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# INFORMED CONSENT AND THE DIFFERENTIAL DIAGNOSIS: HOW THE LAW CAN OVERESTIMATE PATIENT AUTONOMY AND COMPROMISE HEALTH CARE

#### MARC D. GINSBERG<sup>†</sup>

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#### I. Introduction

To suggest that . . . any physician . . . had a duty to obtain informed consent for a non-recommended treatment modality is nonsensical and creates an unnecessary and untenable basis of liability against a physician . . . . Such a requirement would force physicians to describe and discuss treatment options that they have no intention of administering even if, after discussion, the patient would select it. <sup>1</sup>

The doctrine of informed consent is enshrined in medical-legal jurisprudence. "Unquestionably, . . . [it] is one of the hallmarks of the physician-patient relationship." Since the phrase "informed consent" first appeared in a reported American judicial opinion, it has been the frequent subject of legal scholarship, including journals, texts, and casebooks, as well as medical literature. The medical negligence

<sup>1.</sup> Cline v. Kresa-Reahl, 728 S.E.2d 87, 93 (W. Va. 2012).

<sup>2.</sup> Marc D. Ginsberg, Informed Consent: No Longer Just What the Doctor Ordered? The "Contributions" of Medical Associations and Courts to a More Patient Friendly Doctrine, 15 Mich. St. U. J. Med. & L. 17, 18 (2010).

<sup>3.</sup> Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees, 317 P.2d 170, 181 (Cal. Dist. Ct. App. 1957) ("In discussing the element of risk a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an informed consent."); For examples of scholarship attributing the initial use of "informed consent" in case law to Salgo, see Jay Katz, Informed Consent—A Fairy Tale? Law's Vision, 39 U. PITT. L. REV. 137, 138 (1977); Jay Katz, Informed Consent—Must It Remain a Fairy Tale?, 10 J. CONTEMP. HEALTH L. & POL'Y 69, 72 (1994).

<sup>4.</sup> See generally Janet L. Dolgin & Lois L. Shepherd, Bioethics and the Law 46 (3d ed. 2013); Barry R. Furrow et al., Health Law § 6-9 (2d ed. 2000); Mark A. Hall et al., Health Care Law and Ethics 195–96 (8th ed. 2013); Ginsberg, supra note 2; Katz, Law's Vision, supra note 3; Katz, Must It Remain a Fairy Tale?, supra note 3; Marcus L. Plante, Some Legal Problems in Medical Treatment and Research, An Analysis of Informed Consent, 36 Fordham L. Rev. 639 (1968); Leonard L. Riskin, Informed Consent: Looking for the Action, 1975 U. Ill. L. Rev. 580; David E. Seidelson, Medical Malpractice: Informed Consent Cases in "Full-Disclosure" Jurisdictions, 14 Duq. L. Rev. 309 (1976); Daniel P. Sulmasy, Informed Consent Without Autonomy, 30 Fordham Urb. L.J. 207 (2002); Jon R. Waltz & Thomas W. Scheuneman, Informed Consent to Therapy, 64 Nw. U. L. Rev. 628 (1970).

lawsuit is a recognized "occupational hazard," and consent based medical negligence claims are not uncommon.

The purpose of this Article is not simply to re-examine the doctrine of informed consent. The purpose is to identify how the doctrine has evolved, how its scope has expanded, and how it has created serious consequences for physicians and patients. Specifically, this Article focuses on the differential diagnosis —the process by which a physician arrives at a diagnosis—and how some jurisdictions have manipulated informed consent to encompass this process. This Article will urge that the application of informed consent to the differential diagnosis is an unnecessary expansion of the doctrine and potentially compromises health care.

#### II. A BRIEF HISTORY AND BACKGROUND

The history of the informed consent doctrine has been extensively covered in the medico-legal literature and case law; therefore, it is a subject not requiring extensive re-examination here. However, some background is required for contextual purposes—as a foundation for the position that expansion of the doctrine can be detrimental to health care.

<sup>5.</sup> See generally CARL HORN ET AL., LAW FOR PHYSICIANS 95 (2000); William A. Silverman, The Myth of Informed Consent: In Daily Practice and in Clinical Trials, 15 J. MED. ETHICS 6 (1989); Shlomo Cohen, Nudging and Informed Consent, 13 AM. J. BIOETHICS 3 (2013); Graeme Laurie, Recognizing the Right Not to Know: Conceptual, Professional, and Legal Implications, 42 J.L. MED. & ETHICS 53 (2014).

<sup>6.</sup> Louis J. Regan, Malpractice, an Occupational Hazard, 156 JAMA 1317, 1317 (1954).

<sup>7.</sup> See PHYSICIAN LAW-EVOLVING TRENDS & HOT TOPICS 2013, at 97 (Wes Cleveland ed., 2014); Richard G. Roberts, Seven Reasons Family Doctors Get Sued and How to Reduce Your Risk, 10 FAM. PRAC. MGMT. 29, 32 (2003).

<sup>8.</sup> See Robert S. Ledley & Lee B. Lusted, Reasoning Foundations of Medical Diagnosis, 130 SCIENCE 9, 9 (1959) ("[T]o make a differential diagnosis, I list all the diseases which the specific case can reasonably resemble. Then I exclude one disease after another from the list until it becomes apparent that the case can be fitted into a definite disease category, or that it may be one of several possible diseases, or else that its exact nature cannot be determined.). Courts have also used and defined the term "differential diagnosis." See Westberry v. Gislaved Gummi AB, 178 F.3d 257, 262 (4th Cir. 1999) ("Differential diagnosis, or differential etiology, is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated."); Nelson v. Matrixx Initiatives, No. C 09-02904 WHA, 2012 WL 3627399, at \*6 (N.D. Cal. Aug. 21, 2012); Hendrix v. Evenflo Co., 609 F.3d 1183, 1189 (11th Cir. 2010); McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1252 (11th Cir. 2005).

<sup>9.</sup> See Thor v. Superior Court, 855 P.2d 375, 380-83 (Cal. 1993).

There is respectable evidence to suggest that informed consent may have its origins in ancient times. <sup>10</sup> Insofar as American law is concerned, the following pronouncement by Judge Cardozo, in *Schloendorff v. Society of New York Hospital*, <sup>11</sup> that "[e] very human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent, commits an assault, for which he is liable in damages, "<sup>12</sup> has been extolled by courts<sup>13</sup> and is central to the concept of patient autonomy. *Schloendorff*, however, did not speak to the scope of informed consent, or more specifically, to the scope of the physician's required disclosure necessary to obtain the patient's consent. <sup>14</sup> Another equally celebrated opinion, *Canterbury v. Spence*, did. <sup>15</sup> This is the point of departure for this Article.

#### III. A PROCEDURE (OR TREATMENT) BASED DOCTRINE

The doctrine of informed consent should be a focused procedure or treatment based doctrine, not a "full disclosure" doctrine. The distinction should not be blurred or confused. A recent example of this confusion and its eventual, fortunate consequences will be discussed later in this Article. <sup>16</sup>

I have previously written about (and still subscribe to) the fundamental principles of informed consent, <sup>17</sup> as follows: "The doctrine of informed consent requires physicians to disclose to patients (without having been asked by the patient) the risks and benefits of, and alternatives to, proposed treatment. The doctrine may be based in common law or in statute."

<sup>10.</sup> P. Dalla-Vorgia et al., Is Consent in Medicine a Concept Only of Modern Times?, 27 J. MED. ETHICS 59, 59 (2001).

<sup>11. 105</sup> N.E. 92, 93 (N.Y. 1914).

<sup>12.</sup> Id.

<sup>13.</sup> See Canterbury v. Spence, 464 F.2d 772, 780 (D.C. Cir. 1972); Thor, 855 P.2d at 378.

<sup>14.</sup> Schloendorff, 105 N.E. at 93.

<sup>15.</sup> Canterbury, 464 F.2d at 782-83.

<sup>16.</sup> See Jandre v. Wis. Injured Patients & Families Comp. Fund, 813 N.W.2d 627 (Wis. 2012); see also Wis. STAT. § 448.30 (2008), repealed and replaced by Wis. STAT. ANN. § 448.30 (West 2013).

<sup>17.</sup> Ginsberg, supra note 2, at 19-20.

<sup>18.</sup> Id. (citing Canterbury, 464 F.2d at 783; Ficke v. Evangelical Health Sys., 674 N.E.2d 888, 889 (III. App. Ct. 1996); Blotner v. Doreika, 678 S.E.2d 80, 81 (Ga. 2009) (noting that the state of Georgia does not recognize the common law doctrine of informed consent)).

Consequently, the doctrine of informed consent presumes that the physician has engaged in the process of and obtained a differential diagnosis for the patient. <sup>19</sup> This process involves "making a diagnostic choice between alternatives, disproving the unlikely and trying to prove one (or more) to be correct." <sup>20</sup> This process further involves the physician "asking two questions: Does the diagnosis explain all the findings?, and, Are the expected findings present?" <sup>21</sup>

This process is intended to result in a diagnosis and treatment recommendation. It is the treatment recommendation, realistic, available, alternative treatments for the diagnosed condition, and risks and complications of treatment (or no treatment) that must be disclosed by the physician in order to obtain the patient's informed consent to treatment.

These parameters (or limitations) of the doctrine of informed consent cannot be overemphasized. *Canterbury*<sup>22</sup> speaks to the scope of the doctrine:

The context in which the duty of risk-disclosure arises is invariably the occasion for decision as to whether a particular treatment procedure is to be undertaken.

. . .

It is a duty to warn of the dangers lurking in the proposed treatment . . . . We now find, as a part of the physician's overall obligation to the patient, a similar duty of reasonable disclosure of the choices with respect to proposed therapy and the dangers inherently and potentially involved.

. . .

In broad outline, we agree that '[a] risk is thus material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk . . . in deciding whether or not to forego the proposed therapy.'

. . .

<sup>19.</sup> See, e.g., Clausen v. M/V New Carissa, 339 F.3d 1049, 1057 (9th Cir. 2003) (discussing various descriptions of the differential diagnosis).

<sup>20.</sup> Robert B. Price & Z. Reno Vlahcevic, Logical Principles in Differential Diagnosis, 75 Annals Internal Med. 89, 90 (1971).

<sup>21.</sup> Id. at 90-91.

<sup>22.</sup> Canterbury, 464 F.2d 772.

The topics importantly demanding a communication of information are the inherent and potential hazards of the proposed treatment, the alternatives to that treatment, if any, and the results likely if the patient remains untreated.<sup>23</sup>

Canterbury does not solely describe the purpose of the doctrine. It demands the understanding that the doctrine is not simply one of "full disclosure," i.e., that the physician is not obligated to disclose to the patient the entire thought process of the differential diagnosis, diagnoses disregarded, and treatment not recommended as the end product of the differential diagnostic process.<sup>24</sup>

Were this not so, consider the predicament for the physician, especially when caring for patients with common complaints. A patient sees a primary care physician in the office and complains of low back pain. The differential diagnosis of low back pain includes numerous (approximately three dozen) diseases grouped under the headings of mechanical low back pain, non-mechanical spine disease, and visceral disease. Or, assume our hypothetical patient complains of chronic daily headaches. A similarly extensive differential diagnosis applies. This differential diagnosis has been characterized as "challenging." Or, assume our hypothetical patient is a child complaining of acute abdominal pain. Medical literature has reported on eight categories (each with multiple diseases) of causes of acute abdominal pain in children.

Next, consider the process of the differential diagnosis in connection with length of office visit. There is a substantial body of medical scholarship concerning the length of the office visit and quality of care.<sup>29</sup>

<sup>23.</sup> Id. at 781, 782 & 787-88.

<sup>24.</sup> The differential diagnostic process will consider and reject potential diseases. The failure "to investigate an otherwise unindicated disease is not malpractice." Curry v. Dr. Elena Vezza Physician, P.C., 963 N.Y.S.2d 661, 662 (N.Y. App. Div. 2013).

<sup>25.</sup> Steven J. Atlas & Richard A. Deyo, Evaluating and Managing Acute Low Back Pain in the Primary Care Setting, 16 J. Gen. INTERNAL Med. 120, 121 (2001).

<sup>26.</sup> Marcelo E. Bigal & Richard B. Lipton, *The Differential Diagnosis of Chronic Daily Headaches: An Algorithm-Based Approach*, 8 J. HEADACHE PAIN 263, 264 (2007).

<sup>27.</sup> Id.

<sup>28.</sup> Alexander K.C. Leung & David L. Sigalet, Acute Abdominal Pain in Children, 67 Am. FAM. PHYSICIAN 2321, 2322 (2003); see also William G. Sheridan et al., Non-Specific Abdominal Pain: The Resource Implications, 74 ANNALS ROYAL COLL. SURGEONS ENG. 181, 182 (1992) (noting numerous miscellaneous diagnoses for patients with abdominal pain).

<sup>29.</sup> See generally Clarence H. Braddock & Lois Snyder, The Doctor Will See You Shortly—The Ethical Significance of Time for the Patient-Physician Relationship, 20 J. Gen. Intern. Med. 1057 (2005); Lena M. Chen et al., Primary Care Visit Duration and Quality—Does Good Care Take Longer?, 169 Archives Internal Med. 1866 (2009); Ming Tai-Seale et al., Time Allocation in Primary Care Office Visits, 42 Health Serv.

There is evidence to suggest that "factors such as complexity of illness or a growing emphasis on patient participation in clinical decision making" increase the duration of office visits. If the doctrine of informed consent is transformed to a full disclosure doctrine, encompassing the differential diagnosis, treatments available for each possible diagnosis, and discarded diagnoses, a physician would be unable to see more than a few patients each day, and each patient would be overwhelmed with information, much of which would be unhelpful. A full disclosure doctrine is also potentially harmful to a patient's health and involves unnecessary cost. These issues will be discussed later in this Article. It is a supplied to the s

The problems associated with an overly expansive doctrine of informed consent are not theoretical. I now turn to those jurisdictions that have confused full disclosure with the doctrine of informed consent. The examination of relevant case law and statutes must begin in Wisconsin. Wisconsin's experience with the law of informed consent provides the classic example of how the judiciary does not understand medicine well and how a cure to the problem required a professional and legislative response.

#### IV. THE WISCONSIN EXPERIENCE

The history of the doctrine of informed consent in Wisconsin developed as a product of the common law and legislation. A detailed examination of six opinions of the Supreme Court of Wisconsin,<sup>32</sup> one opinion of the Seventh Circuit Court of Appeals,<sup>33</sup> legislative history<sup>34</sup> and two statutes<sup>35</sup> reveals a most interesting story.<sup>36</sup>

RES. 1871 (2007); Kimberly S. H. Yarnall et al., Primary Care: Is There Enough Time for Prevention?, 93 AM. J. PUB. HEALTH 635 (2003).

<sup>30.</sup> Chen et al., supra note 29, at 1869.

<sup>31.</sup> On a related topic, for an excellent discussion of the cost, in the largest sense, of unnecessary annual physical examinations, see Michael B. Rothberg, *The \$50,000 Physical*, 311 JAMA 2175, 2175 (2014).

<sup>32.</sup> Jandre v. Wis. Injured Patients & Fam. Comp. Fund, 813 N.W.2d 627 (Wis. 2012); Bubb v. Brusky, 768 N.W.2d 903 (Wis. 2009); Hannemann v. Bayson, 698 N.W.2d 714 (Wis. 2005); Martin v. Richards, 531 N.W.2d 70 (Wis. 1995); Scaria v. St. Paul Fire & Marine Ins. Co., 227 N.W.2d 647 (Wis. 1975); Trogun v. Fruchtman, 207 N.W.2d 297 (Wis. 1973).

<sup>33.</sup> McGeshick v. Choucair, 9 F.3d 1229 (7th Cir. 1993).

<sup>34.</sup> See Analysis by the Legislative Reference Bureau, A.B. 941 (Wis. 1981).

<sup>35.</sup> WIS. STAT. ANN. § 448.30 (West 2013); WIS. STAT. § 448.30 (1981).

<sup>36.</sup> My former student, Michael Rohde, told a part of the Wisconsin story in Michael Rohde, Information Overload: How The Wisconsin Supreme Court Expanded the Doctrine of Informed Consent, 46 J. MARSHALL L. REV. 1097 (2013); see also Krista J. Sterken et al., Mandatory Informed Consent Disclosures in the Diagnostic Context: Sometimes Less Is More, 17 N.Y.U. J. LEGIS. & PUB. POL'Y 103 (2014).

## A. Trogun v. Fruchtman<sup>37</sup>

The Wisconsin journey began in 1973, rather unremarkably, when the supreme court issued its opinion in *Trogun*. *Trogun* involved a physician's diagnosis of a patient as "possibly a diabetic" and the prescription of a diabetic diet, a diabetes medication, and another medication for "primary TB, inactive." Thereafter, the patient suffered jaundice and hepatitis. He claimed that his physician, an internal medicine specialist, "failed to adequately advise [him] of the potential side effects of the drugs he was prescribing and rendered [him] unable to make an informed consent to such treatment." The trial court granted a non-suit. The trial court granted a non-suit.

On appeal, the supreme court grappled with the doctrine of informed consent in Wisconsin, discussing the theories of liability (battery and negligence) that have historically related to the doctrine.<sup>43</sup> In opting for the negligence theory, the supreme court clearly explained that the doctrine is treatment focused.<sup>44</sup> The supreme court pronounced:

Several reasons exist for the inadequacy of the assault and battery theory . . . where the alleged misconduct on the part of the physician amounts to a failure to disclose the ramifications of a pending course of treatment, therapy or surgery . . . .

. . .

We conclude that the burden of proof is on the plaintiff to establish a physician's failure to disclose particular risk information in connection with contemplated treatment . . . . Experts are unnecessary to establish the materiality of the risk to a patient's decision to undergo treatment or to the "reasonably, expectable effect of risk disclosure on the decision."

<sup>37. 207</sup> N.W.2d 297 (Wis. 1973).

<sup>38.</sup> Id. at 299.

<sup>39.</sup> Id. at 299. See generally Stefan Grzybowski, Tuberculosis: A Look at the World Situation, 84 CHEST 756 (1983); Woa Kyung Moon et al., Mediastinal Tuberculous Lymphadenitis: CT Findings of Active and Inactive Disease, 170 Am. J. ROENTGENOLOGY 715 (1998); P. Van Dyck et al., Imaging of Pulmonary Tuberculosis, 13 EUR. RADIOLOGY 1771 (2003).

<sup>40.</sup> Trogun, 207 N.W.2d at 300.

<sup>41.</sup> Id. at 299.

<sup>42.</sup> Id. at 300.

<sup>43.</sup> Id. at 309-10.

<sup>44.</sup> Id. at 312, 315.

<sup>45.</sup> Id. (quoting Canterbury v. Spence, 464 F.2d 772, 792, n.41).

Indeed, the supreme court referred to Dean Prosser's explanation of the doctrine of informed consent, which he explained as "the duty of the physician or surgeon to inform the patient of the risk which may be involved in treatment or surgery."46

In *Trogun*, therefore, the Wisconsin Supreme Court recognized the classic treatment or procedure based doctrine of informed consent, consistent with *Canterbury*, as a part of Wisconsin's common law. All would not be well for long, however, as the journey would become more complicated and troublesome.

## B. Scaria v. St. Paul Fire & Marine Insurance Co. 47

Scaria deserves significant attention. Not only is it one of the cases which would shape the law of informed consent in Wisconsin; it was, presumably, the impetus for Wisconsin's first informed consent statute. <sup>48</sup> The arrival of the statute six years after Scaria, <sup>49</sup> and its relationship with Scaria's holdings, must be analyzed closely in an effort to understand the supreme court's Jandre<sup>50</sup> opinion in 2012.

Mr. Scaria had suffered a hay fever attack and saw an allergist, who prescribed medication at that time.<sup>51</sup> At a subsequent appointment, the allergist took Mr. Scaria's blood pressure and diagnosed severe hypertension<sup>52</sup> and referred him to an internal medicine/cardiology specialist.<sup>53</sup>

Mr. Scaria was hospitalized for further testing, including an aortogram, a procedure which "will demonstrate renal parenchymal diseases which may result in hypertension." He was advised how the procedure would be performed, including "how the catheter would be introduced into the femoral artery through an incision in the groin,

<sup>46.</sup> Id. at 312 (quoting WILLIAM L. PROSSER, LAW OF TORTS 165 (4th ed. 1971)).

<sup>47. 227</sup> N.W.2d 647 (Wis. 1975).

<sup>48.</sup> WIS. STAT. § 448.30 (1981).

<sup>49. 227</sup> N.W.2d 647.

<sup>50.</sup> Jandre v. Wis. Injured Patients & Fam. Comp. Fund, 813 N.W.2d 627 (Wis. 2012).

<sup>51.</sup> Hay fever is defined as "seasonal allergic rhinitis." Allergic Rhinitis, AMER. ACAD. OF ALLERGY ASTHMA & IMMUNOLOGY, http://www.aaaai.org/conditions-and-treatments/conditions-a-to-z-search/Allergic-Rhinitis.aspx (last visited May 5, 2014); Bonnie Sibbald & Elizabeth Rink, Labelling of Rhinitis and Hayfever by Doctors, 46 THORAX 378, 378–79 (1991).

<sup>52.</sup> See Joseph Varon & Paul E. Marik, The Diagnosis and Management of Hypertensive Crises, 118 CHEST 214, 214 (2000).

<sup>53.</sup> Scaria, 227 N.W.2d at 649.

<sup>54.</sup> Arch W. Templeton, *Renal Aortography*, 95 Am. J. ROENTGENOLOGY 383, 383 (1965).

how... dye would be injected, and how the X rays [sic] would be taken."<sup>55</sup> The procedure commenced, after which Mr. Scaria "experienced a severe pain and involuntary jerking of his legs,"<sup>56</sup> "back pain and a funny feeling in his legs,"<sup>57</sup> leg numbness, <sup>58</sup> leg paralysis and, ultimately, permanent paralysis "from the waist down."<sup>60</sup>

Not surprisingly, the lawsuit that was the subject of *Scaria* alleged "a lack of informed consent and negligent post-operative care." The supreme court opinion makes clear that the plaintiff and defendant had a serious disagreement as to the risks of the aortogram, which had been disclosed to the patient in order to obtain the patient's informed consent. Depending on the testimony, plaintiff was either advised or not advised that:

[O]ne in a thousand cases there will be a possibility of some complications, but that's not important . . . . [T]here was a possibility of a clot forming in the site of the injection . . . .

. . .

[T]he risk of the procedure was less than that of an appendectomy and that the most common problem would be pain in the groin, that he could have a problem bleeding, primarily into the skin near the puncture site, possibly developing into a hematoma or blood clot, that possibly a clot could develop in the vessel at the puncture site or an embolism could go peripherally into his leg.... [H]e could experience an allergic reaction to the dye.....

The defendant physician "testified that he was aware of other risks about which he did not inform Scaria, including the possibility of plaque traveling into a vein in the leg, a punctured artery, a pseudoaneurysm, a punctured aorta, an asthma-like condition, and adverse reactions to the

<sup>55.</sup> Scaria, 227 N.W.2d at 650.

<sup>56.</sup> Id. at 651.

<sup>57.</sup> Id.

<sup>58.</sup> *Id*.

<sup>59.</sup> Id.

<sup>60.</sup> Id. Post-aortography leg paralysis has been described in the medical literature. See Duncan A. Killen & John H. Foster, Spinal Cord Injury as a Complication of Aortography, 152 ANNALS SURGERY 211, 211 (1960).

<sup>61.</sup> Scaria, 227 N.W.2d at 651.

<sup>62.</sup> Id. at 650.

<sup>63.</sup> Id. at 650.

dye."<sup>64</sup> The physician was aware that "[t]he consequences of these occurrences could possibly be death, paralysis or loss of limb."<sup>65</sup> A reading of the supreme court's opinion suggests that Scaria was not advised that paralysis could ensue from a potential complication. Scaria testified that if he had been informed of the risks and complications, he would not have consented to the aortogram.<sup>66</sup>

At trial, the jury returned verdicts for the defendants.<sup>67</sup> On appeal, informed consent was central to the supreme court's review.<sup>68</sup>

With respect to the supreme court's analysis of informed consent and disclosure requirements, it is of paramount importance to understand that *Scaria* focused on a specific medical procedure (aortogram) and the preprocedure disclosure to the patient necessary to obtain the patient's informed consent. It is only with this understanding that a thorough review of *Scaria*, Wisconsin's first informed consent statute, <sup>69</sup> and *Jandre*, <sup>70</sup> is possible.

The supreme court generally previewed the physician's informed consent disclosure requirement as the "doctor's duty to disclose and the patient's right to be informed of the risks of the proposed treatment or surgery." This statement suggests a focus on the specific treatment recommended to the patient. The court continued this theme by commenting that "[t]he right to be recognized and protected is the right of the patient to consent or not consent to a proposed medical treatment or procedure." The disclosure would include not only the proposed treatment but "inherent and potential risks" attendant thereto, "the probabilities of success, and any alternative treatment or procedures if such are reasonably appropriate so that the patient has the information reasonably necessary to form the basis of an intelligent and informed consent to the proposed treatment or procedure." The key here is that the doctrine of informed consent relates to "the treatment or procedure proposed." This is the focus of the doctrine as contemplated by

<sup>64.</sup> Id.

<sup>65.</sup> Id. at 650-51.

<sup>66.</sup> Id. at 651.

<sup>67.</sup> Id. at 651-52.

<sup>68.</sup> Id. at 652.

<sup>69.</sup> WIS. STAT. § 448.30 (1981).

<sup>70.</sup> Jandre v. Wis. Injured Patients & Fam. Comp. Fund, 813 N.W.2d 627 (Wis. 2012).

<sup>71.</sup> Scaria, 227 N.W.2d at 652.

<sup>72.</sup> Id. at 653.

<sup>73.</sup> Id.

<sup>74.</sup> Id.

<sup>75.</sup> Id. at 654.

Canterbury v. Spence. 76 A diagnosis is reached, treatment or a procedure is recommended, and consent is obtained. 77

C. The Original Wisconsin "Informed Consent" Statute<sup>78</sup>

Six years following *Scaria*, in 1981, Wisconsin adopted a statute entitled "Information on Alternate Modes of Treatment." This statute provided as follows:

Any physician who treats a patient shall inform the patient about the availability of all alternate, viable medical modes of treatment and about the benefits and risks of these treatments. The physician's duty to inform the patient under this section does not require disclosure of:

- (1) Information beyond what a reasonably well-qualified physician in a similar medical classification would know.
- (2) Detailed technical information that in all probability a patient would not understand.
- (3) Risks apparent or known to the patient.
- (4) Extremely remote possibilities that might falsely or detrimentally alarm the patient.
- (5) Information in emergencies where failure to provide treatment would be more harmful to the patient than treatment.
- (6) Information in cases where the patient is incapable of consenting.<sup>80</sup>

This is *not* a classic informed consent statute; it is much broader in focus. In fact, it is a "physician disclosure" statute. It is *not* limited to a specifically recommended treatment or procedure, as is contemplated by

<sup>76. 464</sup> F.2d 772 (D.C. Cir. 1973).

<sup>77.</sup> Id. at 272-74.

<sup>78.</sup> WIS, STAT. § 448.30 (1981).

<sup>79.</sup> Id.

<sup>80.</sup> Id.

the doctrine of informed consent. <sup>81</sup> It requires that the physician disclose "the availability of all alternate, viable medical modes of treatment and about the benefits and risks of these treatments." <sup>82</sup> The problem with the scope of the new statute is that it might require the physician's disclosure of the entire differential diagnosis, including discarded diagnoses, and all "viable medical modes of treatment," whether or not recommended by the physician. <sup>83</sup> Essentially, although perhaps not predicted, this statute could substantially and dangerously enlarge the doctrine of informed consent to a doctrine never contemplated and one which is entirely unworkable and potentially dangerous.

It is not clear to this author how this statute became the law of Wisconsin. There is very little legislative history available, but that which is available can be obtained from the Wisconsin Legislative Reference Bureau.<sup>84</sup>

On January 2, 1982, a Fiscal Estimate was prepared regarding the "Regulation of Medical Practice" and the proposed statute.<sup>85</sup> In relevant part, this Fiscal Estimate provides:

This proposal requires physicians to inform patients of available options and treatment methods including information of risks and benefits of treatment procedures. *Presumably, this professional practice requirement will increase complaints against physicians licensed by the Medical Examining Board*.... It is estimated that this proposal would increase the current complaint caseload by approximately 25%. 86

These comments suggest that the new legislation will increase complaints against physicians, presumably because of the breadth of the statute. The Fiscal Estimate also indicates the need to add another "Regulation Compliance Investigator" in order "to process additional complaints generated by the bill."

<sup>81.</sup> See id.

<sup>82.</sup> Id.

<sup>83.</sup> Id.

<sup>84.</sup> The Legislative Reference Bureau home page states "[t]he LRB provides nonpartisan, professional, and confidential bill drafting, legal publishing, research and library services to the legislature and the public." See STATE OF WISCONSIN LEGISLATIVE REFERENCE BUREAU, http://legis.wisconsin.gov/lrb/ (last visited June 27, 2014).

<sup>85.</sup> FISCAL ESTIMATE, A.B. 941 (Wis. 1982).

<sup>86.</sup> Id. (emphasis added).

<sup>87.</sup> Id.

<sup>88.</sup> Id.

Of greater importance is the bill's Analysis by the Legislative Reference Bureau. This analysis provides in relevant part that "[t]his bill places in the statutes the standard of care that physicians are required to meet under Scaria. The bill requires physicians who treat patients to inform their patients about the availability of all alternate, viable medical modes of treatment and about the benefits and risks of these treatments." This analysis misconstrues Scaria and suggests that it was a pronouncement of a full disclosure statute rather than an informed consent statute. There is nothing contained in the legislative history materials obtained from the Legislative Reference Bureau indicating why the proposed legislation was so broad. The proposed legislation may have been a product of a political agenda unknown to this author. Whatever the motivation for the statute, it would become an enemy of Wisconsin physicians.

## D. Martin v. Richards (Court of Appeals)90

The facts in *Martin* are not complicated. A young patient suffered intracranial bleeding after a head injury following a bicycle accident. Unfortunately, an emergency medicine physician diagnosed her with a concussion. Later in the hospital, the patient worsened. She became "somewhat irritable, uncooperative and uncommunicative." Thereafter, she became unresponsive and was transported to a university medical center where CT scans revealed bleeding in her head, requiring surgery. As a result, the patient became "a spastic quadriparetic, with serious speech and physical handicaps, although with normal or near normal intelligence."

The initial emergency medicine physician, having diagnosed a concussion, did not inform the patient's parents "that a CAT scan would disclose whether [the patient] was suffering intracranial bleeding or that the hospital did not have a neurosurgeon on staff or on call." The

<sup>89.</sup> Analysis by the Legislative Reference Bureau, A.B. 941, supra note 34.

<sup>90. 500</sup> N.W.2d 691 (Wis. Ct. App. 1993).

<sup>91.</sup> Id. at 693.

<sup>92.</sup> Id. at 695. A concussion is "an immediate and transient loss of consciousness accompanied by a brief period of amnesia after a blow to the head." Allan H. Ropper & Kenneth C. Gorson, Concussion, 356 New Eng. J. Med. 166, 166 (2007).

<sup>93.</sup> Martin, 500 N.W.2d at 695.

<sup>94.</sup> Id.

<sup>95.</sup> Id.

<sup>96.</sup> Id.

Wisconsin Court of Appeals considered whether this non-disclosure implicated the Wisconsin "informed consent" statute.<sup>97</sup>

The defendant physician reasonably asserted that the statute should not apply insofar as he diagnosed a concussion, and therefore, "he had no duty... to inform [the patient's] parents of modes of treatment for" an intracranial bleed.<sup>98</sup> The court of appeals disagreed, noting that the defendant read the statute "too narrowly," stating that the statute "is concerned entirely with information and knowledge." Curiously, the court also noted that defendant's position "creat[ed] a strong disincentive for full disclosure to the patient" and "is contrary to the intention of the legislature." Again, the doctrine of informed consent was never intended as a full disclosure doctrine. As to the legislative intent of statute 448.30, the mystery continues.

The dissent cogently noted that *Martin* was not an informed consent case. <sup>103</sup> The dissent also correctly noted that *Scaria* provided a narrower, classic approach to the law of informed consent. <sup>104</sup>

Following *Martin*, an anomalous situation confronted Wisconsin physicians. A medical negligence defendant could be found not liable for "negligence" but liable for failing to provide a full disclosure pursuant to the Wisconsin informed consent statute.

#### E. McGeshick v. Choucair 105

Shortly after the *Martin* opinion, the Seventh Circuit Court of Appeals decided *McGeshick v. Choucair*. Here, the court considered a claim against a physician who examined and treated the patient at a clinic to which the patient was referred. The patient suffered low back pain, possibly caused by spinal cord disease. At the initial examination, the defendant physician "could not rule out any of the possible causes of [plaintiff's] myelopathy." Thereafter, a CT myelogram was

<sup>97.</sup> Id. at 696-97

<sup>98.</sup> Id. at 697.

<sup>99.</sup> Id.

<sup>100.</sup> Id.

<sup>101.</sup> Id.

<sup>102.</sup> Id.

<sup>103.</sup> Id. at 701.

<sup>104.</sup> Id. at 702.

<sup>105. 9</sup> F.3d 1229 (7th Cir. 1993).

<sup>106.</sup> Id.

<sup>107.</sup> Id. at 1230.

<sup>108.</sup> Id.

<sup>109.</sup> Id.

performed in order to screen for types of myelopathy.<sup>111</sup> This study was interpreted with certain findings, but the interpretation did not suggest a spinal arteriovenous malformation (AVM).<sup>112</sup> A spinal MRI<sup>113</sup> was recommended, however, due to the CT myelogram findings.<sup>114</sup>

The spinal MRI was performed at a different institution. The interpretation was inconclusive, but referred to the necessity of angiography "[i]f there [were] clinical signs or symptoms of dural or intraspinal AV fistula or malformation . . . . This interpretation was sent to the defendant physician who had ordered the myelogram. He did not recommend the spinal angiogram.

Ultimately, the defendant physician continued to see the plaintiff, who began to develop spinal vascular symptoms. 119 A follow-up MRI was ordered, but before it could be performed (due to an inoperable machine), the plaintiff suffered lower body paralysis. 120 The plaintiff underwent surgery which "revealed that a spinal AVM was the cause of [plaintiff's] myelopathy." 121 The AVM caused plaintiff's permanent paralysis. 122

<sup>110.</sup> See generally AM. COLL. OF RADIOLOGY, ACR-ASNR-SPR PRACTICE GUIDELINE FOR THE PERFORMANCE OF MYELOGRAPHY AND CISTERNOGAPHY (2014), available at http://www.acr.org/~/media/f4c49aa1834d46a081f5f0ff20e1e26b.pdf (explaining myelography).

<sup>111.</sup> McGeshick, 9 F.3d at 1231.

<sup>112.</sup> Id. For discussions of spinal AVM's, see generally Bruce Rosenblum et al., Spinal Arteriovenous Malformations: A Comparison of Dural Arteriovenous Fistulas and Intradural AVM's in 81 Patients, 67 J. NEUROSURGERY 795 (1987); Robert F. Spetzler et al., Modified Classification of Spinal Cord Vascular Lesions, 96 J. NEUROSURGERY 145 (2002).

<sup>113.</sup> See generally AM. COLL. OF RADIOLOGY, ACR-ASNR-SCBT-MR PRACTICE PARAMETER FOR THE PERFORMANCE OF MAGNETIC RESONANCE IMAGING (MRI) OF THE ADULT SPINE (2014), available at http://www.asnr.org/sites/default/files/guidelines/MRI\_Adult\_Spine.pdf.

<sup>114.</sup> McGeshick, 9 F.3d at 1231.

<sup>115.</sup> Id.

<sup>116.</sup> Id.

<sup>117.</sup> Id.

<sup>118.</sup> Id. For a discussion of the history of spine imaging, including spinal angiography, see generally E.G. Hoeffner et al., Neuroradiology Back to the Future: Spine Imaging, 33 Am. J. Neuroradiology 999 (2012); see also Timo Krings et al., Spinal Vascular Malformations, 15 Eur. Radiology 267, 268 (2005) (noting that "[s]elective spinal angiography is the next diagnostic step once neurological symptoms and MRI speak in favor of a SVM [spinal vascular malformations] to define the type of vascular malformation and, thereby, to decide the appropriate therapy.").

<sup>119.</sup> McGeshick, 9 F.3d at 1231.

<sup>120.</sup> Id.

<sup>121.</sup> Id.

<sup>122.</sup> Id.

At trial, "the court . . . refused to give an instruction that [defendant] had a duty to inform [plaintiff] about the possible causes of his myelopathy and the possibility of angiography as a diagnostic measure to exclude one of these causes." It should be recalled that the defendant did *not* order spinal angiography. 124

The Seventh Circuit reviewed the "Wisconsin law on the extent of the duty to inform," specifically referring to Trogun, scaria, specifically referring to Trogun, scaria, specifically referring to Trogun, scaria, series and the 1981 statute, described by the Seventh Circuit as "an informed consent law that codified the common law as it existed at the time in Wisconsin." The Seventh Circuit concluded that "[t]he plain language of both the cases and the statute limit the doctrine of informed consent to apprising the patient of the risks that inhere in a proposed treatment... or in a procedure.... so in a procedure.... so, the court agreed with the Martin dissent (previously discussed in this Article) and pronounced that Wisconsin's statute "does not impose on the physician a general duty to inform the patient; it limits the duty to inform to situations in which the physician has proposed a recommended course of treatment." The Seventh Circuit predicted that the Wisconsin Supreme Court would not "adopt the reasoning of the [Martin] appellate court," and held that the trial court properly refused to give an informed consent instruction in the case at bar. 133

## F. Martin v. Richards (Supreme Court) 134

The Wisconsin Supreme Court did not follow the Seventh Circuit's lead. In recounting the facts, the supreme court noted its understanding that the emergency medicine physician diagnosed a concussion and not an intracranial bleed. The supreme court referred to the statute and stated: "This language appears clear in its directive. The difficulty in applying the statute, however, is in determining how far the duty to

<sup>123.</sup> Id.

<sup>124.</sup> Id.

<sup>125.</sup> Id. at 1232.

<sup>126.</sup> Trogun v. Fruchtman, 207 N.W.2d 297 (Wis. 1973).

<sup>127.</sup> Scaria v. St. Paul Fire & Marine Insurance Co., 227 N.W.2d 647 (Wis. 1975).

<sup>128.</sup> WIS. STAT. § 448.30 (1981).

<sup>129.</sup> McGeshick, 9 F.3d at 1233.

<sup>130.</sup> Id.

<sup>131.</sup> Id. at 1234.

<sup>132.</sup> Id.

<sup>133.</sup> Id. at 1235.

<sup>134. 531</sup> N.W.2d 70 (Wis. 1995).

<sup>135.</sup> Id. at 74.

<sup>136.</sup> WIS. STAT. § 448.30 (1981).

disclose extends, i.e., what is considered an alternate, viable mode of treatment."<sup>137</sup> Of course, the supreme court, by asking this question, really begged the crucial one—does the statute require disclosure of non-diagnosed conditions and treatment options for those conditions?

The Wisconsin Supreme Court referred to the Analysis by the Legislative Reference Bureau—previously discussed in this article—and incorrectly, in my estimation, found that "[t]he language of the statute parrots that of the language in Scaria, requiring physicians to disclose alternate, viable forms of treatment and the risks and benefits of those treatments." The holding in Scaria, as earlier discussed, was actually narrower, focusing on the medical treatment or procedure proposed by the physician, not on the universe of potentially applicable diagnoses and treatments. 139

In the end, in *Martin*, the supreme court characterized the statute as a "right to know"<sup>140</sup> law, requiring the broad disclosure of information not driven by the actual diagnosis. <sup>141</sup> The *Martin* opinion, therefore, provided the foundation for the subsequent, regrettable jurisprudence of the Wisconsin Supreme Court.

## G. Hannemann v. Boyson<sup>142</sup>

In Hannemann, the Wisconsin Supreme Court held "that the scope of a chiropractor's duty to obtain informed consent is the same as that of a medical doctor." In doing so, however, the supreme court referred to its holdings in Scaria and Martin as if they were consistent. For example, the supreme court, pursuant to Martin, couched the concept of informed consent as relating to "the procedure proposed" or to "request an alternative treatment or method of diagnosis." Of course, this is not the classic doctrine of informed consent; it represents a doctrine of full disclosure. In the next sentence, in referring to Scaria, the

<sup>137.</sup> Martin, 531 N.W.2d at 76.

<sup>138.</sup> Id. at 78.

<sup>139.</sup> This is precisely the point of the defendant physician's position, as recognized by the Wisconsin Supreme Court. *Id.* at 80 ("Dr. Richards argues the statute should not impose a duty upon doctors to inform patients of alternate treatments for a condition not diagnosed or not being treated by the physician.").

<sup>140.</sup> Id. at 81.

<sup>141.</sup> Id.

<sup>142. 698</sup> N.W.2d 714 (Wis. 2005).

<sup>143.</sup> Id. at 718.

<sup>144.</sup> Scaria v. St. Paul Fire & Marine Insurance Co., 227 N.W.2d 647 (Wis. 1975).

<sup>145.</sup> Martin v. Richards, 531 N.W.2d 70 (Wis. 1995).

<sup>- 146.</sup> Hannemann, 698 N.W.2d at 728 (quoting Martin, 531 N.W.2d at 79).

<sup>147.</sup> Id.

supreme court defined informed consent as "a duty to 'make such disclosures as appear reasonably necessary under circumstances then existing to enable a reasonable person under the same or similar circumstances confronting the patient at the time of disclosure to intelligently exercise his right to consent or to refuse the treatment or procedure proposed." This statement represents the classic form of the doctrine.

Therefore, the *Hannemann* opinion only served to confuse Wisconsin's common law of informed consent with its post-statutory jurisprudence. This problem would only worsen. 149

## H. Bubb v. Brusky<sup>150</sup>

In *Bubb*, the Wisconsin Supreme Court considered the dismissal of an informed consent claim that was affirmed on appeal. <sup>151</sup> The supreme court adhered to its broad interpretation of statute 448.30, holding that it "requires any physician who treats a patient to inform the patient about the availability of all alternate, viable medical modes of treatment, including diagnosis, as well as the benefit and risks of such treatments." <sup>152</sup> This holding is simply not representative of the classical law of informed consent.

Bubb is another example of a failure to diagnose having been misinterpreted by the supreme court, with the assistance of the statute, as an informed consent claim. Here, an emergency medicine (ER) physician attended to a patient who had fallen from his chair while eating dinner. <sup>153</sup> An ambulance took him to the hospital. <sup>154</sup> The ER physician ordered various tests and the patient began to improve. <sup>155</sup> The ER physician

<sup>148.</sup> Id. (quoting Scaria, 227 N.W.2d at 654).

<sup>149.</sup> It should be noted here that the Wisconsin Supreme Court continued its broad interpretation of section 448.30 of the Wisconsin statute in Johnson v. Kokemoor, 545 N.W.2d 495 (Wis. 1996). The opinion emphasized that Wisconsin's doctrine of informed consent is not limited to the disclosure of "only significant complications intrinsic to the contemplated procedure." *Id.* at 504. The court continued in its position that the statute pertains to disclosure of information. Insofar as *Johnson* focused on a novel issue, the disclosure of physician experience (or inexperience) as a possible risk to the patient, and continued with the previously discussed, strange and confusing approach to informed consent, it is not a case featured in this paper. *Johnson*, however, was discussed by this author in, Ginsberg, *supra* note 2, at 39–40.

<sup>150. 768</sup> N.W.2d 903 (Wis. 2009).

<sup>151.</sup> Bubb v. Brusky, 756 N.W.2d 187 (Wis. Ct. App. 2008), rev'd, 768 N.W.2d 903.

<sup>152.</sup> Bubb, 768 N.W.2d at 925.

<sup>153.</sup> Id. at 905.

<sup>154.</sup> Id.

<sup>155.</sup> Id.

diagnosed a transient ischemic attack (TIA)<sup>156</sup> and contacted a neurology consultant, who agreed to see the patient.<sup>157</sup> The defendant ER physician prescribed aspirin, advised the patient to see the neurologist the next morning, and discharged the patient.<sup>158</sup>

The appointment with the neurologist was scheduled but never occurred. The patient "suffered a large-scale stroke, affecting the right side of his brain." He was left with permanent disabilities.

Suit was filed on behalf of the patient against the ER physician and the neurologist. <sup>161</sup> The complaint contained a claim against the ER physician alleging that he "was liable for failing to properly inform [the patient] of 'additional diagnostic tests or alternate treatment plans' in lieu of discharge from the hospital." <sup>162</sup>

The defendant ER physician cogently urged that this was not an informed consent case. <sup>163</sup> His position was "choosing between two recognized methods [of treatment or diagnosis] doesn't necessarily mean that the physician must instruct the patient on the other recognized method." Essentially, this argument asserts that the doctrine of informed consent does not require the disclosure of the differential diagnosis and does not require the disclosure of treatments for discarded differential diagnoses. If the physician fails to arrive at the correct diagnosis, this implicates classic medical negligence but not the failure to obtain informed consent.

The supreme court reviewed the history of its informed consent jurisprudence and reviewed the statute, <sup>165</sup> as it had done in prior opinions. Again, the supreme court dismissed any incongruity between Wisconsin's pre-statute common law and the post-statute jurisprudence by stating: "Consequently, the standards set forth in *Trogun* and *Scaria* are implicated in the interpretation of Wis. Stat. § 448.30." Again, the

<sup>156.</sup> Id. "A transient ischemic attack (TIA) has been defined classically as 'rapidly developed clinical signs of focal or global disturbance of cerebral function lasting fewer than 24 hours, with no apparent non-vascular cause." S. Claiborne Johnston et al., National Stroke Association Guidelines for the Management of Transient Ischemic Attacks, 60 Annals Neurology 301, 301 (2006). See generally Michael Daffertshofer et al., Transient Ischemic Attacks Are More than "Ministrokes," 35 STROKE 2453 (2004).

<sup>157.</sup> Bubb, 768 N.W.2d at 905.

<sup>158.</sup> Id. at 906.

<sup>159.</sup> Id.

<sup>160.</sup> Id.

<sup>161.</sup> Id.

<sup>162.</sup> Id.

<sup>163.</sup> Id. at 909.

<sup>164.</sup> Id. at 914.

<sup>165.</sup> WIS. STAT. § 448.30 (1981).

<sup>166.</sup> Bubb, 768 N.W.2d at 918.

supreme court persisted in its broad interpretation of the statute, commenting that the medical facts "demonstrate that a reasonable jury could conclude that a reasonable person in [plaintiff's] condition would have wanted to know about the alternative of admission with further diagnostic testing." To this statement, I pose the following question: how would the patient have the wherewithal to know if he should have been admitted to the hospital? This exposes the fallacy of the supreme court's position and the breadth of the statute. The patient should have been admitted to the hospital for tests, and was not; if the ER physician arrived at the improper diagnosis, these facts support a medical negligence claim unrelated to the doctrine of informed consent.

In the end, the Wisconsin Supreme Court approved the jury's verdict in favor of the ER physician on the medical negligence claim and noted this defense-friendly verdict did not relieve the physician from statutory liability for the failure to disclose. <sup>168</sup>

Approximately three years later, the Wisconsin Supreme Court again had the occasion to revisit the law of informed consent.<sup>169</sup> The aftermath caused a profound and necessary change in Wisconsin law.

*I.* Jandre v. Wisconsin Injured Patients & Families Compensation Fund<sup>170</sup>

In *Jandre*, the supreme court once again put its stamp of approval on the law of informed consent as a law of full disclosure.<sup>171</sup> Here, the jury returned a verdict in favor of the defendant physician on the medical negligence claim but in favor of the patient on the informed consent claim.<sup>172</sup>

As with other post-statute cases, the *Jandre* facts focus on an alleged misdiagnosis. The patient suffered drooling, slurred speech and one-sided facial droop, dizziness, and leg weakness.<sup>173</sup> He was taken to the emergency room and was evaluated by the defendant, yielding a "differential diagnosis includ[ing] 'Bell's Palsy, stroke, TIA, all of those stroke syndromes including ischemic as well as hemorrhagic, tumors, syndromes like-things like Guillain-Barre, MS [multiple sclerosis], and

<sup>167.</sup> Id. at 923.

<sup>168.</sup> Id. at 925.

<sup>169.</sup> Jandre v. Wis. Injured Patients & Families Comp. Fund, 813 N.W.2d 627 (Wis. 2012).

<sup>170.</sup> *Id*.

<sup>171.</sup> *Id*.

<sup>172.</sup> Id. at 634.

<sup>173.</sup> Id. at 640.

multiple other things like that."174 The defendant obtained tests to rule out a stroke, but she did not order a carotid ultrasound, a non-invasive procedure that could have been performed at the hospital. 175 Ultimately, the defendant diagnosed "a mild form of Bell's palsy."176 Defendant advised the patient of the diagnosis and "prescribed medication[] and sent him home with instructions to see a neurologist for follow-up care."177 The supreme court specifically noted various medical facts that the defendant did not disclose to the patient, largely concerning the differential diagnosis as including stroke.

Three days later, "[plaintiff] saw a family medicine physician who noted that [he] exhibited signs of resolving Bell's palsy."<sup>179</sup> A week or so later, the plaintiff "suffered a full-blown stroke, which impaired his physical and cognitive abilities."<sup>180</sup> A significant carotid artery blockage was revealed by a carotid ultrasound, the test not ordered by the defendant.<sup>181</sup>

As in its other opinions addressing informed consent, the supreme court reviewed its pre- and post-statutory jurisprudence and, of course, the informed consent statute. It is important to analyze the following comment by the supreme court: "Creating informed consent requirements that allow physicians to confidently perform their all-important work without fearing unfair and unpredictable liability, and that give patients a meaningful opportunity to intelligently exercise their right of self-determination, is the challenge." It would be difficult to argue with this statement as a goal or theory of informed consent, but a doctrine unrelated to a proposed treatment or procedure is neither conventional nor comforting to physicians. One can question whether true informed consent is ascertainable.

The supreme court also stated: "The court has observed that '[w]hat constitutes informed consent in a given case emanates from what a reasonable person in the patient's position would want to know." This comment is significant, as it refers to the adoption of the reasonable

<sup>174.</sup> Id.

<sup>175.</sup> Id. at 641.

<sup>176.</sup> Id. For pertinent medical literature regarding Bell's Palsy, see generally Jeffrey D. Tiemstra & Nandini Khatkhate, Bell's Palsy: Diagnosis and Management, 76 Am. FAM. PHYSICIAN 997 (2007); Anwar Ahmed, When is Facial Paralysis Bell Palsy? Current Diagnosis and Treatment, 72 CLEVELAND CLINIC J. MED. 398 (2005).

<sup>177.</sup> Jandre, 813 N.W.2d at 641.

<sup>178.</sup> Id.

<sup>179.</sup> *Id*.

<sup>180.</sup> Id.

<sup>181.</sup> Id. at 642.

<sup>182.</sup> Id. at 635-36.

<sup>183.</sup> Id. at 636 (quoting Johnson v. Kokemoor, 545 N.W.2d 495, 502-03 (Wis. 1996)).

patient standard to govern the patient's burden of proof in an informed consent claim, <sup>184</sup> as opposed to the physician-based standard or professional model. <sup>185</sup> The latter "requires expert testimony to establish the content of a reasonable disclosure." <sup>186</sup> The former does not. <sup>187</sup> But the choice of standard, for proof purposes, is not the choice of disclosure parameters. Either model can be applied to the determination of whether a physician obtained informed consent limited to the proposed treatment or procedure.

A further comment by the supreme court is: "The court has rejected a proposed bright-line rule that would require physicians 'to disclose only significant complications intrinsic to the contemplated procedure.' The court has observed that '[t]he prudent patient standard adopted by Wisconsin in Scaria is incompatible with such a bright line rule."188 Again, the supreme court has confused the breadth of the doctrine of informed consent and the type of proof required to claim that the necessary disclosures were not made. A physician may diagnose condition "X" and recommend treatment "Y." The informed consent model adopted by the jurisdiction will determine the type of proof necessary (expert or non-expert), i.e., should the patient have been told about certain risks, benefits, and alternatives to the treatment or therapy proposed? The model does not suggest that the physician is obligated to disclose his or her entire thought process, the differential diagnosis, the discarded diagnoses, and whatever is medically possible to explore every conceivable diagnosis. This point is discussed further later in this Article.

The result of *Jandre* was to confirm the supreme court's expansive and impractical view of Wisconsin's law of informed consent. What happened next was remarkable.

#### J. Wisconsin Medicine Strikes Back

The Jandre opinion was issued on April 17, 2012. 189 On the same day, a statement issued by the Wisconsin Medical Society, the Wisconsin Chapter of the American College of Emergency Physicians, and the Wisconsin Hospital Association "expressed their disappointment that the Court's decision today fails to clarify the scope of a physician's duty to inform patients about treatment and diagnostic options the physician

<sup>184.</sup> See FURROW ET AL., supra note 4, at § 6-10(b).

<sup>185.</sup> Id. at § 6-10(a).

<sup>186.</sup> Id.

<sup>187.</sup> See id. at § 6-10(b).

<sup>188.</sup> Jandre, 813 N.W.2d at 636-37 (citing Johnson v. Kokemoor, 545 N.W.2d 495, 504 (Wis. 1996)).

<sup>189.</sup> Jandre, 813 N.W.2d 627.

does not recommend."<sup>190</sup> Among other comments, the statement concluded that "WHA, WACEP and the Society will pursue legislation in the next session to address this important issue."<sup>191</sup>

On May 25, 2012, *The Valued Voice*, a publication of the Wisconsin Hospital Association, noted that various "health care organizations have begun work on draft legislation to address . . . Jandre . . . ." The report focused on a concern with the proliferation of "defensive medicine." Furthermore, from July 2012 through April 2013, various news articles addressed *Jandre* issues. <sup>194</sup>

#### K. The New Informed Consent Statute

A detailed discussion of Wisconsin's political process pertaining to proposed legislation is unnecessary here. It is sufficient, and significant, to report that in December 2013, the governor signed into law Assembly Bill 139, which substantially amended the Wisconsin law of informed consent. <sup>195</sup> The new statute <sup>196</sup> provides as follows:

<sup>190.</sup> Press Release, Wis. Med. Soc'y, Statement by the Wisconsin Hospital Association, the Wisconsin Medical Society and the Wisconsin Chapter of the American College of Emergency Physicians Concerning the Supreme Court Decision on Jandre v Wisconsin Injured Patients and Families Compensation Fund (Apr. 17, 2012), available at <a href="https://www.wisconsinmedicalsociety.org/">https://www.wisconsinmedicalsociety.org/</a>\_WMS/casesummaries/jandre/Jandre\_statement\_04172012.pdf [hereinafter Statement].

<sup>191.</sup> *Id.* 

<sup>192.</sup> WHA Hosts Jandre Work Group, THE VALUED VOICE (Wis. Hospital Ass'n, Madison, WI), May 25, 2012, at 1, available at www.wha.org/pubarchive/valued\_voice/vv5-25-12.pdf.

<sup>193.</sup> Id.

<sup>194.</sup> Dan Shaw, Malpractice Stats Don't Support Fears About Wisconsin's Informed-Law, WIS. LAW JOURNAL (Apr. 12, 2013, http://wislawjournal.com/2013/04/12/malpractice-stats-dont-support-fears-aboutinformed-consent-law/; David Wahlberg, How Much Should Doctor Tell You?, WIS. 2012, JOURNAL (July 9. http://host.madison.com/news/local/health med fit/health-sense/health-sense-how-muchshould-doctor-tell-you/article\_43f5b7bc-c7ca-11e1-92c6-001a4bcf887a.html; Mark Kass, Health Care Guide: Take 5-Eric Borgerding, MILWAUKEE BUS. JOURNAL (Dec. 20, 2012, 6:00 AM); David Wahlberg, State Board Reprimands Doctor Who Was Found Negligent by High Court, WIS. STATE JOURNAL (Mar. 21, 2013, 3:30 PM), http://host.madison.com/news/local/health med fit/state-board-reprimands-doctor-whowas-found-negligent-by-high/article 68b00cc6-9266-11e2-9d7b-001a4bcf887a.html; Guy Boulton, Patients' Right-to-Know at Heart of Wisconsin Debate, MILWAUKEE JOURNAL SENTINEL (Apr. 27, 2013), http://www.jsonline.com/business/patientsrighttoknow-at-heart-of-wisconsin-debate-gu9lf25-205036331.html.

<sup>195.</sup> Recent Legislation, WIS. PSYCHIATRIC ASS'N, http://www.thewpa.org/?page=Recent\_legislation (last visited Oct. 21, 2014).
196. WIS. STAT. ANN. § 448.30 (West 2013).

Any physician who treats a patient shall inform the patient about the availability of reasonable alternate medical modes of treatment and about the benefits and risks of these treatments. The reasonable physician standard is the standard for informing a patient under this section. The reasonable physician standard requires disclosure only of information that a reasonable physician in the same or a similar medical specialty would know and disclose under the circumstances. The physician's duty to inform the patient under this section does not require disclosure of:

- (2) Detailed technical information that in all probability a patient would not understand.
  - (3) Risks apparent or known to the patient.
  - (4) Extremely remote possibilities that might falsely or detrimentally alarm the patient.
  - (5) Information in emergencies where failure to provide treatment would be more harmful to the patient than treatment.
  - (6) Information in cases where the patient is incapable of consenting.
  - (7) Information about alternate medical modes of treatment for any condition the physician has not included in his or her diagnosis at the time the physician informs the patient. 197

The statute is now entitled "informed consent," suggesting that "full disclosure" is no longer the point of departure. The statute incorporates the "professional model" of informed consent—the reasonable physician standard, and, importantly, new subsection (7) links the required disclosure to the actual diagnosis, not the differential diagnosis. Presumably, then, new subsection (7) modifies the initial paragraph of the new statute which, regrettably, continues to refer to "alternate medical modes of treatment" without referring to the proposed treatment. At worst, the amended statute narrows the required

<sup>197.</sup> *Id*.

<sup>198.</sup> Id.

<sup>199.</sup> Id.

disclosure, focusing on the actual diagnosis; at best, it limits the disclosure to the proposed treatment or therapy recommended for the actual diagnosis. Additionally, the amended statute should assist in protecting physicians from fending off informed consent claims when the physician has allegedly made an error in diagnosis. In other words, a physician found not negligent by a jury should not be liable for the failure to obtain the patient's informed consent.

#### V. THE STATE OF WASHINGTON EXPERIENCE

The interesting and curious development of the law of informed consent in the State of Washington may rival that of the law of Wisconsin. An examination of Washington jurisprudence and its informed consent statutes follows.

## A. ZeBarth v. Swedish Hospital Medical Center<sup>200</sup>

The law of informed consent, as it has developed in Washington, may be as curious and unusual as in Wisconsin. In 1972, the Supreme Court of Washington first focused on informed consent in ZeBarth v. Swedish Hospital Medical Center.<sup>201</sup> The supreme court, in ZeBarth,<sup>202</sup> made clear that the doctrine of informed consent pertained to a proposed course of treatment in the following pronouncements:

Informed consent, therefore, is the name for a general principle of law that a physician has a duty to disclose what a reasonably prudent physician in the medical community in the exercise of a reasonable care, would disclose to his patient as to whatever grave risks of injury may be incurred from a proposed course of treatment so that a patient, exercising ordinary care for his own welfare, and faced with a choice of undergoing the proposed treatment, or alternative treatment, or none at all, can, in reaching a decision, intelligently exercise his judgment by reasonably balancing the probable risks against the probable benefits.<sup>203</sup>

<sup>200. 499</sup> P.2d 1 (Wash. 1972).

<sup>201.</sup> Id.

<sup>202.</sup> Id.; see also Edwin Rauzi, Informed Consent in Washington: Expanded Scope of Material Facts That the Physician Must Disclose to His Patient, 55 WASH. L. REV. 655, 659 (1980).

<sup>203.</sup> ZeBarth, 499 P.2d at 8.

The duty of a medical doctor to inform his patient of the risks of harm reasonably to be expected from a proposed course of treatment does not place upon the physician a duty to elucidate upon all of the possible risks, but only those of a serious nature.<sup>204</sup>

. . .

Thus, the information required of the doctor by the general rule is that information which a reasonably prudent physician or medical specialist of that medical community should or would know to be essential to enable a patient of ordinary understanding to intelligently decide whether to incur the risk by accepting the proposed treatment or avoid that risk by foregoing it.<sup>205</sup>

. . . .

Thus, our holding can be stated in general terms: a physician's duty to inform his patient is to inform his patient what a reasonably prudent medical specialist would tell a person of ordinary understanding of the serious risks and the possibility of serious harm which may occur from a proposed course of therapy so that the patient's choice will be an intelligent one, based upon sufficient knowledge to enable him to balance the possible risks against the probable benefits. <sup>206</sup>

These comments of the supreme court are significant. The law of informed consent as announced in *ZeBarth* contemplated that a diagnosis and recommended treatment would trigger the informed consent process.

## B. Miller v. Kennedy<sup>207</sup>

Miller concerned an informed consent claim arising from a kidney biopsy that was recommended as a result of a hospitalization for heart disease. <sup>208</sup> The plaintiff claimed that he was not advised that the

<sup>204.</sup> Id. at 9.

<sup>205.</sup> Id. at 10.

<sup>206.</sup> Id. at 11.

<sup>207. 522</sup> P.2d 852 (Wash. Ct. App. 1974), aff'd, 530 P.2d 334 (Wash. 1975), aff'd after re-trial, 588 P.2d 734 (Wash. 1978).

<sup>208.</sup> Miller, 522 P.2d at 856.

recommended procedure carried a risk of kidney loss.<sup>209</sup> In fact, due to a complication, plaintiff's kidney was surgically removed.<sup>210</sup>

In considering the claim, the court of appeals commented that: "The scope of the duty to disclose information concerning the treatment proposed, other treatments and the risks of each course of action and of no treatment at all is measured by the patient's need to know."

Therefore, the court acknowledged the treatment-focused nature of the doctrine of informed consent. The court of appeals did appear to depart from *ZeBarth* by approving the patient autonomy model of the doctrine instead of the professional model.

On appeal to the Washington Supreme Court, the appellate decision was affirmed.<sup>212</sup> In a per curiam opinion, despite the apparent departure from *ZeBarth*, the supreme court stated: "We can add nothing constructive to the well considered opinion of that court and, accordingly, approve and adopt the reasoning thereof."<sup>213</sup>

By this time, the law of informed consent in Washington seemed without much controversy. It would not remain so.

### C. Washington State Informed Consent Statutes

In 1976, the legislature enacted two statutes relating to informed consent, which would be codified at Wash. Rev. Code § 7.70.050 and Wash. Rev. Code § 7.70.060. The first statute provided as follows:

- (1) The following shall be necessary elements of proof that injury resulted from health care in a civil negligence case or arbitration involving the issue of the alleged breach of the duty to secure an informed consent by a patient or his representatives against a health care provider:
  - (a) That the health care provider failed to inform the patient of a material fact or facts relating to the treatment;
  - (b) That the patient consented to the treatment without being aware of or fully informed of such material fact or facts;

<sup>209.</sup> Id.

<sup>210.</sup> Id.

<sup>211.</sup> Id. at 860.

<sup>212.</sup> Miller, 530 P.2d at 334.

<sup>213.</sup> Id.

- (c) That a reasonably prudent patient under similar circumstances would not have consented to the treatment if informed of such material fact or facts;
- (d) That the treatment in question proximately caused injury to the patient.
- (2) Under the provisions of this section a fact is defined as or considered to be a material fact, if a reasonably prudent person in the position of the patient or his representative would attach significance to it deciding whether or not to submit the proposed treatment.
- (3) Material facts under the provisions of this section which must be established by expert testimony shall be either:
  - (a) The nature and character of the treatment proposed and administered;
  - (b) The anticipated results of the treatment proposed and administered;
  - (c) The recognized possible alternative forms of treatment; or
  - (d) The recognized serious possible risks, complications, and anticipated benefits involved in the treatment administered and in the recognized possible alternative forms of treatment, including nontreatment.
- (4) If a recognized health care emergency exists and the patient is not legally competent to give an informed consent and/or a person legally authorized to consent on behalf of the patient is not readily available his consent to required treatment will be implied.<sup>214</sup>

The statute embodies the doctrine of informed consent and is treatment focused, meaning that the physician has reached a diagnosis and has recommended treatment based on the diagnosis. This statute does not require the disclosure of the differential diagnosis or treatments available to explore the differential diagnosis.<sup>215</sup>

The second statute pertains to the use of a signed consent form to provide evidence of informed consent and provides as follows:

If a patient while legally competent, or his representative if he is not competent, signs a consent form which sets forth the following, the signed consent form shall constitute prima facie evidence that the patient gave his informed consent to the treatment administered and the patient has the burden of rebutting this by a preponderance of the evidence:

- (1) A description, in language the patient could reasonably be expected to understand, of:
  - (a) The nature and character of the proposed treatment;
  - (b) The anticipated results of the proposed treatment;
  - (c) The recognized possible alternative forms of treatment; and
  - (d) The recognized serious possible risks, complications, and anticipated benefits involved in the treatment and in the recognized possible alternative forms of treatment, including nontreatment;
- (2) Or as an alternative, a statement that the patient elects not to be informed of the elements set forth in subsection (1) of this section.

Failure to use a form shall not be admissible as evidence of failure to obtain informed consent.<sup>216</sup>

Again, this statute focuses on proposed treatment and is consistent with the informed consent statute.<sup>217</sup>

<sup>215.</sup> Id.

<sup>216. 1976</sup> Wash. Sess. Laws 218-19.

<sup>217. 1976</sup> Wash. Sess. Laws 218.

## D. Miller v. Kennedy (Again)<sup>218</sup>

After Washington adopted the aforementioned informed consent statutes, the supreme court revisited *Miller* following its retrial and defense verdict. The opinion does not refer to either statute, likely due to the fact that the claim arose and was initially tried before the legislation. The opinion does not specify the date of the second trial, and the supreme court focused on the propriety of the jury instructions. A footnote in the opinion contains the informed consent jury instruction at issue. This jury instruction, approved by the supreme court, specifically refers to "the proposed treatment, operation or procedure." The supreme court affirmed the judgment.

#### E. Gates v. Jensen<sup>225</sup>

In *Gates*, the supreme court expanded the doctrine of informed consent and applied it to circumstances other than the treatment of a diagnosed disease. The opinion does not refer to the informed consent statute, <sup>226</sup> perhaps because the relevant medical facts pre-dated the statute.

Gates concerned an informed consent claim based upon the failure to diagnose glaucoma. The patient's visual complaints commenced in 1972 and included "difficulty in focusing, blurring, and gaps in her vision."<sup>227</sup> Ophthalmologic testing of eye pressure revealed the patient "was in the borderline area for glaucoma."<sup>228</sup> Additional testing yielded results that might have evidenced glaucoma, yet one rather significant test was not performed.<sup>229</sup> The diagnosis was "difficulties with the contact lenses"<sup>230</sup> worn by the patient. The defendant physician did not advise the patient that "he had found high pressure in both eyes which put her in a borderline glaucoma area"<sup>231</sup> or "that her risk of glaucoma was increased

<sup>218. 588</sup> P.2d 734 (Wash. 1978).

<sup>219.</sup> Id.

<sup>220.</sup> Id.

<sup>221.</sup> Id.

<sup>222.</sup> Id. at 736 n.2.

<sup>223.</sup> Id.

<sup>224.</sup> Id. at 738.

<sup>225. 595</sup> P.2d 919 (Wash. 1979).

<sup>226. 1976</sup> Wash. Sess. Laws 218.

<sup>227.</sup> Gates, 595 P.2d at 921.

<sup>228.</sup> Id.

<sup>229.</sup> Id.

<sup>230.</sup> Id.

<sup>231.</sup> *Id*.

considerably by this high pressure and her myopia."<sup>232</sup> Further, the defendant-physician did not disclose the existence of other available tests to examine the eyes.<sup>233</sup>

The patient's symptoms continued. Regrettably, in 1974, the patient was diagnosed with open angle glaucoma<sup>234</sup> and eventually became "functionally blind."<sup>235</sup>

Despite the fact that the *Gates* facts are illustrative of a classic "failure to diagnose" medical negligence claim, the supreme court applied the doctrine of informed consent, focusing on the patient's "right to know," "not confined to the choice of treatment once a disease is present and has been conclusively diagnosed." In doing so, of course, the doctrine of informed consent was converted to a doctrine of full disclosure, the "duty of [which] arises . . . whenever the doctor becomes aware of an abnormality which may indicate risk or danger." <sup>238</sup>

As emphasized early in this Article, this approach to the law of informed consent is neither reasonable nor practical. If a physician incorrectly arrives at a diagnosis, violating the applicable standard of care in the process, medical negligence has occurred. The physician cannot be expected to disclose and discuss the differential diagnosis and all treatment options (including risks of alternatives for treatment) for each potential diagnosis because the patient simply has no ability to understand the information and make a treatment choice. That is the purpose of the differential diagnosis. The patient does not have the capacity to receive copious amounts of medical information and certainly has no basis on which to choose treatment. The patient relies on the physician to arrive at the correct diagnosis and recommend appropriate treatment.

## F. Keogan v. Holy Family Hospital<sup>239</sup>

Keogan is yet another example of a missed medical diagnosis having been transformed into an informed consent claim under the law of

<sup>232.</sup> Id.

<sup>233.</sup> Id.

<sup>234.</sup> *Id.* "Open angle glaucoma . . . is a slowly progressive atrophy of the optic nerve, characterised by loss of peripheral visual function and an excavated appearance of the optic disc by ophthalmoscopy." Harry A. Quigley, *Number of People with Glaucoma Worldwide*, 80 BRIT. J. OPHTHALMOLOGY 389, 389 (1996).

<sup>235.</sup> Gates, 595 P.2d at 922.

<sup>236.</sup> Id.

<sup>237.</sup> Id.

<sup>238.</sup> Id. at 923.

<sup>239. 622</sup> P.2d 1246 (Wash. 1980).

Washington. Here, a patient experiencing chest pain was seen by his family physician.<sup>240</sup> During the evaluation, an EKG was within the range of normal.<sup>241</sup> The defendant-physician "suspected angina pectoris"<sup>242</sup> but did not so inform the patient, did not perform tests to diagnose angina, and, in fact, "diagnosed [the patient's] condition as an inflammation of sternum cartilage."<sup>243</sup>

On a subsequent visit with this physician, the patient reported "pain and gastric problems after eating." After referring to apparently abnormal test results, the physician prescribed an antacid, not advising the patient that he may have angina. 245

The patient's complaints continued, and ultimately he was taken to the emergency room. The ER physician did not perform an EKG. The ER physician consulted with the patient's family physician and the patient would have been discharged but for the insistence of the patient and his wife. He was admitted to the hospital, continued to deteriorate, and was transferred to the coronary care unit, where he died.

The lawsuit against the family physician, the ER physician, and the hospital was tried to a jury, which rendered a defense verdict. The judgment was affirmed on appeal. Plaintiff's motion for reconsideration was stayed pending [the supreme court's] decision in Gates...." The motion was then denied and the supreme court "granted plaintiffs' petition for review of the trial court's refusal to give proposed informed consent instructions and its refusal to find as a matter of law that the defendants had deviated from the medical standard of care applicable to the facts of this case." 252

Essentially, then, the supreme court's review focused on the informed consent claim against the family physician and the negligence claim against the ER physician. This context is significant because it directly relates to the alignment of the supreme court justices' opinions.

<sup>240.</sup> Id. at 1249.

<sup>241.</sup> Id.

<sup>242.</sup> Id.

<sup>243.</sup> Id.

<sup>244.</sup> Id.

<sup>245.</sup> Id.

<sup>246.</sup> Id. at 1250.

<sup>247.</sup> Id.

<sup>248.</sup> Id.

<sup>249.</sup> Id.

<sup>250.</sup> Id. at 1250.

<sup>251.</sup> Id. at 1251.

<sup>252.</sup> Id.

The majority opinion, written by Justice Horowitz, speaks to the negligence of the ER physician as a matter of law.<sup>253</sup> However, one justice published a concurrence in part and a dissent in part and was joined in this opinion by four other justices, thereby constituting a "majority" dissenting from the position that the family physician had the duty to disclose information regarding his "non-diagnosis" of angina and that the trial court should have given an informed consent instruction.<sup>254</sup> The court of appeals' opinion was reversed and the case remanded for additional proceedings.<sup>255</sup>

Following *Keogan*, a legitimate concern existed as to the status of Washington's informed consent law. In 1980, a majority of the supreme court did not believe that the law of informed consent required the disclosure of the differential diagnosis. Speaking to this concern, the "dissenting majority" in *Keogan* noted "[b]y this opinion, this court establishes, as a matter of law, a medical standard in this state that a patient complaining to his doctor of chest pain must be given a short course in medicine in heart disease and everything else that could cause chest pain." Precisely! This statement aptly criticizes the physician's obligation to disclose the differential diagnosis. If the physician fails to arrive at the proper diagnosis, the claim should be for medical negligence, not the failure to obtain the patient's informed consent.

## G. Harbeson v. Parke-Davis, Inc. 257

In *Harbeson*, the Washington Supreme Court considered questions certified by the United States District Court for the Western District of Washington concerning claims for wrongful birth and wrongful life.<sup>258</sup> Here, an epileptic pregnant mother was prescribed Dilantin, an anticonvulsant medication.<sup>259</sup> Apparently, neurologists advised the patient that "Dilantin could cause cleft palate and temporary hirsutism,"<sup>260</sup> but did not "conduct[] literature searches or consult[] other sources for specific information regarding the correlation between Dilantin and birth defects."<sup>261</sup> Ultimately, two of the patients' children, born after pregnancies during which Dilantin was taken, suffered "fetal

<sup>253.</sup> Id. at 1251.

<sup>254.</sup> Id. at 1260 (Hicks, J., dissenting).

<sup>255.</sup> Id. at 1249.

<sup>256.</sup> Id. at 1261 (Hicks, J., dissenting).

<sup>257. 656</sup> P.2d 483 (Wash. 1983).

<sup>258.</sup> Id. at 486.

<sup>259.</sup> Id.

<sup>260.</sup> Id.

<sup>261.</sup> Id.

hydantoin syndrome."<sup>262</sup> The informed consent claim urged that had the parents "been informed of the potential birth defects associated with the use of Dilantin during pregnancy, they would not have had any other children."<sup>263</sup>

The supreme court examined the history of the doctrine of informed consent in Washington, referred to the statute<sup>264</sup> and to the ZeBarth<sup>265</sup> opinion as controlling of the claim based on the time health care was provided, and held that the doctrine required the disclosure of Dilantin's link with birth defects.<sup>266</sup>

In *Harbeson*, the supreme court focused on the anticonvulsant medication prescribed by the patient's physicians.<sup>267</sup> Certainly, the classic doctrine of informed consent applies well here. The patient had the diagnosis of epilepsy.<sup>268</sup> She became pregnant and was prescribed a medication which carried the potential risk to the newborn of birth defects.<sup>269</sup> The parents were entitled to know these risks.<sup>270</sup> *Harbeson* represents a proper application of the law of informed consent to treatment recommended following a diagnosis.

## H. Bays v. St. Luke's Hospital<sup>271</sup>

Bays involved medical negligence and informed consent claims involving the eventual death of an employee injured at work.<sup>272</sup> The injuries included a dislocated shoulder and spinal compression fractures.<sup>273</sup> While in the hospital, Mr. Bays was advised "to move his legs to prevent blood clots from developing."<sup>274</sup> He was "prescribed antiembolism stockings... to wear."<sup>275</sup>

<sup>262.</sup> Id.; see also Bruce A. Buehler et al., Prenatal Prediction of Risk of the Fetal Hydantoin Syndrome, 322 NEW ENG. J. MED. 1567, 1567 (1990) (referring to anti-epileptic medications).

<sup>263.</sup> Harbeson, 656 P.2d at 486.

<sup>264.</sup> WASH. REV. CODE § 7.70.050 (1983).

<sup>265.</sup> ZeBarth v. Swedish Hospital Medical Center, 499 P.2d 1 (Wash. 1972).

<sup>266.</sup> Harbeson, 656 P.2d at 494.

<sup>267.</sup> Id. at 486.

<sup>268.</sup> Id.

<sup>269.</sup> Id.

<sup>270.</sup> Id. at 490.

<sup>271. 825</sup> P.2d 319 (Wash. Ct. App. 1992).

<sup>272.</sup> Id. at 320.

<sup>273.</sup> Id.

<sup>274.</sup> Id.

<sup>275.</sup> Id.

While in the hospital, Mr. Bays developed severe knee pain, for which he was evaluated and diagnosed with a sprained knee ligament. Thereafter, Mr. Bays had an elevated temperature. The defendant-physician was concerned about Mr. Bays' pulmonary function and offered the following differential diagnoses: "pneumonia; atelectasis, which results from lung collapse; blood absorption, which results from bleeding around fractures; and thromboembolism." A "chest X-ray was negative for all of the four medical problems [the defendant-physician] had in mind." Shortly thereafter, Mr. Bays died of a pulmonary embolism.

The trial court had directed a verdict for the defendants on the informed consent claim.<sup>281</sup> On review, the court of appeals first spoke of informed consent in broad terms: "Informed consent focuses on the patient's right to know about a bodily condition and to make decisions about that condition. A physician has a duty to disclose an abnormality which may indicate risk or danger in the patient's body."<sup>282</sup> The court of appeals then referred to the informed consent statute<sup>283</sup> and the plaintiff's position, namely that the statute requires "physicians . . . to disclose material facts relating to treatment of conditions which have not been diagnosed by the physician."<sup>284</sup> An enlightened court of appeals disagreed and quite clearly noted that "the duty to disclose does not arise until the physician becomes aware of the condition by diagnosing it."<sup>285</sup> Bays, then, supports the proposition that the doctrine of informed consent does not require the disclosure of the differential diagnosis.

<sup>276.</sup> Id.

<sup>277.</sup> Id.

<sup>278.</sup> Id.

<sup>279.</sup> Id.

<sup>280.</sup> Id. "Blood clots called deep vein thrombi (DVT) often develop in the deep leg veins. Pulmonary embolism (PE) occurs when clots break off from vein walls and travel through the heart to the pulmonary arteries." Samuel Z. Goldhaber & Ruth B. Morrison, Pulmonary Embolism and Deep Vein Thrombosis, 106 CIRCULATION 1436, 1436 (2002). See generally Paul D. Stein & Jerald W. Henry, Prevalence of Acute Pulmonary Embolism Among Patients in a General Hospital and at Autopsy, 108 CHEST 978 (1995); Jeffrey L. Carson et al., The Clinical Course of Pulmonary Embolism, 326 New Eng. J. MED. 1240 (1992); Joshua A. Beckman, Thrombolytic Therapy for Pulmonary Embolism, 311 JAMA 2385, 2385 (2014) (noting that "[p]ulmonary embolism (PE) accounts for nearly 200,000 hospital discharges and contributes to nearly 30,000 deaths in the United States each year").

<sup>281.</sup> Bays, 825 P.2d at 321.

<sup>282.</sup> Id.

<sup>283.</sup> WASH. REV. CODE § 7.70.050 (1983).

<sup>284.</sup> Bays, 825 P.2d at 322.

<sup>285.</sup> Id.

## I. Backlund v. University of Washington<sup>286</sup>

Backlund involved the birth of a child suffering from jaundice (hyperbilirubnema). The child's parents were advised of the diagnosis and the prescribed phototherapy but were not advised of transfusion as a possible therapy. The trial court found that transfusion therapy constituted possible alternative treatment of which the parents were not aware and that the provision of phototherapy as opposed to transfusion therapy was the proximate cause of injury. The trial court . . . ultimately ruled in favor of the [defendant] finding the [plaintiffs] did not carry their burden to establish . . . that 'a reasonably prudent patient under similar circumstances would not have consented to the treatment if informed of such material fact or facts." The trial court noted that the jury returned a defense verdict on the negligence claim and suggested that the informed consent claim must fail because phototherapy, not transfusion, was recommended for the child. The trial court's ruling was affirmed on appeal.

Although the supreme court affirmed and confirmed that a misdiagnosis constitutes medical negligence, not a failure to obtain informed consent,<sup>293</sup> the supreme court made clear that "[n]egligence and informed consent are alternative methods of imposing liability on a health care practitioner"<sup>294</sup> and "[i]nformed consent allows a patient to recover damages from a physician even though the medical diagnosis or treatment was not negligent."<sup>295</sup> This holding is of concern and, frankly, is an excellent topic for another article at another time. For purposes of this Article, far more concerning is the supreme court's dicta in *Backlund* that: "Whenever a physician *becomes aware* of a condition which indicates risk to the patient's health, he has a duty to disclose it."<sup>296</sup> If this dicta suggests that the physician is obligated to brainstorm with the

<sup>286. 975</sup> P.2d 950 (Wash. 1999).

<sup>287.</sup> Id. at 952.

<sup>288.</sup> Id.; see Meredith L. Porter & Beth L. Dennis, Hyperbilirubinemia in the Term Newborn, 65 AM. FAM. PHYSICIAN 599, 604 (2002) (noting the recommendation for exchange transfusion for significant hyperbilirubinemia, otherwise noting the use of phototherapy in less severe cases).

<sup>289.</sup> Backlund, 975 P.2d at 953-54.

<sup>290.</sup> Id. at 954 (quoting WASH, REV, CODE § 7.70.050(1)(c) (1983)).

<sup>291.</sup> Backlund, 975 P.2d at 954.

<sup>292.</sup> Id.

<sup>293.</sup> Id. at 956.

<sup>294.</sup> Id. at 955.

<sup>295.</sup> Id.

<sup>296.</sup> Id. at 955 (emphasis added) (quoting Burnet v. Spokane Ambulance, 772 P.2d 1027, 1030 (Wash. Ct. App. 1989)).

patient, the doctrine of informed consent becomes a full disclosure doctrine as opposed to a treatment or procedure focused doctrine. There is more to come on this point.

## J. Stewart-Graves v. Vaughn<sup>297</sup>

Stewart-Graves deserves a brief comment. It involves the emergency situation exception to the Washington law of informed consent.<sup>298</sup> The supreme court did, however, state "[u]nder the doctrine of informed consent, a health care provider has a fiduciary duty to disclose relevant facts about the patient's condition and the proposed course of treatment so that the patient may exercise the right to make an informed health care decision."<sup>299</sup> This statement appears to correctly connect the doctrine of informed consent to proposed treatment, a proper application of the doctrine.

#### K. Gomez v. Sauerwein<sup>300</sup>

The journey through the Washington law of informed consent might have ended with *Gomez*. Here, the court of appeals affirmed the trial court's dismissal of an informed consent claim.<sup>301</sup> The claim was based on a diagnosis of a urinary tract infection when, in fact, the patient had a fungal infection and ultimately died of fungal sepsis.<sup>302</sup>

The court of appeals reviewed the history of the doctrine of informed consent in Washington, commencing with ZeBarth.<sup>303</sup> The court of appeals then identified the appellate issue as follows: "[W]hether the trial court correctly dismissed the estate's informed consent claim on the basis that a health care provider's failure to diagnose, or its misdiagnosis, presents a cause of action for medical negligence only, because no informed consent requirement is triggered."<sup>304</sup> The court addressed the expansive approach to informed consent advanced by the supreme court

<sup>297. 170</sup> P.3d 1151 (Wash. 2007).

<sup>298.</sup> Id. at 1154; WASH. REV. CODE § 7.70.050(4) (1983).

<sup>299.</sup> Stewart-Graves, 170 P.3d at 1155.

<sup>300. 289</sup> P.3d 755 (Wash. Ct. App. 2012), aff'd, 331 P.3d 19 (Wash. 2014).

<sup>301.</sup> Gomez, 289 P.3d at 756. The court of appeals also affirmed the jury's defense verdict on the medical negligence claim. Id.

<sup>302.</sup> Id. at 757. For in-depth discussions of this disease process, see generally Guo-Hao Xie et al., Impact of Invasive Fungal Infection on Outcomes of Severe Sepsis: A Multicenter Matched Cohort Study in Critically Ill Surgical Patients, 12 CRITICAL CARE R5 (2008); David W. Warnock, Trends in the Epidemiology of Invasive Fungal Infections, 48 JAPAN J. MED. MYCOLOGY 1 (2007).

<sup>303.</sup> Gomez, 289 P.3d at 759.

<sup>304.</sup> Id.

in Gates<sup>305</sup> and the interesting five justice majority-concurrence in Keogan,<sup>306</sup> previously discussed in this Article, which retreated from Gates. The court of appeals concluded "that Gates has either been abrogated or limited to its facts by Keogan."<sup>307</sup> Alternatively, the court of appeals suggested that Gates was sub silentio overruled by Backlund<sup>308</sup> and by the supreme court's denial of review of other cases.<sup>309</sup> Therefore, the Gomez court, forty years following ZeBarth, declared the doctrine of informed consent returned to its rightful place in medical-legal jurisprudence—applicable only after a diagnosis is made and treatment is recommended.

On June 19, 2014, after a lengthy wait, 310 the Supreme Court of Washington issued its opinion in *Gomez*, 311 affirming the court of appeals, holding that "there is no duty to inform the patient on treatment options pertaining to a ruled out diagnosis." The court noted that the informed consent "statute clearly uses the word 'treatment,' demonstrating the intent to limit informed consent claims to treatment situations." The court refused to overrule *Gates*, 314 but found the *Gates* facts so unusual that the court predicted that "it is unlikely we will ever see such a case again." While it appeared hopeful that Washington courts had received the guidance necessary to apply the doctrine of informed consent as originally intended, the court of appeals readdressed the issue in *Flyte v. Summit View Clinic*. 316

## L. Flyte v. Summit View Clinic<sup>317</sup>

Regrettably, very recently, the Washington Court of Appeals, in *Flyte v. Summit View Clinic*, <sup>318</sup> added to the curious informed consent jurisprudence of the state. Here, a surviving spouse sued a clinic

<sup>305.</sup> Gates v. Jensen, 595 P.2d 919 (Wash. 1979).

<sup>306.</sup> Keogan v. Holy Family Hospital, 622 P.2d 1246 (Wash. 1980).

<sup>307.</sup> Gomez, 289 P.3d at 762.

<sup>308.</sup> Backlund v. University of Washington, 975 P.2d 950 (Wash. 1999).

<sup>309.</sup> Gomez, 289 P.3d at 762.

<sup>310.</sup> The Washington Supreme Court granted a petition for review on June 4, 2013. Gomez v. Sauerwein, 302 P.3d 180 (Wash. 2013).

<sup>311.</sup> Gomez v. Sauerwein, 331 P.3d 19 (Wash. 2014).

<sup>312.</sup> Id. at 25.

<sup>313.</sup> Id. at 22.

<sup>314.</sup> Gates v. Jensen, 595 P.2d 919 (Wash. 1979).

<sup>315.</sup> Gomez, 331 P.3d at 27.

<sup>316. 333</sup> P.3d 566 (Wash. Ct. App. 2014).

<sup>317.</sup> Id.

<sup>318.</sup> Id.

following the death of his wife and infant daughter.<sup>319</sup> His wife was seven months pregnant and became ill with flu-like symptoms at a time when "the Clinic had received public health alerts from various authorities about a global pandemic of 'swine flu,' a potentially fatal illness caused by the H1N1 influenza virus."<sup>320</sup> The recommended treatment for pregnant women was the administration of Tamiflu.<sup>321</sup> Plaintiff's wife was neither informed "about the pandemic or the available treatment."<sup>322</sup> Significantly, the treating physician at the clinic did *not* diagnose plaintiff's wife with influenza.<sup>323</sup> In fact, at trial, he "testified that 'influenza wasn't something I had been concerned about clinically [because] I'd ruled that out."<sup>324</sup> His assessment was an "upper respiratory infection."<sup>325</sup>

Regrettably, plaintiff's wife's condition worsened. Her daughter "was delivered by caesarean section . . . after [plaintiff's wife] had been placed in a medically induced coma." She died about a month and a half later. 327 Her daughter died approximately six months thereafter. 328

The surviving spouse sued the clinic for negligence and for "breach of the duty of informed consent for failing to inform . . . about the pandemic and the available treatment." The jury found for the clinic on both claims, and the trial court denied a motion for a new trial. 330

The court of appeals focused on the trial court's informed consent jury instruction: "A physician has no duty to disclose treatments for a condition that may indicate a risk to the patient's health until the physician diagnoses that condition." The court of appeals reviewed the prior case law and statute, previously discussed in detail in this paper, and stated that the "diagnosis" for the patient was in dispute, and therefore the patient was entitled to information about the public health issue and available treatment. The court of appeals, in effect, held that

<sup>319.</sup> Id. at 568.

<sup>320</sup> Id

<sup>321.</sup> See Penelope Ward et al., Oseltamivir (Tamiflu®) and Its Potential for Use in the Event of an Influenza Pandemic, 55 J. ANTIMICROBIAL CHEMOTHERAPY i5, i11-i12, i15 (2005).

<sup>322.</sup> Flyte, 333 P.3d at 568.

<sup>323.</sup> Id. at 569.

<sup>324.</sup> Id. (alteration in original).

<sup>325.</sup> Id.

<sup>326.</sup> Id. at 568-69.

<sup>327.</sup> Id. at 569.

<sup>328.</sup> Id.

<sup>329.</sup> Id.

<sup>330.</sup> Id.

<sup>331.</sup> Id. (alteration in original).

<sup>332.</sup> Id. at 573-77.

a conclusive diagnosis is not necessary to the informed consent analysis, resurrecting the position that informed consent applies to the differential diagnosis. The court of appeals reversed the jury verdict.<sup>333</sup>

Flyte may add more uncertainty to the status of the Washington law of informed consent. Again, Flyte seems a classic case of an alleged failure to diagnose and treat. The doctrine of informed consent is a poor fit.

#### VI. ALASKA

Another example of the judicial misunderstanding of the doctrine of informed consent is found in the opinion of the Alaska Supreme Court in Marsingill v. O'Malley.<sup>334</sup> Here, the defendant-physician spoke with the patient by phone to discuss the patient's gastrointestinal pain and other symptoms.<sup>335</sup> The physician advised the patient of his inability to evaluate her via a telephone call and he advised her to go to the emergency room (ER).<sup>336</sup> The patient asked what would occur in the ER, and upon receiving that information, she claimed she was feeling better and opted not to go to the ER.<sup>337</sup> She was subsequently found unconscious, taken to the hospital, underwent surgery for intestinal blockage, and suffered shock, brain damage, and paralysis.<sup>338</sup> Suit was filed against the defendant-physician claiming that he failed to communicate the seriousness of her disease during the telephone conversation.<sup>339</sup> It should be emphasized that the defendant was unable to evaluate and diagnose the patient and had advised her to go to the ER.<sup>340</sup>

Alaska has an informed consent statute,<sup>341</sup> which provides, in relevant part, as follows:

A health care provider is liable for failure to obtain the informed consent of a patient if the claimant establishes by a preponderance of the evidence that the provider has failed to inform the patient of the common risks and reasonable alternatives to the proposed treatment or procedure, and that but

<sup>333.</sup> *Id.* at 577. The reversal was also due to an error in instructing the jury about a prior settlement. *Id.* 

<sup>334. 128</sup> P.3d 151 (Alaska 2006).

<sup>335.</sup> Id. at 153.

<sup>336.</sup> Id.

<sup>337.</sup> Id. at 153-54.

<sup>338.</sup> Id. at 154.

<sup>339.</sup> Id.

<sup>340.</sup> Id. at 153.

<sup>341.</sup> ALASKA STAT. ANN. § 09.55.556(a) (West 2013).

for that failure the claimant would not have consented to the proposed treatment or procedure.<sup>342</sup>

This statute quite clearly refers to a recommended treatment or procedure, which would follow a diagnosis. Nevertheless, the supreme court acknowledged the application of the doctrine of informed consent to the patient's claim, <sup>343</sup> despite the fact that the defendant-physician was never in a position to evaluate the patient and arrive at a diagnosis. *Marsingill* has been criticized in legal scholarship, <sup>344</sup> which also noted an unsuccessful effort by the Alaska State Medical Association to amend the informed consent statute. <sup>345</sup>

#### VII. WELL INFORMED COURTS

Happily, there are courts that are well informed about the doctrine of informed consent and related matters, and the following comments derive from them. At the outset, a physician's failure "to investigate an otherwise unindicated disease is not malpractice." The doctrine of informed consent should not require the disclosure of the differential diagnosis, and the doctrine should require disclosures relating to recommended treatment. The doctrine does not contemplate the disclosure of "the availability of diagnostic and treatment procedures [the physician] has concluded are not medically indicated." The failure to obtain informed consent is simply not analogous to a failure to arrive at a proper medical diagnosis and, in this author's estimation, the doctrine of informed consent was never intended to apply to that latter medical mishap.

<sup>342.</sup> Id

<sup>343.</sup> Marsingill, at 157-61.

<sup>344.</sup> Douglas E. Hutchinson, Marsingill v. O'Malley: The Duty to Disclose Becomes the Duty to Divine, 25 ALASKA L. REV. 241 (2008).

<sup>345.</sup> Id. at 261.

<sup>346.</sup> Curry v. Dr. Elena Vezza Physician, P.C., 963 N.Y.S.2d 661, 662 (N.Y. App. Div. 2013).

<sup>347.</sup> Horwitz v. Yale New Haven Hosp., No. CV 910324326, 1996 WL 469727, at \*4 (Conn. Super. Ct. Aug. 6, 1996).

<sup>348.</sup> Vandi v. Permanente Med. Grp., 9 Cal. Rptr. 2d 463, 466 (Cal. Ct. App. 1992); Cline v. Kresa-Reahl, 728 S.E.2d 87, 93 (W. Va. 2012).

<sup>349.</sup> Hall v. Frankel, 190 P.3d 852, 865 (Colo. App. 2008).

## VIII. THE COMPLICATIONS OF AN OVERBROAD DOCTRINE OF INFORMED CONSENT

Although the doctrine of informed consent is thought to foster patient autonomy,<sup>350</sup> an overbroad doctrine may compromise health care. A single hypothetical will suffice. A patient is in the primary care physician's office with a common complaint—headache, stomachache, or backache. The physician takes a history and performs a physical examination. The physician, through education, training, and experience, arrives at a differential diagnosis. The informed consent law of the jurisdiction requires disclosure of the differential diagnosis as well as all available tests (and risks, and complications), to explore the differential diagnosis, which may include a large number of diseases. On the assumption that there is enough time in the day for the physician to disclose this information, the requisite disclosure occurs and the patient tells the physician to arrange for each available test.

At least one court has recognized the extensive medical costs associated with such an expansive doctrine of informed consent.<sup>351</sup> It is quite clear that the history and physical examination will narrow the differential diagnosis and assist in avoiding, or at least lessening, "the cost of valueless routine investigations." This logic dictates that the inapplicability of the doctrine of informed consent to the differential diagnosis should assist the health care system by reducing costs.

In addition to cost consequences, there are medical consequences resulting from the expanded doctrine of informed consent. The hypothetical patient, demanding a medical workup for the differential diagnosis, is seeking "aggressive medical care." 353 It has been noted that:

There is growing evidence that exposure to unnecessary diagnostic tests and specialty referrals can lead to a variety of harms. For example, patients living in regions with more aggressive medical care tend to have worse health outcomes and lower rates of patient satisfaction, findings which may be explained by iatrogenic harms (e.g., injuries during testing, side

<sup>350.</sup> For a critical look at whether true informed consent is a realistic goal, see Katz, Informed Consent—Must It Remain A Fairy Tale?, supra note 3.

<sup>351.</sup> Linquito v. Siegel, 850 A.2d 537, 544 (N.J. Super. Ct. App. Div. 2004).

<sup>352.</sup> Gerald Sandler, Costs of Unnecessary Tests, 2 BRIT. MED. J. 21, 24 (1979); see also Steven R. Brown & Jaclyn Brown, Why Do Physicians Order Unnecessary Preoperative Tests? A Qualitative Study, 43 FAM. MED. 338, 338 (2011).

<sup>353.</sup> M. Brooke Herndon et al., Older Patients Perceptions of "Unnecessary" Tests and Referrals, 23 J. GEN. INTERNAL MED. 1547, 1547 (2008).

effects of marginally effective treatments, psychological harms of labeling, medical errors). 354

There is evidence to suggest that older patients "would want a diagnostic test or specialty referral that their generalist thought was unnecessary." 355

An expansive view of the doctrine of informed consent would not simply create a risk that the patient would demand unnecessary medical testing. Physicians understanding the breadth of the law would be inclined to order more (presumably unnecessary) diagnostic testing through the practice of defensive medicine. When physicians recommend procedures or tests without revealing their defensive motivation, defensive medicine represents a breach of professional trust, a form of deception." 357

An additional complication of an expanded doctrine of informed consent is the extension of an already existing problem—is the patient able to understand and process the physician's disclosure pursuant to the law of informed consent? This is an issue of "health literacy," a topic much discussed in the medical literature.<sup>358</sup>

Health literacy has been defined "as the capacity to acquire, understand and use information in ways which promote and maintain good health" and as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions." Poor health literacy results from various factors, including adult reading levels. [P]atients

<sup>354.</sup> Id.

<sup>355.</sup> Id. at 1551.

<sup>356.</sup> See Kenneth De Ville, Act First and Look Up the Law Afterward?: Medical Malpractice and the Ethics of Defensive Medicine, 19 THEORETICAL MED. & BIOETHICS 569, 570 (1998).

<sup>357.</sup> Id. On a related subject, "many physicians were explicitly trained not to consider costs or came to equate overtesting or unnecessary treatment with being thorough." Bridget M. Kuehn, Guidelines, Online Training Aim to Teach Physicians to Weigh Costs of Care, Become Better Stewards of Medical Resources, 311 JAMA 2368, 2368 (2014).

<sup>358.</sup> See generally Don Nutbeam, Defining and Measuring Health Literacy: What Can We Learn from Literacy Studies?, 54 INT'L J. Pub. Health 303 (2009); Richard S. Safeer & Jann Keenan, Health Literacy: The Gap Between Physicians and Patients, 72 Am. FAM. PHYSICIAN 463 (2005); Ruth Parker, Health Literacy: A Challenge for American Patients and Their Health Care Providers, 15 Health Promotion Int'l 277 (2000); Mark V. Williams et al., The Role of Health Literacy in Patient-Physician Communication, 34 FAM. Med. 383 (2002).

<sup>359.</sup> Nutbeam, supra note 358, at 304.

<sup>360.</sup> Bonne Lorenzen et al., Using Principles of Health Literacy to Enhance the Informed Consent Process, 88 AORN J. 23, 23 (2008) (quoting Institute of Medicine, Health Literacy: A Prescription to End Confusion 37 (2004)).

<sup>361.</sup> Parker, supra note 358, at 278.

commonly complain that physicians do not explain their illness or treatment options to them in terms they can understand." It is not difficult to imagine that "functionally illiterate adults are more likely to have health problems, live in poverty, and have fewer years of education." Furthermore, poor health literacy disproportionately affects the elderly "and inner-city minorities, the primary users of Medicare and Medicaid." Furthermore, there are other factors that might impact health literacy: pain, fright, and the use of medications. Consequently, there are numerous reasons why patients do not have the ability to understand health related information. Any effort to make the informed consent process more efficient must confront the health literacy issue. An expanded doctrine of informed consent, a full disclosure doctrine, compounds the health literacy problems by requiring a patient to receive even more information that will be difficult, if not impossible, to understand.

Last is the element of time. Does an office visit provide the time necessary for the physician to undertake the disclosure requirements of an expansive doctrine of informed consent? "Physicians understand that the time spent with patients is a factor in patients' satisfaction and helps to retain patients in their practice." Although there is a concern that "managed care has substantially reduced the length of patients' office visits with physicians," this concern is, apparently, unsupported by the data. Nevertheless, office visits may not involve much time. It has been observed that an office visit with a family physician may average from thirteen to twenty minutes in length, see certainly an insufficient amount of time for the family physician to (1) disclose the differential diagnosis and possible treatment options available for common complaints, such as headache, back pain, stomach pain, or chest pain, and (2) hope to obtain the patient's consent to treatment.

<sup>362.</sup> Williams et al., supra note 358, at 384.

<sup>363.</sup> Id.

<sup>364.</sup> Id.

<sup>365.</sup> For an interesting and innovative discussion of a personalized, three stage model of informed consent, see Gil Siegal et al., *Personalized Disclosure by Information-on-Demand: Attending to Patients' Needs in the Informed Consent Process*, 40 J. L. MED. & ETHICS 359 (2012) (proposing that the patient determine the level of desired disclosure).

<sup>366.</sup> David Mechanic et al., Are Patients' Office Visits with Physicians Getting Shorter?, 344 New Eng. J. Med. 198, 203 (2001).

<sup>367.</sup> Id. at 198.

<sup>368.</sup> Id. at 203.

<sup>369.</sup> Donna R. Rhoades et al., Speaking and Interruptions During Primary Care Office Visits, 33 FAM. MED. 528, 531 (2001).

#### IX. CONCLUSION

We live in an age of health care consumerism.<sup>370</sup> The doctrine of informed consent, based on patient autonomy, is intended to shift from the physician to the patient the control over medical decision-making by allowing an "informed" patient to choose an appropriate treatment, therapy, or procedure.

With Canterbury v. Spence<sup>371</sup> as its popular point of departure, the doctrine was intended to apply when a physician reached a diagnosis and made a treatment recommendation. It was not intended as a full disclosure doctrine, requiring a physician to disclose the differential diagnosis, every test to explore the differential diagnosis, every treatment available for each possible diagnosis, as well as all related possible complications.<sup>372</sup>

This Article has examined three jurisdictions in which courts have approached the law of informed consent in an unworkable, impractical fashion.<sup>373</sup> It is quite possible that this has occurred (and may occur again) because courts do not understand medicine and rarely, if ever, look to the constraints of medicine when applying the law.

The law will not jettison the doctrine of informed consent. Truly informed consent, however, is a lofty and perhaps unattainable goal. The doctrine has its share of commentators and critics, <sup>374</sup> and the criticism is well deserved. In their efforts to encourage patient autonomy, <sup>375</sup> courts should not create additional impediments for physicians by expanding the doctrine of informed consent beyond its intended purpose. Courts doing so will endanger patient care through the resultant use of unnecessary medical tests and procedures, and will encourage the filing of more informed consent claims when the appropriate claim should be based upon the failure to reach a correct diagnosis. Neither of these outcomes are beneficial.

<sup>370.</sup> See Robert A. Berenson & Christine K. Cassel, Consumer-Driven Health Care May Not Be What Patients Need—Caveat Emptor, 301 JAMA 321, 321 (2009).

<sup>371.</sup> Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972).

<sup>372.</sup> See supra Part III.

<sup>373.</sup> See supra Parts IV-VI.

<sup>374.</sup> See generally O. O'Neill, Some Limits of Informed Consent, 29 J. MED. ETHICS 4 (2003); Oonagh Corrigan, Empty Ethics: The Problem with Informed Consent, 25 Soc. HEALTH & ILLNESS 768 (2003); Katz, Informed Consent—A Fairy Tale?, Law's Vision, supra note 3.

<sup>375.</sup> For a discussion on patient and physician autonomy, see Edmund D. Pellegrino, Patient and Physician Autonomy: Conflicting Rights and Obligations in the Physician-Patient Relationship, 10 J. CONTEMP. HEALTH L. & POL'Y 47 (1994).