STATE OF WISCONSIN
SUPREME COURT

BRAYLON SEIFERT, by his Guardian ad Litem PAUL J. SCOPTUR, KIMBERLY SEIFERT and DAVID SEIFERT,

Plaintiffs-Respondents,

Appeal No. 14-AP-195

DEAN HEALTH INSURANCE and BADGERCARE PLUS,

Grant County Circuit Court
Case No. 11-CV-588

Involuntary Plaintiffs,

v.

KAY M. BALINK, M.D. and PROASSURANCE WISCONSIN INSURANCE COMPANY,

Defendants-Appellants-Petitioners.

BRIEF OF *AMICI CURIAE* WISCONSIN MEDICAL SOCIETY AND AMERICAN MEDICAL ASSOCIATION

On Review From
The Wisconsin Court of Appeals, District IV
Grant County Case No. 11-CV-588
The Honorable Craig Day Presiding

February 1, 2016

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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 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*. Despite thousands of decisions and countless scholarly works, one of the most vexing questions engendered by *Daubert* remains what constitutes reliability when it comes to medical evidence. This case presents not only the opportunity to set the parameters for

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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.

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

Wisconsin *Daubert* jurisprudence, but also to add to the comparably scant body of law applying *Daubert* to medical issues.

The Wisconsin Medical Society and the American Medical Association (jointly, "*amici*") appreciate the opportunity to be heard on a topic for which they have unique expertise. Together, *amici* represent the interests of physicians, medical residents and medical students in Wisconsin and throughout the country. It is their members who perform the research used by physicians to make decisions about patient care and it is they who are affected by rules governing medical testimony. It is *amici's* members whose conduct will be scrutinized, and ultimately tailored, by the standards of care established by evidence deemed reliable in the legal context. Amici invite this Court to adopt a rule for Wisconsin courts to use in assessing the reliability of medical evidence that parallels as closely as possible the methods used by the medical profession.

I. In Determining Whether Medical Evidence Is Reliable Under § 907.02, Courts Should Respect And Adopt The Perspective Employed By Physicians.

From the dawn of the medical discipline, physicians have sworn to respect the knowledge of medicine that has come before them. A modern version of the Hippocratic Oath contains the following covenant:

> 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.[3]

Medicine is first and foremost a scientific endeavor, one in which understanding of the science is ever evolving and expanding, reevaluated and applied by highly educated and skilled physicians to make the best medical decision for their patients possible at the time.

At the time the Supreme Court was handing down *Daubert* and its progeny, 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, medicine began to embrace the concept of "evidence based medicine," which 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 converts the abstract exercise of reading and appraising the literature into the pragmatic process of using the literature to benefit individual patients while simultaneously expanding the clinician's knowledge base."[5] Evidence based medicine does not eschew physician

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[3] *See* Lasagna, L. *Hippocratic Oath – A 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] Evidence Based Medicine—New Approaches and Challenges, Miokovic and Muhamedagic (2008): http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3789163/

experience, judgment or intuition, but rather stresses that physicians adopt the best evidence in individual decision making.[6]

Evidence based medicine is now the most widely accepted standard that physicians use for evaluating, diagnosing and treating patients and is the cornerstone of medical decision making.[7] Wisconsin courts should employ the same principles of reliability embodied in evidence based medicine as the touchstone for evaluating the reliability, and thus admissibility, of medical evidence.

There are two steps in this endeavor. The first requires an assessment of the strength of available medical information. The second requires an understanding of the role of context in determining what type of information one requires for the task at hand. From the medical perspective, the reliability, and thus usefulness of medical information is inextricably tied to both the strength of the science underlying it and its intended use.[8]

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[6] Schwartz and Hupert; Insights from Teaching Evidence-Based Medicine AMA Journal of Ethics, Vol. 13, No. 1: 21-24 (2011); http://journalofethics.ama-assn.org/2011/01/medu1-1101.html

[7] AMA Journal of Ethics, Vol. 13, No. 1:26-30 (January 2011); The Wisconsin Medical 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.

[8] See Miokovic and Muhamedagic, supra.

Types of Medical Information

Physicians gauge the strength of different types of medical evidence in a hierarchical system.[9] Conceptually, the more and stronger data that exist to support a proposition, the more reliable that proposition is thought to be. The strongest, most reliable type of medical evidence is that based upon systematic review of randomized trials, also referred to as meta-analyses.[10] 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.[11] The objective testing underlying these studies makes them among the strongest sources of scientific data available.

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 for reasons of impracticality or ethical constraints.[12] These reviews are followed in the hierarchy by single observational studies,[13] which are, in turn, followed by physiological

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[9] Guyatt, et al., *Users' Guide to Medical Literature: A Manual for Evidence-Based Clinical Practice*, ch. 2, the Philosophy of Evidence-Based Medicine (2d ed. 2008).
[10] *Id.*
[11] *Id.*
[12] *Id.*
[13] *Id.*

studies, generally using animal models and other basic research principles.[14]

The last category in the hierarchy is that of unsystematic clinical observations.[15] In publications, these take the form of "case studies" or "case reports," in which a physician may describe an experience with a single patient or a small group of patients and suggest an interesting hypothesis or correlation they have observed. Also falling into this category would be the honed "instincts" of practitioners built up over years of treating patients, synthesized with existing medical knowledge but not traceable to any specific source.

Within the literature based realm of this hierarchy, there is further distinction. A concept typically employed to verify the reliability of a study's methodology is that of "peer review." Medical journals utilize experienced practitioners knowledgeable in specific areas of medicine and medical research – "peers" – to serve as referees of articles submitted 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

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[14] *Id.*

[15] Miokovic and Muhamedagic, supra; *Id.*

methodology and analysis is in keeping with the high standards of the medical profession.[16]

Contextual Use of Medical Information

The hierarchical categories described above, from systematic reviews of clinical trials to observational and physiological studies, evince a high level of scientific rigor, and each rung up the hierarchy generally carriers increased weight with physicians.[17] These categories carry an accepted level of reliability in a clinical setting for most purposes,[18] but are not always considered necessary to substantiate a position.

Physicians consider the context of the inquiry before them to determine whether a particular study, publication or piece of information is sufficiently reliable for their purposes. By way of example, physicians speak to patients daily who want to know how a disease may progress or what to expect following an injury. Rarely would a physician in such a situation feel the need to support their response with anything more than their own "unsystematic" observations – their general medical knowledge and experience with similar circumstances. In contrast, those same physicians may regularly have committee obligations to assess proposed

[16] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3474310/
[17] Miokovic, *supra*..
[18] Evidence Based Medicine—New Approaches and Challenges, Miokovic and Muhamedagic (2008): http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3789163/

treatment protocols for their respective institutions. Those physicians would never think to propose something such as an institution wide standard of care without referencing literature fairly well up the hierarchy of accepted research.

This approach, central to the practice of evidence based medicine, effectively incorporates the same trilogy of concepts that outline legal requirements for expert testimony – qualification, reliability and fit. *See In re Paoli Railroad Yard PCB Litigation*, 35 F.3d 717, 741-43 (3d Cir. 1994). Recognizing how physicians use medical information, and interpreting rules of evidentiary admissibility to be consistent with those practices, will provide the soundest method for Wisconsin courts exercising their gatekeeper function under *Daubert*. In short, "(A) trial court should admit medical expert testimony if physicians would accept it as useful and reliable." *United States v. Sandoval-Medoza*, 472 F.3d 645, 655 (9th Cir. 2006).

A brief example drawn from existing case law demonstrates appropriate contextual use of medical information. *Sandoval-Mendoza, supra* admitted the experience-based opinions of a qualified neurologist on the effect of brain tumors on a patient's susceptibility to coercive suggestion. 472 F3d at 655. Another court excluded a qualified physician's testimony on standard of care in a medical negligence claim

because it was based "on no scientific support other than his own personal experience . . .". *See Berk v. St. Vincent's Hosp. and Medical Center*, 380 F. Supp. 2d 334, 354-355 (S.D.N.Y. 2005).

From *amici's* perspective, these seemingly inconsistent rulings make excellent practical sense. Physicians should be able to opine on the likely effect of a disease process to help a jury understand what is transpiring with an individual, just as they would help a patient predict a response to the same condition. This does not mean that the opinion would be (or could be) without a scientific basis; it means merely that there is no professional expectation to produce high level academic support for the conclusions reached in a case specific context. Similarly, testifying physicians should not be allowed to use only their personal predilections and experiences as evidence of accepted standards all physicians should be expected to follow. To speak for an entire group of physicians about standards of care requires that the speaker support the opinion they profess with evidence vetted by those physicians as a group. This is no more than what physicians demand of one another.

Against this background, *amici* ask that this Court to interpret §907.02 with respect to medical evidence in a manner that comports, to the extent possible, with medicine's own standards of reliability. First, *amici* ask this Court to recognize that medical opinions supported by

unsystematic clinical observations have reliability limited to those situations where physicians would not be expected to produce extrinsic support for their contentions but presumptively fail to cross the *Daubert* reliability threshold when tendered to establish the standard of care in a medical negligence claim. These include both a physician's subjective beliefs based solely on their personal experience as well as medical literature identified as case reports. In no situation would the mere *ipse dixit* of a physician, without some link to accepted medical consensus, be allowable.

Second, medical evidence based on research further up the recognized 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 when peer-reviewed, employ an objective, reliable methodology on which physicians base important treatment decisions and can reasonably rely as the basis for expert testimony. Finally, in assessing the applicability of purported evidence, courts should be deferential to the opinions of physicians regarding the applicability of medical literature to a given case or set of facts.

II. The Instant Case Presents an Example of Expert Testimony Unsupported by Reliable Medical Evidence in the Context in Which it Was Proffered.

It is clear that both the trial court and the Court of Appeals attempted to incorporate an understanding of medical procedures into their decisions. Unfortunately, both courts failed to appreciate the significance of the context in which it was proffered.

Specifically, the trial court considered what information underlay Dr. Wener's opinion that could be considered known and generally accepted, and then, relying on *Cooper v. Nelson*, 211 F.3rd 1008 (7th Cir. 2000) allowed Dr. Wener to proffer "holistic" opinions regarding the standard of care. The court expressed concern that Dr. Wener's precise opinions may not be testable and that the complexities of medicine thus allowed them to be admissible. The court then allowed Dr. Wener's opinion that he would have performed the delivery different to stand as sufficient to allow a jury to conclude that Dr. Balink's conduct, which was based on specialty guidelines, peer reviewed literature and supported by multiple experts, fell below the standard of care.

The Court of Appeals endorsed the trial court's reasoning, specifically noting that Dr. Wener's unchallenged qualifications provided sufficient reliability. *Seifert v. Balink*, 2015 WI App 59, ¶ 29. In so doing,

it too cited a number of federal cases for the proposition that a physician's training can provide a measure of reliability. *Id.* at ¶ 19. It noted the limits of medical literature, but adopted a dichotomous position that suggested that decisions can be based on either literature or the experience of a physician. *Id.* at ¶ 31. Taken together, the analysis of the courts below arrived at an approach that would astound and disturb most physicians—they allowed an opinion based on personal preference to serve as the basis for determining that another's professional performance fell below the minimum standard of care for all similarly situated physicians.

Dr. Wener's opinion regarding appropriate care would be acceptable for communicating his decisions to his own patients about how he prefers to approach a similar situation. No physician would begrudge him that. However, that is distinctly different from using his own synthesis of medical information as the basis for establishing the standard by which the conduct of another physician, and, by extension, all similarly situated physicians should be judged. The law recognizes that one physician's approach does not define the standard of care, *see* Wis. Civ. J. I. § 1023 (physicians are free to choose among various recognized treatment methods), but that is ultimately the standard that was applied here against Dr. Balink. Whereas the courts below viewed the uncertainty inherent in medical science as reason to give Dr. Wener's opinions a wider berth, the

medical profession would view that uncertainty as all the more reason to exclude such opinions when proffered as the standard for all physicians faced with Dr. Balink's circumstances.

If left uncorrected, the decisions of the lower courts would place an unreasonable burden on physicians. In making decisions about how to treat their patients, not only would physicians have to keep apprised of relevant studies, to ensure they are employing scientifically backed and proven practices, they would have to account for the possibility that the preferences of a physician they have never met and who may have made a different, potentially equally valid, decision could serve as the basis by which their conduct will be judged. That cannot be the hallmark of a functioning legal liability system.

The decisions below create an unbridgeable rift between how the medical community uses medical information and how those courts determined it could be used. *Amici* respectfully ask this Court to correct that approach, determine that Dr. Wener's personal opinions should have been excluded from evidence, and remand the matter so that Dr. Balink's conduct can be measured against a standard that she, as a physician, would be able to predict and which is supported by our current best understanding of the applicable medical science.

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. *Amici* can envision no more logical source of determining the reliability of such evidence than medicine's own standards of reliability. Adopting the paradigm underlying physicians' contextual approach to evidence based medicine and its hierarchy of informational sources both parallels the approach envisioned in *Daubert* and harmonizes the approach of the medical and legal disciplines.

In practice, this means testimony that finds it source in peer reviewed literature in the higher levels of the evidence based medicine hierarchy should be presumed to meet § 907.02's reliability criteria. Evidence grounded on a physician's personal experience and synthesis of medical concepts or limited case studies or reports, should be presumed to fall short of § 907.02's reliability requirements when proffered as evidence of standard of care. If applicable, then medical opinions of qualified practitioners that are derived from accepted medical principles, even if those principles are not specifically explained in literature, may have value to the jury and may be admissible under § 907.02 if the context demonstrates that the medical community would require no greater substantiation of a proposition. Under no circumstances should the pure

ipse dixit of a physician, regardless his or her qualifications, be deemed to cross the reliability threshold of § 907.02.

Dated this 1st day of February, 2016

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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).

The length of this brief is 2,993 words.

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I certify that the text of the electronic copy of the brief is identical to the text of the paper copy of the brief filed with the Court. A copy of this certificate has been served with the paper copies of this brief filed with the court and served on all parties.

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I certify that on February 1, 2016, this brief was picked up by a third-party commercial carrier for delivery to the Clerk of Court of the Supreme Court on February 1, 2016. I further certify that the brief was correctly addressed.

Dated this 1st day of February, 2016

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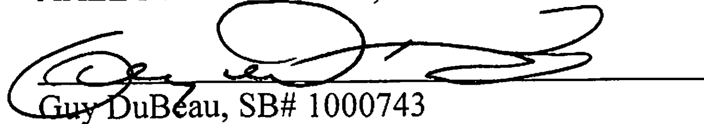

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I certify that the required number of copies of this brief were deposited in the United States mail for delivery to the below-named recipients by first-class mail, or other class of mail that is at least as expeditious, on February 1, 2016. I further 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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