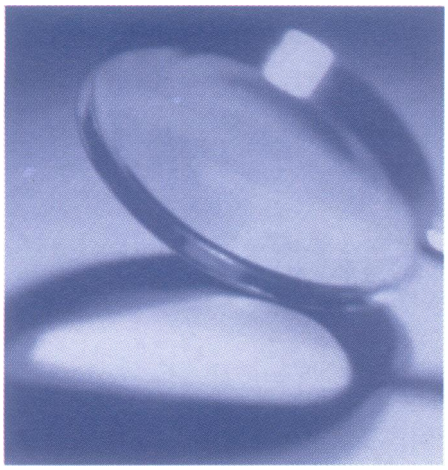

In the Public Eye

Media Watch

Patients for sale: the seamy side of clinical trials

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For physicians who test new drugs and procedures in clinical trials, this hasn't been a good year. One of the federal government's oversight agencies, the Office for the Protection of Research Risks, has used its powers to shut down clinical research at the West Los Angeles V.A.M.C. and at Duke Medical Center in North Carolina (see Media Watch, July 1999 WJM). Meanwhile, some of the nation's leading newspapers have been suggesting that clinical trials harm more patients than they help.

Reporters at the Boston Globe and the New York Times spent months unravelling the underside of clinical trials. Both papers described a dirty business in which physicians knowingly exposed patients to serious risks in order to earn millions of dollars testing new drugs. Using Freedom of Information requests, the two papers obtained court transcripts, notes of hospital injuries, results of clinical trials submitted to the Food and Drug Administration, and records of investigations conducted by the agency.

Their findings made front-page news. The Boston Globe's four-part series ran last November; the New York Times' pair of articles came out in May. For some readers, the papers' efforts may have permanently stained the image of clinical research in this country.

The Boston Globe offered readers what the paper termed "a peek into the financial side of corporate funded research of new drugs." One of the articles in the Globe series described a Minnesota psychiatrist who was a past president of the state psychiatric society and had previously chaired the society's ethics committee. In the course of researching new antipsychotic medications, the psychiatrist, by his own admission, entered "disturbed and vulnerable" psychiatric patients into drug trials, though he knew they did not meet the eligibility criteria. The patients did poorly and at least one woman died. The medical board in Minnesota described the doctor as "reckless" and eventually suspended his license to practice.

After a patient with schizophrenia committed suicide while taking part in a study of an antipsychotic drug, the doctors allegedly bribed staff to keep the death under wraps.

Two other psychiatrists described by the Globe were prominent faculty members at the Medical College of Georgia in Augusta. One chaired the school's psychiatry depart-

ment and the other was a pharmacologist. According to the Globe, the two earned over $10 million during 7 years of conducting clinical trials for numerous drug companies. When the FDA investigated, the agency heard that the two doctors hardly ever saw the patients they enrolled in trials. After a patient with schizophrenia committed suicide while taking part in a study of an antipsychotic drug, the doctors allegedly bribed staff to keep the death under wraps. Their bribery, along with other crimes such as stealing money that was intended for the medical school, enabled the FDA to bring an indictment. Both doctors were found guilty of several charges and sentenced to prison time and fines.

The New York Times ran the first installation of its May series in the Sunday Times, on the front page, above the fold, highlighting the significance of the series. A photograph of a drug company contract stated that physicians who participated in a clinical trial of drugs for migraine headaches would "receive $3,600 for each valid, completed patient." The series was entitled "Research for Hire" and described clinical research as "a multibillion dollar industry." "In this new industry," the Times noted, "patients have become commodities, bought and traded by testing companies and doctors."

The second article in the Times series described a family physician in Whittier, California, who developed a side business as a clinical trialist. In 1997 that business, called the Southern California Research Institute, was raided by the FDA and the doctor was found guilty of fraud. Among other things, the doctor encouraged his research staff to carry out fake lab tests and to falsify lab records. In a table titled "Finding the Loopholes," the Times described several different loopholes as "undetectable" with current oversight procedures.

The Times also claimed that even though informed consent forms for any clinical trial must be approved by ethics boards, and doctors running clinical trials are obliged to present the forms to patients, adequate consent is "not obtained about half the time."

These articles, and the FDA investigations and indictments that they describe, have not gone unnoticed. Already, the president's National Bioethics Advisory Commission has issued a lengthy series of recommendations aimed at ensuring that research with psychiatric patients is conducted in an ethical manner. In the next few months, it is likely that other federal and state agencies will also announce new recommendations and regulations for clinical research.

To media watchers, the Boston Globe and New York Times series represent some of the best reporting on medicine to appear anywhere in the past year. The Globe series was a finalist for a Pulitzer prize in 1998, and few will be surprised if the Times series is nominated for a Pulitzer in 1999.

To view the report of the NBAC: http://bioethics.gov/capacity/TOC.htm

The New York Times articles: http://www.nytimes.com/library/politics/051799drug-trials-industry.html

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