

Wall Street Journal  
Medical Editor Turns Activist On Drug Trials  
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Full Text (1126 words)

JEFFREY DRAZEN, editor of the prestigious New England Journal of Medicine, has prescribed a strong dose of disclosure for the pharmaceutical industry he was once accused of embracing too closely.

This week, Dr. Drazen accused three big pharmaceutical companies of "making a mockery" of a government database designed to provide accessible information about drug trials. He also joined a dozen other medical-journal editors in again warning that they might refuse to publish studies that don't adhere to their disclosure demands. Dr. Drazen has also recently written, and his journal has published, pieces critical of companies suppressing negative information about drug trials.

And the journal today plans to publish a study suggesting that drug companies may be exerting more influence over the supposedly independent academic investigators that they hire to conduct drug trials than had previously been known. The study, a survey of 107 medical-school research centers, shows that half would allow sponsors of their research to draft manuscripts reporting the results while limiting the role of the investigator to suggesting revisions.

In the past, taking on drug makers directly, or being seen as overzealous in trying to uphold the integrity of journals against commercial interests, has been a perilous path for medical-journal editors. The journals rely on the companies for advertising and subscriptions and want to be first to publish new findings that might come from their trials.

The New England Journal says there is no sign that drug companies are striking back by decreasing advertising. The publication doesn't release its own advertising figures. But the disclosure campaign comes at a time when medical journals overall are seeing a decline in their share of advertising dollars from pharmaceutical concerns, amid a rapid growth of direct-to-consumer ads. According to IMS Health Inc., a pharmaceutical information and consulting concern based in Fairfield, Conn., drug makers spent \$448 million, or about 5% of their promotional budgets on advertising in medical journals in 2003; in 1996, they spent \$459 million, or about 11%.

Dr. Drazen's newfound activism is especially striking since he came under fire for his own financial ties to the pharmaceutical industry when he took

his current job at the New England Journal five years ago.

"He's been converted," said Marcia Angell, senior lecturer at Harvard Medical School and Dr. Drazen's predecessor as editor-in- chief. "Through painful experience, Jeff is learning what these companies are about. He sees the ugly side that he hadn't seen before -- the bias that company-sponsored research contains, the suppression of results that they don't like, the spin of unfavorable results."

Ken Johnson, a spokesman for the Pharmaceutical Research and Manufacturers of America, the industry trade group, said Dr. Drazen's comments were "an unfair criticism."

"Our member companies are committed to making certain that all patients and their doctors get the information they need to make informed decisions about medicines," he said. "They're committed to making data available from all ongoing controlled clinical trials and they have until Sept. 13 to post this information."

The trade group has been critical of comments made by Dr. Angell in the past. But one person familiar with the group said they are trying to establish a better working relationship with the medical journals.

Dr. Drazen, a bow-tie wearing pulmonologist and Harvard Medical School graduate who still sees patients at the Brigham & Women's Hospital, said he is no firebrand. But he said he has a new perspective since becoming editor and witnessing more of the inner workings of research publishing.

"This isn't about poking a stick in the eyes of the drug companies," he said, adding that his only mission is to "help physicians do their jobs better and help patients get better information." He adds that one of the things that got the editors of the major medical journals together to try to establish guidelines is that "we've all had these experiences" in which drug researchers "weren't giving us the straight story."

In September, Merck & Co. pulled painkiller Vioxx from the market after years of efforts by the company to keep safety concerns from destroying the drug's commercial prospects. In October, regulators forced several drug companies to add strong warnings about a link between antidepressants and suicidal tendencies among young people to medication labels. After regulators started probing the links, researchers familiar with the data wrote that some unflattering findings about the antidepressants hadn't been published, potentially creating an overly positive portrait of some of the drugs.

Also in September, Dr. Drazen and editors for several other international

medical journals jointly said that they would no longer consider publishing studies that weren't registered with a publicly- available database before the first patient was enrolled. The group said the policy applied to trials that start after July 1, 2005 and set a Sept. 13, 2005 registration deadline. The editors indicated [www.clinicaltrials.gov](http://www.clinicaltrials.gov), an online registry operated by the National Institutes of Health, was the only one meeting its requirements.

This week, Dr. Drazen said Merck, Pfizer Inc., and GlaxoSmithKline PLC were making it extremely difficult to search the NIH database for information because they had not provided the names of many drugs under study. He said his criticism was based on a review of the NIH database by its director, Deborah Zarin. In an interview, Dr. Zarin said drug names were missing in 90% of the 132 Merck trials she reviewed; there were also no drugs named in 53% of the 55 Glaxo trials and 36% of the 75 Pfizer studies.

The three drug companies said their filings in the NIH database are in compliance with federal law and that they are working to expand the amount of data available there and on their own Web sites. A Merck spokeswoman said some drugs are not named until late in their development. A Pfizer spokeswoman said her company's filings omitted some early-stage trials for competitive reasons. A Glaxo spokesman said his company provides additional study details to editors, physicians and patients who inquire.

An asthma specialist, Dr. Drazen had financial ties to more than 20 drug companies when he first became editor. He also came under scrutiny after heaping praise on an asthma drug marketed by a drug company where he was working as a paid consultant. His statements were used in company promotions that were found to be misleading by the Food and Drug Administration. Dr. Drazen said he has severed all his drug company ties.

In 2002, Dr. Drazen was criticized for adopting a new policy whereby doctors writing reviews or editorials for the journal could accept up to \$10,000 a year from drug companies in consulting and speaking fees. Previously, they couldn't accept anything. Dr. Drazen argued at the time that maintaining an absolute ban would have made it too difficult to find writers.

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