Case No. 85369

In the Supreme Court of Nevada

SIERRA HEALTH AND LIFE INSURANCE COMPANY, INC.,

Appellant,

v.

SANDRA L. ESKEW, as Special Administrator
of the Estate of William George Eskew,

Respondent.

On Appeal from the Eighth Judicial District Court,
Clark County, Case No. A-19-788630-C

AMICUS CURIAE BRIEF OF THE NATIONAL ASSOCIATION FOR PROTON THERAPY

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NRAP 26.1 DISCLOSURE

The National Association for Proton Therapy is an independent nonprofit organization with no parent corporation/(s) and no publicly held shares or stock. It is appearing in this matter for the sole purpose of submitting an *amicus curiae* brief to the Court and did not otherwise participate in the district court proceedings below.

Dated: July 5, 2023

By: ______________________

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INTEREST OF AMICUS CURIAE

The National Association for Proton Therapy ("NAPT") is an independent non-profit organization whose members include the nation's leading cancer centers, esteemed medical experts and scientists, and other stakeholders that share its commitment to promoting the highest standards of cancer care—in part, by disseminating accurate information about medical advancements and evidence-based treatment options.

Since its founding in 1990, the NAPT has sought to raise awareness about the clinical benefits and advantages of proton beam therapy ("PBT") over conventional radiation treatments for the targeted treatment of certain cancers and has served as a central educational resource for patients, physicians, hospitals and cancer centers, academic research institutions, government agencies and policymakers alike.

The NAPT's interest in this case arises from its potential implications on the future accessibility of PBT to cancer patients throughout the United States. Although the organization takes no position on the substantive legal dispute between the parties,[1] the NAPT seeks to educate the Court about PBT—which has long been recognized as a safe, clinically effective and superior form of radiation therapy for treating certain types of cancer—and to underscore the barriers that many patients face in accessing this life-saving treatment.

Accordingly, the NAPT respectfully submits this brief to provide the Court with an overview of the science behind PBT, the history of its use in radiation oncology, the reasons why it is still the preferred treatment modality for delivering targeted radiation therapy to tumors presenting near critical organs and structures, and the types of circumstances in which there is broad medical consensus that PBT is a more optimal course of treatment than conventional radiation therapy.

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[1] Dr. Andrew Chang, M.D., who served as an expert witness in the proceedings below, is a member of NAPT's board of directors, but was fully recused from the decision to file this brief and was not involved in its preparation.

ARGUMENT

I. PBT IS AN EFFECTIVE AND OFTEN SUPERIOR RADIATION TREATMENT MODALITY FOR TARGETING CERTAIN TYPES OF CANCER.

In the United States, more than half of all cancer patients receive some form of radiation therapy as part of their treatment plan—which may also include surgery and/or chemotherapy. The principal aim of oncological care is to formulate the most appropriate combination of these therapies that will effectively eliminate the cancer in a patient, while seeking to preserve the anatomical integrity, function, and genetic makeup of surrounding human tissue.

A. The Science and History of Proton Therapy

Radiation therapy works by using high-energy particles or electromagnetic waves to destroy or damage genes (DNA), which control cell growth and division. When radiation damages the genes of cancer cells, they can no longer divide and proliferate; the existing cancer cells eventually die off, shrinking the tumor and preventing further growth.

The downside of radiation therapy, however, is that it does not distinguish between healthy cells and tumor cells. Therefore, although radiation can successfully eliminate cancer from human tissue, its application also presents a risk to the function of healthy cells in the treatment area, which must be mitigated to greatest extent possible in order achieve the best patient outcomes.

Radiation therapy has been used in cancer treatment for more than a century. Over time, however, scientists and physicians have developed increasingly precise and sophisticated techniques for delivering radiation therapy. Indeed, some of the most significant breakthroughs in cancer treatment to date have resulted from innovations enhancing the precision with which radiation can be delivered and directed towards cancerous cells while minimizing damage to healthy cells.

Most types of radiation therapy treatments used in oncological settings fall into one of two categories: (1) conventional photon radiation, and (2) advanced particle radiation. Although both function on the same basic principle of damaging cancerous cells, understanding the difference in how each treatment modality delivers and deposits radiation to the target site is critical to assessing the clinical benefits of one therapy over another.

The most common types of radiation therapy used today involve some form of conventional *photon* radiation. When directed towards the site of a tumor, photon beams travel through the body, continuously depositing radiation throughout their path. Because photons deposit radiation while traveling towards and through the target site, healthy tissues are exposed to radiation as the beams enter and exit the body.

Proton beam therapy ("PBT") is an advanced particle radiation treatment modality that uses *proton* beams, which have a different way of interacting with human tissue and deposit radiation primarily at the end of their path.[2] The major advantage of PBT over conventional photon radiation is that protons slow to a stop and deposit a more targeted dose of radiation directly to the tumor, rather than continuously passing *through* the target site and unnecessarily exposing other parts of the body to radiation.

The idea of using protons in medical treatment was first suggested in 1946 by Robert R. Wilson, Ph.D., an American physicist known for his work on the Manhattan Project and professor of physics at Harvard University.[3] Because protons travel at more predictable distances in human tissue and deposit most of their radiation where they stop (the

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[2] Thomas F. DeLaney, et al., *Proton Therapy in the Clinic*, 43 FRONTIERS OF RADIATION THERAPY AND ONCOLOGY 465 (2011), *available at* https://pubmed.ncbi.nlm.nih.gov/21625169/.

[3] *See, e.g.*, National Association for Proton Therapy: History of Proton Therapy, https://www.proton-therapy.org/about/history-of-proton-therapy/.

Brag Peak), Wilson posited that proton beams could be used to localize energy and increase the radiation dose directed towards tumors in a more precise manner than photons.

The first people to receive PBT were treated with pituitary irradiation to control metastatic breast cancer at a federally funded research center in the 1950s.[4] By the late 1970s, the results of those initial treatments had been duplicated at research facilities around the world. These developments laid the foundation for the use of PBT in modern oncological settings, which was first approved by the U.S. Food and Drug Administration (FDA) in 1988.

Since then, hundreds of thousands of cancer patients have been successfully treated with PBT.[5]

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[4] Courtney Misher , *The History of Proton Therapy*, OncoLink (Feb. 4, 2022), https://www.oncolink.org/cancer-treatment/proton-therapy/overviews-of-proton-therapy/the-history-of-proton-therapy

[5] Particle Therapy Co-Operative Group, htetps://ptcog.site/ ("More than 360,000 patients have been treated worldwide with particle therapy").

B. The Importance of PBT as a Vital Cancer Treatment Modality

The fact that PBT is a more advanced or sophisticated treatment modality than conventional radiation therapy does not render it experimental. Its effectiveness as a cancer treatment was already well-established when it received FDA approval in 1988—and the clinical evidence of its capacity to generate superior outcomes has only continued to accumulate since that time.[6]

The use of PBT is supported by over 1,000 peer-reviewed articles evidencing its ability to yield better patient outcomes by limiting healthy tissue exposure to radiation. As a result, PBT has become the preferred method of radiation therapy for the targeted treatment of solid tumors in pediatric patients—and is widely-considered to be the most optimal

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[6] *See, e.g.*, Robert L. Foote, et al., *The Clinical Case for Proton Beam Therapy*, 7 RADIATION ONCOLOGY 174 (2012), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3549771/; Christine S. Chung, et al., *Incidence of Second Malignancies Among Patients Treated with Proton Versus Photon Radiation*, 87 INTERNATIONAL JOURNAL OF RADIATION ONCOLOGY, BIOLOGY, PHYSICS 46 (2013), *available at* https://pubmed.ncbi.nlm.nih.gov/23778197/.

treatment for adult patients with tumors near critical structures and organs,[7] such as those presenting near the esophagus and lungs.[8]

Although conventional photon radiation has become increasingly precise through the development of advanced delivery mechanisms like IMRT, the unique characteristics of how protons interact with human tissue make PBT a far more optimal treatment for delivering curative

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[7] *See* NAPT Model Policy - Coverage for Proton Therapy, 2-4 (identifying the types of cancer diagnoses where health insurance coverage for PBT should be approved as "medically necessary" based on published clinical data), *available at* http://www.proton-therapy.org/wp-content/uploads/2023/04/2022-NAPT-Model-Policy-for-Coverage-of-Proton-Therapy-2.20.23.pdf.

[8] *See, e.g.*, Masashi Mizumoto, et al., *Hyperfractionated Concomitant Boost Proton Beam Therapy for Esophageal Carcinoma,* 81 INTERNATIONAL JOURNAL OF RADIATION ONCOLOGY, BIOLOGY, PHYSICS 601(2011), *available at* https://pubmed.ncbi.nlm.nih.gov/21511402/; Hidetsugu Nakayama, et al., *Proton Beam Therapy Of Stage II and III Non-Small-Cell Lung Cancer*, 81 INTERNATIONAL JOURNAL OF RADIATION ONCOLOGY, BIOLOGY, PHYSICS 979 (2011), *available at* https://pubmed.ncbi.nlm.nih.gov/20888140/; Emma B. Holliday, et al., *Proton Radiation Therapy for Head and Neck Cancer: A Review of the Clinical Experience to Date*, 89 INTERNATIONAL JOURNAL OF RADIATION ONCOLOGY, BIOLOGY, PHYSICS 292 (2014), *available at* https://pubmed.ncbi.nlm.nih.gov/24837890/; Steven E. Schild, et al., *Proton Beam Therapy for Locally Advanced Lung Cancer: A Review,* 5 WORLD JOURNAL OF CLINICAL ONCOLOGY 568 (2014), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4129522/; Quynh-Nhu Nguyen, et al., *Long-Term Outcomes After Proton Therapy, With Concurrent Chemotherapy, For Stage II-III Inoperable Non-Small Cell Lung Cancer*, 115 RADIOTHERAPY & ONCOLOGY 367 (2015), *available at* https://pubmed.ncbi.nlm.nih.gov/26028228/; Damien C. Weber, et al., *Longterm Outcomes and Prognostic Factors of Skull-Base Chondrosarcoma Patients Treated with Pencil-Beam Scanning Proton Therapy at the Paul Scherrer Institute*, 18 NEURO-ONCOLOGY 236 (2016), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4724177/; Hiromitsu Iwata, et al., *Longterm Outcome of Proton Therapy and Carbon-Ion Therapy for Large (T2a-T2bn0m0) Non-Small-Cell Lung Cancer*, 8 JOURNAL OF THORACIC ONCOLOGY 726 (2016), *available at* https://pubmed.ncbi.nlm.nih.gov/23459403/.

doses of radiation while preserving adjacent tissue and organs. In fact, recent studies comparing the use of proton therapy to more advanced applications of conventional photon therapy (*e.g.*, IMRT) show that PBT still consistently leads to clinically meaningful reductions in acute toxicity, fewer adverse events and long-term side-effects (including secondary cancers caused by irradiation of healthy tissue), better overall survivability with fewer complications affecting patients' quality of life—and even faster recovery times, as measured by the number of days requiring hospitalization after treatment.[9]

Simply put, PBT is the safest and most effective form of radiation therapy for treating certain types of cancer.

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[9] *See, e.g.*, Steven H. Lin, et al., *Randomized Phase IIB Trial of Proton Beam Therapy Versus Intensity-Modulated Radiation Therapy for Locally Advanced Esophageal Cancer*, 38 J. CLINICAL ONCOLOGY 1569 (2020), *available at* https://pubmed.ncbi.nlm.nih.gov/32160096/; Brian C. Baumann, et al., *Comparative Effectiveness of Proton vs Photon Therapy as Part of Concurrent Chemoradiotherapy for Locally Advanced Cancer*, 6 JAMA ONCOLOGY 237 (2020), *available at* https://pubmed.ncbi.nlm.nih.gov/31876914/.

II. PATIENTS FACE SIGNIFICANT STRUCTURAL BARRIERS TO ACCESSING THIS LIFE-SAVING TREATMENT.

Despite overwhelming evidence that PBT is often safer *and* more effective than conventional photon radiation, patients often face significant obstacles to accessing this life-saving treatment.

Until recently, those barriers were largely structural in nature—owing to the fact that only a limited number of facilities around the world had the requisite infrastructure to offer PBT treatment. As of 2006, PBT was only available at a half-dozen cancer treatment facilities in the United States,[10] meaning that decisions about which adult patients should receive this treatment were largely guided by concerns about limited capacity.

That number has steadily grown the last two decades, with 25 facilities having been built by 2016, and nearly 50 facilities currently in operation or under construction as of the date of this writing.[11] Even so, over 70% of Americans still live more than 100 miles from a proton therapy center. And while many NCI-designated cancer centers and

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[10] *See* Particle Therapy Co-Operative Group: Particle Therapy Facilities in Clinical Operation, https://ptcog.site/index.php/facilities-in-operation-public.

[11] *Id.*

hospitals in major metropolitan areas now offer PBT, other facilities may hesitate to undertake the capital risk of adding this technology while there is still a lack of clarity around insurance coverage and reimbursements.

For patients who live within reasonable proximity to PBT facilities—and those willing to travel at the recommendation of their treating physician—concerns about costs and health insurance coverage can present an additional barrier.[12]

Due to the high upfront costs of building and operating PBT facilities, the cost to insurance companies of covering proton therapy is generally more expensive than conventional photon radiation therapies.[13]

Unfortunately, this cost variance has led some insurers to deny coverage for PBT treatment—even when it is deemed by the patient's

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[12] *See* Matthew S Ning, et al, *The Insurance Approval Process for Proton Radiation Therapy: A Significant Barrier to Patient Care*, 104 INTERNATIONAL JOURNAL OF RADIATION ONCOLOGY, BIOLOGY, PHYSICS 724 (2019), *available at* https://pubmed.ncbi.nlm.nih.gov/30557675/

[13] *See* Leticia M. Nogueira, et al., *Assessment of Proton Beam Therapy Use Among Patients With Newly Diagnosed Cancer in the US, 2004-2018,* JAMA NETWORK (April 27, 2022), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2791568 (explaining that "[t]reatment cost [for PBT] can be double the cost of photon-based radiotherapy depending on the indication.").

treating physicians and medical team to be the most optimal course of treatment.[14]

The justifications provided for these denials vary from patient to patient, but generally cite a lack of evidence demonstrating the effectiveness and medical necessity of PBT, as compared to other, less costly, treatment options. Some patients are eventually able to secure coverage by working with their physicians to appeal such denials. But many cancer patients do not have the time or resources to challenge a denial of coverage while undergoing treatment—and others are still denied coverage, even after submitting scientific evidence that PBT would likely yield a superior outcome.

As a result, many patients are essentially forced to accept a less optimal treatment and receive conventional (*i.e.*, photon) radiation therapy with higher risks of side effects and long-term complications.

This has led to devastating consequences for some patients and their loved ones, who are justifiably angry about having been made to

[14] According to NAPT's annual member survey, roughly 43% of prior authorization requests for PBT were initially denied in 2021.

suffer through circumstances that might have been avoidable, but-for their insurers' refusal to cover the best available treatment.

With cancer survivorship at an all-time high, preserving a patient's overall quality of life to the greatest extent possible—by reducing the risk of side effects, hospitalizations, and secondary cancers—is more important than ever to patients and their caregivers. Moreover, to the extent that denials of coverage are driven by cost considerations, the short- and long- term cost-burden of treating adverse effects that can be mitigated with PBT treatment may outweigh the more immediate cost-savings realized by insurers that steer patients towards less optimal treatments; indeed, recent studies suggest that PBT is likely more cost-*effective,* over the long term.[15]

In sum, improving patient access to PBT is not only a moral imperative—but also, increasingly, makes economic sense too. And while fixing the problem of patient access to PBT is neither the job of this Court, nor the subject matter of the controversy in this case, precedent-setting

[15] *See, e.g.,* Brian C. Baumann, et al., *Comparative Effectiveness of Proton vs Photon Therapy as Part of Concurrent Chemoradiotherapy for Locally Advanced Cancer*, 6 JAMA ONCOLOGY 237 (2020), *available at* https://pubmed.ncbi.nlm.nih.gov/31876914/.

decisions concerning the scope of medical necessity for specific treatments always necessarily have implications for the development of insurance policies covering those treatments—which, in turn, implicate accessibility concerns.

CONCLUSION

For these reasons, the NAPT hopes that this Court will consider the potential impact of its decision on the future development of insurance coverage policies concerning PBT, and the extent to which those policies will dictate patient access to this life-saving therapy throughout the United States.

Dated: July 5, 2023

Respectfully submitted,

By: ______________________________

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CERTIFICATE OF COMPLIANCE

1. I hereby certify that this proposed brief complies with the formatting requirements of NRAP 32(a)(4), the typeface requirements of NRAP 32(a)(5) and the type style requirements of NRAP 32(a)(6) because this brief was prepared in a proportionally-spaced typeface (14-point Century Schoolbook font) using Microsoft Word.

2. I further certify that this brief complies with the page-or type-volume limitations of NRAP 32(a)(7) because excluding the parts of the brief exempted by NRAP 32(a)(7)(C), it is proportionally spaced, has a typeface of 14 points or more and contains fewer than 7,000 words.

3. I hereby certify that I have read this amicus curiae brief, and to the best of my knowledge, information, and belief, it is not frivolous or interposed for any improper purpose. I further certify that this brief complies with all applicable Nevada Rules of Appellate Procedure, in particular NRAP 28(e)(1), which requires every assertion in the brief regarding matters in the record to be supported by a reference to the page and volume number, if any, of the transcript or appendix where the matter relied on is to be found. I understand that I may be subject to

sanctions in the event that the accompanying brief is not in conformity with the requirements of the Nevada Rules of Appellate Procedure.

Dated: July 5, 2023

By: ______________________
Daniel T. Hayward

CERTIFICATE OF SERVICE

Pursuant to NRAP 31, I hereby certify that I am an employee of BRADLEY, DRENDEL & JEANNEY, and on this date, I electronically filed and served a true and correct copy of the foregoing **AMICUS CURIAE BRIEF OF THE NATIONAL ASSOCIATION FOR PROTON THERAPY** as follows via eFlex Program, which will send a notice of electronic filing to the following, and U.S. Mail:

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Dated this 5th day of July, 2023.

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