

FILED
SUPREME COURT
STATE OF WASHINGTON
1/31/2022 4:21 PM
BY ERIN L. LENNON
CLERK

No. 1000791

SUPREME COURT
OF THE STATE OF WASHINGTON

MARI YVONNE DAVIES,

Respondent,

v.

MULTICARE HEALTH SYSTEMS, et al.,

Petitioners

**BRIEF OF *AMICI CURIAE* WASHINGTON STATE
MEDICAL ASSOCIATION, WASHINGTON CHAPTER –
AMERICAN COLLEGE OF EMERGENCY
PHYSICIANS, WASHINGTON STATE HOSPITAL
ASSOCIATION, AND THE AMERICAN MEDICAL
ASSOCIATION**

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TABLE OF CONTENTS

	<u>Page</u>
TABLE OF AUTHORITIES	iii
I. IDENTITY AND INTEREST OF <i>AMICI CURIAE</i>	1
II. ISSUE OF CONCERN TO MEDICAL <i>AMICI</i> AND SUGGESTED ANALYTICAL FRAMEWORK.....	5
III. PROCEDURAL BACKGROUND & RULING	10
IV. LEGAL DISCUSSION.....	11
A. The Statutes Governing Informed Consent: RCW 7.70.010, 7.70.030 and 7.70.050.	11
B. The Decision’s Rationale Conflicts With <i>Anaya Gomez</i> and <i>Gates v. Jensen</i>	17
C. The Decision Would Allow The Patient, Not the Health Care Provider, to Choose the Method of Diagnosis, Contrary to Medical Practice and Licensure for Physicians, PA’s, and ARNP’s.	22
D. Examples From Medical Practice Show The Decision Is Inconsistent With And Would Interfere With The Practice Of Medicine.	26
1. Ambulatory settings – earaches, headaches.....	26
2. D-dimer testing in chest pain.	27
V. CONCLUSION.....	29

TABLE OF AUTHORITIES

Page(s)

Washington Cases

<i>Anaya Gomez v. Sauerwein</i> , 180 Wn.2d 610, 331 P.3d 19 (2014)	<i>passim</i>
<i>Backlund v. University of Washington</i> , 137 Wn.2d 651, 975 P.2d 950 (1999)	27
<i>Davies v. Multicare Health Systems</i> , 18 Wn.App.2d 377, 491 P.3d 207 (2021)	<i>passim</i>
<i>Flyte v. Summit View Clinic</i> , 183 Wn.App. 559, 333 P.3d 566 (2014)	10, 21-22
<i>Gates v. Jensen</i> , 92 Wn.2d 246, 595 P.2d 919 (1979):	10, 18-21
<i>In re Detention of DW</i> , 181 Wn.2d 201, 332 P.3d 423 (2014)	2
<i>Keogan v. Holy Family Hospital</i> , 95 Wn.2d 306, 622 P.2d 1246 (1980):	19-20
<i>Miller v. Kennedy</i> , 11 Wn.App. 272, 522 P.2d 852 (1974), <i>aff'd & adopted as decision of the Court</i> , 85 Wn.2d 151, 530 P.2d 334 (1975),	11-12, 16
<i>Stewart-Graves v. Vaughn</i> , 162 Wn.2d 115, 170 P.3d 1151 (2007).	16
<i>Trueblood v. Washington State Department of Social and Health Services</i> , 2017 WL 4700326 (W.D. Wa., 2017).....	3

Page(s)

Statutes and Court Rules

RAP 18.17. 29

RCW 7.70.010 11

RCW 7.70.030 *passim*

RCW 7.70.030(1) 2, 5, 14

RCW 7.70.030(3) *passim*

RCW 7.70.050 *passim*

RCW 7.70.050(1) *passim*

Other Authorities

Daniel Goulet, “My colleagues and my hospital are in crisis,” *Seattle Times* (January 15, 2022), <https://www.seattletimes.com/opinion/my-colleagues-and-my-hospital-are-in-crisis/> (visited 1/15/22)..... 4

Seattle Times, “Caseloads push hospitals to limits,” (January 14, 2022) <https://replica.seattletimes.com/html5/reader/production/default.aspx?pubname=&pubid=84d463e0-c035-4c49-902d-95c722bfe073> (visited 1/14/22)..... 3

Colleen Neal & Mark Helvie, “Overdiagnosis and Risks of Breast Cancer Screening,” 59 *Radiological Clinics of North America* 19 (Jan. 2021), <https://pubmed.ncbi.nlm.nih.gov/33222997/>, (viewed 1/27/22)..... 25

I. IDENTITY AND INTEREST OF *AMICI CURIAE*

Amici Curiae are the Washington State Medical Association (“WSMA”), Washington Chapter-American College of Emergency Physicians (“WA-ACEP”), Washington State Hospital Association (“WSHA”), and the American Medical Association (“AMA”) (“Medical *Amici*”), further identified in their motion to file this brief (“Motion”). They have a continuing interest in cases affecting their members, patients and the health care system. At issue is the scope of informed consent liability adopted in RCW 7.70.030. WSMA and WSHA were *amici curiae* in this Court’s last decision on that scope, *Anaya Gomez v. Sauerwein*, 180 Wn.2d 610, 331 P.3d 19 (2014).

The analysis in *Davies v. Multicare Health Systems*, 18 Wn.App.2d 377, 491 P.3d 207 (2021) (“Decision”; “Op.¶_”), conflicts with the limits on informed consent claims stated in RCW 7.70.030 and RCW 7.70.050(1), and *Anaya Gomez*. The analysis expands the scope of liability for such claims by allowing a misdiagnosis claim to be brought under the informed

consent statutes. That conflicts with the legislature’s narrower scope of informed consent limited to *treatment* stated in RCW 7.70.030, subsection (3), and 7.70.050(1), which is distinct from negligence claims under RCW 7.70.030(1), which can pertain to missed or overlooked *diagnoses*. The statutes, read together, confirm this distinction.

The analysis will harm the health care system, patients, and *Amici’s* members, and increase the cost of care, at the worst possible moment, a tumultuous time in staffing hospitals and other health care facilities to care for the sick and injured with the latest covid surge, the omicron variant now sweeping the state and country. Even before COVID-19, our hospitals were overcrowded and emergency departments used inappropriately, housing persons with serious behavioral health issues with no other place to go, forcing this Court to weigh in.¹ These

¹ See, e.g., *In re Detention of DW*, 181 Wn.2d 201, 332 P.3d 423 (2014) (psychiatric boarding in emergency rooms via “single-bed certifications” for involuntary treatment held illegal, describing the dearth of behavioral health resources).

problems have not abated.²

Tragically, already-overcrowded emergency departments and hospitals now grappling with COVID-19 have no relief, as multiple articles and news reports attest. Staffing is thin, patients are being cared for in lobbies and hallways, and surgeries and procedures are being cancelled for lack of staff or beds, a situation exacerbated by the omicron wave, as the recent *Seattle Times* headline in oversized font trumpeted: “**Caseloads push hospitals to limits.**”³ A recent Op-Ed piece gives an inside view of just how stretched the dedicated professionals serving in

² The federal court continues to fine the State for failing to provide proper evaluation and treatment. *See Trueblood v. Washington State Department of Social and Health Services*, 2017 WL 4700326 (W.D. Wa., 2017) (contempt order), and docket nos. 864, 871, 879, and 883 (contempt judgments from October 2021 to January 2022 totaling \$1,236,750).

³ *See* the headline and front page layout at <https://replica.seattletimes.com/html5/reader/production/default.aspx?pubname=&pubid=84d463e0-c035-4c49-902d-95c722bfe073> (visited 1/14/22). One article is “Inslee calls out National Guard to help with nonmedical tasks.”

our local hospitals are,⁴ dedicated providers who include members of *Medical Amici*.

Nevertheless, even while trying to ensure adequate health care to all who need it in this deluge, *Medical Amici* and their members have a huge interest in how this case is decided. If not corrected, the Decision's analysis will create a massive additional burden on emergency physicians and all physicians, physician assistants, and ARNP's (collectively "providers"), that will slow down, delay, or deny care to patients. That the Decision was issued in the midst of the COVID-19 health care crisis magnifies its error.

⁴ See Daniel Goulet, "My colleagues and my hospital are in crisis," *Seattle Times* (January 15, 2022) (describing the circumstances at his clinic and hospital in Everett), available at <https://www.seattletimes.com/opinion/my-colleagues-and-my-hospital-are-in-crisis/> (visited 1/15/22).

II. ISSUE OF CONCERN TO MEDICAL *AMICI* AND SUGGESTED ANALYTICAL FRAMEWORK

Must the Court of Appeals decision's analysis be rejected as inconsistent with the governing statutes, including RCW 7.70.030(3) and 7.70.050(1), and *Anaya Gomez* by creating a novel cause of action for a misdiagnosis under the misnomer of "informed consent," where that application of informed consent is: 1) inconsistent with the controlling statutes and case law on informed consent; 2) duplicates a misdiagnosis claim under RCW 7.70.030(1); 3) inconsistent with the purpose of informed consent in health care; and 4) would drastically change how medicine is practiced, harming patients and providers?

Medical *Amici* are concerned the Decision did not fully understand informed consent in the current health care system and the full statutory context.

Medically speaking, informed consent is designed to promote and protect patient autonomy for the *treatment* they receive. It is about the patient's right to decide which *course of treatment* to accept, if any, once the physician, PA, or ARNP has made or is considering a diagnosis with a proposed treatment plan; or, when an invasive procedure such as a biopsy is recommended to make or confirm a diagnosis under active consideration in developing a proposed *plan of treatment*. Every

patient has the right to accept or reject the proposed course of treatment based on complete information. The purpose of informed consent in health care thus is to ensure the patient and the provider are in agreement over the provider's proposed treatment for the patient's body, not to have the patient make the diagnosis. The failure, or decision not to take a *diagnostic* step – the complaint here – is a professional negligence issue, not a breach of informed consent.

The Legislature recognized this by making informed consent a separate and distinct part of the statute governing health care claims in RCW 7.70.030(3) and .050(1). As this Court explained, RCW 7.70.050 “clearly uses the word ‘treatment,’ demonstrating the *intent to limit informed consent claims to treatment situations.*” *Anaya Gomez*, 180 Wn.2d at 617, ¶16 (emphasis added). Informed consent relates to treatment, not diagnosis. *Id.*

The Decision abandoned the premise of informed consent liability in health care adopted in RCW 7.70.030(3) and

explained in *Anaya Gomez*. That liability arises only when a provider, after diagnosing, fails to give the patient the opportunity to choose their course of treatment or non-treatment for that diagnosis or is needed to determine a diagnosis actively being pursued. It arises only when a patient has a right to choose treatment. *Anaya Gomez*, 180 Wn.2d at 617 ¶16, 620 n.4; RCW 7.70.030(3); 7.70.050(1).

Instead, the Decision says that the patient is entitled to be informed about tests “to look for the injury which would have led to a different treatment.” Op. ¶30. But here, the test was to find an “injury” which had **not** been diagnosed so that no course of treatment was proposed for it. The asserted missing injury had been ruled out by the ER physician so there was no choice about any form of treatment for the patient to make. Characterizing this alleged failure to diagnose as a violation of informed consent under RCW 7.70.050 is incorrect under the statutes.

Medical *Amici's* concern is that the Decision creates a second basis for a misdiagnosis claim by another name and novel

form of proof: requiring proof of providing the patient all potential diagnostic tools for *any rejected or overlooked diagnosis for which no treatment is proposed or is being considered*. This goes far beyond disclosure for purposes of consenting to diagnostic procedures to confirm diagnoses actively being considered, but which require an invasive procedure needing consent, such as a biopsy. It eviscerates the providers' professional judgment. It says, if there is a test for any arguably possible condition, offer it; even if not deemed medically necessary, even if it delays treatment of the genuine problem, even if very costly. Leave no stone unturned.

In short, the patient must be given information to second-guess the provider's rejection of a diagnosis in real time and become a participant in the process of making the diagnosis – become a co-diagnostician. This is a wholesale transformation not only of health care liability under Washington law, but of how medicine is practiced.

With respect, Medical *Amici* strongly urge the Court to clarify the correct analysis for informed consent claims. They suggest that analysis begins with RCW 7.70.030(3) which, with .050(1), state the limited scope of such claims. Neither the Decision nor the parties below analyzed RCW 7.70.030(3). Instead, the Decision's analysis began with case law and RCW 7.70.050(1), unmoored from section .030(3), a key part of the statutory context governing the scope of informed consent claims. RCW 7.70.030 and subsection (3) must be part of the analysis because, in conjunction with RCW 7.70.050(1), they define the scope and reach of an informed consent claim and distinguish it from negligence claims.

Because that statutory scope is more narrow than the misdiagnosis claim the Decision purports to allow under the misnomer of informed consent, the Court should write a decision grounded in the statutes and which leaves no door open for a misdiagnosis claim to proceed under RCW 7.70.030(3). Medical *Amici* respectfully suggest it also should clarify for future cases

the limited application under the statutes of *Gates v. Jensen*, 92 Wn.2d 246, 595 P.2d 919 (1979), and *Flyte v. Summit View Clinic*, 183 Wn.App. 559, 333 P.3d 566 (2014), to ensure decisions consistent with the legislative directives and the reality of the health care system.

III. PROCEDURAL BACKGROUND & RULING

The Decision reversed the summary judgment dismissal of the plaintiff’s informed consent claim. That claim was based on the fact Dr. Hirsig, the emergency room physician, did not inform the patient of a potential test for a diagnosis that the physician had ruled out and did not propose to treat. After trial on the claim of negligence for misdiagnosis, the jury returned a defense verdict. On appeal the Court of Appeals affirmed the jury verdict on the misdiagnosis negligence claim, but reversed dismissal of the informed consent claim. The Decision, made without oral argument so there was no conversation between the bench and counsel on informed consent, thus revived the plaintiff’s case to try an “informed consent” claim to a new jury.

Medical *Amici* rely on the facts as stated in the Petition for Review and Petitioners' Supplemental Brief.

IV. LEGAL DISCUSSION

A. The Statutes Governing Informed Consent: RCW 7.70.010, 7.70.030 and 7.70.050.

The legislature preempted the field of injuries from health care in 1976 and adopted the then-current definition of informed consent as set out in *Miller v. Kennedy*,⁵ with one minor change. RCW 7.70.010; *Anaya Gomez*, 180 Wn.2d at 617 ¶15. The statutes provide that informed consent claims arise from the right to determine one's *treatment*.

RCW 7.70.030 states the three bases for liability for health care, beginning with a limiting preamble:

No award shall be made in any action or arbitration for damages for injury occurring as the result of health care which is provided after June 25, 1976, ***unless*** the plaintiff establishes one or more of the following propositions:

(1) That injury resulted from the failure of a health care provider to follow the accepted standard of care;

⁵ 11 Wn.App. 272, 522 P.2d 852 (1974), *aff'd & adopted as the decision of the Court*, 85 Wn.2d 151, 530 P.2d 334 (1975).

(2) That a health care provider promised the patient or his or her representative that the injury suffered would not occur;

(3) ***That injury resulted from health care to which the patient or his or her representative did not consent.***

Unless otherwise provided in this chapter, the plaintiff shall have the burden of proving each fact essential to an award by a preponderance of the evidence.

RCW 7.70.030 (emphasis added). This statute sets out the universe of health care claims permitted by the legislature, ***and its limits***. An informed consent claim can only arise from “health care to which the patient...did not consent.”

RCW 7.70.050(1) states the elements for informed consent claims taken from *Miller*, which necessarily must fit within the scope defined in .030 and its subsection (3) (*see* RCW 7.7.010), and within its own terms since the statutes are construed together.⁶ As this Court correctly held, the legislature intended

⁶ Where the language of the statute is unambiguous the Court “must give effect to that plain meaning as an expression of legislative intent.” *Dep’t of Ecology v. Campbell & Gwinn, LLC*, 146 Wn. 2d 1, 9-10, 43 P.3d 4 (2002). Per the “context” approach, legislative intent is determined from the plain terms of the statute and “from all that the Legislature has said in the statute
(Footnote continued next page)

“to limit informed consent claims to treatment situations.” 180

Wn.2d at 617 ¶16. The statute provides:

(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(1) (emphasis added).

and related statutes which disclose legislative intent about the provision in question.” *G-P Gypsum Corp. v. Dep’t of Revenue*, 169 Wn.2d 304, 309-310, 237 P.3d 256 (2010), quoting *Campbell & Gwinn*.

That means informed consent liability is limited to treatment situations – not diagnosis situations. If there is no treatment in the diagnostic process such as a biopsy, there is no informed consent claim for any errors or omissions, but a negligence claim.

Section .050(1) thus states the elements for a claim under section .030(3). Taken together with the preamble to section .030 and subsection (1) defining negligence, informed consent claims are limited to scenarios where a patient received health care treatment to which she did not consent and that treatment was the proximate cause of the injury complained of. These statutes do *not* provide a claim for what the Decision mischaracterized as a violation of informed consent – the failure to discuss and offer the choice of a diagnostic procedure for a condition the physician ruled out and was not treating. *See* Petition for Review at 4-6 and record cites therein.

The essential claim of Ms. Davies, as she recognized, was Dr. Hirsig’s alleged failure to diagnose the injury she asserted caused her stroke, the vertebral artery dissection.⁷ Ms. Davies was not offered an expensive CTA scan to detect this alleged injury because, based on clinical exam, none of the three doctors

⁷ *See* CP 33, page one of “Plaintiff’s Motion for Partial Summary Judgment (emphasis added): **“In fact, Ms. Davies had a vertebral artery dissection that was left undiagnosed.”**”

believed there was such an alleged injury. As such, no one proposed a course of treatment to treat a diagnosis they did not think existed. Since no treatment was proposed, there was nothing to which she could have consented or withheld consent.

That alleged failure to see and treat the claimed injury – the negligence of the missed diagnosis and its consequences – is the claim Ms. Davies presented to the jury, which it rejected. But that is not an informed consent claim under the statutes: her claimed injury did not meet the test of section .030(3) of resulting from “health care to which the patient ... did not consent.” Nor did it meet the plain terms of section .050(1). Ms. Davies complains of a *lack* of treatment, that she was *not* given the diagnostic test for the ruled-out diagnosis. So, even if one assumes she met the first three subsections of .050(1), which she did not, she did not meet subsection (d) which requires proof that the “treatment in question proximately caused the injury to the patient,” because there was no treatment.

By mis-stating the basis for an informed consent claim this way, the Decision transforms an informed consent claim far beyond what the statutes permit and what the cases hold in a way that fundamentally changes and harms health care practice.

Medical *Amici* respectfully remind the Court of the statutory analysis and the underlying common law it incorporated, the elements of the claim from *Miller v. Kennedy*. See *Anaya Gomez*, 180 Wn.2d at 617 ¶15; *Stewart-Graves v. Vaughn*, 162 Wn.2d 115, 125 ¶17, 170 P.3d 1151 (2007). The WSMA and WSHA’s *amicus* brief in *Anaya Gomez* (“*Anaya-Gomez Amicus Brief*”) gave the history of informed consent and practical ramifications of over-broad informed consent claims. See *Anaya-Gomez Amicus Brief*, pp. 3-13 (detailing the development of the informed consent doctrine in Washington before and after the statutes).⁸

⁸ Available at the Court’s website at <https://www.courts.wa.gov/content/Briefs/A08/883076%20Corrected%20Brief%20of%20Amici%20Curiae%20Washington%20State%20Medical%20Association%20and%20Washington%20State%20Hospital%20Association.pdf>.

B. The Decision’s Rationale Conflicts With *Anaya Gomez* and *Gates v. Jensen*.

The Decision reversed dismissal of the plaintiff’s informed consent claim based on the allegation the emergency room physician did not inform the patient of a potential test for a diagnosis he had ruled out and did not propose to treat. That ruling is contrary to this Court’s central holding in *Anaya Gomez*:

¶1 This case asks whether Washington’s informed consent statute, RCW 7.70.050, applies when a health care provider misdiagnoses the patient’s condition....

¶2 **We hold that when a health care provider rules out a particular diagnosis based on the patient’s clinical condition**—including test results, medical history, presentation upon physical examination, and any other circumstances surrounding the patient’s condition that are available to the provider—**the provider may not be liable for informed consent claims arising from the ruled out diagnosis** under RCW 7.70.050.

#

¶30 **We hold that when a health care provider rules out a particular diagnosis** based on the circumstances surrounding a patient’s condition, including the patient’s own reports, **there is no duty to inform the patient on treatment options pertaining to a ruled out diagnosis.** To hold otherwise would require health care providers and patients to spend hours going through useless information that will not assist in treating the patient. Corrected Br. of Amici Curiae [WSMA & WSHA] at 13.

Anaya Gomez v. Sauerwein, 180 Wn.2d at 613, 623 (footnote omitted). See *Anaya-Gomez Amicus* Brief at 13-18 (giving multiple practical problems). But the problems rejected in *Anaya Gomez* are precisely what are created by the Decision’s analysis and another reason why it must be rejected.

Gates v. Jensen, 92 Wn.2d 246, 595 P.2d 919 (1979), does not permit a different result, as this Court explained:

Under *Gates*, there may be instances where the duty to inform arises during the diagnostic process, but this case does not present such facts. **The determining factor is whether the process of diagnosis presents an informed decision for the patient to make about his or her care.** Dr. Sauerwein’s knowledge of the test result provided no treatment choice for Mrs. Anaya to make.

Anaya Gomez, 180 Wn.2d at 623, ¶31 (emphasis added). The *Gates* court expressly cabined the duty to inform to “the presence of a high risk of disease,” **not** one that had been ruled out:

The existence of an abnormal condition in one’s body, the ***presence of a high risk of disease***, and the existence of alternative diagnostic procedures to conclusively determine the presence or absence of ***that*** [high risk] disease are all facts which a patient must know in order to make an informed decision...

Gates v. Jensen, 92 Wn.2d at 251. Critically, the predicate question in *Gates* was whether the physician has a duty “to inform a patient *of a bodily abnormality discovered during a routine examination* and of diagnostic procedures which may be taken to determine the significance of *that abnormality.*” 92 Wn.2d at 247 (emphasis added). Here, Dr. Hirsig did not “discover the bodily abnormality” during his “routine” examination following the serious vehicle accident that Ms. Davies complains of. It was ruled out. Whether it should have been was her claim in negligence which she presented to the jury. It was not a claim cognizable under the informed consent statutes, nor under *Gates*.

Moreover, the Court recognized that, while not overruled, *Gates* was materially limited by *Keogan v. Holy Family Hospital*, 95 Wn.2d 306, 329, 622 P.2d 1246 (1980): “five justices agreed that the duty to disclose does *not* arise ‘whenever [the provider] becomes aware of a bodily abnormality which may indicate risk or danger,’ as stated in *Gates*, but rather *turns on*

*whether or not ‘the diagnosis has been completed.’” Anaya Gomez, 180 Wn.2d at 620 n.4 (italics by the Court; bold italics added). After all, by its plain terms, RCW 7.70.050(1) is limited to consent to **treatment**, which comes **after** the diagnosis.*

Like the test result in *Anaya Gomez*, Dr. Hirsig’s and the specialists’ alleged failure to diagnose the dissection of the vertebral artery did not “present an informed decision for the patient to make about...her care.” With no treatment choice for Ms. Davies to make, there was no factual basis for an informed consent claim. Her remedy, as in *Anaya Gomez*, was her negligence claim.

The Decision also is at odds with this Court’s point that “*Gates* was decided on facts that predated codification of informed consent in RCW 7.70.050,” which demonstrated the “intent to limit informed consent claims to treatment situations,” *Anaya Gomez*, 180 Wn.2d at 617, ¶16. It conflicts with the recognition that the *Keogan* majority held that the duty to disclose arises “when the diagnosis has been completed,” when

“there is something to inform the patient about” related to that proposed course of treatment, *id.*, at 620 n.4, 623 n.7, 626-27 ¶37. And it conflicts with the recognition there is no duty on health providers “to inform every patient about every test result”, *id.*, at ¶37, or thus, about every rejected diagnosis.

Flyte v. Summit View Clinic, 183 Wn.App. 559, 333 P.3d 566 (2014), cannot require a contrary result without being in conflict with *Anaya Gomez* and the statutes. For the reasons given in Petitioner’s response brief below (at pp. 41-43), *Flyte* is distinguished since it involved informing the patient on treatment options for a condition the physician’s notes suggested he had *not* ruled out and the appellate court determined was a disputed issue of fact. *Id.*, 183 Wn. App. at 579 ¶¶ 41-42 (“If the jury believed [the provider] had not ruled out influenza, it could properly have considered [the plaintiff’s] informed consent claim under...*Anaya Gomez*.”). Here, Dr. Hirsig had ruled out the dissection after his clinical exam and consultation with hospital specialists. *Flyte*, even on its own terms, does not allow an

informed consent claim based on a misdiagnosis. Any language in that decision that implies otherwise should be disapproved.⁹

C. The Decision Would Allow The Patient, Not the Health Care Provider, to Choose the Method of Diagnosis, Contrary to Medical Practice and Licensure for Physicians, PA's, and ARNP's.

The Decision asserts that “Davies was never advised of the risk of a vertebral artery dissection or the availability of a CTA scan to look for the injury which would have led to a different treatment.” Op. ¶30. If this becomes the test the consequences are huge. Consider, for just a moment, those triaging and treating health care providers in emergency rooms. Think of them busily and rapidly ruling in and ruling out multiple medical problems and treatment courses for the many patients who present at once. Imposing the obligation to inform patients in real time of potential tests or diagnostics for the conditions and diagnoses that have just been *ruled out* would interfere with, if not

⁹ To the extent that *Flyte's* analysis is inconsistent with footnote 4 of *Anaya Gomez*, see 183 Wn.App. at ¶¶ 36-37, it should be disapproved, particularly since that analysis conflicts with the statutes.

completely frustrate, their ability to attend to the urgent medical conditions and diagnoses that need to be addressed.

The Decision will dramatically affect *Amici's* thousands of members who staff and operate emergency rooms, hospitals, medical clinics, and offices throughout Washington State, and their patients. The increase in the time spent engaged in consultation with the patient on every conceivable diagnosis and the testing necessary to reject such diagnoses would increase the cost of providing the best care the most quickly and effectively, impacting patients and exposing them to unnecessary risks from those tests. It would confound the daily practice of medicine, especially in emergency rooms and urgent care centers. *See Anaya-Gomez Amicus Brief* at 14-18 (giving examples of how requiring disclosures deemed unnecessary by the provider would compromise health care delivery).

The vice of the Decision is ruling the patient has the right to choose the method of *diagnosis* while it is in process. This not only violates Washington's law governing injuries due to

health care as detailed *supra*, it upsets the nature of medical practice. It turns the patient from a collaborator in choosing the proposed course of treatment for what was diagnosed, into a co-diagnostician. But diagnosis is, and always has been, solely the province of the licensed health care provider, not the patient.

The Decision creates a conflict between the layperson's expectations and the clinical judgment of the professionally trained physician, PA, or ARNP. As a practical matter, many, if not most patients will demand every conceivable test, regardless whether medically indicated. The patient is then in the position of directing the clinical medicine, rather than having the provider use his or her education, training, experience and judgment to define the medical probabilities upon which to proceed. Particularly in the ER setting, the Decision upends a reasoned assessment by objective, trained providers for the emotionally-driven desires of the seriously injured or sick patient to leave no stone unturned, no matter how remote.

It can also mean, in a non-urgent setting, acceding to a healthy patient in his or her 20's insisting on a colonoscopy or mammogram that is not clinically indicated in order to definitively rule out feared – but not indicated – abnormalities. Both procedures have risks and costs.¹⁰

Unnecessary testing and false positives can harm patients both physically and by unwarranted anxiety. If the Decision's rationale is accepted, little is left of a health care provider's professional clinical judgment if it can be overruled by the patient's after-the-fact demand for a test that was not indicated at the time by that professional judgment and therefore “not disclosed.”

¹⁰ See, e.g., Colleen Neal & Mark Helvie, “Overdiagnosis and Risks of Breast Cancer Screening,” 59 *Radiological Clinics of North America* 19 (Jan. 2021), <https://pubmed.ncbi.nlm.nih.gov/33222997/>, (viewed 1/27/22) (“like all medical tests and procedures, screening mammography has associated risks, including overdiagnosis and overtreatment, false-positive examinations, false-positive biopsies, and radiation exposure.”).

D. Examples From Medical Practice Show The Decision Is Inconsistent With And Would Interfere With The Practice Of Medicine.

1. Ambulatory settings – earaches, headaches.

A pediatrician gives a non-emergent example of a child with an earache. Motion at 9. The provider will have meningitis on the list of remote possibilities, a serious condition usually ruled out quickly. The pediatrician does not tell parents each diagnosis ruled out. While the pediatrician would consider meningitis in her differential diagnosis, she would not raise it to the parents as a possibility without a clinical indication or question from the parent because, if she did, “it could create unnecessary anxiety or would freak them out, and might lead to a request or demand for unnecessary, costly testing that was not medically indicated. They would want certainty from a test,” and she “would not have done any good” but caused unwarranted anxiety. But under the Decision, if the child develops meningitis the pediatrician can be sued for both negligence for missing the

diagnosis and under informed consent for not telling the parents it was a remote possibility ruled out.

Similarly, as related by a member of WA-ACEP, under the Decision every patient who presents with a headache would need to be told there is a remote chance they have a glioblastoma or a brain aneurism; and then an expensive brain MRI or magnetic resonance angiogram must be offered, even though that condition is not a “material risk” in the vast majority of headache presentations without other clinical indicia. Motion at 9-10. *See Backlund v. University of Washington*, 137 Wn.2d 651, 661 & n. 2, 975 P.2d 950 (1999) (rejecting potential informed consent liability for undetected brain tumor in hypothetical patient presenting with a headache, for whom no tests were clinically indicated after exam).

2. D-dimer testing in chest pain.

A WA-ACEP, ER physician related testing in chest pain cases as an example. Motion at 10-13. There are screening criteria called the PERC (Pulmonary embolism rule out criteria)

that when negative mean the patient has a less than 2% chance of pulmonary embolism. In those cases with low risk, providers do not order D-dimer testing as there is a false positive rate. The D-dimer test detects clotting of all forms anywhere in the body (it is the linkage protein between clots that breaks down as they are remodeled). So if one has a big bruise on the leg or are post-operative, one's D-dimer will be high (as it should be) since the patient is clotting appropriately. But if providers have to give every chest pain patient a D-dimer option, even when ruled out by PERC rule, there will be false positives. This results for the patient in additional radiation as a CT Chest with contrast for pulmonary embolism; that test gives a lot of radiation to sensitive tissues, *i.e.*, thyroid and breasts in the direct line of fire, cataracts and pregnancies with scatter radiation. Allowing the patients to request an unnecessary test can result in harm to the patient and cost to the system for unwarranted care.

V. CONCLUSION

Health Care *Amici* respectfully request the Court to vacate the decision of the Court of Appeals, reinstate the dismissal of the informed consent claim, and restate the correct scope an informed consent claim consistent with the statutes, *Anaya Gomez*, and the nature of medical practice.

I certify that this document contains 4985 words, excluding the parts of the document exempted from the word count by RAP 18.17.

Respectfully submitted this 31st day of January, 2022.

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CERTIFICATE OF SERVICE

The undersigned certifies under penalty of perjury under the laws of the State of Washington that I am an employee at Carney Badley Spellman, P.S., over the age of 18 years, not a party to nor interested in the above-entitled action, and competent to be a witness herein. On the date stated below, I caused to be served a true and correct copy of the foregoing document on the below-listed attorney(s) of record by the method(s) noted:

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January 31, 2022 - 4:21 PM

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Appellate Court Case Number: 100,079-1
Appellate Court Case Title: Mari Davies v. Multicare Health System, et al.

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