No. 99121-9

THE SUPREME COURT OF THE STATE OF WASHINGTON

PHYLLIS COOLEN,

Petitioner,

vs.

GROUP HEALTH COOPERATIVE,

Respondent.

RESPONDENT'S ANSWER TO PETITION FOR REVIEW

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I. IDENTITY OF RESPONDING PARTIES

Respondent Group Health Cooperative submits this Answer to Petition for Review.

II. COURT OF APPEALS DECISION

In this alleged wrongful death action, Phyllis Coolen asserted a medical negligence claim against Group Health Cooperative, alleging that her husband, Patrick Coolen, died from prostate cancer that Group Health failed to diagnose, having instead diagnosed benign prostatic hyperplasia (BPH). On the same facts, Mrs. Coolen tried to assert an informed consent claim, which the trial court precluded in a ruling on Group Health's motion in limine. After both parties rested and before the case went to the jury, the trial court elected not to instruct the jury on Mrs. Coolen's corporate negligence claim. The jury found Group Health not negligent for failing to diagnose Mr. Coolen's cancer. In an unpublished decision issued on August 18, 2020, Division II affirmed the trial court's rulings that kept the informed consent and corporate negligence claims from the jury.

III. COUNTERSTATEMENT OF ISSUES PRESENTED FOR REVIEW

1. Did the trial court properly grant Group Health's motion in limine to exclude evidence of informed consent because under Washington law, Group Health's failure to diagnose Mr. Coolen's cancer could only give rise to a medical negligence claim?

2. Did the trial court properly decline to give Mrs. Coolen's proposed jury instructions on corporate negligence because (1) Washington does not recognize a cause of action against a hospital for allegedly failing to have specific policy regarding prostate screening, and (2) Mrs. Coolen failed to present evidence supporting the required proximate cause element of her claim that Group Health breached a duty to monitor and review providers?

IV. COUNTERSTATEMENT OF THE CASE

A. Factual Background

Patrick Coolen was a long-time patient of Group Health Cooperative. VRP 850-860; 970-990. His primary care provider was family practice physician, Jennifer Williams, M.D. VRP 851. Group Health's clinical recommendations for prostate cancer screening involved "shared decision making" about whether the patient, according to his preferences and values, wished to undergo prostate cancer screening after considering the risks, benefits and limitations. VRP 455-458. Generally, shared decision making for prostate cancer screening was made in the context of a Well Adult Visit. VRP 546-547; VRP 848-849. In the Group Health system, a Well Adult Visit is the opportunity for the primary care provider and the patient to review overall health issues, preventative care, immunization status, medication checks and cancer screening options. *Id.*

It is typically a longer visit than a problem-focused "acute" visit for a discrete, specific health issue. *Id.*; VRP 975-976.

Prostate cancer screening generally entails two potential components, a blood test to measure Prostate Specific Antigen ("PSA") and a digital rectal examination ("DRE"). VRP 545-546.

On January 16, 2003, during a "Well Adult Visit," Dr. Williams offered Mr. Coolen written information on prostate cancer screening. VRP 851-852. Mr. Coolen indicated "Yes" that he wanted information about prostate cancer screening. *Id.* Dr. Williams' note states: "done." *Id.*

On September 26, 2006, again in the context of a Well Adult Visit, Dr. Williams' electronic record indicates she had the standard discussion of the risks, benefits and limitations of prostate cancer screening with PSA testing and a DRE and the controversy surrounding prostate cancer screening. VRP 854-855. Her notes states:

> He indicates understanding of the limitations of this screening test and wishes not to proceed with prostate cancer screening. Digital Rectal Exam for Prostate Screening: deferred.

VRP 856-857.

On March 19, 2009, which was Mr. Coolen's next Well Adult Visit, Randy Weiler, PA-C conducted the examination. VRP 937. PA Weiler's note states:

> The natural history of prostate cancer and ongoing controversy regarding screening and potential treatment outcomes of prostate cancer has been discussed with the patient. Digital Rectal Examination for Prostate Screening: Normal.

Id.; VRP 940.

This was Mr. Coolen's last scheduled Well Adult Visit at Group Health. VRP 859-880. He did not schedule a Well Adult Visit with Group Health after 2009. *Id.*

On September 13, 2010, Mr. Coolen saw Laurie Rogers, PA-C, for an acute visit with specific urinary complaints of increased frequency/urge up to once per hour during the day and urethral irritation. VRP 973-975. Ms. Rogers conducted a DRE which she reported as: "Rectal: prostate enlarged, symmetrical, smooth, elastic, non-tender." *Id.*

These were not "abnormal" findings according to Group Health Prostate Screening Guidelines. VRP 550-551. PA Rogers made a diagnosis of benign prostatic hypertrophy ("BPH") without urinary obstruction or lower urinary tract symptoms. VRP 977. A urinalysis was clean. VRP 977-979. She ordered a blood test to rule out sexually transmitted disease. *Id.* This was negative. *Id.* She recommended reduction of caffeine and alcohol. *Id.* The discharge instructions explained the examination findings and indicated he should return for follow-up if there were continued problems or the symptoms worsened. *Id.*

Ms. Rogers saw Mr. Coolen on January 12, 2011 and February 22, 2011, for knee and shoulder pain, respectively. VRP 980-983. Her notes do not reflect Mr. Coolen made any complaints of urinary symptoms. *Id.* Mr. Coolen was seen at Group Health on March 10, 2011, June 21, 2011, October 11, 2011, and April 4, 2012, for various complaints, none of which related to urinary symptoms or low back pain. VRP 980-983, 859-880. On May 16, 2012, Mr. Coolen had a colonoscopy. VRP 866-867. He affirmatively checked "No" to having pain with urination, difficulty urinating, and blood in urine. *Id.*

Dr. Williams saw Mr. Coolen on April 8, 2013 for an acute visit. VRP 867-870. Mr. Coolen presented with testicular and scrotal pain. *Id.* The complaint was "mostly groin discomfort, both testicles are tender." *Id.* He made no complaint of low back pain. *Id.* She made a diagnosis of epididymitis, which is inflammation of the coiled tubes at the back of the testicles. *Id*. Dr. Williams and Mr. Coolen corresponded by email multiple times after this visit regarding his symptoms and treatment plan. VRP 872-876. Mr. Coolen was offered a urology referral. VRP 876-877.

Mr. Coolen established primary care with Kaiser Permanente in Hawaii on May 7, 2014. VRP 787-789. After he reported low back pain, fever, and weight loss, the physician ordered a PSA test. VRP 1166. He

then had a prostate biopsy, which showed high-grade, high volume malignancy. VRP 412-416.

Mr. Coolen returned to Washington State for treatment. Given the advanced nature of the widely-metastatic cancer, he underwent radical, experimental treatments (including chemotherapy) and enlisted in a number of experimental clinical trials through the Seattle Cancer Care Alliance/University of Washington. Unfortunately, Mr. Coolen passed away on June 13, 2016, at the age of 67. VRP 769.

B. Procedural History

Mrs. Coolen, individually and as personal representative of her husband's estate, sued Group Health, alleging medical negligence under RCW 7.70.040 and lack of informed consent under RCW 7.70.050. CP 5-15. She claimed Group Health negligently failed to diagnose Mr. Coolen's cancer and failed to inform Mr. Coolen fully of all material facts relating to his diagnosis and treatment.

1. The Trial Court Granted Group Health's Motion in Limine to Exclude Evidence of Informed Consent

Group Health filed a motion in limine arguing that "[Mrs. Coolen]'s lack of informed consent claim is not cognizable in the setting of her allegations that Group Health failed to diagnose her decedent's prostate cancer. Such claims are mutually exclusive in Washington and [Mrs. Coolen] must not be permitted to introduce evidence, argument or

submit jury instruction supporting a lack of informed consent claim." CP 969-971.

Mrs. Coolen opposed the motion, but cited no authority in her briefing or oral argument. CP 1030-1031; VRP 54-60.

The following colloquy took place at the end of the hearing:

> [GH COUNSEL]: Your Honor, I think it's really telling that in the reply to this, plaintiffs make no argument supported by any case law to challenge the *Backlund* and its progeny. You go through that response, and you won't find a case, because there isn't a case.
>
> The essence, the gravamen of this particular complaint is, there was a failure to diagnose prostate cancer. They have experts that are going to say, in the face of a diagnosis of BPH, you should have done PSA test. That's what they can do. And that's negligence. But we don't interject informed consent on a failure to diagnose when you haven't made the diagnosis.
>
> THE COURT: I agree.
>
> [GH COUNSEL]: Thank you, Your Honor.
>
> THE COURT: That's the state of the law. It's consistent with the complaint, and it's consistent with the position of the parties, and it's consistent with the framework of this case. VRP 59-60.

2. The Trial Court Elected Not to Instruct the Jury on Corporate Negligence

At the close of Mrs. Coolen's case, Group Health moved for a directed verdict on the corporate negligence claim. CP 1949-1960. The trial court denied the motion because it believed there was sufficient

evidence for the following issues to go to the jury: (1) whether Group Health was negligent in not adopting policies and procedures for treating patients diagnosed with BPH; and (2) whether Group Health was negligent in not periodically monitoring and reviewing the competency of its health care providers. VRP 833-834.

At the close of Group Health's case, the trial court revisited the issue. It determined the "policies and procedures" claim was not legally supported and the "monitoring and reviewing" claim was not factually supported. VRP 1360-1368. As a result, the trial court elected not to instruct the jury on corporate negligence. *Id.*

The jury returned a verdict answering "No" to the question: "Was Group Health negligent?" CP 2310-2311.

V. ARGUMENT WHY REVIEW SHOULD BE DENIED

Mrs. Coolen cites RAP 13.4(b)(1), (2), and (4) in seeking review of the affirmance of the trial court's rulings that kept the informed consent and corporate negligence claims from the jury. However, Division II's decision is not in conflict with any decision of this Court or the Court of Appeals so as to warrant review under RAP 13.4(b)(1) or (2), and the decision does not involve any interest of substantial public importance so as to warrant review under RAP 13.4(b)(4), Mrs. Coolen's Petition for Review should be denied.

A. Division II's Affirmance of the Trial Court's Order Granting Group Health's Motion in Limine Regarding Mrs. Coolen's Informed Consent Claim Is Not in Conflict with Any Decision of this Court or the Court of Appeals

Mr. Coolen argues that Division II's affirmance of the trial court's motion in limine ruling that kept the informed consent claim from the jury conflicts with *Gates v. Jensen*, 92 Wn.2d 246, 595 P.2d 919 (1979); *Backlund v. Univ. of Washington*, 137 Wn.2d 651, 975 P.2d 950 (1999); and *Anaya Gomez v. Sauerwein*, 180 Wn.2d 610, 331 P.3d 19 (2014). *Pet.* at 8-15. She incorrectly argues that those decisions prohibit negligent misdiagnosis and informed consent claims based on the same set of facts only where a medical provider "rules out a particular diagnosis based on the circumstances surrounding a patient's condition," and that here Group Health "never ruled out prostate cancer as a diagnosis."

Division II's decision is not in conflict with *Gates*, *Backlund*, and *Anaya Gomez*. *See Slip. Op.* at 16-20. As this Court ruled in *Backlund*, 137 Wn.2d at 661:

> A physician who misdiagnoses the patient's condition, and is therefore unaware of an appropriate category of treatments or treatment alternatives, may properly be the 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.

"In misdiagnosis cases, this rule is necessary to avoid imposing double liability on the provider for the same alleged misconduct." *Anaya Gomez*, 180 Wn.2d at 618 (citing *Backlund*, 137 Wn.2d at 661-62 n.2).

In *Anaya Gomez*, this Court affirmed a Division III decision upholding the dismissal of a lack of informed consent claim. After specifically noting that "[i]nformed consent and medical negligence are distinct claims that apply in different situations," the court concluded that "[t]he doctrine of informed consent has been distinguished from malpractice as applying to fundamentally different situations," noting the *Backlund* ruling. *Id.* at 617-618. The physician determined the blood culture for yeast was a false positive based on the patient's presentation and history, and there was "nothing further to diagnose" with the information available. *Id.* at 622. This Court concluded: "[t]his is a misdiagnosis case. Accordingly, the *Backlund* rule applies and the trial court properly dismissed the informed consent claim as a matter of law." *Id.* at 623.

In *Anaya Gomez*, after learning that the patient who had initially presented complaining of a urinary tract infection was feeling better, the physician did not inform the patient, who had uncontrolled diabetes that made her susceptible to infections, of a concerning lab result he received suggesting a yeast infection of the blood because, given the improvement

in her condition, he concluded that the lab result was most likely a false positive due to contamination rather than reliable evidence of a very dangerous infection. *Id.* at 613-14. The physician moved up the patient's next appointment, but when the patient's condition worsened, she returned to the hospital, where she was diagnosed with a rare yeast infection in the blood that caused fungal sepsis and death. *Id.* at 614-15.

The patient's husband proceeded to trial against the physician on both medical negligence and failure to obtain informed consent claims, but at the close of the husband's case the trial court, concluding that this was a medical negligence failure to diagnose case and not an informed consent case, dismissed the informed consent claim. *Id.* at 614-15. This Court affirmed, agreeing that "[o]n one set of facts the two theories are mutually exclusive" – either the physician "knew" the patient had a yeast infection, "giving rise to the failure to inform claim," or "he failed to know she had a yeast infection, giving rise to the negligence claim." *Id.* at 619.

The Court rejected the husband's claim that providers must inform patients "of all positive test results," recognizing "the importance of taking the patient's condition into account while making a diagnosis" and that lab tests are just "one tool among many that a health care provider uses to form a diagnosis." *Id.* "[T]he duty to disclose does *not* arise 'whenever [the provider] becomes aware of a bodily abnormality which may indicate

risk or danger' ... but rather turns on whether or not 'the diagnosis has been completed.'" *Id.* at 620 n.4 (emphasis in original) (quoting five-justice concurrence/dissent in *Keogan v. Holy Family Hosp.*, 95 Wn.2d 306, 329, 622 P.2d 1246 (1980)). The *Anaya Gomez c*ourt concluded as a matter of law that the husband could only state a cause of action for medical negligence based on the failure to diagnose. *Anaya Gomez*, 180 Wn.2d at 623.

Like the claims in *Anaya Gomez*, Mrs. Coolen's claims in this case are mutually exclusive – either Group Health knew Mr. Coolen had cancer (giving rise to an informed consent claim), or it failed to diagnose the condition (giving rise to a medical negligence claim). The factual allegations here only support a medical negligence cause of action. This conclusion in supported primarily by *Backlund* and *Anaya Gomez*

In relying on *Gates*, Mrs. Coolen ignores what the *Anaya Gomez* Court had to say about it. While the Court in *Anaya Gomez*, citing *Gates*, 92 Wn.2d at 250-51, recognized that "[i]n certain circumstances [it had] held that the right to informed consent can include the process of diagnosis," it also recognized that *Gates* predated RCW 7.70.050's codification of informed consent and its clear use of the word "treatment." *Anaya Gomez*, 180 Wn.2d at 617. Also, the *Anaya Gomez* Court recognized that "[t]he *Gates* court allowed the informed consent claim

based on a unique set of facts," *id.* at 623, that "*Backlund* clarifies that *Gates* is the exception and not the rule with regard to the overlap between medical negligence and informed consent, and that "[g]iven the unique factual situation in *Gates*, it is unlikely we will ever see such a case again." *Id.* at 626.

This case does not involve the unique factual situation presented in *Gates.* Here, Mr. Coolen had discussions regarding prostate screening procedures—and the controversy surrounding them—with his Group Health providers in 2003, 2006, and 2009. In 2010, PA Rogers from Group Health diagnosed Mr. Coolen with BPH, a condition shared by half of all men his age. VRP 167. PA Rogers ordered a urinalysis and blood test, recommended reduction of caffeine and alcohol and indicated he should return for follow up if he had continuing or worsening symptoms. Over the next 18 months, Mr. Coolen visited Group Health six times, and never complained of continuing or worsening urinary or lower back symptoms. Mrs. Coolen's urology expert, Dr. Bretan, agreed with the following statement from the American Urological Association regarding treatment of patients with BPH: "[I]f the symptoms are not significantly bothersome or if the patient does not want treatment, no further evaluation is recommended. The patient should be reassured and be seen again if necessary. This recommendation is based on the opinion that patients with

non-bothersome lower urinary tract symptoms are unlikely to experience significant health problems in the future due to their condition." VRP 176-177.

PA Rogers diagnosed Mr. Coolen with a common condition that the American Urological Association concluded was unlikely to cause significant health problems in the future. She properly advised him to follow up if the symptoms continued or worsened. To the extent Mrs. Coolen claimed Group Health's providers failed to "follow up" regarding additional testing, the *Anaya Gomez* Court recognized that such a duty to "follow up" is only relevant to a medical negligence claim.

Division II's affirmance of the trial court's order keeping Mrs. Coolen's informed consent claim from the jury was consistent with *Backlund*, *Gates,* and *Anaya Gomez*.

B. The Court of Appeals' Affirmance of the Trial Court's Decision Not to Instruct the Jury on Mrs. Coolen's Corporate Negligence Claim Is Not in Conflict with Any Decision of this Court or the Court of Appeals

1. Claim Regarding Failure to Adopt Policies and Procedures

Division II correctly determined that having a specific policy regarding prostate screening is not a cognizable corporate negligence duty. There is no basis under RAP 13.4 for review of its decision.

Mrs. Coolen argues that Division II's affirmance of the trial court's decision not to instruct the jury on corporate negligence conflicts with *Douglas v. Freeman*, 117 Wn.2d 242, 814 P.2d 1160 (1991), but she acknowledged in her appeal to Division II that *Douglas* "does not impose a duty to adopt policies and procedures." *Slip Op.* at 10.

Mrs. Coolen argues that RCW 70.41.030 required Group Health to adopt policies and procedures regarding prostate screening. Division II correctly determined that chapter 7.70 "created the exclusive statutory claim for medical negligence" and RCW 70.41.180 "prevent[s] [DSHS] from establishing standards for physicians." *Slip Op.* at 11. No decision from this Court or the Court of Appeals holds otherwise.

Finally, Mrs. Coolen argues that WAC 246-320-226 imposed a duty on Group Health to adopt particular policies for screening prostate cancer. Division II correctly determined that the administrative rule "says nothing about 'a hospital's . . . obligation to establish policies and procedures with respect to a *particular* area of care,' such as prostate cancer screening." *Slip Op.* at 12. Again, no decision from this Court or the Court of Appeals holds otherwise.

2. Claim Regarding Duty to Monitor and Review Providers

Division II correctly affirmed the trial court's decision not to instruct the jury on Mrs. Coolen's claim that Group Health failed to adequately monitor and review its providers because Mrs. Coolen presented no evidence of proximate cause. The decision conflicts with no decisions of this Court or the Court of Appeals.

VI. CONCLUSION

None of the grounds for acceptance of review under RAP 13.4 exist in this case. The Petition for Review should be denied.

Respectfully submitted this 16th day of November, 2020.

FORSBERG & UMLAUF, P.S.

By: _____

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CERTIFICATE OF SERVICE

The undersigned certifies under the penalty of perjury under the laws of the State of Washington that I am now and at all times herein mentioned, a citizen of the United States, a resident of the State of Washington, over the age of eighteen years, not a party to or interested in the above-entitled action, and competent to be a witness herein.

On the date given below I caused to be served the foregoing **ANSWER TO PETITION FOR REVIEW** on the following individuals in the manner indicated:

Mr. Ron Meyers
Mr. Matthew G. Johnson
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SIGNED this 16th day of November, 2020, at Seattle, Washington.

s/ Lynda T. Ha
Lynda Ha

FORSBERG & UMLAUF, P.S.

November 16, 2020 - 1:52 PM

Transmittal Information

Filed with Court:	Supreme Court
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Appellate Court Case Title:	Phyllis Coolen v. Group Health Options, Inc., et al.
Superior Court Case Number:	16-2-05084-8

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