Who Controls a Researcher's Files?

A Massachusetts judge gave R.J. Reynolds access to the records, letters, and peer reviews of a tobacco researcher whose conclusions they didn't like—so they could check his work for bias or fraud

Here's a researcher's nightmare: The results of your latest study on a socially controversial subject dear to your heart have been blessed by your peers and published in the leading journal in your field. Yet a well-financed opponent with a clear vested interest in your conclusions accuses you of skewing the results. But rather than address the issue with a scholarly debate in the "letters to the editor" column, your opponent takes a different approach and goes to court for permission to check for evidence of bias in your private records—including notes and letters to your colleagues, copies of peer reviews, and the names of study subjects to whom you have promised confidentiality. Incredibly, the court ignores the hallowed principles of privacy and sides with your opponent. And, to cap it off, when the opponent gets your papers, it releases them to the mass media.

Can't happen in the United States, you say? Guess again. This nightmare recently turned into waking reality for Joseph DiFranza, a family physician in Fitchburg, Massachusetts. In DiFranza's case, the opponent was R.J. Reynolds, maker of Camel cigarettes, and the study in question was one of three published in the *Journal of the American Medical Association (JAMA)* last December on how children respond to "Old Joe Camel," the cartoon character used to advertise Camels. Reynolds had subpoenas served on the lead authors of the three papers—in three different states—requesting the researchers' materials, notes, and correspondence, along with the names of children interviewed in the studies.

The litigation ran different courses in the three states, and only DiFranza in Massachusetts found himself facing a court order to obey the subpoena. On 14 May DiFranza turned over all his files—minus the subjects' names—to Reynolds. The Massachusetts judge exempted DiFranza from identifying his subjects, an order that was already moot because Reynolds had withdrawn its request for the names. But DiFranza lost control of the rest of his research documents, which Reynolds turned over to a reporter from its hometown newspaper, the *Winston-Salem Journal*. These developments raise troubling questions about the confidentiality of research notes, as well as the issue of how a party that suspects bias in research—as Reynolds did—should address that concern.

SHARON GUYNAP

Smoke signals. Published research suggests "Old Joe Camel" ads—such as this Manhattan billboard—are recognized by children as young as 3.

Bystander drawn in. The implications for confidentiality are especially striking since DiFranza was a legal bystander who was not a party to or a witness in the lawsuit from which the subpoenas arose. That suit was filed in San Francisco Superior Court last December by San Francisco attorney Janet Mangini. Mangini charged Reynolds with violating California's Unfair Business Practices Act by distributing T-shirts, mugs, and other items bearing the Old Joe Camel character without including the surgeon general's warning that must accompany cigarette advertising. Cited in the suit were three papers published in the 11 December 1991 issue of *JAMA* showing that ads featuring Joe Camel are recognized by children as young as 3 and seem to influence cigarette brand choice by teenagers who smoke.

Reynolds served subpoenas on the three lead authors: John Pierce of the University of California, San Diego, Paul Fischer of the Medical College of Georgia, and DiFranza. Fischer and DiFranza went to court to contest the subpoenas. Fischer won in Georgia; DiFranza wasn't so lucky. Not only did a Massachusetts judge side with Reynolds, but DiFranza lost an appeal. According to the appeals court judge, DiFranza's article in *JAMA* and the research behind it "are relevant enough [to the Mangini case] to enable Reynolds to get its nose under the tent." (Pierce never got to court because Reynolds withdrew his subpoena after it obtained his data tapes through an information request filed with the state of California.)

Shortly after DiFranza was ordered to turn over his notes, the California judge put the Mangini lawsuit on hold until a U.S. Supreme Court decision (due later this month) determines whether federal or state law takes precedence on warning-label issues. The judge also issued a stay of discovery, blocking Reynolds' right to press on with its subpoenas. But the stay, signed on 19 May, was too late for DiFranza: His files were already in Reynolds' hands.

Needless to say, Reynolds sees nothing wrong with its requests: The company argues that it needed the papers to check up on whether the studies were biased—or even fraudulent. "We have a right to defend ourselves," says Reynolds spokeswoman Peggy Carter, "so we needed to understand that research." But then, why did the company need to release the materials to the press? Carter says the company refused to turn over the documents to the *Journal* reporter until it learned that DiFranza had "mischaracterized" their content—leading the reporter to believe most of the materials showed no evidence of bias. Carter says Reynolds found ample evidence that DiFranza's work was slanted by an antitobacco bias and wanted "to set the record straight" by letting the reporter read the documents and make a decision for herself.

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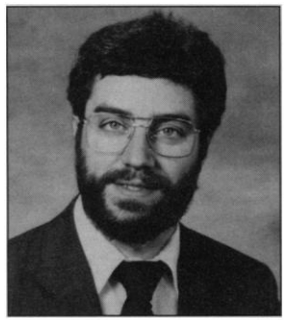
–Peggy Carter, Reynolds spokesperson

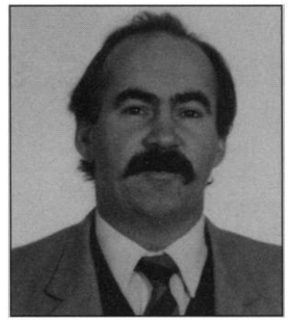
In the resulting article, headlined "Study on Old Joe Ads May Be Flawed," *Journal* business reporter Stella Eisele reports that the material showed that DiFranza had a bias against the cigarette company. She quotes from a letter to collaborators at other institu-

- P.M. Fischer, M.P. Schwartz, J.W. Richards, A.O. Goldstein, and T.H. Rojas, "Brand Logo Recognition by Children Aged 3 to 6 Years: Mickey Mouse and Old Joe the Camel," *Journal of the American Medical Association* **266**, 3145 (1991).
- J.R. DiFranza, J.W. Richards, P.M. Paulman, N. Wolf-Gillespie, C.Fletcher, R.D. Jaffe, D. Murray, "RJR Nabisco's Cartoon Camel Promotes Camel Cigarettes to Children," *ibid.*, **266**, 3149 (1991).
- J.P. Pierce, E. Gilpin, D.M.Burns, E. Whalen, B. Rosbrook, D. Shopland, M. Johnson, "Does Tobacco Advertising Target Young People to Start Smoking? Evidence From California," *ibid.*, **266**, 3154 (1991).

tions in which DiFranza wrote: "I have an idea for a project that will give us a couple of smoking guns to bring to the national media." She also quotes DiFranza as acknowledging that a potential bias was introduced into his study by the order in which the questions were asked. And she reports that he omitted data that didn't support his conclusions.



Joseph DiFranza



John Pierce

Paul Fischer

DiFranza doesn't deny that he started out with a point of view. "Every scientist is biased toward his own hypotheses," he says. "That's why we have to design studies to try to counter that." He acknowledges that there was a potential question-order bias in his study, because the subjects in the study saw Camel ads before being asked what brand they smoke. But he points out that the questions had to be asked in that order, because the purpose of showing the children Camel ads was to see if they knew they were advertising cigarettes. And, he says, several other studies that don't have that potential problem—including the study by Pierce in *JAMA*—found similar percentages of teenagers smoking Camels.

As for the accusation that he didn't publish data that ran counter to his hypothesis, DiFranza says Reynolds and reporter Eisele misinterpreted notes and hand-drawn graphs that dealt with very small numbers of subjects in pilot studies, or even with his sketched prediction of what the results might look like before any data were collected. The actual results of the study, he says, were quite different—and were reported accurately. "It's very easy to confuse nonscientists about how scientific investigations work," says DiFranza. "You could take any study and misrepresent it, or cite inconsistencies, and convince a nonscientist that something was wrong."

The investigators whose work was subpoenaed don't believe Reynolds' claim that the company's only motivation was to examine scientific integrity. They argue that the appropriate means of checking a scientist's conclusions is not to examine the raw materials of research but to design a similar study to try and reproduce the results. "If they wanted to validate the quality of the science they could have reproduced the study for what it took them to pay a couple of hours of their lawyers' time," says Georgia's Fischer. "This had nothing to do with the science...it had more to do with harassment and intimidation."

Reynolds hasn't done its own research, according to Carter, because it hasn't seen a need to. There are plenty of studies in the literature, she says, that already support Reynold's position that tobacco advertising doesn't influence the smoking habits of children. Besides, she adds, "we don't do research on anyone under the age of 18...because they cannot legally purchase the product."

Implications for researchers. Whatever the company's motivation, the legal implications for researchers are disturbing, according to DiFranza's attorney, Edward Greer of Brookline, Massachusetts. There have been other cases in which researchers were forced to turn over research material, says Greer, such as the 1989 case of Irving Selikoff, a medical researcher at the Mt. Sinai School of Medicine, who was required to give the tobacco industry his data tapes from a study of lung disease in asbestos workers. But the Massachusetts decision, says Greer, differs from Selikoff's case in two important ways: First, Selikoff had to turn over only his data tapes, and not any personal notes or correspondence, and second, Selikoff's study was a longitudinal case study of asbestos workers and couldn't have easily been reproduced. The Massachusetts decision is troubling, says Greer, because Reynolds not only got the records on the basis of relatively weak evidence of need, but also because the judge gave Reynolds access to everything but the subjects' names. "What I fear will be the consequence if these new cases are generalized," he adds, "is that somebody does some research, publishes some finding someone doesn't like, and then all of their work is scrutinized with a fine-tooth comb to try to discover something they've done wrong."

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–Paul Fischer

"To go on a hunting expedition for possible misconduct just because you dislike the outcome of a study is certainly not at all what the people who write regulations about misconduct have in mind," says Barbara Mishkin, a Washington attorney who deals with issues of scientific ethics. "It's a new twist on discovery." But regardless of Reynolds' intent, the mention of the research in the California lawsuit made it fair game, adds Robert Charrow, a Washington, D.C. attorney who specializes in science and the law. "Anyone whose research is used for any purpose in litigation could be subject to this type of process," he says.

In spite of the gloomy predictions, though, the results could have been even worse. If Reynolds had been able to obtain not only the research materials but also the names and phone numbers of the research subjects, as it had initially requested, the outcome would have struck even deeper fear into the hearts of any investigator who has ever promised confidentiality to study subjects in return for answers to personal or embarrassing questions. But even the potential risk of a breach of confidentiality could undermine future studies, says San Diego's Pierce: "If parents think R.J. Reynolds is going to call their kids, they won't let their kids talk to us."

Indeed, court documents make it clear that the company may decide to ask for subjects' names later, and Carter insists that there was nothing unethical about asking for the names in the first place. Her justification? Reynolds offered to have the names turned over to a third party, who would call and verify that the children had actually participated in the study. "There have been a number of stories that have come up in recent years where scientists claimed to have produced research that...was never done at all," says Carter. "We simply wanted to verify that they did do it."

What's next? DiFranza may still face more interrogation by Reynolds. The company has filed a motion to lift the California judge's ban on discovery so it can conduct a deposition of DiFranza, although it has dropped for the present its efforts to get materials from the other two *JAMA* authors. DiFranza suggests that may be because his paper, unlike the other two *JAMA* papers, is being used as evidence for a complaint made to the Federal Trade Commission by DiFranza and several voluntary health organizations that Camel advertising is increasing illegal sales of their cigarettes to teenagers. But Carter says it is merely a matter of "evaluating our options and needs" regarding Reynolds' defense in the Mangini case. Whatever Reynolds' reasons, its success in getting DiFranza's records will have other researchers watching nervously for the appearance of their adversaries' noses under their own tent flaps.

–Marcia Barinaga

With reporting by Eliot Marshall.