-reviewed journals or in symposia proceedings favored the funding company's drug.

Equally troubling, drug companies frequently own and control the data collected in drug trials. Even the university scientists conducting the trial may not be given all the data they need. Companies sometimes publish data favorable to their product while suppressing unfavorable data.

Take the case of Dr. James O. Kahn, who not long ago published a study in the *Journal of the American Medical Association*. His study concluded that a vaccine for AIDS simply didn't help patients. The corporate funder of that study refused to give Dr. Kahn (the principal investigator) all the data. It then tried to block publication of the research. When the study was finally published, the corporation initiated a multimillion-dollar legal action against Dr. Kahn and his employer, the University of California at San Francisco. In light of such intimidation, few researchers will have the courage to stand up to the companies that fund them.

Added to the problem of publication rights is the issue of how clinical research is designed and executed. Pharmaceutical companies have designed studies to

make their drugs look more effective and less toxic than they really are.

For example, according to a 1994 Archives of Internal Medicine study, in 54 percent of company-sponsored arthritis-drug trials, the dose of the funding company's drug was higher than that of the comparison drug, increasing the likelihood that the funder's drug would appear more effective.

Similarly, in the case of the diabetes drug Rezulin, the Los Angeles Times recently reported that the manufacturer hid data showing that the drug could cause liver failure. The drug was withdrawn after being the suspected cause of 391 deaths.

Real patients suffer real harm from biased studies that offer false or incomplete information, including information about a doctor's financial ties to a pharmaceutical company. Reform needs to begin with the clinical drug trial process, where there must be some form of credible and independent third-party testing of drugs.

Additionally, scientists outside the walls of the manufacturing company should have the final say on the design of drug trials. And all relevant data must be made available to project investigators, and likewise to the subjects, public and press, whenever possible. Finally, all financial ties to interested companies should be made public.

The public needs more safety and more information. The time has come for the nation's universities, medical centers, scientists, medical journals and governmental agencies - the Food and Drug Administration and National Institutes of Health - to get together and advise lawmakers how to re-draw the rules under which pharmaceutical products are tested and approved.

*Thomas Bodenheimer, M.D., is a clinical professor in the Department of Family & Community Medicine at the University of California, San Francisco. Ronald Collins directs the Integrity in Science project at the Center for Science in the Public Interest, a nonprofit health-advocacy group in Washington, D.C.*