

# HOW DOES SCIENCE COME TO SPEAK IN THE COURTS? CITATIONS, INTERTEXTS, EXPERT WITNESSES, CONSEQUENTIAL FACTS, AND REASONING

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## I

### INTRODUCTION

Citations, in their highly conventionalized forms, visibly indicate each text's explicit use of the prior literature that embodies the knowledge and contentions of its field. Each text explicitly and implicitly invokes prior literature in order to provide resources for its claims, to identify issues at stake, to define its unique claim, and to create a stance toward all that has gone before. This relation to prior texts has been called *intertextuality* in literary and literacy studies. Because science and law are both complex, communal projects deeply reliant on the existence and production of texts, the study of intertextuality in each can tell us much about how each field operates and what it accomplishes as a communal, literate project. Studying how the intertextual systems of both meet in court can help us understand more deeply the ways in which science and the scientific literature are and are not consequential for legal deliberative processes.

In this Article I first put citation practices and intertextuality in science and the law in theoretical and historical perspective, and then consider the intersection of science and law by identifying the judicial rules that limit and shape the role of scientific literature in court proceedings. One particular focus is the idiosyncrasies of the U.S. legal system that have specific consequences for both scientific and legal intertextuality in judicial reasoning. As an exploratory example of how these issues work in practice, I look at litigation surrounding phenylpropanolamine (PPA), with particular attention to one crucial study and one crucial case. The analysis of the court documents focuses particularly on the

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judicial opinion as the site of judicial reasoning, though there are many other sites of legal argument that precede the judge's rulings.

Both from the historical and theoretical analysis and from the evidence of this one case, it is clear that, in the United States, judicial reasoning is an intertextually tight and self-referring system that pays only limited attention to documents outside the laws, precedents, and judicial rules. The window for scientific literature to enter the courts is narrow, focused, and highly filtered. It serves as a warrant for the expert witnesses' expertise, which in turn makes opinion admissible in a way not available to ordinary witnesses. In an adversarial system, the way to attack the opinion of an expert witness or to make the witness and testimony inadmissible is in fact to attack the professional standing of the literature on which the witness relies. Although the ruling in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,<sup>1</sup> approached this state of affairs with a particular set of rules, the tension goes deeper than the particulars of the *Daubert* rules or the ways in which they have been applied.

## II

### CITATION FORM AND INTERTEXTUALITY

No aspect of academic writing seems so conventional as citation format. It is the subject of tedious stylebooks, which define arcane rules of punctuation, abbreviation, and information requirements that are policed beyond the point of irritation by editors and instructors, requiring endless last-minute work by writers who did not have the foresight to anticipate all the conventional requirements when first beginning the project.<sup>2</sup> The stylebooks seem so unsubstantive and yet so demanding—the epitome of empty convention. But of course there are reasons for getting citations right: to provide accurate and convenient access to the literature cited, so readers can follow the author back to his sources—not just to check up on his honesty and trustworthiness, but because each statement rests on an intertextual world of prior meanings, reasonings, reported facts, and theories. Each new statement draws on and focuses a previous discussion and history of communal work. Each reader potentially has a stake in that discussion and, in response, can be drawn further into the relevant literature. Each new statement using that literature provides a new framework of relevance and interpretation as applied to the issue at hand.

Whereas the body of the new text provides the substantive and conceptual synthesis, interpretation, and deployment of the prior discussions, the citations provide the logistical, technical access to that literature. As such, they give clues to how that literature is organized and what the reader needs to know to locate any specific item in the archive of knowledge. These directions for finding the literature specifically point the reader to certain spots where only specific kinds

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1. 509 U.S. 579 (1993).

2. See, e.g., THE BLUEBOOK: A UNIFORM SYSTEM OF CITATION (Columbia Law Review Ass'n et al. eds., 18th ed. 2005).

of documents on particular topics are to be found. The documents provide the relevant domain of discussion. Thus, the genres and topics of biochemistry literature pointed to by the citation formats and bibliographic tools of that field are distinct from those of trademark litigation, and both are distinct from those of forensic accounting—each with its distinct citation practices and bibliographic tools.<sup>3</sup>

Each field of professional endeavor has its own methods of citation, developed from the dynamics of its work and the accidents of its history. These citation practices reflect and are part of the organization of the professional literature and help define what is important to know about the literature and how one should access it. Indeed, the conventions of citations arose out of managing the texts that emerged historically as relevant to the evolving field and that were part and parcel of its manner of work and reasoning. The problem that those contributing to this symposium aim to understand—how scientific knowledge is used in public policy and law—can be seen as a technical problem in intertextuality: When, how, in what form, and through what vehicle does the literature of science (embodying the knowledge of that field) enter into the textualized discussion of the differently organized domains of law, litigation, and public policy? Once elements of that scientific literature are admitted to other domains in forms acceptable and appropriate to those domains, how are these transformed texts used, with what standing, and with what consequences?

It is within the successful speech acts of those texts—those enduring utterances that create the record of the professional endeavor—that the facts of the endeavor (whether law, science, bureaucratic registry, or sports history) are established and used to come to conclusions. Further, the facts remain in the relevant literature for others to build on, use, or attempt to write over with new facts. Whatever the world is outside the textualized endeavors, to be part of the calculation, memory, and continuing thought of these literate endeavors, the facts must be inscribed within the relevant texts in a way that will be perceived as having both standing within its field and the robustness to continue that standing. Those texts provide the common knowledge and reference point for all individuals versed in the field. Nonetheless, for those textually located facts in the archive of the field to have meaning and relevance in any new or current issue before the field, these prior texts must be reprised and invoked either explicitly or implicitly, so that they are alive in the new space of calculation.<sup>4</sup>

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3. See, e.g., COUNCIL OF SCI. EDITORS, SCIENTIFIC STYLE AND FORMAT: THE CSE MANUAL FOR AUTHORS, EDITORS, AND PUBLISHERS (7th ed. 2006); Editorial Policy and Style Information, ACCT. REV. (Am. Acct. Ass'n, 2008), available at [http://aaahq.org/pubs/EdPolicies/REV\\_EdPolicy.pdf](http://aaahq.org/pubs/EdPolicies/REV_EdPolicy.pdf).

4. For the theoretical underpinnings of this chapter as articulated in this paragraph, see generally J.L. AUSTIN, HOW TO DO THINGS WITH WORDS (J.O. Urmson & Marina Sbisa eds., Harvard Univ. Press 1975) (1962) (discussing speech-act theory); Charles Bazerman, *Intertextualities: Volosinov, Bakhtin, Literary Theory, and Literacy Studies*, in BAKHTINIAN PERSPECTIVES ON LANGUAGE, LITERACY, AND LEARNING 53 (Arnetha F. Ball & Sarah Warshauer Freedman eds., 2004) (parsing Bakhtin's theory of intertextuality); CHARLES BAZERMAN, SHAPING WRITTEN KNOWLEDGE: THE GENRE AND ACTIVITY OF THE EXPERIMENTAL ARTICLE IN SCIENCE (1988) (setting out the history

### A. Inscribing Justice: The Law as a System of Literate and Communal Order

Law as an activity system serves to regulate human behavior through an ordered system of laws, providing rules for behavior, punishment, liability, and recompense, and applied to specific cases and adjudicated in the courts. Through legal action, everyday matters are brought into the disciplines of law. Courts become theatres of determination, looking for closure at the end of each performance or episode, inscribing culpability, damage, reward, and punishment, and reaffirming a legal order that sets the stage for all future legal actions. Related episodes will follow with different actors, settings, and facts. At the end of each episode, rewards, punishments, liabilities, and benefits must be distributed and settled so life can go on. In its role as the theatre for these actions, courts determine facts of events, intentions, and injuries—issues of human social life and meaning—that must be set aright by the system of justice to maintain social order.

Courts do not seek, as a direct aim, the best account of nature or scientific causality, though judgments on these matters may enter incidentally in judging human actions and injury as, for example, intentional or inadvertent. Further, courts render judgment only on the immediate matter at hand, although judgment as to other, subsidiary matters may be involved, as well, and although the reasoning and principles invoked may be consequential as precedent. If the evidence or reasoning is inadequate to determine culpability or injury, by whatever standard the law determines for the criminal or civil case, the case is decided for the defense. If the court is caught in a dilemma, it works its way through the dilemma via more legal reasoning. The appellate process that reexamines cases is entirely about legal procedures and reasoning, not about the facts of the case, which are determined in the trial court. Opening up a case for new evidence is permitted only in certain instances and carries a higher standard and specific focus. Even then, the matter is usually sent back to the trial court, especially in U.S. criminal cases, though less so in civil proceedings.

The court's judgment is made by a single individual or a panel. In the United States, this judgment is cast in a written statement—whether in the

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and spread of a central scientific genre over four centuries); Charles Bazerman, *Systems of Genres and the Enactment of Social Intentions*, in *GENRE AND THE NEW RHETORIC* 79 (Aviva Freedman & Peter Medway eds., 1994) (theorizing the orderly relationship of genres within organized activity systems); Charles Bazerman, *Singular Utterances: Realizing Local Activities Through Typified Forms in Typified Circumstances*, in *ANALYZING PROFESSIONAL GENRES* (Anna Trosborg ed., 2000) (examining how specific forms of information appear and are reasoned about within relevant genres); Charles Bazerman, *Textual Performance: Where the Action at a Distance Is*, 23 *J. ADVANCED COMPOSITION* 379, no. 2 (2003) (considering how meanings and actions are accomplished at a distance through writing); H.L.A. HART & A.M. HONORÉ, *CAUSATION IN THE LAW* (1959) (setting out how interpersonal actions are accomplished in speech); G.H. MEAD, *MIND, SELF, AND SOCIETY* (1934) (identifying the role of social communication in the formation of identity and cognition); David R. Russell, *Rethinking Genre in School and Society: An Activity Theory Analysis*, 14 *WRITTEN COMM.* 504 (1997) (providing a structural model for understanding the relationship between genres in different activity systems); JOHN SEARLE, *SPEECH ACTS* (1969) (elaborating technical issues in speech-act theory); WILLIAM I. THOMAS, *THE UNADJUSTED GIRL* (Comm. on Publ'ns of the Am. Inst. of Criminal Law and Criminology ed., 1923) (observing the sociological concept of social facts).

summary form of a jury ballot or the more extended statement of a judge's opinion. Once the judgment enters the record, the conclusion stands as law unless overturned by a higher court. The opinion written by the judge further sorts out the relevancy and relationships of the various evidence and arguments with respect to law and precedent, thereby setting the file in order.

The law is conservative. New laws are sought only as the conditions of life, community values, and perceptions of problems change, so that a rule of law can then once again be imposed on an unruly world. Even progressive, pragmatic orientations to the law always focus backwards to precedent, introducing change only gradually. Both criminal and civil-court cases attempt to place the particulars of each case and problematic circumstance into that rule of law. In Roman and Napoleonic law, this conservatism and text-boundedness are particularly strong: the law is taught and treated as a rational, self-contained system, although the history of its interpretation and application as decisions and commentary must always have weight, and thus some bearing, on each case and on the code. Nonetheless, orderly access to the statutory law has been at the heart of the intertextual system within the Roman and Napoleonic systems, and references are mediated through the editors or compilers of the law.<sup>5</sup> Thus Justinian's Institutes, Code, and the lost and recovered Digest became the keys to citation practice through the medieval period, drawing on the volume name and then the *incipit* or initial words of the statute.<sup>6</sup>

#### B. Common Law, Precedent, and Judicial Opinion in Britain and the United States

In medieval England, practices of statutory citation developed using the name of the act and the year of the monarch's reign or parliamentary meeting. By the mid-sixteenth century, however, the dominant printer of legal texts in England, Richard Tottell, and the bibliographic system he imposed on his legislative yearbooks became the standard for citations.<sup>7</sup> This citation format reinforced Tottell's volumes as the definitive location of texts, and other printers found it useful to copy his organization even to the numbering of the folios or the pagination.<sup>8</sup>

Anglo-American law has evolved with a further wrinkle in inscribing the world into the law, so that it may be regulated by the law. Because of the legal standing given to customary or common law that existed outside royal and parliamentary determination, the history of judicial decisions carries special weight in determining what the law in any particular case may be and how it is

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5. See Byron D. Cooper, *Anglo-American Legal Citation: Historical Development and Library Implications*, 75 LAW LIBR. J. 3, 4-6 (1982) (providing a history of the English origin of citation practices as derived from the Romans in the Middle Ages).

6. See *id.*

7. *Id.* at 9-10.

8. See *id.* at 10 (describing Tottell's practice of standardizing foliation).

to be applied. This means that, in addition to the crafted logic of legislative statutes, the various judicial opinions carry weight in creating new law.

In England, the unwritten law, carried in the memories and judgments of the judges and elite barristers, still has standing. Its emphasis is not on the exact wording of the opinion, but on its decision and its underlying principle. The development of printing provided an increasingly accurate written record, which served as a memory aide and as more-certain evidence of the oral opinion. Again, the indexing system and pagination of the leading publishers became the standard, helping to maintain the place of those practices in the market, though over time new indexes replaced the old.<sup>9</sup> Still, as with statutory law, it was the leading commercial compilation products that defined and maintained bibliographic order, and became key reference points for access to the law. This commercial compilation and ordering also helped maintain a coherence and finiteness to the legally relevant corpus.<sup>10</sup>

In the United States, however, the common law has been textualized as much as the statutory law. Almost from the beginning of the republic, appellate judges were required to write their opinions,<sup>11</sup> and this is what the common law has come to consist of.<sup>12</sup> Although the statutes that might bear on any case are finite and specified in the charge or tort, this body of common-law opinions has created a large archive that potentially can bear on any decision within the appropriate jurisdiction. Since the 1970s, though, courts have been able to withhold decisions from publication that they consider not weighty enough or not so universal as to be worthy of setting precedent. So, although these decisions may be published in some form, it is clearly signaled that they are not of precedential value.<sup>13</sup> This set of precedential decisions being limited to those approved for publication limits their numbers somewhat, but this emphasizes the importance of those so selected.

Judges have written these decisions with an increasing awareness of their role not only in deciding the cases before them, but in directing or constraining the actions of future courts—the development of rules or tests that lower courts must follow as *stare decisis* precedent. The *Daubert* rule for the admissibility of expert testimony is one such precedent issued by the Supreme Court. It figures strongly in the litigation around PPA, to be examined below. Rules or tests are also issued by lower courts to set terms of practice and adjudication in their jurisdictions. The reports containing carefully written opinions form the largest part of the extensive law library needed for effective practice and have provided lucrative businesses for the small number of specialized publishers that provide

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9. Peter M. Tiersma, *The Textualization of Precedent*, 82 NOTRE DAME L. REV. 1187, 1197–98 (2007).

10. *Id.*

11. *Id.* at 1225.

12. *Id.* at 1188 (“[T]he common law consists of what judges write in their opinions.” (emphasis omitted)).

13. *E.g.*, *Folks v. State Farm Mut. Automobile Ins. Co.*, No. 05-1356, 2007 WL 2993595, at n.\*\* (10th Cir. Oct. 15, 2007).

case reports and the related bibliographic tools for their access. West Publishing's policy of comprehensiveness and accuracy since its founding in 1876 caused it to become the primary print custodian of judicial opinions, and its organization and pagination informed documentation practice.<sup>14</sup> The primary legal search tool, Shepherd's Citations, was also keyed to the West reports.<sup>15</sup>

Standard bibliographic styles for legal publications emerged fairly recently and are regulated primarily through *The Bluebook: A Uniform System of Citation*.<sup>16</sup> *The Bluebook* first appeared in 1926, replacing earlier style manuals.<sup>17</sup> It relied on West's organization and pagination of cases. *Bluebook* style moved into court practice only in the 1970s, although with it came an almost fetishistic obsession with citation correctness, according to a recent article by Gallacher.<sup>18</sup> Nonetheless, some variation in judicial use remains, with some states such as California having distinctive styles based on the local publisher of reports and the Supreme Court continuing to go its own way.

With the advent of electronic publication and distribution, LEXIS (now LexisNexis) entered the market and eventually was purchased by Elsevier, which also purchased Shepherd's Citations.<sup>19</sup> West was purchased by Thomson Publishing and became WESTLAW.<sup>20</sup> In 2000, the Association of Legal Writing Directors issued a competing system, which has gained some acceptance in law schools though only limited acceptance in the courts.<sup>21</sup> Despite the increasing presence of electronic access and dissemination, both publishers (West and LexisNexis) and both citation systems rely on the paper pagination in West, which is the most comprehensive publisher of federal and state cases.<sup>22</sup>

In the scientific world, Elsevier, Thomson, and other large publishers made a somewhat similar attempt to gain control over the corpus of scholarly publication, but in that world the domains are much more open, and the task is much more difficult. Despite Thomson's accumulation of the core access tools of the Web of Science (formerly the Science Citation Index) and Current

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14. Robert Berring, *Chaos, Cyberspace and Tradition: Legal Information Transmogrified*, 12 BERKELEY TECH. L.J. 189, 191-92 (1997).

15. *Id.* at 194-95.

16. THE BLUEBOOK: A UNIFORM SYSTEM OF CITATION (Columbia Law Review Ass'n et al. eds., 18th ed. 2005).

17. ERWIN GRISWOLD, A UNIFORM SYSTEM OF CITATION: ABBREVIATIONS AND FORM OF CITATION (1st ed. 1926).

18. Ian Gallacher, *Cite Unseen: How Neutral Citation and America's Law Schools Can Cure Our Strange Devotion to Bibliographical Orthodoxy and the Constriction of Open and Equal Access to the Law* 7-8 (Berkeley Electronic Press Legal Series, Working Paper No. 1505, 2006), available at <http://law.bepress.com/expresso/eps/1505/>.

19. See Berring, *supra* note 14, at 198.

20. *Id.*

21. DARBY DICKERSON, ALWD CITATION MANUAL: A PROFESSIONAL SYSTEM OF CITATION (1st ed. 2000). The manual is now in the third edition.

22. One scholar argues that this use of West pagination, tied to West's aggressive legal action to maintain copyright control over the pagination, supports monopolistic ownership and that legal practice should adopt vendor-neutral citation practices to open up democratic access. See Gallacher, *supra* note 18, at 33-34.

Contents, along with ownership of a large portfolio of major journals, it has not accomplished monopoly control.

These issues over citation format and monopolistic control of knowledge highlight how closely linked citation is to the form and ownership of the intertextual corpus that constitutes relevant knowledge. Law has come to depend on the emergence of a finite, though growing, corpus of definitive texts of precedential cases studied in their letter as well as their spirit. Further, this body of texts has become associated with a set of reasoning practices that read, interpret, synthesize, and apply the precedential decisions. Particularly in the context of *stare decisis*, this intertextual corpus reduces the flexibility of common law,<sup>23</sup> while it keeps the pool of relevant intertexts finite. What remains of interpretation and interpretive flexibility now tends to center on legal reasoning about the precedents, their meanings, implications, and applications. Accordingly, the citation system facilitates reference to precise pages and paragraphs, pointing to specific, quoted words or phrases or to principles embodied within short, focused text passages.

### C. Scientific Intertextuality and the Communal Project of Scientific Truth

Science is also a cumulative communal project, but its citation systems and underlying intertextual practices are substantially different, coming from a different history of citation that really started only in the latter half of the eighteenth century. Before that, regularized citation was left largely to the humanist scholars and historians who had a finite corpus of well-organized- and scrutinized classic texts and chronicles, with multiple editions and copies to sort out. Although earlier books of natural philosophy did refer to one another, there was little regularized expectation of familiarity with the prior literature, let alone any expectation of citing it, summarizing it, and positioning one's work within it. An ideology of natural philosophy as a communal enterprise with communal procedures for inscription and aggregation was earlier associated with Sir Francis Bacon's vision of Salomon's House in the *New Atlantis*.<sup>24</sup> This ideology was invoked in the formation of practices of communal witnessing and attesting to observed phenomena in the Royal Society and similar natural philosophic societies.<sup>25</sup> Nonetheless, publications presented work largely as individual discovery, coming from the insight, observational acuity, and methodological cleverness of the individual investigator.

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23. See Tiersma, *supra* note 9, at 1205–06 (describing how precedent continues to bind English courts).

24. See generally SIR FRANCIS BACON, *THE NEW ATLANTIS* (1626) (describing a mythical enlightened land and its institutions of knowledge).

25. See generally DWIGHT ATKINSON, *SCIENTIFIC DISCOURSE IN SOCIOHISTORICAL CONTEXT* (Charles Bazerman ed., 1999) (analyzing the relation between linguistic forms and social factors in the emergence of scientific argument); BAZERMAN, *SHAPING WRITTEN KNOWLEDGE*, *supra* note 4; ALAN G. GROSS, JOSEPH E. HARMON & MICHAEL REIDY, *COMMUNICATING SCIENCE* (2002) (comparing the development of scientific writing in England, France and Germany); STEVEN SHAPIN & SIMON SCHAFFER, *LEVIATHAN AND THE AIR-PUMP: HOBBS, BOYLE AND THE EXPERIMENTAL LIFE* (1985) (examining the social and ideological origins of scientific argument in seventeenth century England).

The emergence of natural philosophic journals starting in 1665<sup>26</sup> created more opportunity for exchange that included overt reference to the work and statements of others. Such exchange most frequently arose in the context of explicit controversy and contestation, as in the exchange over Newton's new theory of light and colors in the *Philosophical Transactions of the Royal Society*, beginning in 1672 and comprising eighteen published exchanges.<sup>27</sup> However, the initiating article was told as an individual narrative and set of assertions.<sup>28</sup> After the exchange of argument and counterargument, Newton withdrew from the hand-to-hand combat of journal publication. He published his *Opticks*<sup>29</sup> three decades later as a self-contained logical system with no citation of the opposing views nor of prior relevant work. In fact, an investigation of all of the *Philosophical Transactions* reveals that a semblance of modern citation practice emerged only at the beginning of the nineteenth century.<sup>30</sup>

One of the pioneers of modern citation practice and literature review was Joseph Priestley, best known for his work as a chemist, but who carried a broad enlightenment portfolio from theology, philosophy, and language to history and politics, as well as the sciences. In *History and Present State of Electricity*, he argued for taking into account the collected experience of humankind as recorded in all scientific works.<sup>31</sup> An empirically grounded natural philosophy, he argued, needed a comprehensive review of all prior experiences and experiments, as well as a history of theories, apparatuses, and investigative procedures.<sup>32</sup> This shared attention to the collective literature, Priestley believed, would not only aggregate experience, but would build common understanding, moving science from contestation to communal cooperation and shared, explicit, public reasoning about investigation, finding, and theories.<sup>33</sup> While competitive individuality and contestation remain major mechanisms of science, they have become embedded within the collective frame of the communal record of data and reasoning embodied in the literature. Each new contribution must locate itself within and contribute to the literature, while distinguishing itself by defining its unique contribution to the collective enterprise.

The specific citation practices for the various disciplines that became labeled science in the nineteenth century varied from each other somewhat and were gradually codified in this past century in a number of different styles regulated

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26. The first issue of the French *Journal des Sçavans* is dated January 5, 1665 and the first issue of the *Philosophical Transactions of the Royal Society* is dated March 6, 1665.

27. BAZERMAN, *SHAPING WRITTEN KNOWLEDGE*, *supra* note 4, at 100.

28. *Id.* at 87–99.

29. SIR ISAAC NEWTON, *OPTICKS: OR, A TREATISE OF THE REFLECTIONS, REFRACTIONS, INFLECTIONS & COLOURS OF LIGHT* (1704).

30. BAZERMAN, *SHAPING WRITTEN KNOWLEDGE*, *supra* note 4, at 78–79.

31. JOSEPH PRIESTLEY, *HISTORY AND PRESENT STATE OF ELECTRICITY*, Vol. 1, xviii (1767).

32. Charles Bazerman, *How Natural Philosophers Can Cooperate*, in *TEXTUAL DYNAMICS OF THE PROFESSIONS* 13, 16–17 (Charles Bazerman & James Paradis eds., 1991).

33. *Id.* at 37–39.

through manuals and specified by disciplinary journals. Some styles are enforced discipline-wide as part of a definition of scientific quality, particularly when the most influential journals are owned by the professional society that also publishes the manual, as with the American Psychological Association.<sup>34</sup> In other disciplines, journals vary in their preferred styles. But all of the styles are built around and enforced by articles appearing in those journals, with primary locators being the journal title, volume or date, and pagination, and the publication identifiers being author and title. The differences have to do with punctuation, use of abbreviations, placement of the date, and, perhaps most significantly, how the citation is tagged to the body of the text. A citation can be tagged as an obscure footnote reference number or as a parenthetical reminder of author and date, whether in a format that facilitates quotation and specific page reference or in a format that facilitates treating the cited text as a single unit. Every variation from the conventionally anticipated information (easily represented within the standard format) requires extra work and an unusual citation form. The disciplinary variations in format generally have arisen from the nature of the materials used in the discipline, from the way they enter into the discussion, and from the ultimate goals of the work—whether clinical, applied, or theoretical. Citation styles and bibliographic tools also embody ideas about how knowledge accumulates and interacts to form a collective body of disciplinary knowledge.<sup>35</sup>

Whichever style is employed, the intertext is treated as fluid and progressive, with new knowledge constantly being sought to replace the old, and citation lists being biased towards more-recent publications defining a research front, against which the new article defines its contribution. Each citation, therefore, has a half-life, either deteriorating into obscurity or becoming such a standard part of knowledge that it no longer requires citation.<sup>36</sup> The knowledge of fields is codified through this sorting process of citation and incorporation into the body of disciplinary knowledge.<sup>37</sup> But this is a rolling codification, in which new claims and theories replace old ones. Through novel investigation by new researchers, the literature constantly reaches out into new phenomena, new forms of data, new theories, and more fundamental explanations. It does not remain fixed, nor does it seek finality and fixity. If it achieves these things, it is no longer a research field, but a fixed body of

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34. AM. PSYCHOLOGICAL ASS'N, PUBLICATION MANUAL OF THE AMERICAN PSYCHOLOGICAL ASSOCIATION (5th ed. 2001).

35. See generally Charles Bazerman, *Codifying the Social Scientific Style: The APA Publication Manual as Behaviorist Rhetoric*, in THE RHETORIC OF THE HUMAN SCIENCES 125 (John S. Nelson, Allan Megill & Donald N. McCloskey eds., 1987).

36. Derek J. de Solla Price, *Citation measures of hard science, soft science, technology, and nonscience*, in COMMUNICATION AMONG SCIENTISTS AND ENGINEERS 3, 9 (C.E. Nelson & D.K. Pollack eds., 1970).

37. ROBERT K. MERTON, THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATIONS 516 (1973).

knowledge ready for commodification, without need of a supporting profession.<sup>38</sup>

The ultimate judgment as to which investigations, findings, and publications will stand over time as credible and usable is not up to any individual or panel. Instead, the judgment is made in the aggregate, communal determination of what is useful and cited, as each scientist builds new work on the basis of what came before. Results mount up in the literature, and carry force. If a case is uncertain or if reasoning and evidence are insufficient, one does not take strong stands on the prior work, but rather modulates, proposes alternatives, or seeks more evidence through new methods. The need to build on what is credible and reliable inflects usability judgments, leading colleagues to evaluate the quality of related work. But scientists also evaluate the importance of others' findings to their own work, and therefore the patterns of citation also sort out what is most important in the collective enterprise from what is irrelevant, trivial, or just uninteresting. In most cases there is little reason to rule negatively on any publication that is faulty, obvious, or unenlightening because, in most cases, it will simply fade into uncited obscurity. Citation studies regularly show there are few negative citations, and many articles are rarely or never cited. Most articles are more likely to be ignored than criticized.

In this process of selective citation, the literature gets organized around focused findings associated with particular articles. The findings or meaning of each article tends to get compacted into a single concept, and citations become concept symbols.<sup>39</sup> After a perhaps brief period of uncertain meaning, there is less focus on particular wording than on the abstracted finding.<sup>40</sup> The article has come to be seen as supporting the finding, and the exact words are at stake only rarely, when the validity of the claim is being contested. As a result, citations have migrated in the direction of holistic citations to entire articles, and formats are less convenient for specific page and quotation identification.

In scientific publication, the practice closest to legal admissibility is the refereeing process, which allows a finding to enter into the literature, but which transforms it by the pressures of the reviewing process to meet the criteria of the referees.<sup>41</sup> Nonetheless, the relevance of a published article then is up to each new researcher who selects and repurposes articles from the literature.

Within this communal project of scientific inquiry, publication, and codification of the intertext, there is no fixed time frame within which any problem must be solved or any account must be settled, unlike each judicial proceeding, in which the case must be decided. Although, in science, various practical concerns might place an exigency on finding a solution—for example, on treating an epidemic disease or on producing results that might warrant

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38. ANDREW ABBOTT, *THE SYSTEM OF PROFESSIONS* 146–47 (1988).

39. Henry G. Small, *Cited Documents as Concept Symbols*, 8 *SOC. STUD. SCI.* 327, 328 (1978).

40. See generally Susan E. Cozzens, *Comparing the Sciences: Citation Context Analysis of Papers from Neuropharmacology and the Sociology of Science*, 15 *SOC. STUD. SCI.* 127 (1985).

41. GREG MYERS, *WRITING BIOLOGY* 63–100 (1990).

continuation of a grant—there is no absolute institutional time exigency on any matter. Additionally, in the course of investigation, a researcher might find something she was not looking for, transform one research question into another, narrow or broaden her focus, or otherwise get sidetracked from the initial task. In fact, such evolution of attention and effort is the expectation in most investigations as one finds out about one's subject.

Whereas law is constituted and regulated in each jurisdiction, with supreme authority currently located in the nation or state, science is international, although its practice might be regulated, sponsored, or used within each jurisdiction. So, while science in each state might be responsive to and dependent on political, social, economic, and legal conditions, science as a whole is a separate system, unregulated except by its internal dynamic. The work of science may migrate to any hospitable state, and the findings can migrate across borders (except when the findings are created under conditions of state secrecy). So, again, it is the collective judgment of working scientists that evaluates what constitutes valid and significant work.

#### D. The Meeting of the Legal and Scientific Documentary Systems

Both legal and scientific systems are intended to inscribe significant parts of the world, but in ways that are not necessarily congruent. One system, law, judges human actions and intentions in order to regulate behavior and to sort out punishments, liabilities, and transfers, and so to maintain an appearance and substance of justice that facilitates citizen adherence to the regulated order. The other system, science, attempts to come to truths about the physical, biological, and social worlds, but without passing judgment or ascribing punishment or reward (although these may appear as secondary consequences).

Nonetheless, science and law often meet. As science is carried out within one political jurisdiction or another, its practitioners are attentive to the regulations, needs, and opportunities of that jurisdiction. For example, scientists are at times the litigants in judicial cases, either as plaintiffs suing for rights or for resources to practice science or as defendants whose scientific practice is being regulated.<sup>42</sup> Many of the expert witnesses or scientists whose published work is used in cases are employed by state agencies or in institutions that receive state support and are responsive to state mandates.<sup>43</sup> The key study in *In re Phenylpropanolamine Products Liability Litigation*,<sup>44</sup> the Yale Hemorrhagic Stroke Project (HSP),<sup>45</sup> for example, was at the intersection of complex public, private, and corporate interests, since it was carried out by the FDA in

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42. These issues are not discussed here, although it is obvious that the research on PPA was focused and shaped by the jurisdiction in which science was practiced—the regulated medical and pharmaceutical practice within the United States.

43. See, e.g., William N. Kernan et al., *Phenylpropanolamine and the Risk of Hemorrhagic Stroke*, 343 NEW ENG. J. MED. 1826 (2000).

44. *In re Phenylpropanolamine Prods. Liab. Litig.*, 289 F. Supp. 2d 1230 (W.D. Wash, 2003).

45. Kernan et al., *supra* note 43.

collaboration with authors employed at both public and private universities, using data from public and private hospitals, and funded by highly regulated pharmaceutical corporations.<sup>46</sup>

The focus here is rather on the court's need for science in making its judgments. How do courts admit scientific knowledge? What weight does scientific literature carry in the legal system? And how is science used in deliberating judgments once it appears in court? In particular, this article looks at two related documents that still have authoritative presence in medical science and in court: the published study of the Yale Hemorrhagic Stroke Project<sup>47</sup> and Judge Rothstein's opinion on the *Daubert* hearing in *Phenylpropanolamine Products*.<sup>48</sup> This opinion admits expert testimony on the strength of the HSP study, published in *The New England Journal of Medicine* (NEJM). Both the HSP study and the opinion are considered here in the context of prior texts on the science and litigation of PPA. And although both have authoritative presence concerning PPA and some special characteristics related to that authority, they share many characteristics with texts of a period before the issues came to be sorted out into authoritative views.

### III

#### EXPERT TESTIMONY AS THE ENTRY POINT OF SCIENCE INTO THE COURTS

In all the many PPA court cases, scientific literature and scientific opinion are filtered through the testimony of expert witnesses. That is, individuals testify, and it is they—not the science—who are being measured for their credibility, just as any other witness would be. But an expert witness's authority to speak comes from his expertise, which allows him to comment on and evaluate the state of knowledge and the particular medical records of a case. Accordingly, the scientific literature and other documentary records (other than those reporting directly on matters in the case) are not direct evidence in the case, in the way a bank robber's note to the teller or a surveillance-camera photo would be; instead, the scientific foundation serves only to authenticate the expert's expertise and opinion. The scientific literature is neither read directly nor taken as a whole by the fact finder. Its general weight is not evaluated. Nor is the relative weight and meaning of each constituent part—nor its contributory role to a larger conclusion—considered. Scientific conclusions are not drawn through scientific reasoning, nor are they used in pursuit of further inquiries. Rather, the scientific literature comes filtered, shaped, and accountable through the individual expert witness, who must be taken as speaking authoritatively even to be permitted to be heard.

The aspect of the testimony subject to judicial opinion is its admissibility—whether the expert witness may testify or whether the expert's deposition can

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46. *Id.* at 1826, 1832.

47. *Id.*

48. *Phenylpropanolamine Prods.*, 289 F. Supp. 2d 1230.

be entered into the court record as evidence. The deposition process, in fact, allows the judge to evaluate beforehand the testimony of the expert witness to see whether it meets the criteria for admissibility. Of course, all evidence, even a bank robber's note, is subject to rules and challenges about admissibility. If they are judged as admissible, these documents can stand as evidence. In the case of expert witnesses, however, it is only their opinions or testimony that carries evidentiary weight, with the underlying scientific literature merely supporting admissibility and credibility.

A complete study of the ways the scientific literature is used to establish admissibility and credibility would require a full examination of all the legal filings, depositions, briefs, and courtroom arguments on both sides. However, this article is limited to judicial rulings and opinions on admissibility and weight once admitted. These judicial opinions, reflecting a judge's evaluation of all the issues and evidence presented, constitute the residue of legal reasoning, which forms the primary record and statement of the meaning of the case after its conclusion.

The court establishes standards to regularize what is admissible as expert testimony. The federal rules of evidence presuppose two distinct kinds of witness. The lay witness is important strictly for what he has observed, not what he thinks or knows beyond the case, and the main evaluation of the testimony is of the trustworthiness of the witness's character and observational skills. Expert witnesses, on the other hand, likely will not have specific personal knowledge of the case at hand. Typically, they learn the particulars of the case only through records or through examining artifacts. The judgments they make may rely on evidence beyond what might be admissible. Their expertise grants them broader license for their opinions than that given lay witnesses, even to the point of permitting their direct opinions on the issue being judged in the case.<sup>49</sup> In short, expert witnesses do not necessarily have any direct observations to report but are valued for their opinions, not, like lay witnesses, for their personal trustworthiness, but for their expertise. Their testimony can be impeached only by attacking that expertise or, more precisely, its relevance and use in the case at hand. Thus, it is not uncommon in cases ruling on the admissibility of testimony for the judge to offer effusive praise for the credentials, reputation, and competence of the expert witness while ruling her testimony inadmissible.

The question of admissibility of expert testimony in the United States goes back at least as far as the 1923 case *Frye v. United States*, which resulted in a broad test of general acceptance within any one relevant scientific community.<sup>50</sup> Since 1993, the Supreme Court decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,<sup>51</sup> has been the ruling law. It reaffirms the role of the judge as the gatekeeper of scientific-expert testimony as expressed in the Federal Rule of Evidence 702, which reads,

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49. Except their opinion concerning criminal insanity. See FED. R. EVID. 704(b).

50. *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923).

51. 509 U.S. 579 (1993).

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.<sup>52</sup>

The *Daubert* decision explicitly recognizes the judicial procedures as being different from evaluative procedures in science. The judicial gatekeeping has to do with the relevancy and usefulness to trying the matter at hand, rather than the long-term production of scientific truth.

Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly. The scientific project is advanced by broad and wide-ranging consideration of a multitude of hypotheses, for those that are incorrect will eventually be shown to be so, and that in itself is an advance.<sup>53</sup>

Despite its recognition of these evaluative differences, the Court held that the trial judge needed to rule on whether the testimony was grounded in science, which would include an evaluation of both scientific knowledge and method.<sup>54</sup> The Court identified four criteria for determining whether expert testimony is valid scientific knowledge: first, “whether [the theory or technique] can be (and has been) tested”; second, “whether the theory or technique has been subjected to peer review and publication”; third, “the known or potential rate of error”; and, fourth, the “identification of a relevant scientific community and an express determination of a particular degree of acceptance within that community.”<sup>55</sup> The court further instructed that judicial inquiry should be limited to “principles and methodology, not on the conclusions that they generate.”<sup>56</sup>

Insofar as the court’s logic suggests criteria different from that practiced in the expert’s field, there is the potential for tension over the value of the expert’s findings. Since *Daubert*, there has been controversy over the reasonableness of these criteria and whether they are based on an appropriate understanding of science.<sup>57</sup> There also has been controversy on how strictly and comprehensively these criteria should be applied and whether all need be met. Further, there is unease in the way scientific knowledge gets played out within an adversarial court system in which each side tries to establish its witnesses as more expert and to undermine the expertise of the other side—that is, whose knowledge (and method upon which such knowledge rests) will stand as fact within the court records.<sup>58</sup>

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52. FED. R. EVID. 702.

53. *Daubert*, 509 U.S. at 597.

54. *Id.* at 592–93.

55. *Id.* at 593–94.

56. *Id.* at 594.

57. *See, e.g.*, 95 AM. J. PUB. HEALTH (SUPPLEMENT 1) S1 (2005). The entire special issue is devoted to the implications of *Daubert*.

58. Even further, commercial interests brought into court may suppress scientific findings or otherwise intervene in scientific debate for commercial advantage, as was reported to have occurred in

Despite the controversies over the *Daubert* rules or the particulars in each case, once a court has ruled those criteria as having been met by testimony, the science is “authoritative” from the court’s perspective, obviating the need for any finer judgments.

#### IV

##### THE CASE OF PPA LITIGATION

A number of PPA cases have been litigated in the post-*Daubert* period. They concern whether hemorrhagic strokes or other medical conditions were caused by PPA, a common ingredient in appetite suppressant and in cough and cold products from the 1970s until recently. In November 2000, the FDA recommended a voluntary withdrawal of products containing PPA; subsequently it started procedures to outlaw over-the-counter sales of these products. As of February 22, 2007, LexisNexis listed one U.S. Supreme Court ruling, eighteen federal courts of appeals rulings, and ninety-four federal-district-court rulings relating to PPA.<sup>59</sup> State cases are many times that number.<sup>60</sup> Most of the federal rulings represent distinct cases, but twenty-nine ruled on the multiparty, multidistrict case *In re Phenylpropanolamine*.<sup>61</sup>

Some of the cases occurred before work was completed on an epidemiological HSP study that came to be treated as authoritative by scientists, regulators, courts, and pharmacological companies alike. This study was first issued as a report on May 10, 2000, then published in the NEJM.<sup>62</sup> Once this study became accepted as adequate epidemiological evidence to be admitted and upheld in major rulings, it dampened the controversy and made moot some of the complex handling of expert testimony in earlier cases. This article examines the study as an example of scientific patterns of intertextuality and then considers the ruling that accepted the study as the basis of authoritative opinion.

##### A. Intertextuality in the NEJM Paper

The NEJM paper is typical of scientific papers in its intertextuality, and it indeed cites much of the prior literature on the issue of the kind and substance that would have been available in the previous court cases.<sup>63</sup> The most overt

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the case of PPA. Kevin Sack & Alicia Mundy, *Over-the-Counter Peril*, L.A. TIMES, Mar. 28, 2004, at A1.

59. LexisNexis online search under “Phenylpropanolamine,” Feb. 22, 2007.

60. *Id.*

61. *In re Phenylpropanolamine Prods. Liab. Litig.*, 289 F. Supp. 2d 1230 (W.D. Wash. 2003).

62. Kernan, *supra* note 43, at 1826.

63. The original HSP study, issued eight months earlier, is similar in structure and citation patterns to the published article, and therefore this analysis with minor modifications would hold for that one as well. *Accord* RALPH I. HORWITZ, LAWRENCE M. BRASS, WALTER N. KERNAN, & CATHERINE M. VISCOLI, PHENYLPROPANOLAMINE AND RISK OF HEMORRHAGIC STROKE: FINAL REPORT OF THE HEMORRHAGIC STROKE PROJECT (2000), available at [www.fda.gov/ohrms/dockets/ac/00/backgrd/3647b1\\_tab19.doc](http://www.fda.gov/ohrms/dockets/ac/00/backgrd/3647b1_tab19.doc).

sign of intertextuality is the explicit citation, but it is worthwhile considering as well some implicit intertextual references and reliances. The citation system in NEJM uses superscript numbers keyed to a references list presented in the sequential order they first appear in the article. It is a kind of hybrid of “works cited” with footnote systems. Though the sequential numbering system is far from universal in the sciences, the substance of the information presented within the citation, as well as the punctuation, are common. The citation system in NEJM allows efficient repetition of the citations, but is more cumbersome than most science-citation systems for specific page references because the citation list includes only inclusive pagination, and the superscript numbers do not provide an easy place for exact page references. Further, using superscript numbers as text anchors (rather than parenthetical author names or other recognizable text identifiers) suppresses author identification in the text as well as specific discussion of the article. It does not easily facilitate identification of quotations. Instead, it treats references as background in the literature, to be taken as underlying support but not to be actively discussed.

This system presents the HSP investigation reported on in the article in an unencumbered foreground even more than most systems. Indeed, in several places citations are presented en masse, to demonstrate the weight of the literature rather than indexing a specific determinative finding or identifying a finding to be discussed in detail. Thus the first cited claim aggregates nine citations, which then embeds even more reports: “Since 1979, more than 30 case reports have been published that describe the occurrence of intracranial hemorrhage after ingestion of phenylpropanolamine.<sup>1, 2, 3, 4, 5, 6, 7, 8, 9</sup>”<sup>64</sup> The next sentence repeats three citations and adds four more, to make a further specifying claim about documented cases: “Affected patients were most commonly adolescent girls or young women between the ages of 17 and 45 years who were using phenylpropanolamine-containing appetite suppressants, often for the first time.<sup>7, 8, 9, 10, 11, 12, 13</sup>”<sup>65</sup> The characterization of these articles as case reports identifies the level of data they provide, and allows them to be taken as a kind of anecdotal evidence of a possible association, significant in their accumulation as indicating something worth investigating further and more systematically, but not yet establishing any relation. Other, even less-formal evidence is then cited from medical reports filed with the FDA, but not rising to the level of peer-reviewed scientific publication. For example, “In addition to the published reports, between 1969 and 1991, the Food and Drug Administration (FDA) received 22 spontaneous reports of hemorrhagic stroke associated with phenylpropanolamine in appetite suppressants (16 cases) or cough and cold remedies (6 cases) (Jolson HM: personal communication).”<sup>66</sup>

These case reports constitute the entire review of the literature. They also constitute well over half of the cited papers (thirteen of twenty-three, plus the

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64. Kernan, *supra* note 43, at 1826.

65. *Id.*

66. *Id.*

FDA spontaneous reports not in the numbered reference list). No biology, chemistry, medical analysis, public health, or other literature is overtly referenced, though the existence of that literature is implicit within the definitions and uses of PPA presented in the opening sentences: “Phenylpropanolamine is a synthetic sympathomimetic amine commonly found in appetite suppressants and cough and cold remedies. Each month, millions of Americans use products containing phenylpropanolamine.”<sup>67</sup> The general chemical, pharmacological, and public-health backgrounds, along with the specific case reports, establish the research space and problem for the current investigation, typical of the “create a research space” model found across contemporary sciences.<sup>68</sup> Although the general problem comes from pharmacology, medicine, and public health, the immediately relevant literature—the research-space framework, actively invoked to define the current limits and knowledge and a gap to be filled by the study—is anecdotal case reports. Their use indicates a potential problem. Implicitly, according to the standards of the field, such a concern would call for a randomly sampled, large-scale epidemiological study. The current article then aims to fill this gap: “In response to the concern raised by these case reports, in 1992 we collaborated with the FDA and manufacturers of phenylpropanolamine to design the Hemorrhagic Stroke Project, a case-control study . . . .”<sup>69</sup>

The methods section, for the most part, does not explicitly refer to other literature, though the standards of the field embodied in the cumulative literature are implicit throughout in the identification of the studied population, in the manner of data collection, and in the statistical analyses applied. As is standard practice for statistical analysis, specific named tests and procedures are applied, each of which has an embedded literature. Some of the procedure names were in fact eponymic (Fisher’s test, O’Brien-Fleming spending function).<sup>70</sup> Specific computer programs and commercial software suppliers used for the analysis are mentioned as well,<sup>71</sup> to verify the standardness of procedures and to allow reexamination of the data and analysis. Moreover, the tools of investigation are themselves congealed literature, embodying principles from the literature used in their design.<sup>72</sup> Although scientific articles do sometimes cite methodological literature—particularly if something is novel, unusual, or in question—here, in the paper’s methods section, procedures are treated as largely standard, except for the particular difficulties of the study, which are treated as local adaptations of general principles. Also, the critical procedures referred to in such a section would be read by a professional audience,<sup>73</sup> who

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67. *Id.*

68. JOHN M. SWALES, *GENRE ANALYSIS: ENGLISH IN ACADEMIC AND RESEARCH SETTINGS* 140 (1990).

69. Kernan, *supra* note 43, at 1826.

70. MERTON, *supra* note 37, at 298–302.

71. Kernan, *supra* note 43, at 1827.

72. BRUNO LATOUR & STEVE WOOLGAR, *LABORATORY LIFE* 66 (1979).

73. BAZERMAN, *supra* note 4, at 260.

would confirm the procedures' conformity with standard practice in the literature of the field. One rhetorical function of such sections is to confirm that this work was done as any competent scientist in the field would do it, and therefore the results should not be questioned. Clear conformity to the literature avoids raising any red flags regarding methodology and is thus a useful strategy for gaining acceptance. The primary exception to the implicitness of the literature in the methods section is the citation of three articles pointing to specific findings that help identify procedures for data collection and analysis.

Some patients with subarachnoid or intercerebral hemorrhage may have a transient headache hours or days before the onset of symptoms that lead them to seek medical attention.<sup>14, 15</sup> The cause of these sentinel headaches is not known, although clinicians infer that some may be due to minor bleeding.<sup>16</sup> Accordingly, for patients with such headaches we defined a modified focal time as the time of onset of the sentinel headache. We used this definition in secondary analysis.<sup>74</sup>

Two standard reference works were also cited to confirm the formulation of the products patients reported as using. In certain cases, when questions had arisen of product change or generic or store brand, the authors had cross-checked with manufacturers, making manufacturers' records also part of the implicit intertext.

There is another kind of intertextuality in the use of hospital and interview records as data for the study, including many reported compromises made to address the contingencies of the study, with explanations and rationales as to why these should be allowed without compromising the integrity of the study.<sup>75</sup> The authors of the NEJM article work hard to argue that the available records meet the standard of epidemiological method despite a number of specific shortcomings and compromises. The data tables aggregate these inscribed data and are intertextually dependent on them, as are the discussion and conclusions about health risks. One method of questioning the claims of the article would be to examine the records and interview data in order to seek irregularities within them, the way they are aggregated in the article, or their reliability as epidemiological data.

In the discussion portion of the paper, citations of a prior epidemiological study and previously cited case reports are presented as agreeing with the study. But they do not live up to the accomplishment boasted: "Our study establishes strong epidemiological evidence of the association . . . ."<sup>76</sup> This is the desired speech act the article aims to accomplish—the illocutionary force, as Austin would call it.<sup>77</sup> But of course, as Austin would also point out, the success of the speech act would depend on the uptake of the readers, that is, how the readers would use their understanding of the text in consequent actions, what he would

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74. Kernan, *supra* note 43, at 1827.

75. *Id.* at 1828.

76. *Id.* at 1831.

77. See AUSTIN, *supra* note 4, at 121–22.

call the perlocutionary effect.<sup>78</sup> To forestall objections readers might have that might undermine their understanding of the claim as a speech act, three more citations recognize potential limits of the study based on potential biases established in the literature.<sup>79</sup> But each of these potentially undermining citations is met with a methodological rejoinder explaining how each potential bias was controlled for in this case.<sup>80</sup> A final citation is used to calculate potential overall impact if carried across the entire population.<sup>81</sup>

Overall, this article draws widely and complexly on a multidimensional research and methodological literature, some evoked implicitly and other, specific items brought explicitly to the citational foreground in order to frame the importance, meaning, and value of the current study and its findings. However, none of this literature is quoted, examined in detail, or interpreted as to the exact meaning, limitations, or implications of its precise wording. In using this literature, the authors distinguish between that which is widely known and accepted and that which is contested, uncertain, and at stake. The widely accepted is typically taken as common knowledge, a given, or as guidance for pursuing the investigation in ways that will be credible, meeting the expectations of good work. Widely accepted work thus establishes criteria for the acceptance of new work, thereby helping establish conditions that must be met in order for the new work to accomplish successfully the desired act associated with the genre. Such epidemiological studies and the articles reporting them aim at establishing an association between a condition (medical, pharmacological, environmental, et cetera), and a health result within a substantially sized, defined population. To do so, an epidemiological study must match multiple expectations of what constitutes a valid piece of work; such expectations have developed over the history of contention in the literature of what findings could be taken as valid. Nonetheless, findings of a lesser sort, which do not match the standards to which the NEJM article aspires or which attempt to accomplish something different, are cited and used as positive indicators of a problem to be investigated, or as a clarifying constraint directing analytical procedures, or confirmation of the study. Further shortcomings of the sample, data, and analysis are also recognized and explained. Thus, the article depends on a complex weighing and argumentative synthesis of many pieces, leading to an overall evaluation of the weight of the evidence. In the long run, whether the speech act stands and the claimed association is taken to be true, acted upon, and accepted as the basis for further studies that reconfirm and extend its truth, depend on the readers' uptake in their future actions.

If there were no urgent health, regulatory, commercial production, or legal consequences of the article's findings, there would be no exigency for a reading audience to make an immediate, definitive judgment on its content. Rather, the

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78. *Id.*

79. *See* Kernan, *supra* note 43, at 1831.

80. *See id.*

81. *See id.*

study would go into the mill of ongoing science to see whether it would be accepted as reliable and useful to future researchers. That usefulness and reliability would establish the facticity or solidity of the result, leading to its codification within the canon of knowledge. The exigency of legal proceedings, reflecting urgent human stakes, however, puts new pressures on the gradual judgments of science and pushes for judgment even when scientific judgment is not yet final.

#### B. Science in the *Daubert* Consideration of *In re Phenylpropanolamine*

Legal cases concerning PPA before and after the Yale study vary in the extent to which they pay attention to the scientific literature. Most are concerned entirely with legal matters and do not cite or mention the scientific literature.<sup>82</sup> Typically, the matters being ruled on involve only legal questions and not the substance or admissibility of expert testimony. Even when considering issues surrounding expert witnesses, the discussion may be entirely legal. However, when it concerns admissibility, the discussion may briefly include the science, though within a predominantly legal context, framed by the *Daubert* criteria.<sup>83</sup> In a rare case, the judge undertakes a detailed scrutiny of specific procedures, analyses, and practices that stand behind the opinions of the expert witnesses. Most notably, in a lengthy opinion in *Soldo v. Sandoz*, the defendants were granted summary judgment on the grounds that the plaintiff's expert testimony was inadmissible.<sup>84</sup> The ruling was based on a detailed critique of the methods and practices of the plaintiff's expert witnesses respecting specific facts and opinions they had reported.<sup>85</sup> In effect, the judge was ruling on specific "scientific facts" that would have been relied on in the plaintiff's case.<sup>86</sup>

In the multidistrict litigation *In re Phenylpropanolamine*, the Yale study was accepted as authoritative science and as the basis of admissible expert opinion.<sup>87</sup> In its *Daubert* hearing, the lawyers for the several plaintiffs offered the testimony of fourteen expert witnesses, all advancing the theory of the Yale study and relying on that study as evidence.<sup>88</sup> Defendants moved to have this expert testimony excluded. They particularly called into question the experts' reliance on the Yale study, which their attorneys claimed was unreliable in some respects.<sup>89</sup> In this hearing, testimony on several items not covered in the

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82. See, e.g., *Love v. Wyeth*, 569 F. Supp. 2d 1228 (N.D. Ala. 2008); *Kobar ex rel. Kobar*, 378 F. Supp. 2d 1166 (D. Ariz. 2005).

83. See, e.g., *Globetti v. Sandoz Pharms., Corp.*, 111 F. Supp. 2d 1174 (N.D. Ala. 2000) (considering whether expert testimony on the causation of myocardial infarction satisfied the *Daubert* requirements of scientific methodology and evidentiary reliability).

84. *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 577 (W.D. Pa. 2003).

85. *Id.*

86. Almost three-fourths of the *Soldo* opinion consists of findings of fact. See *id.*

87. See *In re Phenylpropanolamine Prods. Liab. Litig.*, 289 F. Supp. 2d 1230, 1239–40 (W.D. Wash. 2003) (reviewing the qualifications of the Yale study as basis for expert testimony).

88. *Id.* at 1236.

89. *Id.* at 1245–46.

Yale study was also ruled on—some ruled admissible, some inadmissible.<sup>90</sup> The comparison of how these issues were handled provides insight into the ways in which scientific literature enters into judicial reasoning.

In the *In re Phenylpropanolamine* opinion, the judge first reviews the history of the use of PPA in pharmaceuticals and in associated reports of hemorrhagic strokes.<sup>91</sup> This history is told as uncontested factual background in an absolute narrative, without citation or contestation, referring to many documents, published and unpublished, including “thirty published case reports” (apparently taken uncited from the language of the NEJM article on the Yale study).<sup>92</sup> Governmental groups and actions are mentioned and their rules actually quoted, but with no specific, standard citations to anchor the events and quotations, or to make them accessible to others.<sup>93</sup> Similarly, studies are mentioned by the name of the primary author, such as the published “Jick Study”<sup>94</sup> and the unpublished “O’Neill and Van de Carr study”<sup>95</sup> and “Dr. Jolson’s SRS study”<sup>96</sup> of the FDA database of spontaneous reports—but again without formal citation or a convenient way to locate the texts. This background ends with an extensive discussion of the history, methods, and findings of the Yale study, mentioning the final report—but not providing a citation—and then reporting the FDA request for voluntary withdrawal of the product, again without specific documentation.<sup>97</sup> This is all presented as history stipulated by the court, an official narrative of the facts, not needing specific anchoring in the actual documents.

The only document actually cited in this section is at the end of this narrative, the NEJM study itself.<sup>98</sup> The citation is presented as part of a historical event bearing on the admissibility of the expert testimony—in particular, in relation to the *Daubert* criteria of peer review and publication. That is, the fact of publication is used as evidence of the expertise of the witnesses, not as a way of engaging the substance of the scientific intertext.

### C. Legal Reasoning About Meeting the *Daubert* Standard

After this background narrative, the judge begins the discussion with four pages of the *Daubert* standard and related cases, with detailed legal citations, including page or paragraph references to the Federal Rules of Evidence and

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90. See, e.g., *id.* at 1251 (finding certain testimony on the relationship between PPA and cardiac injuries inadmissible for lack of evidentiary support).

91. *Id.* at 1234.

92. *Id.* at 1235.

93. E.g., *id.* at 1234 (“In 1976, an FDA advisory review panel recommended . . .”).

94. *Id.* at 1241.

95. *Id.*

96. *Id.* at 1235.

97. *Id.* at 1236.

98. *Id.* (“In December 2000, The New England Journal of Medicine (NEJM) published the HSP results in a lead article. See Walter N. Kernan et al., *Phenylpropanolamine and the Risk of Hemorrhagic Stroke*, 343 NEW ENG. J. MED. 1826 (2000) [hereinafter NEJM Article]).

several cases, including *Kennedy v. Collagen Corp*, *Kumho Tire Co. v. Carmichael*, *General Electric Co. v. Joiner*, *Domingo v. T.K.*, and two opinions in *Daubert*.<sup>99</sup> This detailed analysis of the legal precedents includes quotations from rules and judgments, which are then interpreted as to limits, applications, and implications.<sup>100</sup> The analysis proceeds through legal reasoning to determine what the *Daubert* standard is and how it is to be applied.<sup>101</sup> This is a discussion of legal rules, reasoned through legal documents. The precise reading is made explicit so that litigants can satisfy themselves about what these documents say, or can contest the interpretation in a further appeal. The judge notes, in particular, that epidemiological studies are already held in legal literature as well received by courts in mass tort cases, stating “well-conducted studies are uniformly admitted.”<sup>102</sup>

In the next section, entitled “Defendants’ *Daubert* Challenges,” the judge considers challenges to documents underlying the study.<sup>103</sup> These preliminary rulings refer to the defendants’ claim that evidence of causation for medical events occurring more than three days after ingestion of PPA was insufficient.<sup>104</sup> Because none of the cases in the litigation went outside the three-day window, and because the plaintiffs offered no further argument or evidence on this, the judge excludes opinions on injuries outside the three-day window as unreliable.<sup>105</sup> This section is under a page in length.

The most substantive and complex discussion, which is at the heart of the defendants’ claims, involves causation of “Hemorrhagic Stroke in Women Between the Ages of Eighteen and Forty-nine.”<sup>106</sup> This is the lengthiest section of the article, encompassing six pages.<sup>107</sup> In it, many court opinions are cited formally and in detail as part of the legal reasoning.<sup>108</sup> It includes as well some citations to other kinds of documents. Some of these cite specifically to legal handbooks on the use of scientific evidence in courts in order to establish standard legal procedure, such as *Modern Scientific Evidence: The Law and Science of Expert Testimony*,<sup>109</sup> and the Federal Judicial Center’s *Reference Manual on Scientific Evidence*.<sup>110</sup> The opinion includes quotations from both the FDA study and the NEJM article to show the methodological caution they exhibit, so as to meet objections based on their “flaws” and to handle those

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99. *In re Phenylpropanolamine Prods. Liab. Litig.*, 289 F. Supp. 2d. at 1236–38.

100. *Id.*

101. *Id.*

102. *Id.* at 1238.

103. *Id.* The judge had already ruled on two documents that had been specifically cited.

104. *Id.*

105. *Id.*

106. *Id.* at 1238–44.

107. *Id.*

108. *Id.*

109. *Id.* at 1239 (citing David L. Faigman et al. eds., *MODERN SCIENTIFIC EVIDENCE: THE LAW AND SCIENCE OF EXPERT TESTIMONY* (1997)).

110. *Id.* at 1240 (citing Federal Judicial Center, *REFERENCE MANUAL ON SCIENTIFIC EVIDENCE* (2d ed. 2000)).

objections as advised in the legal canon.<sup>111</sup> The quotations are not for scientific interpretation but only to demonstrate that the studies correspond with the *Daubert* standard. One footnote indicates textbooks cited by the expert witnesses to show the general acceptance of the PPA causation theory.<sup>112</sup> The textbook and treatise citations are evidence of widespread scientific acceptance, specifically of PPA as a risk factor for strokes, which enhances the reliability of the plaintiffs' experts' opinions and which is mentioned in *Daubert* as a potential factor in admissibility.<sup>113</sup>

#### D. Defense Challenges to the Science and the Court's Reasoning About the Scientific Literature

At this point in the ruling, however, in responding to specific challenges to the scientific status of the findings relied on by the plaintiffs' expert witnesses, as well as to their conclusions, the judge's handling of the scientific literature changes. First, the judge cites an article invoked by the defense that appeared after the NEJM publication of the Yale study:

During the final day of the *Daubert* proceedings, defendants raised challenges relating to a new article by the HSP investigators to be published in the June 2003 issue of the journal "Stroke." See Joseph P. Broderick et al., *Major Risk Factors for Aneurysmal Subarachnoid Hemorrhage in the Young are Modifiable*, (Stroke, 2003) (hereinafter "Stroke Article"). Defendants assert that this article demonstrates the lack of association between PPA and SAHs resulting from the rupturing of an aneurysm ("aneurysmal SAH"). The court finds that the defendants distort and misinterpret the Stroke Article.<sup>114</sup>

The judge then carefully analyzes this article, focusing on what evidence is offered in support of which exact claims, and how it does not bear on the matter at hand.<sup>115</sup> In this sense, the judge engages in a scientific form of reasoning about both the Yale HSP study and the more recent article. For example, in support of her accepting the explanation of the plaintiffs' expert that "a p-value cannot provide evidence of lack of an effect," the judge cites an epidemiological handbook authored by one of the plaintiff's expert witnesses.<sup>116</sup> The third section of the opinion, "Hemorrhagic Stroke in the Various 'Sub-populations,'" follows in the same vein, as the judge counters defense claims that it is inappropriate to extrapolate the findings of the Yale study to men, children, or

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111. See *id.* at 1240–41 (citing, inter alia, *Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1230–31 (9th Cir. 1998), for otherwise useful, opposing, scientific-expert opinions and evidence as going to the weight of the evidence, not to its admissibility).

112. *Id.* at 1242 n.11 ("Plaintiffs list over a dozen medical textbooks associating PPA with high blood pressure and stroke. See, e.g., John C.M. Brust, *Stroke and Substance Abuse*, in UNCOMMON CAUSES OF STROKE 132, 133 (Julian Bogousslavsky & Louis R. Caplan eds., 2001); THE LITTLE BLACK BOOK OF NEUROLOGY 170–72 (James S. Bonner & Jo Jaeger Bonner eds., 2d ed. 1991).") (citation format modified).

113. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 594 (1993).

114. *In re Phenylpropanolamine Prods. Liab. Litig.*, 289 F. Supp. 2d at 1243.

115. *Id.* at 1243–44.

116. *Id.* at 1243 (citing Kenneth J. Rothman, EPIDEMIOLOGY, AN INTRODUCTION (2002)).

people over age forty-nine.<sup>117</sup> The judge cites medical literature to establish that, in the matter of PPA and similar issues, it is standard medical practice to extrapolate.<sup>118</sup> She then cites legal precedent to show that such extrapolation has been ruled admissible in other cases.<sup>119</sup>

In this third section and in a preceding subsection entitled “Recent Article on Aneurysmal SAH [Subarachnoid Hemorrhage],” a challenge is raised by the defense as to the scientific validity of claims made by the plaintiffs’ expert witnesses.<sup>120</sup> It is at this point that the judge again enters into scientific reasoning. She is put in a position of adjudicating what is appropriate scientific procedure and whether certain reported conclusions and findings count as proper scientific knowledge so as to be admissible. Thus, the judge must sort out conflicting claims, each presenting itself as defining appropriate scientific behavior, in order to decide which claims will stand in court as admissible expert testimony. In contrast to two earlier subsections of the opinion,<sup>121</sup> in which the judge was ruling on the general admissibility of a certain kind of study, here the court must rule on specific contested claims.

In subsequent sections,<sup>122</sup> the judge is drawn further into sorting out conflicting scientific claims against the background of the scientific literature to determine the admissibility of the testimony of two of the plaintiff’s expert witnesses. Section four considers the testimony of Dr. Steven Levine on Ischemic stroke potentially caused by PPA (as opposed to Hemorrhagic stroke, which was the subject of the Yale HSP).<sup>123</sup> Section five considers Dr. Irvin Goldenberg’s testimony on potential PPA causation of cardiac injuries.<sup>124</sup> Neither of these witnesses’ testimonies is supported by the “gold standard” epidemiological study, and each must delve more deeply into other types of studies in the scientific literature. As the judge notes, they bear a similarity to each other in this way; they also bear a similarity to the cases litigated before the publication of the Yale study. The judge applies a similar kind of intertextual test to each and comes to opposite conclusions. The comparison is instructive about the way this judge, at least, considers the cumulative value of the scientific literature. The judge notes that Levine’s claim about the causation of Ischemic stroke “rests on case and adverse drug reports, biological plausibility, comparison to other sympathomimetics and naturally occurring conditions with altered sympathetic tone, PPA blood pressure studies, textbook and other references, and both [Levine’s] own and others’ clinical experience.”<sup>125</sup> She notes as well that “the lack of epidemiological evidence does

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117. *Id.* at 1244–46.

118. *Id.* at 1244–45.

119. *Id.* at 1245.

120. *Id.* at 1243–44.

121. *See id.* at 1239–43 (sections 2(a) and (b)).

122. *Id.* at 1246 (section 4, *Ischemic Stroke*); *id.* at 1249 (*Cardiac Injuries*).

123. *Id.*

124. *Id.* at 1250.

125. *Id.* at 1246.

not render expert opinions on this issue unreliable” and again cites precedent standing for the rule the weakness or flaws in scientific expert evidence go to its weight, not to its admissibility.<sup>126</sup> Because the volume of evidence is lower than that respecting hemorrhagic stroke, the judge calls for a more detailed scrutiny of that evidence.<sup>127</sup> The judge rehearses the line of reasoning and evidence that she finds plausible and relevant. Further, the judge repeats some of the citations to the scientific literature that Levine relied on in supporting his own reasoning.<sup>128</sup> The judge concludes, “The court again finds that the cumulative effect of this evidence satisfies the mandate of *Daubert*.”<sup>129</sup>

Although, superficially, Dr. Goldenberg’s expert testimony for the defense followed a similar form of reasoning to Dr. Levine’s, the judge rules it inadmissible:

Lacking epidemiological evidence, Dr. Goldenberg drew upon animal studies, human clinical trials, case reports, clinical experience, comparison to other sympathomimetics, and text book references. He testified as to, inter alia, biological plausibility, temporal association, and dose response. Thus, at first glance, Dr. Goldenberg’s methodology mirrors that employed by Dr. Levine.<sup>130</sup>

Upon “closer analysis,” though, the judge finds “critical distinctions” between the two experts. Dr. Goldenberg’s evidence “spreads far too thin to reliably support expert testimony.”<sup>131</sup> The judge finds, too, that Dr. Goldenberg failed to offer any support for his opinion that “some thirty-five different biological mechanisms” could account for the link between PPA and cardiac injuries.<sup>132</sup> Goldenberg’s “primary explanation” for that link was “PPA’s vasoconstrictive effect”<sup>133</sup>; yet another expert witness for the defense had testified that “PPA’s vasoconstrictive effect on coronary arteries was extremely limited.”<sup>134</sup>

The judge notes other differences between Goldenberg’s testimony and what was actually to be found in the literature. For example, whereas Dr. Goldenberg presented testimony as to individuals consuming human therapeutic doses of PPA, “three of the animal studies found no pathology at doses significantly beyond human dose, including doses 1000 and 235 times that level.”<sup>135</sup>

The judge goes on to remark that “beyond offering a few isolated examples, Dr. Goldenberg only alluded to the . . . numerous textbooks and treatises supporting his opinions.”<sup>136</sup> The judge ruled that Goldenberg’s testimony was

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126. *Id.* (citing Kennedy, 161 F.3d at 1229–30).

127. *Id.*

128. *Id.* at 1247.

129. *Id.* at 1248 (citations omitted).

130. *Id.* at 1250.

131. *Id.*

132. *Id.*

133. *Id.*

134. *Id.*

135. *Id.* at 1251 (citing *Daubert* Hearing Record (May 29, 2003) at 75–76, 83–84).

136. *Id.*

inadmissible on the grounds that it “lack[ed] both the cumulative evidentiary support and the thoroughness the court found reliable with respect to both hemorrhagic and ischemic strokes.”<sup>137</sup> Thus, the underlying issue seemed to be how thoroughly the witness drew on the evidence in the literature and how tightly he argued from it. The key to judicial evaluation of the admissibility of an expert’s testimony, then, is the judge’s evaluating the expert’s use of the scientific intertextual resources.

The *Daubert* standard of measuring scientific method, on its face, appears to evaluate the experimental procedure, itself, as it certainly does in evaluating the NEJM article that underlay the testimony of most of the plaintiffs’ expert witnesses. Even then, it is ultimately a matter of the experts’ reading and application of the literature. With a “gold standard” epidemiological study, however, that becomes less problematic. But in the more problematic cases that do not rely on a single, definitive study, admissibility was a matter of judging how well, comprehensively, and carefully the literature was read by the witnesses and how it was used to reason.

In the PPA products-liability case, the judge seemed willing to accept something less than absolute certainty and judge according to the weight of published evidence and the arguments based upon it, even when the most authoritative kind of study was lacking. In fact, willingness to engage with the literature leads the judge to admit expert testimony, so that the jury (should the case reach a jury) can decide on the testimony’s value.

Judges in other cases have taken different positions on the requisite level of certainty about causation to make evidence relevant and admissible in determining liability.<sup>138</sup> Notably, *In re Phenylpropanolamine* was a group action, which puts the issue of statistical probabilities in a different light. The causality can be considered in aggregate without sorting out whether it was more likely than not to be the cause in each particular case. In that case, too, the judge seemed willing to strike a balance between legal reasoning and scientific reasoning on issues of admissibility. In many other PPA cases, the judges ruled on admissibility only on legal grounds, without significant investigation of the scientific literature—which frequently resulted in finding that defense challenges raised sufficient doubt to rule the plaintiff’s expert testimony inadmissible.<sup>139</sup> On the other hand, other judges, as those in *In re Phenylpropanolamine* and in *Soldo*,<sup>140</sup> scrutinized the scientific literature and practices engaged by the expert witnesses in order to determine the method behind specific, detailed claims made by the witnesses. This scrutiny resulted in giving credence to most of the shadows of doubt that defense attorneys attempted to cast on the plaintiffs’ expert testimony, so as to render that

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137. *Id.*

138. *See, e.g.*, *Buxton v. Lil’ Drug Store Prods., Inc.*, No. 2:02-CV-178-KS-MTP, 2007 WL 2254492 (S.D. Miss. Aug. 01, 2007).

139. *See, e.g., id.*

140. *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434 (W.D. Pa. 2003).

testimony inadmissible and to leave the defendant's set of facts standing as the facts of the case.<sup>141</sup> In such a case, the court becomes full arbiter of what science the fact finder is to hear and attempts to prevalidate what is to be admitted. In *Soldo*, the result was summary judgment in favor of the defendants, for there was no substantial case left for the plaintiffs once the expert testimony was excluded.<sup>142</sup> In taking a middle course, the judge in *In re Phenylpropanolamine* took the scientific challenges seriously enough to examine their plausibility, but did not foreclose evaluation of the credibility and relevance by a subsequent fact finder.

## V

### CONCLUDING OBSERVATIONS

Science and the courts are distinct intertextual systems, with different domains of relevant texts, different ways of deploying and reasoning with the texts, and different methods of inscribing evidence from the nontextualized world into their deliberations. Further, they each have limited admission of texts from other domains, with procedures for admitting foreign texts, and differing uses to be made of them. Neither science nor law is a homogenous domain where texts flow freely. Judicial handling of legal texts is bounded by national and state jurisdictions and hierarchies within jurisdictions. Scientific literatures aggregate in disciplines, specialties, and theory groups, with criteria of admission, attentiveness, and forms of reasoning appropriate to each, with border controls and suspicion over immigrant texts from neighboring or more-distant scientific fields. Within each of the domains, the border controls are determined by the inhabitants, not the neighbors. Rarely does the neighbor have enough standing to negotiate, let alone demand, the terms of admission.

In the PPA litigation, even in the cases in which science seems to be treated most even-handedly, the gatekeeping is entirely on the legal side of the border. In the communal process of science, a complex discussion sorts itself out only over time by what gets cited in ongoing publication, under no focused institutional, situational exigency for immediate resolution. But when science is applied to legal matters with judicial exigencies, it is the legal system that decides what meanings should be taken from the scientific literature and what functional role those meanings will have in legal proceedings. The science is carried across the border largely by selected agents within a strategically stage-managed, advocacy proceeding. The science is filtered through the testimony of the (mostly paid) expert witness, and then admissibility as scientific knowledge is ruled on by a judge following legal reasoning within the intertext of the law. As a result, the intertext of science has only a tenuous and filtered standing in relation to specific cases. Scientific findings do not stand as effective and

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141. *See id.* at 576–77 (demonstrating domino effect of concluding plaintiff's experts do not offer scientifically reliable testimony).

142. *Id.* at 577.

prominent speech acts in themselves, establishing facts on the landscape that must be attended to. Rather, the scientific literature is at best a warrant for the expertise of the opinions expressed by individuals in the roles of expert witnesses. It is those admissible acts of opinion that are potentially consequential facts within the legal proceeding.

It offends science, which prides itself on both internationalism of cooperation and universality of truth, if its truths and authority cannot flow freely across borders. Yet these are different kinds of borders—borders of human endeavors and activity systems. Intertextual analysis can help parse out what the exact border regulations are and what gets across, with what use and effect, according to the procedures established and judgments made by the courts. But unless intertextual analysis finds some flimflam in the procedures, it cannot pass judgment on what those procedures should be. It is up to the participants in the various activity systems to sort out whether those procedures meet their needs.

Nonetheless, scientists are also citizens, who expect their legal systems to act justly. If their knowledge as scientists helps them identify injustice, then as citizens they have the right and the obligation to ask the courts to redress procedures to bring about justice in a complex world, about which science has gained some knowledge. Moreover, since so many actors in the world are themselves engaged with science as part of their actions (whether pharmaceutical companies, environmental organizations, or silicon-chip manufacturers), scientists are likely to have observations about the justice with which these actors operate. The opinions of scientists might help us better evaluate the legality and liability of parties acting with scientific knowledge. Intertextual analysis might provide a means of identifying whether the most credible science gets into court to have standing as significant fact with appropriate bearing in the judicial deliberation.

Similarly, the courts are committed to justice, and their officers understand that in many matters, scientific opinion must be factored in to reach just conclusions. Accordingly, courts have adopted procedures, following judicial forms of reasoning, to admit scientific and other expert opinions in ways that will maintain the character and authority of their courts. If, in examining their procedures, they find that the knowledge necessary to make just decisions is not being admitted (that is, relevant facts are missing, not part of the record or deliberations), or that the manner of admission is impeding knowledge from being used in the way most conducive to justice (that is, the perlocutionary uptake of the speech act and fact is skewed), they must reconsider their procedures. Again, intertextual analysis might serve as a useful tool for courts to sort out whether their procedures lead to the most useful knowledge being brought to bear on questions of justice in the most useful way.

My comments are professionally cautious, because evaluation of the use of scientific knowledge in PPA cases involves knowledge and judgment of both science and justice—in neither area do I have expertise. I bring only a mode of

analysis of literate activity systems to examine how they carry out their deliberative work. However, as a citizen, from the vantage of my professional knowledge, in becoming familiar with PPA litigation I have noted that the current and recent procedures for admission of expert testimony have created an opening for an aggressive strategy of challenge to keep scientific knowledge from court, by casting shadows of doubt. That strategy has also created space for pharmaceutical companies and other corporate actors in scientific arenas to keep facts from being established in court by keeping findings from publication and by sponsoring other publications that muddy the scientific waters.

This observation brings a third set of institutions into the analysis: proprietary corporate organizations with their own sets of interests and modes of operation. They also depend on their own complex intertextual systems; nonetheless, because they appear in courts—usually as defendants—they are treated as legal persons, insulated by the advocates who present their interests. The intertextual systems within which they carry out their corporate monitoring, reasoning, and governance are not available or accountable to the court unless specific documents are subpoenaed or the defendants are charged with fraud or malfeasance. Nonetheless, the corporate reasoning embodied in their intertextual systems can indirectly affect the scientific intertext available to the court. Further, through their advocates, they can make salient particular parts of the legal intertext and can bring other suits that will change the legal landscape. Finally, they may attempt to influence legislatures and government agencies to affect laws, regulations, regulatory policies, and procedures, thereby changing the larger context in which courts adjudicate. Thus we might best consider the problem of science and the law as a three-body intertextual problem—or ultimately an  $n$ -body problem, as regulatory agencies, consumer groups, legislatures, and other players with their own intertexts of knowledge, fact, and reasoning carry out their activities and define their interests. As with any  $n$ -body problem, it is often useful to make simplifying assumptions based on which systems exert the greatest gravitational force in each case.