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February 11, 2014

The Honorable David Schweikert, Chairman  
The Honorable Suzanne Bonamici, Ranking Member  
House Committee on Science, Space, and Technology  
Subcommittee on the Environment  
Washington, D.C. 20515

Re: Secret Science Reform Act, H.R. 4012

Dear Chairman Schweikert and Ranking Member Bonamici,

We are professors of environmental and administrative law who specialize in the agencies' use of science in policymaking. We believe that H.R. 4012, the "Secret Science Reform Act," contains a number of significant problems that cumulatively threaten to undermine, rather than enhance the scientific rigor of EPA's decision-making. We urge you to reconsider the need for the bill. At the very least, the bill should be revised significantly before it is considered further by the Committee.

As drafted, H.R. 4012 suffers, at best, from a dangerous lack of clarity. It forbids EPA from relying on scientific and technical information unless that information is both "specifically identified" and "publicly available in a manner that is sufficient for independent analysis and substantial reproduction of research results." Neither of the quoted phrases is self-defining. Thus, as it stands, the bill will unnecessarily encourage litigation and could lead to a number of other significant problems that we identify below.

***H.R. 4012 threatens to undermine the scientific rigor of EPA's decision-making while leaving the true "secret science" problem untouched.***  
"Secret science" is indeed pervasive in some regulatory programs, yet H.R. 4012 does nothing to address the most serious problems since it inoculates from its reach existing, outdated legal provisions that tolerate the sequestration of research. For example, under Section 10(g) of the Federal Insecticide, Fungicide, and Rodenticide Act, the public and affected parties are not allowed to view the studies underlying EPA's licensing of pesticides until after the agency's registration decision is concluded, and even then the research is available only to

the public under tightly constrained circumstances.<sup>1</sup> Even more problematic, as a result of aggressive trade secret claims, the research on the safety of more than 17,000 chemicals regulated by EPA under the Toxic Substances Control Act is completely insulated from public view by law.<sup>2</sup> Such impediments to public access undermine independent evaluations of the evidence used by EPA in its regulation, yet they remain untouched by the very bill that promises to expose this secret science.

By contrast, H.R. 4012 targets publicly available research, much of which has been published in peer reviewed journals, as the area in need of heightened transparency. Even more perplexing, the bill tasks EPA -- not the researchers -- with the enormous task of amassing the data underlying each relevant study. If EPA is unable to summon the resources or time to access this underlying information or is otherwise unable to acquire the data, it is apparently prohibited from considering the stud(ies) in its regulatory decision.

This draconian requirement will significantly undermine the scientific integrity of EPA's regulation, rather than enhance it, by placing out of the agency's consideration relevant and material studies when EPA is unable to acquire the underlying information. Such an approach also provides the opportunity for strategic games. For example, under H.R. 4012, sponsors who learn of adverse effects from their products through internal research could attempt to limit EPA's consideration of their findings simply by denying EPA access to their data. Since the data underlying privately-funded research apparently remains the property of private parties, they can control how their research is used by EPA as best suits their interests.

**The costs of the requirements in H.R. 4012 are grossly disproportionate to any plausible benefits.** Before imposing this new requirement on the thousands of science-intensive projects at EPA, the proponents of such legislative requirements should consider the costs and delays to taxpayers and weigh them against the social benefits. The costs are likely to entail tens of millions of dollars of staff time, years of delay per standard, and the possibility that EPA will either have to bypass considering relevant studies because they cannot make the data available or avoid regulatory action altogether. Consider the bill's requirement as applied to a typical NAAQS science assessment by EPA, for example. In its bibliography for this assessment, EPA cites to hundreds of peer reviewed, published studies that it considered.<sup>3</sup> H.R. 4012, as we read it, would require EPA to make the "materials, data, and associated protocols, computer codes and models, and recorded factual materials" underlying each of these hundreds of studies "publicly available in a matter that is sufficient for independent analysis and substantial reproduction of research

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<sup>1</sup> A person seeking access to the studies underlying a pesticide registration must certify that he/she will not share the information with manufacturers in other countries. In addition, the pesticide manufacturers must be notified of each person who views their information; the information must be viewed at the agency's office; and the information is available only after a pesticide registration decision is made. 7 U.S.C. § 136a(c)(2)(A).

<sup>2</sup> See *Declassifying Confidentiality Claims to Increase Access to Chemical Information*, EPA, <http://www.epa.gov/oppt/existingchemicals/pubs/transparency-charts.html> (last visited Apr. 15, 2013) (listing, in Table 4, 17,031 CBI chemicals on TSCA inventory).

<sup>3</sup> See EPA's Integrated Science Assessment for Particulate Matter, Dec. 2009, Annex E References, at E-522, available at [http://www.epa.gov/ncea/pdfs/partmatt/Dec2009/PM\\_ISA\\_full.pdf](http://www.epa.gov/ncea/pdfs/partmatt/Dec2009/PM_ISA_full.pdf).

results.” Indeed, aggressive interest groups could even argue that the bill requires EPA to put the raw data into an electronic database to expedite statistical analysis. The costs resulting from such a demand on EPA would be extremely high—a wasteful outcome in an era of budget shortages.

The benefits to regulatory quality – by contrast – seem minuscule. In how many of these agency actions will affected groups actually benefit from this enhanced access to underlying data? And who are the groups with the resources and interest to reanalyze the data or reproduce the study? They certainly are not the groups that are thinly financed. And what is to be gained from the resultant reanalysis? Is the agency equipped to review meta-analyses of data bases that have not been peer reviewed, published, or restricted methodologically? Indeed, as between peer reviewed studies and non-peer reviewed re-analyses of data, is Congress suggesting the latter is preferable or even desirable?<sup>4</sup>

Moreover, while we strongly support extending the Data Access Act to private parties, as has been suggested by the BiPartisan Policy Center, the Administrative Conference of the U.S., and in articles we’ve written, such a requirement should never preclude the agency from using studies when the data is not publicly available.<sup>5</sup> Imposing such a prohibition on the agencies makes “the perfect the enemy of the good” – limiting the agency’s access to scientific research based on expensive and often fruitless paperwork requirements.

**H.R. 4012 facilitates further mechanisms for harassing scientists.** There have been repeated, documented incidents of the harassment of researchers whose results produce unwanted results for regulated parties.<sup>6</sup> In a number of these incidents, the harassing party’s first line of attack begins with subpoena-ing or otherwise acquiring the underlying data and then statistically reanalyzing the data in ends-oriented ways that attempt to cast doubts on the integrity of the researcher.<sup>7</sup> H.R. 4012 provides still more tools for disgruntled interests to “manufacture doubt.” If Congress seeks to legislate additional opportunities to enable this type of harassment, it should also legislate protections for researchers so that our most talented scientists do not leave the health and environmental science field altogether. As Dr. Donald Kennedy, the former Editor in Chief of *Science*, warns:

I know what many of my fellow scientists are saying to one another . . . . They wonder whether the data underlying their findings may be subject to examination

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<sup>4</sup> See generally Sheila Jasanoff, *Transparency in Public Science: Purposes, Reasons, Limits*, 69 LAW AND CONTEMPORARY PROBLEMS, Summer 2006, at 22 (providing an excellent overview of the dangers of hyper-transparency provisions, such as those embodied in the Secret Science Reform Act).

<sup>5</sup> See, e.g., BiPartisan Policy Center, Improving the Use of Science in Regulatory Policy 43 (Aug. 2009); ACUS Recommendation 2013-3; Wendy Wagner and David Michaels, *Equal Treatment for Regulatory Science: Extending the Controls governing the Quality of Public Research to Private Research*, 30 AMERICAN JOURNAL OF LAW & MEDICINE 119 (2004).

<sup>6</sup> See, e.g., DAVID MICHAELS, *DOUBT IS OUR PRODUCT* (2008); NAOMI ORESKES & ERIK CONWAY, *MERCHANTS OF DOUBT* (2009); THOMAS O. MCGARITY & WENDY E. WAGNER, *BENDING SCIENCE: HOW SPECIAL INTERESTS CORRUPT PUBLIC HEALTH RESEARCH* (2008).

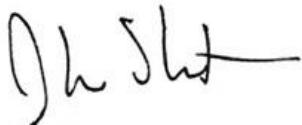
<sup>7</sup> Herbert L. Needleman, *Salem Comes to the National Institutes of Health: Notes from Inside the Crucible of Scientific Integrity*, 90 PEDIATRICS 977 (1992); Paul M. Fischer, *Science and Subpoenas: When Do the Courts Become Instruments of Manipulation*, 59 L. & Contemp. Problems 159 (1996) (both articles are included as attachments to the letter on file with the Subcommittee).

and reinterpretation, perhaps with some ‘spin’ supplied by the revisionists. They know that charges of research misconduct could arise from hostile access to their scientific work. They know they are vulnerable to personal attack from those whose interests may be adversely affected by the product of their research.<sup>8</sup>

These are only a few of the many problems we have identified with the bill, but given your upcoming hearing, we believe it is better to share some of them early in the discussions. We are happy to provide a more comprehensive assessment later on, as the legislative drafting progresses.

Thank you for your consideration.

Sincerely,



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<sup>8</sup> Don Kennedy, *Prologue*, at xxiii, in RESCUING SCIENCE FROM POLITICS (Wendy Wagner & Rena Steinzor eds. 2006).

# Salem Comes to the National Institutes of Health: Notes From Inside the Crucible of Scientific Integrity

Herbert L. Needleman, MD

**ABBREVIATIONS.** NIH, National Institutes of Health; EPA, Environmental Protection Agency; WISC-R, Wechsler Intelligence Scale for Children-Revised.

Many readers of *Pediatrics* may have only a dim idea of the combative arena in which environmental research is conducted. Probably, very few have had the experience of being investigated for scientific misconduct. My aim in reviewing these two topics is to provide a preventive road map to others and to reveal some inadequacies and inequities in the investigative process. It is necessary, to accomplish this, to be direct and specific. Tact is sacrificed here for the sake of clear instruction.

In 1972 I published 700 words in *Nature* reporting that Philadelphia inner-city children had higher dentine lead levels than suburban children.<sup>1</sup> The paper suggested that the tooth might be a useful marker to estimate body lead burden after exposure had ended. I did not know then that I was taking the first step toward being investigated for scientific misconduct by my university and the National Institutes of Health (NIH) Office of Scientific Integrity.

The Environmental Protection Agency (EPA) asked me to present the 1972 tooth lead paper in Amsterdam at an international meeting on lead. I was unprepared by my past attendance at pediatric meetings for what I encountered there. This was no scholarly debate on the toxicology and epidemiology of lead; this was war. The speakers did not behave like academics hoping to embellish their reputations by parading the results of their last 6 months in the lab. These stakes were much higher.

Arrayed against each other were a small and defensive group of environmentalists and health scientists on one side, and on the other the representatives of the gasoline companies, including such formidable entities as El DuPont, Associated Octel, Dutch Shell, and Ethyl Corporation of America. Any paper suggesting that lead was toxic at lower doses immediately faced a vocal and well-prepared troop that rose in concert to attack the speaker. My 10-minute talk was not spared; giving it marked the beginning of my post-postgraduate education.

This encounter pushed me, on returning to the United States, to look into the history of lead research.

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I found that my experience was not new. Two Australians, A. J. Turner and J. L. Gibson, who first described childhood lead poisoning in Brisbane in 1892, were derogated by industry and by a segment of the medical community. When Randolph Byers, one of the earliest pediatric neurologists, first suggested in 1943 that some school dysfunction might be due to undiagnosed lead toxicity, he was threatened with a million dollar lawsuit by Lead Industries Association.<sup>2</sup> Clair Patterson, the geochemist credited with dating the age of the earth, was publicly vilified as a crank by the industry and had his career threatened when he suggested that civilization had raised everyone's body lead burdens to 1000 times that of our ancient ancestors (personal communication, 1992). All of the early research in lead toxicity was funded by the industry, who had a tight grip on what the public was permitted to know.<sup>3</sup>

Reading these records vividly brought back an experience I had when I was in medical school. One summer I worked as a laborer at the Deepwater, NJ, DuPont plant, where tetraethyl lead had been synthesized years before. Workers were forbidden to carry matches, and when the smoking whistle blew at 10 AM and 2 PM, we poured out of our buildings by the hundreds to collect at wooden smoking shacks in open areas. There we lined up at two glowing cigar lighters imbedded in the shack wall. While I smoked two cigarettes back-to-back in the 15-minute break, I inspected my coworkers.

Off to the side sat a few older men, obviously slow and clumsy, staring silently into middle space. When they did speak, they seemed remote and out of touch. A veteran worker told me that they were from "The House of Butterflies." They had been poisoned while making tetraethyl lead. Years later, I would read in the *American Journal of Public Health* that during the early stages of tetraethyl lead production at Deepwater,<sup>4</sup> there had been an outbreak of poisoning among the work force. More than 300 men had been affected, often with full-blown psychotic symptoms; at least 4 had died. Affected workers were frequently seen brushing hallucinated insects off their bodies, hence the name. Production was temporarily stopped by the Public Health Service, but this ban was lifted after a superficial investigation. These damaged men were some of the survivors.

Years later, having satisfied myself that the tooth was a valid marker of past exposure, with Alan Leviton and Bob Reed, I studied a sample of children who were asymptomatic for lead, classifying them by dentine lead levels. The data showed that after con-

trolling for a number of covariates, children with elevated lead in their teeth scored lower on tests of psychometric IQ, speech and language function, and on measures of attention.<sup>5</sup> The study seemed to respond to a number of research difficulties that had until then vexed the field, and as a result it received considerable attention. The lead industry, in the form of the International Lead Zinc Research Organization, was uncharacteristically silent for about 6 months. Then they began to call for copies of my original data. I declined. I had seen what had happened to good data when massaged and distorted by industry technicians, and while I was happy to share my data with any bona fide scientist—and did—I was not willing to include the lead industry.

In 1982, the EPA began to rewrite the Air Lead Standard. I was asked to participate. Also invited was Dr Claire Ernhart, a psychologist who had published a paper in 1974<sup>6</sup> that reported that lead was associated with lower IQ in a group of Long Island black preschoolers. In 1981, she published a paper (in this journal) which criticized my study and said that when followed into the first grade, the lead effect she had previously reported was no longer significant.<sup>7</sup> Close examination of the paper showed that school-age blood lead levels were in fact significantly related to IQ. Ernhart dismissed this finding as due to chance, and stated that: "If there are, in fact, behavioral and intellectual sequelae of low levels of lead burden... these effects are minimal." Shortly after that paper she became a grantee of the International Lead Zinc Research Organization and began to speak against controlling lead in the environment. When there was a move to put lead back in gasoline, Ernhart appeared in testimony for Lead Industry Associates, asserting that there was no valid health reason to ban its use.<sup>8</sup>

The industry began to raise public questions about the integrity of my studies. In 1983, EPA's Clean Air Scientific Advisory Committee thoroughly reviewed industry-generated charges that my work was flawed. They concluded:

A pioneering general population study was reported by Needleman et al (1979)... Significant effects ( $p < .05$ ) were reported for full scale WISC-R [Wechsler Intelligence Scale for Children-Revised] scores, WISC-R verbal IQ scores, for 9 of 11 classroom behavioral scale items, and several experimental measures of perceptual motor function. . . .

Reanalyses carried out in response to the Committee's recommendations have been reported by Needleman (1984), Needleman et al (1985) and US EPA's Office of Policy Analysis (1984) as confirming the published findings on significant associations between elevated dentine lead levels and decrements in IQ. . . .<sup>9</sup>

I thought that this official statement had finally and permanently sealed the argument. I could have not conceived that these same charges would be resuscitated 7 years later.

In 1990, an attorney from the Department of Justice asked me to participate in what he described to me as a landmark suit brought under the Superfund Act against three lead polluters in Midvale, UT. Among the witnesses for the defense were Dr Ernhart and Dr Sandra Scarr. Scarr had been a member of the government committee that had reviewed my work for EPA. She now appeared in a different role, this time

on behalf of the lead industry, reviving the same charges that had been settled in 1986. They came to my lab for 2 days to examine my raw data in preparation for the trial.

Before going to trial, the case was settled. Sixty-three million dollars was awarded to the federal government to clean up the mine site. After the case was settled, I found out that Scarr and Ernhart had written a lengthy document accusing me of unscientific behavior. They maintained that their conclusions grew out of their examination of my printouts. This document was forwarded to NIH's office of scientific misconduct by David Genesson, an attorney for the Washington, DC, law firm of Hunton and Williams. It was also given to defense lawyers in a number of lead damage cases. I had encountered the name of Hunton and Williams before. This firm had represented Ethyl Corporation of America and EI DuPont, contesting the regulation of lead additives in federal court and before the EPA and the Federal Trade Commission. In reading the Scarr/Ernhart document, I found numerous allegations and hints of unscientific behavior.

As I perceived them, their major criticisms of my work were (1) that I did not properly control for confounding; (2) that I selected cases in a biased fashion; and (3) that multiple tests were done, and this could lead to positive associations on the basis of chance.

These kinds of issues are generally considered methodological disagreements and are fought out in the pages of journals; I could not understand why they were defined by my critics as scientific misconduct. Similar criticisms were raised before the EPA in 1982 and dismissed. These facts notwithstanding, in October of 1991, I was notified by the Dean of my medical school that an inquiry into charges of misconduct was being done at the instruction of NIH's Office of Scientific Integrity.

When the proceedings began, I was confident that the printouts would be examined, that I would explain how I analyzed the data, and that like the EPA, the university would rapidly put matters right. I thought this would end this matter quickly and permanently. But the university's behavior seemed odd and troubling. They chose to ignore a number of rather obvious facts that I repeatedly brought to their attention: that the charges were initially raised by two individuals who had been supported by the lead industry; that they had been raised before and dismissed by the Clean Air Science Advisory Committee of the EPA; that my work had been replicated more than 12 times since its publication; and that I had shared my data with other scientists in the past.

Instead, the preliminary Inquiry Panel issued a strange report. The Panel stated that it "found no evidence of fraud, falsification or plagiarism," but inexplicably added that it "is not able at this time to exclude the possibility of scientific misconduct in terms of misrepresentation." The report argued that the models I chose were selected to optimize a lead effect, and that I may have selected cases in a biased fashion. The report presented no evidence in support of this assertion, only conjecture.

I rebutted their charges in a letter to the Dean and showed that the charge of misrepresentation was based on false evidence. The Dean declined to review my letter. Instead, he turned it over to the Panel for comment. They also did not respond to any of the facts that I raised in the letter. Instead, they stated that the material I supplied in rebuttal of the report of the Inquiry Panel was "not directly relevant." They recommended a full investigation.

During the time the investigation was being arranged, I requested of the Dean that the Hearing Board he appointed include experts of international standing in the fields of behavioral toxicology and epidemiology. This was denied. I was told that there was no need for this expertise in the two disciplines that my work spanned. I requested that the hearings be open to the university community and the press. Again, this was denied. I asked that two members of the Hearing Board be replaced for possible conflict of interest. One, Dr Robert McCall, was a developmental psychologist whose appointments on many professional committees overlapped with Dr Scarr, and who frequently cited her work in support of his. The second, Dr Herbert Rosenkranz, had been Director of the Environmental Sciences Center at Case Western Reserve University, where Dr Ernhart was a faculty member. This request was also denied.

I began to feel uneasy and increasingly certain that if the case were reviewed *in camera*, I would be found guilty of something. I went before the Faculty Assembly of the university and requested their support in my demand for open hearings. The faculty emphatically supported me. The Assembly passed a unanimous resolution asking the university to open the hearings. At the Faculty Senate, a representative of the administration argued against open hearings, because, he said, it was necessary to "protect the process." The "need to protect the process" was a phrase I was to hear repeated many more times. I argued that the process did not have a nervous system; that it was people who required protection; and that the given reason that hearings were closed was to protect the reputation of the accused. I was in this instance the accused, and I wanted the hearings to be open. The Senate unanimously voted for open hearings.

Pressure began to build on the administration, and I began to receive letters of support from colleagues around the country. Six eminent health scientists, Frank Oski, Arthur Upton, Samuel Epstein, Philip Landrigan, David Bellinger, and Bernard Weiss sponsored a petition to the Chancellor demanding open hearings. It listed almost 400 scientists' signatures. I filed a complaint in federal court asking for open hearings. Reluctantly, for the first time in its history, the university agreed to open hearings.

My accusers, who until then had been quite public and emphatic in their allegations, and who had said that they would willingly come to Pittsburgh to be questioned by me, reversed their field. They were now reluctant to attend. After lengthy negotiations with the administration, they agreed to attend the hearings as witnesses.

The hearing room was filled with scientists, faculty, and members of the local and national press. My

accusers became surprisingly reticent. Dr Scarr, in a lecture at the Massachusetts Mental Health Center,<sup>10</sup> said: "What we have done is to report. . . Dr Needleman to the Office of Scientific Integrity at the NIH, because we feel there are significant deviations from normal scientific practice here and we feel that the data has been massaged, to put it mildly. . . ." Now, in an open hearing, she revised her complaint to say that she merely "had suspicions" that I had consciously manipulated the data to present a false case.

Both witnesses were accompanied by their attorney, Mr David Genesson of Hunton and Williams of Washington, DC. When I asked Dr Ernhart who was paying her legal bills, she refused to answer. She stated that she did not know that Hunton and Williams had represented EI DuPont and Ethyl Corporation of America before the Food and Drug Administration and Federal Trade Commission. In the newspaper the next day, it was reported that there was a "trust fund" established to cover my accusers' legal expenses, but that Scarr and Ernhart did not know who had contributed to it.

During my examination of my accusers, it became clear that a different standard, perhaps an ad hoc standard, was being applied to my work as contrasted to theirs. One of the charges raised by my accusers was that I did not control for age in evaluating the effect of lead on IQ. I pointed out in my cross-examination that the WISC-R IQ was age-adjusted.

DR NEEDLEMAN: Isn't the Wechsler age adjusted?

DR ERNHART: The norming of the Wechsler is age adjusted. . . norming alone is not sufficient to handle age variation. . .

DR NEEDLEMAN: So it would be better to enter age into the model?

DR ERNHART: Yes. . .

DR NEEDLEMAN: In your 1981 paper did you put age into the model?

DR ERNHART: My study is irrelevant to the issues here today.<sup>11</sup> [Ernhart had not controlled for age.]

Since Ernhart had raised these criticisms of my work in 1981, and examined my printouts in 1990, I asked her whether it was not true that she had concluded that my study misrepresented the data before she had ever examined my data. Her answer was intriguing.

DR ERNHART: On advice of counsel, I'm not answering that question.

Another claim was that I excluded subjects on the basis of head injury or history of exposure or being non-English speaking *after* I knew their IQ scores, in order to maximize the effect of lead. In the hearing I showed her a piece of computer code from my printout that headed every data analysis. Translated, it said: "Select if lead level equal high or low, and head injury equal 'no,' and plumbism equal 'no' and English is the first and only language in the home." This proved conclusively that the subjects were excluded on criteria that were identified before the study was begun, and that the exclusion was executed by computer without any human judgment. Because Dr Ernhart had spent 2 days with my printouts as part of the Midvale suit, I asked whether she had seen this piece of code.

DR NEEDLEMAN: . . . does this look familiar to you at all?

DR ERNHART: I don't recall having seen this.

This piece of computer code appeared 24 times in the printouts I furnished them. It is difficult to see how it could have been overlooked by anyone looking for problems in case selection.

There was a general retreat by both witness in the degree of certainty with which they indicted me. Scarr, who had been direct and accusatory in a lecture at Harvard, was much less sure about whether I committed scientific misconduct in the public hearing. I asked her about it directly:

DR NEEDLEMAN: Are you certain that you are right when you say I selected the cases consciously knowing the outcome in relation to lead?

DR SCARR: I know you had the opportunity to do that. I don't know what you did.

At the conclusion of the cross-examination, Dr William Cooley, Chairman of the Hearing Board, who had frequently advised my accusers that they were not required to answer my questions, addressed himself to Dr Scarr:

I believe that, if I may ask a clarifying question, it is my impression that you have gone on record here today as essentially indicating that you had ample basis for being suspicious of the scientific work that's under consideration here, but have no specific charges of misconduct.

DR SCARR: Yes, that's correct.

The 2-day hearings were widely reported in the lay press<sup>12,13</sup> and in *Science*<sup>14</sup> and the *Journal of the National Institutes of Health*. Two months later, on May 20, 1992, the Hearing Board unanimously found no evidence of scientific misconduct.

What is there to be learned from this story? I believe that the spectrum of those behaviors labeled as misconduct in scientific enterprises is disturbingly common and that both the public and the scientific enterprise needs to be protected from inferior or dishonest studies that open the door to procedures or pharmaceuticals of dubious efficacy or that distort our understanding of the way that nature works. I believe that because of the intensely competitive business that science has become, the ethos in which young scientists are socialized and the actual work is conducted has fundamentally changed, and not for the better. Young scientists are regularly exposed to the gap between the professed idealistic standards of practice and the actual, often cynical, conduct of grant getting, data collecting, interpreting, and publishing. There needs to be better policing of our profession.

But the entire tangled process of identifying putative cases of scientific misconduct, and of fairly judging them, is open to abuse at a number of points. If my case illuminates anything, it shows that the federal investigative process can be rather easily exploited by commercial interests to cloud the consensus about a toxicant's dangers, can slow the regulatory pace, can damage an investigator's credibility, and can keep him tied up almost to the exclusion of any scientific output for long stretches of time, while defending himself.

Some way must be found to screen out frivolous or harassing charges of misconduct and shield investigators from this form of tribulation. Once an inquiry

or investigation has begun, it should operate under formal principles of due process. The option as to whether the investigation is open should lie with the accused. If an open hearing is requested, it should be freely granted. One should not be required to fight for this long-honored right. Certainly there is stigma and embarrassment attached to this charge; these are trivial compared with the risks that attend closeted star-chamber proceedings. One can live with embarrassment.

The charges should be given in specific written form to the accused party. They should take the shape of single valued propositions that can be disproven. Vague charges of guilt are out of place in a free society. The accused should have an attorney of his or her choice furnished by the university. The rules of evidence and the burden of proof should be clearly defined. Full and unhindered cross-examination of the accusers should be allowed. Each authority, whether university, hospital, or research institute, should have an ombudsman group with official, not advisory status. At my university, there is a standing committee on academic freedom which serves this role, but it has little official standing. A majority of the members of any investigative panel should be constituted from experts outside the university. Full disclosure to avoid conflicts should be required. These should be chosen in the same fashion as a jury, with challenges for cause allowed.

What can a young investigator do to avoid this unpleasantries? First, be honest. I do not intend this to be facetious. Begin by avoiding work that you believe is clouded by proprietary interests. Avoid contract work to fill our your salary or the department's budget. I say this recognizing that this is a difficult imperative, particularly for young investigators in difficult funding times, but much of this work can carry pressure, even if unstated, to find a certain effect. Recognize the pressure that accompanies the need to produce a publishable study or a given effect. Evaluate what the cost to you might be. In choosing a mentor, select one whose value system places honest science over publishable results.

Discuss with your associates steps to take to minimize bias, conscious or unconscious. Consult a good biometrician or epidemiologist about these questions early in the planning of the project. Record these discussions in a bound book. Remember that years later you may be asked to defend your choices of methods. Keep your data in two secure places, and document the means taken to find, classify and scale subjects and any changes in protocol. In a recent paper, Freedland and Carney<sup>15</sup> polled a group of highly regarded investigators and found that a majority had trouble recalling the methods used to classify patients. Keep minutes of staff meetings, and document discussion of problems. Consult with experts in the difficult methodological areas. Ask them for written comments. Be skeptical of your conclusions. Write up and submit negative studies for publication. Be modest in your claims.

Finally, work to reform the system at every level. Discuss these issues in research conferences, at institutional review board meetings, and at meetings of

scientific societies. Do not avoid difficult areas of investigation. Take risks. If scientists exclusively choose the safe routes, avoid controversial research problems, and play only minor variations of someone else's themes, they voluntarily turn themselves into technicians. Our craft will indeed be in peril. Find and nurture good colleagues who will insist on the best from you, tell you when you are wrong, and stand with you in a difficult time. They are truly treasures, and their friendship will endure and sustain you past all confusion and pain. This article is a deeply felt thank you note to the many valued men and women who did precisely that for me.

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## Editor's Note

I asked Dr Needleman to write up his experience with the court system and the National Institutes of Health Office of Scientific Integrity. I tried to follow this case in the press, but I didn't find this very satisfactory. If you're searching for truth you rarely find it in newspapers. Now that I've read Dr Needleman's story I have a clearer idea of his ordeal, but I am confused. Dr Needleman believes he has been found not guilty. The government (Environmental Protection Agency) and other scientists also believe this, but others may not (see page 978, the preliminary report of the Inquiry Panel).

How long must this go on? Has Dr Needleman been victimized over a difference of opinion about the quality of his science?

Editors are exposed daily to conflicting opinions. It has never occurred to me to take such matters to court to be settled! Conflicting opinions are common and very important in science. Truth doesn't emerge easily. Many studies are often needed before one side convinces the other that they are right. Scientific debates can't be settled in courts!

I expect that we will hear the opinions and viewpoints of others about this in our Letters to the Editor column in the next issue of *Pediatrics*.

J. F. L., MD

## WRITING AND THINKING

As anyone knows who has ever sat down to write, writing is thinking. The thought not only precedes the word, it follows it too: we do not know what we mean to say until, after many trials and errors, we have found the words. The purpose of writing well is thinking well.

Raimi J. By any other name. *Columbia Magazine*. 1991; (Spring):36-37.

Submitted by Student

# SCIENCE AND SUBPOENAS: WHEN DO THE COURTS BECOME INSTRUMENTS OF MANIPULATION?

PAUL M. FISCHER, M.D.\*

## I

### INTRODUCTION

On December 11, 1991, the *Journal of the American Medical Association* ("JAMA") published three studies that examined the effect of the Camel cigarette "Old Joe" advertising campaign on adolescents and children.<sup>1</sup> I was lead author on the study that showed that "Old Joe" was nearly universally recognized by six-year-old children, a level of awareness that matched the logo for the Disney channel. Because cigarette smoking is the leading preventable cause of death and disease in this country, I recognized that this research might play a prominent role in the subsequent debate about tobacco advertising. As a scientist, I naively assumed that this discourse would be conducted in academic journals based upon rigorous research and leading to an improved understanding of whether and how advertising influences adolescent experimentation with cigarettes. To date, most of the subsequent debate has occurred in court.

From the beginning, the tobacco industry attempted to discredit this research and harass the researchers. My experience in confronting the tobacco industry has taught me how easily the courts can become the unwitting accomplices of an industry whose goal is profit, not the identification of scientific truth. In his paper in this issue of *Law and Contemporary Problems*, Michael Traynor states that with "common sense and goodwill in every quarter" there should be few problems due to compelled discovery of scholarly research.<sup>2</sup> Unfortunately, in some cases, neither common sense nor goodwill prevail. In such cases, the court can become an instrument of abuse.

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1. Joseph R. DiFranza et al., *RJR Nabisco's Cartoon Camel Promotes Camel Cigarettes to Children*, 266 JAMA 3149 (1991); Paul M. Fischer et al., *Brand Logo Recognition by Children Aged 3 to 6 Years: Mickey Mouse and Old Joe the Camel*, 266 JAMA 3145 (1991); John P. Pierce et al., *Does Tobacco Advertising Target Young People to Start Smoking?*, 266 JAMA 3154 (1991).

2. Michael Traynor, *Countering the Excessive Subpoena for Scholarly Research*, 59 LAW & CONTEMP. PROBS. 119, 148 (Summer 1996).

## II

## MY INTRODUCTION TO EXCESSIVE SUBPOENAS

## A. A Chronology of Events

The "Old Joe" studies were published in a *JAMA* theme issue dealing with tobacco research.<sup>3</sup> The American Medical Association also held a press conference in New York to present the findings,<sup>4</sup> which received wide coverage in the press.<sup>5</sup>

On March 9, 1992, The American Medical Association, the Surgeon General, the American Cancer Society, the American Heart Association, and the American Lung Association called for a ban on "Old Joe" advertising attractive to children.<sup>6</sup> The following day, James Johnson, C.E.O. of the R.J. Reynolds Tobacco Company ("RJR"), defended "Old Joe" in an interview published on the editorial page of *U.S.A. Today*.<sup>7</sup> In this interview, he attacked the "Old Joe" studies and its researchers.<sup>8</sup> Mr. Johnson argued that the "studies are flawed in very serious ways. The scientists who wrote these studies are not unbiased."<sup>9</sup> He made two specific claims about our research that were not true. He stated that the sample size was twenty three people<sup>10</sup> when in reality it was 229 people. He also claimed that we called the parents of the three- to six-year-old children in our study the night before the data collection and asked them only about cigarette use.<sup>11</sup> This statement was a total fabrication. Such a call to the parents would have obviously biased the results.

On March 27, I was served a subpoena duces tecum by RJR.<sup>12</sup> A suit had been filed in California by Janet Mangini against RJR, based on RJR's failure to place health warnings on promotional products such as Camel caps and t-shirts.<sup>13</sup> I received the subpoena even though my research had not been named in the Mangini complaint, I was not a witness to either side in the case, and my 1991 *JAMA* research had no bearing on the issue of health warnings.

The subpoena ordered me to produce the following: the names and tele-

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3. See *supra* note 1.

4. See Stuart Elliott, *Top Health Official Demands Abolition of "Joe Camel" Ads*, N.Y. TIMES, Mar. 10, 1992, at A1.

5. See, e.g., Jane E. Brody, *Smoking Among Children Is Linked to Cartoon Camel in Advertisements*, N.Y. TIMES, Dec. 11, 1991, at D22.

6. Elliott, *supra* note 4.

7. *R.J. Reynolds: Ads Do Not Cause Kids to Smoke*, U.S.A. TODAY, Mar. 10, 1992, at 9A.

8. See *id.*

9. *Id.*

10. See *id.*

11. See *id.*

12. Defendant's Notice of Out of State Deposition on Oral Examination and Request for Production of Documents and Things, Mangini v. R.J. Reynolds Tobacco Co., No. 939359 (Super. Ct., San Francisco Cty., Cal., Mar. 30, 1992).

13. See *Mangini v. R.J. Reynolds Tobacco Co.*, 21 Cal.Rptr.2d 232 (Cal. Ct. App.), *rev. granted & opinion superseded*, 859 P.2d 672 (Cal. 1993), *cert. denied*, 875 P.2d 73 (Cal. 1994) (en banc), *cert. denied*, 115 S. Ct. 577 (1994).

phone numbers of all of the children who participated in the study; all drafts of the study design; all notes, memos, and videotapes pertaining to the study; the names, addresses, telephone numbers, background information, and occupations of all interviewers; hard copy tabulations and data tapes; originals of all test materials; all correspondence relating to the research; the names, addresses, and background information of all consultants; the names and addresses of all funding sources; and the names and telephone numbers of all respondents who were excluded from the study.

Given the published implications of my research, I had assumed that I might at some point be deposed about this study. I was, however, not prepared to receive a subpoena of this breadth and one that would require turning over the names of three- to six-year-old children. Such disclosure would have violated written confidentiality agreements that I had signed with each parent before conducting the research.

I had also anticipated that the Medical College of Georgia ("MCG"), on whose faculty I was a full professor and under whose auspices the research had been conducted, would provide appropriate legal support for my position. However, Michael Bowers, the Attorney General of the State of Georgia and the official counsel for the medical school, took the position that the prevailing legal issue was not human subject confidentiality, academic freedom, or the reasonableness of the subpoena power, but rather the Georgia Open Records Act, a law designed to permit public access to "official records."<sup>14</sup> Mr. Bowers took this position even though RJR did not, at that time, request the records via the Open Records Act. I refused to comply with the subpoena and MCG refused to provide me with legal assistance.

I contacted my own lawyer, Robert W. Hunter, III, who prepared a motion to quash the RJR subpoena.<sup>15</sup> On April 28, 1992, Chief Superior Court Judge William M. Fleming, Jr., ruled in favor of our motion to quash.<sup>16</sup> RJR immediately appealed the ruling to the Georgia Court of Appeals, but that court, on February 9, 1993, ruled in our favor arguing that the requested documents were beyond the bounds of reasonable discovery.<sup>17</sup>

Two weeks later, in an article in a local newspaper, MCG lawyer Clay Stedman stated that the school had not supported my legal efforts because of their position on the Open Records Act.<sup>18</sup> Stedman said that MCG "decline[d] to object to [the] release of this information on the basis that although it was not an Open Records [Act] request, Open Records would have required us to release it."<sup>19</sup> Ironically, RJR attorneys did not know of MCG's position on this

14. Open Records Act, GA. CODE ANN. § 50-18-70 to -76 (Supp. 1996).

15. Motion to Quash, Fischer v R.J. Reynolds Tobacco Co., No. 93-RCCV-230 (Ga. Super. Ct. Richmond County, Apr. 16, 1992).

16. *See Fischer v R.J. Reynolds Tobacco Co.*, No. 93-RCCV-230 (Ga. Super. Ct. Richmond County, Apr. 28, 1992) (order granting motion to quash).

17. *See R.J. Reynolds Tobacco Co. v Fischer*, 207 Ga. App. 292 (1993).

18. Kathleen Donahue, *Researcher Has Hefty Legal Fees*, THE AUGUSTA CHRONICLE, Feb. 27, 1993, at 17A.

19. *Id.*

issue and had previously admitted in their Court of Appeals brief that they believed the records were not accessible to them under the Open Records Act because the research had not been supported by state funds.<sup>20</sup>

One week after the publication of this article, James R. Johnson, legal counsel for RJR sent a letter to H. Dean Propst, Chancellor of the University System of Georgia, and subsequently to Francis Tedesco, President of MCG, requesting that my research records be released to RJR under the Open Records Act.<sup>21</sup> I was given forty-eight hours to turn over all of the previously described records with the exception of the children's names. Clay Stedman, as MCG legal counsel, indicated that I would be suspended if I did not turn over the documents. Francis Tedesco, M.D., President of MCG, indicated that the Attorney General would have me arrested if I did not comply with the request.

At the advice of my lawyer, I turned all of the documents over to the court for protection until such time as the legal issues relating to the Open Records Act, academic freedom, and human subject confidentiality could be resolved. The court accepted the documents and approved a temporary restraining order against the Open Records request.<sup>22</sup>

One month later, RJR petitioned the court to assist MCG and the Attorney General in the action against me.<sup>23</sup> Both the Attorney General's Office and MCG supported RJR's compelled disclosure motion.<sup>24</sup> Ironically, this action united the medical school and a tobacco company against one of the school's own faculty members.

On August 12, 1993, I received a nine-page letter listing documents and data requested by RJR through the Open Records Act.<sup>25</sup> It stated that RJR wanted all documentation related to the study regardless of when it was generated or by whom.<sup>26</sup> In response to a 1993 change in the Open Records Act which excluded release of the names of research participants, RJR did request that the subject names be redacted from the submitted documents.

On December 1, 1993, I resigned from the faculty of MCG and entered private practice in Augusta. On July 20, 1994, Judge John H. Ruffin signed an RJR request to release all of the records held by the court. The records were released to an RJR lawyer before we were notified of the decision, making an appeal of this decision moot.

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20. Petitioner's Brief, R.J. Reynolds Tobacco v. Fischer, 207 Ga. App. 292 (1993).

21. Letter from James R. Johnson, Legal Counsel, RJR, to Francis J. Tedesco, President, MCG (Mar. 10, 1993) (on file with author).

22. Motion for Temporary Restraining Order, *Fischer*, No. 93-RCCV-230 (Ga. Super. Ct. Richmond County, Mar. 12, 1993).

23. See James R. Johnson's Motion to Intervene as a Defendant, *Fischer*, No. 93-RCCV-230 (Ga. Super. Ct. Richmond County, Apr. 22, 1993).

24. Letter from David M. Monde, Attorney, Jones Day, Reavis & Pogue, to Kathryn L. Allen, Senior Assistant Attorney General (Apr. 20, 1993) (on file with author).

25. Letter from RJR to author (Aug. 12, 1993) (on file with author).

26. See *id.*

### B. Lessons Learned

Every day in every academic institution, people request information from scientists. Most of the time this is done by fellow scientists in the process of scientific research. For example, after the publication of the "Old Joe" study, I received requests from other researchers for specific information about our study and how it was done. Such requests are usually limited to information that would permit replication of the research. Successful replication is essential to establish scientific validity, and therefore scientists are usually pleased to share information.

Scientists do not use subpoenas to seek scientific truth! Thus, the subpoena of a researcher's files is evidence that the process has moved outside of the realm of scientific inquiry. As the cases cited in this paper illustrate, a subpoena usually means that the research in question has commercial implications and that a company has decided that its lawyers, rather than its scientists, are in the best position to protect the company's interests.

Nevertheless, many subpoenas for research are routine. For example, a medical researcher might discover and report a series of side-effects in patients taking a new drug. The pharmaceutical company that manufactures the drug may then subpoena the records to see if there is an alternative explanation for the patients' symptoms. Other than concerns about patient confidentiality, such a subpoena would be handled in a routine fashion.

However, not all compelled disclosure is routine. In the extreme, subpoenas can be unwittingly used in a manner that is damaging to the researcher, the scientific process, and the greater public good.

## III

### DAMAGING EFFECTS OF EXTREME SUBPOENAS

#### A. Discredit the Research. Discredit the Researcher.

It was clear from the *U.S.A. Today* interview that RJR wanted to discredit me and my research.<sup>27</sup> Furthermore, this refutation would not follow the usual "rules" of science.

The standards for a published scientific paper require that the report include sufficient detail about the scientific methods utilized so that another individual in the field could duplicate the study. This was precisely what *Advertising Age* did after initially expressing reservations about the "Old Joe" research. They commissioned research that was published five months later and showed that the Camel campaign was indeed highly effective in reaching young people, especially children younger than age thirteen.<sup>28</sup> The president of the research company said, "I was blown away by the number of smaller kids who could

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27. See R.J. Reynolds, *supra* note 6.

28. See Gary Levin, *Poll: Camel Ads Effective with Kids*, ADVERTISING AGE, Apr. 27, 1992, at 12.

name cigarettes."<sup>29</sup> Had RJR been concerned about the veracity of our findings, they could have duplicated our research in several weeks for a few thousand dollars. Instead, they spent two and a half years, and a great deal more money, in an attempt to access every page in my files.

Why would RJR be interested in every scrap of paper in a research file? The answer to this question became clear from the experience of Dr. Joseph DiFranza, the lead author of one of the "Old Joe" studies.<sup>30</sup> His research showed that Camel cigarettes' share of the youth market increased from a mere 0.5% to a substantial 32.8% following the "Old Joe" advertising campaign.<sup>31</sup> Dr. DiFranza received a similar subpoena and turned over his records to RJR. In one of the letters to a colleague that was included in the disclosed documents, Dr. DiFranza wrote, "I have an idea for a project that will give us a couple of smoking guns to bring to the national media."<sup>32</sup> RJR released this letter to the press and claimed that it proved that the researchers were biased and that the research was fraudulent.<sup>33</sup>

It is easy to characterize any scientist as being biased. The public assumes that scientists enter into research without a point of view. Nothing could be further from the truth. Science is impossible to do without passion about an idea. Scientists are not without opinions, but they agree to subject these opinions to objective experiments to see if they are true. In every researcher's files, there are notes that could be taken out of context and characterized as proving bias.

In addition, every research study represents a series of methodological decisions about how data are collected and analyzed. These decisions require expert judgment and each of these judgments, when viewed in isolation, could be challenged. It is precisely because of this, that the final published paper becomes the record of the research. In the published manuscript, the researcher must describe the findings, discuss their meaning, and most importantly, identify the study's limitations.

The broad subpoena filed by RJR is akin to requiring a Supreme Court Justice to report every private note made and every comment spoken in considering a case, rather than merely being responsible for the contents of the final opinion. It would be quite easy to discredit the decisions of even the best judges if their private notes and thoughts were publicly open on demand.

## B. Human Subject Confidentiality

The conduct of research on human subjects requires that the public have confidence that its best interests will be protected and that its confidentiality will be preserved. In the case of our research, RJR requested the names and

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29. *Id.*

30. DiFranza, *supra* note 1.

31. *See id.*

32. *See* Maria Mallory, *That's One Angry Camel*, BUS. WK., Mar. 7, 1994, at 94.

33. *See id.*

addresses of 239 three- to six-year-old children whose parents had signed agreements in which we promised complete confidentiality. According to Peggy Carter, an RJR spokesperson, the company intended to use this information to contact the research subjects.<sup>34</sup> Her reason for requesting this breach of confidentiality was that “[t]here 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.”<sup>35</sup> While this reasoning is paranoid at best, it would not be necessary for RJR to knock on children’s doors at night to prove that the data in question were collected, rather than fabricated.

The issue of subject confidentiality took an interesting legal turn in my case. MCG initially acknowledged the potential for abuse. In a letter from Carol Huston, one of the school’s attorneys, to the Attorney General’s office, she stated that

[Fischer’s] concern, which I believe is well founded, is that Reynolds is attempting to harass him (and other researchers) through tactics such as this in order to discourage future research, the results of which may not be favorable to the tobacco industry.... We also believe if [RJR] obtains the names of the respondents, it seems very likely that [it] may contact them and attempt to harass them. This, in turn, may discourage other individuals from participating in future research projects.

Despite these observations by an MCG lawyer, the Attorney General’s position prevailed, and the school insisted that all names be released.

As a general matter, institutions that participate in federally funded medical research must sign agreements with the Department of Health and Human Services (“DHHS”), by which they agree to conduct research according to federally-established guidelines. Human subject confidentiality is well-protected by these standards. My study, however, was not federally funded and was subject to these guidelines only because of contractual agreements between DHHS and MCG.

On September 8, 1992, I was contacted by the acting chief of the Office of Protection from Research Risks of the National Institutes of Health. He had heard of my case and wanted information about any breach of human subject protection. He subsequently sent a letter to the school alleging noncompliance with their DHHS contract because of the school’s position requiring release of my subjects’ names. The school responded that the federal regulations could be avoided because my research was not federally funded. DHHS and MCG subsequently signed a revised contract in which only federally funded research was governed by federal regulations regarding subject confidentiality.

### C. Harassment

The tobacco industry approach to litigation has been described by Lawton M. Chiles, Jr., Governor of the State of Florida, as “designed to confuse the medical evidence, stone-wall, delay, refuse reasonably to settle claims, and to

34. See Marcia Barinaga, *Who Controls a Researcher’s Files? Tobacco Company R.J. Reynolds Subpoenas Research Study Data*, 1256 SCI. 1620 (1992).

35. *Id.*

run up plaintiffs' attorneys' fees in a war of attrition.<sup>36</sup> He cites a memo written by J. Michael Jordan, an attorney for RJR:

The aggressive posture we have taken regarding depositions and discovery in general continues to make these cases extremely burdensome and expensive for plaintiffs' lawyers, particularly sole practitioners. To paraphrase General Patton, the way we won these cases was not by spending all of Reynolds' money, but by making the other son of a bitch spend all his.<sup>37</sup>

This same approach was used to wear down my resources, including my time, attention, and money. The ultimate goal is to make the process sufficiently painful so that the researcher cannot complete further research and so that other scientists are discouraged from conducting similar studies.

Scientists are perfect subjects for harassment by litigation. They often have little knowledge of the law and little patience for the slow and subtle workings of the legal system. The distraction and anxiety caused by depositions, legal costs, and court appearances can easily put an abrupt end to a promising line of research or a research career.

It should be noted that RJR did not limit its harassment efforts to the use of the press and the courts. It also attempted to conscript the institution at which I worked. Bernard Wagner, M.D., Professor at the New York University School of Medicine and paid consultant to RJR, contacted my research colleagues and the President of MCG with accusations of scientific fraud.<sup>38</sup> A similar letter was sent to the University of Massachusetts regarding Dr. DiFranza's "Old Joe" study.<sup>39</sup> While MCG did not respond, the University of Massachusetts used these baseless accusations to initiate scientific misconduct hearings against Dr. DiFranza. He was eventually found innocent of these charges.<sup>40</sup>

#### IV

#### SUGGESTIONS

As a researcher who has been through the experience of compelled disclosure, many of the suggestions outlined in this paper do not appear to be viable solutions to the problem that I faced. I would not argue that scientists deserve special protection under the law in the same way that lawyers, priests, or journalists have claimed the need for protection of their relationships with clients, parishioners, and confidential sources. Science, after all, is based on a shared and open search for truth. I am not, however, so naive as to believe that most subpoenas for research records are based on goodwill, public interests, or the search for truth. I offer the following thoughts:

36. Complaint, Florida v. American Tobacco Co. et al., No. CL-1466A0 (Circuit Ct., 15th Circuit, Palm Beach, Fla., Apr. 18, 1995)

37. *Id.* at 28-29 (memorandum from J. Michael Jordan, legal counsel, RJR).

38. Letter from Bernard Wagner to Tina Rojar (Mar. 29, 1993) (on file with author).

39. Based on the author's conversations with Dr. DiFranza.

40. *Id.*

First, if a request for compelled disclosure has been made, realize that the process has moved outside of the normal exchange between scientists. It is likely that a commercial entity and its profits are at stake. It is also likely that the company will have greater legal resources and experience than the scientist, who may have never stepped foot inside a courtroom.

Second, despite institutional affiliation and responsibilities to protect academic freedom, universities may provide poor legal counseling to scientists facing compelled disclosure. This problem may become greater due to the increased reliance of universities on corporate support. We might expect to see university presidents siding with corporate contributors rather than their academic faculty.

Next, if a subpoena is requested by an industry, consider the industry's past record in dealing with the scientific community. Consider whether the industry has used the legal system to discourage good science in the past.

Also, consider the breadth of the request. If it goes far beyond what a reasonable scientist would require to duplicate the research, then there may be other ways that the company could validate the research findings without violating the privacy of the scientist's records.

Ask the scientist to identify specifically how compelled discovery could impede his research. It is impossible for the court to balance the rights of the company with those of the scientist unless it understands the implications of the legal process on the scientist's time, attention, and financial resources.

Finally, human subject confidentiality, promised as part of the research process, must be protected at all costs. There are excellent ways to identify scientific fraud without violating anonymity, such as the use of an independent review panel of scientists.

## V

### CONCLUSION

The uneasy relationship between law and science is likely to continue regarding disclosure of scientific research materials. Law and science are worlds apart in terms of values that they hold and the rules that they follow. Whether it be DNA evidence or silicone breast implants, it appears that these two worlds will collide with ever-increasing frequency. This inevitable collision will require that scientists have a better understanding of the legal implications of their research and that judges have a better understanding of the impact of their decisions on the progress of science.