RESEARCHERS' REACTIONS TO COMPELLED DISCLOSURE OF SCIENTIFIC INFORMATION

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I
INTRODUCTION

Researchers have become increasingly aware of opportunities to act as expert witnesses in various kinds of criminal and civil litigation. Many, however, are unaware of the possibility that they and their data may be subpoenaed in connection with lawsuits in which they have not been retained as experts or named as parties. Such situations raise significant concerns about confidentiality of data (particularly from identifiable research participants) and premature disclosure of ongoing research. They also can impose substantial economic and temporal burdens on researchers and disrupt their research programs. While Federal Rule of Civil Procedure 45 provides protections for researchers whose data are subpoenaed for use in litigation,[1] the experience of researchers suggests that significant personal and professional burdens inherent in compelled production of research data are likely to remain.

This article was prepared for a workshop on judicially compelled disclosure of researchers' data and scholars' testimony, sponsored by the Program for Science and Law at Georgetown University. It was intended to lend a real-world flavor to issues discussed in more detail by others at the workshop. The article first reviews a collection of published legal opinions concerning the enforceability of such subpoenas and then describes researchers' concerns, focusing on three major issues: the economic and temporal demands of subpoenas; the impact of breached promises or expectations of confidentiality on individual privacy and research interests; and the consequences of releasing incomplete and unpublished research findings. The article concludes with suggestions about how the burdens of compelled disclosure of research data may be minimized without jeopardizing the legitimate interests of litigants.

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1. *See, e.g.*, Michael Traynor, *Countering the Excessive Subpoena for Scholarly Research*, 59 LAW & CONTEMP. PROBS. 119, 127 (Summer 1996), for a discussion of these protections. *See generally* Paul D. Carrington & Traci L. Jones, *Reluctant Experts*, 59 LAW & CONTEMP. PROBS. 51 (Summer 1996), for a general discussion of the right of litigants to obtain possibly relevant evidence and citizens' concurrent duty to supply such evidence.

II

CASES REVIEWED

Because our analysis includes only cases described in *published* court opinions, it does not provide an estimate of the number of subpoenas and requests for information to which researchers have actually been required to respond. A project conducted in the 1970s, however, identified approximately two dozen social science researchers who had been subpoenaed or threatened with a subpoena, which suggests a higher level of activity than might be inferred from the number of published court opinions.[2] Moreover, some researchers and institutions are often targets of subpoenas because their work focuses on frequently litigated topics. One member of the legal department of Mount Sinai Medical Center reported to us that she has handled numerous requests and subpoenas for research information, mostly related to epidemiological studies, that Mount Sinai has not contested. Similarly, the Centers for Disease Control ("CDC") receives information requests routinely. An Assistant U.S. Attorney who frequently represents the CDC reported to us that the agency usually is able to provide sufficient information to meet the requesting party's needs without compromising its own interests or formally opposing the request. Such requests generally are handled by the CDC's agency counsel; they are referred to the U.S. Attorney's Office only when the CDC cannot reach a negotiated disclosure agreement with the requestor. As it is the policy of both Mount Sinai and the CDC to release information unless there is a compelling reason to withhold it, they can deal with most requests in the ordinary course of business.

Neither are published opinions necessarily representative of the types of litigation in which scientific information is likely to be subpoenaed or of the areas of research most vulnerable to subpoena. They reflect only the efforts and opinions of litigants who had sufficient means to seek scientific information and later to oppose a motion to quash, and of researchers who had sufficient means to contest the subpoena. A comprehensive survey of researchers in various disciplines and at different types of research institutions would provide more representative information about researchers' views of the problems associated with releasing their data pursuant to subpoena.

Except as described below, we obtained our information about each case from two sources: the court's published opinion and telephone interviews in the summer of 1991 with a researcher named in the subpoena and/or his attorneys.[3]

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2. James D. Carroll & Charles R. Knerr, *Report of the APSA Confidentiality in Social Science Research Data Project*, 1975 POL. SCI. 258.

3. Because our task for the workshop was limited to examining a small number of cases to illustrate the nature of burdens on researchers and research participants, we did not reinterview our respondents or seek to interview researchers in cases that have been litigated since our initial work. Two matters of interest that occurred after we had completed our interviews involve requests for disclosure of research findings related to (1) the effects of the Exxon Valdez oil spill on Alaskan Native communities and (2) children's reactions to cigarette advertisements featuring Joe Camel. *See* Marcia Barinaga, *Who Controls a Researcher's Files?*, 256 SCI. 1620 (1992); J. Steven Picou, *Compelled Disclosure of Scholarly Research: Some Comments on "High Stakes Litigation,"* 59 LAW & CONTEMP. PROBS. 149 (Summer 1996); Eliot Marshall, *Court Orders Sharing of Data*, 261 SCI. 284 (1993).

Although time constraints precluded us from interviewing everyone involved in each subpoena dispute, we attempted to speak with at least one person with first-hand knowledge of each case. An outline of the issues covered in the interviews is presented in the appendix to this article; sometimes, of course, given issues were more or less relevant to particular cases. Information about *In re Grand Jury Subpoena dated January 4, 1984*[4] was obtained from the published court opinions, an *amicus curiae* brief submitted by three scholarly associations, and an account of the experience published by the researcher himself.[5] Information about *Wilkinson v. Federal Bureau of Investigation*[6] was obtained from the court opinion, an interview with Harold L. Miller, an archivist at the State Historical Society of Wisconsin, and an article describing the case.[7] Finally, information about *Richards of Rockford, Inc. v. Pacific Gas & Electric Co.*[8] was obtained only from the published court opinion.

We describe below, for nine sets of cases, the litigation giving rise to the subpoenas, the type of research information subpoenaed, and the outcome of the subpoena disputes. We elaborate on the cases later in the article as necessary to illustrate particular points.

A. Tobacco/Asbestos Litigation

One set of cases involved the subpoena of information related to studies of the synergistic effects of cigarette smoking and asbestos exposure in the development of cancer. In one case, various tobacco company defendants sought detailed information about certain studies conducted by Dr. Irving Selikoff, in association with the American Cancer Society, at the Mount Sinai School of Medicine. The subpoenas were extremely broad: They covered ongoing research as well as studies published in 1968, 1978, and 1979—and demanded production of, among other things, the following: all documents related to the studies that "describe, constitute, comment upon, criticize, review, or concern the research design, methodology, sampling protocol, and/or conduct of any of the studies;" copies of "questionnaires, answers to questionnaires, interview forms, responses to interviews, death certificates, autopsy reports, and other cause of death … ;" and "data sheets, computer tapes and/or copies of computer discs containing all coded data … in as 'raw' a form as possible." A New York state trial court quashed the subpoenas, finding that compliance with them would place an unreasonable burden on Mount Sinai and the American Cancer Society, and would unduly disrupt ongoing research.[9] The tobacco companies did not appeal.

In a similar case, the defendant tobacco companies served narrower subpoe-

4. 583 F. Supp. 991 (E.D.N.Y.), *rev'd and remanded*, 750 F.2d 223 (2d Cir. 1984).

5. Mario Brajuha & Lyle Hallowell, *Legal Intrusion and the Politics of Field Work: The Impact of the Brajuha Case*, 14 URBAN LIFE 454 (1986).

6. 111 F.R.D. 432 (C.D. Cal. 1986).

7. Harold L. Miller, *Will Access Restrictions Hold Up in Court? The FBI's Attempt to Use the Braden Papers at the State Historical Society of Wisconsin*, 52 AM. ARCHIVIST 180 (1989).

8. 71 F.R.D. 388 (N.D. Cal. 1976).

9. *In re* R.J. Reynolds, 518 N.Y.S.2d 729 (Sup. Ct. 1987).

nas, requesting information about two of Dr. Selikoff's published studies. These subpoenas requested only computer tapes containing the data underlying the two studies and documentation necessary to understand the tapes (for example, blank coding forms and questionnaires, protocol documents, and documents describing the methods of analysis). The subpoenas did not seek information about Dr. Selikoff's ongoing research. Mount Sinai and the American Cancer Society again moved to quash the subpoenas, but the court denied the motion, instead entering a protective order that permitted the researchers to redact information identifying research participants and that prohibited the tobacco companies from using the released data to identify the research participants.[10]

B. Litigation Involving the Negligent Design of Intrauterine Devices

Six lawsuits against the manufacturer of an intrauterine device ("IUD") known as Copper-Seven were consolidated for discovery. The plaintiffs claimed that the IUD had been negligently designed: A "tailstring" used to determine if the IUD had been properly inserted, and later to remove it, was alleged to facilitate bacterial colonization and migration from the vagina to the uterus. The alleged result was pelvic inflammation, leading to hysterectomies and/or infertility among IUD users.

Plaintiffs served notice that they would depose Dr. Malcolm Potts, then president and chief executive of Family International Health ("FIH"), a nonprofit organization. FIH had conducted a study sponsored by the Agency for International Development, comparing IUDs with and without tailstrings (the "string-no string" study). The initial subpoena demanded production of seventy-seven categories of documents and covered not only the "string-no string" study but all other IUD studies conducted by the organization since 1985. The plaintiffs later narrowed their request to fifty-five categories of documents, but, according to Dr. Potts and the court, the subpoena was still very expansive. Indeed, Dr. Potts estimated that compliance with the request would entail producing at least 300,000 pages. The court found that the burden of producing the research information outweighed the plaintiffs' need for it, and quashed the subpoena.[11]

C. Dioxin Litigation

The underlying issue in this case was whether the Environmental Protection Agency should cancel the registration for certain herbicides containing the substance commonly known as dioxin. Dow Chemical Company and the class of veterans in the "Agent Orange" litigation were permitted to intervene.[12] An administrative subpoena *duces tecum* required researchers James R. Allen and John Van Miller of the University of Wisconsin Medical School to produce documents and records related to four studies of the chemical 2,3,7,8-tetrachlorodibenzo-p-

10. *In re* American Tobacco Co., 880 F.2d 1520 (2d Cir. 1989); *In re* American Tobacco Co., 866 F.2d 552 (2d Cir. 1989).

11. Anker v. G.D. Searle & Co., 126 F.R.D. 515 (M.D.N.C. 1989).

12. *In re* Agent Orange Litigation, 597 F. Supp. 740 (E.D.N.Y. 1984).

dioxin, one completed (500 ppt study), one near completion (50 ppt study), and two in preliminary stages (25 and 5 ppt studies). The subpoenas defined "documents and records" broadly as the following:

> all letters, memoranda, correspondence, reports, notes, drafts, working papers, protocols for scientific studies, laboratory notebooks, raw data, data compilations, graphs, charts or papers of any kind, whether hand-written, typed, printed, or reproduced photostatically or photographically, all film, photographs, videotapes, drawings, or other visual representations, and all magnetic, mechanical, or electronic recordings or other form of data compilation. The term "documents and records" does not include articles published in recognized scientific journals of wide circulation.

The administrative law judge quashed the subpoena with respect to the 500 and 50 ppt studies because of an understanding that this information would be turned over voluntarily, but denied the motion to quash with respect to the 25 and 5 ppt studies. Pursuant to a *de novo* review, the district court quashed the subpoenas, finding that (1) the probative value of the 25 and 5 ppt studies was limited because the studies were incomplete and their findings inconclusive, (2) Dow's need for the information was not great because Allen was no longer scheduled to testify at the cancellation hearing, EPA did not intend to introduce any of the documents or information sought by Dow, and the information about the 25 and 5 ppt studies was not needed to evaluate the 500 and 50 ppt studies, and (3) producing information related to incomplete studies that have not been peer reviewed would place a substantial burden on researchers. The United States Court of Appeals for the Seventh Circuit affirmed. The district court ordered Dow Chemical to pay attorneys' fees incurred by the researchers and intervening veterans in opposing the subpoenas.[13]

D. Utility Vehicle Litigation

One set of cases stemmed from the publication of the report *On-Road Crash Experience of Utility Vehicles* by the Highway Safety Research Institute of the University of Michigan (now the University of Michigan Transportation Research Institute). That report provided preliminary evidence that utility vehicles in general, and Jeep CJ-5 models in particular, experienced a disproportionately high rollover rate in accidents. In numerous products liability suits involving Jeeps and other utility vehicles, plaintiffs' experts relied or intended to rely on facts and opinions in the report. In several of these suits, defendants American Motors Corporation and its subsidiary, Jeep Corporation, served subpoenas on the report's principal author, Professor Richard G. Snyder, to produce and testify at a deposition about all research data, memoranda, drafts, correspondence, lab notes, reports, calculations, moving pictures, photographs, slides, statements, and the like pertaining to the study.[14]

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13. Dow Chemical Co. v. Allen, 494 F. Supp. 107 (W.D. Wis. 1980), *aff'd*, 672 F.2d 1262 (7th Cir. 1982); Dow Chemical Co. v. Allen, 578 F. Supp. 468 (W.D. Wis. 1982). For a more in-depth discussion of the dioxin litigation, see Barbara B. Crabb, *Judicially Compelled Disclosure of Researchers' Data: A Judge's View*, 59 LAW & CONTEMP. PROBS. 9, 21-22 (SUMMER 1996).

14. *In re* Snyder, 115 F.R.D. 211 (D. Ariz. 1987); Buchanan v. American Motors Corporation, 697 F.2d 15 (6th Cir. 1983); Wright v. Jeep Corporation, 547 F. Supp. 871 (E.D. Mich. 1982).

In *Buchanan v. American Motors Corporation*, the district court quashed the subpoena on the grounds that it was unreasonably burdensome, as it would require an eminent expert who was a stranger to the litigation to spend a great deal of time explaining the raw data that led him to his opinions. The United States Court of Appeals for the Sixth Circuit agreed. While the appeal in *Buchanan* was pending, however, the district court in *Wright v. Jeep Corporation* reversed a magistrate's order quashing an identical subpoena. Although the *Wright* court ruled that Professor Snyder would be required to testify, it also held that he was entitled to a reasonable fee for doing so, "not only a professional fee and the cost of supplying the documents and remuneration for the inconvenience, but also … a charge for a portion of the expenses of the original research."[15] The court also indicated that the interested persons should submit other proposals for minimizing the burden imposed by the subpoena. The *Wright* case settled before Professor Snyder was deposed. Even after the Sixth Circuit's decision in *Buchanan*, the same district judge who decided *Wright* decided the same issue in another case, again ruling that Professor Snyder would be required to testify. That case was also settled before Professor Snyder was deposed.

E. DES Litigation

In 1972, Dr. Arthur Herbst created the Registry for Hormonal Transplacental Carcinogenesis ("the Registry") at the University of Chicago. The Registry monitors the clinical, pathological, and epidemiological aspects of clear cell adenocarcinoma, and is the only centralized repository of data on that disease. Because the work of Dr. Herbst and others posited an association between the disease and *in utero* exposure to the drug diethylstilbestrol ("DES"), the information collected by the Registry is relevant to products liability suits stemming from the use of DES by pregnant women.

In connection with a number of such suits against it, DES manufacturer E.R. Squibb & Sons, Inc., served Dr. Herbst with a subpoena to testify and to produce the records of every person in the Registry who has clear cell adenocarcinoma of the genital tract and every person with a history of exposure to DES or other synthetic estrogens. The subpoena also demanded production of records and testimony about investigative techniques used by the Registry, including questionnaires, protocols, and statistical and computer analyses. Finally, the subpoena called for all drafts and final articles, studies or reports prepared or published referring to the Registry data.

The district court quashed these subpoenas,[16] concluding that Squibb had not made an adequate showing of what it hoped to prove by access to the Registry data. The fact that Dr. Herbst would not be a witness for the plaintiffs at trial, the court said, tended to reduce Squibb's need for the data. As will be further described below, the appellate court disagreed, and remanded the case to the district court for further proceedings, ordering it to fashion an appropriate protec-

15. *Wright*, 547 F. Supp. at 877.

16. Andrews v. Eli Lilly & Co., 97 F.R.D. 494 (N.D. Ill. 1983).

tive order, taking into account Squibb's need for the information as well as Dr. Herbst's and the Registry's legitimate interests.[17]

F. Tampon-related Toxic Shock Syndrome Litigation

In the 1980s, Procter & Gamble Company ("P&G") found itself the target of numerous products liability cases alleging that its "Rely" brand tampon caused toxic shock syndrome, a rare but sometimes fatal disease. In these cases, plaintiffs' experts based their opinions in part on a study by the Centers for Disease Control ("CDC") that showed a link between the syndrome and the use of tampons, particularly Rely. To prepare for and blunt the effect of the experts' testimony, P&G sought full disclosure of certain records and documents pertaining to the CDC study. The CDC records comprised information obtained from health care providers and others. The information included medical records and the responses of women who answered questions about their medical history, sexual practices, contraceptive methods, pregnancy histories, menstrual activity, tampon usage, and douching habits.

CDC wanted to remove from the documents before production all information that would allow identification of study participants who did not consent to release of information pertaining to them. P&G pressed for identifying information to enable it to contact the subjects of the CDC investigations personally, "to determine whether the studies were properly conducted." Declining to rule on the CDC's claim of a general confidential privilege for information provided by study participants, the courts in the reported decisions invoked Federal Rule of Civil Procedure 26(c) and quashed the subpoenas to the extent they sought production of identifying information.[18]

G. Sociological Study of the American Restaurant

Mario Brajuha, a sociology graduate student, was preparing his dissertation on the sociology of the American restaurant. To conduct the necessary research, Mr. Brajuha worked as a waiter in a restaurant, keeping a journal of his observations and conversations with co-workers. During the course of his study, a fire broke out in the restaurant under suspicious circumstances. A federal grand jury investigating the matter subpoenaed Mr. Brajuha to testify and to produce his research journal. He testified fully about his observation of events at the restaurant but refused to provide his several hundred page journal. Although the district court quashed the subpoena, the appellate court reversed and remanded the case for further proceedings,[19] as more fully discussed below.

17. Deitchman v. E.R. Squibb & Sons, Inc., 740 F.2d 556 (7th Cir. 1984).

18. Lampshire v. Procter & Gamble Co., 94 F.R.D. 58 (N.D. Ga. 1982), *vacated,* 708 F.2d 732 (11th Cir. 1983) (unpublished table decision); Farnsworth v. Procter & Gamble Co., 101 F.R.D. 355 (N.D. Ga. 1984), *aff'd,* 758 F.2d 1545 (11th Cir. 1985).

19. *In re* Grand Jury Subpoena dated January 4, 1984, 583 F. Supp. 991 (E.D.N.Y.), *rev'd and remanded,* 750 F.2d 223 (2d Cir. 1984).

H. Personal Archives Donated to a State Historical Society

In its defense of a civil rights suit by the National Committee Against Repressive Legislation ("NCARL") and its executive director Frank Wilkinson, the FBI sought the production of personal papers of NCARL members Carl and Anne Braden. After Carl Braden's death, Anne Braden had made a restricted donation of the papers to the State Historical Society of Wisconsin; the Society was to grant others access to the documents only with her permission. In *Wilkinson v. Federal Bureau of Investigation*,[20] the court issued an order granting access to the FBI, but also providing Braden thirty days to assert privilege as to documents that raised concerns regarding First Amendment rights to freedom of association. The court reasoned that the documents remained within at least partial control of the donor, and would have been fully discoverable had the Bradens kept the papers in their basement rather than donating them to the Historical Society. In the meantime, Ms. Braden and the FBI disagreed about the breadth of the court order—the FBI maintained that the order pertained to the entire Braden collection whereas she felt that it pertained only to the papers concerning NCARL. Ms. Braden claimed privilege as to about one-half of her NCARL files; the district court judge found this claim disingenuous and issued a second order requiring her to open up her entire collection to the FBI. The underlying litigation was settled, however, before Ms. Braden produced the papers she considered privileged.

Anne Braden was not a third-party researcher—indeed, she was a member of the plaintiff class in *Wilkinson*—and thus arguably waived her right to keep the papers confidential. We nevertheless include this case because the archivists at the State Historical Society expressed concerns about the current trend for organizations and even private individuals to destroy documents as soon as it is feasible to do so, for fear that they will be subpoenaed or otherwise be made public. Archivists fear that, if donors' requests to restrict access to documents such as Ms. Braden's are not honored, important historical information will be lost and scholars' ability to conduct research will be diminished.

I. Research on Organizational Decisionmaking

Richards of Rockford, Inc. ("Richards"), a manufacturing company that had contracted to supply certain equipment to Pacific Gas & Electric Co. ("PG&E"), sued PG&E for breach of contract and defamation. Richards deposed a Harvard professor who had recently interviewed employees of PG&E as part of a research project examining how utilities make environmental decisions. The professor also had interviewed employees of five other utility companies. At his deposition, the professor refused to disclose the identity of the employees interviewed or the content of the interviews. Richards moved to compel the professor's research assistant to reveal the employees' identities and to produce any existing interview notes. The court denied this motion, finding that the public interest in maintaining confidential relationships between academic researchers and their

20. 111 F.R.D. 432 (C.D. Cal. 1986).

sources outweighed the plaintiff's interest in the subpoenaed information because the information sought was largely supplementary with respect to the contract claim and there was no *prima facie* evidence that the plaintiff was defamed during interviews with the professor.[21]

III

CONCERNS RAISED BY SUBPOENAS TO RESEARCHERS

Absent a clear privilege mandating protection of the subpoenaed information, courts deciding disputes over subpoenas seeking relevant data in the possession of an expert not retained for purposes of the litigation balance the interests of litigants, researchers, and, in certain instances, research participants.[22] Courts have focused primarily on the interests of the researcher (or of science in general) in protecting the future flow of information, or in honoring promises of confidentiality. With rare exceptions, the privacy interests of individual research participants are not directly represented in this type of dispute.[23] Nevertheless, as will be seen, courts sometimes base their decisions on such interests (see, for example, the toxic shock cases discussed below). Although the interests of researcher and research participant are conceptually distinct, they often converge; for convenience, we will address them together.

We treat the subpoenas described here as though they sought only the production of documents, with testimony, if any, limited to authentication of the documents. We do not address the question of whether, and under what conditions, a court may compel the opinion testimony of unretained expert witnesses. Although that question is implicated in some of the cases we describe (for example, *Wright v. Jeep Corp.*[24]), our task was narrower. Suffice it to say that compelling researchers to prepare for and testify at a deposition and/or at trial about their research and opinions would substantially increase the burdens described herein.

Our review of the published opinions and our interviews were directed to obtaining information about how researchers perceived the court's balancing test, and how the experience and the court's decision affected the scientist's work. In the cases reviewed, researchers argued, among other things, the following: that compelled disclosure of scientific information in the requested manner would violate the privacy rights of individual research participants and force the researchers to breach promises of confidentiality; that the breach of such promises or equivalent expectations would detrimentally affect future research; that scientists suffer reputational harm from premature disclosure of incomplete research

21. Richards of Rockford, Inc. v. Pacific Gas & Elec. Co., 71 F.R.D. 388 (N.D. Cal. 1976).

22. A detailed explanation of the rules governing the enforcement or quashing of subpoenas for scientific information is beyond the scope of this paper. For discussion of such, see Carrington & Jones, *supra* note 1, Crabb, *supra* note 13, and Traynor, *supra* note 1.

23. Gary B. Melton, *When Scientists are Adversaries, Do Participants Lose?*, 12 LAW & HUM. BEHAV. 191 (1988).

24. 547 F. Supp. 871 (E.D. Mich. 1982).

and embarrassment from disclosure of unpublished materials such as drafts and notes; and that compliance with the subpoena would cause substantial economic and temporal burdens. We now turn to some of the arguments used to oppose enforcement of subpoenas of research data and consider how these arguments fared.

A. Economic and Temporal Burdens

1. *Burdens of Complying with Discovery Requests.* Researchers may object to subpoenas on the grounds that compliance would be unduly expensive, time-consuming, and disruptive of their research productivity. Where production as requested would be unduly burdensome, courts may order that discovery not be had.[25] Wildly overbroad subpoenas are the most likely to elicit this response from courts, particularly where the information they target is only marginally relevant to the underlying litigation. For example, the court in *Anker v. G.D. Searle & Co.*[26] quashed the subpoenas directed to the research of Dr. Malcolm Potts because the subpoenas were overbroad and burdensome. Dr. Potts had conducted a study comparing IUDs with and without tail strings that was relevant to the litigation. The initial subpoena covered not only this study but also all other IUD studies conducted by Dr. Potts during several preceding years. The plaintiffs later narrowed the request, but, even so, much of the information sought was not directly related to the underlying issues in dispute. Moreover, some of the documents requested were already publicly available. Dr. Potts estimated that complying with the subpoena would have stopped the activities of his organization for two to three weeks as employees assembled and produced over 300,000 pages of documents. The plaintiffs did not even offer to compensate him for complying with the subpoena. Dr. Potts's motion to quash the subpoena was granted because the court found that the burden of producing the research information outweighed the plaintiffs' need for it. The court also stated the subpoena was so unmanageable that an effort by the court to narrow it was not justified. The court rejected the assertion of a statutory or common-law privilege for academic or scientific researchers, but stated that Dr. Potts's status as a nonparty and involuntary expert witness was one factor to be considered.

Where the information is clearly related to the litigation and should be produced in some form, courts may take an intermediate position and narrow overly broad discovery requests.[27] Cases illustrating this intermediate position, such as *Deitchman v. E. R. Squibb & Sons, Inc.*,[28] are discussed in more detail later in this article.

Research information was produced pursuant to a subpoena in four of the matters we reviewed in Part II of this article,[29] and was produced "voluntarily" in

25. FED. R. CIV. P. 26.
26. 126 F.R.D. 515 (M.D.N.C. 1989).
27. FED. R. CIV. P. 26.
28. 740 F.2d 556 (7th Cir. 1984).
29. *In re* American Tobacco Co., 880 F.2d 1520 (2d Cir. 1989); *In re* American Tobacco Co., 866

a fifth.[30] One case involved a subpoena by a grand jury pursuant to a criminal investigation. The other four cases involved subpoenas by defendants in civil suits. Two additional subpoenas in personal injury suits involving utility vehicles were not quashed, but the underlying litigation was settled before the information was produced. At least three of the four defendants who received research information compensated the researchers for costs incurred in providing the information.[31]

The direct burden on researchers' time, and therefore the effect on their scientific productivity, can be overstated. For example, redaction of the data in *American Tobacco* required none of Dr. Selikoff's personal time. Statisticians and computer specialists at the American Cancer Society and on Dr. Selikoff's staff did all the necessary work. Similarly, records produced from the DES Registry were prepared for production by clerical personnel and supervised by research assistants. Only after the research assistants had reviewed the redacted documents did Dr. Herbst perform a final check to ensure that no identifying information remained in the documents that would be released. Anne Braden, rather than the Wisconsin State Historical Society, prepared her documents for release. Finally, there was no evidence from the reported decision that any extraordinary effort would be required for Mario Brajuha to prepare his journal for release to the grand jury, although such work is by its very nature painstaking, if not effectively impossible. Still, to the extent that laboratories are disrupted or direct supervision by principal investigators is required, the burden of production can be significant.

Our analysis of the reported decisions suggests that courts make reasonable attempts to limit the burdens on researchers. In the cases reviewed, compliance with subpoenas did not place undue demands on the principal investigators' own time or resources. However, the burdens on the principal investigators' staff and others involved can be great, and it is not difficult to envision situations in which compliance with subpoenas would place severe temporal, and perhaps economic, demands on researchers. Whether a subpoena places an extraordinary demand on a researcher depends on the nature of the information request and the researcher's circumstances. For example, what type of information is to be released? What type of preparatory work must be done before its release? Must the researcher personally do the work or can the work be delegated to a member of the researcher's staff? Does the researcher have a staff to whom the work can be delegated? Would the time required interfere with the completion of ongoing research? Would the disruption threaten professional development (for example,

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F.2d 552 (2d Cir. 1989); Wilkinson v. Federal Bureau of Investigation, 111 F.R.D. 432 (C.D. Cal. 1986); *In re* Grand Jury Subpoena dated January 4, 1984, 583 F. Supp. 991 (E.D.N.Y.), *rev'd and remanded*, 750 F.2d 223 (2d Cir. 1984); Deitchman v. E.R. Squibb & Sons, Inc., 740 F.2d 556 (7th Cir. 1984).

30. Dow Chemical Co. v. Allen, 494 F. Supp. 107 (W.D. Wis. 1980).

31. We were unable to ascertain whether the FBI compensated Anne Braden for the costs incurred in her initial release of documents. In any event, the underlying case was settled before Ms. Braden was forced to prepare the entire collection for the FBI's perusal.

completion of a thesis or progress toward tenure)?

2. *Burdens of Litigating Discovery Requests.* Opposing or negotiating the breadth of a subpoena may itself place significant demands on researchers. Most of the researchers in the cases we reviewed received extensive monetary and nonmonetary support from a party to the litigation, from their institutions, and/or from professional organizations in meeting these demands. None of the researchers were required to pay for legal representation. Legal counsel for Irving Selikoff was provided by Mount Sinai Medical Center. Similarly, legal counsel for Richard Snyder (at least before his retirement) and Arthur Herbst was provided by their universities or research institutes. Mario Brajuha received *pro bono* representation from a New York attorney and later from a legal clinic associated with New York University Law School, but only after university counsel refused to represent his interests and he had testified in court unrepresented. Legal representation of Malcolm Potts was provided largely by the defendant in the underlying litigation, although the organization for which Dr. Potts worked also employed independent counsel. In the dioxin litigation, the researchers' legal fees were paid by the class of veterans in the *Agent Orange* case.[32]

Researchers whose opposition to a subpoena is handled by counsel for one of the party litigants may not incur legal fees, but they should be aware that such representation can be offered only to the extent that the researchers' interests are aligned with those of the litigant whom the attorney represents. As a result, intermediate positions that may be acceptable to researchers may not be advanced by counsel for a party whose main interest is in preventing all disclosure of the research. Similarly, counsel for such a party may be considerably less concerned than the researcher about participant privacy or implications of disclosure for future research.

Two researchers were supported by *amicus* briefs submitted to the court by their professional organizations. Three briefs were submitted on behalf on Mario Brajuha; one by three professional associations, one by the American Association of University Professors, and one by the New York Civil Liberties Union. Similarly, two *amicus* briefs supporting the archivists' interests were filed in *Wilkinson*.[33] One brief was prepared by an organization representing oral historians, librarians, and historians. The Society of American Archivists decided the facts of the case were not strong enough to warrant joining in the brief. The other brief was filed on behalf of the State Historical Society by the Wisconsin Attorney General. This brief described a state statute, enacted at the request of the State Historical Society, authorizing restrictions on access to archives. In addition, affidavits cited in *Andrews v. Eli Lilly*[34] show extensive professional support for Dr. Herbst's resistance to disclosure of the DES Registry information.

32. *In re* Agent Orange Litigation, 597 F. Supp. 740 (E.D.N.Y. 1984).
33. Wilkinson v. Federal Bureau of Investigation, 111 F.R.D. 432 (C.D. Cal. 1986).
34. 97 F.R.D. 494 (1983).

Only two researchers reported that their home institutions did not play a sufficiently supportive role during their subpoena disputes. Mr. Brajuha has described in detail the vacillating level of university and departmental support he received.[35] Dr. Van Miller reported that his university was slow to recognize the effects of the legal proceedings on his ability and the ability of other graduate students to complete their thesis work.

In sum, most researchers in the cases reviewed appear to have received at least minimally adequate support in opposing subpoenas of their research. It may be unreasonable to assume, however, that all researchers faced with a subpoena will receive a similar level of support; indeed, researchers who do not receive support are unlikely to be able to contest subpoenas and therefore would not be the subject of published opinions.

B. Confidentiality of Data and Privacy of Research Participants

Notwithstanding the breadth of the typical "opening bid" subpoena, litigants seeking disclosure of research information are often uninterested in the identity of study participants. They seek information about the researcher's work because they are likely to be faced at trial with an expert whose testimony will be based on that work. In these instances, aggregated data and information about the methods used in the study may be sufficient for the litigants' purposes. Even where disaggregated data are needed, for example, where a reanalysis of raw data will be performed, the identities of the data sources are often unimportant. The experts with whom we spoke were unanimous in their belief that disclosure of data is appropriate only if sources are sufficiently disguised, as by removal of identifying information. Typically, they asserted the privacy interests of their subjects (which, in some instances, had led them to promise their subjects confidentiality) and their belief that disclosure of confidential information, particularly individual participant data, would jeopardize researchers' ability to obtain candid information in future research.

The *Andrews*/*Deitchman* set of cases, in which DES manufacturer E.R. Squibb & Sons, Inc., sought to compel production of all information in the University of Chicago's DES Registry, implicated both the privacy interest of patients and the researcher's interests in future data collection. A brief description of the Registry and of how it obtains information will illustrate the point.

Dr. Herbst began the DES Registry by requesting information from physicians worldwide about all women born after 1940 who had contracted clear cell adenocarcinoma of the genital tract. In every case, Dr. Herbst promised the submitting physician that the information received would be maintained in confidence. Once records were received for an individual patient, Dr. Herbst would contact her and her mother's obstetrician to request additional records and information about the use of DES. In his subsequent contacts with patients and their mothers' physicians, confidentiality of the information was again assured. By this assurance, Dr. Herbst intended to promise that the information received

35. *See* Brajuha & Hallowell, *supra* note 5, at 468-70.

would be used for research purposes only and would be released only in a form that did not allow identification of any patients. Monitoring of adenocarcinoma patients was ongoing when the *Andrews*/*Deitchman* cases were decided; data were expected to be received well into the 1990s, as the use of DES for pregnant women was not proscribed until 1971.

Dr. Herbst believes, and argued in his effort to quash the broad subpoena of every document in the Registry, that release of individually identifiable information would violate the privacy rights of the patients whose medical information is contained in the Registry. He also believes release of information traceable to particular submitting physicians would be a breach of his promise of confidentiality. Physicians who had administered the drug to the patients' mothers could very well fear that release of the information would encourage lawsuits that would not otherwise be filed.

Dr. Herbst also argued that the effects of breaching his promises of confidentiality would be devastating for the Registry and for other researchers. He submitted the affidavits of numerous researchers and contributors to the Registry to illustrate the general and specific harms that would result from release of confidential information. Squibb appeared to concede that the loss of confidentiality would adversely affect the Registry, and was willing to have identifying information removed from the data, although it is not clear that Squibb expressed this willingness before the issue was litigated. Dr. Herbst maintained that the task of deleting identifiers was "herculean" and could not be completed by the date of trial which, because the subpoena was not served until the eve of trial on the merits, was imminent. He also argued that the material in the Registry contained so much individualized information that the identity of patients and doctors could be traced even if the names were deleted. The district court agreed that Squibb's eleventh hour proposal to redact the records was unworkable, and that the Registry would be "little short of devastated if confidential information in the Registry [was] disclosed to outsiders, such as Squibb," concluding, "We will not jeopardize the vital mission of the Registry, and future of the medical profession's ability to understand and combat this truly dreaded and dreadful disease for the sake of the speculative and uncertain interest Squibb asserts."[36]

The appellate court gave considerably more weight to Squibb's need for the data. It was undisputed that Dr. Herbst's published articles would be used by the plaintiffs against Squibb, even though Dr. Herbst himself would not testify. As a result, the court observed, Squibb was threatened with "having Dr. Herbst as a potent expert witness against it without his even taking the stand or being subject to cross-examination."[37] Moreover, the court regarded the confidentiality problem as surmountable. Measures to preserve confidentiality, the court mused, are "easily contrived, especially if one does not confine the protection to mere deletion of informants' names from copies of papers furnished."[38] The appellate court

36. Andrews v. Eli Lilly & Co., 97 F.R.D. 494, 502 (N.D. Ill. 1983).
37. 740 F.2d 556, 561 (7th Cir. 1984).
38. *Id.* at 560.

therefore vacated and remanded the matter for further proceedings, ordering the district court to fashion an appropriate protective order taking account of the interests of all concerned. The opinion makes it clear, however, that patient confidentiality is an entirely appropriate interest to be accommodated; the appellate court did not hold that identifying information should be released.[39]

In some cases, of course, the identity of the research participants is precisely the information sought. In the *Farnsworth* and *Lampshire* cases, for example, Procter and Gamble sought the names and addresses of women who participated in the CDC's study of toxic shock syndrome so the company could validate the CDC's results by re-interviewing the participants. Recall that participants had provided information about such subjects as their medical, menstrual, and pregnancy histories, tampon usage, sexual and contraceptive practices, and douching habits. Although the information had been gathered *without* a promise of confidentiality (the CDC generally does not provide such guarantees), the CDC asserted that production would violate the participants' privacy rights. The CDC did attempt to contact all the participants to relay P&G's request, and released the names and addresses of participants who consented to such release. The CDC was unwilling to divulge identifying information about the other participants, although all other data were supplied. The *Lampshire* court concluded that personal identifying information about the CDC subjects should be redacted from all produced documents, stating: "It is imminently [sic] appropriate to protect the subjects of the CDC studies, who may have no connection with this lawsuit, from questions by strangers about such personal matters."[40] The district court in *Farnsworth* also agreed with the CDC that the research participants should be protected from the potential embarrassment and annoyance attendant to disclosure of their identities to P&G. That court, however, also focused on the effect of such embarrassment and annoyance on future research. The court reasoned that there was a compelling social interest in promoting research of the sort conducted by the CDC, and that the possible future harm to the CDC's public health mission from disclosure outweighed P&G's need for the information. The P&G argument that access to the withheld information would help it to demonstrate flaws in the CDC's results was, the court concluded, "undercut by the increasing amount of research, including some funded by Procter & Gamble, that supports the CDC's finding of some relationship between [toxic shock syndrome] and tampon usage."[41]

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39. The DES cases also illustrate the snail's pace of high stakes litigation. The cases covered by the reported opinions appear to have been filed in 1982 and 1983. These federal court cases ultimately settled before trial. In the interim, other cases were filed in state court, and the subpoena issues discussed in *Andrews/Deitchman* also arose there. After procedural wrangling and much negotiation, the parties reached agreement on a method of producing the requested data stripped of its identifiers. When we spoke with Dr. Herbst on August 8, 1991, the first batch of Registry documents being produced to Squibb had just been readied for shipment.

40. Lampshire v. Procter & Gamble Co., 94 F.R.D. 58, 60 (N.D. Ga. 1982), *vacated*, 708 F.2d 732 (11th Cir. 1983) (unpublished table decision).

41. Farnsworth v. Procter & Gamble Co., 101 F.R.D. 335, 358 (N.D. Ga. 1984), *aff'd*, 758 F.2d 1545 (11th Cir. 1985).

On appeal, the Eleventh Circuit agreed that the disclosure of the identifying information could seriously damage the voluntary reporting on which the CDC relied: "Even without an express guarantee of confidentiality there is still an expectation, not unjustified, that when highly personal and potentially embarrassing information is given for the sake of medical research, it will remain private."[42] Frustration of that expectation, the court implied, would harm the CDC's ability to collect sensitive medical information. The appellate court's reasoning is supported by research showing that compliance with requests for information may depend more on a person's trust that the soliciting agency will use the information appropriately rather than on explicit guarantees of confidentiality.[43]

Faced with similar arguments, but different facts, the Second Circuit reached a conclusion different from that of the Eleventh Circuit. *In re Grand Jury Subpoena* arose from a grand jury investigation into arson at a restaurant where sociology graduate student Mario Brajuha was conducting fieldwork while employed as a waiter. Petitioning the court to quash the subpoena ordering production of fieldnotes summarizing his conversations with restaurant employees, Mr. Brajuha stated that "many" of the research sources identifiable from the notes had been promised confidentiality. Without fully developing the facts relevant to Mr. Brajuha's claim, the district court granted his motion to quash. Citing a limited federal scholar's privilege analogous to the limited news reporter's privilege recognized in *Branzburg v. Hayes*,[44] the district court concluded that, in this case, societal interests in fostering research outweighed the government's interests in obtaining information about possible criminal activity.

In an *amicus curiae* brief, the American Sociological Association, the American Political Science Association, and the American Anthropological Association explained the importance of maintaining the confidences of sources in a field study such as Mr. Brajuha's, citing a letter by John Lofland, then chair of the American Sociological Association's Committee on Professional Ethics:

> Ethically, social scientists have desired not to harm people who have been kind enough to make them privy to their lives. At the level of sheer civility, indeed, it is rankly ungracious to expose to public view personally identified and inconvenient facts on people who have trusted one enough to provide such facts! Strategically, fieldwork itself would become for all practical purposes impossible if fieldworkers routinely aired their raw data—their fieldnotes—without protecting the people studied. Quite simply, no one would trust them. Analytically, fieldworkers in particular and social scientists in general are *not* muckrakers or investigative reporters (as important as these roles are). Their goal, as researchers, is not moral judgment or social change, but *understanding.* Concealment of specific identities helps everyone focus on whatever generic topic may be at issue, avoiding deflection into personalistic matters.[45]

The *amicus* brief also described the organizations' positions with respect to

42. *Farnsworth*, 758 F.2d at 1547.

43. *See generally* Eleanor Singer et al., *Confidentiality Assurances and Response: A Quantitative Review of the Experimental Literature*, 59 PUB. OP. Q. 66 (1995).

44. 408 U.S. 665 (1972).

45. *Amici Curiae* Brief of the American Sociological Association, American Political Science Association, and Anthropological Association (2d Cir. 1984) (No. 84-6146), at app. 1.

the confidentiality of information obtained from research participants. Of particular interest was the ASA's Code of Ethics, which prescribed the following: "Confidential information provided by research participants must be treated as such by sociologists, *even when this information enjoys no legal protections or privilege and legal force is applied.*"[46]

The district court referred extensively to the *amicus* brief in its opinion quashing the grand jury subpoena, but the *amici*'s triumph was short-lived. The appellate court, while acknowledging that the record contained "statements by scholars asserting in the abstract the need for" a scholar's privilege, declined to decide whether such a privilege could be asserted under Rule 501 of the Federal Rules of Evidence. If such a privilege is cognizable, the court indicated, one who invokes it must not only describe the nature and seriousness of the study and the methodology employed, but must make at least a "threshold showing … of the need for assurances of confidentiality to various sources to conduct the study, and of the fact that the disclosure requested by the subpoena will seriously impinge upon that confidentiality."[47] On the record before it, the appellate court concluded that there had been no such showing. Consequently, the appellate court reversed and remanded the matter to the district court to allow Mr. Brajuha to designate those portions of the journal he argued were privileged; after *in camera* inspection, the district court could order appropriate redactions. Nonprivileged portions of the journal were to be disclosed, and the court cautioned: "Actual observation of criminal activity is not subject to a claim of privilege."[48] In the end, the federal prosecutor accepted production of the journal edited by Mr. Brajuha to remove privileged material as full compliance with the subpoena.

The same types of concerns about disclosure's impact on the future flow of information to researchers were advanced by archivists who argued against compelled disclosure of personal archives in *Wilkinson v. Federal Bureau of Investigation*. That case concerned the extensive files of information collected and generated by Anne Braden over many years of activism with her husband Carl Braden. Ms. Braden had donated these papers to the Wisconsin State Historical Society with the restriction that the Society would grant others access to the documents only with her permission. This access agreement, renewable at five-year intervals, required the Historical Society to oppose to a reasonable extent any subpoena seeking the Braden papers without her consent.

In light of the access agreement between Ms. Braden and the Society, the FBI's subpoena was directed to her. The Historical Society, however, argued that once the Braden files were in the possession of the Society, they were protected from disclosure by an archival privilege established by common law or by a Wisconsin statute. The district court rejected this argument, noting that even if the Wisconsin legislature intended to create such a privilege, state privilege law was not controlling because the underlying claims in the case were based on federal,

46. AM. SOCIOLOGICAL ASS'N, CODE OF ETHICS § I.E.5 (1982) (emphasis added).
47. *In re* Grand Jury Subpoena dated January 4, 1984, 750 F.2d 223, 225 (2d Cir. 1984).
48. *Id.* at 226.

not Wisconsin, law. The *Wilkinson* court did not decide whether a researcher's privilege was cognizable, because it ruled that any such privilege would not apply in this case because Ms. Braden was not a *third-party* researcher.

As Ms. Braden was a member of the plaintiff class, her own situation (unlike the Historical Society's) was more akin to that of a research participant who later becomes a litigant. For example, the DES Registry contained medical information about certain individual plaintiffs in the *Andrews/Deitchman* cases. As these plaintiffs had freely disclosed all relevant medical information from other sources, the *Andrews* court concluded that the plaintiffs themselves did not consider the information confidential. Further, the plaintiffs raised no privilege claim. Accordingly, the court ordered Dr. Herbst to release any records relating to the individual plaintiffs or their mothers.

Consider, however, the situation where a patient/plaintiff does not consent to release of medical records because such records could jeopardize the plaintiff's case. For example, suppose data collected in a longitudinal study would reveal a long history of heavy smoking by a former asbestos worker. The principle that medical records belong to the patient would lead some medical researchers to divulge the information only to the patient's representatives. Absent a statute to the contrary, however, such information *should* be fully discoverable by the defendant because it is by the researcher's own definition within the patient's control, even if not in his possession or custody.[49] Although some medical practitioners believe they can or must protect the identity of their patients as well as details about their medical status, such a position may not be well founded.[50] It is unclear why, in the ordinary situation, the names of research participants who are party litigants are entitled to more protection. This is not to suggest that the medical researcher should produce a list of all participants in a study. Indeed, simply being identified as a participant in some studies would disclose private information such as a medical condition. Rather, it seems reasonable that a researcher should be required to reveal, when properly asked, whether an identified *litigant* was a participant in the researcher's study. A researcher in possession (and, in the case of a deceased participant, potentially *sole* possession) of a fact relevant to a pending case should be as susceptible as any other fact witness to questions about a party litigant.

Would the inability to promise participants unconditional confidentiality impede the flow of information? Although it is often argued that confidentiality is necessary to ensure the future flow of candid, complete information to researchers, empirical support for this proposition is seldom presented to the courts. When the CDC argues that disclosure will inhibit future research, for example, it typically submits affidavits to that effect from a CDC researcher or high-ranking administrator. The Assistant U.S. Attorney who has argued these cases for the CDC indicated that she knew of no empirical support for the proposition that

49. *See* FED. R. CIV. P. 34.

50. Jeffrey A. Klotz, *Limiting the Psychotherapist-Patient Privilege: The Therapeutic Potential*, 27 CRIM. LAW BULL. 416, 432-33 (1991).

disclosure actually affected the amount or quality of information the CDC could obtain. She maintains, however, that numerous statutes protecting the private deliberations of such bodies as medical staff review boards, as well as those protecting certain kinds of public health reports, reflect a codification of a widely-held, common-sense belief that confidentiality is essential to candid, accurate reporting.

Because disclosure was ordered in relatively few of the reviewed cases, our respondents could shed only a little light on the issue. Dr. Herbst reported that, as predicted in the affidavits he submitted, some physicians who became aware of the dispute over the DES Registry records stopped sending information to the Registry, even though identifying information has not been released. Harold Miller, archivist at the Wisconsin State Historical Society, reported that Anne Braden said that had she foreseen the dispute with the FBI, she would have donated her papers to the society, but might have screened them more carefully.

To be sure, the inhibitory effects of information disclosure or lack of confidentiality may be difficult for individual researchers to document, and the search for such effects would lead many researchers off in directions other than their main interests. Dr. Selikoff noted that it was "up to the medical sociologists" to investigate this area. It is beyond the scope of this paper to discuss the evidence already adduced on the question. Generally speaking, evidence suggests that the common sense notion that research participants will be less available, less cooperative, and less candid without an assurance of confidentiality is probably an overly simplistic description of reality.[51] For example, one study found that an assurance of confidentiality does enhance response rate and quality, but only when the information requested is sensitive.[52]

Despite the concern of the researchers with whom we spoke about privacy and disclosure issues, they did not report changing their data collection or storage procedures to protect research participants better. (From the outset, Dr. Potts had collected and stored his data so that the confidentiality of the research participants would be protected in the event of compelled disclosure.) Similarly, none of the researchers reported changing the nature of the confidentiality assurances provided to research participants. In light of the vulnerability of research data to discovery and the increasing vulnerability of researchers to charges of misrepresentation or breach of contract for violating promises of confidentiality, researchers should keep in mind that courts are more likely to protect the identity of research participants than the information they provide. Thus, researchers should fashion their confidentiality assurances accordingly.[53] Further, researchers should consider when designing a research project how to collect and store data

51. *See* Joe S. Cecil & Robert F. Boruch, *Compelled Disclosure of Research Data: An Early Warning and Suggestions for Psychologists*, 12 LAW & HUM. BEHAV. 181 (1988); Singer et al., *supra* note 43, at 74-75.

52. Singer et al., *supra* note 43, at 74.

53. For a discussion of the relevant case law and suggestions for avoiding such suits, *see* Traynor, *supra* note 1.

so as to minimize, to the extent possible, participant identifiability.[54] Such forethought is also likely to minimize the burden on the researcher should production of the data later be required.

IV

DISCLOSING INCOMPLETE AND UNPUBLISHED RESEARCH FINDINGS

Most of the researchers with whom we spoke distinguished between data underlying published studies and data underlying incomplete and unpublished studies. At least one researcher thought that as long as scientific information is trustworthy (presumably in the opinion of the researcher), its publication status is irrelevant in determining whether it should be disclosed. Among our other respondents, there was general agreement that, subject to the resolution of participant confidentiality concerns, researchers have an ethical and scientific responsibility to make available data on which a published report is based, but many believed that information about unpublished or incomplete research should not be disclosed. These categorical distinctions are not always clear. Reports may be published throughout the life of a project, particularly if a longitudinal study is underway. For example, the Chicago DES Registry contains both data underlying published reports and newer, unanalyzed data.

Courts should distinguish research that is incomplete and inconclusive from research that is complete but unpublished. In all but rare instances, incomplete research will not be probative of any matter in dispute, and therefore should not be admissible.[55] Nor is incomplete research a proper foundation for expert testimony, as it is not reasonably relied on by experts in forming opinions or inferences.[56] Consequently, there is seldom a need for any party to the lawsuit to obtain access to data or other information relating to incomplete research. In contrast, the findings of complete but unpublished research may provide reliable information to the fact-finder and may, under some circumstances, be reasonably relied upon by experts in forming an opinion. The lag between completion of a study and publication of its results may be substantial. Moreover, there are numerous reasons for non-publication, some of which have nothing to do with the conclusiveness or quality of the research.

Premature release of data from ongoing research may make completion of the study difficult or impossible, and may perpetuate unsubstantiated and possibly invalid scientific conclusions. Because the research is incomplete, the researchers themselves can provide at best only tentative interpretations of the data. Research that is complete but unpublished also may be subject to misinter-

54. *See* ROBERT F. BORUCH & JOE S. CECIL, ASSURING THE CONFIDENTIALITY OF SOCIAL RESEARCH DATA chs. 4-9 (1979).

55. One can imagine exceptional circumstances in which claims that research is incomplete may raise suspicions that the withheld information might constitute legitimate fodder for cross-examination, particularly to attack the credibility of witnesses. One such circumstance might be where a party claims that research was abandoned or not published because its likely results would be contrary to the interests of its sponsors.

56. FED. R. EVID. 703.

pretation, and thus requires more scrutiny by the court than published work. Misinterpretation is especially likely if the original researchers are not given adequate opportunity to explain their own findings. Even when given such an opportunity, some researchers may feel uncomfortable describing their research publicly before it has been peer-reviewed, because to do so does not comport with their perceived ethical and scientific responsibilities.

The consequences to researchers of releasing incomplete or unpublished data may be serious and far-reaching. Researchers' professional reputations may be damaged if they do not complete and present their work to the scientific community, if they fail to receive sufficient credit for their work, and if faulty interpretations of their research are attributed to them. Young scientists may be affected especially harshly by compelled disclosure of their work; disclosure may interfere, for example, with the ability of graduate students to complete their degrees or of young professors to obtain tenure.

Courts have been reasonably sensitive to these issues. In *Dow Chemical*, where no human subjects were involved, the researchers' primary concerns related to release of data from an ongoing, unpublished study. As researcher Van Miller said, "academic data can be a person's life and future and must be considered in that light." The district court judge quashed the subpoena, saying:

> I take judicial notice that it would be a substantial burden on respondents to force them to produce the information requested from the 5 ppt and 25 ppt studies which are nowhere near completion and which have not been subjected to peer review. In the early stages of any research project there are likely to be false leads or problems which will be resolved in the course of the study with no ultimate adverse effect on the validity of the study. To force production of all information demanded by the subpoenas is likely to jeopardize the study by exposing it to the criticism of those whose interest it may ultimately adversely affect, before there has been an opportunity for the researchers themselves to make sure the study is the result of their best efforts. This is not the kind of burden which can be lightened by a protective order. Putting this study in jeopardy would be a heavy burden not only on those involved in the research, but also on the public which has helped to fund it through tax money and which ultimately stands to gain from knowledge of the final results.[57]

The Seventh Circuit affirmed, stating that the district court should have properly considered the subpoena's "chilling effect" on academic freedom in reaching its decision; a concurring opinion did not join in the discussion of academic freedom.[58]

The *Andrews* court was similarly sympathetic to such an argument. In that case, Squibb's subpoena sought production not only of data for a study still in progress, but of all drafts and analyses related to such studies "no matter how tentative." Dr. Herbst submitted affidavits describing the problems created by premature disclosure of research. As affiant Leonard T. Kurland of the Mayo Clinic explained:

> Disclosure of information from ongoing epidemiological research can seriously undermine the study since premature disclosure of information, before valid conclusions

57. Dow Chemical Co. v. Allen, 494 F. Supp. 107, 113 (W.D. Wis. 1980).

58. 672 F.2d 1262, 1276 (7th Cir. 1982); *see also* Robert M. O'Neil, *A Researcher's Privilege: Does Any Hope Remain?*, 59 LAW & CONTEMP. PROBS. 35 (Summer 1996).

> can be reached by the researchers, may suggest faulty conclusions. These in turn may improperly discredit the study. On the other hand, given an opportunity to complete the research unobstructed by disclosure request[s], would have the greatest likelihood of achieving tested and supported conclusions. Any forced premature disclosure could subject the researchers to professional ridicule and criticism.[59]

The district court accepted the argument that disclosure of tentative analyses and results could adversely affect researchers' free exchange of thoughts and speculations about ongoing research. To illustrate the point, the court quoted the affidavit of researcher Robert E. Scully, submitted by Dr. Herbst:

> Epidemiological investigators, and indeed medical investigators in general, pursuing the spirit of scientific inquiry, often speculate, hypothesize, and draw possible and probable conclusions as they probe various questions related to their research. Freedom to proceed in this manner requires confidentiality. Involuntary disclosure of this uninhibited communication among scientists to parties that are not participants in the research demolishes the freedom of thought and interchange of ideas that is so essential to productive research. Also, interpretation of the speculations, hypotheses, and possible or probable conclusions by outsiders carries a serious risk of being faulty, resulting in medical misinformation and possibly unjustifiably discrediting the investigators.[60]

The *Andrews* court also quoted the section of the district court's opinion in *Dow Chemical Co. v. Allen* set forth above and noted that the court of appeals had fully approved of the district court's approach in that case. Although the court of appeals vacated the *Andrews* court's order, it did acknowledge the court's duty, when possible, to guard against premature publicity of tentative research and disclosure of ongoing development of ideas. With a nod to its decision in *Dow Chemical*, the Seventh Circuit ruled that Dr. Herbst's questionnaires, protocols, and analyses should be discoverable, but limited discovery of such material to that which it called "wholly factual." Even as to such nonconfidential items, the court refrained from ordering discovery of "any material reflecting development of Dr. Herbst's ideas or stating his or others' conclusions not yet published."[61]

V

BALANCING THE INTERESTS OF RESEARCHERS AND LITIGANTS

Attention to the researchers' experiences and concerns can help courts focus on factors to be considered when deciding whether to quash or modify subpoenas. Similarly, the experiences of the researchers and attorneys we interviewed, as well as the published opinions, suggest ways courts might ease the burden on researchers who are required to turn over information at the request of litigants, including protective orders, document depositories, and neutral information brokers.

Researchers expressed frustration with and ignorance of the legal system in general, and third-party discovery in particular. Several of them properly ques-

59. Andrews v. Eli Lilly & Co., 97 F.R.D. 494, 502-03 (N.D. Ill. 1983).
60. *Id*. at 503.
61. Deitchman v. E.R. Squibb & Sons, Inc., 740 F.2d 556, 565 (7th Cir. 1984).

tioned the *breadth* of the subpoenas they received, particularly if the subpoena encompassed identifying information about data sources. On the whole, the researchers were willing to supply information they believed would be used, and used properly, if the information seemed important to the issues being litigated. For example, Dr. Potts reported that he would have gladly shared information about the relevant study with the plaintiffs, including protocols, summary tables, and raw data if needed, had the information been subpoenaed in a reasonable way. However, the subpoena as drafted was so overbroad that he was compelled from a practical standpoint to oppose it.

Researchers are likely to view a subpoena as a nonnegotiable command of the court. Most attorneys, on the other hand, view the scope of the subpoena's document request as an opening bid. Attorneys accustomed to opponents who construe discovery requests narrowly to avoid producing evidence will err on the side of over-inclusiveness. This tendency to ask for all conceivably relevant information may be compounded by the attorney's ignorance of the research process. Fortunately, the 1991 amendments to Rule 45 of the Federal Rules of Civil Procedure requires subpoenas to include information about protections available to unretained experts and witnesses who are served with subpoenas for research information.

Other researchers were more concerned with the possibility that they would be subjected to an endless number of subpoenas. For example, Mount Sinai's counsel said that there were about 1,000 cases similar to those underlying the two published opinions involving the Selikoff studies. Dr. Selikoff and the Medical School were concerned that they would receive requests in all of these cases and that Dr. Selikoff might feel compelled to defend his professional reputation repeatedly in court if opposing experts criticized his work. Similarly, multiple suits involving utility vehicles could generate duplicative subpoenas to Professor Snyder for records and testimony about his study. The latest published opinion quashing a subpoena to him acknowledged this burden:

> Snyder has incurred the legal expense and personal disruption required to respond to such subpoenas on at least four occasions. Snyder's counsel alleged that there are as many as eighty-eight suits involving utility vehicles pending in federal courts. Further, other makers of utility vehicles might also have an interest in drafting Snyder's expertise, because his report was critical of several makes in addition to Jeep.[62]

Researchers also exhibited a frustration with lawyers' ignorance of science. Two researchers suggested that judges need to be aware of scientific practices that protect the integrity of research findings. Most scientific laboratories, for example, have internal procedures to ensure the reliability of data. In addition, science's mechanism for verifying research findings is replication. If multiple researchers reach the same basic conclusions, it is assumed that the methods used by any one of them are sound. Thus, there is little need to release overly detailed information about any given study.

In cases where participant identity is irrelevant to the requesting party, the re-

62. *In re* Snyder, 115 F.R.D. 211, 214 (D. Ariz. 1987).

searcher's desire or duty to protect the privacy of study participants creates a burden that varies depending on data collection and storage methods, the scope of the study, and other factors. In most of the cases we examined, removal of identifying information was a workable, if sometimes expensive, option. The research population had been large enough that tracing the identity of participants from the remaining information would be (or could be made) extremely difficult.

In some kinds of research (for example, small scale epidemiological studies and qualitative field studies), removing the usual identifiers is insufficient to preclude recipients of the information from tracing data sources.[63] In these instances, the court may be able to craft an order to protect the privacy of the participants. In *American Tobacco Company*, for example, the court ordered production of computer tapes containing data underlying two published studies, but allowed Mount Sinai to remove from the data the names, addresses, town or village of residence, social security number, and union registration numbers of patients, and the names of their employers. Although the court denied Mount Sinai's request also to remove data concerning patients' county of residence and union local, and to summarize birth and death data by decade, it entered an order prohibiting recipients of the information from using the released data to identify research participants. Dr. Selikoff, however, expressed some skepticism about whether protective orders are sufficient to guard against unauthorized attempts to use the produced information to ascertain improperly the identity of research participants, and suggested that courts should monitor vigilantly compliance with their orders.

Transferring the data to a neutral third party may be useful when balancing the interests of researchers and litigants, particularly when information about unpublished research is being sought. For example, the researchers in *Dow Chemical Co. v. Allen* discussed the possibility of transferring the data to a neutral party who could then report to the court on the issues raised by the subpoena, but neither Dow Chemical nor the administrative law judge would agree to this.[64] Where there is some legitimate need to learn participant identities to validate research, the neutral information broker approach also may serve as a scientific analogue to the "attorneys' eyes only" protective order sometimes used in trade secret litigation. This might prove especially useful where the discovering party also has less legitimate reasons for trying to obtain information about research participants who are not yet litigants.

Finally, the use of a document depository was suggested by the court in *Anker v. G.D. Searle & Co.* as appropriate for multiple plaintiff litigation:

> [I]f an expert gives one deposition and produces records, the court may protect the non-party, involuntary expert by requiring that the party who conducts the deposition keep such records and make them available to subsequent requesters. Then other courts may require potential inquisitors to show why a review of previously taken

63. For a discussion of the problems unique to qualitative research findings, see Sheila Jasanoff, *Research Subpoenas and the Sociology of Knowledge*, 59 LAW & CONTEMP. PROBS. 95 (Summer 1996).

64. *See also Deitchman*, 740 F.2d at 564.

depositions and document production would not be sufficient to satisfy their needs.[65]

In the tobacco/asbestos litigation, for example, R.J. Reynolds agreed to serve as a central depository for the information released about the Selikoff studies. The court entered a protective order requiring Reynolds to notify Mount Sinai and the American Cancer Society if any third party seeking the information refused to execute an acknowledgment that would not attempt to identify the research participants from the disclosed data.

VI

CONCLUSION

Our interviews and review of published opinions suggest that demands placed on researchers by subpoenas for scientific information, while substantial, are not necessarily any greater than those placed on other third-party recipients of subpoenas. With sufficient sensitivity to the professional and scientific issues discussed above, courts can minimize litigation-related disruption of the development of medical and scientific knowledge without denying litigants access to the evidence necessary to legitimate claims and defenses. Researchers also can learn how to minimize litigation-related disruptions of their work from the experiences of those whose work has been subpoenaed by anticipating the problems and planning an appropriate response to requests or subpoenas for their data.

65. Anker v. G.D. Searle & Co., 126 F.R.D. 515, 521 (M.D.N.C. 1989).

APPENDIX

JUDICIALLY COMPELLED DISCLOSURE OF RESEARCH DATA: ISSUES TO BE EXPLORED

We addressed the issues raised by the following set of questions in our interviews of researchers and their attorneys.

General

1. What was the nature of the information sought? In what form?

Confidentiality

2. Did you provide any assurance of confidentiality to participants in the subpoenaed research? If so, what was the nature of that assurance?

3. If you were required to disclose any or all of the subpoenaed information, what measures, if any, did you or the court take to protect the privacy of the research participants? Were such measures adequate? What other procedures would you have liked the court to order or the parties to adopt?

4. Since the subpoena, have you changed the nature of assurances that you give to research participants? Have you changed the way you maintain data? What effect do you think these changes have had on your research?

Financial and Non-Financial Burdens

5. What monetary and non-monetary costs were or would have been involved in supplying the requested documents? How could or did the court help minimize these costs? If you were required to produce documents, were you adequately compensated?

6. If you were deposed or if you testified in court, were you adequately compensated for the time you spent in preparation and in deposition or trial?

7. What type of support, if any, was offered by your institution, by professional groups, or by a party to the litigation? For example, did they help defray your legal expenses?

Legal Procedure and Outcome

8. Did the party seeking the information ask you to produce the information voluntarily before they subpoenaed you? Did you negotiate with that party to narrow the scope of the subpoena?

9. Was there other information that could have been substituted for the information sought? For example, did scientists independent of your research group have sufficient access to your work to confirm the accuracy of your data, analyses, or conclusions?

10. Did you have sufficient opportunity to present your position to the

court? What issues, if any, did the court ignore or fail to give proper weight?

Professional Costs

11. Was the research completed when you received the subpoena? If not, what effect did the subpoena have on its completion?

12. At the time of the subpoena, had you published any articles on the research findings? What effect, if any, did the subpoena have on your publication plans?

13. Have you changed your areas of research or your research practices as a result of this experience? Were your other research, teaching, or professional activities disrupted?

14. Was this experience unique or have you faced similar situations before or since the one described?

Other Questions

15. Do you know of other researchers who have faced situations similar to yours? Have you advised them? What is (or would be) the nature of your advice to other researchers in like situations?

16. Can you suggest alternatives to compelling researchers to testify or to turn over information to litigants who request it? Would you prefer to transfer the data to a neutral broker who could then report to the court on the issues raised by the litigant? Would you prefer to testify as a neutral expert appointed by the court?

17. What advice do you have for judges who must balance the interests of researchers, research participants, and litigants when science has produced information relevant to a lawsuit?