

The Role of Scientific Data in Litigation

How to Avoid Roadblocks to Collecting and Assessing Scientific Data

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I. Introduction

It is no secret that scientific research is playing an increasingly important role in the courtroom. For example, many of today's products liability cases involving the pharmaceutical industry have been initiated by the publication of scientific research. However, scientists do not always welcome the increasing role their research plays in litigation. On the contrary, researchers often bristle at the thought of their work being analyzed by attorneys and experts and used in a court of law. As a result, the tension between the legal world and the scientific world continues to mount.

In order to be successful in this environment, defendants must find a way to minimize the friction between science and law while ensuring that all scientific data being used by plaintiffs to support a product liability claim are intensely scrutinized. There is simply no substitute for direct access to the scientific research and data in order to craft a solid defense. However, the roadblocks to accessing such scientific data continue to mount as scientists fight to protect their research. The key to finding a way around these roadblocks is to strike a reasonable balance between accessing all scientific data necessary to develop a defense and addressing the concerns of the scientists whose research is under scrutiny.

II. Scientific Data—How to Get What You Need

A. What to Collect

When faced with the challenge of defending against litigation based upon a scientific study, the obvious first step is to identify and obtain a copy of the published study in question. However, the defense should not rest at just reviewing the published study. There are many other documents that must be identified and collected in order to put the published study in context and analyze the reliability of the study results. These documents include, but are not limited to, the raw scientific data, all drafts and versions of the study protocol, medical records for study participants, and interview forms. In addition, e-mail and other written communications between the study investigators can be a source of revealing information about the study and should always be requested. These documents should be thoroughly analyzed by both attorneys and defense experts in order to ascertain the validity and strength of the study whose publication led to the litigation in the first place.

B. How to Collect It

1. The scientific study and underlying data

In order to obtain data relating to a scientific study, the typical approach is to serve a subpoena *duces tecum* upon the institution that conducted the study pursuant to Rule 45 of the Federal Rules of Civil Procedure. Federal Rule 45 allows a party to subpoena "designated books, documents, electronically stored information, or tangible things" as long as the materials are not privileged and as long as production of the materials is not unduly burdensome. Consider including in the subpoena the following requests:

- all documents relating to the study itself including the conduct of the study;
- all documents relating to organizational structure of persons involved in the study;

- all documents relating to the study personnel's experience and credentials, including but not limited to *curriculum vitae*;
- all medical literature and case reports used by personnel at any point during the inception and duration of the study, all documents relating to the protocol of the study;
- all documents relating to data collection, processing, and analysis;
- all documents regarding communications concerning the study;
- all documents relating to the publication of the study if applicable;
- all documents regarding meetings or any communications with the FDA concerning the study.

However, parties seeking scientific data need to be mindful of overbroad subpoenas and need to consider addressing the confidential nature of some scientific data in the subpoena. It may be wise to consider raising the issue of redactions and work with the institution to create a redaction protocol in order to ease the mind of scientific researchers who are worried that revealing the personal information of study participants may jeopardize the research. A party requesting scientific data should also be particularly sensitive when the data relate to scientific research that is ongoing and has not yet been published. Finally, it may behoove the requesting party to agree to reimburse the institution for copy costs.

2. Medical records of study participants

Upon review of the scientific data, a defendant may decide to request medical records relating to the participants in the study *via* a subpoena *duces tecum*. This is often a wise decision. The subpoena should be as narrowly tailored as possible while at the same time ensuring that all relevant information is included. However, even the most conservative subpoena may be challenged for various reasons. First, the defendant may not possess the names of the individuals for whom he is seeking medical records. One way around this obstacle is to provide the hospital with the patient's date of admission, date of birth, gender, age, and medical record number and perhaps the patient's study number, if applicable. The hospital will require enough information to identify the correct patient. Second, a request of this nature will often generate a motion to quash from the plaintiff and/or from the institution. The motion to quash may even be preceded by a letter from plaintiffs' counsel to the hospital requesting that it refrain from producing the requested records until an order is handed down. The defendant should be prepared to respond to the plaintiff's motion to quash. It is important to convince the court that the medical records are vital to analyzing the validity of the scientific data. With regard to the issue of patient confidentiality, it is wise to ensure that the initial subpoena addresses the issue of confidential information and suggests a solution such as a redaction protocol. If the identifying patient information has been redacted, patient confidentiality becomes a nonissue, and the plaintiffs will have one less argument to make in support of a motion to quash.

3. Depositions of researchers

Although the scientific study and its underlying data are crucial to establishing a defense, they may not tell the whole story. The rest of the story, as it were, may need to be told by those individuals who planned and conducted the study. However, deposing the study investigators is often challenging, and defendants should be prepared for resistance. Researchers will often argue that compelling them to prepare for and attend a deposition is unduly burdensome. Again, it is important to emphasize the importance of the investigators' testimony to the court while suggesting ways to minimize the burden on the investigators. Moreover, there is ample support for the argument that scientific researchers should be treated like any other witness. For example, Wig-

more rejects the idea of excusing researchers from being called to depositions or to testify at trial. See 8 John H. Wigmore, *Wigmore on Evidence* §2203 (McNaughton rev. 1961). Wigmore bases his argument on the following:

- the expert is giving testimony, not providing a professional service;
- the hardship on the expert in losing income-producing time is no greater than in the case of any other witness;
- the expert becomes desirable as a witness only by accident, not because of the litigation itself;
- it is impractical to attempt to distinguish between kinds of experts, or between what is opinion and what is fact; and
- no one will refrain from becoming an expert because of fear of being called to testify.

Id. at 137–38.

III. Roadblocks to Obtaining Scientific Data and How to Address Them

A. Scientific/Researcher's Privilege

As noted above, scientists' initial response to a subpoena seeking the disclosure of their scientific data is likely to be a motion to quash given their interests in protecting their research. In many instances, scientists have argued that the data underlying their research are protected from judicially compelled disclosure by a researcher's privilege. The privilege claim is generally based on several arguments. For example, researchers claim that compelled disclosure can have a chilling effect on future scientific research; it can destroy confidentiality; and it can cause the researcher to lose control of the reporting and disclosure process. Robert M. O'Neil, *A Researcher's Privilege: Does Any Hope Remain?*, 59 *Law & Contemp. Probs.* 35, 36 (Summer 1996). Courts have not been particularly receptive to these arguments, as shown in the context of the following cases.

1. *Deitchman v. E.R. Squibb & Sons, Inc.*

Deitchman v. E.R. Squibb & Sons, Inc. has been described as the “paradigmatic case on the conflict between the demands of the legal system and the legitimate concerns of researchers.” Barbara B. Crabb, *Judicially Compelled Disclosure of Researcher's Data: A Judge's View*, 59 *Law & Contemp. Probs.* 9, 10 (Summer 1996). Plaintiffs sued Squibb claiming that while pregnant with them, their mothers ingested the drug diethylstilbestrol (“DES”), which caused plaintiffs to develop adenocarcinoma of the vagina or cervix. *Deitchman v. E.R. Squibb & Sons, Inc.*, 740 F.2d 556, 557–58 (7th Cir. 1984).

Dr. Arthur L. Herbst of the University of Chicago was the foremost researcher of this disease. He established and maintained the Registry for Hormonal Transplacent, which became a significant repository of data on adenocarcinoma of the female genital tract. *Deitchman*, 740 F.2d at 558. In 1971, based on the registry's data, Dr. Herbst published a landmark study that suggested an association between *in utero* exposure to DES and adenocarcinoma of the vagina and cervix. Due to Dr. Herbst's preeminence and research, plaintiffs' experts were universally relying on his work and articles in the DES litigation to establish causation, although he refused to become personally involved as an expert for either party. *Id.* at 561. Squibb believed it needed access to the data underlying Dr. Herbst's studies. Crabb, *supra*, at 12. So, Squibb served a subpoena on Dr. Herbst that sought virtually every document in the registry. *Deitchman*, 740 F.2d at 558.

Dr. Herbst responded by filing a motion to quash claiming that the registry data were privileged and confidential. Dr. Herbst argued that piercing the registry's confidentiality would literally destroy it and offered a number of affidavits from other researchers who agreed and claimed they would stop supplying data to the

registry if it were subject to a subpoena. *Id.* at 559–60. The trial court agreed with Dr. Herbst and quashed the subpoena. *Id.* at 561. On appeal, the Seventh Circuit disagreed, and vacated the district court’s decision. The appellate court found that while the registry data *may* enjoy a qualified (and undefined) privilege protecting them from disclosure, such a privilege would not be absolute and must yield when its enforcement would result in an injustice. *Id.* Further, the court found that Squibb was “threatened with having Dr. Herbst as a potent expert witness that they would not have the opportunity to cross-examine since he was not taking the stand.” *Id.* Without access to the data, Squibb was also precluded from any meaningful cross-examination of plaintiffs’ experts since their opinions were based on the registry’s data. *Id.* at 561–62. The matter was remanded to the district court with instructions to fashion an appropriate protective order.

2. *In Re: Application of American Tobacco Co.*

Another leading case on this issue arose out of the mass tort litigation against tobacco companies brought by plaintiffs claiming that their decedents’ lung cancer was caused by cigarette smoke and asbestos exposure. *In Re: American Tobacco Co.*, 880 F.2d 1520 (2d Cir. 1989). Plaintiffs’ experts were expected to rely on three articles published by a Dr. Irving Selikoff of the Mount Sinai School of Medicine (“Mount Sinai”) that suggested combining cigarette smoke with occupational exposure to asbestos significantly increased the risk of developing lung cancer when compared to the risk associated with exposure to only one of those substances. *Id.* at 1522. In an earlier round of litigation, R.J. Reynolds issued subpoenas that sought all of Dr. Selikoff’s underlying data. A New York state court quashed those subpoenas, finding that the data were protected by a qualified research scholar’s privilege. *Id.* at 1524; see *Dow Chem. Co. v. Allen*, 672 F.2d 1262 (7th Cir. 1982).

The tobacco companies served another round of subpoenas from a New York federal district court, seeking the same data. Again, they were met with a motion to quash, arguing the data were protected by an absolute privilege for unretained experts and a qualified research scholar’s privilege. This time, the court denied the motion to quash and entered a protective order to address confidentiality issues. Mount Sinai and the American Cancer Society appealed that ruling. The appellate court quickly dispensed with the claim of an absolute privilege for unretained experts, finding that it was not applicable to the present case. *Id.* at 1527–28. The court analyzed the qualified research scholar’s privilege in more detail, but ultimately reached the same result, finding that even if it existed under New York law, it was qualified, not absolute, and subject to a balancing test to determine whether the need for the data outweighed the potential adverse effects of disclosure. *Id.* at 1528–29. As to the potential adverse effects, appellants argued that compliance would be unduly burdensome and have a chilling effect on future scientific research. They also argued that there was no great need for the data since the tobacco companies could conduct their own studies, therefore, the harmful effects of disclosure outweighed the need for the underlying information. *Id.* at 1529.

The court of appeals disagreed, finding that the chilling effect argument was legitimate only where judicially compelled disclosure of research results occurred prior to publication, which was not the case here. Dr. Selikoff’s articles had been published for years. *Id.* The tobacco companies had also agreed that they would reimburse the researchers’ for the reasonable expenses associated with compliance, so that it would not be unduly burdensome. As to their need for the data, given Dr. Selikoff’s preeminence in the field and plaintiffs’ experts’ reliance on his findings, the court did not believe that forcing the tobacco studies to conduct their own studies was justified or reasonable. *Id.* Based on these findings, the court concluded that the qualified researcher’s privilege (assuming it existed) did not apply here, provided that reasonable limitations were placed on the subpoenas to prevent compliance from becoming unduly burdensome. *Id.* at 1530.

3. The “chilling effect” of compelled disclosure

The argument that compelled disclosure of a researcher’s data can have a chilling effect on future scientific endeavor was made, in one form or another, in both the *Deitchman* and *American Tobacco Co.* cases above. The benefit of hindsight however suggests that the fear of a chilling effect is unfounded. As a practical matter, Dr. Herbst’s registry was not destroyed and his sources did not dry up. It remains active, accepting cases and serving its intended purpose with Dr. Herbst as its director. See <http://obgyn.bsd.uchicago.edu/registry.html>. Presumably, Dr. Herbst’s personal reputation has not suffered and he was not deterred from pursuing further research based on the registry’s data. Dr. Selikoff also persevered beyond the *American Tobacco Co.* case; the Center for Occupational and Environmental Medicine at the Mount Sinai School of Medicine bears his name, and research on cigarettes and lung cancer continues. Richard L. Marcus, *Evidence: Discovery Along the Litigation/Science Interface*, 57 Brooklyn L. Rev. 381, 409 (Summer 1991). In fact, some evidence suggests the opposite of a chilling effect occurs, and that law may actually encourage science. For instance, the onset of mass tort litigation involving Bendectin made it a hot scientific topic. Litigation caused Bendectin to gain wide notoriety and made it likely that studies and research would be published by prestigious journals and periodicals. The FDA offered grants for Bendectin research, encouraging further work, as did parties themselves. *Id.* at 409 (summarizing Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 Hastings L. J. 301 (Jan. 1992)).

B. Constitutional Protection of Academic Freedom—*Dow Chemical Co. v. Allen*

Closely related to the existence of a researcher’s privilege are claims that the First Amendment’s protection of academic freedom extends to protect scholarly work by university researchers from judicially compelled disclosure. While no courts have explicitly held that academic freedom protection exists in this context, at least one has suggested that the First Amendment may offer some protection against judicially compelled disclosure of scholarly research by university researchers. See *Crabb, supra*, at 21.

This case arose out of four research studies at the University of Wisconsin involving rhesus monkeys and ingestion of the chemical compound known as TCDD. Based in part on the evidence of one of those studies, the EPA ordered emergency suspension of two TCDD-containing herbicides manufactured by Dow Chemical. *Dow Chemical Co. v. Allen*, 672 F.2d 1262, 1266 (1982). Dow scheduled cancellation hearings with the EPA regarding the suspension and had the EPA issue administrative subpoenas to University of Wisconsin researchers seeking disclosure of all materials related to two ongoing TCDD studies that had not been part of the basis for the EPA’s emergency ruling. *Id.* The researchers moved to quash the subpoenas. The First Amendment issue was raised in the trial court but not resolved. Instead, the subpoenas were found to unduly burdensome and quashed. *Id.* at 1268, *Crabb, supra*, at 22.

The court of appeals discussed the academic freedom issue in some detail, finding that Dow’s subpoena was a “substantial intrusion into the enterprise of university research . . . capable of chilling the exercise of academic freedom.” *Dow Chem.*, 672 F.2d at 1276. While the court did not hold that researchers were entitled to an evidentiary privilege, they did conclude that where researchers’ academic freedom is involved, the interests for disclosure must be strong and any intrusion should be carefully limited. *Id.* at 1275. Neither of these factors was present. Dow was not going to be confronted with the two studies at the administrative hearings since they had yet to be completed or published. So, there was little interest in favor of disclosure. Compliance would also be a significant burden on the researchers, so the intrusion was not limited. Based on these findings, court of appeals affirmed the district court’s decision. *Id.* at 1278.

Two significant facts distinguish the *Dow Chemical* case from the *Deitchman* and *American Tobacco Co.* cases and help to explain how the courts reached different results. First, Dow was seeking data from studies

that were ongoing, and the researchers had yet to publish any findings or conclusions from the two studies at issue. This allowed them to argue that disclosure and scrutiny of their ongoing work was likely to have a significant adverse impact. Second, the subpoenaed data were not going to be part of the government's case against Dow in the administrative proceedings that generated the subpoenas. This is vastly different from the defendants in *Deitchman* and *American Tobacco Co.*, who were directly confronted with published study data that they sought to discover.

C. Proprietary Interests in Scientific Data

Compelled disclosure also raises the issue of proprietary interests in scientific data. In the context of federal litigation, Rule 45(c)(3)(B) of the Federal Rules of Civil Procedure offers some protection that may prevent compelled disclosure of an unretained expert's research or opinions, unless special circumstances are present. Even if those circumstances are present, the expert is entitled to reasonable compensation for the disclosure of this intellectual property. The rule recognizes a researcher's proprietary interest in that information and is based on the idea that compelling an unretained expert to disclose it without being compensated could result in a "taking." Fed. R. Civ. P. 45(c)(3)(B) advisory committee's note to 1991 Amendment; see *Klay v. All Defendants*, 425 F.3d 977, 984 (11th Cir. 2005).

D. Confidentiality of Scientific Data

When scientific research and litigation cross paths, confidentiality is an issue. Defendants should be aware of the following issues with regard to confidentiality of scientific data.

1. Personal identifying information

In most cases, defendants will concede that personal identifying information should be protected from disclosure and redacted from records prior to production; however, situations may arise where clients believe that exploring every possible defense depends on obtaining personal information as well. If so, existing case law does not bode well for those requests. In two reported cases involving records from the Centers for Disease Control ("CDC") in Atlanta, Procter & Gamble ("Procter") took this issue head on. Both cases arose out of Procter's defense of product liability actions across the country involving a Procter manufactured tampon and toxic shock syndrome ("TSS"). *Farnsworth v. Procter & Gamble Co.*, 758 F.2d 1545 (11th Cir. 1985); *Lampshire v. Procter & Gamble Co.*, 94 F.R.D. 58 (N.D. Ga. 1982).

In those cases, plaintiffs intended to rely on CDC studies that purportedly linked Procter's product with TSS. Procter subpoenaed the CDC's records from this study and the CDC complied with the request, producing "every piece of information" they had. *Farnsworth*, 758 F.2d at 1546. The CDC however redacted the names and addresses of the study participants prior to production. Procter wanted the redacted information in order to personally contact each of the study participants to explore whether the studies' methodology was proper or contained biases. *Id.*, *Lampshire*, 94 F.R.D. at 60. In both cases, the courts sided with the CDC and determined that confidentiality of the subjects' identities outweighed Procter's discovery interests. *Farnsworth*, 758 F.2d at 1548; *Lampshire*, 94 F.R.D. at 61.

2. Federal confidentiality protection

Federal law offers researchers confidentiality protection that may act as absolute bars against the compelled disclosure of certain information. For instance, federal statutes restrict the use and disclosure of information obtained during research supported or conducted by the Public Health Service, which includes the National Institutes of Health and the Agency for Health Care Policy and Research. 42 U.S.C. §299c-3(c). This

statute does not give the researcher any discretion, subjects him to a civil penalty for any violations, and is applicable regardless of who requests the information. Michael Traynor, *Countering the Excessive Subpoena for Scholarly Research*, 59 Law. & Contemp. Probs. 119, 123 (Summer 1996).

Similarly, the secretary of health is authorized by statute to grant federal confidentiality certificates for both public and private research projects. 42 U.S.C. §241(d). The procedures for obtaining such a certificate are found at 42 C.F.R. §2a. This statute provides the researcher with some discretion but only extends protection a person's "identifying characteristics." Traynor, *supra*, at 123–24.

3. HIPAA

The Health Insurance Portability & Accountability Act of 1996 ("HIPAA"), Pub. L. No. 104–191, places limitations on the disclosure of medical records by certain health care entities. HIPAA's rules governing disclosure of health care information in a judicial or administrative proceeding are found at 45 C.F.R. §164.512(e). Generally, the rules provide that health information may be disclosed in response to a court order or in response to a subpoena or discovery request if the party seeking the information has made reasonable efforts to give notice of the request to the individual whose records are being sought. As such, HIPAA should not be a significant barrier to access of data underlying a scientific study. However, defendants should be aware its provisions concerning disclosure of records in judicial or administrative proceedings.

IV. Recommendations for Seeking Scientific Data in Litigation

It is unlikely that the scientific community will abandon its efforts to keep scientific data out of the courtroom. However, these roadblocks are not insurmountable if defendants are creative and recognize all options available to them for obtaining scientific data.

A. FOIA

In the event the scientific data are in the possession of a governmentally funded entity, a Freedom of Information Act ("FOIA") request may be such an option. See 5 U.S.C. §552. Nearly every state has its own version of FOIA, often using titles like the Open Records Act (Kansas, Georgia), Sunshine Law (Florida), or Public Information Act (Texas). Defendants should determine which statute is applicable and become familiar with its provisions to determine if the information they are seeking might be subject to such a request. The case of *R.J. Reynolds Tobacco Co. v. Fischer*, 207 Ga. App. 292, 427 S.E.2d 810 (Ct. App. 1993), illustrates the benefits of utilizing a FOIA request. In this case, R.J. Reynolds' subpoena for study data was quashed in an earlier round of litigation. The company later pursued and prevailed on a FOIA claim and ultimately obtained the data it sought. O'Neil, *supra*, at 43 (discussing Paul M. Fischer, *Fisher v. The Medical College of Georgia and the R.J. Reynolds Tobacco Company: A Case Study of Constraints on Research*, Academic Freedom: An Everyday Concern 33, 41 (E. Benjamin & D. Wagner eds. 1994)).

B. Concede Confidentiality of Certain Information

Prior to issuing the research subpoena, develop a redaction protocol to protect the confidentiality of certain personal information if the defendant does not truly need it. Including the protocol with the subpoena should nullify one of the researcher's more persuasive arguments in opposition to disclosure and perhaps increase the likelihood that a court would view defendant's request for disclosure more favorably. Offer the protocol as a starting point for negotiations and be open to modifications or suggestions from the researcher that do not ultimately affect the data being sought.

C. Be Willing to Negotiate

Defendants often knowingly and intentionally draft and serve an overly broad subpoena since they may have difficulty identifying the specific information they are seeking. This raises several issues. If the subpoena is truly overbroad and requests information that is not legitimately related to the defendant's need for the data, then a court may be more likely to side with the researcher and grant a motion to quash. Therefore, defendants should remain flexible and present the subpoena and protocol as a starting point for negotiations with researchers. Attempt to engage them in dialogue about the volume, location, and content of the data being sought and offer to reimburse them for the costs associated with locating, copying, redacting, and producing the sought-after data.

Ideally, these concessions and willingness to negotiate will relieve many of the researcher's concerns with the request and allow the parties to resolve any differences they may have without a court's assistance. If not, the court may nonetheless look favorably upon the defendant's efforts to resolve as many issues as possible before judicial intervention. Defendants should also do their homework before making a request for the data and use all available information to learn as much as possible about the data (content, location, organization, *etc.*) before a formal request is made. This will enable the subpoena to be drafted as narrowly as possible and in a way that the researcher understands what is being sought.