74600-6

No. 95449-6

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.

FILED
Jun 10, 2016
Court of Appeals
Division I
State of Washington

APPEAL FROM THE SUPERIOR COURT
FOR KING COUNTY
THE HONORABLE MONICA J. BENTON

BRIEF OF APPELLANTS

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I. INTRODUCTION

Appellant John Strauss had health insurance through respondent Premera Blue Cross ("Premera"). Premera provided coverage for medically necessary treatments that a prudent physician would provide as clinically appropriate and effective for treating an insured patient's illness, that were not primarily for the convenience of the patient or physician, in accordance with generally accepted standards of medical practice, and more effective than a less expensive alternative treatment.

Mr. Strauss was diagnosed with prostate cancer. Premera denied coverage for proton beam therapy ("PBT"), a form of radiotherapy recommended by Mr. Strauss' oncologist as a "medically necessary" treatment – an opinion supported by peer reviewed medical literature demonstrating that PBT provided superior treatment with fewer side effects. In denying coverage, Premera relied on a pediatrician with no knowledge of or expertise in radiology or oncology who cited the lack of randomized clinical trials conclusively proving that PBT had a superior "side effect profile," even though Premera's policy does not require such randomized clinical evidence in order for a treatment to qualify as medically necessary.

At a minimum, the opinions of Mr. Strauss' clinical oncologist and an expert oncologist raised a triable issue of fact whether proton beam therapy was superior and a medically necessary treatment under the Premera policy that could not be resolved on summary judgment. A jury also could find that Premera's investigation failed to comport with its duty of good faith and was thus unfair and deceptive. This Court should reverse the summary judgment order and remand for a trial of Mr. Strauss' breach of contract, insurance bad faith, and Consumer Protection Act claims.

II. ASSIGNMENTS OF ERROR

The trial court erred in entering its Order Granting Premera Blue Cross's Motion for Summary Judgment. (CP 1472-73) (App. A)

III. STATEMENT OF ISSUES

1. Did the trial court err in holding as a matter of law that a health insurer properly denied coverage for proton beam therapy for prostate cancer despite expert testimony supported by numerous peer reviewed studies establishing PBT was "medically necessary" under the terms of its policy?

2. Did the health insurer breach its statutory and common law duty of good faith by denying its insured's claim for coverage for cancer treatment based on an erroneous reading of the

policy and by assigning a physician who lacked training and expertise to investigate the issue of medical necessity?

IV. STATEMENT OF THE CASE

Because Mr. Strauss was the nonmoving party, this Court views the evidence in the light most favorable to him in determining whether a reasonable jury could have found in his favor on his claims for breach of contract, insurance bad faith, and violation of the Consumer Protection Act. *Versuslaw, Inc. v. Stoel Rives, LLP*, 127 Wn. App. 309, 320, ¶22, 111 P.3d 866 (2005), *rev. denied*, 156 Wn.2d 1008 (2006).

A. After being diagnosed with "high intermediate risk" prostate cancer, Mr. Strauss sought proton beam radiotherapy to minimize the severity of side effects associated with prostate cancer treatments.

In October 2008, when he was 59 years old, appellant John Strauss was diagnosed with prostate cancer. (CP 69, 72, 1336) Given his age, tumor staging, and the nature of his "high-volume" and "high-grade disease," his physician advised Mr. Strauss "to seek treatment to address his prostate cancer" rather than engage in "active surveillance." (CP 1336-37, 777, 96)

There are several treatment options for intermediate risk prostate cancer: (1) surgery (prostatectomy); (2) external beam radiotherapy (standard radiation therapy using photon beams, the

most common method being intensity modulated radiation therapy, or "IMRT"); (3) proton beam therapy; or (4) brachytherapy (seed implant) in combination with IMRT, plus or minus the use of additional hormonal therapy. (CP 88, 691, 94) Mr. Strauss' physician Dr. Lin recommended surgery or radiation, and because Mr. Strauss had a history of heart problems that made surgery inadvisable, Mr. Strauss and his physicians determined that radiotherapy would be the best treatment option for him. (CP 88, 110, 700)

In November 2009, Mr. Strauss consulted with Dr. David Bush, a Board Certified oncologist at Loma Linda University Medical Center ("Loma Linda") in Loma Linda, California. (CP 241, 1334, 1392) Loma Linda is located approximately an hour away from Mr. Strauss' residence and provides proton beam therapy for prostate cancer treatment. (CP 700, 1334, 1393) Dr. Bush recommended PBT over IMRT to Mr. Strauss, as his cancer "was still within the gland" and thus "appropriate to be treated with the proton beam radiation." (CP 1392) Although more expensive than IMRT (CP 243), PBT is superior in that it results in fewer side effects caused by radiation to healthy tissues. (*See* CP 1125-26) With PBT, "the volume of normal tissue receiving radiation is typically reduced by a factor of 2-3, even

when compared to a modern, refined, x-ray based treatment plan" such as IMRT.[1] (CP 1125)

Mr. Strauss began receiving proton beam therapy treatment from Dr. Bush at Loma Linda in February 2010. (CP 249) Since he finished treatment in April 2010, his physicians have described Mr. Strauss' outcome as "[e]xcellent." (CP 133, 137)

B. Prior to receiving proton beam therapy, Mr. Strauss sought coverage for his treatment under his policy with Premera Blue Cross.

1. Premera's medical insurance policy provides "medically necessary" treatment for its insureds.

Prior to receiving proton beam therapy, Mr. Strauss sought coverage for the treatment under his Premera policy. (CP 10, 241) The Strauss' policy with Premera provided coverage for "medically necessary" treatments "furnished in a medically necessary setting." (CP 177) An endorsement to the policy, effective January 1, 2008 (CP 208), defined "medically necessary" as:

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[1] As Dr. Bush noted, although IMRT is considered by many to be the standard radiation treatment, "the use of conformal proton beam therapy in prostate cancer treatment pre-dates the introduction of IM[R]T by approximately two decades," and "[m]any of the techniques required to deliver IM[R]T . . . were first developed for conformal proton beam treatment" before being "adapted by the radiation oncology community at large." (CP 1126) "[P]ublished data on the safety and efficacy of conformal proton beam radiotherapy in the treatment of prostate cancer has been available for over three decades." (CP 1126)

> 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 patients illness, injury or disease.

(CP 212)

The endorsement further defined "generally accepted standards of medical practice":

> [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)

2. Premera denied Mr. Strauss' request for coverage for proton beam therapy on the grounds that "clinical outcomes" had not shown PBT to be more effective or cost-efficient than traditional radiation.

Dr. Bush submitted a pre-authorization request for Mr. Strauss' proton beam radiation therapy on November 12, 2009. (CP 241) The medical examiner that reviewed Mr. Strauss' claim was Dr. Neil Kaneshiro, a pediatrician with a pediatric practice who had been working part-time for Premera as an Assistant Medical Director since 2000 or 2001, reviewing requests for medical procedures two days a week. (CP 1360-61, 1364)

Dr. Kaneshiro admits he is "not an expert" on Gleason scores[2] and their significance, did not review any peer-reviewed literature on proton beam therapy, and did not consult an oncologist when reviewing Mr. Strauss' request. (CP 1362, 1363, 1366, 1368) Instead, Dr. Kaneshiro denied the request on the grounds that it was not medically necessary "because the clinical outcomes have not been

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[2] Beam radiation therapy is appropriate for more aggressive cancers. (*See* CP 110) Oncologists determine the severity of a patient's prostate cancer by looking at a patient's T stage, Gleason score, and PSA. While low-risk patients have Gleason scores of three plus three, a T stage of T1c, and PSA of less than 10, Mr. Strauss had a Gleason category of "four plus three rather than three plus four," a PSA of 14.9, in addition to being T2B. (CP 777, 1336) All of these factors combined put Mr. Strauss at "the higher end of the intermediate risk profile." (CP 777, 1336-37)

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." (CP 243)

In denying coverage, Dr. Kaneshiro relied on Premera's Corporate Medical Policy (CP 1335-36)[3], which provides that proton beam therapy "may be considered not medically necessary in patients with localized prostate cancer because the clinical outcomes with this treatment have not been shown to be superior to other approaches." (CP 1005) Dr. Kaneshiro noted that Mr. Strauss had localized prostate cancer, and made his decision based on that information. (CP 1005, 1368) Dr. Kaneshiro admitted that he "didn't have any specific knowledge on what IMRT costs, what proton costs" (CP 1368); notwithstanding its express disclaimer that it is not contractually binding, he instead based his understanding of costs solely on Premera's Corporate Medical Policy. (CP 1004, 1368) Dr. Kaneshiro looked at Mr. Strauss' medical records, but he did not talk

[3] The Corporate Medical Policy includes this disclaimer: "Medical policies are systemically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures." (CP 1004) Such policies are not part of an insured's contract, but rather "a guide in evaluating the medical necessity of a particular service or treatment." (CP 1004)

to Dr. Bush at Linda Loma about PBT as a treatment for Mr. Strauss' condition because Dr. Kaneshiro did not "feel[] the need to." (CP 1369)

3. Mr. Strauss exhausted his administrative remedies by appealing Premera's decision three times.

Premera's internal review process allows an insured to appeal a denial of coverage by requesting a Level I Appeal. Following the determination of the Level I Appeal panel, a policyholder may request a Level II Appeal before a panel of individuals who did not participate in any earlier decisions regarding the request for coverage. If a Level II Appeal affirms denial of coverage, a policyholder may request an independent review by an outside Independent Review Organization ("IRO"). The IRO's coverage decision is binding on Premera. (CP 244-45, 290)

Mr. Strauss appealed Premera's decision in accordance with Premera's internal review process. (CP 244-45, 247-53) Mr. Strauss' cardiologist, Dr. Douglas Stewart, submitted a letter to Premera "advocating that [Mr. Strauss] be approved for the proton beam therapy" "considering his cardiac condition." (CP 253) Dr. Stewart noted that while comparative studies between PBT and IMRT are not yet available, PBT is an approved treatment and "there is strong

preliminary evidence that the side effects associated with proton beam therapy are significantly lower." (CP 253)

As part of its appeals process, Premera submitted Mr. Strauss' claim to the Medical Review Institute of America ("MRIoA"), an independent review organization, for a "same specialty" review, as required by WAC 284-43-525. (CP 272-75, 25) MRIoA erroneously relied on an outdated contract definition of "medically necessary" in finding that proton beam therapy was not medically necessary because "the evidence of clinical efficacy of proton therapy relies to a large extent on non-controlled studies, and this is associated with a low level of evidence according to standards of health technology assessment and evidence-based medicine criteria." (CP 273, 288) MRIoA concluded that because "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," PBT was not covered by the policy. (CP 274) On February 1, 2010, Premera denied Mr. Strauss' Level I Appeal based on the MRIoA report. (CP 277)

Deciding not to further delay his treatment, Mr. Strauss received proton beam therapy at Loma Linda University Medical Center in February 2010 (CP 249), and filed a Level II Appeal to Premera. (CP 280) Mr. Strauss' oncologist Dr. Bush supported the

appeal with a "Letter of Medical Necessity" detailing the benefits of PBT as compared to IMRT (referred to as "Intensity Modulated X-ray Therapy," or "IMXT," in Dr. Bush's March 29, 2010 letter). (CP 1124-26) In addition to his own clinical expertise with prostate cancer and PBT in particular, Dr. Bush based his recommendation on 22 articles and studies, "including data obtained in a prospective *randomized* fashion."[4] (CP 1126, 1127-28) (emphasis added)

In the course of the Level II Appeal, Premera discovered that MRIoA had relied on the outdated definition of "medically necessary" when reviewing Mr. Strauss' claim. (CP 288) Premera resubmitted the appeal to MRIoA with the correct contract language. (CP 288) Both reviews concluded that proton beam therapy was not medically necessary. (CP 289) Premera denied Mr. Strauss' Level II Appeal on April 9, 2010. (CP 288-90)

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[4] There have in fact been several clinical studies demonstrating that proton beam therapy results in fewer side effects than IRMT. One study, published in the *Journal of Clinical Oncology* in 2010, and collected "long-term data on patients treated on a prospective, randomized dose escalation trial" between 1996 and 2000. (CP 1126) The data showed that the high-dose group exhibited "statistically significant improvement in biochemical disease-free survival," and that "a radiation oncologist can use conformal proton beams to dose-escalate without increasing long-term patient side effects." (CP 1126) These findings are in contrast to at least "one large prospective, randomized, IMXT-based prostate cancer trial [that] has reported that increasing radiation dose to levels approximately equivalent to that which" was delivered at Loma Linda University Medical Center "was associated with a substantial increased risk" of rectal side effects. (CP 1126)

Mr. Strauss appealed by choosing to have Premera submit the case to an Independent Review Organization "for a coverage decision that will be binding" on Premera. (CP 290, 297) Premera submitted the appeal request to the Washington State Office of Insurance Commissioner, which assigned it to Managing Care Managing Claims ("MCMC") for independent review. (CP 302-03, 305-06) MCMC upheld Premera's denial of coverage, concluding:

> *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 or HDR, 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.

(CP 309) (emphasis added)

C. Mr. Strauss brought this action against Premera for breach of contract, insurance bad faith, and violation of the Consumer Protection Act.

The Strausses sued Premera in August 2013, alleging breach of contract, insurance bad faith, and violation of the Consumer Protection Act. (CP 2-9) Premera moved for summary judgment (CP 19-43), arguing "[t]here is <u>no</u> evidence that PBT results in any better outcomes for patients with prostate cancer." (CP 19) (emphasis in original)

The parties agreed that on the breach of contract claim, "[t]he only issue before the Court is whether PBT is medically necessary because it leads to fewer side effects." (CP 19, 748) Mr. Strauss' expert Dr. George Laramore,[5] addressed the superior side effect profile of PBT in a declaration filed in response to Premera's motion. (CP 1337-54)

There are four primary side effects that can result from either form of radiotherapy. The first is sexual function, which is "often a key factor when a patient chooses a particular treatment for prostate cancer." (CP 1347: at the time of his diagnosis, Mr. Strauss had excellent sexual function) The second is the risk of bladder and bowel dysfunction from excess radiation. (CP 1338) The third side effect is the risk of joint deterioration and the development of hip symptoms. (CP 1348) The fourth side effect is the risk of secondary malignancy, or secondary cancer. (CP 1338, 1348-50) In analyzing these side effects, Dr. Laramore cited 27 different articles and

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[5] Dr. Laramore is Board Certified with the American Board of Radiology in both Therapeutic Radiology and Radiation Oncology, and is a Fellow of the American College of Radiology. (CP 1332) Having completed his residency in radiation oncology in 1980, served as the University of Washington Department Chair in Radiation Oncology for 16 years, and written research protocols for treating most of the major cancers, Dr. Laramore's knowledge, skills, and experience qualify him as one of the foremost experts in radiation oncology. (CP 1332)

studies, (CP 1352-54)[6] to support his conclusion that "[a]lthough IMRT and Proton Radiotherapy are biologically equivalent in radiating the prostate tumor" (CP 1335), they "are not equivalent in terms of the side effect profile and so the overall therapeutic results

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[6] These clinical studies all demonstrate fewer side effects from PBT than IMRT. For instance, several studies have shown that lower radiation doses to the penile bulb are "significant for maintaining sexual function," while "a median dose" "was associated with a greater risk of subsequent impotence." (CP 1347) Because "[p]roton radiotherapy with its more precise targeting will generally result in a lower dose to the penile bulb than IMRT photon irradiation," these studies support the conclusion that PBT will result in less detriment to sexual potency than IMRT. (CP 1348)

Another study at the University of Florida Proton Therapy Institute focused on treatment related side effects on "a mix of patients with low, intermediate, and high risk tumors," accounting for the range of radiation doses that were given. (CP 1346) The study concluded that incidence of rectal bleeding "strongly correlated" with the percentage of the rectal wall receiving radiation. (CP 1346)

A separate study analyzed the radiation dose to the rectum with PBT and IMRT "and found a substantially lower dose with proton radiotherapy." (CP 1346) In comparing both treatments at low and high radiation doses, "the amount of rectum treated was twice as large with IMRT as compared to proton radiotherapy." (CP 1347) These studies support the finding that "[t]he low rectal doses achievable with proton radiotherapy" "account for the low incidence of rectal toxicity noted with this modality." (CP 1347)

Yet another study examined the risk of secondary malignancy, as "patients treated with ionizing radiation . . . are at increased risk of developing another cancer in the irradiated area." (CP 1348) The probability of a second cancer occurring "relates to both the delivered dose and the volume of tissue treated and so varies according to the region of the body treated." (CP 1348) One study "critically reviewed" the "many treatment planning studies estimating the risk of radiation induced second malignancies" and "concluded that dose planning studies consistently showed a risk reduction with proton radiotherapy" compared to "either 3-D conformal or IMRT photon radiation." (CP 1350)

are not equivalent but would be better with proton radiotherapy." (CP 1351) (emphasis in original)

During the summary judgment hearing, however, Premera argued that "this is a theoretical – frankly, on both sides – argument, because there are no clinical trials," claiming that "[t]here is no scientific evidence that [proton beam therapy] is a superior treatment." (RP 32) Premera argued that since both sides were relying on "theory," it was entitled to summary judgment:

> And to say that, [w]ell, just give a chance for Dr. Laramore to come talk to a jury. Maybe Dr. Laramore could convince a jury. Maybe he could. I think Dr. Laramore is an impressive individual and will be, you know, dazzling to a jury. I found him impressive when I deposed him. However, that's not the law. The law is there has to be credible scientific evidence, not theory, that would show that this treatment was superior and not more costly. There just isn't.

(RP 32)

The trial court granted Premera's motion for summary judgment, dismissing all of Mr. Strauss' claims. (CP 1472-73) The Strausses appeal. (CP 1469)

V. ARGUMENT

A. This Court reviews the record in the light most favorable to Mr. Strauss, the nonmoving party.

This Court reviews the trial court's summary judgment order de novo and views the evidence and all facts and reasonable inferences in the light most favorable to the nonmoving party. *Keck v. Collins,* 184 Wn.2d 358, 357 P.3d 1080 (2015). The moving party "has the initial burden to show the absence of an issue of material fact, or that the plaintiff lacks competent evidence to support an essential element of [his] case." *Seybold v. Neu,* 105 Wn. App. 666, 676, 19 P.3d 1068 (2001). If the defendant meets this burden, the inquiry shifts to the plaintiff. *Seybold,* 105 Wn. App. at 676.

Summary judgment is proper only "if the pleadings, affidavits, depositions, and admissions on file demonstrate the absence of *any* genuine issues of material fact," and "reasonable minds could reach but one conclusion on the evidence." *Versuslaw, Inc. v. Stoel Rives, LLP,* 127 Wn. App. 309, 319, ¶22, 111 P.3d 866 (2005) (citing CR 56(c)) (emphasis added). "Where different competing inferences may be drawn from the evidence, the issue must be resolved by the trier of fact." *Versuslaw,* 127 Wn. App. at 320, ¶22.

B. There was a genuine issue of material fact regarding whether proton beam therapy was "medically necessary."

In light of competent expert evidence that proton beam therapy was "medically necessary," the trial court erred in granting Premera's motion for summary judgment by imposing a requirement of randomized clinical studies that is not contained in the policy.

1. Proton beam therapy is medically necessary under the plain language of Premera's policy.

Proton beam therapy is "medically necessary" as defined by the plain language of the policy. This Court "interpret[s] an insurance policy using contract analysis as a matter of law." *Moeller v. Farmers Ins. Co. of Wash.*, 155 Wn. App. 133, 140, ¶12, 229 P.3d 857 (2010), *aff'd* 173 Wn.2d 264 (2011). "The court examines the terms of an insurance contract to determine whether under the plain meaning of the contract there is coverage." *Kitsap County v. Allstate Ins. Co.*, 136 Wn.2d 567, 576, 964 P.2d 1173 (1998). "If terms are defined in a policy, then the term should be interpreted in accordance with that policy definition." *Kitsap County*, 136 Wn.2d at 567.

a. Medical necessity turns on whether proton beam therapy had a superior side effect profile.

The Premera policy provided coverage for "medically necessary" treatments "furnished in a medically necessary setting." (CP 177) "Medically necessary" is defined by the policy as:

> 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) (emphasis added) The policy further defines "generally accepted standards of medical practice" by reference to "credible scientific evidence:"

> [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)

Premera conceded below that the issue of medical necessity turned solely on whether proton beam therapy has a superior side effect profile to IMRT. (CP 19, 748; RP 14) That question is essentially a factual one. As the evidence before the trial court, viewed in the light most favorable to Mr. Strauss as the nonmoving party, raised a triable issue of fact regarding PBT's side effects, Mr. Strauss was entitled to present his claims to the jury.

b. Proton beam therapy has fewer adverse side effects.

Expert testimony and medical literature established proton beam therapy's superior side effect profile. Mr. Strauss presented his physicians' recommendations and other credible scientific evidence to survive summary judgment.

Two highly-qualified, Board Certified radiation oncologists testified to proton beam therapy's superiority, basing their conclusions on credible scientific evidence. (CP 1124, 1335) In addition to recommending PBT for Mr. Strauss in November 2009 (CP 241), Dr. Bush submitted a three-page letter to Premera detailing

PBT's benefits as a medically necessary treatment. (CP 1124-26) Dr. Bush relied upon 22 different sources of credible scientific literature published in reputable, peer reviewed journals such as the *Journal of Clinical Oncology*, including studies and data obtained in a "prospective, *randomized* dose-escalation trial." (CP 1126, 1127-28) (emphasis added). Dr. Bush concluded that "[c]onformal proton beams represent the 'ultimate' form of conformal treatment delivery because of their inherent superior dose-deposition characteristics," and thus "a radiation oncologist can use conformal proton beams to dose-escalate without increasing long-term patient side effects." (CP 1126)

Dr. Laramore, who by Premera's own admission is an "impressive" expert (RP 32), supported Dr. Bush's clinical view that proton beam therapy treatment was medically necessary and had a superior side effect profile to IMRT. (CP 1336) "Rel[ying] upon credible scientific evidence" and 27 "studies published in peer review medical literature that is generally accepted by the oncology medical community" (CP 1336), Dr. Laramore concluded that "while IMRT and proton radiotherapy . . . may be expected to give approximately the same tumor control probability, they <u>are not equivalent</u> in terms of the side effect profile," and thus "the <u>overall</u> therapeutic results are

not equivalent *but would be better with proton radiotherapy*." (CP 700) (underline in original, italics added) Thus, whether PBT had fewer side effects than IMRT presented, at a minimum, an issue of material fact that precluded summary judgment.

2. The trial court imposed conditions on Mr. Strauss' treatment that went beyond the plain language of the policy.

The trial court's dismissal was not based on Premera's policy language, but on Premera's argument that Mr. Strauss fell short of his burden in proving that proton beam therapy has a superior side effect profile to IMRT because (1) "[t]here are no randomized controlled studies to show superiority," (2) "no clinical practice guidelines support the use for PBT in prostate cancer outside of controlled studies," and (3) "none of Mr. Strauss' treating physicians in Washington recommended PBT to him." (CP 40) Premera contended that Mr. Strauss' evidence was "inadmissible theoretical evidence [that] relies heavily on cross-study comparisons" (CP 40) – comparisons between the "results of one clinical study to an entirely separate study." (CP 33) But Premera's policy language requires neither randomized controlled studies, clinical practice guidelines, nor a treating physician's recommendation in order for a treatment to be deemed "medically necessary." The trial court erred by using

the wrong criteria to interpret the policy definitions and by ignoring credible scientific evidence demonstrating a factual dispute between the efficacy of PBT and IMRT, impermissibly deciding as a matter of law an issue that should have gone to the jury.

a. Premera's policy does not require that medical necessity be established by randomized clinical trials or be recommended by practice guidelines.

The policy requires neither evidence from randomized clinical trials nor that a treatment be recommended by practice guidelines for it to be medically necessary. To be "medically necessary," a treatment must be, among the other factors, "[i]n accordance with generally accepted standards of medical practice." (CP 212) As defined by the policy, a treatment is in accord with such "generally accepted 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." (CP 212)

Because the policy allows for consideration of "any other relevant factors," "generally accepted standards of medical practice" can be established in a variety of ways and no particular weight should be given to any one factor listed in the definition. The

Insurance Commissioner's regulations confirm that no one factor is controlling. *See* WAC 284-43-5440(3) ("An issuer's medical necessity determination process may include, but is not limited to, evaluation of the effectiveness and benefit of a service for the individual patient based on scientific evidence considerations, up-to-date and consistent professional standards of care, convincing expert opinion and a comparison to alternative interventions, including no interventions.")

Both Dr. Bush and Dr. Laramore based their opinions on "credible scientific evidence," including peer-reviewed medical literature and a total of 49 reputable cited sources and studies. Both Dr. Bush and Dr. Laramore are radiation oncologists and provided their opinions and views as "physicians practicing in relevant clinical areas." (CP 1332, 892-93; *see* CP 212) Although there have been no randomized clinical studies comparing IMRT and proton beam therapy, both Dr. Bush and Dr. Laramore provided a plethora of admissible and *credible scientific evidence* that PBT is in accord with "generally accepted standards of medical practice," thereby satisfying the "medically necessary" definition of Premera's policy.

b. Premera's policy does not require that a Washington provider expressly recommend a treatment.

Under the plain language of the policy, a treatment is medically necessary if it is one "that a physician, exercising prudent clinical judgment, would provide to a patient," and is "[c]linically appropriate" and "considered effective" for the patient's illness. (CP 212) The policy nowhere requires that a Washington physician expressly recommend the treatment; the treatment must merely be one that the physician *would* provide to a patient as being clinically appropriate and effective for that patient's illness. Regardless, Dr. Lin (a Washington physician) *did* recommend radiotherapy to Mr. Strauss, finding that either IMRT or proton beam therapy would be an appropriate treatment for his prostate cancer. (CP 110) Dr. Bush, exercising his prudent clinical judgment, not only recommended but actually provided PBT to Mr. Strauss at Loma Linda because it was clinically appropriate and effective for treating his prostate cancer. (CP 241, 1392)[7]

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[7] Although Premera's policy was issued in Washington, the Strausses own a residence in California, approximately an hour away from where he was treated at Loma Linda Medical Center. (CP 1334)

c. Proton beam therapy's superiority is based on credible scientific evidence.

Premera's characterizations of Dr. Bush's and Dr. Laramore's testimony as "inadmissible theoretical evidence" because it was not based on randomized clinical studies is without merit. Just as scientific evidence need not be based on randomized studies to be credible under ER 702 and 703, this type of evidence is likewise credible under the policy's definition of "medically necessary." Under the *Frye* test,[8] courts routinely admit evidence derived from a novel scientific theory or principle if that theory or principle "has achieved general acceptance in the relevant scientific community." *Kaech v. Lewis County Pub. Util. Dist. No. 1*, 106 Wn. App. 260, 273, 23 P.3d 529 (2001) (citations omitted), *rev. denied*, 145 Wn.2d 1020 (2002); *see also State v. Copeland*, 130 Wn.2d 244, 922 P.2d 1304 (1996).

"General acceptance may be found from a number of sources, including from 'testimony that asserts it, from articles and publications, from widespread use in the community, or from the holdings of other courts.'" *Advanced Health Care, Inc. v. Guscott*,

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[8] *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923).

173 Wn. App. 857, 872, ¶29, 295 P.3d 816 (2013) (quoted source omitted); *see also Kaech*, 106 Wn. App. at 273 ("The court may look *to a number of sources* to determine whether it meets *Frye*.") (emphasis added). The *Frye* test is analogous to the Premera test for medical necessity, defined by "generally accepted standards of medical practice" as demonstrated through "any . . . relevant factors." (CP 212)

Even if the absence of a randomized controlled study establishing proton beam therapy's superiority made Dr. Laramore's opinion "theoretical," evidence based on scientific theory is not inherently unreliable. *See, e.g.*, *In re Detention of Taylor*, 132 Wn. App. 827, 836, ¶28, 134 P.3d 254 (2006) ("The core concern . . . is only whether the evidence being offered is based on established scientific *methodology*.") (emphasis added) (quoted source omitted), *rev. denied*, 159 Wn.2d 1006 (2007); *Advanced Health Care*, 173 Wn. App. at 873, ¶31 (specific conclusions drawn from scientific data do not have to be generally accepted in the scientific community; "*concerns about the possibility of error or mistakes made in the case at hand can be argued to the factfinder*") (emphasis in original) (quoted source omitted). Dr. Laramore relied on evidence from studies conducted with generally accepted methods to

make deductions and reach conclusions. Neither the Premera policy nor case law prohibits an expert from surveying clinical studies and scientific literature to come to a conclusion. Any arguments as to the number or accuracy of those studies, deductions, or conclusions go to the *weight* of testimony, not the admissibility of this evidence.

Baxter v. MBA Group Ins. Trust Health and Welfare Plan, 958 F. Supp. 2d 1223 (W.D. Wash. 2013), relied upon by Premera below (CP ____), is inapposite. In *Baxter*, the plaintiff sought coverage under ERISA and, as here, the issue turned on whether proton beam therapy had a superior side effect profile. Both parties moved for summary judgment on the issue, and the court found in favor of the insurer, "based on clinical outcomes of patient treatment." *Baxter*, 958 F. Supp. 2d at 1234, 1237-38. *Baxter* is distinguishable because it involved an employee benefit plan covered by ERISA, and not an issue of contract interpretation under Washington law. *In re Elliot*, 74 Wn.2d 600, 602, 446 P.2d 347 (1968) (state courts are not bound by federal court interpretations of state law); *In re Salvini's Estate*, 65 Wn.2d 442, 446-47, 397 P.2d 811 (1964) (holding that federal courts' interpretation of state statutes do not bind Washington courts).

Further, both parties in *Baxter* had moved for summary judgment, thus "conced[ing] that there were no material issues of fact." *Tiger Oil Corp. v. Dep't of Licensing, State of Wash.*, 88 Wn. App. 925, 930, 946 P.2d 1235 (1997). In such a case, the only question for the reviewing court is "whether the [trial] court's legal conclusions were correct." *Tiger Oil*, 88 Wn. App. at 930. Here, only Premera moved for summary judgment, and Mr. Strauss argued an issue of material fact regarding whether proton beam therapy is medically necessary based on credible scientific evidence published in peer reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, the views of physicians practicing in relevant clinical areas, and any other relevant factors. (CP 212)

In any event, as a district court decision, *Baxter* is not binding precedent upon this Court, even as an interpretation of ERISA. *Home Ins. Co. of New York v. N. Pac. Ry. Co.*, 18 Wn.2d 798, 808, 140 P.2d 507 (1943) (interpretation of federal law by inferior federal courts is not binding upon state courts). This Court is not required to follow *Baxter*. Nor should it, given the procedural posture of Mr. Strauss' claim under Washington's common law of contracts and insurance. This Court should reverse the trial court's summary

judgment and remand for a trial on whether proton beam therapy was "medically necessary" under Mr. Strauss' policy with Premera.

C. The trial court erred in dismissing the bad faith and CPA claims not just because of the erroneous denial of Mr. Strauss' claim but because Premera's inadequate investigation breached its statutory and common law duty of good faith.

Whether Premera breached its duty of good faith in investigating Mr. Strauss' claim and denying coverage, and whether it thus violated the Consumer Protection Act, presented factual issues for a jury to resolve. Even if this Court affirms the merits of Premera's denial of coverage, Premera may nonetheless be liable for its inadequate claims handling procedures.

An insurer has both a statutory and common law duty of good faith to its policyholder. *See* RCW 48.01.030. A violation of that duty may give rise to a tort action for bad faith. *Smith v. Safeco Ins. Co.*, 150 Wn.2d 478, 484, 78 P.3d 1274 (2003) (citing *Truck Ins. Exch. v. Vanport Homes, Inc.*, 147 Wn.2d 751, 765, 58 P.3d 276 (2002)); *see also Pleasant v. Regence Blue Shield*, 181 Wn. App. 252, 270, ¶49, 325 P.3d 237 (insured brought action against insurer for acting in bad faith by failing to provide any reasonable explanation for denying coverage of medical procedure), *rev. denied*, 181 Wn.2d 1009 (2014). "The implied covenant of good faith and fair dealing in

the policy should necessarily require the insurer . . . to conduct a reasonable investigation before denying coverage. In the event the insurer fails [to do so], it will have breached the covenant." *Coventry Associates v. American States Ins. Co.*, 136 Wn.2d 269, 281, 961 P.2d 933 (1998) (quoted source omitted). An insurer's breach of the duty of good faith is a per se violation of the CPA. *Safeco Ins. Co. of America v. JMG Restaurants, Inc.*, 37 Wn. App. 1, 11, 680 P.2d 409 (1984) ("An insurance company violates the Consumer Protection Act if it acts without reasonable justification in handling a claim by its insured.").

Because whether an insurer acted in bad faith is a question of fact, an insurer is only entitled to a dismissal on summary judgment "if there are no disputed material facts pertaining to the reasonableness of the insurer's conduct under the circumstances." *Smith*, 150 Wn.2d at 484. When reasonable minds could differ over whether "the insurer's conduct was reasonable, or if there are material issues of fact with respect to the reasonableness of the insurer's action, then summary judgment is not appropriate." *Smith*, 150 Wn.2d at 486.

Although an insurer's reasonable basis for its action is significant evidence that it did not act in bad faith, "*the existence of*

some theoretical reasonable basis for the insurer's conduct does not end the inquiry." *Smith*, 150 Wn.2d at 486 (emphasis added). "The insured may present evidence that the insurer's alleged reasonable basis was not the actual basis for its action, or that other factors outweighed the alleged reasonable basis." *Smith*, 150 Wn.2d at 486. For this Court to affirm, "there must be *no disputed facts* pertaining to the reasonableness of the insurer's action *in light of all the facts and circumstances of the case.*" *Smith*, 150 Wn.2d at 486 (emphasis added) (internal quotations omitted). Here, a jury could find that both Dr. Kaneshiro's review and Premera's denial of Mr. Strauss' claim were unreasonable and in bad faith.

1. Premera acted unreasonably by misapplying its definition of medical necessity in its policy and in denying coverage based on the lack of randomized clinical trials.

A jury could find Premera acted in bad faith in refusing to approve proton beam therapy as a "medically necessary" treatment when Mr. Strauss demonstrated that PBT therapy met the criteria under the terms of the policy and yet Premera denied Mr. Strauss' claim on the grounds that Mr. Strauss' evidence was "theoretical" because its superior side effect profile was not based on randomized clinical trials. (CP 243; *see* CP 40; RP 32)

Any questions of coverage or ambiguities in insurance policies "are liberally construed to provide coverage wherever possible." *Bushnell v. Medico Ins. Co.*, 159 Wn. App. 874, 881-82, ¶20, 246 P.3d 856, *rev. denied*, 172 Wn.2d 1005 (2011); *Starr v. Aetna Life Ins. Co.*, 41 Wash. 199, 203, 83 P. 113 (1905) ("It is the established and universal law that insurance policies are to be construed in favor of the insured, and most strongly against insurance companies."). Premera ignored this principle, failing to apply the plain language of its own policy, refusing to take into account credible evidence of proton beam therapy's side effect profile, and instead basing its determination entirely upon the lack of randomized controlled studies even though its policy did not require such studies to find a treatment "medically necessary."

Premera's imposition of these additional requirements goes to its core duties of good faith under RCW 48.01.030 and the common law; it put its own pecuniary interests above those of its insureds in imposing them. Approval of its conduct here would encourage health insurers to decline coverage for medically necessary treatments based solely on a lack of randomized clinical trials, even in the face of other credible scientific evidence demonstrating the treatment's efficacy and superiority over existing methods, depriving

policyholders of access to the newest and most effective treatments for their medical conditions.

2. A jury could find that Premera acted in bad faith by not providing coverage when proton beam therapy was conceivably "medically necessary" under the policy.

Even if Premera's conclusion that proton beam therapy was not "medically necessary" was ultimately correct, a jury could nevertheless find that it conducted its investigation in bad faith. Even where the insurer's ultimate coverage decision is correct, an insured has a claim for violation of the duty of good faith and RCW 19.86.090 where, as here, the insurer acts unreasonably in its handling of the claim. *Coventry*, 136 Wn.2d at 279; *see St. Paul Fire and Marine Ins. Co. v. Onvia, Inc.*, 165 Wn.2d 122, 134, ¶ 26, 196 P.3d 664 (2008).

As "the insurer establishes the conditions for making and paying claims," "evaluates the claim, [and] determines coverage," an insurance contract "brings the insured a certain peace of mind that the insurer will deal with it fairly and justly when a claim is made." *Coventry*, 136 Wn.2d at 282-83. Whether the ultimate coverage decision is right or wrong, "[c]onduct by the insurer which erodes the security purchased by the insured breaches the insurer's duty to act in good faith." *Coventry*, 136 Wn.2d at 283.

By regulation of the Insurance Commissioner, health insurers have the obligation to decide the issue of medical necessity "fairly, and with transparency," taking into account "services that are a logical next step in reasonable care if they are appropriate for the patient," "the treating provider's clinical judgment and recommendations regarding the medical purpose of the requested service, and the extent to which the service is likely to produce incremental health benefits for the enrollee." WAC 284-43-5440(2)(b), (c), (h). A jury could find a violation of these duties of good faith here.

Premera acted unreasonably in assigning a pediatrician, with no expertise in radiology or oncology, and without any guidance or consultation from an expert or physician in the field, who determined that Mr. Strauss' proton beam therapy treatment was not medically necessary based solely on its cost and Premera's corporate policy guidelines – which were intended to be used as *assistance* – rather than on the basis of the contract. (*See* CP 216: medical policies are "a *guide* in evaluating the medical necessity" of a treatment) (emphasis added) Premera's consultant admitted that he "didn't have any specific knowledge on what IMRT costs, what proton costs" (CP 1368), and did not contact Mr. Strauss' treating

oncologist Dr. Bush because he did not "feel[] the need to" before denying coverage. (CP 1369)

A jury could find that Premera acted unreasonably in misapplying its own policy language and denying Mr. Strauss' claim without reasonably investigating it. This Court should reverse the summary judgment and remand for trial on Mr. Strauss' bad faith and Consumer Protection Act claims.

D. Mr. Strauss is entitled to his attorney fees.

Mr. Strauss should be awarded his fees in this Court and in the trial court for the wrongful denial of the benefits of his insurance policy and under the CPA. *Olympic Steamship Co., Inc. v. Centennial Ins. Co.*, 117 Wn.2d 37, 811 P.2d 673 (1991); RCW 19.86.090. This Court should award fees or direct the trial court to do so upon entry of a final judgment.

VI. CONCLUSION

This Court should reverse and remand for a trial of Mr. Strauss' claims for breach of contract, insurance bad faith, and violation of the Consumer Protection Act.

Dated this 10th day of ~~May,~~ June 2016.

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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 June 10, 2016, I arranged for service of the foregoing Brief of Appellants, to the court and to the parties to this action as follows:

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DATED at Seattle, Washington this 10th day of June, 2016.

Jenna L. Sanders

Honorable Monica J. Benton
Trial Date: February 8, 2016
Hearing Date: December 11, 2015
Hearing Time: 10:00 A.M.

SUPERIOR COURT OF WASHINGTON FOR KING COUNTY

JOHN STRAUSS and MICHELLE STRAUSS, husband and wife, and their marital community, Plaintiff, v. PREMERA BLUE CROSS, Defendant.	No. 13-2-28143-1 SEA ORDER GRANTING PREMERA BLUE CROSS'S MOTION FOR SUMMARY JUDGMENT

This matter came on regularly for hearing upon Premera Blue Cross's Motion for Summary Judgment ("Motion for Summary Judgment"). The Court reviewed the files and records herein, including the submissions of the parties, and finding that there exist no genuine issues of material fact and that Premera Blue Cross is therefore entitled to summary judgment as to breach of contract, bad faith and consumer protection act violations under *Young v. Key Pharms, Inc.*, 112 Wn.2d 216 (Wash App. 1989), *Pleasant v. Regence Blue Shield*, 181 Wash. App. 252 (2014) and *Overton v. Consol. Ins. Co.*, 145 Wash. 2d 417 (2002) and *Villella v. Pub. Employees Mut. Ins Co.*, 106 Wash. 2d 806 (1986), respectively, as a matter of law, NOW, THEREFORE,

IT IS HEREBY ORDERED that Premera Blue Cross's Motion for Summary Judgment is GRANTED.

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Dated this 14 day of December, 2015.

HONORABLE MONICA J. BENTON

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