WISCONSIN COURT OF APPEALS
DISTRICT III

UNITY BAYER, by her Guardian
ad Litem Vincent R. Petrucelli,
LEAH BAYER, and ANDREW BAYER,

Plaintiffs-Respondents,

JOHN ALDEN LIFE INSURANCE COMPANY,

Involuntary Plaintiff,

v. Appeal No. 2015AP1470

BRIAN D. DOBBINS, M.D.,
MMIC INSURANCE, INC., PREVEA CLINIC, INC.,
and DEF INSURANCE COMPANY,

Defendants-Appellants,

INJURED PATIENTS AND FAMILIES COMPENSATION FUND,

Defendant-Co-Appellant.

WISCONSIN MEDICAL SOCIETY'S BRIEF *AMICUS CURIEA*

ON APPEAL FROM CIRCUIT COURT FOR MARINETTE COUNTY
HONORABLE DAVID G. MIRON, PRESIDING
Circuit Court Case No. 13-CV-271

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> *In this age of science, science should expect to find a warm welcome, perhaps a permanent home, in our courtrooms. The reason is a simple one. The legal disputes before us increasingly involve the principles and tools of science. Proper resolution of those disputes matter not just to the litigants, but also to the general public – those who live in our technologically complex society and whom the law must serve. Our decisions should reflect a proper scientific and technical understanding so that the law can respond to the needs of the public.* [1]

Stephen Breyer, Associate Justice, United States Supreme Court

INTRODUCTION

At the time of Justice Breyer's above statement, Federal Courts were grappling with the relatively new *Daubert*[2] standard and their role as gatekeepers of what passes scientific muster. Over two decades have passed since *Daubert* was decided. Despite thousands of decisions and countless scholarly works, one of the most vexing questions engendered by *Daubert* remains what to do with medical evidence. This case presents not only the opportunity to set the parameters for Wisconsin *Daubert* jurisprudence, but to add to the comparably scant body of law applying those principles to medical issues.

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[1] *Reference Manual on Scientific Evidence, (3d ed.)* p. 2, published by the Federal Judicial Council and National Research Council. The quoted language was derived from remarks Justice Breyer made at the 150th Annual meeting of the American Association for the Advancement of Science in 1998. The *Reference Manual* is a resource used by the federal bench to help it understand complex scientific and technical matters that come before the courts. Many of the observations and citations provided in this brief find support in the *Reference Manual* where they are explored in far greater depth than this brief can accommodate.

[2] *Daubert v. Merrill Dow*, 509 U.S. 579 (1993)

The Wisconsin Medical Society ("the Society") appreciates the opportunity to be heard on a topic for which it has unique expertise. Comprised of Wisconsin physicians, medical resident and medical students, the Society represents the interests of its members and their patients in Wisconsin. Its members are affected by rules governing medical testimony. They provide expert medical testimony. They perform the medical research assessed and utilized by physicians to make decisions about patient care, the same research courts must deem reliable or not. Their conduct will be scrutinized, and ultimately tailored, by the standards of care established by such evidence. Their patients are directly affected by those adopted standards. As such, physicians, are uniquely positioned to aid the Court in understanding what constitutes reliable medical evidence in the medical field.

I. In Determining Whether Medical Evidence Is Reliable Under § 907.02, Courts Should Respect And Adopt The Process Employed By Physicians To Assess Its Reliability.

From the dawn of the medical discipline, physicians have sworn to abide by the knowledge of medicine that has come before them. The modern version of the Hippocratic Oath contains the following covenants:

> *I will respect the hard-won scientific gains of those physicians in whose steps I walk, and gladly share such knowledge as is mine with those who are to follow.*
>
> * * *

> *I will remember there is an art to medicine as well as a science, and that warmth, sympathy and understanding may outweigh the surgeon's knife or the chemist's drug.*[3]

Notwithstanding the long recognized and ubiquitous "art" in medicine, medical decision making is first and foremost a scientific endeavor, one in which understanding of the science is ever evolving and expanding.

As the Supreme Court was handing down *Daubert*, the field of medicine was undergoing a similar paradigmatic shift. In the early 1990s, in response to a recognized variation in the delivery of medical care to similarly situated patients, practitioners began to embrace the concept of "evidence based medicine." Evidence based medicine has been described as:

> (t)he conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient. It means integrating individual clinical expertise with the best available external clinical evidence from systematic research.[4]

Evidence based medicine is now the most widely accepted standard physicians across the country use for evaluating patient diagnosis and treatment.[5] In evaluating the reliability of medical evidence, Wisconsin Courts should employ the same principles of reliability that physicians follow in medical decision making.

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[3] *See* Lasagna, L. *Hippocratic Oath – Modern Version*, University of California San Diego, University Ethics Center.

[4] Sackett, et al., *Evidence Based Medicine: What it Is and What it Isn't*, 312 BMJ 71-72, 71 (1996).

[5] The Society's own Policy Compendium references evidence based principles over two dozen times. *See* 2015-2016 Wisconsin Medical Society Policy Compendium at https://www.wisconsinmedicalsociety.org/_WMS/about_us/governance/policy_compendium/2015/2015-2016_policy_compedium.pdf.

To apply these principles, courts must begin with an understanding of how medical knowledge is evaluated by physicians. Physicians gauge the strength of different types of medical evidence in a hierarchical system. The strongest, most reliable type of medical evidence is that based upon systematic review of randomized trials, also referred to as meta-analyses.[6] These are studies which synthesize key findings from related randomized studies performed over time. Meta-analyses are followed in hierarchical order by single randomized trials where a discreet hypothesis is tested in a statistically significant population, generally using a double blind methodology.[7]

Next in the hierarchy are systematic reviews of observational studies, which bring together research from different sources on a topic that is not amenable to random testing.[8] As the Court no doubt appreciates, much of the advancement in medicine comes from an understanding of treatment actually rendered to patients in situations where random or double blind study constructs are impractical or unethical. These systematic reviews of observational studies are where much of the advancement of medical understanding takes place. These reviews are followed in the hierarchy by single observational studies,[9] which are, in

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[6] Guyatt, et al., *Users' Guide to Medical Literature: A Manual for Evidence-Based Clinical Practice* (2d ed. 2008).
[7] *Id.*
[8] *Id.*
[9] *Id.*

turn, followed by physiological studies, generally using animal models and other basic research principles.[10] Each of the methods described above, though differing in breadth and specific process, require an accepted method of scientific testing and evaluation and thus carry an accepted level of reliability in a clinical setting.

The last recognized category in the hierarchy is unsystematic clinical observations.[11] In the publishing arena, these take the form of case studies or case reports. These are reports in which a physician may describe an experience with a single patient or a small group of patients and suggest to the larger medical community an interesting hypothesis or correlation they have observed. Also falling into this category of unsystematic clinical observation would be the honed "instincts" of practitioners built up over a lifetime of treating patients. Such sources can be valuable contributions to the advancement of medicine, but do not by themselves carry a high level of reliability or applicability due to their limited, more anecdotal, nature.

Within the literature based realm of this hierarchy, there is an important distinction among publications. A concept typically employed to verify the reliability of a study's methodology is that of "peer review." Most medical journals utilize experienced practitioners, who are knowledgeable in specific areas of medicine and medical research, to serve

[10] *Id.*
[11] *Id.*

as referees of articles submitted to them for publication. The purpose of this peer review process is not to endorse the conclusions of the authors, but rather to confirm that the author's methodology and analysis is in keeping with the high standards of the medical profession.

Peer review is not itself a proxy for reliability. For example, a peer reviewed case study based on clinical observation only ensures that the study is sufficiently compelling or based in sound medical principles to warrant publication and further exploration. However, peer review is an important marker relied upon by physicians in determining the credibility and soundness of methodology employed by a work's authors.

Added to this mix is the ever-increasing[12] prevalence of guidelines, many of which are published in some of the same journals that publish research works. Clinical practice guidelines are not so much medical research as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."[13] Such guidelines are typically developed by professional organizations based on extensive review of applicable research. However, they also can be influenced by external factors such as political

[12] One study documented a 100-fold increase in the number of published guidelines over the decade of the 1990s. *See* Hibble, et al., *Guidelines in General Practice: The New Tower of Babel?* 317 BMJ 862-3 (1998).

[13] Committee to Advise Public Health Service on Clinical Practice Guidelines, Institute of Medicine, Clinical Practice Guidelines: Directions for a New Program, 8 (Field & Lohr, eds. 1994).

considerations and even the threat of litigation.[14] While guidelines are useful regarding various aspects of a patient's care, they should not be confused with medical standards of care. Different subspecialties of medicine may develop different guidelines on the same subject, all equally useful and soundly based.[15]

Courts elsewhere have recognized, at least implicitly, this hierarchy and excluded "unsystematic clinical observations" from evidence. By way of example *Berk v. St. Vincent's Hosp. and Medical Center*, 380 F. Supp. 2d 334, 354-355 (S.D.N.Y. 2005) analyzed the following testimony.

> Q: You do a lot of arthroscopic surgery, do you not?
> A: Yes.
> Q: Do patients have synovial fluid from time to time draining from their knee?
> A: I've never seen it. That's over 2,000 arthroscopies. I've never seen it post-op. If I did see it, it's indicative of infection, period.
>
> Q: You've never seen anyone oozing from their knee at any time after your surgeries?
> A: No. If there is any oozing, that's a cause for concern. There should not be. There should not be. Because that kind of — you've got to jump on it.

Id. at 354. In barring the testimony, the district court wrote that the physician's conclusion, "appears to be based on no scientific support other than his own personal experience of not having encountered instances of

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[14] *See* Kraemer, et al. *Science, Politic and Values: the Politicization of Professional Practice Guideline*, 301 JAMA 665-67 (2009).

[15] For example, there are different recommendations for routine mammography in otherwise healthy women. *See* U.S. Preventative Task Force, *Screening for Breast Cancer: USPST Recommendation Statement*, 151 Annals of Int. Med. 716-26 (2009); *cf.* Lee, et al. *Breast Cancer Screening with Imaging: Recommendations from the Society of Breast Imaging and the ACR on the use of Mammography*, 7 J. Am. C. Radiology 18-27 (2010).

fluid draining from knees of patients on whom he has operated" and, as a result, "bears none of the hallmarks of reliability necessary for it to be considered admissible under *Daubert* and Rule 702." *Id.*

From the Society's perspective, this makes excellent practical sense, especially in medical negligence cases. Physicians make treatment decisions with knowledge that their decisions will be scrutinized against objective standards and evidence based medicine. If that standard could be established solely by the personal predilections of an individual physician of whom they have no knowledge, physicians would be left in the untenable position of never knowing by what standard their conduct will be measured.

Moving ever so slightly up the hierarchical ladder of reliability, but still within the definition of "unsystematic clinical observations" are case studies. It has been recognized that case reports, as opposed to empirical studies, often lack information about whether individuals evaluated are typical of the population and at best can serve to generate hypotheses. *See Siharath v. Sandez Phar., Corp.* 131 F. Supp. 2d 1347, 1361 (N. D. Ga. 2001). Accordingly, that court found that they cannot provide a reliable basis for a conclusion that a particular act or omission caused an injury. *Id.*

The Society asks that this Court's opinion comport, to the extent possible, with medicine's own standards of reliability. No single inviolable rule will cover all cases, but this Court can promote better uniformity and

proper application of this standard by providing sound guidance in this case.

First, the Society asks this Court to recognize that medical opinions that are supported solely by unsystematic clinical observations presumptively fail to cross the *Daubert* reliability threshold. These include both a physician's subjective beliefs based solely on their personal credentials and experience as well as medical literature identified as case reports. While such evidence may be properly part of physicians' decision making process, it lacks an objective methodology on which physicians, and in turn courts, can rely.

This is not to say that physician experience and clinical observations have no place in expert testimony. Training and experience plays a large role in medical analysis and decision making, and that training and experience can be incorporated into expert testimony. However, from a medical perspective, conclusions based solely on experience and anecdote are regarded with suspect in their application to other patients and circumstances.

Second, while there will always be the possibility of case specific exceptions, the Society believes medical evidence based on research further up the hierarchy should be presumed reliable by courts for purposes of exercising their gatekeeper function. Randomized trials, meta-analyses, systematic reviews, observational studies and physiological studies,

especially peer-reviewed literature based on these methods, employ an objective, reliable methodology on which physicians base important treatment decisions and on which courts can generally rely as scientifically sound.

The Society adopts this position recognizing that medical opinions based solely on unsystematic clinical observations are not necessarily wrong; they may in fact be the first signals of associations later confirmed through larger controlled studies. Similarly, even well-constructed systematic studies may be proved erroneous with advances in knowledge. However, courts, like physicians, can only do their best to understand and evaluate the reliability of medical evidence as it exists at the time, knowing full well that our collective understanding will no doubt evolve and expand in the future. As the Court in *Daubert* recognized:

> Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly.

Daubert at 597. Cases must be decided on the best available methodology at the time; today, that is evidence based medicine.

II. The Trial Court's Decision In This Case Exemplifies The Need For Better Understanding Of What Constitutes Reliable Medical Evidence.

These principles demonstrate why the trial court's analysis in this case was in error. The most glaring effect of the Court's analysis was the exclusion from evidence of a publication of the American College of

Obstetricians and Gynecologists, entitled *Neonatal Brachial Plexus Palsy.* The publication was the product of a task force comprised of nine subject matter experts presented with the following charge:

> To review and summarize the current state of the scientific knowledge, as set forth in the peer reviewed and relevant historical literature, about the mechanisms which may result in neonatal brachial plexus injury. The purpose of conducting such review is to produce a report which will succinctly summarize relevant research on the pathophysiology of neonatal brachial plexus palsy.

This resource, which Dr. Dobbins' experts used to support their opinions, is an example of a systematic review of observational studies. In the hierarchy of medical research, publications like this represent some of the best evidence available to physicians in medical decision making.

Additionally, the Court seemed particularly concerned that some of the proffered articles dealt with temporary, as opposed to permanent, brachial plexus injuries. The trial court's attention to this distinction fundamentally departs from how many physicians would evaluate the reliability of such evidence. From a medical perspective, a permanent brachial plexus injury is a temporary brachial plexus injury that did not recover, as was noted in the forward of the review:

> Neonatal brachial plexus palsy (NBPP) is a rare occurrence, with an overall incidence of 1.5 per 1,000 births. Favorable outcomes or complete recovery are variously estimated as low as 50% and as high as 80%, considering all types of lesions.

The entire premise of the collected research on this topic is that some brachial plexus injuries will heal, i.e., be temporary, and some will be permanent; they are still brachial plexus injuries nonetheless. One cannot

hope to understand one subset of this injury without understanding the other. Moreover, barring physicians from testifying regarding a theory based on a court's belief that the peer reviewed literature providing the basis for those opinions does not state the physicians' conclusions in sufficiently explicit terms subverts the role physician experts play in extrapolating, applying and explaining medical science for the benefit of courts and juries.

From a physician's perspective it makes little sense to think one could opine in an informed way about any brachial plexus injury without the ability to rely on research that touches upon all brachial plexus injuries. By ruling that Dr. Dobbin's experts cannot rely on studies that rely or at least extrapolate from peer reviewed, evidence based studies, it is deeply concerned that the trial Court confused its role as gatekeeper of reliable information with that of fact finder determining the weight of the information.

CONCLUSION

This Court has the opportunity with this case to provide significant guidance to Wisconsin's trial courts in applying Wis. Stat. § 907.02 to medical evidence. The Society can envision no more logical source of determining the reliability of such evidence than medicine's own standards of reliability. The paradigm underlying evidence based medicine and its

hierarchy of informational sources parallels the approach envisioned in the *Daubert* standard.

In practice, this means testimony, even by well-credentialed physicians, that is grounded solely on personal experience and preference, or that lacks other objective evidence bases, should be presumed to fall short of § 907.02's reliability requirements. Such testimony may still be proper when combined with other, more objective methods. Conversely, testimony that finds it source in peer reviewed literature, objective studies or trials, or exploration or aggregation of multiple resources, should be presumed to meet § 907.02's reliability criteria and be evaluated on other evidentiary criteria. When this approach is applied to this case, it is clear the trial court should be reversed as requested in the Petition.

Dated this 11th day of December, 2015.

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FORM AND LENGTH CERTIFICATION

I hereby certify that this brief conforms to the rules contained in § 809.19(8)(b) and (c) for a brief produced with a proportional serif font (Times New Roman 13 pt for body text and 11 pt for quotes and footnotes).

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I certify that on December 11, 2015, this brief was picked up by a third-party commercial carrier for delivery to the Clerk of Court of Appeals on December 11, 2015. I further certify that the brief was correctly addressed.

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I certify that the required number of copies of this brief were deposited in the United States mail for delivery to the below-named recipients by first-class mail, or other class of mail that is at least as expeditious, on December 11, 2015. I further certify that the brief was correctly addressed and postage was pre-paid and that the below recipients were additionally served with the brief via the Court's efiling system.

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