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Most experienced product liability counsel have confronted an expert at trial who insists his or her own ''clinical experience'' has proven that a drug or other product can cause some disease, whether or not that association has been established in controlled epidemiological studies, say attorney Peter Grossi and law student Holly Barker. This testimony is often devastating when the opposing counsel does not have the records of those alleged cases to use as a basis for effective cross-examination, the authors say.

The authors discuss several rulings in the Diet Drug Litigation that recognized the inherent problems with ''unsupported testimony'' and required experts who intended to offer such observations to first provide the full record of their experiences. The authors review the law surrounding this testimony and argue this approach is not only consistent with federal procedural rules and the Health Insurance Portability and Accountability Act, but actually mandated by those provisions.

'Because I Say So': The Problem of Unsupported Anecdotal Expert Proof in Product Liability Litigation

By Peter Grossi and Holly Barker

Consider the following scenario: A pharmaceutical company is accused of selling a drug that has allegedly caused a serious medical condition in a plaintiff who used it for only a few weeks. The epidemiological studies show an increase in that risk with the drug, *but only after a year or more of use*. The plaintiff has no studies to support her view that a much shorter exposure can similarly produce the condition.

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At trial, defense counsel assumes the plaintiff's expert will try to draw invalid inferences from the studies showing an increased risk only after prolonged exposure, or perhaps offer some speculation based on animal studies that bear no relation to how patients actually used the drug. The defense is cautiously optimistic the jury will agree the plaintiff has not carried her burden of proof—that she has not demonstrated that it is ''more likely than not'' that her condition was caused by her brief use of the drug.

And that is how the testimony unfolds for an hour or so. But then, toward the end of the direct, plaintiff's counsel shifts to a different gear:

> **Counsel:** In your opinion doctor, was my client's condition caused by taking the defendant's drug?
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> **Expert:** Yes. Absolutely.
>
> **Counsel:** How do you know that her condition can be caused by the defendant's drug after only a few weeks of use?
>
> **Expert:** *Because I have seen similar cases in my own practice. Some of my own young and otherwise healthy patients have developed this serious, life-threatening condition after short-term use — for just a few days.*
>
> **Counsel:** Could the condition in those patients you just mentioned have been caused by something else?
>
> **Expert:** No. I always use the process of differential diagnosis to determine the cause of my patients' illnesses. I ruled out alternative causes in these unfortunate patients.
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> **Counsel:** Thank you, doctor. That is all.

Most product liability lawyers have been confronted with this type of unsupported ''clinical'' testimony. Despite two well-established rules that together reflect the most basic notions of a fair trial — first, that expert testimony must be based on ''reliable evidence'' and, second, that a party is required to disclose an expert's opinions *and supporting data* prior to trial — the courts do not routinely require physicians to produce patient records even when they purportedly base their opinions on such personal ''clinical experience.''

This article argues that such unsupported testimony is contrary to those rules governing the admissibility of expert testimony and is not justified by any countervailing policy. We review the vice of such unsupported testimony; discuss some of the decisions that have recognized the problem; and use some well-known — but all too often ignored — rules of evidence and discovery to show how the problem can be avoided.

I. The Vice of Unsupported Anecdotal Testimony Based on 'Clinical Experience' Under Both Scientific and Legal Standards

Unlike testimony from a lay witness, expert testimony must meet scientifically-based reliability requirements before it can be admitted. And for a number of good reasons:

First, expert opinion, by definition, reflects ''wisdom'' derived from some specialized knowledge that extends beyond an individual's firsthand observations. Experts are thus permitted far more latitude than lay witnesses when they testify. They may express opinions without any personal knowledge of the facts; draw inferences from otherwise inadmissible documents and literature; and then testify to the ultimate issue in a case.[1] As the Supreme Court noted in *Daubert v. Merrell Dow*:

> Presumably, this relaxation of the usual requirement of firsthand knowledge — a rule which represents ''a most pervasive manifestation of the common law insistence upon 'the most reliable sources of information' '' — is premised on an assumption that the expert's opinion will have a reliable basis in the knowledge and experience of his discipline.[2]

Second, juries rely heavily on expert testimony precisely because, again by definition, an expert's opinion goes well beyond the jurors' own knowledge base.[3] Unless a defendant is lucky enough to have another doctor on the jury — a situation which most plaintiffs' counsel work hard to make as common as human spontaneous combustion — *any* doctor comes with knowledge few lay people possess.

Third, ''experts'' dazzle. The very label ''expert'' — and their formal ''acceptance'' by the trial judge after a discussion of their qualifications — gives them an aura of special credibility. Moreover, testifying experts are often professional witnesses and accordingly are more persuasive than the ''amateur'' fact witness they may follow to the stand.

Fourth, while the refutation of lay testimony is often relatively simple, that is generally not so with experts. When caught in a clear contradiction to the factual record (the proverbial traffic light was *not* red), the consequences for a lay witness can be swift and devastating. Medical experts, on the other hand, express complex and largely theoretical opinions based on any number of different second-hand sources, and hence their unsupported claims are far more difficult to unravel. Moreover, because medical witnesses generally testify to ''probabilities,'' and scientific experiments may reasonably yield differing results, expert opinions on causation can appear to be ''honest'' and yet in fact be completely unjustified.

Finally, the responsibility for determining the threshold reliability of expert testimony, especially medical causation testimony, often requires probing and sophisticated inquiry. Where jurors are usually able to evaluate an inexperienced lay witness' credibility through non-verbal cues and testimonial inconsistencies, that is often not the case when an expert testifies.

For all of these reasons, the *Daubert* Court rejected the long-standing ''general acceptance'' test in *Frye*,[4] developed a new, more flexible approach for evaluating the reliability of expert testimony, and then charged the trial judges with the duty to keep ''unreliable'' expert testimony from the jury.[5] Two subsequent Supreme Court opinions further explained how *Daubert* was to be enforced.

In *General Electric Co. v. Joiner*, the Court made it clear that trial judges were to enjoy considerable discretion in applying *Daubert's* non-exhaustive, multi-factor test.[6] And, in *Kumho Tire Co. v. Carmichel*, the Court rejected the Eleventh Circuit's view that *Daubert* applied only where the expert relies on ''scientific'' meth-

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[1] Fed. R. Evid. 703 and 704.

[2] *Daubert v. Merrell Dow Pharm. Inc.*, 509 U.S. 579, 592 (1993) (citation omitted).

[3] *See* Fed. R. Evid. 702.

[4] 54 App. D.C. 46, 47 (D.C. Cir. 1923).

[5] *Daubert*, 509 U.S. at 587-89, 597.

[6] *General Elec. Co. v. Joiner*, 522 U.S. 136, 146-47 (1997).

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ods in reaching his conclusions, but not ''where an expert 'relies on skill or experience-based observation,' '' and held that the *Daubert* approach to evaluating admissibility applied to *all* expert testimony.[7]

In 2000, Congress amended Rule 702 of the Federal Rules of Evidence to codify *Daubert*, *General Electric*, and *Kumho*.[8] As amended, the Rule now provides that where ''scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence,'' an expert possessing the requisite ''knowledge, skill, experience, training, or education'' may testify and give opinions related to his or her field of expertise *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.''[9]

Daubert in turn provides a more detailed set of factors to make this assessment of reliability.[10] The first is whether the method relied on by the expert is testable. If an experiment cannot be replicated, it is of little scientific value because it cannot be either verified or disproved. The second is whether the theory has been published and subjected to peer scrutiny; that is, whether other experts have had the opportunity to uncover experimental or theoretical flaws. The third is the potential rate of error—a consideration that in turn depends on the rigor of the particular methodological approach. And the final factor—a holdover from *Frye*—is whether the theory has achieved ''general acceptance'' in the relevant scientific community.

Daubert and Rule 702 thus in many respects track the standards for assessing the reliability of any purported ''causal relationship'' through epidemiological analysis codified by Sir Bradford Hill some 40 years ago.[11] Those criteria have been widely adopted by scientists and are often explicitly applied by courts.[12]

Although strictly speaking there are nine criteria, there are really five general areas of inquiry:[13]

1. *Biological Plausibility*. Is there already a scientific basis to explain the biological mechanism by which the agent could cause a given disease? If so, the purported relationship is more likely to be valid. Conversely, the more a theory of causation is inconsistent with what we already know, the more likely it is wrong.

2. *Consistency of the Association*. If two variables are consistently associated under a variety of circumstances, it usually means that at least some likely alternative causes can be ruled out. To determine whether an association is consistent, courts must look to the underlying data itself. Where well-controlled studies have been conducted, and the same result has been reproduced under varying conditions, confounding factors may be accounted for, and a more meaningful causal inference may be drawn.

3. *Whether the Results Show that the Cause Preceded the Effect*. Although this seems like an incredibly obvious test, a surprising number of studies and disorganized datasets actually fail to establish that the alleged cause in fact preceded the effect. Some diseases persist for many years before surfacing and hence may have existed prior to the administration of a drug. Where a study design or set of anecdotal reports fails to document when the subject actually *acquired* the disease, or relies on inaccurate data on that point, its reliability is doubtful.

4. *The Extent to Which the Cause and Effect Are Specific to Each Other*. Where the effect never occurs in the absence of a single cause, that improves the probability of a causal relationship between those two variables. But that is usually not the case; typically there can be a number of alternative causes for any given medical condition. And where there are many other known potential causes, it is difficult to single out any one in particular.

5. *Strength of the Association*. This inquiry focuses on how extreme the association appears to be based on the difference in the incidence of the medical condition as between the exposed and unexposed groups, any apparent dose-response relationship, and the study design. Normally these differences are tested with standard statistical tools to assess their level of ''significance.''

Like the factors identified in *Daubert*, none of these Bradford Hill indicators, standing alone, is either necessary or sufficient to establish causation. Rather, it is their cumulative effect that either gives an opinion credibility or undermines it as flawed.

These factors, of course, are all relevant in pharmaceutical products liability litigation where the plaintiff must show, typically through expert testimony, (1) that the indicted drug is capable of causing the specified injury (general causation), and (2) that the drug in fact caused the injury to the specific plaintiff (specific causation).[14] This two-step approach tracks the standard medical method of differential diagnosis — when properly applied, a reliable way to establish specific causa-

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[7] *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 151-52 (1999) (citation omitted).

[8] *See* Fed. R. Evid. 702 advisory committee's notes.

[9] Fed. R. Evid. 702.

[10] *Id.* at 593-96.

[11] A.B. Hill, *The Environment and Disease: Association or Causation?*, Proc. R. Soc. Med. 58:295-300 (1965).

[12] *See* Smith v. Wyeth, 278 F. Supp.2d 684, 693-694 n. 17 (W.D.N.C. 2003) (citing the Bradford Hill criteria as '' epidemiology basics''); *Merrell Dow v. Havner*, 953 S.W.2d 706, 718-19 (Tex. 1997) (''The strong consensus among epidemiologists is that conclusions about causation should not be drawn, if at all, until a number of criteria have been considered'' and citing the Bradford Hill criteria); *In re Breast Implant Litigation*, 11 F. Supp.2d 1217, 1233 (D. Colo. 1998) (rejecting expert testimony concerning the relationship between breast implants and rheumatoid arthritis and noting that ''[t]he rheumatology community looks to controlled studies (epidemiology) and the Bradford Hill criteria to determine the cause of diseases''). *See also Amorgianos v. Natn'l Railroad Passenger Corp.*, 137 F. Supp.2d 147, 168 (E.D.N.Y. 2001):

> Even when an appropriately designed study yields evidence of a statistical association between a given substance and a given health outcome, epidemiologists generally do not accept such an association by itself as proof of a causal relationship between the exposure and the outcome. Epidemiologists generally look to several additional criteria to determine whether a statistical association is indeed causal. These criteria are sometimes referred to as the Bradford Hill criteria, after the author of a leading statement of the principles.
>
> (internal citations omitted).

[13] *See* PHARMACOEPIDEMIOLOGY 20-22 (Brian L. Strom, ed., John Wiley & Sons Ltd. 3d ed. 2003).

[14] *E.g.*, *Farris v. Intel Corporation*, 493 F. Supp. 2d 1174, 1181-82 (D.N.M 2007); *In re Meridia Prod. Liab. Litig.*, 328 F. Supp. 2d 791, 798 (N.D. Ohio 2004); *In re Breast Implant Litig.*, 11 F. Supp.2d 1217, 1224 (D. Colo. 1998).

tion[15] — which requires first assembling all reasonably foreseeable potential causes and then ruling out each one based on a patient's medical history, until a single most likely cause remains.[16]

Because a physician has no reason to suspect the possible adverse effect of a drug until the weight of scientific studies establishes that it is capable of causing such an injury, where a plaintiff fails to demonstrate such ''general causation,'' the court need not even consider the question of specific causation.[17] Both medical science and the law recognize that there are differing degrees of ''proof'' on that first critical question of ''general causation,'' or what epidemiology generally refers to as the ''association'' between an agent and a medical condition. Yet, as we shall now discuss, although the courts too recognize this hierarchy of reliability, they all too often abandon it when a physician, on the stand—and sometimes off–the–cuff—cites his or her *own* personal ''clinical experience.''

Randomized, Controlled Studies

Though expensive and complex to conduct, the randomized, controlled study remains far and away the preferred method for establishing medical causation.[18] Epidemiologists begin by making observations about a well-defined population — ideally, a random sample under controlled conditions. From those observations, they then identify ''associations,'' comparing the incidence of some disease in a group exposed, versus a group not exposed, to some substance. They then must evaluate the underlying data, typically applying the Bradford Hill criteria, and determine the statistical probability that the association in fact reflects a true causal relationship.[19]

A well-designed, randomized and controlled study is thus the gold standard for reliability: ''The very purpose of epidemiology is to serve the type of testing function required by *Daubert*, *i.e.*, to discern accurately the effect of a particular agent on a disease against the background of the natural occurrence of the disease in the relevant population.''[20] Indeed, courts claim to be reluctant to find a sufficiently reliable basis where the underlying evidence lacks statistically significant epidemiological support.[21]

Some courts have even set their own special standards for ''significance'' in deciding whether to admit a given study. For example, in 1997 the Texas Supreme Court in *Merrell Dow v. Havner* concluded that because a proffered epidemiological study was not statistically significant, unpublished and isolated, it could not reasonably form the basis of a ''more probable than not'' finding that the drug at issue, Bendectin, actually caused birth defects.[22] Similarly, in *Brock v. Merrell Dow*, the Fifth Circuit held that, because of an intolerably low confidence interval and a lack of peer review, the one and only epidemiological study proffered by the plaintiff's experts was ''unreliable.''[23] Without such ''conclusive'' epidemiological evidence, the plaintiff's claim failed.[24]

Adverse Drug Event Reports

Lower down the epidemiological food chain, we find anecdotal ''case reports'' in the medical literature or files of the FDA. Such ''adverse drug reports'' and other anecdotal reports are generated when a patient, while taking a given drug, also develops some kind of medical condition. They thus merely report a temporal ''association'' and, accordingly, are more appropriate for generating hypotheses to be confirmed or refuted by real testing.[25]

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[15] *E.g.*, *Smith v. Wyeth-Ayerst Lab. Co.*, 278 F. Supp. 2d 684, 696-97 (W.D.N.C. 2003) (''A differential diagnosis like other expert testimony is deemed reliable when supported by scientific, technical, or other specialized knowledge or inferences derived from scientific or other valid methods.''); *Roche v. Lincoln Prop. Co.*, 278 F. Supp. 2d 744, 751 (E.D. Va. 2003) (''If faithfully applied, the methodology of differential diagnosis 'has widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results.' '') (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999)).

[16] *See generally Roche*, 278 F. Supp. 2d at 750-64 (discussing the characteristics of reliable differential diagnosis and thoroughly evaluating an expert's application of differential diagnosis before excluding it).

[17] *See, e.g.*, *Leathers v. Pfizer Inc.*, 233 F.R.D. 687, 694 (N.D. Ga. 2006) (''Having concluded that Plaintiff's expert failed to establish general causation, the Court need not discuss specific causation.''); *In re Meridia,* 328 F. Supp. 2d at 799 (where the plaintiffs offer insufficient evidence on general causation, ''it stops plaintiffs from demonstrating specific causation''); *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 525 (W.D. Pa. 2003) (''If plaintiff has not demonstrated sufficiently reliable evidence of general causation, her claims fail and there is no need to consider specific causation.'').

[18] *See generally* PHARMACOEPIDEMIOLOGY, *supra*, 22.

[19] *See, e.g.*, Smith, 278 F. Supp. At 693094; *Caraker v. Sandoz Pharms. Corp.*, 188 F. Supp. 2d 1026, 1031-32 (S.D. 111. 2001); *In re Breast Implant Litig.*, 11 F. Supp. At 1233; *See generally* PHARMACOEPIDEMIOLOGY *supra*, 17-28.

[20] *Soldo* at 533. *Accord In re Meridia*, 328 F. Supp. 2d at 791, 800 (N.D. Oh. 2004) (noting that although epidemiological evidence is not required, it is the primary method for establishing medical causation and '' '[w]hen an expert does not rely on the primary methodology for establishing causation, then that places a burden on the expert to explain his choice of methodologies' '') (quoting *Conde v. Velsicol Chem. Corp.*, 804 F. Supp. 972, 1025-26 (S.D. Ohio 1992)); *Gass v. Marriot Hotel Services Inc.*, 501 F. Supp 2d 1011, 1019 (' 'Under the *Daubert* standard, epidemiological studies are not necessarily required to prove causation, as long as the methodology employed by the expert in reaching his or her conclusion is sound.' '' (quoting *Benedi v. McNeil-PPC Inc.*, 66 F.3d 1379, 1384 (4th Cir. 1995))).

[21] *Soldo*, 244 F. Supp. 2d at 532-33 (listing cases reflecting the judicial disinclination to allow experts to rely on anything less than a statistically significant epidemiological study).

[22] *Merrell Dow Pharm. Inc. v. Havner,* 953 S.W.2d 706, 725-28 (Tex. 1997).

[23] *Brock v. Merrell Dow Pharm.*, 874 F.2d 307, 311-15 (1989) (identifying other factors that could also cause birth defects). *Accord Soldo*, 244 F. Supp. 2d at 533; *Daubert v. Merrell Dow Pharm. Inc.,* 43 F.3d 1311, 1319 (9th Cir. 1995).

[24] *Brock*, 874 F.2d at 313 (finding lack of reliable epidemiological evidence ''fatal'' where the only other evidence were animal studies of questionable applicability to humans).

[25] *See e.g., Amorgianos v. Nat'l R.R. Passenger Corp.*, 137 F. Supp. 2d 147 (E.D.N.Y. 2001) at 168 (referencing uncontrolled case studies and case-series reports in the context of occupational causes of disease, the court stated, ''because of their inherent limitations, these two study designs 'usually represent preliminary or pilot investigations used to screen for possible workplace hazards or to generate hypotheses for testing in more complex designs' ''); *Brumbaugh v. Sandoz Pharm. Corp.*, 77 F. Supp. 2d 1153, 1156 (D. Mont. 1999) (refusing to admit expert testimony on whether Parlodel caused plaintiff's injury where expert relied primarily on case reports because they merely reflect ''temporal associations between a

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The use of such adverse event reports (ADEs) to *begin* the process of scientific inquiry is likewise one important purpose of the ''Spontaneous Reporting'' or ''MedWatch'' system of the FDA. Pursuant to a series of detailed regulations and informal advisories,[26] the Agency requires all drug manufacturers (and encourages health practitioners as well) to report adverse events that appear to be temporally related to the administration of a drug. The form provided by the Agency for such reports[27] calls for information on the nature of the medical problem, the dose of the drug, the relative timing of drug use and the event, and all laboratory tests or other data that might be relevant.

Significantly, the FDA form also asks for any relevant information on ''pre-existing'' medical conditions and all concomitant medications, in recognition of the fact that such other conditions or products could be an alternative cause of the reported adverse event. And in practice, most drug manufacturers will attempt to obtain as many of the patient's medical records as possible to document and elaborate on these reports.

Yet despite this relatively robust level of detail, the official FDA form and related regulations state that ''Submission of a report does not constitute an admission that the medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.''[28] And, consistent with this cautionary note, ''the great weight of authority—and the most current authority—squarely rejects the use of ADEs and case reports for the purposes of establishing general causation.''[29]

For example, in *Soldo v. Sandoz Pharmaceuticals*, the court, in excluding an expert's opinion that the drugs in question could cause postpartum stroke, expressed doubt that such case reports could ever constitute a reliable basis for determining causation.[30] The court noted first that such reports typically contain only general information: The depth of their content rarely exceeds the observation that an injury surfaced while an individual was ingesting a specified substance, and ''they don't isolate and investigate the effects of alternative causation agents.''[31] The *Soldo* court further expressed concern that the information contained in case reports may well be inaccurate and/or biased—''they are second-or-third hand reports, are affected by medical or mass media attention, and are subject to other distortions.''[32]

To be sure, while most courts have thus held that case reports are not *per se* ''evidence'' of causation,[33] some have decided they can be an acceptable basis for expert testimony under certain conditions. For example, case reports could conceivably provide a reliable basis where they are numerous, they are highly detailed, the disease is extraordinarily rare, and there are no well-developed epidemiological studies establishing contrary findings.[34] But even here the report itself is available to use to challenge the expert's reliance and the inferences he or she draws from them.

Mere ''Clinical Experience''

Pushing even these conditions on adverse effect data, many courts have been persuaded to permit experts to rely on unvarnished ''clinical experience,'' even where that experience has not been recorded in a formal ''adverse event report'' or case report in the medical literature.[35] Such ''I know it because I've seen it'' testimony ignores the warning in *Daubert* that ''the more subjective an expert's inquiry, the more likely the testimony should be excluded as unreliable.''[36]

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drug's administration and an unexpected physical reaction''). *See also* PHARMACOEPIDEMIOLOGY *supra*, 22 (''Case reports are useful for raising hypotheses about drug effects, to be tested with more rigorous study designs.'').

[26] *See* Adverse Experience Reporting Requirements for Licensed Biological Products; Final Rule, 59 Fed. Reg. 54, 034-44 (1994); Food and Drug Administration, Center for Biological Evaluation and Research, Guideline for Adverse Event Reporting for Licensed Biological Products (1993).

[27] Over time, the form has variously been denominated as ''Form 1639,'' ''Form 3500-A'' and now the ''MedWatch Form.''

[28] Form 3500-A, Food and Drug Administration.

[29] *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 537042 (W.D. Pa. 2003). *See also In re Baycol Prod. Liab. Litig.*, 532 F. Supp. 2d 1029, 1039-40 (D.C. Minn. 2007) (excluding expert opinion on the toxicity of Baycol relative to other statins where opinion was based on adverse experience data and otherwise unsupported); *Farris v. Intel Corp.*, 493 F. Supp. 1174, 1182 (D.N.M. 2007) (''It is generally recognized that in the toxic tort context, 'with respect to general causation the relevant scientific field is epidemiology and not clinical medicine.' '') (quoting *Siharath v. Sandoz Pharm. Corp.*, 132 F. Supp. 2d 1347, 1351 (N.D. Ga. 2001)); *Leathers v. Pfizer Inc.*, 233 F.R.D. 687, N.D. 692-93 (N.D. Ga. 2006) (observing that adverse incident reports do not alone render an expert's opinion reliable); *Amorgianos* at 186 (rejecting expert testimony on relationship between exposure to xylene and nervous system damage, the court noted, ''[g]iven their anecdotal nature, the four case reports would for that reason alone probably not provide an epidemiologically reliable basis for an opinion on causation'').

[30] *Soldo*, 233 F. Supp. 2d at 540-41.

[31] *Id.* at 539-40 (quoting *Brumbaugh* at 1156). *See also Leathers*, 233, F.R.D. at 694 (''Some case reports are a very basic form report of symptoms with little or no patient history, description or course of treatment, or reasoning to exclude other possible causes.'').

[32] *Soldo*, at 539 (quoting *DeLuca v. Merrell Dow Pharm., Inc.*, 791 F. Supp. 1042, 1051 (D.N.J 1992)), 244 F. Supp. 2d.

[33] *See, e.g. Leathers* 233 F.R.D. at 694 (N.D. Ga. 2006) (''As an initial matter, adverse incident reports generally do not, standing alone, render an expert's opinion reliable under *Daubert*.''); *In re Diet Drugs*, 532 F. Supp. 2d 1029, 1040 2001 WL 454586 (2001 E.D. Pa.) (''[A]necdotal case reports . . . are universally recognized as insufficient and unreliable evidence of causation.'').

[34] *See Caraker v. Sandoz Pharm. Corp.*, 188 F. Supp. 2d 1026, 1035 (S.D. Ill. 2001) (''Granted, an overwhelming amount of case reports of a temporal proximity between a very specific drug and a very specific adverse event might be enough to make a general causation conclusion sufficiently reliable''); *In re Baycol Products Liability Litigation*, 532 F. Supp. 2d 1029, 1042-43 (D. Minn 2007) (emphasizing that exclusion of expert's testimony was not a holding that adverse event reports could not be proffered as evidence as a causal relationship); *Siharath v. Sandoz Pharm. Corp.*, 132 F. Supp. 2d 1347, 1351 (N.D. Ga. 2001) (excluding testimony because case reports lacked ''the requisite quantity, nature, and content'').

[35] *See Giles v. Wyeth*, 500 F. Supp. 2d 1048, 1061-62 (D. Ill. 2007) (allowing experts to testify that the anti-depressant Effexor could cause people to commit suicide in part based on their ''personal experience''); *Caraker v. Sandoz*, 188 F. Supp. 2d 1011, 1020-21 (D. Ill. 2001) (suggesting that an expert could rely on experience treating ''over 1,000 other patients for chemical and/or pesticide exposure,'' but must offer more than conclusory explanations).

[36] I*n re Meridia Prod. Liab. Litig.*, 328 F. Supp. 2d 791, 806 (citing *O'Conner v. Commonwealth Edison Co.*, 13 F.3d 1090

Indeed, Wigmore long ago recognized the vice of such testimony:

> To allow any physician to testify who claims to know solely by personal experience is to appropriate the witness-stand to imposters. Medical science is a mass of transmitted and collated data from numerous quarters; the generalizations which are the result of one man's personal observation exclusively are the least acceptable of all.[37]

As the Advisory Committee Note to the 2000 Amendments on the Rules of Evidence counsels, the courts should be particularly guarded in admitting such testimony:

> If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply taking the expert's word for it.[38]

This is especially true where, as is often the case, ''experience-based'' testimony is offered as a last resort. Indeed, experts will generally not turn to ''personal experience'' where there is other, more reliable data. Yet, as noted above, it is precisely where there is no evidence establishing general causation, that a physician making a differential diagnosis has no reason to suspect the substance as a potential cause. Judged by the proper *Daubert* standards, such *ipse dixit* testimony, even by the best-intentioned expert, should not be admissible.[39] As another court put it,

> [T]he problem with the opinions of [the testifying doctors] is that their ''ruling in'' decision requires too many analytical leaps and involves a loose application of purportedly objective scientific causation standards. For these and other reasons, the data these experts used to extrapolate their conclusions is suspect, and their opinions are more like personal opinions than products of any scientific method rigorously applied.[40]

In short, given the courts' rigorous evaluation of even controlled epidemiological studies, their general disdain for case reports even in the published literature, and their more probing analysis of differential diagnosis when used to establish *specific* causation, it is unfortunate that many then drop their guard and allow a physician to testify about causation based on his or her ''personal experience,'' without at least first producing the underlying data. Indeed, unless the underlying medical records are produced, a court simply cannot evaluate the reliability of such ''experience-based'' testimony. As we shall now show, such a minimal requirement is both legally and practically appropriate.

II. Limits on the Use of 'Clinical Experience' in the Diet Drug Cases

The litigation against Wyeth with respect to its diet drugs, Pondimin and Redux, produced some significant rulings in which more thoughtful judges recognized the inherent unfairness of permitting an expert to testify based on his or her own ''clinical experience'' *unless* that doctor first provided opposing counsel with the medical records concerning the patients he or she purported to describe. That litigation arose from an association between the Wyeth drugs and increased levels of heart valve insufficiency—the backward flow of blood through a valve that most people have to some degree, but can prove harmful if increased to ''severe'' levels—first observed in a series of patients from a clinic in Fargo, North Dakota.

Following that initial observation, Wyeth withdrew the two drugs from the market to permit it, as well as other independent researchers, to study the possible association in greater detail by comparing precise echocardiographic readings from large numbers of people who had, and had not, taken the drugs. Over the course of the next few years, as tens of thousands of lawsuits were filed, most in the scientific community came to a consensus based on those *controlled* studies that (1) the drugs in fact could increase the level of such incorrect blood flow in *some* patients, *but that* (2) real harm occurred only in those who had taken the drugs for a relatively long period (at least three months or more) *and* (3) the adverse effect of the drugs did not appear to continue (''progress'') after a patient ceased taking them.

Despite these findings from the controlled studies, however, many plaintiff attorneys continued to pursue claims of valvular heart disease on behalf of patients who had taken the drugs for very brief periods and/or plaintiffs who had at most ''mild'' levels of valvular insufficiency (common in the general population) on the theory that *in the future* they would progress to the point they would require surgery. Wyeth, in turn, defended those lawsuits by having its expert witnesses point out that both propositions—that short-term use could lead to serious problems or that a mild condition would progress to the point of surgery—were inconsistent with the results of the controlled studies. The plaintiffs predictably responded with testimony from their retained experts that, notwithstanding that rather clear epidemiological evidence, they believed the drugs *could* cause valvular heart disease in a particular plaintiff on a short-term basis and/or that their plaintiffs with only a mild insufficiency would likely progress to surgery be-

(7th Cir. 1992), *Daubert v. Merrell Dow Pharm. Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995)).

[37] *Wigmore*, EVIDENCE, § 687 (2d ed. 1923).

[38] Fed. R. Evid. 702 advisory committee note.

[39] *Daubert v. Merrell Dow Pharm. Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995) (''[A]n expert's bald assertion of validity is not enough.''). *See also, e.g.*, Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997) (''[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the ipse dixit of the expert.''); *Merrell Dow v. Havner*, 153 S.W. 2d 706, 712 (Tex. 1997) (reiterating that courts must look beyond the expert's mere assertion of validity); *In re Breast Implant Litig.*, 11 F. Supp. 1217, 123 (D. Colo. 1998) (''A statement does not become scientific knowledge because it is uttered by a doctor. Nor can an expert witness' self-serving assertion that his conclusions were derived by a scientific method be deemed conclusive.''); *Grimes v. Hoffmann-LaRoche, Inc.*, 907 F. Supp. 33, 38 (D.N.H. 1995) (finding that ''notwithstanding [the expert's] undeniable expertise,'' he could not ''establish that a fact is generally accepted merely by saying so'').

[40] *Caraker*, 11 F. Supp. 2d, 88 F. Supp. 2d at 1030-31 (D.C. Ill. 2001). *See also In re Breast Implant Litig.* at 1234 (excluding testimony where ''in the face of numerous epidemiological studies, [the expert] relies on his clinical experience, differential diagnosis, and his review of the medical literature'' and ''does not explain what alternative causes he considered, or how he ruled out other possible causes''); *Gass v. Marriott Hotel Services*, 501 F. Supp. 2d 1011, 1020-21 (D. Mich. 2007).

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cause, according to those experts, they had seen such cases in their own practices.

The problem with such ''clinical experience'' testimony from a scientific perspective was that, as even plaintiff's experts were forced to concede, such heart valve insufficiency can be found in the *general* population who had *never* taken a diet drug — in part because it can be caused by a host of other factors (simple hypertension, rheumatic heart disease, kidney problems, other drugs) which would readily explain the problem if such conditions or agents were noted in the medical history of the patients at issue. Similarly, such full medical histories might well show that there were signs that the patients in question had already had heart valve disease—for example, a simple heart murmur which indicates that condition — *before* the patient ever took the diet drug. These types of facts would, of course, be relevant under the Bradford Hill factors and would permit any epidemiologist—or any other doctor who had taken even a basic course in epidemiology—to dispute the expert's reliance on such cases.

But when Wyeth attempted to obtain such records from the experts who intended to rely on their ''clinical experience,'' they were rebuffed by plaintiff's counsel ostensibly on grounds of ''patient privacy.'' Wyeth took those disputes to a number of courts that generally ruled in favor of Wyeth's position, and required the plaintiff's expert either to turn over the relevant medical records or to drop that part of his or her testimony.

The most extensive and thoughtful decision was rendered by Judge Keith Starrett of the Circuit Court of Pike County, Mississippi, in *Allen v. Wyeth*.[41] In that case, Judge Starrett, after noting that that particular lawsuit was one of a thousand diet drug cases filed in that state, agreed that Dr. Malcolm Taylor, one of the principal cardiologists used by the plaintiff's bar in the Diet Drug Litigation, should produce to defense counsel the individual medical records concerning any patients on whom he intended to rely to support his views. Judge Starrett agreed that Wyeth was entitled to test the credibility of Dr. Taylor and the bases for his opinions by reviewing that underlying data:[42]

> An expert, or any other witness, should not be allowed to testify without giving the other side the right to question the reliability of the data that the expert bases his opinion on, the expert's technique for compiling and applying the data, whether the expert's opinion is generally accepted in the medical community and whether it is based on established reliable authority or confirmed by other expert studies. The degree of control over the data compilation and whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion is also proper for inquiry. All of these would be done to test the credibility of the witness and his opinions. A witness should not be allowed to boldly state an opinion, say it is based on data or studies and then refuse to disclose the data.[43]

Significantly, Judge Starrett rejected the plaintiffs' argument that producing such patient information would compromise patient confidentiality, noting that the identifying information could easily be redacted:

> The names and all identifying data are to be redacted from the patients' charts unless it has been previously furnished to the defendants in other litigation. If his database, or basis for his opinion, includes patients in litigation who have waived medical privilege regarding the defendant obtaining possession of medical records, they need not have the identifying data redacted. In fact, it would be beneficial for them to be identified and should remain so.[44]

In other Diet Drug cases, Wyeth secured similar relief. Most notably, the co-ordinating judges of the Philadelphia Court of Common Pleas ruled, in a ''global order'' applicable to all of the 8,000 cases filed in that court, that when a plaintiff expert intended to assert that they were aware of individuals who had gone on to surgery long after they ceased taking the Wyeth drugs, they must first provide the medical records to permit defense counsel to parse them for such things as alternative causes or disease that existed even before the diet drugs had been taken.[45] In all but one case where that requirement was imposed, the plaintiffs' experts promptly dropped their ''clinical experience'' from their testimony, rather than try to support it with the relevant medical records. And in the one case where a plaintiff expert did provide the information and was then cross-examined at trial, defense counsel was able to point out such alternative causes or pre-existing conditions to the jury.

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[41] Civ. No. 01-106-A (March 18, 2003).

[42] Although Judge Starrett began his decision by focusing on Rule 611(b) of the Mississippi Rules of Evidence, which provides that cross-examination is not expressly limited to matters of direct examination and matters affecting credibility of the witness, those two areas for inquiry — which are expressly permitted in cross by the Federal Rules — would in fact be in issue where such ''clinical experience'' is cited, and hence the same logic should apply under the Federal Rules or any state analog.

[43] *Id.* at 7-8.

[44] *Id.* at 8.

[45] *Hansen v. Wyeth*, No. 1063, (P.C.C.P. Sept. 15, 2004) (''If any such quantification [as to the risk of surgery ''based on non-litigation related clinical (defined as patient-care) experience''] is to be offered in direct examination, plaintiff is to provide notice with supporting documentation to opposing counsel prior to jury selection''); *Sinagra v. Wyeth*, No. 0337 (P.C.C.P. Dec. 30, 2004) (requiring plaintiff's expert to produce patient records and providing that ''if plaintiff fails to produce the materials . . . prior to jury selection'' plaintiff's expert will be precluded from relying on such experience to estimate the risk of future surgery); *Fontenoy v. Wyeth*, No. 124374 (P.C.C.P. Jan. 4, 2005) (''globalizing'' that prior order to all Diet Drug Cases in Philadelphia).

These rulings in the Diet Drug cases demonstrate the proper solution to the problem of unsupported ''clinical'' testimony: The court may permit experts to use such ''clinical data'' as one basis for its opinion, but only after providing opposing counsel with the relevant materials so as to permit effective and fair cross-examination. As we will now discuss, that approach should, in fact, be standard operating procedure under the Federal Rules.

III. Required Disclosure of the Bases of Expert Opinion Under the Federal Rules

Under Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure, and its corollary in the many states which have adopted the same policies, a party must produce a report for each expert it plans to call at trial containing a ''complete statement of all opinions the witness will express and the reasons for them.''[46] The party likewise must produce the ''data or other information'' on which the expert relied in forming his or her opinions,[47]

This rule is fully applicable to testifying physicians. Even treating physicians must disclose the bases for their opinions when they go beyond their factual account of the treatment of a plaintiff and extend to more general issues such as ''causation.'' Although that requirement seems obvious, there had previously been some confusion over whether treating physicians were experts for purposes of such disclosure under Rule 26. Most courts, however, now agree that where a treating physician testifies on general causation, he has crossed into expert territory and is thus equally subject to the written report requirement.[48]

In the event a party fails to supply an adequate report sufficiently in advance of trial, the courts will either limit a treating physician's testimony or exclude it entirely.[49] As the Advisory Committee Notes to Rule 26 recognize, this policy of full disclosure is especially appropriate where expert testimony on scientific issues is involved: ''In cases of this character, a prohibition against discovery of information held by expert witnesses produces in acute form the very evils that discovery has been created to prevent'' since ''effective cross-examination of an expert requires advance preparation.''[50]

Daubert likewise assumes that ''vigorous cross examination'' will be one of ''the traditional and appropriate means of attacking shaky but admissible [expert] evidence.''[51] But that, of course, requires prior knowledge of the bases of the expert's direct testimony. As another court recognized:

> Before an attorney can even hope to deal on cross-examination with an unfavorable expert opinion he must have some idea of the bases of that opinion and the data relied upon. If the attorney is required to await examination at trial to get this information, he will often have too little time to recognize and expose vulnerable spots in the testimony. He may need advice of his own experts to do so and indeed, in certain cases, his experts might require time to make further inspections and analyses of their own.[52]

The Rules of Evidence thus assume that there will be extensive pre-trial disclosure—at least if opposing counsel has been careful to demand it. For example, although Rule 703 formally permits experts to testify without expressly restating all the underlying facts or data in his or her direct testimony, Rule 705 then provides that ''the expert may in any event be required to disclose the underlying facts or data on cross-examination.''[53] And, the Advisory Committee Note to that rule in turn assumes that, in such cases, ''the cross-examiner has the advance knowledge which is essential for cross-examination.''[54] The effect of Rule 705 thus ''is to place the full burden of exploration of the facts and assumptions underlying the testimony of an expert witness'' on opposing counsel, which is appropriate only where there has been extensive pre-trial disclosure.[55]

An attorney faced with a witness who intends to rely on undisclosed ''clinical experience'' can also find assistance in Rule 403 which generally provides that even relevant evidence ''may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.''[56] The *Daubert* Court recognized that Rule 403 is fully applicable to expert testimony since, ''Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge in weighing possible prejudice against probative force under Rule 403 of the present rules exercises more control over experts than over lay witnesses.''[57]

Even before the Diet Drug decisions discussed above, thoughtful judges had used this combination of rules to exclude expert testimony purportedly based on undisclosed ''clinical'' assessments. For example, in the *Agent Orange Litigation,* Judge Weinstein rejected the affidavits of two physicians who had ostensibly analyzed the medical histories of some class members in

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[46] Fed. R. Civ. P. 26(a)(2)(B)(i).

[47] Fed. R. Civ. P. 26(a)(2)(B)(ii).

[48] *See, e.g., Leathers v. Pfizer*, 233 F.R.D. 687, 693, 696-98 (N.D. Ga. 2006) (noting that no matter how the witness is labeled, causation testimony is expert testimony, citing cases from a number of circuits in support of its position). *Accord Roche v. Lincoln Prop. Co.*, 278 F. Supp. 2d 744, 750 (E.D. Va. 2003) (concluding that a characterization as non-expert testimony will not be controlling, and that when testimony falls ''well within the role of a testifying expert,'' Rule 26 disclosure requirements cannot be avoided).

[49] *See* Fed. R. Civ. P. 37. *See generally Calhoun v. Klingensmith Healthcare Inc.,* 2007 WL 4205818 (W.D. Pa.) (discussing the various ways that courts approach the question of whether treating physicians must produce an expert report and how that will affect the scope of their testimony at trial).

[50] *See* Fed. R. Civ. P. Rule 26 advisory committee note (referencing ''food and drug, patent, and condemnation cases'' in its comment to Rule 26(b)(4)(A), which allows a party to ''depose any person who has been identified as an expert witness whose opinions may be presented at trial'').

[51] *Daubert v. Merrell Dow Pharm. Inc.*, 509 U.S. 579, 596 (1993).

[52] *Smith v. Ford Motor Co.*, 626 F.2d. 784, 794 (10th Cir. 1980) (quoting Friedenthal, Discovery and Use of an Adverse Party's Expert Information, 14 Stan. L. Rev. 455, 485 (1962)).

[53] Fed. R. Evid. 705.

[54] Fed R. Evid. 705 advisory committee's notes.

[55] *See Smith*, 626 F.2d at 793 (quoting Grahm, Discovery of Experts under Rule 26(b)(4) of the Federal Rules of Civil Procedure: Part One, An Analytical Study, 1976 U. Ill. L. F 895, 897).

[56] Fed. R. Evid. 403.

[57] *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 596.

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part because ''no medical records of any of the 300 opt-out plaintiffs [had] been submitted by the plaintiffs.''[58] Focusing on some of the epidemiological problems noted above — the failure to account for contrary studies; the ''inadequacy'' of the doctors' efforts to exclude alternative causes; and the absence of thorough discussions of the ''individual plaintiff's medical histories and personal habits'' — Judge Weinstein concluded that such conclusory and subjective opinions simply were not admissible under Rule 703.[59] Judge Weinstein then went further and held that ''the doctors' unfounded insistence that Agent Orange caused these afflictions only exacerbates the already emotionally charged atmosphere of this case and requires exclusion under Rule 403 of the Federal Rules of Evidence.''[60]

Another district court has likewise held that Rule 403 is thus an appropriate basis to require more than unsupported statements on the alleged link between a drug and some disease:

> In a highly technical case like this, where a lay trier of fact cannot possibly determine the precise etiology of the injury without guidance from expert opinions, there is a risk that the jury would make an irrational finding of causation based upon the siren-like allure of opinions stated by highly qualified experts. Thus, an expert's opinion must have some basis other than hypothesis before the opinion may have the privilege of being assailed by cross-examination.[61]

The combination of the procedural requirements of Rule 26 together with the ''gate-keeping'' functions of *Daubert* and these Rules of Evidence provide an opposing counsel with a more than sufficient basis to demand the medical records of patients that an expert intends to cite—especially when the expert is allegedly divining from those ''cases'' causation conclusions that are not supported by controlled studies. It should also be remembered that Rule 26(a)(2)(B) requiring these detailed expert reports and Rule 37(c)(1) provide for exclusion where testimony is not so supported, and even provides that a party should not be allowed to avoid disclosure of an expert's underlying data in federal court by asserting that the information is privileged.[62] The Advisory Committee Notes to Rule 26 recognizing that such disclosure trumps even traditional ''work product'' objections likewise support this conclusion.[63] In short, if for any reason, an expert cannot produce the underlying data that purportedly supports his or her opinion, the simple solution is to preclude such ''clinical'' testimony.[64]

To be sure, in an attempt to avoid the disclosure the Federal Rules thus effectively mandate, the sponsors of physicians who wish to rely on ''clinical experience'' may argue that disclosure of such patient records is impractical or even illegal. Not so.

Federal law does not prohibit the appropriate disclosure of non-party patient medical records in a litigation context. To the contrary, the Health Insurance Portability and Accountability Act (HIPAA) ''created a procedure for obtaining authority to use medical records in litigation.''[65] Under the related HIPAA regulations, a ''covered entity'' may disclose patient medical records, without any other authorization, ''in any judicial or administrative proceeding'' where (1) a court has ordered disclosure and such disclosure is limited to the information ''expressly authorized by such order,'' or (2) ''in response to a subpoena, discovery request, or other lawful process,'' where the covered entity has received ''satisfactory assurance'' that the party requesting the records has obtained a protective order that limits use of the information to the proceeding for which it was requested.[66]

Although a state law addressing identifiable patient medical information which is more protective can take precedence in some other contexts,[67] HIPAA, not state law, governs where identifying information about the patient has been redacted.[68] In that case, any more stringent state requirements do not apply.[69] As a result, patient records need only be redacted to be disclosed.[70]

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[58] 611 F. Supp. 1223, 1247 (E.D.N.Y 1985).

[59] *Id.* at 1251-55. *Accord Emigh v. Consolidated Rail Corp.*, 710 F. Supp. 608 (W.D. Pa. 1989) (where a testifying expert provided no evidence that he had considered critical information, including the plaintiff's medical history and potential for alternative causes, and the defendants were not aware that the expert was going to rely on the underlying reports supplied by two physicians who would be unavailable at trial, the prejudice to the defendant — arising from the fact that they ''had no opportunity to investigate, expose and rebut'' any of the testimony, the expert's opinion had to be excluded pursuant to Rules 703 and 403).

[60] *Id.* at 1253.

[61] *Porter v. Whitehall Lab. Inc.*, 791 F. Supp. 1335, 1345 (S.D. Ind. 1992). *See also United States v. Downing*, 753 F.2d 1224, 1239 (3d Cir. 1985) (''The danger that scientific evidence will mislead the jury might be greater, for example, where the jury is not presented with the data on which the expert relies, but must instead accept the assertions as to the accuracy of his conclusions.'').

[62] *See* Fed. R. Civ. P. 26 advisory committee's notes. (''Litigants should no longer be able to argue that materials furnished to their experts to be used in forming their opinions — whether or not ultimately relied upon by the expert — are privileged or otherwise protected from disclosure when such persons are testifying or being deposed.'') *Accord* WRIGHT, MILLER & MARCUS, FEDERAL PRACTICE & PROCEDURE § 2031.1 (''The Advisory Notes indicate that this requirement should apply even if these materials are otherwise privileged. . . .'').

[63] *See* the 1970 advisory committee notes to Fed. R. Civ. P. 26(b)(4), ''[The revision] also rejects as ill-considered the decisions which have sought to bring expert information within the work-product doctrine,'' and the 1993 advisory committee notes to Rule 26(a)(2)(B), ''[l]itigants should no longer be able to argue that materials furnished to their experts to be used in forming their opinions — whether or not ultimately relied upon by the expert — are privileged or otherwise protected from disclosure when such persons are testifying or being deposed.''

[64] *See Apicella v. McNeil*, 66 F.R.D. 78 (E.D.N.Y. 1975) (denying discovery motion for data underlying an article in a medical journal based on journalist's privilege but excluding the article from evidence pursuant to Rule 403).

[65] *United States v. Hi-Bek*, 493 F.3d 790, 802 (7th Cir.) at 802 (citing *Northwestern Mem'l Hosp.*, 362 F.3d at 926).

[66] 45 C.F.R. § 164.512(e).

[67] 45 C.F.R. § 160.203(b) (providing for an exception to the general rule that HIPAA preempts state law where ''[t]he provision of state law relates to the privacy of *individually identifiable health information* and is more stringent than a standard, requirement, or implementation specification adopted under subpart E of 164 of this chapter'') (emphasis added).

[68] 45 C.F.R. § 160.20.

[69] 45 C.F.R. § 164.502(d)(2). *See also* 45 C.F.R.§ 160.203 (providing for preemption); 45 C.F.R. § 164.514 (describing the requirements for de-identification).

[70] 45 C.F.R. § 164.514.

And the HIPAA regulations further provide that those redactions—primarily personal identifiers such as names and Social Security numbers—can be made while still leaving the important information on prior medical conditions or commitant medications that a cross-examiner needs to refute unjustified reliance by a physician on ''clinical experience.''

Finally, as a practical matter, asking a doctor to produce the medical records underlying his or her opinion is not an unduly burdensome request in an age where such records are centralized and often computerized.[71] Indeed, most physicians regularly supply third parties with patient medical data in seeking reimbursement from insurance companies, reporting ''adverse events'' patient drug-responses to pharmaceutical companies, or in reporting to the Department of Health and Human Services. The mechanisms for efficiently producing such data are thus already in place.

Conclusion

Expert or treating physicians who intend to rely on their ''clinical experience'' to support their medical opinions at trial — especially when their ''conclusions'' are inconsistent with the findings of *controlled* studies — should be required as much as any other expert to disclose fully the ''bases'' of that testimony, *i.e*. the medical records of the patients they purport to describe. The rules of both civil procedure and evidence provide ample authority for such pre-trial disclosure; and commonsense cross-examination practice requires no less.

[71] HIPAA, in fact, was enacted in response to the explosion of the ''electronic record.'' *See Arons v. Jutkowitz*, 880 N.E. 2d 831, 839-40 (Court of Appeals, N.Y. November 27, 2007). The goal was to facilitate ''portability,'' but ''this shift away from paper-based to systematized electronic records was perceived to threaten the confidentiality of sensitive patient information.''

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