95449-6

No. _____

SUPREME COURT
OF THE STATE OF WASHINGTON

No. 74600-6-I

COURT OF APPEALS, DIVISION I
OF THE STATE OF WASHINGTON

JOHN STRAUSS and MICHELLE STRAUSS,
husband and wife, and their marital community

Petitioners,

v.

PREMERA BLUE CROSS,

Respondent.

PETITION FOR REVIEW

SMITH GOODFRIEND, P.S.

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A. Identity of Petitioners and Decision Below.

Petitioners John and Michelle Strauss ("Strauss") seek review of Division One's published decision affirming the summary judgment dismissal of Strauss' breach of contract, insurance bad faith, and Consumer Protection Act claims. The Court of Appeals granted Strauss' motion to publish its September 5, 2017 opinion (App. A) on December 29, 2017. (App. B)

B. Issues Presented for Review.

1. In determining whether a particular medical treatment is superior to another and therefore should be covered by a health insurance policy, is a policyholder entitled to resolution by a fact-finder of conflicting expert testimony based on credible scientific evidence and peer-reviewed medical literature?

2. Did the Court of Appeals impose an additional requirement beyond the plain language of a health insurance policy by relying on the absence of randomized clinical trials to hold that proton beam therapy was not superior to conventional radiation therapy in the treatment of prostate cancer, thereby frustrating the ability of patients to benefit from new treatments that are recommended by their physicians based on competent scientific evidence?

C. Statement of the Case.

1. To minimize the severity of traditional radiation side effects, John Strauss' physician recommended proton beam radiotherapy to treat his "high-risk" prostate cancer.

Petitioner John Strauss, then age 59, was diagnosed with "high-risk," "high-volume" prostate cancer in October 2008. (CP 69, 72, 1336-37) Strauss discussed his treatment options at length with his physicians, who confirmed that Strauss' "adverse cardiac history which includes bypass heart surgery, and cardiac arrhythmia" put him at a "higher operative risk" for surgical treatment. (CP 110, 1334-35, 1337) A surgical prostatectomy also included a "higher risk of impotency and urinary incontinence" as side effects. (CP 69, 1335) In light of these increased risks, Strauss chose radiotherapy treatment. (CP 69, 73, 88, 110, 1335-37)

Strauss consulted with Dr. David Bush, a Board Certified oncologist at Loma Linda University Medical Center ("Loma Linda"), regarding his radiotherapy options. (CP 892, 899, 1392) There are two primary types of radiotherapy: proton beam therapy ("PBT") and traditional intensity modulated radiation (photon x-ray) therapy ("IMRT"). (CP 88, 94, 691, 1125) The "significant side effects from radiation therapy . . . are damage to the rectum from excess radiation

which can lead to bladder and bowel dysfunction; radiation damage to the penile bulb which can lead to sexual function issues; and, secondary cancer from excess radiation to surrounding tissue." (CP 1338) In contrast, by more precisely targeting a "well-defined high dose" of radiation at the target location, "the volume of normal tissue receiving radiation is typically reduced by a factor of 2-3" by PBT rather than IMRT. (CP 1125) While more expensive than IMRT, PBT thus is a superior treatment, resulting in fewer side effects caused by "excess radiation" to healthy tissue. (CP 1125-26, 1338)

Dr. Bush recommended PBT over IMRT to Strauss because PBT risked fewer side effects, particularly given the location and size of his cancer. (CP 895, 1392) Heeding Dr. Bush's advice, Strauss received PBT treatment at Loma Linda from February to April 2010. According to his physicians, he has been in "[e]xcellent" condition since then. (CP 133, 137)

2. Premera Blue Cross denied coverage for proton beam therapy on the basis that it was not "medically necessary" under its policy in the absence of randomized clinical studies.

Prior to receiving PBT in February 2010, Strauss sought coverage for the treatment under his health insurance policy with respondent Premera Blue Cross ("Premera"). (CP 10, 241) The policy provided coverage for "medically necessary" treatments:

> Those covered services and supplies that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:
>
> - In accordance with generally accepted standards of medical practice;
>
> - Clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease; and
>
> - Not primarily for the convenience of the patient, physician, or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

(CP 212) The policy further defined "generally accepted standards of medical practice" as:

> [S]tandards that are based on credible scientific evidence published in peer reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations and the views of physicians practicing in relevant clinical areas and any other relevant factors.

(CP 212)

Dr. Neil Kaneshiro, a pediatrician working part-time for Premera examining coverage requests, reviewed the pre-authorization request for Strauss' PBT therapy. (CP 241, 1360-64) Conceding he was "not an expert" in oncology or radiology, Dr. Kaneshiro denied Strauss'

claim, concluding that PBT was "not medically necessary" in the absence of "clinical outcomes" showing PBT's superiority "to other approaches." (CP 243, 1368) In reaching his conclusion, Dr. Kaneshiro relied exclusively on Premera's Corporate Medical Policy, stating that PBT "*may* be considered not medically necessary in patients with clinically localized prostate cancer," because he "understood" based on the Policy that PBT cost more than IMRT. (CP 1005, 1366, 1368-69) (emphasis added) Dr. Kaneshiro relied on the Policy despite the disclaimer that it is merely a "guideline[] that serve[s] as a resource for Company staff when determining coverage for specific medical procedures," and without consulting with an oncologist, with no expertise in the field nor "any specific knowledge on what IMRT costs, what proton costs." (CP 1004-05, 1368) Dr. Kaneshiro did not review any peer-reviewed medical literature and declined to speak with Strauss' treating physician Dr. Bush about his cancer before denying Strauss' claim. (CP 1366, 1368-69)

Strauss exhausted his administrative remedies by appealing Premera's denial of coverage three times and submitting additional evidence from his physicians approving PBT as a medically necessary treatment. (CP 244-45, 247-53, 280-81, 283, 1124-28) Premera repeatedly denied Strauss coverage, claiming there was "*no* evidence

in the recent peer-reviewed medical literature" of PBT's superiority. (CP 272-75, 277, 288-90) (emphasis added) Strauss finally sought independent review from the Washington State Office of Insurance Commissioner, who designated Managing Care Managing Claims as ("MCMC") as the independent review organization. (CP 290, 297, 302-03, 305-06) MCMC upheld Premera's denial of coverage despite conceding there was evidence of "positive data available . . . for this technology in prostate cancer." (CP 309)

3. The Court of Appeals affirmed the trial court's dismissal of Strauss' claims, holding that only clinical evidence directly comparing proton beam therapy with traditional radiation therapy would be sufficient to demonstrate medical necessity under the policy.

Strauss sued Premera in August 2013 for breach of contract, insurance bad faith, and violation of the Consumer Protection Act. (CP 3-9) Agreeing with Premera's contention on summary judgment that the only issue before the trial court on the breach of contract claim was "whether PBT is medically necessary because it leads to fewer side effects" (CP 19, 748), Strauss submitted expert testimony from his treating physician Dr. Bush and from Dr. George Laramore addressing PBT's superior side effect profile. (CP 1122-28, 1331-54)

Dr. Laramore considered the four primary side effects of any form of radiotherapy – sexual function, bladder and bowel

dysfunction, joint deterioration and the development of hip symptoms, and risk of secondary cancer – and relied on 27 different peer-reviewed articles and studies. (CP 1338, 1347-50, 1352-54) He concluded that "[a]lthough IMRT and Proton Radiotherapy are biologically equivalent in radiating the prostate tumor," they "are not equivalent in terms of the side effect profile and so the overall therapeutic results are not equivalent but would be better with proton radiotherapy." (CP 1335, 1351) (emphasis in original)

The trial court granted Premera's motion for summary judgment and dismissed all of Strauss' claims. (CP 1472-73) In a published opinion (App. B), Division One affirmed. (App. A at ¶ 60) After weighing the parties' conflicting scientific evidence, the Court of Appeals held as a matter of law that Strauss was not entitled to benefit from proton beam therapy in the absence of randomized clinical studies conclusively proving PBT's superiority over IMRT:

> Because the record establishes there are peer-reviewed medical studies that show the side effects of PBT may be superior to IMRT and other peer-reviewed medical studies that show the side effects of IMRT may be superior to PBT, reasonable minds could only conclude that absent clinical evidence directly comparing PBT and IMRT, the treatments are equivalent and Strauss cannot show PBT was medically necessary.

(App. A at ¶ 59)

D. Argument Why Review Should Be Granted.

1. The Court of Appeals' published decision conflicts with the well-established law that an expert's affidavit based on credible scientific data is sufficient to defeat a motion for summary judgment. (RAP 13.4(b)(1), (2))

Division One's conclusion that plaintiffs' expert testimony, based on credible scientific data, was too speculative and theoretical to establish a triable issue of fact conflicts with decisions from this Court and the Court of Appeals. Washington courts have repeatedly recognized that affidavits from competent expert witnesses are sufficient to raise factual issues precluding summary judgment. This Court should accept review under RAP 13.4(b)(1) and (2) because Division One improperly invaded the province of the jury by weighing conflicting evidence, viewing that evidence in the light most favorable to the moving party, and requiring the party opposing summary judgment to submit conclusive evidence on the merits, in conflict with numerous cases from this Court and the Court of Appeals.

a. Expert testimony based on peer-reviewed medical literature and data from scientific studies is neither conclusory nor speculative.

The Court of Appeals decision disregards the well-established law that "an affidavit containing expert opinion on an ultimate issue of fact [is] sufficient to create a genuine issue of fact which would

preclude summary judgment." *Lamon v. McDonnell Douglas Corp.*, 91 Wn.2d 345, 352, 588 P.2d 1346 (1979) (affirming reversal of trial court's dismissal on summary judgment); *N.L. v. Bethel Sch. Dist.*, 187 Wn. App. 460, 468, ¶ 15, 348 P.3d 1237 (2015) (reversing summary judgment dismissal because "[a]dmissible expert opinion testimony on an ultimate issue of fact is sufficient to create an issue as to that fact, precluding summary judgment"), *aff'd* 186 Wn.2d 422, 378 P.3d 162 (2016); *J.N. v. Bellingham Sch. Dist. No. 501*, 74 Wn. App. 49, 60-61, 871 P.2d 1106 (1994) (reversing summary judgment dismissal where expert affidavit created factual issue).

Strauss provided affidavits and reports of two highly-qualified, Board Certified radiation oncologists. Pursuant to ER 703, both experts based their opinions on "credible scientific evidence published in peer reviewed medical literature generally recognized by the relevant medical community" (CP 1336), citing 59 peer-reviewed articles and studies, including "[p]ublished data from a number of institutions (including data obtained in a prospective randomized fashion)" (CP 1126), that demonstrated – at a minimum – a factual issue as to PBT's superior side effect profile. (CP 1122-1322, 1331-54)

This evidence was neither conclusory nor speculative. Indeed, Premera never challenged the admissibility of the testimony of either plaintiffs' experts, conceding that their "opinion[s] might qualify as a scientifically valid theory under *Frye*." (Resp. Br. 29-30; RP 32; Reply Br. 10) As the Court of Appeals recognized, PBT was both clinically appropriate and a "generally accepted" treatment for Strauss' prostate cancer. (App. A at ¶ 57 n. 19) Division One then wrongly disregarded this substantial credible scientific evidence, dismissing the plaintiffs' expert testimony as mere "theory" under the erroneous premise that, in the absence of randomized clinical trials *conclusively* proving PBT's superiority, any inferences, opinions, and conclusions drawn by experts from actual scientific data and medical literature are unreliable and insufficient to raise an issue of fact.

But this Court held that an expert may properly draw inferences from scientific data in arriving at his or her conclusions in *Anderson v. Akzo Nobel Coatings, Inc.*, 172 Wn.2d 593, 611, ¶ 22, 260 P.3d 857 (2011) (even where novel scientific evidence is implicated, "*Frye* does not require every *deduction* drawn from generally accepted theories to be generally accepted") (emphasis added). Division One's published decision conflicts with *Anderson*

and with *Reese v. Stroh*, 128 Wn.2d 300, 309, 907 P.2d 282 (1995), in which this Court held that it is for the jury, not the court, to "evaluate . . . [a] lack of substantial statistical support concerning [a] therapy's efficacy." (quoted source omitted); *Anderson*, 172 Wn.2d at 607, ¶ 17 ("evidence is tested by the adversarial process within the crucible of cross-examination, and adverse parties are permitted to present other challenging evidence") (citing *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 596, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993)).

In *Reese*, for instance, the plaintiff sued his doctor for negligently failing to treat his emphysema, caused by "AAT deficiency," a blood-borne protein deficiency, with Prolastin, a protein replacement therapy. 128 Wn.2d at 302-03. Similar to here, the defendant "did not argue that the theory or the methodology involved in Prolastin therapy lacks acceptance in the scientific community," and "uncontroverted testimony" demonstrated "that the FDA approved the use of Prolastin in treating AAT-deficient patients." *Reese*, 128 Wn.2d at 307. Instead, the defendant objected to the "expert causation opinion on the basis that there have been no statistically significant studies proving the efficacy of Prolastin therapy when used to treat AAT deficiency." *Reese*, 128 Wn.2d at 307.

In reversing the trial court's directed verdict for the defendant, this Court held that, "[w]hile an expert may express an opinion based on statistics, such a basis is certainly not required." *Reese*, 128 Wn.2d at 309. Where the expert's opinion was "based on his extensive experience in treating AAT deficiency," "his participation in and reliance on studies using Prolastin therapy," and "the information known to the medical profession at the time of Plaintiff's treatment," this Court did "not find that lack of statistical support fatal" to the expert's causation opinion. *Reese*, 128 Wn.2d at 309-10. This Court held that the courts must trust the adversarial process and the jury's ability to "evaluate the foundation for [the expert's] opinion" accordingly. *Reese*, 128 Wn.2d at 309.

Just as in *Reese*, Drs. Bush and Laramore's "status as an expert is not in dispute," "[n]or should it be disputed that his testimony would prove helpful to the trier of fact" given that "[f]ew lay persons are well versed" in radiotherapy treatment for prostate cancer. 128 Wn.2d at 308-09. In considering whether plaintiffs' expert testimony was "speculative" or "theoretical," the Court of Appeals' concern should have been solely whether it would "prove so technical that the jury is unable to judge its reliability." *Reese*, 128 Wn.2d at 309.

Here, neither expert's testimony was "so technical" that the jury could not "judge its reliability." As Dr. Bush explained, "the deleterious effects of any amount [of] radiation on human tissue have been well-known for nearly a century." (CP 1125) A proton "is a positively-charged subatomic particle" that "interacts with human tissue differently than does an x-ray beam." (CP 1125) PBT can be targeted more precisely to administer a "well-defined high dose" of radiation at the target location; in contrast, IMRT delivers the "highest dose relatively close to the skin surface," requiring the radiation beam to "traverse[] the remainder of the body" while getting "exponentially" weaker as it does so. (CP 1125) Because IMRT requires "multiple beams to hit any one particular area, giving the highest dose where all of the beams intersect," a "large volume of normal, 'innocent bystander,' tissue receives a low to medium dose of radiation." (CP 1125)

In contrast to "inevitably radiat[ing]" healthy tissue with IRMT, studies confirm that the volume of healthy tissue "receiving radiation is typically reduced by a factor of 2-3" with PBT. (CP 1125) Relying on his "extensive experience in treating" prostate cancer with PBT, "his participation on and reliance on studies using [PBT]," and "the information known to the medical profession at the time of

[Strauss'] treatment," *Reese*, 128 Wn.2d at 309-10, Dr. Bush concluded that the "clinical benefits inherent in this [proton beam] radiation dose reduction are both intuitively obvious and well established." (CP 1125)

Although Division One may have disagreed with the conclusions of plaintiffs' experts, the Court of Appeals improperly "evaluate[d] . . . the lack of substantial statistical support concerning the therapy's efficacy," when the jury would have been "perfectly capable of determining what weight to give this kind of expert testimony." *Reese*, 128 Wn.2d at 309 (quoted source omitted); *see also Anderson*, 172 Wn.2d at 610-11, ¶ 21 ("If we were to . . . require 'general acceptance' of each discrete and evermore specific part of an expert opinion, virtually all opinions based upon scientific data could be argued to be within some part of the scientific twilight zone."). This Court should accept review and remand for trial.

b. In disregarding plaintiffs' expert testimony, the Court of Appeals invaded the province of the jury by impermissibly weighing the evidence and deciding as a matter of law an issue that should have gone to the jury.

Nothing in the Premera policy requires evidence from randomized clinical trials to prove that a treatment is medically necessary. Yet Division One held that because conflicting evidence

existed as to the superiority of PBT versus IMRT, "reasonable minds could only conclude that absent clinical evidence directly comparing PBT and IMRT, the treatments are equivalent and Strauss cannot show PBT was medically necessary." (App. A at ¶ 59) The Court of Appeals erred by going beyond the plain language of the policy to impose the additional requirement of randomized clinical trials to conclusively prove PBT's superiority.[1] Scientists have questioned the presumed superiority of randomized clinical trials. *See* J. Grossman and F. Mackenzie, "The Randomized Clinical Trial: gold standard, or merely standard?" *Perspectives in Biology and Medicine*, Vol. 48, No. 4, 2005, pp. 516-34.

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[1] Other courts have expressly rejected a health insurer's denial of coverage based on a lack of randomized clinical studies. *See, e.g., Pirozzi v. Blue Cross-Blue Shield of Virginia*, 741 F. Supp. 586, 593 (E.D. Vir. 1990) (insurer's reliance "on the absence of phase III studies relating to the efficacy" of the treatment in denying coverage "is misplaced": "[t]o begin with, nothing in the Plan requires that a treatment be the subject of completed phase III studies to escape the experimental treatment exclusion"); *Wilson v. Office of Civilian Health & Med. Programs of the Uniformed Serv.*, 65 F.3d 361, 365-66 (4th Cir. 1995) (randomized "Phase III clinical trials are not the critical aspect in determining whether a therapy has become 'generally accepted' within the medical community"; "[i]n addition to overemphasizing the necessity of Phase III clinical trials, [insurer] ignored abundant evidence that [the treatment] is gaining widespread acceptance within the medical community"); *Sluiter v. Blue Cross & Blue Shield of Michigan*, 979 F. Supp. 1131, 1144 (E.D. Mich. 1997) ("The inability to complete phase III trials does not demonstrate that high dose chemotherapy is an unproven form of treatment.").

Division One wrongly weighed conflicting evidence, and impermissibly decided as a matter of law an issue that should have gone to the jury. A plaintiff does not have to conclusively prove his or her case on the merits to avoid dismissal on summary judgment. Rather, "it is the duty of the . . . court to consider all evidence and all reasonable inferences therefrom in a light most favorable to the nonmovant." *Barber v. Bankers Life & Cas. Co.*, 81 Wn.2d 140, 142, 500 P.2d 88 (1972) (reversing summary judgment dismissal). "Where different, competing inferences may be drawn from the evidence, the issue *must* be resolved by the trier of fact." *Versuslaw, Inc. v. Stoel Rives, LLP*, 127 Wn. App. 309, 320, ¶ 22, 111 P.3d 866 (2005), *rev. denied*, 156 Wn.2d 1008 (2006) (emphasis added) (reversing summary judgment dismissal); *Busenius v. Horan*, 53 Wn. App. 662, 666, 769 P.2d 869 (1989) (the court does "not . . . resolve any existing factual issue" on summary judgment; reversing summary judgment dismissal); *Larson v. Nelson*, 118 Wn. App. 797, 810, 77 P.3d 671 (2003) (reversing summary judgment where "competing, apparently competent evidence demonstrates the need for a trial to resolve these factual issues").

Division One's holding that PBT is not more "likely to produce equivalent therapeutic or diagnostic results" than traditional IBRT

treatment (App. A at ¶¶ 56, 59) not only perverts the legal standard on summary judgment, it defies logic: that Division One devoted most of its published decision to impermissibly weighing the evidence (App. A at ¶¶ 30-44, 58-59) itself demonstrates that "competing, apparently competent evidence" of factual issues precluding summary judgment existed. Improperly viewing the evidence in the light most favorable to Premera, the moving party, Division One took it upon itself to decide as a matter of law that the "testimony of Dr. Laramore and Dr. Bush and the peer-reviewed medical studies they rely on do not create a material issue of fact" because "there were no published clinical studies directly comparing PBT and IMRT." (App. A at ¶ 59)

2. The Court of Appeals' published decision will prevent an insured from proving "medical necessity" unless randomized clinical trials conclusively establish a treatment's superiority over all others. (RAP 13.4(b)(4))

Division One's published decision will keep insureds from benefiting from the most technologically advanced and superior medical treatments in the absence of randomized clinical trials conclusively establishing that treatment's superiority. Allowing health insurers to deprive patients of advances in medical technology on the ground that they are more costly than traditional therapies presents an issue of substantial public concern. RAP 13.4(b)(4).

As this Court recognized in *Anderson*, 172 Wn.2d at 607, ¶ 18, while the courts "envisioned an evolutionary process" where novel scientific techniques would pass through an "'experimental' stage, during which they would be scrutinized by the scientific community until they arrive at a 'demonstrable' stage" under *Frye*, "science never stops evolving and the process is unending." Instead, every "scientific inquiry becomes more detailed and nuanced."[2] *Anderson*, 172 Wn.2d at 607, ¶ 18. In requiring randomized clinical trials, Division One ignores that "there is a difference between the quest for truth in the courtroom and in the laboratory. Law must resolve disputes finally and quickly, whereas science may consider a

[2] Indeed, this Court in *Anderson* recognized that "the degree of certainty required for general acceptance in the scientific community is much higher than the concept of probability used in civil courts." 172 Wn.2d at 607-08, ¶ 19. Whereas civil cases require a "preponderance" of evidence, "or more than 50 percent," "[f]or a scientific finding to be accepted, it is customary to require a 95 percent probability that it is not due to chance alone." *Anderson*, 172 Wn.2d at 608, ¶ 19 (alteration in original; quoted source omitted). As a consequence, this Court declined "[t]o require the exacting level of scientific certainty to support opinions on causation," as doing so "would, in effect, change the standard for opinion testimony in civil cases." *Anderson*, 172 Wn.2d at 608, ¶ 19; *see also Matter of Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 744 (3d Cir. 1994) ("The evidentiary requirement of reliability is lower than the merits standard of correctness."), *cert. denied*, 513 U.S. 1190 (1995). By requiring conclusive evidence of randomized clinical studies in order to survive summary judgment, Division One's holding in this case mandates that "exacting level of scientific certainty" this Court rejected in *Anderson*.

multitude of hypotheses indefinitely." *Anderson*, 172 Wn.2d at 607, ¶ 18 (internal quotation marks and cited source omitted).

Rather than liberally construing a health insurance policy to effectuate coverage, the courts below went beyond the plain language of the policy to require conclusive proof of PBT's superiority on the merits on summary judgment. If allowed to stand, Division One's published decision will prevent insureds from accessing crucial medical advances advocated by their physicians as medically necessary until those treatments receive uniform acceptance in the medical community. Few patients have the means to benefit from those advances without health insurance coverage. The vast majority of Washington citizens will be relegated to inferior treatments, or worse still, no treatment at all, as health insurers, emboldened by the Court of Appeals' published decision, adopt a restrictive interpretation of "medical necessity" to deny coverage, based on cost considerations alone, of new treatments whose superiority is supported by credible scientific evidence.

E. Conclusion.

This Court should accept review and reverse the Court of Appeals. If this Court reinstates the breach of contract claim, it should also remand for trial on whether Premera's wrongful denial of coverage violated its duty of good faith and the CPA.

Dated this 29th day of January, 2018.

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DECLARATION OF SERVICE

The undersigned declares under penalty of perjury, under the laws of the State of Washington, that the following is true and correct:

That on January 29, 2018, I arranged for service of the foregoing Petition for Review, to the court and to the parties to this action as follows:

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DATED at Seattle, Washington this 29th day of January, 2018.

Peyush Soni

2017 WL 6819015
Court of Appeals of Washington,
Division 1.

John STRAUSS and Michelle Strauss, husband and wife, and their marital community, Appellants,

v.

PREMERA BLUE CROSS, Respondent.

No. 74600-6-I

FILED: September 5, 2017

Synopsis

Background: Insured, who was diagnosed with intermediate-risk prostate cancer, and his wife brought action against health insurer for breach of contract, bad faith, and violation of the Consumer Protection Act after insurer denied authorization for proton beam therapy (PBT) treatment. The Superior Court, King County, No. 13-2-28143-1, Monica Benton, J., entered summary judgment in favor of insurer. Insured and his wife appealed.

[Holding:] The Court of Appeals, Schindler, J., held that PBT was not "medically necessary" under health insurance policy.

Affirmed.

Appeal from King County Superior Court, No. 13-2-28143-1, Honorable Monica Benton.

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PUBLISHED OPINION

Schindler, J.

¶1 John Strauss and Michelle Strauss (collectively, Strauss) appeal summary judgment dismissal of the lawsuit against Premera Blue Cross for breach of contract, bad faith, and violation of the Consumer Protection Act, chapter 19.86 RCW. We affirm.

Prostate Cancer Diagnosis

¶2 In September 2008, doctors diagnosed 59-year-old John Strauss with intermediate-risk prostate cancer. Strauss met with University of Washington urologist Dr. Daniel Lin on October 6. Dr. Lin described the treatment options of surgery or radiation. Dr. Lin noted Strauss had "quite a lot of questions about proton therapy versus standard radiation" because "he lives part of the year in Southern California" and "heard about the proton facility at Loma Linda Hospital." But Dr. Lin said the focus of the conversation was on surgery and the advantages of surgery. Dr. Lin referred Strauss to Seattle Cancer Care Alliance radiation oncologist Dr. Kenneth Russell to learn more about "radiation treatment options."

¶3 Dr. Russell met with Strauss and discussed the medical literature on "long-term results and short-term side effects" of surgery "versus radiation therapy." Strauss told Dr. Russell he was "very interested in pursuing proton therapy, as he lives 45 minutes from Loma Linda." Dr. Russell discussed proton beam therapy (PBT) and intensity-modulated radiation therapy (IMRT). Dr. Russell told Strauss there is a "lack of clear, long-term evidence showing improved side effect profile for patients who undergo proton therapy versus [IMRT]."

Premera Blue Cross Medical Insurance Policy

¶4 Strauss was insured by Premera Blue Cross (Premera) under the "Heritage Preferred Plus 20 Plan." The policy covered "medically necessary" treatment, including "radiation." The policy states benefits "must be, in our judgment, medically necessary." The policy states, in pertinent part:

WHAT ARE MY BENEFITS?

This section of your contract describes the specific benefits available for covered services and supplies. Benefits are available for a service or supply described in this section when it meets all of these requirements:

- It must be furnished in connection with either the prevention or diagnosis and treatment of a covered illness, disease or injury
- It must be, in our judgment, medically necessary and must be furnished in a medically necessary setting.

¶5 The policy defines "medically necessary" as in accord with generally accepted standards of medical practice and not more costly than an alternative treatment "at least as likely to produce equivalent" treatment results.

*2 MEDICALLY NECESSARY

Those covered services and supplies that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- In accordance with generally accepted standards of medical practice;
- Clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease; and
- Not primarily for the convenience of the patient, physician, or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations and the views of physicians practicing in relevant clinical areas and any other relevant factors.

Prostate Cancer Guidelines

¶6 The National Comprehensive Cancer Network (NCCN) is an organization that includes "the largest and best-known cancer centers" in the United States. The NCCN issues clinical practice guidelines that "describe best practices for cancer care." The NCCN guidelines "do not consider cost" and recommend all "available options that are supported by evidence."

¶7 The 2009 and 2010 NCCN "Clinical Practice Guidelines in Oncology" for prostate cancer do not mention PBT.

¶8 In 2015, the NCCN issued clinical oncology guidelines for prostate cancer and "Guidelines for Patients." The guidelines describe treatment options and the side effects of surgery; radiation therapy that uses "high-energy rays to treat cancer"; and photon radiation beams, "a stream of particles that have no mass or electric charge," including three-dimensional conformal radiation therapy (3D-CRT), IMRT, and "proton beams." The 2015 NCCN Guidelines for Patients describes the three radiation therapies as follows:

> In 3D-CRT, the radiation beams match the shape of your tumor to avoid healthy tissues. IMRT is a more precise type of 3D-CRT that may be used especially for more aggressive prostate cancer. The radiation beam is divided into smaller beams, and the strength of each beam can vary.... Proton beams are a stream of positively charged particles that emit energy within a short distance.

¶9 The 2015 NCCN Clinical Practice Guidelines in Oncology (2015 Guidelines) state that "external beam radiation therapy" such as IMRT is "one of the principle treatment options for clinically localized prostate cancer."

> Over the past several decades, [radiation therapy] techniques have evolved to allow higher doses of radiation to be administered safely. [3D-CRT] uses computer software to integrate CT [1] images of the patients' internal anatomy in the treatment position,

> which allows higher cumulative doses to be delivered with lower risk of late effects. The second generation 3D technique, [IMRT], is used increasingly in practice because compared to 3D-CRT, it significantly reduces the risk of gastrointestinal toxicities and rates of salvage therapy in some, but not all studies, although treatment cost is increased.[2]

*3 ¶10 According to the 2015 Guidelines, the attempt to use dosimetric or treatment plan studies to try to compare IMRT and PBT is not meaningful and does not favor one treatment over the other.

> **Proton Therapy**
>
> ... Proponents of proton therapy argue that this form of radiation therapy could have advantages over X-ray (photon) based radiations in certain clinical circumstances. X-ray based therapies like IMRT and proton therapy can deliver highly conformal doses to the prostate. Proton-based therapies will deliver less radiation dose to some of the surrounding normal tissues like muscle, bone, vessels and fat not immediately adjacent to the prostate. These tissues do not routinely contribute to the morbidity of prostate radiation, are relatively resilient to radiation injury, and so the benefit of decreased dose to these types of normal, non-critical tissues has not been apparent. The critical normal structures adjacent to the prostate that can create prostate cancer treatment morbidity include the bladder, rectum, neurovascular bundles, and occasionally small bowel.
>
> The weight of the current evidence about prostate cancer treatment morbidity supports the notion that the volume of the rectum and bladder that receives radiobiologically high doses of radiation near the prescription radiation dose is what accounts for the likelihood of long-term treatment morbidity, as opposed to higher volume lower dose exposures. Numerous dosimetric studies have been performed trying to compare X-ray based IMRT plans to proton therapy plans to illustrate how one or the other type of treatment can be used to spare the bladder or rectum from the higher dose parts of the exposure.... Although dosimetric studies in-silico can suggest that the right treatment planning can make an IMRT plan beat a proton therapy plan and vice-versa, they do not predict accurately clinically meaningful endpoints.

The 2015 Guidelines conclude that absent randomized clinical trials directly comparing IMRT and PBT, there is "no clear evidence supporting a benefit or decrement to proton therapy over IMRT for either treatment efficacy or long-term toxicity."

¶11 The 2015 Guidelines note that the American Society of Radiation Oncology (ASTRO) evaluated PBT and concluded PBT " 'for primary treatment of prostate cancer should only be performed within the context of a prospective clinical trial or registry.' "[3] The ASTRO policy on PBT states:

> In the treatment of prostate cancer, the use of PBT is evolving as the comparative efficacy evidence is still being developed. In order for an informed consensus on the role of PBT for prostate cancer to be reached, it is essential to collect further data, especially to understand how the effectiveness of proton therapy compares to other radiation therapy modalities such as IMRT and brachytherapy. There is a need for more well-designed registries and studies with sizable comparator cohorts to help accelerate data collection. Proton beam therapy for primary treatment of prostate cancer should only be performed within the context of a prospective clinical trial or registry.
>
> ....
>
> **Don't routinely recommend proton beam therapy for prostate cancer outside of a prospective clinical trial or registry.**
>
> *4 There is no clear evidence that proton beam therapy for prostate cancer offers any clinical advantage over other forms of definitive radiation therapy. Clinical trials are necessary to establish a possible advantage of this expensive therapy.

¶12 Consistent with the clinical oncology guidelines, the 2015 NCCN Guidelines for Patients state, "To date, research hasn't shown that proton treatment is any better or worse for treating cancer or causing side effects."

¶13 The United States Department of Health and Human Services Agency for Healthcare Research and Quality

(AHRQ) also publishes guidelines for PBT. The AHRQ guideline states that "[m]embers of the working group do not currently recommend that patients with prostate cancer ... be referred for proton beam radiotherapy, due to an insufficient evidence base."

Premera Medical Policy on PBT

¶14 In July 2009, Premera issued a "Corporate Medical Policy" on "Charged Particle (Proton or Helium Ion) Radiation Therapy" based on "careful review of published peer reviewed scientific literature, national guidelines and local standards of practice."

¶15 The policy describes clinical circumstances where PBT may be considered medically necessary.

> Charged particle irradiation with proton or helium ion beams may be considered **medically necessary** in the following clinical situations:
>
> • Primary therapy for melanoma of the uveal tract (iris, choroid, or ciliary body), with no evidence of metastasis or extrascleral extension, and with tumors up to 24 mm[4] in largest diameter and 14[ ]mm in height.
>
> • Postoperative therapy (with or without conventional high-energy X-rays) in patients who have undergone biopsy or partial resection of the chordoma or low grade (I or II) chondrosarcoma of the basisphenoid region (skull-base chordoma or chondrosarcoma) or cervical spine. Patients eligible for this treatment have residual localized tumor without evidence of metastasis.

¶16 By contrast, the medical policy states PBT is not medically necessary for those "with clinically localized prostate cancer because the clinical outcomes ... have not been shown to be superior to other approaches," such as IMRT.

> Charged-particle radiation with proton beams using standard treatment doses may be considered **not medically necessary** in patients with clinically localized prostate cancer because the clinical outcomes with this treatment have not been shown to be superior to other approaches including [IMRT] or conformal radiation therapy yet [PTB] is generally more costly than these alternatives.

Denial of Request for PBT

¶17 On November 12, 2009, Loma Linda University Medical Center (LLUMC) radiation oncologist Dr. David Bush sent Premera a letter to obtain preauthorization of nine weeks of daily PBT for Strauss.

¶18 On November 18, Premera sent a letter to Strauss denying authorization of PBT. The letter states, in pertinent part:

> Charged-particle irradiation with proton beams using standard treatment doses may be considered not medically necessary in patients with clinically localized prostate cancer because the clinical outcomes with this treatment have not been shown to be superior to other approaches including intensity modulated radiation therapy (IMRT) or conformal radiation therapy yet proton beam therapy is generally more costly than these alternatives....

*5 ¶19 If you decide to receive this service, you will have to pay for it yourself. The letter provides a copy of the procedure for an internal appeal and for external review by an independent review organization (IRO).

Level I Appeal of Denial of PBT

¶20 On December 30, 2009, Strauss filed a "Level I Appeal." Strauss provided a letter from his cardiologist Dr. Douglas Stewart. Dr. Stewart admits there are no comparative studies for IMRT and PBT but states there is "strong preliminary evidence" that the side effects of PBT are "significantly lower." The letter states, in pertinent part:

> Radiation therapy is recommended and exists in two forms, the currently practiced conventional therapy and a newer form, porton [sic] beam radiation.

> Both techniques are approved. Comparative studies are not yet available. However, there is strong preliminary evidence that the side effects associated with [PBT] are significantly lower. As [Strauss'] cardiologist, considering his cardiac condition, I am advocating that he be approved for the [PBT].

¶21 Premera submitted the Level I Appeal to the Medical Review Institute of America Incorporated (MRIoA) for review by an independent radiation oncologist. WAC 284-43-3110(6) (formerly WAC 284-43-525 (2010)) provides:

> Review of adverse determinations must be performed by health care providers or staff who were not involved in the initial decision, and who are not subordinates of the persons involved in the initial decision. If the determination involves, even in part, medical judgment, the reviewer must be or must consult with a health care professional who has appropriate training and experience in the field of medicine encompassing the appellant's condition or disease and make a determination that is within the clinical standard of care for an appellant's disease or condition.[5]

¶22 The MRIoA radiation oncologist concluded PBT was not medically necessary under the Premera policy. The January 8, 2010 report states, in pertinent part:

> Conclusion/Decision to Not Certify:
>
> Although there has been increased interest in the use of protons for the definitive treatment of prostate cancer recently, there is no evidence in the recent peer-reviewed medical literature of improved efficacy or reduced toxicity with the use of protons compared to photons. As protons are significantly more expensive, the treatment is defined as not medically necessary in this particular case according to the plan language.[6]
>
> Premera denied the Level I Appeal.

Level II Appeal of Denial of PBT

¶23 On March 2, 2010, Strauss filed a "Level II Appeal." Dr. Bush submitted a letter in support of the appeal. Dr. Bush states that unlike IMRT, a proton beam interacts with human tissue differently with "a relatively low 'entrance dose.' " By contrast, IMRT "x-rays ... deliver their highest dose relatively close to the skin surface." Dr. Bush acknowledged that IMRT is considered the " 'gold standard' " and that the medical studies he cites are not randomized studies that directly compare PBT and IMRT. But Dr. Bush states the "benefit of conformal treatment techniques has been clearly established in the treatment of prostrate and other cancers" and PBT represents "the 'ultimate' form of conformal treatment delivery because of their inherent superior dose deposition characteristics." Dr. Bush also states that "[p]ublished data from a number of institutions" demonstrates the "efficacy in controlling prostate cancer" and "minimal risk of moderate to severe morbidity."

*6 ¶24 Premera submitted the Level II Appeal to MRIoA. On April 6, a different MRIoA independent radiation oncologist concluded PBT was not medically necessary under the Premera policy.

> Medical necessity is not met in that alternative treatments are available with similar efficacy and toxicity, but at a significant reduction in cost. Additionally, there is considerable controversy in the radiation oncology community as to whether proton treatments should be considered a medically necessary treatment option for patients with localized prostate cancer, and it is therefore not in accordance with generally accepted standards of medical practice at this time. Therefore, proton treatment is considered not medically necessary in this particular case.
>
> ....
>
> Conclusion/Decision to Not Certify:
>
> Although there has been increased interest in the use of protons for the definitive treatment of prostate cancer recently, there is no evidence in the recent peer-reviewed medical literature of improved efficacy or reduced toxicity with the use of protons compared to photons. As protons are significantly more expensive, the treatment is defined as not medically necessary in this particular case according to the plan language.

The additional documents submitted do not change the initial determination.[7]

¶25 On April 9, a Premera appeal panel denied the request to approve payment of PBT for treatment of Strauss' intermediate-risk localized prostate cancer. The letter states, in pertinent part:

It is the decision of the appeal panel to deny your request for an exception in this case. Proton Beam therapy is not medically necessary as it is generally more costly than other traditional treatments, such as surgery or external radiation for localized prostate cancer.

....

Both the first and second independent review conducted by MRIoA supported the company's medical policy that Proton Beam Therapy is not medically necessary....

....

In addition to both MRIoA reports, I have enclosed a copy of the company's medical policy. Please note that Premera's medical policy was updated on treatment of prostate cancer with a literature search using PubMed [8] through December 2009. The articles identified did not lead to any changes in the policy statement.

IRO Review

¶26 Strauss requested an external review of the decision to deny coverage. On July 19, 2010, Premera requested external review of the Level II Appeal decision. Premera asked the Washington State Office of the Insurance Commissioner (OIC) to select an IRO. The OIC designated Managing Care Managing Claims (MCMC) as the IRO. MCMC upheld the decision to deny coverage.

- "[T]he health plan should not cover the requested proton therapy."
- "Even though there are positive data available from Loma Linda and other centers for this technology in prostate cancer, other more established alternative treatments such as brachytherapy either with LDR [9] or HDR [10], IMRT and prostatectomy, have longer follow-up time and experience available and better known outcomes in terms of efficacy, toxicities and effects on quality of life."

*7 • "Per NCCN, the recommended radiation therapy treatments for Prostate Cancer include 3D conformal therapy, IMRT and brachytherapy. There is no consensus or mentioning of Proton therapy."

- "A search in clinicaltrials.gov supports that this type of treatment is currently undergoing several phase II studies."

¶27 The MCMC radiation oncologist concluded:

There are other standard treatment options available to the patient which he is a good candidate. These standard treatment options include radical prostatectomy either open or robotic (this was offered by patient's urologist), external beam radiotherapy either IMRT or 3D conformal therapy and brachytherapy either LDR or HDR. There is an abundance of medical data and experience to support these treatment options with known efficacy, toxicity, and quality of life. In contrast, clinical evidence to support proton therapy for prostate cancer is limited in terms of efficacy, toxicity and effects on quality of life. A search in clinicaltrials.gov supports that this type of treatment is currently undergoing several phase II studies.

Per NCCN, the recommended radiation therapy treatments for Prostate Cancer include 3D conformal therapy, IMRT and brachytherapy. There is no consensus or mentioning of Proton therapy.[11]

¶28 Strauss decided to undergo PBT at LLUMC with Dr. Bush. Strauss began PBT treatment in February 2010 and successfully ended PBT in April 2010.

Complaint for Damages against Premera

¶29 On August 1, 2013, Strauss and his spouse Michelle Strauss (collectively, Strauss) filed a complaint for damages against Premera. Strauss alleged breach of contract, that the denial of coverage was "without reasonable justification and therefore in bad faith," and violation of the Consumer Protection Act (CPA), chapter 19.86 RCW. Strauss sought damages for the cost of PBT, bad faith damages, and treble damages under the CPA.

¶30 In October 2015, Strauss' expert witness Dr. George Laramore, the former University of Washington Department of Radiation Oncology Chair, issued a 13-

page report. The report describes the diagnosis and treatment of Strauss using PBT and cites medical studies to conclude PBT was medically necessary for Strauss. The report states:

> Proton radiotherapy is a safe and effective form of treatment for patients with localized prostate cancer. It was an appropriate choice for Mr. Strauss. This is supported not only by the published literature at the time of his diagnosis but also in subsequent work. As such, it meets the standard of being "medically necessary."

¶31 Dr. Laramore concedes IMRT and PBT are equivalent in treating prostate cancer but states the two treatments are not equivalent "in terms of the side effect profile."

> [W]hile IMRT and proton radiotherapy to biologically-equivalent tumor doses may be expected to give approximately the same tumor control probability, they are not equivalent in terms of the side effect profile and so the overall therapeutic results are not equivalent but would be better with proton radiotherapy.[12]

*8 Dr. Laramore concedes there are no "direct randomized trials" comparing IMRT and PBT but states he can "infer the advantages and disadvantages" from medical studies.

¶32 On November 12, 2015, Premera expert Dr. Tomasz Beer, director of the prostate cancer research program at the Knight Cancer Institute of Oregon Health and Science University, issued a 23-page report addressing the use of PBT and IMRT for Strauss' localized intermediate-risk prostate cancer. Dr. Beer states that because IMRT is the standard treatment and PBT "has never been compared head to head to conventional [IMRT] therapy ..., it cannot be said that [PTB] is superior." Dr. Beer concludes the "available data are insufficient to make definitive statements about how proton therapy compares to IMRT with respect to side effects" and PBT "has not been shown to have a clinical advantage over other forms of radiation."

> Proton therapy is not a standard treatment for prostate cancer and has never been studied in a proper randomized trial. It is probably reasonable to suspect that with regard to cancer control, proton therapy yields similar results to conventional therapy—although it would be correct to say we don't really know that to be true. The available data are insufficient to make definitive statements about how proton therapy compares to IMRT with respect to side effects —but one can safely conclude that there is no evidence of an advantage with respect to bladder and bowel side effects or other potential adverse effects. If there is a difference—which we do not know, the data actually suggest a bit of an advantage for IMRT—although this is far from definitive. Authoritative bodies that are beyond reproach, such as the NCCN and [ASTRO] strongly agree that [PBT] has not been shown to have a clinical advantage over other forms of radiation. [PBT] is not a standard of care, and should not be recommended to patients outside of a properly designed clinical trial.

Motion for Summary Judgment Dismissal

¶33 Premera filed a motion for summary judgment dismissal of the lawsuit. Premera argued Strauss could not meet his burden to show PBT was "medically necessary" under the policy. Premera asserted there was no dispute that PBT is more costly than IMRT or that PBT and IMRT result in equivalent therapeutic outcomes. Premera pointed out there were no studies that directly compare PBT and IMRT. Premera also pointed out that Dr. Laramore admitted he did not consider the NCCN guidelines and instead relied on cross studies and theoretical models.

¶34 Premera submitted a number of exhibits, including the NCCN guidelines; the report of Dr. Beer; excerpts of depositions, including the deposition of Dr. Stewart, Dr. Bush, and Dr. Laramore; and the report of Prostate Cancer Center of Seattle Executive Director Dr. Peter Grimm.

¶35 Dr. Stewart testified that because there are "no randomized studies" that compare PBT and IMRT, he was "hesitant" to write the letter in support of Strauss' administrative appeal. Dr. Stewart said the "idea" of PBT having fewer side effects was "theoretical." Dr. Stewart testified that he wrote the letter based on "the hope that [PBT] would have fewer side effects."

*9 ¶36 Dr. Bush testified that there are no oncology guidelines that recommend PBT over IMRT. Dr. Bush testified there is a current ongoing randomized study but no published randomized studies directly comparing PBT and IMRT. Dr. Bush testified tumor control using PBT and IMRT is equivalent. With regard to whether "there is a difference in [PBT and IMRT] side effects," Dr. Bush testified, "[T]hat's a hard question to answer. There's data to support, I think, both sides."

> You know, it can be demonstrated that less tissue gets radiated. That's something that's usually pretty easy to show and is, I think, agreed upon. To show that the side effects are, in a scientific way, right, that proves that side effects are substantially less with proton, I would say the evidence as of today is not as strong as we would like to see. It's something that's still evolving but there is some. There is some.

Dr. Bush agreed that many of the medical studies he relied on were based on theoretical models.

¶37 Dr. Laramore also testified that medical studies show "equivalent control" of prostate cancer with PBT and IMRT. But Dr. Laramore believed there were fewer side effects from PBT. Dr. Laramore testified that PBT was superior in "maintaining sexual potency with testosterone levels not falling with protons, but falling with IMRT," and there were fewer risks of secondary cancer. Dr. Laramore testified PBT is more costly than IMRT.

¶38 Dr. Laramore conceded he did not rely on the NCCN guidelines in preparing his report and reaching his conclusions. Dr. Laramore testified there "has not been the gold standard of a randomized study" and because "there have been no randomized trials at this stage," he had "to look at literature and kind of infer differences."

¶39 Dr. Grimm addressed Dr. Laramore's report and deposition testimony. Dr. Grimm agreed that "there have not been randomized studies to directly compare Proton therapy with IMRT" and that PBT and IMRT "have the same cancer control rate at 5 years out from treatment." Dr. Grimm agreed PBT "was a reasonable choice of treatment" for Strauss but states PBT was "not medically necessary" under the policy.

¶40 Dr. Grimm described the limitations of the studies Dr. Laramore relies on to support his opinion that PBT has fewer side effects than IMRT. For example, Dr. Grimm states:

> [T]he Shipley article ... was a comparison between two similarly dosed patients groups, one receiving proton boost of 25.2 Gy[13] after 50.4 Gy conformal photon therapy and the other receiving a similar photon therapy followed by 1.8 Gy photon conformal treatment (not IMRT). The study stated, "We found no significant differences in [overall survival], [disease specific survival], TRFS [14] or local control between the two arms." [TRFS] was defined as clinically free, prostate specific antigen (PSA) less than 4 [nanogram]/[milliliter] and a negative prostate rebiopsy. Only a small select group was found to have an improvement in local control, i.e. poorly differentiated cancer. As previously noted by Dr[.] Laramore, the control rate for IMRT and protons in the current era are similar. This study evaluated different doses and techniques than those delivered today, and different from those delivered when Mr. Strauss was treated. Therefore, this observation should not be construed as any advantage of protons over IMRT, particularly as the doses given for both IMRT and protons currently prescribed and as were given for Mr. Strauss are the same and would be expected to have the same cancer control outcomes.
>
> *10 ....
>
> ... The PROG study compared two Proton doses schedules, 79.2 Gy vs 70.2 Gy which determined the 79 Gy arm had better cancer control. This 79 Gy arm had

an 83% long term 10 year biochemical control rate for low risk disease, similar to current IMRT results. [15]

¶41 With respect to sexual function side effects, Dr. Grimm states:

> Sexual function comparisons, as reported here by Dr[.] Laramore, used general terms and are not stratified by age, or other factors which have a bearing on long term sexual function. There is no data presented here that suggests that protons have a documented improved ability to avoid dose to the penile bulb better than IMRT. Dose to the penile bulb is a targeting issue not a specific treatment issue. It is not necessary to treat the penile bulb under either treatment. While the lowering of testosterone may be due to scattered radiation, the effect is temporary for IMRT and testosterone levels return to near normal within 1 year with both treatments ....
>
> ....
>
> ... Dr. Laramore states that the effect on testosterone is greater with IMRT than with surgery. However the effect is ... very short lived, with testosterone typically returning to near pretreatment levels within a year with either modality .... Potency rates issues suggesting better potency in proton patients in Hoppe reference were short term and the study was only in healthy men less than 60 years old, a highly select group, and not a comparable group to the general IMRT population. Dr. Laramore admits there may be a mismatch between any comparison. [16]

¶42 As to Dr. Laramore's opinion on secondary malignancy, Dr. Grimm states:

> Regarding secondary malignancies, there are no direct comparisons of the risk of secondary malignancies between IMRT and protons. The one attempt at comparison, the Fontenot article, was an article based on conjectural evidence on dose estimates from 3 patients and applying a theoretical model of presumed, not actual dose to patients from IMRT. Not a scientific study. [17]

¶43 Premera also relied on a federal district court case that addressed the exact same "medically necessary" policy language and the expert testimony of Dr. Laramore on side effects. See Baxter v. MBA Group Insurance Trust Health and Welfare Plan, 958 F.Supp.2d 1223 (W.D. Wash. 2013). In Baxter, the court concluded on summary judgment that the plaintiff could not show there was a genuine issue of material fact as to "whether proton therapy is superior to IMRT." Baxter, 958 F.Supp.2d at 1237-38.

> Plaintiff has not met his burden to show that there is a genuine issue of material fact whether proton therapy is superior to IMRT. The current non-randomized observational studies demonstrate that proton therapy provides equivalent treatment to IMRT in terms of cancer control and side-effects. Plaintiff focuses on studies involving mathematical modeling that show that the long-term risk of developing a secondary malignancy may be higher with proton therapy.... No study cited by either party provides statistically significant evidence that one therapy is superior to the other.
>
> ***11** Baxter, 958 F.Supp.2d at 1237-38.

¶44 In opposition to summary judgment, Strauss argued there were genuine issues of material fact as to whether PBT is medically necessary—"at the very least ... there are questions of fact on whether Proton Beam Radiation Therapy is superior to IMRT as far as side effects." Strauss submitted the letter from Dr. Bush in support of the Level II Appeal, the medical studies cited by Dr. Bush, the report and declaration of Dr. Laramore, and excerpts of depositions, including the deposition of Dr. Bush, Dr. Laramore, and Strauss.

¶45 In reply, Premera argued reliance on medical experts' theoretical assumptions and inferences on side effects did not establish PBT was medically necessary or create a material issue of fact.

¶46 The court granted the motion for summary judgment and dismissed the lawsuit.

Appeal

¶47 Strauss argues the court erred in granting summary judgment dismissal of his lawsuit. We review summary judgment de novo. Hartley v. State, 103 Wash.2d 768, 774, 698 P.2d 77 (1985). Summary judgment is appropriate when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. CR 56(c).

¶48 The defendant on summary judgment has the burden of showing the absence of evidence to support the plaintiff's case. Young v. Key Pharms., Inc., 112 Wash.2d 216, 225, 770 P.2d 182 (1989). Once the moving party shows an absence of a genuine issue of material fact, the burden shifts to the nonmoving party. Young, 112 Wash.2d at 225, 770 P.2d 182.

¶49 While we construe the evidence and reasonable inferences in the light most favorable to the nonmoving party, if the nonmoving party " 'fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial,' " summary judgment is proper. Young, 112 Wash.2d at 225, 770 P.2d 182 (quoting Celotex Corp. v. Catrett, 477 U.S. 317, 322, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986)); Jones v. Allstate Ins. Co., 146 Wash.2d 291, 300-01, 45 P.3d 1068 (2002). Questions of fact may be determined on summary judgment as a matter of law where reasonable minds could reach but one conclusion. Smith v. Safeco Ins. Co., 150 Wash.2d 478, 485, 78 P.3d 1274 (2003).

[1] ¶50 The nonmoving party may not rely on speculation to create a material issue of fact. Ranger Ins. Co. v. Pierce County, 164 Wash.2d 545, 552, 192 P.3d 886 (2008). "[M]ere allegations, denials, opinions, or conclusory statements" do not establish a genuine issue of material fact. Int'l Ultimate, Inc. v. St. Paul Fire & Marine Ins. Co., 122 Wash.App. 736, 744, 87 P.3d 774 (2004).

[2] [3] [4] [5] ¶51 Interpretation of an insurance contract is a question of law that we also review de novo. Overton v. Consol. Ins. Co., 145 Wash.2d 417, 424, 38 P.3d 322 (2002); Quadrant Corp. v. Am. States Ins. Co., 154 Wash.2d 165, 171, 110 P.3d 733 (2005). We construe insurance policies as contracts. Kut Suen Lui v. Essex Ins. Co., 185 Wash.2d 703, 710, 375 P.3d 596 (2016). The principles of contract interpretation apply. Quadrant Corp., 154 Wash.2d at 171, 110 P.3d 733. If the language in an insurance contract is not ambiguous, the court must enforce it as written. State Farm Mut. Auto. Ins. Co. v. Ruiz, 134 Wash.2d 713, 721, 952 P.2d 157 (1998).

*12 [6] ¶52 Under RCW 48.18.520, we construe an insurance contract according to the entirety of its terms and conditions as set forth in the policy and as modified by any endorsement made a part of the policy. Kut Suen Lui, 185 Wash.2d at 711, 375 P.3d 596. If a term is defined in a policy, the term should be interpreted in accordance with that policy definition. Kitsap County v. Allstate Ins. Co., 136 Wash.2d 567, 576, 964 P.2d 1173 (1998).

[7] [8] ¶53 Insurance policies are liberally construed to provide coverage wherever possible. W. Nat'l Assurance Co. v. Shelcon Constr. Grp. LLC, 182 Wash.App. 256, 261, 332 P.3d 986 (2014). The party seeking to establish coverage bears the initial burden of proving coverage under the policy. Pleasant v. Regence Blue Shield, 181 Wash.App. 252, 261-62, 325 P.3d 237 (2014).

[9] ¶54 If the insured claims the insurer denied coverage unreasonably in bad faith, then the insured must come forward with evidence that the insurer acted unreasonably. Smith, 150 Wash.2d at 486, 78 P.3d 1274. The insurer is entitled to summary judgment if reasonable minds could not differ that its denial of coverage was based upon reasonable grounds. Smith, 150 Wash.2d at 486, 78 P.3d 1274.

[10] ¶55 Strauss contends the testimony of Dr. Bush and Dr. Laramore and the peer-reviewed medical studies they relied on create a genuine issue of material fact as to whether PBT results in fewer side effects and is medically necessary under the language of the Premera policy.

¶56 The January 1, 2008 Premera contract endorsement defines "medically necessary" services as "not more costly than an alternative service ... at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease." [18]

¶57 Strauss does not dispute that PBT is more costly than IMRT [19] or that PBT and IMRT are equally effective in treating prostate cancer. Therefore, Strauss concedes he

must show PBT results in superior or fewer side effects than IMRT.

¶58 The testimony of Dr. Laramore and Dr. Bush and the peer-reviewed medical studies they rely on do not create a material issue of fact on side effects. The undisputed record establishes there were no published clinical studies directly comparing PBT and IMRT. Accordingly, Dr. Laramore and Dr. Bush cite published medical studies to support the opinion that PBT results in fewer side effects than IMRT. Dr. Laramore and Dr. Bush draw inferences from the studies and theoretical models to conclude PBT is superior to IMRT. Dr. Laramore testified that "because there ... have been no randomized trials at this stage [,] ... that's what I mean by having to look at literature and kind of infer differences." Dr. Laramore admits his opinion that PBT is superior for the risk of contracting secondary cancers is "theoretical." Dr. Laramore testified that he based his opinion on the superiority of PBT over IMRT regarding sexual potency on the "assumptions" that "patient groups are basically equivalent" across two different studies. Dr. Laramore based his opinion on the side effects from radiation to the rectal wall on one medical study.

*13 ¶59 Because the record establishes there are peer-reviewed medical studies that show the side effects of PBT may be superior to IMRT and other peer-reviewed medical studies that show the side effects of IMRT may be superior to PBT, reasonable minds could only conclude that absent clinical evidence directly comparing PBT and IMRT, the treatments are equivalent and Strauss cannot show PBT was medically necessary. See also Baxter, 958 F.Supp.2d at 1234 (rejecting argument that the side effects of PBT are superior to IMRT).

¶60 We affirm summary judgment dismissal of the lawsuit for breach of contract, bad faith, and violation of the CPA.[20]

WE CONCUR:

Mann, J.

Appelwick, J.

All Citations

--- P.3d ----, 2017 WL 6819015

Footnotes

1 Computerized tomography.
2 Footnotes omitted.
3 But the 2015 Guidelines also note there is currently an "ongoing prospective randomized trial accruing patients" to compare PBT to IMRT.
4 Millimeter.
5 See also former WAC 284-43-630 (2008) ("**Independent review of adverse determinations.** Carriers must use the rotational registry system of certified independent review organizations (IRO) established by the commissioner.")
6 The report cites a number of published medical articles and studies in support of its decision.
7 The report cites a number of published medical articles and studies in support of its decision.
8 PubMed is an online database of biomedical literature, journal articles, and books.
9 Low-dose rate.
10 High-dose rate.
11 The report cites a number of published medical articles and studies in support of its decision.
12 Emphasis in original.
13 Gray.
14 Total recurrence-free survival.
15 Footnotes omitted.
16 Footnote omitted.
17 Footnote omitted.
18 (Emphasis added.) As previously noted, the policy defines "generally accepted standards of medical practice" as follows:
For these purposes, "generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer reviewed medical literature generally recognized by the relevant medical

community, physician specialty society recommendations and the views of physicians practicing in relevant clinical areas and any other relevant factors.

19 There is no dispute that PBT was "[c]linically appropriate" and complied with "generally accepted standards of medical practice."

20 We therefore deny Strauss' request for attorney fees on appeal.

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FILED
12/29/2017
Court of Appeals
Division I
State of Washington

IN THE COURT OF APPEALS OF THE STATE OF WASHINGTON
DIVISION ONE

JOHN STRAUSS and MICHELLE STRAUSS, husband and wife, and their marital community, Appellants, v. PREMERA BLUE CROSS, Respondent.	No. 74600-6-I ORDER TO PUBLISH

Appellants John Strauss and Michelle Strauss (Strauss) filed a motion to publish the opinion filed on September 5, 2017. Respondent Premera Blue Cross filed an answer to the motion. Strauss mischaracterizes the opinion and therefore, the panel disagrees with his reasons for publication. But because the decision relies on Washington law in addressing an issue of general public interest or importance, the panel has determined the opinion shall be published. Now, therefore, it is hereby

ORDERED that the September 5, 2017 opinion shall be published.

FOR THE COURT:

Judge

SMITH GOODFRIEND, PS

January 29, 2018 - 4:39 PM

Filing Petition for Review

Transmittal Information

Filed with Court:	Supreme Court
Appellate Court Case Number:	Case Initiation
Appellate Court Case Title:	John Strauss and Michelle Strauss, Appellant v. Premera Blue Cross, Respondent (746006)

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