

No. 88307-6

RECEIVED BY E-MAIL

SUPREME COURT OF
THE STATE OF WASHINGTON

RODOLFO ANAYA-GOMEZ, as Personal Representative
of the Estate of Christina Palma-Anaya, deceased,

Petitioner,

v.

MARK F. SAUERWEIN, M.D. and
THE YAKIMA FARM WORKERS CLINIC, a Washington corporation,

Respondents.

FILED
SUPERIOR COURT
STATE OF WASHINGTON
2013 OCT -8 A 10:04
BY RONALD R. CARPENTER
CLERK
b/h

Corrected BRIEF OF AMICI CURIAE
WASHINGTON STATE MEDICAL ASSOCIATION AND
WASHINGTON STATE HOSPITAL ASSOCIATION
Corrected

Gregory M. Miller, WSBA No. 14459
Justin P. Wade, WSBA No. 41168

CARNEY BADLEY SPELLMAN, P.S.
701 Fifth Avenue, Suite 3600
Seattle, Washington 98104-7010
(206) 622-8020

*Attorneys for Amici Curiae Washington
State Medical Association and
Washington State Hospital Association*

ORIGINAL

TABLE OF CONTENTS

	<u>Page</u>
I. IDENTITY AND INTEREST OF AMICI CURIAE	1
II. THE LAW OF INFORMED CONSENT IN WASHINGTON	3
A. The Common Law Roots of the Informed Consent Doctrine.....	3
B. Codification and Definition of Informed Consent Claims	7
C. After the Legislature Codified the Then-Existing Doctrine of Informed Consent in 1975, a Later, Tail-End Development to the Pre-Statutory Common Law Ceased to Matter	8
D. No Case Under RCW 7.70.050 Has Required Disclosure of Treatment Options Before the Physician Makes a Diagnosis or Proposes a Diagnostic Procedure	9
E. This Court Affirmed in <i>Backlund</i> That Failure to Diagnose is a Matter of Medical Negligence, Not a Violation of the Duty to Inform a Patient	12
III. THERE IS NO NEED TO CHANGE THE CURRENT RULE	13
A. Informed Consent Addresses Different Concerns Than Negligence; Conflating the Two Would Not Serve Either or Be Consistent with the Statute.....	13
B. Plaintiff’s Claimed “Bright Line Rule” is Not Simple But is Inconsistent With RCW 7.70.050. Adoption of Plaintiff’s Proposed Rule Would Not Benefit Patients and Would Harm the Health Care System.....	14
IV. CONCLUSION.....	18

TABLE OF AUTHORITIES

Page(s)

Washington Cases

Backlund v. University of Washington,
137 Wn.2d 651, 975 P.2d 950 (1999)..... 10-12, 16

Bays v. St. Lukes Hospital,
63 Wn. App. 876, 825 P.2d 319 (1992).....10

Burnet v. Spokane Ambulance,
54 Wn. App. 162, 772 P.2d 1027 (1989)..... 9-11

Estate of Lapping v. Group Health Coop, of Puget Sound,
77 Wn. App. 612, 892 P.2d 1116 (1995)11

Gates v. Jensen,
92 Wn.2d 246, 595 P.2d 919 (1979)..... 2, 9-12

Gustav v. Seattle Urological Associates,
90 Wn. App. 785, 954 P.2d 319 (1998).....11, 12

Mason v. Ellsworth, 3 Wn. App. 298, 474 P.2d 909 (1970)5

Miller v. Kennedy,
11 Wn. App. 272, 522 P.2d 852 (1974) 4-6, 8

Miller v. Kennedy,
85 Wn.2d 151, 530 P.2d 334 (1975).....4

Smith v. Shannon,
100 Wn.2d 26, 666 P.2d 351 (1983).....9

Stewart-Graves v. Vaughn,
162 Wn.2d 115, 170 P.3d 1151 (2007).....8

Thomas v. Wilfac,
65 Wn. App. 255, 828 P.2d 597 (1992)..... 10-12

Watkins v. Parpala, 2 Wn. App. 484, 469 P.2d 974 (1970)5

TABLE OF AUTHORITIES

Page(s)

ZeBarth v. Swedish Hospital Medical Center,
81 Wn.2d 12, 499 P.2d 1 (1972).....3, 5

Other Cases

Canterbury v. Spence,
464 F.2d 772 (D.C. Cir. 1972).....5

Cobbs v. Grant,
8 Cal.3d 229, 104 Cal. Rptr. 505, 502 P.2d 1 (Cal. 1972).....5

Statutes, Rules, Regulations

RCW 7.701, 9, 10

RCW 7.70.0107, 8

RCW 7.70.0302

RCW 7.70.030(1).....18

RCW 7.70.030(3).....7

RCW 7.70.0402

RCW 7.70.050 *passim*

Other Authorities, Treatises

16 D. DeWolf & K. Allen, WASHINGTON PRACTICE: TORT LAW &
PRACTICE § 15:19 (3d. ed. 2006 & 2012-13 Supp.).....13

Keri K. Hall & Jason A. Lyman, *Updated Review of Blood Culture
Contamination*, 19 CLINICAL MICROBIOL. REV. 788 (2006).....17

Joann G. Elmore et al., *Ten-Year Risk of False Positive Screening
Mammograms and Clinical Breast Examinations*,
338 NEW ENG. J. MED. 1089 (1998).....17

TABLE OF AUTHORITIES

	<u>Page(s)</u>
<i>Blood Donor Has False Positive HIV Test Result – What Does This Mean?, Go Ask Alice!</i> (June 6, 1997), http://goaskalice.columbia.edu/blood-donor-has-false- positive-hiv-test-result-what-does-mean	18
Jennifer E. Lafata et al., <i>The Economic Impact of False-Positive Cancer Screens</i> , 13 <i>CANCER EPIDEMIOL. BIOMARKERS PREV.</i> 2126 (2004).....	17

I. IDENTITY AND INTEREST OF *AMICI CURIAE*

The Washington State Medical Association (“WSMA”) and the Washington State Hospital Association (“WSHA”) (“Health Care Amici”), are state-wide non-profit organizations which represent the medical and osteopathic physicians and surgeons and physicians assistants, and the state’s 97 community hospitals and other health related organizations, as further described in the motion for permission to file this brief. The WSMA and WSHA have both appeared before this Court many times as *amici curiae* and are well known to the Court.

Health Care Amici closely follow the law that affects them, patients, and the health care system. This includes the law related to informed consent that has been settled since adoption of Ch. 7.70 RCW in 1976, which incorporated recent case law. Amici believe Division III’s decision accurately applied the law under the statute and cases. But since the Court accepted review and Petitioner is seeking what he asserts is a bright line rule that would dramatically change the settled law of the past 35 years by imposing what amounts to strict liability for non-disclosure of preliminary test results, Health Care Amici want to make sure the Court is fully versed in the history of the doctrine and the well-established bright line rule as to informed consent.

The settled rule is that misdiagnosis or a failure to diagnose subjects a physician to a negligence action but not also to an action based on informed consent. The duty to inform does not arise until the physician becomes aware of the condition by diagnosing it or proposes diagnostic

tests which require consent. The reason for this rule is simple: the physician cannot inform the patient of a potential treatment, alternatives, and their risks, for a condition the physician has ruled out, has not diagnosed, or failed to diagnose. There must be a proposed course of treatment for there to be alternatives and risks which can be disclosed. When one is proposed, the informed consent statute can come into play if proper information is not then provided. But before such time, a claim for a naked failure to disclose simply cannot fit under the informed consent doctrine. If any claim exists, it is for negligence under RCW 7.70.040.

Washington cases recognized the doctrine of informed consent in 1970 and developed it briefly before the legislature codified the claim in 1976 in RCW 7.70.030 & .050. Its history explains its purpose and limits, and the apparent confusion caused by a decision that straddles the statutory definition of the claim, *Gates v. Jensen*, 92 Wn.2d 246, 595 P.2d 919 (1979). Division III addressed the apparent inconsistency between some language in *Gates* and later law to reach the correct result: a failure to diagnose, or a misdiagnosis of a condition, states only a claim for medical negligence and not an informed consent claim, consistent with the original purpose of the doctrine, the legislative mandate, and later cases.

Health Care Amici submit this brief to demonstrate the correctness of the decision below and why the rule proposed by Petitioner, based on *Gates*—strict liability for failure to immediately disclose a factor informing the physician’s progress toward making a diagnosis—is inconsistent with the doctrine as established, codified and developed.

It also is bad policy. Such a rule would impose untoward hardships on health care providers and institutions statewide at great cost to the health care system and to providers' work without corresponding benefits to patients. Health Care Amici ask the Court to reject the attempt to impose a new, unworkable disclosure requirement on health care professionals. It should confirm the settled rule—adopted by this Court and relied on to decide four Court of Appeals cases—that informed consent does not impose a duty on doctors to inform their patients about potential treatments and risks for medical conditions the physician concludes the patient does not have.

This is based on common sense and the law: How is a physician supposed to disclose potential treatments and risks for a disease other than the one he or she diagnosed? Liability cannot be imposed for a “failure” to provide “informed consent” for courses of treatment or procedures for diseases the physician ruled out. Under informed consent, the physician must give the patient sufficient information to evaluate whether to follow the *proposed* course of treatment, given the diagnosis; any error in ruling out a disease is subject to a claim of negligence, not failure to inform.

II. THE LAW OF INFORMED CONSENT IN WASHINGTON

A. The Common Law Roots of the Informed Consent Doctrine.

This Court first recognized the doctrine of informed consent in 1972 in *ZeBarth v. Swedish Hospital Medical Center*, 81 Wn.2d 12, 499 P.2d 1 (1972). The doctrine was intended to cover “situations where

medical treatment involves grave risk of collateral injury and puts the physician under a duty to advise the patient of such risks before initiating treatment.” *Id.*, at 23.¹ The Court of Appeals developed the principles supporting the doctrine to take into account developments from other courts in *Miller v. Kennedy*, 11 Wn. App. 272, 522 P.2d 852 (1974). This Court took the unusual step of adopting the Court of Appeals’ reasoning and result. *Miller v. Kennedy*, 85 Wn.2d 151, 152, 530 P.2d 334 (1975). Judge Callow’s decision thus was the state of the law when the legislature passed the statute in 1976, adopting the standard set forth in *Miller*.

In *Miller*, the defendant physician elected to perform a kidney biopsy to diagnose the cause of Mr. Miller’s heart disease. 11 Wn. App., at 274. Mr. Miller alleged the biopsy needle was negligently inserted during the diagnostic procedure, causing him to lose his kidney. He testified the doctor did not advise him of the risk of loss of the kidney from the biopsy or of alternative ways to perform the biopsy. *Id.* He challenged the informed consent instruction on the basis it “wrongfully imposes on the plaintiff the obligation to prove by medical testimony a

¹ Informed consent . . . identifies a principle covering **situations where medical treatment involves a grave risk of collateral injury** and puts the physician under a duty to advise the patient of such risks **before initiating the treatment**. Informed consent . . . is the name for a general principle of law that a physician has a duty to disclose . . . 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. [citation omitted]. Failure to impart such information to the patient is by the great weight of authority deemed negligence rendering the physician liable for injuries proximately caused thereby. *ZeBarth v. Swedish Hosp. Med. Ctr.*, 81 Wn. 2d 12, 23, 499 P.2d 1 (1972) (bold added).

breach of a medical standard of disclosure.” *Id.*, at 281. The court ultimately agreed.

Relying heavily on *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972), *Cobbs v. Grant*, 8 Cal.3d 229, 104 Cal. Rptr. 505, 502 P.2d 1 (Cal. 1972), and earlier Court of Appeals decisions,² Judge Callow explained that informed consent is grounded in the relationship of trust between a doctor and a patient, giving rise to a fiduciary duty of disclosure. *Miller*, 11 Wn. App. at 282. The physician owes a duty to “acquaint the patient with the perils of each medical course of action.” *Id.* at 281. While *ZeBarth* had held the physician had a duty to disclose “what a reasonably prudent physician in the medical community” would disclose to allow the patient to make an intelligent balancing of the probable risks against the probable benefits of the proposed treatment, *Miller* shifted the focus of disclosure from the doctor to the patient, consistent with patient autonomy principles developed by other courts. Underlying this patient-centered approach is the concept that the “patient has the right to chart his own destiny, and the doctor must supply the patient with the material facts the patient will need in order to chart that destiny with dignity.” *Id.*, at 282.³

² E.g., *Watkins v. Parpala*, 2 Wn. App. 484, 490-92, 469 P.2d 974 (1970); *Mason v. Ellsworth*, 3 Wn. App. 298, 305-14, 474 P.2d 909 (1970).

³ The *Miller* decision’s full rationale, expressly adopted by this Court, is instructive:

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. The inquiry as to each item of information which the doctor knows or should know about the patient’s physical condition is ‘Would the patient as a human being consider this item **in choosing his or her course of treatment?**’ *Cobbs v. Grant* referring to the *Canterbury* case states at page 243:

Necessarily implicit in this analysis is that a course of treatment (including an invasive diagnostic procedure) is proposed by the physician and the patient is informed of all options so he or she can choose which to do or to refuse. *Miller* thus held that a plaintiff is entitled to an instruction on the informed consent duty if there is evidence tending to prove that:

- (1) the risk of injury *inherent in the treatment* is material; (2) there are feasible alternative courses available; and (3) the plaintiff can be advised of the risks and alternatives without detriment to his wellbeing.

Miller, 11 Wn. App. at 286-87 (emphasis added). The instruction should state that the physician's duty is to disclose all material information "the patient will need to make an informed decision whether to consent or reject **the proposed treatment or operation.**" *Id.*, at 289 (bold added).

The plaintiff must prove by a preponderance of the evidence that:

- (1) that physician failed to inform the patient of a material risk involved in submitting to the **proposed course of treatment;**
- (2) the patient consented to **the proposed treatment** without being aware of or fully informed of the material risks of each choice of treatment and of no treatment at all;

The court in *Canterbury v. Spence*, *supra*, 464 F.2d 772, 784, bluntly observed: 'Nor can we ignore the fact that to bind the disclosure obligation to medical usage is to arrogate the decision on revelation to the physician alone. Respect for the patient's right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves.' Unlimited discretion in the physician is irreconcilable with **the basic right of the patient to make the ultimate informed decision regarding the course of treatment to which he knowledgeably consents to be subjected.**

Indeed, it is the prerogative of the patient to choose his treatment. A doctor may not withhold from the patient the knowledge necessary for the exercise of that right. Without it, the prerogative is valueless. *Canterbury v. Spence*, *supra*, 464 F.2d at 781, 782, 786.

Miller v. Kennedy, *supra*, 11 Wn. App. at 282-83 (bold added).

(3) a reasonable, prudent patient probably would not have consented to **the treatment** when informed of the material risks; and

(4) the **treatment chosen** caused injury to the patient.

Id., at 289 (bold added).

This was the state of the law before the legislature acted in 1976. Central to a claim under the doctrine of informed consent was that a course of treatment was proposed and needed to be disclosed so the patient could choose. Absent a proposed course of treatment, there could be no issue of an informed consent thereto.⁴

B. Codification and Definition of Informed Consent Claims.

In 1976, the legislature exercised “its police and sovereign power” to take control of health care claims from the common law by modifying the substance and procedure for “all civil actions and causes of action, whether based on tort, contract, or otherwise, for damages for injury occurring as a result of health care which is provided after June 25, 1976.” RCW 7.70.010. The statute provides three bases for recovery for health care-related injuries, only one of which relates to and defines the claim under informed consent: “No award shall be made . . . unless the plaintiff establishes . . . (3) That injury resulted from health care to which the patient or his or her representative did not consent.” RCW 7.70.030(3).

The statutory claim, like the common law claim, is premised on proposed treatment. *See* RCW 7.70.050. The legislature confirmed this

⁴ A proposed course of treatment that required informed consent would be an invasive procedure done for purposes of diagnosis, such as the biopsy in *Miller v. Kennedy*.

when it defined the “necessary elements of proof” for informed consent, essentially the *Miller* elements.⁵

(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 or her 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;

(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.

RCW 7.70.050 (emphasis added).

C. After the Legislature Codified the Then-Existing Doctrine of Informed Consent in 1975, a Later, Tail-End Development to the Pre-Statutory Common Law Ceased to Matter.

While *Miller* represents the existing law the legislature intended to reflect when enacting RCW 7.70.050, post-enactment decisions based on the common law doctrine cannot inform the now-statutory-based informed consent claims because there is no longer any common law duty of informed consent. RCW 7.70.010. Due to this history and the statute’s express terms, changes to the common law of informed consent that

⁵ This Court observed that the legislature intended RCW 7.70.050 to reflect the “existing law with respect to the doctrine of informed consent,” adopting the principles in *Miller*. See *Stewart-Graves Vaughn*, 162 Wn.2d 115, 125, 170 P.3d 1151 (2007) quoting from Final B. Rep. of Sub. H.B. 1470, 44th Leg, 1st Ex. Sess., at 23 (Wash. 1976).

occurred after the Legislature enacted Ch. 7.70 RCW do not affect or control statutory action for claims of lack of informed consent. *See Smith v. Shannon*, 100 Wn.2d 26, 38, 666 P.2d 351 (1983) (declining to review waived issue related to common law standard of care for a case arising before the effective date of chapter 7.70 RCW because determining that issue would “be of little or no precedential value for future cases[.]” arising under the statute).

Gates, though decided in 1979, was actually decided under the common law doctrine because the health care at issue occurred before June 25, 1976. Even though made after the legislature adopted RCW 7.70.050, its holdings cannot be deemed as incorporated into the statutory standard, nor to change or modify the statutory standard. For that reason, *Gates* is “of little precedential value for [this]future case[.]” that arose under the statute. *See Smith*, 100 Wn.2d at 38.

D. No Case Under RCW 7.70.050 Has Required Disclosure of Treatment Options Before the Physician Makes a Diagnosis or Proposes a Diagnostic Procedure.

The Court of Appeals decided the first cases involving the interplay between statutory claims for failure to diagnose a condition and informed consent. In *Burnet v. Spokane Ambulance*, the plaintiffs claimed the defendant-doctor owed a duty to inform them of the decision not to provide any further diagnostic tests or treatment. 54 Wn. App. 162, 168, 772 P.2d 1027, *review denied*, 113 Wn.2d 1005 (1989).⁶ But the

⁶ *Burnet* does not rely on *Gates* for any more than boilerplate statements about the nature of an informed consent claim.

plaintiff's expert stated the defendant physician was unaware of the condition which implicated risk to the patient. Accordingly, *Burnet* held that the physician had no duty of disclosure where he was unaware of the plaintiff-patient's condition which implicated risk to her. *Id.*, 54 Wn. App. at 169 (upholding trial court's grant of summary judgment).

Bays v. St. Lukes Hospital holds that "the duty to disclose does not arise until the physician becomes aware of the condition by diagnosing it. 63 Wn. App. 876, 891, 825 P.2d 319, *review denied*, 119 Wn.2d 1008 (1992).⁷ *Bays* correctly rejected the plaintiff's argument that Ch. 7.70 RCW imposed upon physicians the duty to disclose material facts relating to treatment of conditions which have not been diagnosed by the physician. *Id.* *Bays* declined to create a "second or alternate cause of action on informed nonconsent to a diagnostic procedure predicated on the same facts necessary to establish a claim of medical negligence." *Id.*, at 883. *Bays* cited *Burnet* as the source of that rule. *Id.*, at 881. Its analysis did not use *Gates* as providing any law relevant to that issue.⁸ More to the point, *Bays*' informed consent holding was adopted by this Court in *Backlund v. University of Washington*, 137 Wn.2d 651, 661, 975 P.2d 950 (1999).

Thomas v. Wilfac, 65 Wn. App. 255, 261, 828 P.2d 597, *review denied*, 119 Wn.2d 1020 (1992), holds that "[f]ailure to diagnose a

⁷ *Bays* held that the trial court did not err in granting a directed verdict in the defendant doctor's favor on the informed consent claim. 63 Wn. App. at 879-82.

⁸ As in *Burnet*, *Bays* does not rely on *Gates* for any more than boilerplate statements about the nature of an informed consent claim.

condition is a matter of medical negligence, not a violation of the duty to inform a patient.”⁹ *Thomas* cites *Bays* and *Burnet* as the source of the rule that informed consent and medical negligence are alternate theories of liability and does not mention *Gates*. *Id.* *Thomas*’ informed consent holding was adopted in *Backlund*. See 137 Wn.2d at 661 & fn. 2.

In *Gustav v. Seattle Urological Associates*, the Court of Appeals once again held that the defendant physician’s failure to diagnose a condition “is a matter of medical negligence, not a violation of the duty to inform.” 90 Wn. App. 785, 790, 954 P.2d 319 (1998), *review denied*, 136 Wn.2d 1023. *Gustav* cited to *Thomas*, 65 Wn. App. at 261, and *Bays*, 876 Wn. App. at 881, for that proposition. “The duty to disclose does not arise until the physician becomes aware of the condition by diagnosing it.” *Gustav*, 90 Wn. App. at 789, citing *Bays*, 876 Wn. App. at 881, and *Burnet*. *Gustav* rejected the plaintiff’s argument that the duty to inform is implicated where a misdiagnosis occurs, holding that the case relied on, *Estate of Lapping v. Group Health Coop, of Puget Sound*, 77 Wn. App. 612, 892 P.2d 1116 (1995), was a case involving a diagnostic procedure and the duty to warn of the risks inherent in that procedure. 90 Wn. App. at 791. Without citing to *Gates*, *Gustav* affirmed the trial court’s dismissal of the informed consent claim based on a misdiagnosis. 90 Wn. App. at 792. “To hold otherwise would be to merge two distinct and logically separate causes of action.” *Id.*, 90 Wn. App. at 791-92.

⁹ In *Thomas*, the jury returned a defense verdict on the informed consent claim and the Court of Appeals upheld the trial court’s refusal to rule as a matter of law that there was a failure to secure informed consent. 65 Wn. App. at 259.

E. This Court Affirmed in *Backlund* That Failure to Diagnose is a Matter of Medical Negligence, Not a Violation of the Duty to Inform a Patient.

A year after *Gustav* was decided, the issue came to this Court in *Backlund*, which does not cite *Gates* at all. In *Backlund*, the physician undertook the more conservative, but unsuccessful, treatment option for jaundice. The plaintiffs brought claims of negligence and failure to obtain informed consent. The jury found the physician was not negligent and did not reach a verdict on the informed consent claim, leading to a bench trial on that claim. The trial court found against the plaintiffs and they appealed on whether they had a claim for failure to obtain informed consent under RCW 7.70.050. *Backlund* embraced the standard in *Bays* and *Thomas*:

A physician who misdiagnoses the patient's condition, and is therefore unaware of an appropriate category of treatments or treatment alternatives, may properly be subject to a negligence action where such misdiagnosis breaches the standard of care, **but may not be subject to an action based on failure to secure informed consent.**

Backlund, 137 Wn.2d at 661 (emphasis added).

Backlund explained the reason for this rule by the example of a physician who "misdiagnosed a headache as a transitory problem and failed to detect a brain tumor." *Id.*, 137 Wn.2d at 661 n.2. That physician could be liable for negligence for the misdiagnosis, but "it seems anomalous to hold the physician culpable under RCW 7.70.050 for failing to secure the patient's informed consent for the undetected tumor." *Id.*, citing to *Thomas*.

That informed consent does not apply in misdiagnosis cases is settled in Washington is recognized as such by Washington Practice:

The failure to inform a patient of potential risks for a condition that the physician has not yet diagnosed does not violate the duty to obtain informed consent; instead, the patient must demonstrate that the failure to diagnose constituted an act of professional negligence. The duty to disclose risk associated with a condition arises only when the physician becomes aware of a condition by diagnosing it.

16 D. DeWolf & K. Allen, WASHINGTON PRACTICE: TORT LAW & PRACTICE § 15:19, at 474 (3d. ed. 2006 & 2012-13 Supp.).

III. THERE IS NO NEED TO CHANGE THE CURRENT RULE

A. Informed Consent Addresses Different Concerns Than Negligence; Conflating the Two Would Not Serve Either or Be Consistent with the Statute.

Informed consent protects patient autonomy, the right to decide on which course of treatment to accept (if any) once the physician has made a diagnosis with a proposed treatment plan, or when a procedure such as a biopsy is recommended to make or confirm a diagnosis in developing a proposed plan of treatment. The patient has the right to accept or reject the proposed course of treatment based on complete information. An informed consent claim is different from a misdiagnosis or failure to diagnose claim, reflecting why it is a distinct part of the statute and why they are not properly combined.

B. Plaintiff's Claimed "Bright Line Rule" is Inconsistent With RCW 7.70.050. Adoption of Plaintiff's Proposed Rule Would Not Benefit Patients and Would Harm the Health Care System.

Bays rejected the argument that physicians have a statutory duty to disclose material facts relating to treatment of conditions which have not been diagnosed by the physician, holding the duty to disclose "does not

arise until the physician becomes aware of the condition by diagnosing it.” 63 Wn. App. at 881. Petitioner seeks a new rule from this Court under the informed consent label whereby physicians and all other health care workers would have to immediately report every preliminary test result for every patient and, necessarily, at the same time give “informed consent” of all potential ramifications and outcomes of the test result, even if that preliminary result is but one factor informing the physician’s progress toward making a diagnosis. This is untenable for many reasons, both legal and practical.

First, the proposed rule is not consistent with the statute. In a case like this one, the plaintiff cannot meet the second requirement of the statute, “that the patient consented to the treatment without being aware of or fully informed of such material fact or facts.” There was no course of treatment in the case before the Court because, as in countless clinics and hospitals throughout the state every day, the health care provider was confronted with *preliminary, unconfirmed* results which required additional work and time to determine what they meant. The physician could only determine whether and what course of treatment is recommended after diagnosing the plaintiff’s condition.

Second, Petitioner’s standard is unworkable. If the argument is accepted, health care providers will have to give each patient every preliminary test result immediately, even when inconclusive, even when not confirmed, even when clinical judgment directs the practitioner otherwise. And the practitioner will also have to explain all the

possibilities and permutations when giving the preliminary, inconclusive result, even though nothing has been established and the practitioner cannot properly determine or recommend any proposed course of action until the results are confirmed. Health care professionals would lose the ability to exercise that judgment under plaintiff's propose rule.

The facts from *Bays* show why an expanded duty of disclosure would be unworkable. There, the patient had an increased temperature while admitted to the hospital after being crushed by an 800 pound spool of wire. The physician ordered a chest x-ray to determine which of four medical conditions—pneumonia; alectasis (results from lung collapse); blood absorption (from bleeding around fractures); or thromboembolism (a blood clot moving through the venous system)—could have been causing that the increased temperature.¹⁰ The next day the temperature returned to normal and the diagnostic test (the chest x-ray) did not appear to indicate any of the four medical problems. Under Petitioner's proposed rule, the physician would have had to disclose the treatments, alternatives, risks, and other material facts related to treating all four potential causes of the patient's increased temperature, despite excluding all four as possible causes. This is both unnecessary and unworkable.

Backlund's hypothetical is also instructive as to the unworkability of an expanded duty of disclosure. There, the patient presents with a

¹⁰ This is a standard differential diagnosis: "an identification of possible bodily conditions causing patient's present symptoms." *Bays*, 63 Wn. App. at 882-83, citing *STEDMAN'S MEDICAL DICTIONARY* 437 (21st ed. 1966). Plaintiff would have physicians disclose all material facts related to every possible condition identified in a differential diagnosis.

headache, which the physician misdiagnoses as being transitory. The doctor then fails to detect the tumor causing the headache. *See Backlund*, 137 Wn.2d at 661, n.2. Under Petitioner's standard, the physician would have a duty to disclose to the patient the treatments, alternatives, risks, and other material facts related to treating tumors (in addition to *all* other conditions which could cause a headache), even though that condition was not known to the physician to be the cause of headache. In other words, physicians would bear the unattainable burden of knowing the unknowable, and then face liability for not disclosing what was not known to the physician. Instead, if the physician negligently fails to make a diagnosis, the patient's remedy is and should be a medical malpractice action, not an informed consent claim.

Third, the circumstances in this case give an unfortunate example of why imposing such liability is improper as a practical matter. Had Petitioner's proposed rule been followed and the physician reported the potential abnormality of "possible" yeast, a patient concerned about the preliminary result would have had to demand immediate treatment before the specific strain could be determined by the culture grown days later for there to be even arguable liability under the statute. But immediate treatment for otherwise unspecified "yeast" in the blood by the standard medication would have been ineffective on the strain of yeast she actually had, *Candida glabrata*. The medication that could be used on that strain (Amphotericin B) is so dangerous to kidneys it would not be started by an infectious disease specialist until the strain was conclusively determined.

See Supplemental Brief of Respondents, pp. 4-6, 8-9, 16.

Importantly, getting lab test confirmations takes time, particularly when cultures are involved.¹¹ Unfortunately in this case, getting inconclusive test results to the patient earlier, on which no meaningful action could be taken, would not have made a difference.

Another practical reason weighing against adoption of the proffered rule is that the everyday medical world is replete with preliminary results that are inconclusive or false positives, and which then require additional analysis or tests or examination to know just what condition the patient has and what the treatment options may be.¹²

¹¹ There is a large literature on false positives, confirmation of tests, and the problems with contamination of test results, both as to blood tests and biopsies. Tests which require growth of cultures, like yeasts, simply take time to determine the specific result with certainty, while other tests have similar problems and generally mean that more testing and time is required to confirm if a problem exists and, if so, what it is. See, e.g., Keri K. Hall & Jason A. Lyman, *Updated Review of Blood Culture Contamination*, 19 CLINICAL MICROBIOL. REV. 788 (2006), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1592696/> (last viewed, 9/25/13) (“Blood culture contamination represents an ongoing source of frustration for clinicians and microbiologists alike. . . . A variety of strategies have been investigated and employed to decrease contamination rates. . . . While it is clear that progress is being made, fundamental challenges remain Contaminated cultures have been recognized as a troublesome issue for decades and continue to be a source of frustration for clinical and laboratory personnel alike. Faced with a positive blood culture result, clinicians must determine whether the organism represents a clinically significant infection associated with great risk of morbidity and mortality or a false-positive result of no clinical consequence.”).

¹² In addition to the Hall & Lyman article cited in fn. 11, *supra*, see the following for descriptions of the physician’s world of false positives and the art of determining what the test results mean and whether and what course of treatment to propose and give information about to the patient: Joann G. Elmore et al., *Ten-Year Risk of False Positive Screening Mammograms and Clinical Breast Examinations*, 338 NEW ENG. J. MED. 1089 (1998) (“**Conclusions** Over 10 years, one third of the women screened had abnormal test results requiring additional evaluation, even though no breast cancer was present.”) (bold in original); Jennifer E. Lafata et al., *The Economic Impact of False-Positive Cancer Screens*, 13 CANCER EPIDEMIOL. BIOMARKERS PREV. 2126 (2004), available at <http://cebp.aacrjournals.org/content/13/12/2126> (“Conclusion: The results here indicate that false-positive results among some available cancer screening tests are relatively

IV. CONCLUSION

Washington's law on informed consent properly focuses on whether the provider gave the patient sufficient information so the patient can give a fully informed consent for proposed courses of treatment. Under RCW 7.70.050 and its case law, informed consent only comes into play where there has been a diagnosis and there are proposed forms of treatment, or diagnostic procedures. It does not, and cannot apply where, as here, the allegation amounts to a misdiagnosis which results in no proposed course of treatment about which the patient can be advised. This is the current rule that properly governs these cases.

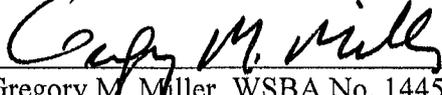
This appeal asserts a claim of nondisclosure from a misdiagnosis – a potential negligence claim under RCW 7.70.030(1) which, in fact, was submitted to the jury and rejected. Petitioner had his day in court. It would conflict with the statute and settled law to now characterize such claims as an “informed consent” claim for a second bite at the apple. Such an unwarranted expansion of settled and properly functioning law would also have serious adverse consequences for physicians and hospitals and the health care system. Health Care Amici therefore urge the Court to confirm

common, that patients incurring a false-positive screen tend to receive follow-up testing, and that such follow-up is not without associated medical costs.”); *see also* Columbia University's Q & A on a notice of reaction to the anti-HIV-2 antibody in screening for blood donation, describing the test result as showing a “false positive”, then listing several factors that contribute to false positive HIV test results, and that “it is also possible for test results to indicate false negatives.” Available at *Blood Donor Has False Positive HIV Test Result – What Does This Mean?*, Go Ask Alice! (June 6, 1997), <http://goaskalice.columbia.edu/blood-donor-has-false-positive-hiv-test-result-what-does-mean> (last updated July 5, 2012).

the settled law and the meaningful and practical distinction between an informed consent claim and a mis-diagnosis or failure to diagnose claim.

Respectfully submitted this 30th day of September, 2013.

CARNEY BADLEY SPELLMAN, P.S.

By: 
Gregory M. Miller, WSBA No. 14459
Justin P. Wade, WSBA No. 41168

*Attorneys for Amici Curiae Washington State
Medical Association and Washington State
Hospital Association*

CERTIFICATE OF SERVICE

I certify under penalty of perjury of the laws of the State of Washington that on October 1, 2013, I caused a true and correct copy (**Corrected**) BRIEF OF *AMICI CURIAE* WASHINGTON STATE MEDICAL ASSOCIATION AND WASHINGTON STATE HOSPITAL ASSOCIATION to be delivered via email and U.S. Mail to the following:

ATTORNEYS FOR PETITIONER:

Richard R. Johnson, WSBA #6481
DELORIE-JOHNSON, PLLC
917 Triple Crown Way, #200
Yakima, WA 98908
Ph: (509) 469-6900
Fax: (509) 454-6956
E-mail: richard@deloriejohnson.com

Ian S. Birk, WSBA #31431
Benjamin Gould, WSBA #44093
Isaac Ruiz, WSBA #35237
Harry Williams, IV, WSBA #41020
KELLER ROHRBACK LLP
1201 Third Avenue, Suite 3200
Seattle, WA 98101
Ph: (206) 623-1900
Fax: (206) 623-3384
E-mail: ibirk@kellerrohrback.com
bgould@kellerrohrback.com
iruiz@kellerrohrback.com
hwilliams@kellerrohrback.com

ATTORNEYS FOR RESPONDENTS:

Pamela A. Okano, WSBA #7718

REED MCCLURE

1215 Fourth Avenue, Suite 1700

Seattle, WA 98161-1087

Ph: (206) 386-7002

Fax: (206) 223-0152

E-mail: pokano@rmlaw.com

David A. Thorner, WSBA# 4783

Megan K. Murphy, WSBA #31680

THORNER, KENNEDY & GANO, P.S.

101 South 12th Avenue

P.O. Box 1410

Yakima, WA 98907-1410

Ph: (509) 575-1400

Fax: (509) 453-6874

E-mail: David Thorner c/o Melinda@tkglawfirm.com
mkm@tkglawfirm.com

ATTORNEYS FOR WDTL *AMICUS CURIAE*:

Stewart Estes, WSBA #15535

KEATING, BUCKLIN & McCORMACK, INC., P.S.

800 Fifth Avenue, Suite 4141

Seattle, WA 98104-3175

Ph: (206) 623-8861

Fax: (206) 223-9423

E-mail: sestes@kbmlawyers.com

Matthew W. Daley, WSBA #36711

Ryan M. Beaudoin, WSBA #30598

WITHERSPOON, KELLEY, DAVENPORT & TOOLE

422 W. Riverside Avenue, Ste. 1100

Spokane, WA 99201

Ph: (509) 624-5268

F: (509) 458-2728

E-mail: MWD@witherspoonkelley.com
RMB@witherspoonkelley.com

Elizabeth K. Morrison, WSBA #43042

LORBER, GREENFIELD & POLITO, LLP

1000 Second Avenue, Ste. 1700

Seattle, WA 98104

Ph: (206) 832-4900

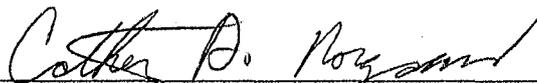
F: (206) 832-4901

E-mail: emorrison@lorberlaw.com

ATTORNEY FOR WSAJ FOUNDATION *AMICUS CURIAE*:

Bryan Harnetiaux, WSBA #5169
517 E 17th Avenue
Spokane, WA 99203-2210
Ph: (509) 624-3890
Email: amicuswsajf@wsajf.ORG

DATED this 1st day of October, 2013.



Catherine A. Norgaard, legal assistant

CARNEY BADLEY SPELLMAN PS
701 Fifth Avenue, Suite 3600
Seattle, Washington 98104-7010
(206) 622-8020

OFFICE RECEPTIONIST, CLERK

To: Norgaard, Cathy
Cc: 'richard@deloriejohnson.com'; 'ibirk@kellerrohrback.com'; 'bgould@kellerrohrback.com'; 'iruiz@kellerrohrback.com'; 'hwilliams@kellerrohrback.com'; 'pokano@rmlaw.com'; 'Melinda@tkglawfirm.com'; 'mkm@tkglawfirm.com'; 'sestes@kbmlawyers.com'; 'MWD@witherspoonkelley.com'; 'amicuswsajf@wsajf.ORG'; 'emorrison@lorberlaw.com'; 'RMB@witherspoonkelley.com'; Miller, Greg; Wade, Justin P.
Subject: RE: Anaya-Gomez v. Sauerwein, SCT No. 88307-6 - Filing Attachments to Email on behalf of Amici Curiae WSMA (Wash State Medical Assn) and WSHA (Wash State Hospital Assn) - corrected brief

Rec'd 10-1-13

Please note that any pleading filed as an attachment to e-mail will be treated as the original. Therefore, if a filing is by e-mail attachment, it is not necessary to mail to the court the original of the document.

From: Norgaard, Cathy [<mailto:Norgaard@carneylaw.com>]
Sent: Tuesday, October 01, 2013 8:47 AM
To: OFFICE RECEPTIONIST, CLERK
Cc: 'richard@deloriejohnson.com'; 'ibirk@kellerrohrback.com'; 'bgould@kellerrohrback.com'; 'iruiz@kellerrohrback.com'; 'hwilliams@kellerrohrback.com'; 'pokano@rmlaw.com'; 'Melinda@tkglawfirm.com'; 'mkm@tkglawfirm.com'; 'sestes@kbmlawyers.com'; 'MWD@witherspoonkelley.com'; 'amicuswsajf@wsajf.ORG'; 'emorrison@lorberlaw.com'; 'RMB@witherspoonkelley.com'; Miller, Greg; Wade, Justin P.
Subject: Anaya-Gomez v. Sauerwein, SCT No. 88307-6 - Filing Attachments to Email on behalf of Amici Curiae WSMA (Wash State Medical Assn) and WSHA (Wash State Hospital Assn) - corrected brief

Court Clerk:

Attached for filing is a (**corrected**) Brief of *Amici Curiae* WSMA (Wash State Medical Assn) and WSHA (Wash State Hospital Assn) and Certificate of Service attached to the back of the brief. The corrections are to a factual error on pages 15-16, to make it clear the example discussed was the Court's hypothetical example from the appellate decision, not from the facts and circumstances of that case, and omissions in the table of authorities. The content is otherwise unchanged. Mr. Miller apologizes for any inconvenience.

Case Name: Anaya-Gomez v. Sauerwein
Case No.: SCT No. 88307-6
Filers: Gregory M. Miller (WSBA #14459) – miller@carneylaw.com, and
Justin P. Wade (WSBA #41168) – wade@carneylaw.com

Cathy

Catherine A. Norgaard, legal assistant to Gregory M. Miller
CARNEY BADLEY SPELLMAN, P.S.
701 Fifth Ave., Suite 3600
Seattle, WA 98104-7010
Phone: (206) 607-4163 (direct)
Phone: (206) 622-8020 (main)
Fax: (206) 467-8215

Email: Norgaard@carneylaw.com