

HIGH HEALTH CARE SPENDING AND DEVELOPING TECHNOLOGY: PROTON BEAM THERAPY

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ABSTRACT

Rising health care spending is a source of concern in the U.S. With new, high-cost health care technology, paying higher prices for the use of new technology without considering cheaper, equally effective alternatives leads to inefficient spending. This Note focuses on proton beam therapy (“PBT”) for treatment of prostate cancer to explore several causes that contribute to high health care spending in the U.S. In treating prostate cancer, PBT has not been shown to be more effective than its cheaper alternative, IMRT. Yet, investors and many states continue to encourage its use for prostate cancer. This Note argues that inefficient use of PBT increased because existing standard for review of new health care technology and its reimbursement often suggest new health care technology will be reimbursed at a prime rate. Hence, private investors fueled the development of PBT Centers indiscriminately, expecting a high return on their investment. Then, this Note proposes several ways to encourage a more efficient use of PBT.

INTRODUCTION

The term “technology evolution” is used when a new technology develops and improves upon an existing technology.¹ When a technology evolution imposes much larger costs for medical treatment than existing technology, the new technology should be evaluated critically to examine its efficacy. This is difficult in medical technology (“medtech”) because clinical trials often take a long time to conduct. Often, during the time in which researchers conduct trials to demonstrate the efficacy of a new medtech, tension arises between those who want to encourage patient access to potentially promising treatment and those who want to save costs until efficacy of the new technology is proven.²

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¹ Anthony Zietman et al., *Technology Evolution: Is It Survival of the Fittest?*, 28 J. CLINICAL ONCOLOGY 4275, 4275 (2010).

² See Richard S. Saver, Note, *Reimbursing New Technologies: Why Are the Courts Judging Experimental Medicine?*, 44 STAN. L. REV. 1095, 1096 (1992).

Proton Beam Therapy (“PBT”), a technology used for treating cancer by delivering conformal external beam radiation with positively charged atomic particles to a well-defined treatment volume,³ is an apt example of a technology evolution. PBT is currently used to treat a variety of cancers, but opinions about the appropriateness of its use for different cancers vary wildly. Agreement on its effectiveness is strongest for tumors surrounded by critical structures like the eye, brain, and spinal cord, and for solid tumors in children.⁴ For other types of cancers, such as prostate cancer, opinions diverge because currently, there isn’t much concrete evidence.⁵ Some argue that PBT is more effective than intensity-modulated radiation therapy (“IMRT”), which is a widely adopted treatment for prostate cancer, because of its improved precision of the radiation beams. However, because PBT is much more costly than IMRT, its efficacy should be assessed carefully.

This Note examines the current landscape of PBT, its use in prostate cancer, and its efficacy as a technological evolution. Part I compares PBT with IMRT. Part II examines PBT’s rise in use and the reasons behind it. Part III proposes a movement to encourage a more efficient development of PBT use, while encouraging a continuance in research.

I. PROTON BEAM THERAPY (PBT) VS. INTENSITY-MODULATED RADIATION THERAPY (IMRT)

To understand the efficacy of adopting PBT for the treatment of prostate cancer, PBT must be compared to the existing alternative for treating prostate cancer, IMRT. IMRT uses a disseminated distribution of *photon* radiation to target tumors.⁶ Photon beams deposit the greatest amount of energy “beneath the patient’s surface with a gradual reduction in energy deposition” as photons pass through the target, then exit through an exit point.⁷ Comparatively, PBT uses *proton* particles and

³ AM. SOC’Y FOR RADIATION ONCOLOGY, ASTRO MODEL POLICIES, PROTON BEAM THERAPY (PBT) 1 (June 2017), https://www.astro.org/uploadedFiles/_MAIN_SITE/Daily_Practice/Reimbursement/Model_Policies/Content_Pieces/ASTROPBTModelPolicy.pdf [hereinafter ASTRO].

⁴ Stephanie Jarosek et al., *Proton Beam Radiotherapy in the U.S. Medicare Population: Growth in Use Between 2006 and 2009*, 10 DATA POINTS 1 (2012).

⁵ See *infra* Part II.

⁶ INST. FOR CLINICAL AND ECON. REVIEW, BRACHYTHERAPY & PROTON BEAM THERAPY FOR TREATMENT OF CLINICALLY-LOCALIZED, LOW-RISK PROSTATE CANCER 36 (2008), https://icer-review.org/wp-content/uploads/2016/02/BT-PBT_Rpt_Final.pdf [hereinafter ICER].

⁷ ASTRO, *supra* note 3.

allows “for the majority of its energy to be deposited over a very narrow range of tissue at a depth largely determined by the energy of the proton beam.”⁸ Because the energy deposition of a proton beam rapidly increases over a narrow range at a desired depth to produce an intense dose, proton beam deposits relatively less radiation energy when entering and exiting the body.⁹

IMRT is currently the standard form of radiotherapy for treating prostate cancer.¹⁰ IMRT was quickly and widely adopted when its relative effectiveness to existing treatment was uncertain.¹¹ In 2000, IMRT treated less than 1% of localized prostate cancers; by 2008, it treated 96% of prostate cancer patients.¹² Its quick adoption was based on two potential benefits: first, IMRT would deliver higher doses of radiation to cancer sites, and second, it would reduce radiation exposure to surrounding tissue.¹³ Despite IMRT’s wide adoption, its superiority and cost-effectiveness over the alternative treatment still was being studied in 2010.¹⁴

Similar to the adoption of IMRT, many health care providers quickly adopted PBT as a treatment for prostate cancer despite its uncertainty. PBT gained popularity as a prostate cancer treatment based on the potential theory that it benefits prostate cancer patients by reducing the amount of radiation that surrounding organs receive.¹⁵

⁸ *Id.*

⁹ *Id.*

¹⁰ See James B. Yu et al., *Proton Versus Intensity-Modulated Radiotherapy for Prostate Cancer: Patterns of Care and Early Toxicity*, 105 J. NAT’L CANCER INST. 25, 25 (2012).

¹¹ Bruce L. Jacobs et al., *Growth of High-Cost Intensity-Modulated Radiotherapy for Prostate Cancer Raises Concern About Overuse*, 31 HEALTH AFF. 1, 1 (2012).

¹² Ryan Jaslow, *IMRT Is Best Radiation for Early Prostate Cancer, Study Finds*, CBS NEWS (Apr. 18, 2012), <https://www.cbsnews.com/news/imrt-is-best-radiation-for-early-prostate-cancer-study-finds/>.

¹³ Jacobs et al., *supra* note 11, at 2.

¹⁴ See generally VARIAN MED. SYS., A REVIEW OF INTENSITY MODULATED RADIATION THERAPY (IMRT): A COST EFFECTIVE, PERSONALIZED FORM OF RADIATION THERAPY 2–3 (2010), http://www.equiphos.com/wp-content/uploads/2015/05/IMRT_Clinical_Perspectives.pdf (describing the state of clinical trials that compare IMRT and another method of treatment for prostate cancer, which was widely adopted before IMRT, and stating that there are still studies being conducted to compare the comparative effectiveness of the two treatments).

¹⁵ See Nathan C. Sheets et al., *Intensity-Modulated Radiation Therapy, Proton Therapy, or Conformal Radiation Therapy and Morbidity and Disease Control*

However, studies have failed to demonstrate that PBT provides better outcomes than IMRT for prostate cancer patients.¹⁶ A study reviewing Medicare records of nearly 55,000 prostate cancer survivors found that PBT is associated with small reductions in urinary effects, but only within the first six months of treatment.¹⁷ After that, researchers found no difference in side effects between patients treated with PBT and those treated with IMRT.¹⁸

Some studies actually suggest that PBT may result in more toxicity than IMRT because PBT has greater physical and biological uncertainties than IMRT.¹⁹ This means that PBT may be more prone to errors related to patient set up, positioning, and organ movement during treatment.²⁰ A 2012 study of long-term morbidity found that localized prostate cancer patients who received PBT had a higher rate of gastrointestinal morbidity than those who received IMRT.²¹ The researchers found no other significant differences in rates of other morbidities between IMRT and PBT.²²

In addition to uncertainty over its relative efficacy and possible toxicity, cost is an issue with PBT. Despite the lack of evidence of its superiority, PBT treatment can cost 48,000 dollars or more, while IMRT treatment costs around 20,000 dollars.²³ PBT treatment is expensive because PBT Centers require a huge capital cost. Construction of earlier PBT Centers, which were the size of a football field with concrete walls

in Localized Prostate Cancer, 307 J. AM. MED. ASS'N 1, 7 (2012) (“[PBT] relative to IMRT may reduce the proportion of each surrounding organ that receives low doses of radiation . . .”); ICER, *supra* note 6, at 36.

¹⁶ See Sheets et al., *supra* note 15, at 6–7.

¹⁷ Yu et al., *supra* note 10, at 27.

¹⁸ *Id.*

¹⁹ Justin E. Bekelman et al., *Randomized Trials of Proton Therapy: Why They Are at Risk, Proposed Solutions, and Implications for Evaluating Advanced Technologies to Diagnose and Treat Cancer*, 36 J. CLINICAL ONCOLOGY 2461, 2461 (2018).

²⁰ Sheets et al., *supra* note 15, at 7.

²¹ *Id.*

²² *Id.*

²³ Jay Hancock, *As Proton Centers Struggle, a Sign of a Health Care Bubble?*, WASH. POST (May 2, 2018), https://www.washingtonpost.com/national/health-science/as-proton-centers-struggle-a-sign-of-a-health-care-bubble/2018/05/02/54a598a6-4de9-11e8-85c1-9326c4511033_story.html?utm_term=.7e18e6cd1ed4.

up to thirteen feet thick,²⁴ cost between 120 million and 250 million dollars.²⁵

Although lack of demonstrable efficiency and cost-effectiveness are problems with PBT, there are benefits to allowing further research. Prostate cancer is slow-developing. Complete studies about long-term effectiveness of PBT can take decades to develop. For example, research demonstrated IMRT's effectiveness for prostate cancer treatment years after its adoption. Presently, only a few randomized control trials or well-conducted cohort studies comparing PBT to other treatments exist.²⁶ Although irresponsible spending must be avoided, in order to form an informed judgment about PBT use in prostate cancer, researchers must be able to continue their research about PBT's effectiveness in prostate cancer treatment.

II. EXPECTATION OF DEMAND, PROFIT, AND THE RISE OF PBT

Use of PBT for prostate cancer accounts for an increasing portion of Medicare spending. PBT use for prostate cancer increased drastically since 2006, increasing by 68 percent from 2006 to 2009.²⁷ From 2010 to 2016, Medicare spending for PBT increased from 47 million to 115 million dollars.²⁸ Prostate cancer treatment is the most common use of PBT and accounts for almost half the spending and volume.²⁹ It is also the most expensive. Average total Medicare reimbursements ranged from about 5,000 dollars for ocular tumors to

²⁴ Matt Goodman, *How a Cyclotron Saves Lives*, D MAG. (Oct. 2015), <https://www.dmagazine.com/publications/d-magazine/2015/october/cyclotron-cancer-fighting-machine/>.

²⁵ See Ezekiel J. Emanuel and Steven D. Pearson, *It Costs More, But Is It Worth More?*, N.Y. TIMES: OPINIONATOR (Jan. 2, 2012), <https://opinionator.blogs.nytimes.com/2012/01/02/it-costs-more-but-is-it-worth-more/> (stating that PBT Centers cost \$180 million); Glenda Chui, *The Power of Proton Therapy*, SYMMETRY (Dec. 1, 2008), <https://www.symmetrymagazine.org/article/december-2008/the-power-of-proton-therapy> (“[PBT Centers] cost in the neighborhood of \$120 million to \$180 million . . .”); Bonnie Berkowitz & Aaron Steckelberg, *How Proton Therapy Attacks Cancer*, WASH. POST (Mar. 30, 2018), https://www.washingtonpost.com/graphics/2018/health/proton-beam-therapy/?utm_term=.390e8cd25d03 (stating that PBT Centers cost \$200 million to \$250 million).

²⁶ See Jarosek et al., *supra* note 4, at 1.

²⁷ *Id.* at 2, 8.

²⁸ MEDICARE PAYMENT ADVISORY COMM’N, MEDICARE COVERAGE POLICY AND USE OF LOW-VALUE CARE 294 (June 2018).

²⁹ *Id.* at 323.

25,000 dollars for prostate cancer.³⁰ This rate of reimbursement is also much higher than the rate of reimbursement for IMRT.³¹

PBT Centers are extremely costly and treating a high patient volume is the only way to recover construction costs.³² Because prostate cancer is one of the most common³³ and one of the most generously reimbursed cancers, treating prostate cancer patients is one of the ways in which PBT Centers can profit. With over 150,000 new cases diagnosed every year,³⁴ even a small percentage of prostate cancer patients seeking to use PBT would lead to a large increase in the use of the technology.³⁵ In fact, statistics suggest that PBT Centers do rely on prostate cancer patients to increase their patient volume. Within the region of referral, 9 percent of prostate cancer patients received PBT treatment for their prostate cancer.³⁶ For patients outside the region of referral, only 2 percent of the patients received PBT.³⁷ This shows that PBT Centers are looking for ways to doing more procedures.³⁸

Investors and hospitals alike investing in PBT Centers relied on the assumption that PBT Centers will treat large numbers of prostate cancer patients and insurers will generously reimburse that.³⁹ Hospitals

³⁰ Jarosek et al., *supra* note 4, at 5.

³¹ See Kilian C. Schiller et al., *Protons, Photons, and the Prostate—Is There Emerging Evidence in the Ongoing Discussion on Particle Therapy for the Treatment of Prostate Cancer?*, 6 *FRONTIERS IN ONCOLOGY* 1, 5 (Jan. 28, 2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4729886/> (stating that reimbursement for PBT is almost twice as high as that for IMRT).

³² See Jenny Gold, *Proton Beam Therapy Heats Up Hospital Arms Race*, *KAISER HEALTH NEWS* (May 31, 2013), <https://khn.org/news/proton-beam-therapy-washington-dc-health-costs/>.

³³ See CTRS. FOR DISEASE CONTROL AND PREVENTION, *LEADING CANCER CASES AND DEATHS, MALE AND FEMALE, 2016*, <https://gis.cdc.gov/Cancer/USCS/DataViz.html> (last visited March 25, 2020) (showing that, in 2016, prostate cancer was the second most common cancer to develop).

³⁴ See CTRS. FOR DISEASE CONTROL AND PREVENTION, *PROSTATE CANCER STATISTICS*, <https://www.cdc.gov/cancer/prostate/statistics/index.htm> (last visited May 11, 2019) (see information on main page, then click on “trends”).

³⁵ Jarosek et al., *supra* note 4, at 9.

³⁶ Roxanne Nelson, *Uncertainty About Proton-Beam Radiotherapy Lingers*, *MEDSCAPE* (Jan. 30, 2013), https://www.medscape.com/viewarticle/778466#vp_2.

³⁷ *Id.*

³⁸ See *id.* (quoting a doctor who states that because PBT Centers have excess capacity and high costs, they are looking for ways to do more procedures).

³⁹ Hancock, *supra* note 23; Jarosek et al., *supra* note 4, at 9.

built their centers with equity and bank loans, expecting to make profits and high returns for equity investors.⁴⁰ Some hospitals partnered with for-profit developers to fund the construction of a PBT Center.⁴¹ Under the assumption that they would treat a large percentage of prostate cancer patients, PBT Centers anticipated treating more than 85 patients per day.⁴² Some Centers, such as the Maryland Proton Therapy Center, expected to treat about 70 prostate cancer patients a day.⁴³

Then-existing legal and legislative structures surrounding reimbursements for health technology revolution supported this expectation. Structurally, Medicare typically reimburses new technologies without scrutinizing their cost-effectiveness. Medicare's decision typically affects reimbursement from private insurers as well, because private insurers traditionally follow Medicare's lead for reimbursing for new technology.⁴⁴ Further, there has been an increase in legislatively mandated review processes of medical necessity denials.⁴⁵ Some states' regulations even specifically require insurers to defer to the judgment of physicians.⁴⁶

In addition, under a theory of breach of contract, insurers face potential liability for denying coverage for procedures.⁴⁷ Traditionally, where insurance companies' policies stated that they do not cover "experimental" technology, most courts employed the *ambiguities rule*, stating that "experimental technology" was an ambiguous term and interpreting it to favor reimbursement.⁴⁸ In other cases, courts used the

⁴⁰ See Hancock, *supra* note 23; David Whelan & Robert Langreth, *The \$150 Million Zapper*, FORBES (Feb. 26, 2009), https://www.forbes.com/forbes/2009/0316/062_150mil_zapper.html#85a9bf82068f.

⁴¹ See, e.g., Gold, *supra* note 32 (stating that the Baltimore facility is funded by a for-profit developer, Advanced Particle Therapy).

⁴² See Hancock, *supra* note 23.

⁴³ See Gold, *supra* note 32 (stating that Maryland Proton Therapy Center anticipated treating about 200 patients a day, 35% of which would be prostate cancer patients).

⁴⁴ See Wendy Netter Epstein, *The Health Insurer Nudge*, 91 S. CAL. L. REV. 595, 598, 617–18, 620–22 (2018) (citing Bradley Sawyer & Cynthia Cox, *How Does Health Spending in the U.S. Compare to Other Countries?*, PETERSON-KAISER: HEALTH SYSTEM TRACKER (Feb. 13, 2018), <https://www.healthsystemtracker.org/chart-collection/health-spending-u-s-compare-countries/#item-start>).

⁴⁵ See Epstein, *supra* note 44, at 623.

⁴⁶ See *id.*

⁴⁷ See *id.* at 624–25.

⁴⁸ Saver, *supra* note 2, at 1100.

reasonable expectations test: where the insurance policy did not clearly, conspicuously and plainly notify the insured that the disputed technology would not be covered, courts expanded insurance coverage to include the new technology.⁴⁹

To the surprise of many, however, PBT Centers' profit from prostate cancer patients has not lived up to the investors' expectations, and many PBT Centers are struggling recoup their large capital cost.⁵⁰ In 2013, several major insurers stopped reimbursing PBT use in treating prostate cancer.⁵¹ Medicare patients alone have been insufficient to recoup the massive capital cost of PBT Centers.⁵² In 2014, Indiana University's PBT Center became the first facility to close.⁵³ A number of other PBT Centers followed, closing their facilities or restructuring in bankruptcy courts.⁵⁴

Many PBT Centers are adapting to the changing landscape. Some new centers are smaller, with one or two treatment rooms compared to four or five.⁵⁵ Smaller PBT Centers can cost less than 50 million dollars,⁵⁶ which lessens the burden on the Centers to recoup its capital cost by treating a large volume of patients. Some Centers are adapting by modifying their pricing system: University of Pennsylvania, the Mayo Clinic and University of Maryland, for example, have set the price of PBT equal to IMRT while researchers continue to examine the effectiveness of PBT for prostate cancer.⁵⁷ Others, such as Northwestern Proton Therapy, Provision CARES Cancer Center and the Seattle Cancer Alliance, have payment programs for patients where the Center, not the patients, takes on the financial risk if PBT is not covered by insurance on appeal.⁵⁸ Other efforts are being conducted to make PBT treatment cheaper and more efficient. Several manufacturers, including Mevion Medical Systems, Hitachi, and Varian Medical Systems, are invested in

⁴⁹ *Id.* at 1102.

⁵⁰ Hancock, *supra* note 23.

⁵¹ Melinda Beck, *Big Bets on Proton Therapy Face Uncertain Future*, WALL ST. J. (May 26, 2015), <https://www.wsj.com/articles/big-bets-on-proton-therapy-face-uncertain-future-1432667393>.

⁵² Hancock, *supra* note 23.

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ Hancock, *supra* note 23; *see* Beck, *supra* note 51.

⁵⁶ Hancock, *supra* note 23; *see* Beck, *supra* note 51.

⁵⁷ Janet Weiner, *How to Pay for Proton Therapy in Cancer Clinical Trials*, PENN LDI BLOG (July 20, 2018), <https://ldi.upenn.edu/healthpolicysense/how-pay-proton-therapy-cancer-clinical-trials>.

⁵⁸ Berkelman et al., *supra* note 19, at 2462.

building compact PBT systems that cost much less than traditional systems.⁵⁹ Studies are under way to find new ways to make PBT faster, more agile, and more compact.⁶⁰

On the other hand, some PBT Centers continue to cast their bets on profiting from treating high volume of prostate cancer patients. As of 2018, there were 27 PBT units in the U.S. and more than 20 Centers under construction or in development.⁶¹ A PBT Center that opened in Manhattan in 2019 cost 300 million dollars⁶² and expects to treat around 1,400 patients annually.⁶³ Out of those 1400 patients, the Center anticipates that 20 percent will be prostate cancer patients.⁶⁴

III. PROPOSED METHODS TO CURTAIL EXPECTATIONS

The legal and legislative systems should aim to curb uncontrolled and inefficient development of new health care technology. For starters, they should clearly establish guidelines around reimbursement of new health care technology and promote cost-effective development. Further, the federal and state governments should reconsider federal and state regulations that limit competition of PBT Centers.

A. Federal Government

Uniform federal regulation signaling more rigorous scrutiny of inefficient, wasteful use of medical technology would help control the expectation of profit-seeking parties and to mitigate state regulation encouraging inefficient use. Currently, the FDA's approval of and Medicare's reimbursement processes

⁵⁹ See Beck, *supra* note 51.

⁶⁰ *Researchers Aim to Develop Radiation Therapy with Short Exposure Times*, STAN. MED. NEWS CTR. (Jan. 9, 2019), <http://med.stanford.edu/news/all-news/2019/01/researchers-aim-to-develop-radiation-therapy-with-short-exposure.html>.

⁶¹ *Id.*

⁶² Charles B. Simone, *New York Proton Center Advances Mesothelioma Treatment*, ASBESTOS.COM (Aug. 30, 2019), <https://www.asbestos.com/blog/2019/08/30/new-york-proton-center-for-mesothelioma/>.

⁶³ Melanie Grayce West, *New York's First Proton Therapy Center to Open in July*, WALL ST. J. (May 16, 2019), <https://www.wsj.com/articles/new-yorks-first-proton-therapy-center-to-open-in-july-11558030007>.

⁶⁴ Barbara Benson, *Meet Harlem's \$238 Million Cancer Killer*, CRAIN'S N.Y. BUS. (Mar. 20, 2015), https://www.crainsnewyork.com/article/20150320/HEALTH_CARE/15032991/meet-harlem-s-238-million-cancer-killer.

for new technology does not identify unnecessary care, tending to cover new technologies for procedures without demanding demonstrated effectiveness.⁶⁵

The FDA should enforce a more stringent device reviews processes of new health technology to assess their safety and effectiveness. During the initial approval process, for many categories of health care technology, the FDA does not require randomized studies showing its safety or effectiveness for approval.⁶⁶ Instead, most categories of medical devices are subject to a 510(k) approval process, which only require preclinical studies—studies done in laboratory settings, unlike clinical studies which involve humans—or that it is “substantially equivalent” to an existing, already-approved medical device.⁶⁷ As a result of this lenient approval process, several alarming failures have taken place.⁶⁸ The post-approval studies (PAS), which allow the FDA to obtain information about “device safety, effectiveness, and/or reliability over long-term use of the device[,]” have not been rigorously enforced, either.⁶⁹

The FDA should subject PBT to a higher standard of review to ensure its safety and effectiveness. Since approving PBT for cancer treatment in 1988, the FDA has cleared numerous developments in PBT units for marketing under the substantial equivalence review standard of 510(k) without considering cost-effectiveness or effectiveness of the technology for certain uses.⁷⁰ Some leniency in initial FDA approval

⁶⁵ See Epstein, *supra* note 44, at 622.

⁶⁶ See Alan M. Garber, *Modernizing Device Regulation*, 362 NEW ENG. J. MED. 1161, 1161–62 (Apr. 1, 2010) (stating that for class I, class II, and some class III medical devices, clinical trials to show their safety and efficacy are unnecessary for FDA approval); JUDITH A. JOHNSON, CONG. RESEARCH SERV., FDA REGULATION OF MEDICAL DEVICES 2–3 (Sept. 14, 2016) (naming recent FDA approved medical devices that caused patient injury and death, including metal-on-metal hip plants, pacemakers, defibrillators).

⁶⁷ See JOHNSON, *supra* note 66, at 19–25 (describing the 510(k) process and stating that many types of 510(k) processes are less rigorous than PMA process).

⁶⁸ See *id.* at 2–3 (naming recent FDA approved medical devices that caused patient injury and death, including metal-on-metal hip plants, pacemakers, defibrillators); Garber, *supra* note 66, at 1162 (mentioning defibrillators that have gone through PMA approval process but caused serious harm to patients by failing to discharge or discharging inappropriately).

⁶⁹ *Id.* at 11.

⁷⁰ See U.S. FOOD & DRUG ADMIN., 510(K) SUMMARY FOR RADIATION THERAPY BEAM-SHAPING APERTURE AND RANGE COMPENSATOR APPROVAL (Oct. 23, 2012); U.S. FOOD & DRUG ADMIN., 510(K) SUMMARY MEVION S250I APPROVAL (Dec. 27, 2017); *Hitachi Receives FDA Clearance for Probeat*

processes is necessary to allow consumers to have quick access to new and improved medical devices.⁷¹ However, when the FDA first approved PBT, there were minimal studies available about the effectiveness of IMRT and studies had not yet demonstrated that PBT may be riskier than IMRT.⁷² The landscape of research showing PBT's safety and effectiveness compared to IMRT is currently different.⁷³ Therefore, if the FDA enforced a more stringent PAS and re-reviewed the safety and effectiveness of PBT in comparison to IMRT, it may lead to a re-consideration about whether PBT should continue to be used without restrictions for treating prostate cancer.⁷⁴

Medicare's reimbursement procedures present a similar issue. "Medicare performs no evaluation of the benefits associated with new medical technologies, and in its fee-for-service incarnation does not ask if care could be better managed."⁷⁵ Medicare is also very slow to update its coverage decisions.⁷⁶ Hence, Medicare tends to discourage cost-saving innovation and efficient insurance coverage denials.⁷⁷

In 2017, American Society for Radiation Oncology (ASTRO) proposed a policy for PBT. The ASTRO model suggests that until further findings demonstrate its safety and effectiveness, the use of PBT for prostate cancer should only be reimbursed when it is used as a part of a clinical trial furthering research.⁷⁸ This strikes the balance between discouraging uncontrolled, irresponsible and profit-seeking development PBT and allowing reimbursement for the use of PBT where it is apt and helpful for further research. Several private insurers have since adopted this model.⁷⁹ So far, however, Centers for Medicare & Medicaid

Proton Beam Therapy System, HITACHI (Mar. 21, 2006), <http://www.hitachi.us/press/03212006> (stating that as one of three PBT Centers that are hospital-based in the U.S. at the time, it received FDA approval under substantial equivalence standard).

⁷¹ JOHNSON, *supra* note 66, at 2.

⁷² See *supra* notes 15–16 and accompanying text.

⁷³ See *supra* Part I.

⁷⁴ See Garber, *supra* note 66, at 1163.

⁷⁵ Baicker et al., *Saving Money or Just Saving Lives? Improving the Productivity of US Health Care Spending*, 4 ANN. REV. ECON. 33, 40–41 (Apr. 5, 2012).

⁷⁶ Epstein, *supra* note 44, at 622.

⁷⁷ Baicker et al., *supra* note 75, at 41.

⁷⁸ *ASTRO Updates Insurance Coverage Recommendations for Proton Therapy*, AM. SOC'Y FOR RADIATION ONCOLOGY (July 12, 2017), <https://www.astro.org/News-and-Publications/News-and-Media-Center/News-Releases/2017/ASTRO-updates-insurance-coverage-recommendations-f>.

⁷⁹ AM. SOC'Y FOR RADIATION ONCOLOGY *supra* note 3, at 4.

Services (CMS) has not released a national coverage determination for PBT, leaving reimbursement decisions up to Local Medicare Administrative Contractors (LCDs).⁸⁰

Instead of relying on state Medicare decisions, the national CMS should state that use of PBT in prostate cancer will only be reimbursed when it is a part of a clinical trial until further findings demonstrate its safety and effectiveness. A clear guidance from the national CMS could encourage an exercise of prudence from those seeking to invest in, or develop, PBT Centers expecting to quickly recoup the high investment. At the least, it could encourage PBT Centers to develop on a smaller and cheaper scale or seek funding from non-profit entities so they can focus on patient care and research rather than profit. Decreased pressure from investors to recoup the costs would allow PBT Centers to be more flexible with the use and price of PBT. For instance, the Mayo Clinic built its PBT Center financed by a 100-million-dollar donation rather than relying on private equity.⁸¹ The lack of pressure from investors allows the Mayo Clinic to charge the same rates for PBT as for IMRT.⁸²

Further, the federal government should preempt state regulations which retard the movement towards efficient use of PBT. For example, some state bills discourage private insurers from declining coverage of PBT treatment for prostate cancer for lack of evidence demonstrating effectiveness.⁸³ In 2015, Oklahoma's bill prohibited health benefit plans from "holding [PBT] to a higher standard of clinical evidence for medical policy benefit coverage decisions than the health plan requires for coverage of any other radiation therapy treatment."⁸⁴ Senator Marian Cooksey, the author of the bill, stated that insurance companies' decision to not reimburse PBT because of its lack of long-term studies is a "very

⁸⁰ Jarosek et al., *supra* note 4, at 2; *see e.g.*, FALLON HEALTH, PROTON BEAM THERAPY CLINICAL COVERAGE CRITERIA 2 (Apr. 1, 2018), <https://www.fchp.org/en/providers/criteria-policies-guidelines/medical-policies.aspx> (click on Proton Beam Therapy to download) (stating that coverage for Medicare based plans is in accordance with Medicare Local Coverage Determination).

⁸¹ *See* Beck, *supra* note 51.

⁸² *See id.*

⁸³ *Cf.* Daniel Siegal, *Aetna Owes \$26M Over Denied Cancer Treatment, Jury Says*, LAW360 (Nov. 8, 2018), <https://www.law.com/2018/11/14/25-6m-okla-verdict-against-aetna-in-denied-treatment-case-raises-bad-faith-issues/?sreturn=20190022132147> (finding the insurance company to be in bad faith for repeatedly refusing to cover PBT for a patient's tumor in her throat and awarding nearly \$25.6 million in damages including punitive damages).

⁸⁴ *See* H.B. 1515, 2015 Leg., 1st Sess. (Okla. 2015).

weak argument.”⁸⁵ Oklahoma law, in turn, “ensur[es] that the physician has the final say in the treatment, not the insurance company.”⁸⁶

Another example of an inefficient state regulation is State Certificate of Need (CON) law, which regulates medtech. State CON laws require health care providers to obtain a permit from the state before offering new services, constructing new buildings, or purchasing new medical equipment.⁸⁷ Once upon a time, the federal government supported CON laws and considered them to be cost-containment mechanisms.⁸⁸ But, over time, CON laws were found to have the opposite effect. When states enacted CON laws, their Medicare spending increased by 6.9 percent because the CON laws restricted the supply of health care.⁸⁹ When repealed, state health care spending decreased by .8 percent per year, leveling out at 4 percent after five years.⁹⁰ The federal government has spoken out against state CON laws.⁹¹ The FTC stated that CON laws “create barriers to expansion, limit[s] consumer choice, and stifle[s] innovation.”⁹²

Despite the statistics, 35 states and the District of Columbia continue to enforce CON laws for at least some health care services.⁹³ Some states specifically proposed regulation to limit the number of PBT Centers in the state.⁹⁴ Even if state CON laws are not aimed specifically

⁸⁵ *New Law Will Protect Proton Therapy Coverage*, OK HOUSE, <https://www.okhouse.gov/Media/ShowStory.aspx?MediaNewsID=5045> (last visited Sept. 22, 2019).

⁸⁶ *Id.*

⁸⁷ Emily Whelan Parento, *Certificate of Need in the Post-Affordable Care Act Era*, 105 KY. L.J. 201, 205 (2017).

⁸⁸ *See id.* at 205, 207 (stating that the federal government first perceived CON laws to be cost-containing mechanisms and required states to enact CON laws for a brief period in 1970s and 1980s).

⁸⁹ James Bailey, *Can Health Spending Be Reined in Through Supply Constraints? An Evaluation of Certificate-of-Need Laws*, MERCATUS CTR. (Aug. 1, 2016), <https://www.mercatus.org/publication/health-spending-reined-in-CON-laws>.

⁹⁰ *Id.*

⁹¹ *See Parento, supra* 87, at 215 (stating that the federal government has not been neutral towards CON laws and that both the FTC and DOJ have spoken out against it).

⁹² *Agencies Submit Joint Statement Regarding Virginia Certificate-of-Need Laws for Health Care Facilities*, FEDERAL TRADE COMM’N (Oct. 26, 2015), <https://www.ftc.gov/news-events/press-releases/2015/10/agencies-submit-joint-statement-regarding-virginia-certificate>.

⁹³ Parento, *supra* note 87.

⁹⁴ Jay Greene, *Local Proton Beam Planners March On: McLaren Rivals Say Need Supports Multiple Centers*, CRAIN’S DETROIT BUS., (Sept. 29, 2009),

to control PBT Centers, operation of PBT facilities often does not pass regulatory muster without approved CON.⁹⁵

The FTC should enforce antitrust laws against states that adopted CON laws where they are violative of federal antitrust laws. Requiring PBT units to obtain a CON before operating in a state harms consumers by “creat[ing] market power” and “limit[ing] patient choice” and “creat[ing] opportunities for existing competitors to thwart or delay new competition.”⁹⁶ Under CON law, once a state allows the development of one PBT Center, other PBT Centers face extremely high barriers to enter the market.⁹⁷ This effectively tells the PBT Centers that once they establish a large Center in a state and becomes approved under CON law, they are not likely to have competition. This can have negative effects on cancer patients because this limits patient choice and excludes cheaper, or more superior, alternatives that a competitive market may offer.⁹⁸

Additionally, with little room to enter the market, new actors lack incentive to find cheaper methods of entry.⁹⁹ Higher barriers of entry into the market therefore impede efforts to improve the efficiency

<https://www.craigslist.com/article/20090929/EMAIL01/309299993/local-proton-beam-planners-march-on-mclaren-rivals-say-need> (stating that in 2008, Michigan Certificate of Need Commission approved regulation to limit the number of PBT Centers to a single collaborative of five hospitals).

⁹⁵ See Memorandum regarding Proton Beam Therapy from Thomas Jung, Acting Director of the Division of Health Facility Planning of New York to Members of the State Hospital Review and Planning Council (Mar. 11, 2010), https://www.health.ny.gov/facilities/cons/proton_beam_therapy_demonstration_project/docs/memorandum.pdf (addressing the question whether operating a PBT facility requires CON approval and concluding that it’s difficult, if not impossible, to imagine a PBT facility that would pass regulatory muster without CON approval).

⁹⁶ See, e.g., U.S. DEP’T OF JUSTICE, ANTITRUST DIV., COMMENTS ON PROPOSED CERTIFICATE OF NEED STANDARDS FOR PROTON BEAM THERAPY SERVICES, <https://www.justice.gov/atr/comments-proposed-certificate-need-standards-proton-beam-therapy-services> (June 6, 2008).

⁹⁷ See *id.* (stating that the proposed CON law allows for only one PBT Center to operate, and in addition, the approved entities may set terms and standards of operation for other seeking to enter the market, and existing entities may thwart or delay new competition).

⁹⁸ See *id.* (“[CON] law regimes, by their nature, limit competitive entry and impede the proper functioning of the market process. They can create market power where it may not otherwise exist, limit patient choice, and create opportunities for existing competitors to thwart or delay new competition”).

⁹⁹ See *id.*

or cost of PBT. In a 2014 report, Ernst & Young (EY) compared the medtech market to the personal computer industry in the 90s, arguing that low barriers to market entry for the personal computer industry encouraged and accelerated the development of the market.¹⁰⁰ Lowering barriers to market entry in the PBT market is likely to promote development of already existing efforts¹⁰¹ to make PBT units faster, cheaper, and more efficient by encouraging “reverse innovation”—finding ways to produce relatively inexpensive, stripped-down versions of the units—and encouraging international manufacturers to seek to enter the U.S. market as well.¹⁰²

The presence of CON law affects the behavior of existing PBT Centers and their interaction with potential patients as well. With the rising health care costs in the U.S. continuing to be a looming issue, the medical health technology field is shifting its focus. Hospitals are increasingly shifting simple cost-cutting to increasing value,¹⁰³ and health care purchasers are prioritizing devices that reduce the total cost of care.¹⁰⁴ “Payers and providers are most interested in highly differentiated medtech products that represent a significant improvement over the standard of care.”¹⁰⁵ PBT, without further research on its effectiveness or the value of its technology transfer from IMRT, is more likely to be scrutinized under this focus. Increasing competition is likely to encourage PBT Centers to find ways to cut costs and find ways to make PBT treatment more efficient.

¹⁰⁰ ERNST & YOUNG, PULSE OF THE INDUSTRY: MEDICAL TECHNOLOGY REPORT 9 (2014).

¹⁰¹ See *supra* notes 59 and 60 and accompanying text.

¹⁰² See *generally* ERNST & YOUNG, *supra* note 100.

¹⁰³ See *id.* at 6.

¹⁰⁴ *Id.* at 8.

¹⁰⁵ *Id.*

B. Insurance Companies

Private insurers have been playing a key role in curbing PBT reimbursement. In defiance of their traditional ways, insurance companies have declined to reimburse PBT treatment of prostate cancer.¹⁰⁶ In 2013, three major insurers—Regence, Blue Shield of California, and Aetna—changed their policies to stop covering PBT for prostate cancer, stating that PBT is more costly but without demonstrated increased benefits compared to IMRT.¹⁰⁷ Currently, nearly all commercial insurers and state Medicaid plans do not cover PBT for prostate cancer.¹⁰⁸

Several recent court decisions have supported the insurance companies' decisions to deny coverage for the use of PBT in prostate cancer. In *Baxter v. MBA Group Ins. Trust Health and Welfare Plan*,¹⁰⁹ the plaintiff patient brought a claim for wrongful denial of coverage against his insurance after being denied reimbursement for PBT for early stage prostate cancer. His insurance plan stated that PBT was not "medically necessary" as stated by their medical policy because it has not been shown to be superior to other approaches.¹¹⁰ Finding that the burden of proof was on the plaintiff to establish medical necessity, the effectiveness of PBT, and the cost of PBT, the court granted the insurance company's motion for summary judgment.¹¹¹

Similarly, in *Woodruff v. Blue Cross and Blue Shield of Alabama*,¹¹² the plaintiff claimed that Blue Cross Blue Shield (BCBS) wrongfully denied his claim for reimbursement of PBT treatment for his prostate cancer. The court granted BCBS's motion for summary judgment, concluding that the court's role was only to decide whether BCBS's judgment was "reasonable."¹¹³ There, the court found that BCBS's decision to deny coverage was reasonable based on the lack of randomized, published studies showing that it is superior to its

¹⁰⁶ Ron Winslow & Timothy W. Martin, *Prostate-Cancer Therapy Comes Under Attack*, WALL ST. J. (Aug. 28, 2013), <https://www.wsj.com/articles/prostatecancer-therapy-comes-under-attack-1377734990?tesla=y>; Jaimy Lee, *As a Proton Therapy Center Closes, Some See It as a Sign*, MODERN HEALTHCARE (Sept. 18, 2014), <https://www.modernhealthcare.com/article/20140918/NEWS/309189939>.

¹⁰⁷ See Winslow & Martin, *supra* note 106.

¹⁰⁸ Bekelman et al., *supra* note 19.

¹⁰⁹ 958 F. Supp. 2d 1223 (W.D. Wash. 2013).

¹¹⁰ *Id.* at 1225.

¹¹¹ *Id.* at 1230–38.

¹¹² 2018 WL 571933 (N.D. Ala. Jan. 26, 2018).

¹¹³ *Id.* at *7.

alternatives.¹¹⁴ The court further found that the opinions of a treating physician were not “entitled to a presumption of deference.”¹¹⁵ In *Howard v. Blue Cross and Blue Shield of Arizona*,¹¹⁶ too, the district court upheld the insurer defendant’s denial of PBT use in prostate cancer, finding that the insurer defendant was not “clearly erroneous” in finding that PBT use in the plaintiff’s case was not “medically necessary.”

In all three cases, courts refer specifically to the language in the insurance plan. In *Woodruff* and *Howard*, the insurer defendants clearly stated that “medically necessary” encompasses considerations of cost.¹¹⁷ The *Woodruff* and *Howard* insurer defendants further stated in their policy that under their “medically necessary” definition, PBT for prostate cancer was not covered.¹¹⁸

Because insurance policies are read as contracts, where the definition of “medically necessary” is clearly stated to include cost-effectiveness, or PBT is specifically listed in the plan as a non-medically necessary treatment based on existing evidence, courts may be less likely to inject their own patient-friendly, broad definitions of “medical necessity.” Therefore, until there are sufficient studies on PBT use for localized prostate cancer that support its cost compared to that of IMRT, courts may continue to rule in the insurer’s favor if the insurance plan includes the right language. This may help curb PBT Centers’ reckless

¹¹⁴ *Id.* at *10.

¹¹⁵ *Id.* at *8.

¹¹⁶ *Howard v. Blue Cross Blue Shield of Ariz.*, No. CV-16-03769-PHX-JJT, 2019 U.S. Dist. LEXIS 116058 (D. Ariz. July 12, 2019).

¹¹⁷ See *Woodruff*, 2018 WL 571933, at *6 (“If a service or supply is not addressed . . . it will be considered to be medically necessary only if . . . it is appropriate and necessary . . . and performed in the least costly setting, method, or manner, or with the least costly supplies required by [the patient’s] medical condition.”); *Baxter v. MBA Grp. Ins. Tr. Health and Welfare Plan*, 958 F. Supp. 2d 1223, 1228–29 (W.D. Wash. 2013) (“[I]n accordance with generally accepted standards of medical practice; clinically appropriate . . . ; not more costly than an alternative service or sequence of services or supply at least as likely to produce equivalent therapeutic or diagnostic results . . .”).

¹¹⁸ See *Woodruff*, 2018 WL 571933, at *6 (“[PBT] does not meet [BCBS’s] medical criteria for coverage in patients with clinically localized prostate cancer, because the clinical outcomes with this treatment have not been shown to be superior to other approaches including [IMRT] yet proton beam therapy is generally more costly . . .”); *Howard*, 2019 U.S. Dist. LEXIS 116058, at *9 (“[PBT] is considered not medically necessarily for clinically localized prostate cancer based upon insufficient evidence to support improvement of the net health outcome, and insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.”).

use of PBT for prostate cancer without substantiating its safety or effectiveness.

At the same time, a complete ban on coverage of PBT use by private insurers is likely premature. One of the problems with PBT is that there are no randomized trials showing its effectiveness. But, conducting randomized trials is difficult if there are not enough patients to participate in the trials.¹¹⁹ Lack of reimbursements for PBT can result in lack of enrollment of patients in clinical trials that may provide concrete answers about the long-term effectiveness of PBT. Coverage from Medicare helps, but the number of patients who can participate would be significantly limited.¹²⁰ Additionally, Medicare includes mostly patients over 65, which may reduce the generalizability of the results.¹²¹

To deal with this dilemma, some insurers cover PBT for selected cancers being studied to support clinical trials.¹²² For example, Cigna, Independence Blue Cross, and Blue Cross Blue Shield of Florida cover PBT for selected cancers under study or have established coverage with study participation policies.¹²³ This practice curbs irresponsible use of PBT treatment but allows clinical trials to continue their research on PBT's effectiveness and safety. In the past, continued use of IMRT, despite its lack of demonstrated effectiveness, allowed clinical trials to continue their studies, which ultimately proved IMRT to be an effective method of treatment for prostate cancer. Such results would have been close to impossible had patients been unable to afford IMRT. Therefore, rather than implement a total ban on reimbursement of PBT, private insurers should consider the policy of reimbursing those participating in clinical trials.

CONCLUSION

Uncontrolled and unregulated health care spending on new technology without adequate findings of its effectiveness takes away funds that could be spent efficiently elsewhere. PBT demonstrates promise for various types of cancers, but so far, for localized prostate cancer, there is a significant lack of research showing its effectiveness compared to its alternatives.

¹¹⁹ Weiner, *supra* note 57.

¹²⁰ *Why Randomized Trials for Proton Therapy are Difficult to Complete (and What We Can Do About It)*, SCI. DAILY (July 11, 2018), <https://www.sciencedaily.com/releases/2018/07/180711141353.htm>.

¹²¹ *Id.*

¹²² Weiner, *supra* note 57.

¹²³ Bekelman et al., *supra* note 19.

The U.S. has seen a rise in the number of PBT Centers and the use of PBT, mainly driven by the anticipated profit stemming from the its use for treatment of prostate cancer. This expectation was likely fostered by the existing environment facilitating generous reimbursement for new medical technology. Despite the recent financial problems that existing PBT Centers have experienced, many PBT Centers continue to build, still anticipating high patient volume from prostate cancer patients. Curtailing the expectation of demand and profit by establishing a level of scrutiny towards inefficient use of PBT on a federal level is likely to encourage a more efficient growth of the PBT market.