No. 954496

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,

Appellants,

v.

PREMERA BLUE CROSS,

Respondent.

PREMERA BLUE CROSS'S ANSWER TO APPELLANTS' PETITION FOR REVIEW

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I. IDENTITY OF ANSWERING PARTY

Respondent Premera Blue Cross ("Premera") files this answer to the petition for review of Petitioners /Plaintiffs John Strauss and his spouse, Michelle Strauss (collectively, "Strauss"). The Superior Court dismissed Strauss's complaint by summary judgment, and the Court of Appeals, Division I, unanimously affirmed the dismissal.

II. COURT OF APPEALS DECISION

The Court of Appeals, Division I, unanimously affirmed the Superior Court's order dismissing with prejudice Strauss's claim for health care benefits under the health insurance policy ("the Plan") that Premera issued to Strauss. *See Strauss v. Premera Blue Cross*, --Wn. App--, 408 P.3d 699 (2017).

III. INTRODUCTION AND SUMMARY OF ARGUMENT

As the party seeking discretionary review, Strauss bears the burden of showing that the Court of Appeals' unanimous decision conflicts with a decision of the Supreme Court or with another decision of the Court of Appeals; involves a significant question of law under the state or federal Constitution; or involves an issue of substantial public interest. Rule of Appellate Procedure ("RAP") 13.4(b)(1)-(4). Strauss does not meet this burden.

The Court of Appeals' opinion applied well-settled law regarding summary judgment standards under CR 56 and rules for construction of insurance contracts. The Court of Appeals' opinion did not address any unsettled issue of substantial public interest because it only interpreted the Plan and applied the Plan's "medically necessary" requirement to the unique facts of this case. This is evident from the very language that Strauss uses in the Petition for Review, which complains that the Court of Appeals "improperly invaded the province of the jury by weighing conflicting evidence, viewing that evidence in the light most favorable to the moving party." Strauss's Petition ("Pet.") at 8.

Arguments that the trial court and the Court of Appeals "improperly invaded the province of the jury by weighing conflicting evidence" are garden variety on appeal, and do not satisfy RAP

13.4(b)'s standards for Supreme Court review. With respect to his own specific grievance here, Strauss has had his day in court.

Finally, Strauss mischaracterizes the Court of Appeals' holding in his discussion of the fourth prong of RAP 13.4(b).[1] Strauss claims that "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." Pet. at 2. The Court of Appeals did not hold that randomized clinical trials must conclusively establish a proposed treatment's superiority in order to meet the Plan's medically necessary requirement. Instead, the Court of Appeals properly held that Strauss failed to prove that proton beam therapy ("PBT") was "medically necessary" pursuant to the Plan's definition of "medically necessary," in light of the existing scientific evidence—including the lack of randomized trials *or any other evidence* supporting medical necessity.

There is no basis under RPC 13.4 for the Court to grant review of the Court of Appeals' decision, which is consistent with every court in the country that has considered similar claims for coverage of PBT under similar plan language as are at issue here, including the federal Western District of Washington.

IV. COUNTERSTATEMENT OF ISSUES

Whether this Court should deny review under RAP 13.4(b) where Strauss fails to establish a basis for review because:

(1) the Court of Appeals' opinion applied well-settled law regarding summary judgment standards under CR 56 and rules for construction of insurance contracts;

[1] In granting Strauss's motion to publish the Court of Appeals' decision, the court chided Strauss for mischaracterizing its holding: "Strauss mischaracterizes the opinion and therefore, the panel disagrees with his reasons for publication." Doc. 38. Here again Strauss mischaracterizes the Court of Appeals' holding, in the same way, in seeking review. (Although the Court of Appeals granted Strauss's motion to publish because its opinion "address[ed] an issue of general public interest or importance," presumably, this refers to the axiom, "The business of insurance is one affected by the public interest." RCW 48.01.030. Of course, this does not mean that every case addressing an insurance coverage dispute should be reviewed by the Supreme Court.)

(2) the Court of Appeals' opinion did not address any unsettled issue of substantial public interest because it only interpreted the Plan and applied the Plan's medical necessity requirement to the record facts; and

(3) Strauss mischaracterizes the Court of Appeals' holding as requiring all health insureds to prove "medical necessity" with randomized clinical trials that conclusively establish a treatment's superiority.

V. COUNTER-STATEMENT OF THE CASE

A. Strauss' Diagnosis and Treatment.

Petitioner John Strauss was diagnosed with intermediate risk prostate cancer in October 2008. CP 69. Strauss's urologist, Dr. Lin, reviewed his treatment options, which included "radiation and surgical management of the disease." *Id*. In this initial consultation following the diagnosis, Strauss told Dr. Lin that he preferred radiation because some of his "golf buddies" and other friends had told him about positive experiences with it. *Id*.; CP 94 (Strauss Depo at 28); CP 110 (Lin Depo at 44). He also told Dr. Lin that he had heard good things about proton beam therapy treatment at the Loma Linda University Medical Center (Loma Linda) in Southern California. *Id*.; CP 94 (Strauss Depo at 28); CP 110 (Lin Depo at 44). Dr. Lin, however, did not recommend PBT over any other radiation treatment option. CP 84, 110 (Lin Depo at 44, 64); CP 94 (Strauss Depo at 27).

Dr. Lin referred Strauss to Dr. Russell, a radiation oncologist, for consultation regarding radiation treatment options. CP 72; CP 88 (Russell Depo at 31); CP 94 (Strauss Depo at 28). Even before Strauss saw Dr. Russell, he was "leaning pretty heavily toward" PBT based on the advice of his friends, his own internet research, and the fact that his winter home was only 45 minutes away from Loma Linda. CP 94 (Strauss Depo at 28-29); CP 1020. Like Dr. Lin, Dr. Russell did not recommend PBT to Strauss. CP 88 (Russell Depo at 32-33). On the contrary, Dr. Russell told Strauss of the "lack of clear, long-term evidence showing improved side effect profile for patients who undergo proton therapy versus intensity-modulated radiation technique therapy." CP 1020. Still, Strauss told Dr. Russell he was "most interested in seeking proton therapy since [Loma

Linda] is near his family." *Id*. Later, like Dr. Lin and Dr. Russell, Strauss's cardiologist Dr. Stewart did not recommend PBT. CP 91 (Stewart Depo at 103-04). But Strauss told Dr. Stewart that he wanted PBT, based on "his own research." CP 76-78; CP 91 (Stewart Depo at 102).

At the time, no national association of cancer specialists recommended PBT to treat prostate cancer, and that is still true. CP 368, 482; CP 554-624, CP 648. PBT is not recognized as superior to other forms of radiation therapy. *Id.* Rather, the national association guidelines and the radiation oncologist community uniformly consider intensity-modulated radiation technique, or "IMRT," to be the generally accepted standard of care for radiation therapy to treat prostate cancer. *Id.*; CP 439-40 (Bush Depo at 185-87); CP 940 (Bush Depo at 203-04); CP 663 (Russell Depo at 30). In rendering its decision, the Court of Appeals considered the following examples of responses by national associations to availability of PBT:

- The National Comprehensive Cancer Network (NCCN) publishes Clinical Practice Guidelines in Oncology for Prostate Cancer (NCCN Guidelines), CP 315-412, which are used by oncologists in their practice. When Strauss considered options for radiation therapy to treat his prostate cancer, and later appealed Premera's coverage decision denying coverage for PBT, the NCCN Guidelines did not even *mention* PBT. CP 554-99 (2009 guidelines); CP 601-24 (2010 guidelines). Subsequent versions of the guidelines compared various forms of radiation therapy, including IMRT and PBT[2]. CP 367-68. The current NCCN Guidelines state, based on peer-reviewed studies and trials, as follows: "The NCCN panel believes there is no clear evidence supporting a benefit or decrement to proton therapy over IMRT for either treatment efficacy or long-term toxicity." CP 368. NCCN's guidelines for patients likewise advises: "To date, research hasn't shown that proton treatment is any better or worse for treating cancer or causing side effects." CP 482.

[2] NCCN is an alliance of the leading cancer centers and the authoritative source of evidence-based guidelines for the treatment of cancer, including the field of radiation oncology. CP 416-18, 420. Strauss's urologist similarly testified that NCCN is the "governing body of cancer treatment protocols" and its guidelines the "go-to resource for most practicing cancer physicians." CP 446-47 (Lin Depo at 29-30).

- The American Society for Radiation Oncology (ASTRO) publishes a model policy on PBT. CP 626-44.3 As it relates to the treatment for prostate cancer, ASTRO concludes: "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." CP 642. Thus, ASTRO recommends PBT serve as a primary treatment for prostate cancer "only ... within the context of a prospective clinical trial or registry." *Id*.
- The Agency for Healthcare Research and Quality (AHRQ), an agency of the U.S. Department of Health and Human Services, likewise recommends: "Members 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." CP 648.

As Strauss's own radiation oncologists conceded, all nationally recognized medical guidelines for prostate cancer treatment identify IMRT—not PBT—as the standard of care, and no guidelines conclude that PBT is superior to IMRT. CP 439-40 (Bush Depo at 185-87); CP 940 (Bush Depo at 203-04); CP 663 (Russell Depo at 30).

Although PBT pre-dates IMRT by decades, there has not been a single randomized trial—which is the only definitive means for comparing different treatment types—involving PBT and IMRT. CP 419-21 (Beer Report); CP 686 (Stewart Depo at 110, 113); CP 653, 680, 902 (Bush Depo at 29, 55, 61); CP 657, 660 (Laramore Depo at 62-63, 65, 174); CP 691 ("there has not been any direct randomized trial comparing the different options"). PBT "has never been compared head to head to conventional radiation therapy." CP 420 (Beer Report).

Those claiming that PBT is superior or comparable to IMRT (often, doctors working at hospitals that sell PBT) must therefore rely exclusively on predictions and assumptions derived from mathematical models, dosimetric studies (studies that compare treatment plans) and retrospective cross-study comparisons (comparing the results of separate studies). CP 419, 424(Beer Report); CP 683, 901-03 (Bush Depo at 51-52, 54, 55, 58, 59-60, 68-69); CP 657, 778-79, 787 (Laramore Depo at 57-58,62-64,93); CP 691 (Laramore Report).

Even these limited studies actually suggest that PBT may have the same or worse side-effect profile as IMRT and other forms of radiation therapy. CP 421, 428-31 (Beer Report). Accordingly, the scientific consensus may be summarized as that "[c]laims of [PBT] clinical superiority are basically claims based on hope, and not evidence." CP 422 (Beer Report).

Nevertheless, Strauss decided that he wanted PBT, based on "his own research." CP 76-78; CP 91 (Stewart Depo at 102). Strauss received PBT at Loma Linda for approximately two months, ending in April 2010. CP 133. According to Strauss and his doctors, the treatment was successful. CP 137 (Jenson Depo at 104); CP 140 (Lin Depo at 92); CP 143 (Strauss Depo at 107).

B. Strauss' Claim and Appeals.

At the time of his prostate cancer and diagnosis, Strauss was insured under Premera's Heritage Preferred Plus 20 Plan ("the Plan"). CP 4 (¶ 3.1); CP 169-206. The Plan covers radiation therapy services, CP 186, but only if such services are "medically necessary." CP 177.

The Plan defines "medically necessary" as follows:

> Those covered services ... 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 ... at least 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 view of physicians practicing in the relevant clinical areas and any other relevant factors.

CP 212. Premera publishes a Corporate Medical Policy concerning PBT, which is used to evaluate medical necessity based on peer-reviewed medical literature, national guidelines and local

standards. CP 216-22. The Medical Policy—consistent with NCCN's and ASTRO's guidelines for radiotherapy treatment of prostate cancer—states that PBT is not medically necessary "because the outcomes have not shown to be superior to other approaches including intensity modulated radiation therapy (IMRT)... yet proton beam therapy is generally more costly than these alternatives." CP 217. Premera therefore denied Strauss' claim for coverage of PBT.

After Premera denied Strauss's claim, he pursued an appeal through Premera's internal process. The appeals process for Strauss's health plan, as regulated by Washington law, provided for two levels of internal appeals and an external review by an Independent Review Organization (IRO). Strauss filed a Level I Appeal on December 30, 2009. CP 247-52. Premera referred Strauss's Level I Appeal to Medical Review Institute of America (MRIoA), an external review organization, for a "Same Specialty Review." CP 272-73.

On January 8, 2010, a MRIoA radiation oncologist upheld Premera's initial coverage decision. CP 272-73. The MRIoA specialist found that "most experts recommend further study of safety and efficacy of proton treatment for prostate cancer at this time because there is no evidence in the recent peer-reviewed 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." CP 273-74. Based on MRIoA's independent review, Premera denied Strauss's Level I Appeal on February 1, 2010. CP 277-78; see also, CP 288-90, CP 292-95.

Strauss requested a Level II Appeal, which under Washington law was required to be an external review by a new IRO. CP 297. As required by Washington law, Premera requested a random IRO selection from the Office of the Insurance Commissioner (OIC). The OIC assigned Managing Care Managing Claims (MCMC). CP 302-06. On August 3, 2010, MCMC's reviewer, also a radiation oncologist, upheld Premera's denial. CP 308-13.7 MCMC's reviewer found that "Proton therapy is not medically necessary in this case" because while "[t]here is an abundance of medical data and experience to support . . . treatment options" available to Strauss and for which Premera provided coverage—including "external beam radiotherapy either IMRT or 3D conformal

therapy and brachytherapy either LDR or HDR"—"with known efficacy, toxicity, and quality of life," "clinical evidence to support [PBT] for prostate cancer is limited in terms of efficacy, toxicity and effects on quality of life." CP 312. The reviewer noted that the NCCN-recommended treatments for prostate cancer "include 3D conformal therapy, IMRT and brachytherapy. There is no consensus or mentioning of Proton therapy." CP 312.

VI. ARGUMENT WHY REVIEW SHOULD BE DENIED

A. Strauss Must Satisfy the Criteria that Govern Petitions for Supreme Court Review.

RAP 13.4(b) provides: "Considerations Governing Acceptance of Review. A petition for review will be accepted by the Supreme Court only: (1) If the decision of the Court of Appeals is in conflict with a decision of the Supreme Court; or (2) If the decision of the Court of Appeals is in conflict with another decision of the Court of Appeals; or (3) If a significant question of law under the Constitution of the State of Washington or of the United States is involved; or (4) If the petition involves an issue of substantial public interest that should be determined by the Supreme Court." Strauss purports to rely on only sub-parts (1), (2) and (4). However, Strauss's Petition for Review does not analyze any of these standards as they pertain to the Superior Court's or the Court of Appeals' decision, only referencing them in passing.

B. Strauss Fails to Satisfy Any of the RAP 13.4 Criteria.

1. In Affirming Dismissal of Strauss's Breach Of Contract Claim, the Court of Appeals Concluded that Strauss Did Not Satisfy His Contractually Established Burden Of Proof That PBT Was "Medically Necessary."

a. The Court of Appeals applied well-settled law regarding summary judgment standards under CR 56 and rules for construction of insurance contracts.

The Court of Appeals applied well-settled law in affirming dismissal of Straus's claim:

- Summary Judgment Standards. "While [in reviewing a summary judgment] 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." *Strauss*, 408 P.3d at 709–10 (quoting *Young v. Key Pharms., Inc*., 112 Wn.2d 216, 225, 770 P.2d 182 (1989) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 106 S. Ct. 2548, 91 L.Ed.2d 265 (1986)) (citing *Jones v. Allstate Ins. Co.*, 146 Wn.2d 291, 300-01, 45 P.3d 1068 (2002)). "The insurer is entitled to summary judgment if reasonable minds could not differ that its denial of coverage was based upon reasonable grounds." *Id*. at 710 (citing *Smith v. Safeco Ins. Co*., 150 Wn.2d 478, 486, 78 P.3d 1274 (2003)).

- Insured's Duty to Prove Coverage Under the Insuring Clauses. "The party seeking to establish coverage bears the initial burden of proving coverage under the policy." *Id.* at 710 (citing *Pleasant v. Regence Blue Shield*, 181 Wn. App. 252, 261-62, 325 P.3d 237 (2014)).
- General Rules for Contract construction. "We construe insurance policies as contracts." *Id*. at 710 (citing *Kut Suen Lui v. Essex Ins. Co*., 185 Wn.2d 703, 710, 375 P.3d 596 (2016)). "The principles of contract interpretation apply." *Id.* (citing *Quadrant Corp. v. Am. States Ins. Co*., 154 Wn.2d 165, 171, 110 P.3d 733 (2005). "If the language in an insurance contract is not ambiguous, the court must enforce it as written." *Id.* (citing *State Farm Mut. Auto. Ins. Co. v. Ruiz*, 134 Wn.2d 713, 721, 952 P.2d 157 (1998)). "Interpretation of an insurance contract is a question of law that we also review de novo." *Id*. (citing *Overtonv. Consol. Ins. Co*., 145 Wn.2d 417, 424, 38 P.3d 322 (2002); *Quadrant Corp. v. Am. States Ins. Co*., 154 Wn.2d 165, 171, 110 P.3d 733 (2005)).
- Special Rules for Interpretation of Insurance Contracts. "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." *Id*. (citing *Kut Suen Lui*, 185 Wn.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." *Id*. (citing *Kitsap County v. Allstate Ins*. Co., 136 Wn.2d 567, 576, 964 P.2d 1173 (1998)). "Insurance

policies are liberally construed to provide coverage wherever possible." *Id*. (citing *W. Nat'l Assurance Co. v. Shelcon Constr. Grp. LLC*, 182 Wn. App. 256, 261, 332 P.3d 986 (2014)). The foregoing principles are universally established in Washington, and there is no conflict between the Court of Appeals' decision and decisions of other Washington courts.

b. Strauss Had the Burden to Prove Medical Necessity.

Strauss does not deny that he bears the burden to prove that PBT is medically necessary, i.e., that PBT leads to fewer side effects. Indeed, his Petition for Review does not even address proof burdens, and leaves unchallenged the Court of Appeals' conclusion that Strauss bore the burden of proof that PBT was medically necessary. *Strauss*, 408 P.3d at 710 ("The party seeking to establish coverage bears the initial burden of proving coverage under the policy") (citing *Pleasant*, 181 Wn. App. at 261-62).

"The insured bears the burden of showing that coverage exists; the insurer that an exclusion applies." *Mutual of Enumclaw Insurance Co. v. T&G Construction, Inc.*, 165 Wn.2d 255, 259, 199 P.3d 376 (2008) (citing *Am. Star. Ins. Co. v. Grice*, 121 Wn.2d 869, 875, 854 P.2d 622 (1993)). In *Baxter v. MBA Grp. Ins. Tr. Health & Welfare Plan*, 958 F. Supp. 2d 1223 (W.D. Wash. 2013), the Western District of Washington rejected the insured's claim for coverage of PBT, following an exhaustive analysis which concluded that the "medically necessary" requirement was not an exclusion because it appeared in the "Medical Benefits" section of the Plan, and therefore the insured bore the burden of proof. *Id.* at 1229-30.

Baxter contained the identical definition of "medically necessary" that is at issue here, and here it is likewise located in the Benefits section of the policy. *Compare* 958 F. Supp. 2d at 1228-29, 1233 to CP 212. Likewise, here Strauss's Plan states that, "[b]enefits are available for a service ... when it meets all of these requirements:... It must be, in our judgment, medically necessary." CP 177. The Plan then goes on to define "medically necessary." *Compare* 958 F. Supp. 2d at 1228-29, 1233 to CP 212; *see also, infra* at 6-7.

Thus, the Court of Appeals properly required Strauss to bear the burden to prove that PBT was medically necessary.

c. The Court of Appeals Properly Affirmed Dismissal of Strauss's Breach Of Contract Claim Because Strauss Did Not Satisfy His Burden Of Proof That PBT Was "Medically Necessary."

It is undisputed that the medically necessary determination turned on whether PBT has superior or fewer side-effects. "Strauss does not dispute that PBT is more costly than IMRT 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." *Strauss*, 408 P.3d at 710. However, because there are no randomized trials comparing PBT to IMRT, there is no clinical evidence that PBT is superior in any way. Therefore the Court of Appeals affirmed the trial court's dismissal of the case, which was proper.

As the Court of Appeals explained:

> The testimony of [Strauss's experts] 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.
>
> 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).

Strauss, 408 P.3d at 710–11.

This application of the record evidence to the Plan's medical necessity requirement does not conflict with any Supreme Court or Court of Appeals precedent, nor does it involve an issue of substantial public interest. *See* RAP 13.4. The holding has no application outside the specific

contract provisions and facts at issue in this case. In attempting to meet the RAP 13.4(b) requirement, Strauss complains that the Court of Appeals considered the cost of the treatment; but this is a factor identified in the Plan's definition of "medically necessary" (along with others relating to efficacy of the proposed treatment), and the Court of Appeals' application of that contractual requirement does not merit Supreme Court review.

The Court of Appeals' decision contains an extensive summary of the scientific evidence offered by both sides, and concludes that "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." *Id.*; *see also, Strauss*, 408 P.3d at 710 (citing *Smith*, 150 Wn.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.").

As the Court of Appeals explained, all that researchers have done with respect to PBT to the extent relevant in this case—side-effects caused by PBT—is predict that PBT may cause fewer side-effects based on models, dosimetric studies (studies that compare treatment plans) and cross-study comparisons. CP 419 (Beer Report). Every single study cited by Strauss's experts (many of which do not involve IMRT at all) suffer from this defect. Strauss's expert, Dr. Laramore, was candid about this. He admitted that PBT's alleged superiority over IMRT is "theoretical," and based on "assumptions" and "inferences" drawn from the literature. *Id*.; CP 657,778-79, 787 (Laramore Depo at 57-58, 62-64, 93); see also CP 691 (Laramore Report: "there have not been direct randomized trials ... but rather one must review the literature to infer the advantages and disadvantages").

Strauss's argument that PBT is "medically necessary" under the Plan relies on the opinion of two doctors, his doctor at Loma Linda (Dr. Bush) and his paid expert (Dr. Laramore). *See* Strauss's Pet. at 9-14. Strauss argues that because these opinions are admissible under *Frye* as "novel scientific evidence," they necessarily raise an issue of fact on the question of "medically necessary." *Id*. at 10-11. But the dispositive issue here is not admissibility of Dr. Bush's or Dr. Laramore's testimony; the dispositive issue is contract interpretation and application of the facts

to the parties' contract. Strauss cites no case for the nonsensical position that any admissible scientific opinion automatically satisfies the contractual defining of "medically necessary."

Scientific evidence may be admissible under *Frye* but not meet the Plan's "medically necessary" requirement. "[S]cientific standards and legal standards do not always fit neatly together." *Anderson v. Akzo Nobel Coatings, Inc*., 172 Wn.2d 593, 607, 260 P.3d 857 (2011). Under *Frye*, a court first considers whether a particular theory is generally accepted and, if it is, then whether that theory would be helpful to the trier of fact under ER 702. *Id*. at 603. Under the general acceptance inquiry, a scientific theory passes muster under *Frye* so long as the "science and methods are widely accepted in the relevant scientific community ... without separately requiring widespread acceptance of the plaintiffs theory" itself. *Id*. at 609.

That Dr. Bush's and Dr. Laramore's opinions might qualify as a scientifically valid *theory* under *Frye* does not mean that they support Strauss's allegation that PBT is superior. Indeed, both Dr. Bush and Dr. Laramore conceded that it is not superior. CP 683 (Bush Depo at 68-69);CP657, 660 (Laramore Depo at 62-64, 174). The Plan's definition of "medically necessary" is an objective standard that evaluates whether an alternative treatment is "at least likely to produce equivalent" results. CP 212.

Strauss's experts agree that randomized trials are the "gold standard" for an evidence-based comparison of different treatment methods. CP 660 (Laramore Depo at 174). As Dr. Bush, who treated Strauss at Loma Linda, put it: "in today's world, [it] is what most people point to as being kind of definitive data for scientific folks." CP 902 (Bush Depo at 55).

A randomized trial is relevant to comparing treatment methods because it eliminates the variables and "sampling bias" that render modeling and cross-study comparisons (articles comparing the results of separate studies) unreliable—i.e., different patient pools, testing methods, grading scales, frequency and completeness in patient follow up. CP 424 (Beer Report); CP 901-03 (Bush at 54, 55, 58). Again, Strauss's experts agree: absent a randomized trial, "you're grabbing two groups of patients who, of course, you try to make as similar as you can, but there may be differences between the groups that you can't control." CP 901 (Bush Depo at 52); CP 657

(Laramore Depo at 63: "And so there may be a mismatch in the patient cohorts under the study. This is the purpose of doing a randomized trial."). It is undisputed that no randomized trial compares PBT and IMRT.

Regardless, even the non-controlled studies upon which Strauss relies offer mixed conclusions on the theoretical benefit of PBT—another point that Strauss's own experts concede. CP 683 (Bush Depo at 68: "[t]here's data, I think, to support both sides."). Indeed, a significant number of dosimetric and comparative studies suggest that IMRT results in the same or fewer side-effects than PBT. For example, as NCCN noted:

> The largest retrospective comparative effective analysis to date comparing IMRT to proton therapy has been performed using SEER-Medicare claims data .... With follow-up as mature as 80 months and using both propensity scoring and instrumental variable analysis, the authors concluded that men receiving IMRT therapy had statistically lower gastrointestinal morbidity than patients receiving proton therapy, whereas rates of urinary incontinence, non-incontinence urinary morbidity, sexual dysfunction, hip fractures, and additional cancer therapies were statistically indistinguishable between the cohorts.

CP 368. Many other studies have reached the same conclusion. CP 421,428-31 (Beer Report); also CP 1300 ("there was no advantage of protons over photons."). In sum, and as the Superior Court and the Court of Appeals concluded, Strauss cannot show that PBT is superior to IMRT as a matter of law when there is no direct clinical evidence establishing that fact, and even the predictive and comparative literature disputes it.

For these reasons, the medical community considers IMRT the standard of care for radiation therapy to treat prostate cancer. This is reflected in the fact that no recognized national association of radiologists or oncologists recommends PBT. CP 416 (Beer Report); CP 827 (Laramore Depo at 248-49); CP 439-40, 940 (Bush Depo at 185-86, 202-05); CP 663 (Russell Depo at 30). On the contrary, NCCN's and ASTRO's guidelines, which reflect the generally accepted consensus among experts in this field, uniformly state that there is "no clear evidence" that PBT offers any clinical advantage over IMRT. CP 368, 482 (NCCN Guidelines); CP 642 (ASTRO). Strauss's expert, Dr. Laramore, agreed with that statement. CP 827 (Laramore Depo at 247-48).

No doubt for these same reasons Strauss's Washington doctors did not recommend PBT (and only Dr. Bush at Loma Linda, where Strauss received the treatment, did). CP 84, 110 (Lin Depo at 44, 64); CP 88 (Russell Depo at 32-33); CP 91 (Stewart Depo at 103-04); CP 81 (Jensen Depo at 88-89). In fact, Dr. Russell told Strauss that there exists a "lack of clear, long term evidence showing improved side effect profile for patients who undergo proton therapy versus [IMRT] therapy." CP 1020.

In addition, medical experts with the two independent review organizations, IROs, Medical Review Institute of America (MRIoA) and Managing Care Managing Claims (MCMC), reviewed Strauss's claim—as required by Washington law—and agreed with Premera that Strauss's PBT was not "medically necessary." CP 272-74; 292-95; 308-13. Washington law requires that IRO reviewers make determinations "based upon their expert medical judgment, after consideration of relevant medical, scientific and cost-effectiveness evidence, and medical standards of practice in the state of Washington." RCW 48.43.535(6). Strauss has not contended that MRIoA or MCMC violated this standard. Indeed, an IRO may "override the health plan's medical necessity ... standards" if they are "unreasonable or inconsistent with evidence-based medical practice," *id*., but both MRIoA and MCMC upheld Premera's denial of Strauss's claim, which further substantiates Premera's denial.

For the same reasons, the federal Western District of Washington, in *Baxter*, 958 F. Supp. 2d 1223, held as a matter of law that PBT was not a "medically necessary" treatment for prostate cancer under the terms of a health care plan that contained the identical definition of "medically necessary" that is at issue here. *Compare* 958 F. Supp. 2d at 1228-29, 1233 to CP 212. As in the case at bar, the plaintiff in *Baxter* concluded that receiving PBT at Loma Linda was "the best option" for him, and like here, his claim, internal appeals, and IRO were denied on the basis of the Plan's "medically necessary" term because the "clinical outcomes with this treatment have not been shown to be superior to other approaches including intensity modulated radiation therapy (IMRT)." Id. at 1225-26. Notably, the plaintiff submitted letters from his treating physician at

Loma Linda and Dr. Laramore—the same expert who testified for Strauss in this case—to support the alleged superiority of PBT to IMRT. *Id*. at 1226.

The district court in *Baxter* concluded as a matter of law that PBT was not "medically necessary" under the plan because the plaintiff did not meet "his burden to show that there is a genuine issue of material fact whether proton therapy is superior to IMRT." *Id*. at 1237. In reaching its conclusion, the court held that whether PBT was medically necessary notwithstanding the availability of IMRT "must be answered based on clinical outcomes of patient treatment"—specifically, randomized clinical trials—because, among other reasons, the "inconsistencies in the current observational studies [cross-study comparisons] comparing proton therapy with other modalities of treatment for prostate cancer are consistent with NCCN's conclusion that ... clinical trials have not yet yielded data that demonstrates superiority to, or equivalence of, proton beam and conventional external beam for treatment of prostate cancer."[3] *Id*. at 1234, 37-38.

Likewise, here the Court of Appeals properly affirmed the district court's dismissal of Strauss's claim by applying the Plan's "medically necessary" requirement to the record facts.

2. Strauss Mischaracterizes the Court of Appeals' Holding As Requiring All Health Insureds To Prove a Proposed Treatment is "Medically Necessary" With Randomized Clinical Trials That Conclusively Establish a Treatment's Superiority.

Strauss mischaracterizes the Court of Appeals' holding in an attempt to make it plausibly satisfy RAP 13.4(b)'s fourth standard. According to Strauss:

> 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.

Pet. at 2.

The Court of Appeals did not so hold, and it made no such generalization. Rather, the Court of Appeals' decision was based on the specific facts, including the pertinent Plan language

[3] *Baxter* involved an employee benefit plan governed by ERISA, but the court's analysis was not affected by ERISA. The court applied a de novo review standard to the health insurer's denial of coverage. *Id*. at 1227. The court decided the issue under an identical summary judgment standard as the Superior Court and the Court of Appeals applied here. *Id*. As in the case at bar, the issue was whether PBT satisfied the plan's identical definition of "medically necessary." *Id*. at 1228.

and scientific evidence, particular to this case. The Court of Appeals held that, on the record before it, Strauss had failed to carry his burden to prove that PBT was medically necessary, as defined by Premera's policy, and therefore covered by the policy. *Strauss*, 408 P.3d at 711-12. As in *Baxter*, here the Court of Appeals did rely on the absence of randomized clinical trials, because of the lack of any other evidence that PBT was superior to IMRT, considering that it is substantially more expensive. *Baxter*, 958 F.Supp.2d 1237 ("The inconsistencies in the current observational studies comparing proton therapy with other modalities of treatment for prostate cancer are consistent with the NCCN's conclusion that the use of proton therapy is not recommend for routine use in the treatment of early stage prostate cancer at this time 'since clinical trials have not yet yielded data that demonstrates superiority to, or equivalence of, proton beam and conventional external beam for treatment of prostate cancer.'").

The Court of Appeals applied well-settled law to the factual record before it. There simply is no dispute about the law applied by the Court of Appeals. The parties did not disagree, in their briefing or at oral argument, about the legal standard to apply to the facts of this case. The Court of Appeals' holding followed fundamental Washington insurance coverage law concerning interpretation of policy contracts and the insured's burden of proof. Applying these principles of insurance law, the Court of Appeals held that Strauss failed to satisfy his initial burden to offer evidence that proton beam therapy was medically necessary, as defined by Premera's policy, and therefore covered by the policy. *Strauss*, 408 P.3d at 701.

Therefore, the Court of Appeals did not address any unsettled issue of substantial public interest. There is no confusion among litigants in Washington courts about the principles of law that are to be applied to insurance contracts. Further, other courts that have addressed the issue of whether proton beam therapy for prostate cancer is medically necessary have unanimously come to the same conclusion as the Court of Appeals, including a prior decision applying Washington law.[4]

[4] *See Baxter*, 958 F. Supp. 2d 1223; *Woodruff v. Blue Cross & Blue Shield of Alabama*, No. 2:16-CV-00281-SGC, 2018 WL 571933, at *9 (N.D. Ala. Jan. 26, 2018) (Applying de novo review standard: "The Plan's provisions concerning experimental treatments, as well as the multiple

The Court of Appeals reasoned as follows:

First, the Court of Appeals noted that "[t]he policy covered 'medically necessary' treatment, including 'radiation.'" *Strauss*, 408 P.3d at 701.

Second, the Court of Appeals turned to the Plan's definition of "medically necessary." "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." *Id.*

As the Court of Appeals noted, the policy further provides, "'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." *Id.*

Third, because the medical necessity requirement appears in the section of the policy that describes the benefits provided, the Court of Appeals followed the well-established principle, "The party seeking to establish coverage bears the initial burden of proving coverage under the policy." *Id.* (citing *Pleasant*, 181 Wn. App. at 261–62, 325 P.3d 237).

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layers of medical review which consistently concluded [PBT] was investigatory and therefore not covered under the Plan, substantiates the reasonableness of [Blue Cross Blue Shield's] decision to deny the plaintiff's claim for benefits"); *Turner v. Alcoa Inc.*, No. 3:15-CV-270-TAV-HBG, 2016 WL 8257672 (E.D. Tenn. Dec. 29, 2016) (Magistrate's report and recommendation, holding that insurer's denial of proton beam therapy for prostate cancer was not arbitrary or capricious, writing "it is not the Court's role to determine which study prevails. Instead, the Court's role is to determine whether the administrator's decision was the "result of a deliberate, principled reasoning process ...supported by substantial evidence."); *Turner v. Alcoa, Inc.*, No. 3:15-CV-270-TAV-HBG, 2017 WL 627447 (E.D. Tenn. Feb. 15, 2017) (adopting Magistrate's report and recommendation in whole, writing "several district courts faced with a situation similar to that facing the Court in this case upheld a plan administrator's determination that proton beam therapy is experimental/investigative when used to treat prostate cancer."); *Gardner v. Grp. Health Plan*, No. 5:09-CV-00152-BO, 2011 WL 1321403, at *7 (E.D.N.C. Apr. 4, 2011) ("Defendant's decision to deny coverage [for PBT] was reasonable, supported by substantial evidence, and in no way an abuse of discretion. Indeed, it is the only conclusion Defendant could have made under the clear language of the plan."); *Dillon v. Timken Co.*, No. CIV. 11-195 ERIE, 2013 WL 4508975, at *1 (W.D. Pa. Aug. 26, 2013) ("The documents in this case overwhelmingly show that the Defendant did not abuse its discretion in its denial of benefits to Mr. Dillon [under an ERISA plan for PBT].")

Fourth, the Court of Appeals held that Strauss failed to carry the initial burden as to coverage because: (i) "Strauss does not dispute that PBT is more costly than IMRT [intensity modulated radiation therapy, which Premera offered to cover] 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," *id*. at 710, and (ii) "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." *Id*. at 711 (citing *Baxter*, 958 F.Supp.2d at 1234 (rejecting argument that the side effects of PBT are superior to IMRT)); *see also, id*. at 710 ("The insurer is entitled to summary judgment if reasonable minds could not differ that its denial of coverage was based upon reasonable grounds.").

Nowhere does the Court's opinion say that, as a matter of law, PBT is not a medically necessary treatment for prostate cancer in the absence of "published clinical studies directly comparing" PBT and traditional radiation therapy. Therefore, the Court of Appeals' decisiondoes not meet the requirements of RAP 13.4 because the Court decided the case on the facts and did not address an unsettled issue of substantial public interest.

VII. CONCLUSION

The petition does not satisfy any of the requirements of RAP 13.4(b), and therefore should be denied.

DATED: February 28, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury of the laws of the State of Washington that on the 28th day of February, 2018, I caused to be served a copy of the foregoing on the following person(s) in the manner indicated below at the following address(es):

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February 28, 2018 - 1:54 PM

Transmittal Information

Filed with Court:	Supreme Court
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Appellate Court Case Title:	John Strauss and Michelle Strauss v. Premera Blue Cross
Superior Court Case Number:	13-2-28143-1

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