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PRACTICE TIP

Pleading Medical Device Complaints

By Larry Goldhirsch

The heightened pleading requirements of *Bell Atlantic Corp. v. Twombly*, 550 US 544 (2007), require that practitioners who plan to file a complaint in a medical device case be even more cautious than usual. Otherwise, they may be subject to a dismissal on the pleadings. To begin with, a product liability case for the failure of a medical device is unlike other product cases. For Class III Medical Devices — those that are most critical to human health and subject to extensive federal premarket approval regulations — a mere failure of the product is insufficient to bring an action. When "ordinary" products fail, the plaintiff can sue under state causes of action in negligence, strict liability in tort or breach of warranty; however, when a Class III device fails, such actions are expressly preempted by the Medical Device Act. 21 U.S.C. 360k(a).

State-Based Causes of Action

The statute expressly preempts state common law actions arising out of malfunctioning devices if they are "different from or in addition to any federal requirement applicable … to the device." This means that any state law — whether a common law cause of action , state

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Effective Use of Evidence-Based Medicine to Challenge Causation Testimony

By John D. Sear

Medical experts testifying about causation in toxic tort, medical device, and pharmaceutical litigation frequently claim to base opinions upon a dispassionate review of the scientific literature, purporting to do the same analysis they perform in their clinical practices. But peeling back the façade often reveals that they have done nothing of the kind. In fact, although many medical experts proclaim adherence to scientific methods and procedures adopted or endorsed by various organizations, cross-examination often reveals the falsity of that assertion. By contrasting the experts' litigation analysis to the analytical standards of their profession, a party can effectively challenge the admissibility of causation testimony.

Explanation

In the last decade, medical organizations and peer-reviewed journals have adopted principles of evidence-based medicine, which can apply to an expert's medical causation analysis. According to the Ninth Circuit, evidence-based medicine compares a patient's condition against a background of peer-reviewed literature. *See Primiano v. Cook*, 598 F.3d 558, 567 (9th Cir. 2010). *Primiano* explains that evidence-based medicine embodies science and judgment:

> The classic medical school texts … explain that medicine is scientific, but not entirely a science. Medicine is not a science but a learned profession, deeply rooted in a number of sciences and charged with the obligation to apply them for man's benefit. Evidence-based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. Despite the importance of evidence-based medicine, much of medical decision-making relies on judgment — a process that is difficult to quantify or even to assess qualitatively. Especially when a relevant experience base is unavailable, physicians must use their knowledge and experience as a basis for weighing known factors along with the inevitable uncertainties to make a sound judgment.

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Id. at 565 (quotations and footnotes omitted). While many medical experts claim to adhere to evidence-based medicine principles both inside the courtroom and out, their adherence often amounts to little more than lip service. When the experts' analysis reflects more litigation-driven judgment and less scientific method, their testimony can and should be challenged and excluded.

Evidence-Based Medicine Principles

Many organizations and scientific journals have adopted evidence-based medicine in one form or another. Oxford University's Centre for Evidence Based Medicine is well-known. *See* www.cebm.net/index.aspx?o=1001 (last visited July 7, 2011). While many organizations embrace evidence-based medicine concepts, not everyone subscribes to them. *See Hendrix v. Evenflo Co.*, 255 F.R.D. 568, 607 n.72 (N.D. Fla. 2009) ("Some in the medical community appear opposed to this, calling it derogatory of traditional clinical experience."), aff'd, 609 F.3d 1183 (11th Cir. 2010). To illustrate the use and application of evidence-based medicine principles, orthopedic medicine standards are illustrative.

The American Academy of Orthopedic Surgeons (AAOS) recognizes evidence-based medicine principles. *See, e.g.*, Joseph Bernstein, M.D., M.S., Evidence-Based Medicine, 12 J. *Am. Acad. Orthop. Surg.* 80 (2004); Kurt P. Spindler, M.D., et al., Reading and Reviewing the Orthopaedic Literature: A Systematic, Evidence-Based Medicine Approach, 13 *J. Am. Acad. Orthop. Surg.* 220 (2005). AAOS evidence-based medicine attempts to infuse some objectivity into medical decision-making:

> It requires us to make decisions by critically reading and reviewing the literature, then weighing the findings reported in studies by the scientific validity of the work and the researchers' approach. *Evidence-based medicine asks us to be more critical about the changes that we make in our practice. It requires us to use the best evidence by placing more value on well-designed and well-executed clinical investigations and less value on expert opinion and uncontrolled observational studies (e.g., case reports and case series).*

Reading and Reviewing the Orthopaedic Literature, *supra*, at 220–21 (emphasis added).

AAOS evidence-based medicine methodology treats different types of evidence differently:

> In clinical research, not all sources of evidence are created equal. Among studies reporting on treatment outcomes, most epidemiologists would agree with the following pyramid of evidence:
>
> Randomized controlled trial
> Prospective cohort study
> Retrospective cohort study
> Case-control study
> Case series
> Case report
> Expert opinion
> Personal observation

Evidence-Based Medicine, *supra*, at 83. "[W]eaker study designs are frequently used to generate hypotheses in a field, whereas stronger designs are used to test hypotheses." Reading and Reviewing the Orthopaedic Literature, *supra*, at 221; Mininder S. Kocher, M.D., M.P.H. & David Zurakowski, Ph.D., Clinical Epidemiology and Biostatistics: A Primer for Orthopaedic Surgeons, 86 *J. Bone & Joint Surg.* 607, 608 (Mar. 2004) (" … [C]ase series are often anecdotal, are subject to many possible biases, lack a hypothesis, and are difficult to compare with other series. Thus, case series are usually viewed as a means of generating hypotheses for additional studies but not as conclusive."). Evidence-based medicine requires scientific consideration of the strength, validity, and type of

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Litigation Update

By David R. Geiger and Creighton K. Page

Supreme Court Holds Federal Vaccine Statute Expressly Preempts All State Law Design Defect Claims Against Vaccine Manufacturers Rather Than Only Claims Where Injury Could Not Have Been Avoided By Feasible Alternative Design

In *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068 'Feb. 22, 2011), a child's pediatrician administered doses of the diphtheria-tetanus-pertussis (DTP) vaccine according to the Center for Disease Control's recommended childhood immunization schedule. Within 24 hours of her vaccination, the child began to experience seizures, suffering over 100 of them within a single month. Her doctors eventually diagnosed her with "residual seizure disorder" and "developmental delay." Thereafter, the child's parents commenced a proceeding seeking compensation for her injuries pursuant to procedures set forth in the National Childhood Vaccine Injury Act of 1986 (NCVIA).

Under the NCVIA, a person injured by a vaccine may file a petition for compensation from the manufacturer in the United States Court of Federal Claims, naming the Secretary of Health and Human Services as the respondent. Within 240 days, a special master is required to make an informal adjudication of the petition applying a detailed no-fault compensation scheme set forth in the statute. Any objections are subject to review under similar time constraints by the claims court, which then enters final judgment. A claimant may choose either to accept the court's judgment or forego a tort action against the manufacturer or reject the judgment and pursue such an action.

After the special master denied plaintiffs' claim and the claims court confirmed the denial, plaintiffs filed suit in Pennsylvania state court, alleging that the defective design of the DTP vaccine caused their child's disabilities and the manufacturer was subject to both strict and negligence liability for defective design under Pennsylvania common law. Upon removal of the action to federal court, the United States District Court for the Eastern District of Pennsylvania granted summary judgment for the defendant, holding that Pennsylvania law was expressly preempted by an NCVIA provision that "[n]o vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side-effects that were unavoidable, even though the vaccine was properly prepared and was accompanied by proper directions and warnings." Plaintiffs appealed, and the United States Court of Appeals for the Third Circuit affirmed. The United States Supreme Court granted certiorari to address the scope of the NCVIA's preemption provision.

The Court held that the NCVIA preempts all design defect claims seeking compensation for injury or death caused by a vaccine's side-effects. The Court reasoned that the language of the provision referring to side-effects that were "unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings" took the vaccine's particular design as a given and thus extinguished liability for injuries arising out of that design. In addition, the three traditional bases for product liability are defects in design, manufacture and warnings, and the provision's mention only of the latter two suggested that claims arising from the first were what Congress intended to preempt. By contrast, plaintiffs' argument that the NCVIA preempts only claims arising from side-effects that were unavoidable by the adoption of feasible alternative designs was not supported by the statutory language. Further, plaintiffs' contention that design defect claims were immunized only if the manufacturer had properly manufactured the vaccine and warned about its risks was not grammatically supported, as the statute used the phrase "even though" rather than "and" after the word "unavoidable."

Beyond the language of the preemption clause itself, the Court noted that other provisions of the statute, and of the United States Food and Drug Administration (FDA) regulations thereunder, impose various requirements on both vaccine manufacture and vaccine warnings, while there are no provisions about vaccine design. Thus both the statutory structure and language supported the result reached by the Court. In light of this, the Court stated there was no need to resort to consideration of legislative history, but in any event, examination of that history provided no support for plaintiffs' arguments. Indeed, part of a House committee report counseled claimants who could not prove a manufacturing or warning defect to pursue the compensation scheme rather than a tort remedy, again supporting the conclusion that there was no tort remedy for design defects.

MA Federal District Court Holds Defense Expert's Testimony on Lack of Causal Link Between Drug and Suicide Attempts Admissible Because Expert Relied on His Own Peer-Reviewed Study

In *In re Neurontin Marketing and Sales Practices and Products Liability Litigation*, 2011 WL 1048971 (D. Mass. Mar. 18, 2011), over 100 individuals experienced behavioral disturbances, depression and ultimately suicidal actions, including completed suicide, after their doctors prescribed an anti-epileptic drug, gabapentin. The individuals

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Litigation Update

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and their estates' representatives sued the drug's manufacturers in the United States District Court for the District of Massachusetts, alleging the drug caused the individuals' injuries and deaths. Since 2004, gabapentin has been the subject of a protracted multi-district litigation with two distinct parts: 1) "sales and marketing" actions brought by consumer purchasers and third-party payors stemming from an alleged fraudulent off-label marketing scheme; and 2) "products liability" actions, such as this one, alleging injuries resulting from the use of gabapentin. In the latter type of action, plaintiffs bear the burden of establishing both general and specific causation. As explained in the Federal Judicial Center's Reference Manual on Scientific Evidence, cited by the court, "General causation is established by demonstrating, often through a review of scientific and medical literature, that exposure to a substance can cause a particular disease … . Specific, or individual, causation, however, is established by demonstrating that a given exposure is the cause of an individual's disease … ."

In support of their theory of general causation, plaintiffs relied upon a meta-analysis by the FDA of various manufacturers' clinical trials. The analysis supported an association between one class of anti-epileptic drugs — which included gabapentin and four others — and an elevated risk of suicidal thoughts and behavior short of an actual suicide attempt. The Defendants' expert, however, conducted studies specifically of gabapentin, which were published in a peer-reviewed journal, from which he concluded that, regardless of whether the drug causes an increase in suicidal thoughts or behavior, there was no increased risk of actual suicide attempts. In an unpublished supplemental report, the expert expanded his conclusion, opining that the drug did not even increase the risk of suicidal thinking or behavior.

Plaintiffs moved to partially exclude the testimony of the defendants' expert because the methodology of his studies was unreliable. Specifically, plaintiffs argued the expert's findings should be characterized in terms of "associations" rather than "causal inferences," and attacked his methodology on the basis that it did not take into account the concomitant effect of certain other drugs taken by the gabapentin patients.

The court denied the motion to exclude the defendants' expert's testimony despite finding that plaintiffs' criticisms "undermined" the expert's opinion. Citing the publication of the expert's study in a peer-reviewed journal, the court explained that the expert's opinion was not so fundamentally unsupported that it must be excluded. Instead, the conflicting views of the plaintiffs' and defendants' experts should be explored through cross-examination and submitted for a jury's consideration. However, the court did preclude the defendants' expert from testifying that his studies supported any conclusion relating to suicidal thoughts (as discussed in his unpublished supplemental report), as the studies had been specifically limited to the issue of suicide attempts.

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study in drawing conclusions, not merely spouting off one's "inference" or "judgment" after reading a bundle of articles:

> [A] well designed and executed double-blind randomized controlled prospective clinical trial with excellent follow-up provides stronger evidence for the use of diagnostics and therapeutics than do weaker designs. *Although case reports and case series still have value (such as alerting clinicians to new diseases or alerting researchers to new treatments that may be worthy of study), study designs that use appropriate comparison groups and pay careful attention to sources of bias should be held in higher regard when accumulating evidence to change the way we practice.*
>
> *This concept of ranking research studies in terms of their methodological strength is called the hierarchy of evidence.* It is being used by many journals, including The Journal of Bone and Joint Surgery, Clinical Orthopaedics and Related Research, Arthroscopy, and The American Journal of Sports Medicine to classify published manuscripts … . In considering whether to change one's practice based on the results of an evidence-based study, it is imperative to know the type of study used in order to judge the methodologic strength of the study.

Reading and Reviewing the Orthopaedic Literature, *supra*, at 223 (emphasis added); Clinical Epidemiology and Biostatistics, *supra*, at 613 ("The steps of evidence-based medicine involve converting the need for information into an answerable question; tracking down the best evidence to answer that question; critically appraising the evidence with regard to its validity, impact, and applicability; and integrating the critical appraisal with clinical expertise and the patient's unique values and circumstances."). Only valid, reliable evidence can support inference of causation:

> *[T]he standard to prove cause-effect is set higher than the standard to suggest an association.* Inference of causation requires supporting data from non-observational studies such as a randomized clinical trial, a biologically plausible explanation, a relatively large effect size, reproducibility of findings, a temporal relationship between cause and effect, and a biological gradient demonstrated

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Judge Rules GSK's 'Nerve Center' in Philadelphia for Paxil Suits

Calls DE Office No More Than 'Closet'

By Shannon P. Duffy

Lawyers for GlaxoSmithKline (GSK) were enjoying something of a winning streak in their efforts to remove drug product liability lawsuits to federal court — and keep them there — by arguing that it has converted to a limited liability company that is based in Delaware. But that streak may now be over.

U.S. District Judge Timothy J. Savage ruled that GSK cannot claim Delaware citizenship for purposes of federal diversity jurisdiction because its true "nerve center" is in Philadelphia and its Delaware office is nothing more than a "closet" that measures 10'-by-10' and is almost never used.

Delaware vs. Philadelphia

While other judges had accepted affidavits from GSK executives that described the corporation's presence in Delaware, Savage ordered extensive discovery, including the deposition of GSK's CFO in London, to explore more deeply whether Delaware is truly where GSK's officers "direct, control and coordinate" the corporation's activities.

GSK argued that, because it is an LLC, Savage should look to the citizenship of the LLC's members, and that GlaxoSmithKline Holdings (Americas) Inc., which is headquartered in Wilmington, DE, is the only member of GlaxoSmithKline LLC. But Savage said the evidence showed that the holding company "does no more in Wilmington than is necessary to preserve its corporate status as a Delaware corporation under Delaware law." The holding company's board meetings "are mere formalities to ratify decisions made elsewhere," Savage found, and its Delaware office "is the size of a closet and not used to conduct any business."

As a result, Savage remanded eight lawsuits to the Philadelphia Common Pleas Court brought by women who claim they took the drug Paxil while pregnant and that their babies now suffer from birth defects.

Broad Impact

The impact of Savage's opinion in *Brewer v. GlaxoSmithKline* could be broad, potentially making it impossible for GSK ever to remove lawsuits successfully to the federal courts in Pennsylvania if other judges adopt Savage's reasoning.

GSK could now face the prospect of a Philadelphia state court jury in defending a growing wave of lawsuits over drugs such as Avandia, a diabetes treatment, and Lamictal, an anti-seizure drug. Many of the plaintiffs in those cases hail from other states, but chose to sue on GSK's home turf in order to avoid removal to federal courts in their home states.

The ruling's impact could go much further, too, because Savage lays out a roadmap for plaintiffs' lawyers to prove, whenever a corporation is claiming Delaware citizenship, that the company's Delaware presence is minimal and does not satisfy the U.S. Supreme Court's new "nerve center" test.

GSK's lawyer, Joseph E. O'Neil of Lavin O'Neil Ricci Cedrone & DiSipio, said the company is disappointed by Savage's ruling and that "we continue to believe the facts and law support GSK's right to remove these cases to federal court." Although Savage's ruling is not appealable, O'Neil said GSK "will continue to pursue its procedural options in other cases."

Attorney Rosemary Pinto of Feldman & Pinto, who argued the remand motion for the plaintiffs, said Savage had recognized the import of the U.S. Supreme Court's 2010 decision in *Hertz Corp. v. Friend*, which specifically said a corporation's citizenship cannot be based on nothing more than a "mail drop box." Pinto said that if Savage had accepted GSK's arguments, "then any corporation could establish diversity jurisdiction by simply creating a holding company."

Savage, however, found that the extensive discovery in the Paxil cases showed that the board meetings are very brief and that board members from Philadelphia often participate by phone. The bulk of Savage's opinion focuses on describing the complex corporate structure of GSK and the nature and activities of the holding company. GlaxoSmithKline plc is a British company that is at the top of the GlaxoSmithKline global group of companies, Savage found, and GlaxoSmithKline LLC is the entity through which the British parent conducts its pharmaceutical and consumer health care business in the United States.

Until October 2009, the parent company had conducted its United States business through SmithKlineBeecham (SKB), a firm headquartered in Philadelphia. But for tax purposes, SKB was converted to a Delaware LLC as part of a joint venture with Pfizer. Savage accepted GSK's explanation that Delaware was chosen because, unlike Pennsylvania, it allows a corporation to convert to a limited liability company without liquidating or dissolving the corporation.

Savage found that his task, in applying the nerve center test, was to determine where the LLC's principal place of business is, and that the justices instructed courts to look for the "brain" of the corporation. Although GSK urged Savage to find that the holding company, as the only member of the LLC, conducted its business from Delaware, Savage concluded that the evidence proved otherwise.

"In short, the operational and business decisions affecting LLC are not made by [the holding company] or its board of directors, but are made and directed by the officers and directors of LLC," Savage wrote. In Hertz, Savage said, the justices made a distinction "between the place where the operational goals are set and where the operations are carried out." The

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Shannon P. Duffy is a Court Reporter for ALM. This article also appeared in *The Legal Intelligencer*, an ALM sister publication of this newsletter.

'Nerve Center' Ruling

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focus, Savage said, is on the operational decision-making process.

"A holding company, unlike an operating company, does not typically make decisions directly affecting business operations of its constituent companies. Those decisions are usually made by each of the companies under its umbrella. That is the situation here," Savage wrote. Under Delaware law, Savage said, the holding company is not a "member-managed" company, but rather a "manager-managed" company. As a result, Savage found that the holding company "has delegated the operational decision-making authority and power of LLC to LLC's officers and directors. Put another way, [the holding company] has determined that the directors and officers of LLC are to be LLC's 'managers.'"

That fact proved fatal to GSK's arguments because Savage concluded that the holding company "has factually and legally delegated the vast majority of its decision-making to LLC's officers and directors — the 'managers' of LLC — who operate from Philadelphia." Savage emphasized that he was "not focusing on the business activities taking place in Philadelphia," but instead was focused only on "the place from where those operations are directed, controlled and coordinated."

"That place is Philadelphia, where the top-level officers to whom [the holding company] delegated the decision-making authority are headquartered," Savage wrote. "Having delegated the direction, control and coordination of LLC to managers who operate from Philadelphia," Savage said, the holding company "has effectively transplanted the vast majority of its 'brain' or 'nerve center' to its managers in Philadelphia, leaving only a small part of its 'brain' in Delaware.

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by a dose-response relationship.

Clinical Epidemiology and Biostatistics, *supra*, at 608 (emphasis added).

Admissibility

Plaintiffs and defendants frequently differ, often stridently, over admissibility of case series and reports and whether they can reliably support causation. *See, e.g., Hollander v. Sandoz Pharms. Corp.*, 289 F.3d 1193, 1210 (10th Cir. 2002) (discussing arguments for and against admissibility of case reports and case series). Of course, case reports and case series can provide valuable information a clinician can use in treating a patient and generating hypotheses for further study. *See* Evidence-Based Medicine, *supra*, at 83 ("Therefore, absent other evidence, a case report can be the legitimate basis for action. Weak evidence is not the same as no evidence."). But a clinician's use of case reports to support treatment decisions, however, is a far cry from basing conclusions of causation on them. *See e.g., Hollander*, 289 F.3d at 1213 ("The data on which they rely might well raise serious concerns in conscientious clinicians seeking to decide whether the benefits of the drug outweigh its risks. However, in deriving their opinions that Parlodel caused Ms. Hollander's stroke from the various sources we have outlined, [the experts] all made several speculative leaps."). So, admissibility hinges not on the expert's consideration of case reports or series, but, rather, on the use to which they put them in their overall analysis.

Evidence-Based Medicine Versus Unconstrained Judgment

Evidence-based medicine methodology, therefore, requires "conscientious, explicit and judicious" consideration of available scientific data with due regard for the relative weight and validity of the studies that data comprises. Litigation experts, by contrast, often lump all scientific studies together regardless of their type, weight, or validity, giving inconclusive and often conflicting, paradoxical case reports, literature reviews, and in vitro and in vivo animal studies predominant weight on the question of causation. The record may reveal no critical analysis of the data or dispassionate balancing or weighting of the evidence by the experts, but only a bundling of articles without regard for their limitations. Such analysis reflects a result-oriented approach, the very antithesis of "conscientious, explicit and judicious use of current best evidence" advocated by their profession.

The court in *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584 (D.N.J. 2002), addressed a similar issue. In *Magistrini*, the plaintiff's expert purported to consider the weight of the evidence to determine that dry-cleaning fluid caused the plaintiff's cancer. The court explained that a valid weight of the evidence methodology, comparable to evidence-based medicine principles, involves more than simply reading and concluding:

> Importantly, because the weight-of-the-evidence methodology involves substantial judgment on the part of the expert, it is crucial that the expert supply his method for weighting the studies he has chosen to include in order *to prevent a mere listing of studies and jumping to a conclusion*. How else can one expert's choice of "weight" be helpful to a jury which may be called on to assess a "battle of weighers"? The particular combination of evidence considered and weighed here has not been subjected to peer review. However, the weight-of-the-evidence methodology has been used, in a non-judicial context, to assess the potentially carcinogenic risk of agents for regulatory purposes. The existence and maintenance of standards controlling the technique's operation when used for regulatory purposes is informative here … . When a weight-of-the-evidence evaluation is conducted, all of the relevant evidence must be gathered, and the assessment or weighing of that evidence must not be arbitrary, but must itself be based on methods of science.
> * * *
> In order to ensure that the "weight-of-the-evidence" methodology is truly a methodology, rather than

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> a mere conclusion-oriented selection process that weighs more heavily those studies that supported an outcome, there must be a scientific method of weighting that is used and explained.

Id. at 602, 607 (emphasis added). Because the expert could not explain "what 'methodical systematic process'" he used, the court excluded the testimony:

> "Judgment" does not substitute for scientific method; without a reliable method, result-oriented "judgment" cannot be distinguished from scientifically or methodologically-based judgment. Where, as here, elements of judgment pervade the methodology, it is essential that the expert set forth the method for weighing the evidence upon which his opinion is based. Absent that, this Court's role as gatekeeper to assess the reliability of the methodology applied in this case is nullified.

Id. at 608 (most quotations and citations omitted).

When experts base causation conclusions upon "judgment" and "inferences" from their review of the literature, instead of "the conscientious, explicit and judicious use of current best evidence" as dictated by the standards of their profession, their testimony, opinions, and conclusions cannot pass muster under *Daubert* and Rule 702. *See Zenith Elecs. Corp. v. WH-TV Broad. Corp.*, 395 F.3d 416, 419 (7th Cir. 2005) ("Shapiro's method, 'expert intuition,' is neither normal among social scientists nor testable-and conclusions that are not falsifiable aren't worth much to either science or the judiciary.").

Assessing whether a medical expert adheres to principles of evidence-based medicine is a revealing way to gauge the reliability of the testimony. Straying too far from sound methodology and closer to the realm of *ipse dixit* raises serious questions about the reliability of the testimony:

> Expert opinion rests near the bottom of the pyramid of evidence, a position that has metaphoric significance: the teaching of experts is the foundation upon which all other knowledge rests. Good students turn to teachers and textbooks (not journal articles) to begin their study of a given area. But as a form of evidence, expert opinion is subordinate to systematic research. The reason is that history is full of examples in which experts were egregiously wrong. For instance, William Harvey was criticized harshly by the "experts" for his radical notion that blood circulates … .
>
> … Orthopaedics is based on a more objective foundation than psychoanalysis, but we share with that field a method of professional training in which the novice is placed in the role of apprentice to the master. *Because we are appropriately conditioned to accept the teachings of the experts when it comes to the basics, we may find it hard to reject their pronouncements when they veer into speculation. Yet we must. We are obliged to remember the hierarchy of evidence: expert opinion certainly trumps nonexpert opinion, but it is weaker than good clinical research*.

Evidence Based Medicine, *supra*, at 84-85 (emphasis added). Scientific reliability suffers — and admissibility pays the price — when testimony and conclusions disengage from the non-litigation methods and procedures the experts themselves claim to follow. *See, e.g., Truck Ins. Exch. v. Magnetek, Inc.*, 360 F.3d 1206, 1213 (10th Cir. 2004) (affirming exclusion of causation expert testimony in part because the expert's opinion "did not meet the standards of fire investigation [the expert] himself professed he adhered to"); *In re Breast Implant Prods. Liab. Litig.*, 11 F. Supp. 2d 1217, 1236 (D. Colo. 1998) (excluding causation testimony in part because the expert "[w]ithout explanation … disregards the methodology of his specialty"); cf. *Gross v. King David Bistro, Inc.*, 83 F. Supp. 2d 597, 601 (D. Md. 2000) (holding that the "*Daubert* analysis commands that in court, science must do the speaking, not merely the scientist").

CONCLUSION

Medical experts commonly profess to employ in the courtroom the level of intellectual rigor governing their work in their clinical practice. But scrutinizing their analysis and measuring it against the principles of evidence-based medicine can help reveal the flaws in their methodology and the inadmissibility of their testimony.

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statute or regulation — that would impose on a medical device subject to FDA regulation any standard of care, safety, effectiveness, manufacturing, labeling or any other requirement that goes beyond the responsibilities imposed by the FDA is "different from or in addition to" the federal requirements and thus pre-empted; *Becker v. Optical Radiation Corp.*, 66 F.3d 18 (2nd Cir. 1995). In 1996, however, the Supreme Court held in *Medtronic v. Lohr*, 518 U.S. 470, that the statute did not pre-empt common law negligence and strict liability claims for Class III devices where the claims are premised on a violation of federal regulations. The statute only pre-empted cases based on common law actions and state regulations. Thus, state-based causes of action alleging a violation of federal regulations would be permitted as they "parallel" rather than add to the federal requirements. *Riegel v. Medtronic Inc.*, 552 U.S. 312, 330 (2008). Even if state law required the plaintiff to prove that the violations of federal regulations were the result of negligence or a

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defective product, such additional state elements would make the state requirements narrower, not broader, than the federal requirement and thus be "parallel."

Avoiding Dismissal on Pre-emption Grounds

Therefore, in order to avoid dismissal on pre-emption grounds in a medical device case, the state-based causes of action must allege conduct that is prohibited by FDA regulations and that such conduct was a cause of the plaintiff's injury. It is not necessary that a complaint allege facts to counter a preemption argument because a plaintiff is not required to rule out an affirmative defense. In such cases, it is a good idea first to identify in the complaint the conduct that violated the FDA regulations. Then one must plead how the violation rendered the product unsafe or defective and also, how the violation caused the injury.

For example, in *Gelber v. Stryker*, __F.Supp,2d__, 2010 WL 4740432 (S.D.N.Y. 2010) the complaint summarily alleged that the defendants failed "to act as required under the specific federal requirements… which are applicable to the defective device, including violating federal code and rule … " The court, in dismissing the suit, said that plaintiffs cannot simply incant the magic words that the "defendant violated FDA regulations" in order to avoid a dismissal.

Another case amplifies a possible pitfall in pleading. In *Ilarraza v. Medtronic, Inc.*, 677 F.Supp.2d 582 (E.D.N.Y. 2009), the plaintiff claimed an implanted pain medication pump was negligently manufactured in violation of 11 Current Good Manufacturing Practices (CGMP) regulations. (CGMPs are quality control regulations that must be followed by device manufacturers to ensure safety.) The court dismissed the complaint because the plaintiff failed to allege how the CGMPs relied upon referred specifically to the medical device at issue. Each of the regulations was nothing more than a general standard that was intended only to serve as "an umbrella quality system," citing *Horowitz v Stryker*, 613 F.Supp. 271 (E.D.N.Y. 2009).

An example of sufficient pleading was presented in *Purcel v. Advanced Bionics*, 2008 WL 3874713 (N.D. Tex. 2008), in which an infant plaintiff sued the manufacturer of a cochlear ear implant, claiming that moisture levels in the device's circuitry were higher than allowed by the FDA. The plaintiff claimed the moisture levels were elevated due to a change in the mechanical design and configuration of a component part — a feedthrough — made by a supplier and that the infant suffered damages due to the higher moisture. The plaintiff pleaded that the defendant violated the federal regulations when it failed to notify the FDA that it had changed the supplier of the feedthroughs. The defendant's motion to dismiss causes of action for strict liability and implied warranty on the grounds of preemption was denied because, in the court's view, the injury was sufficiently pleaded to have been caused due to the violation of federal regulations.

Breathing Space for Plaintiffs

While most courts have dismissed cases where the pleading alleged nothing more than the violation of a federal regulation in support of a parallel claim, the most recent case on this subject has given plaintiffs some breathing space. In *Bausch v. Stryker*, ___F.3d___, 2010 WL 5186062 (7th Cir. 2010), a hip implant case, the court reversed the lower court's dismissal of a complaint and its refusal to permit the plaintiff to file an Amended Pleading. The Seventh Circuit reaffirmed that the federal standard of notice pleading is applicable, so long as the plaintiff alleges facts sufficient to meet the new "plausibility" standard applied in *Ashcroft v. Iqbal*, ___U.S.___,129 S. Ct. 1937 (2009) and *Twombly, supra* ("claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged."). The complaint alleged that prior to implantation, the FDA had written to the defendant warning it that the hip implant was "adulterated due to manufacturing methods not in conformity with industry and regulatory standards." The defendant convinced the lower court to dismiss the case because the complaint failed to specify the precise defect or the specific federal regulatory requirement what was violated; however, in reversing, the Seventh Circuit ruled that although the complaint would have been stronger had it done so, the absence of such details was not a failure to comply with the pleading requirements of Federal Rules of Civil Procedure (FRCP) 8, nor are such details required by FRCP 9, such as in fraud claims. The court went on to say that, although the failure to comply with "industry standards" was not actionable, there was no reason to dismiss the entire complaint with prejudice and without leave to replead.

Conclusion

These examples show how muddled the state of the law is today. If you are planning to start a medical device case, read the most recent decisions before filing the Complaint. Product liability cases are difficult enough; medical device cases are worse.

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