		CERTIFIED
1	STATE OF CONNECTICUT	COPY
2	OFFICE OF HEALTH STRATEGY	
3		
4	DOCKET NO. 19-32339-CON	
5	CONNECTICUT PROTON THERAPY CENTER, LLC	, HARTFORD
6	SERVICES CORPORATION AND YALE NEW HA	AL FOR THE
7	ACQUISITION OF NEW TECHNOLOGY AND ACQUI	SITION OF A
8	COMPUIED IOMOGRAPHY ("CI") SIMUL	AIOR.
9	VIA ZOOM AND TELECONFERENCE	
10		
11	Public Hearing held on Wednesday, Nov	ember 18,
12	2020, Degrinning at 10.03 a.m. Via remo	te access.
13	Held Before:	
14	MICHEALA MITCHELL, ESQ., Hearing O	fficer
15	Administrative Staff.	
16	LINDSEV DONSTON Healthcare Analys	+
17	BRIAN CARNEY, Research Analyst	oordinator
18	Appearances:	
19	For the Applicant:	
20	UPDIKE, KELLY & SPELLACY, P.C.	
21	New Haven, Connecticut 06510	
22	BI. UENNIFER GROVES FUSCO, ESQ	•
23		
24		
25	Reporter: Lisa L. Warner, CSR	#061

(Whereupon, the hearing commenced at 10:03 a.m.)

1

2

3

4

5

6

7

8

25

HEARING OFFICER MITCHELL: Good morning, everyone. This hearing before the Health Systems Planning Unit identified by Docket No. 19-32339-CON is being held on November 18th to establish proton therapy services in Wallingford, Connecticut by acquisition of new technology and a computed tomography simulator.

9 On March 14 of 2020, Governor Ned 10 Lamont issued Executive Order 7B which in relevant 11 part suspended in-person open meeting requirements. I will note that Executive Order 7B 12 13 was scheduled to expire after having been extended 14 to November 9th of 2020, and then was extended a 15 second time by Executive Order 9L to February 9th 16 To ensure continuity of operations while of 2021. 17 maintaining the necessary social distance to avoid 18 the spread of COVID-19, the Office of Health 19 Strategy is holding this hearing remotely.

We ask that all members of the public and everyone who is not actively testifying mute their device that they are using to access the hearing and silence any additional devices that are around them.

The public hearing is being held

pursuant to Connecticut General Statute, Section 19a-639and will be conducted as a contested case in accordance with the provisions of Chapter 54 of the Connecticut General Statutes.

My name is Micheala Mitchell. Victoria Veltri, the executive director of the Office of Health Strategy, has designated me to serve as the hearing officer for this matter. My colleagues, Brian Carney and Lindsey Donston, are also here to assist me in gathering facts related to this application.

The certificate of need process is a regulatory process, and as such, the highest level of respect will be afforded to the parties, members of the public, and our staff. Our priority is the integrity and transparency of this process, and accordingly we ask that decorum be maintained by all present during these proceedings.

The hearing is being recorded and will be transcribed by BCT Reporting LLC.

All documents related to this hearing that have been or will be submitted to the Office of Health Strategy are available for review through our CON portal which is accessible on the

1

2

3

4

5

6

7

Office of Health Strategy's CON webpage.

1

2

3

4

5

б

7

8

9

10

11

12

13

14

15

16

17

18

19

In making its decision, the Health Systems Planning Unit, or HSP, will consider and make written findings concerning the principles and guidelines set forth in Section 19a-639 of the Connecticut General Statutes.

Yale New Haven Health Services Corporation and Hartford HealthCare Corporation are parties to this proceeding.

At this time, I'm going to ask Mr. Carney to read into the record those documents already appearing in HSP's table of record in this case. All documents have been identified in the table of record for reference purposes.

Brian, are you all set?

MR. CARNEY: Good morning. This is Brian Carney of the Office of Health Strategy unmuted. At this time, I would like to enter into the record Exhibits A through U.

HEARING OFFICER MITCHELL: So, in
addition to that, Attorney Fusco, we have proposed
Exhibits B. B is the hearing agenda. W is the
table of record which probably we shouldn't do
that as W. So actually W is not going to be the
table of record. W is going to be the Connecticut

Post article which I sent to you. I don't know if you've had time to kind of look over that and tell me what your thoughts are about it.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

MS. FUSCO: This is Jen Fusco. I did have a chance to look it over. We have no objection to it being entered as long as we have an opportunity to respond to it. And I assume you folks have questions on it, so we're comfortable with you putting it in.

HEARING OFFICER MITCHELL: Thank you. So that is going to be Exhibit W. We may need some Late-Files, but the final table of record will also receive an exhibit number at the end of the hearing and after we have taken in all evidence. So B is the agenda, and then W is the Connecticut Post article. Thank you so much.

Any objections on any of the other exhibits?

¹⁹ MS. FUSCO: No objection, but I did ²⁰ just want to clarify on both the hearing agenda ²¹ and I see on your introductory slide the docket ²² number is incorrect. You have it listed as ²³ "20-32339." It's actually 19. I know, it's been ²⁴ a long year. And I see several of the documents ²⁵ have had it different, but just for the record

it's 19-32339-CON.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

HEARING OFFICER MITCHELL: Got it. And we're going to revise all of those for the record. MS. FUSCO: That's fine.

HEARING OFFICER MITCHELL: Thank you for bringing that to our attention.

All right. So, what is going to happen next is the applicants will present their direct testimony. HSP will ask questions of the applicant. We're going to hear from the public at 4 p.m. I do know that there have been some requests to have some members of the public speak earlier, and I do reserve the right to allow public officials and members of the public to testify outside of the order of the agenda. So we'll work that through with the applicants as that occurs.

¹⁸ I'm just going to ask Attorney Fusco to ¹⁹ just kind of give me a little bit of a reminder in ²⁰ terms of when people have to leave. So we'll ²¹ accommodate you in that way.

MS. FUSCO: Great. Thank you.
 HEARING OFFICER MITCHELL: I would like
 to also advise the applicants that we may ask
 questions related to your application that you

feel -- you might feel that you've already addressed. And we are going to do that for the purpose of ensuring that the public has knowledge about the proposal and also for the purpose of clarification. But I just want to reassure you that we've read the application, completeness responses and prefile testimony. So just bear with us if we ask you something that you feel like you've already answered.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

In addition to that, as this hearing is again being held virtually, we ask that all participants to the extent possible enable use of their video cameras when testifying or commenting during the proceedings, and that anyone who is not testifying or commenting mute their electronic devices, including telephones, televisions and any other devices that are not being used to access the hearing.

And then when we go off the record, participants in the hearing can mute their devices and disable their cameras when we do that so that conversations could be held privately.

If we go off the record, I will make sure that I provide a warning to the parties one minute prior to going back on the record so that

you can situate yourselves accordingly. If you need any additional time for cleaning, you know, for any type of COVID protocol, just let me know. Registration to render public comment will begin at 3 p.m. OHS will hear public comment at 4 p.m. Comments will be taken during the hearing in the order established by OHS, and I will call each individual by name when it is his or her turn to speak.

I do want to say that we are going to take a break from 1 o'clock to about 1:45 so that people can eat lunch or, you know, confer with one another with regard to any questions. We're just going to make sure that we take a break from 1 to 1:45.

16 At this time, I would like all of the 17 individuals who are going to testify on behalf of 18 the parties to this application to be formally 19 identified by their attorney after which I'm going 20 to swear them in. And I just want to acknowledge, 21 Attorney Fusco, thank you for sending the witness 22 list for the court reporter. So we'll just swear 23 everyone in at this time.

24 MS. FUSCO: Okay. And I don't know if 25 you want folks to -- I can introduce you to the

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

people who are in the room, and then I think I sent you the list of folks who would be remote. But we can start with Art Lemay from Yale New Haven, Donna Handley from Hartford HealthCare, Lori Pickens from Yale New Haven, Kristi Gafford from Yale New Haven -- I'm sorry, from Hartford HealthCare. We have Dr. Ken Roberts from Yale New Haven, Dr. Andy Salner from Hartford HealthCare. And then also to testify remotely we have Chris Chandler from Proton International, and Nancy Mendenhall from the University of Florida Proton Therapy Institute.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

And I know I did give you a list of others. So it would include Gerry Boisvert from Hartford HealthCare, Tom Newman from Yale New Haven, Mario Donini from Yale New Haven, Fred Sorbo from Hartford HealthCare. Those are finance folks. Susan Manning from FTI, she's the healthcare economist who did the report.

Am I missing anyone else? I think that's it. If I've missed anyone, I can -- but I think that sounds right. I have a list. Yeah, I think that's everyone. If for some reason we need someone else to answer a question, they could be sworn in. I mean, I don't anticipate anyone

1	beyond these folks, but if something comes up that
2	requires a different witness, could you swear them
3	in during the hearing, if need be?
4	HEARING OFFICER MITCHELL: Yes,
5	absolutely. So I'm going to try to remember
6	everyone that you named off because I don't have
7	the list in front of me. But I'm going to ask
8	everybody who is going to be testifying today, if
9	you wouldn't mind raising your hand for me so that
10	I can swear you in.
11	ARTHUR LEMAY,
12	DONNA HANDLEY,
13	LORI PICKENS,
14	KRISTI GAFFORD,
15	BARBARA DURDY,
16	KENNETH ROBERTS,
17	ANDREW SALNER,
18	CHRIS CHANDLER,
19	NANCY MENDENHALL,
20	GERRY BOISVERT,
21	THOMAS NEWMAN,
22	MARIO DONINI,
23	FRED SORBO,
24	SUSAN MANNING,
25	called as witnesses, being first duly sworn

Γ

ſ	
1	(remotely) by Ms. Mitchell, were examined and
2	on their oath as follows:
3	HEARING OFFICER MITCHELL: I'm going to
4	start with Mr. Lemay.
5	THE WITNESS (Lemay): I do.
6	HEARING OFFICER MITCHELL: Ms. Handley.
7	THE WITNESS (Handley): I do.
8	HEARING OFFICER MITCHELL: Ms. Pickens.
9	THE WITNESS (Pickens): I do.
10	HEARING OFFICER MITCHELL: Ms. Gafford.
11	THE WITNESS (Gafford): I do.
12	HEARING OFFICER MITCHELL: Ms. Durdy.
13	THE WITNESS (Durdy): I do.
14	HEARING OFFICER MITCHELL: Mr. Roberts.
15	THE WITNESS (Roberts): I do. Dr.
16	Roberts.
17	HEARING OFFICER MITCHELL: Dr. Roberts.
18	Pardon me if I don't say doctor. I'm so sorry.
19	Dr. Salner.
20	THE WITNESS (Salner): I do.
21	HEARING OFFICER MITCHELL: Okay.
22	Mr. Chandler.
23	THE WITNESS (Chandler): I do.
24	HEARING OFFICER MITCHELL: Dr.
25	Mendenhall.

1 THE WITNESS (Mendenhall): I do. 2 HEARING OFFICER MITCHELL: 3 Mr. Boisvert? 4 (No response.) 5 HEARING OFFICER MITCHELL: He's out of 6 the room? 7 MS. FUSCO: He's remote. I don't know 8 if he's muted. 9 HEARING OFFICER MITCHELL: Okay. 10 MS. FUSCO: We can move on maybe and 11 come back. 12 HEARING OFFICER MITCHELL: No worries. 13 THE WITNESS (Boisvert): Can you hear 14 me now? I do. Sorry about that. 15 HEARING OFFICER MITCHELL: Perfect. 16 Thank you. 17 Tom Newman. 18 THE WITNESS (Newman): I do. 19 HEARING OFFICER MITCHELL: Mr. Donini. 20 THE WITNESS (Donini): I do. 21 HEARING OFFICER MITCHELL: Mr. Sorbo. 22 THE WITNESS (Sorbo): I do. 23 HEARING OFFICER MITCHELL: Ms. Manning. 24 THE WITNESS (Manning): I do. 25 HEARING OFFICER MITCHELL: All right.

Thank you, everybody, for your patience.

1

2

3

4

5

6

7

8

9

10

11

12

13

Just remember when giving your testimony, make sure you state your full name and adopt any written testimony that you have submitted on the record prior to testifying today. The applicants may now proceed with their testimony at this time.

MS. FUSCO: Thank you very much.

THE WITNESS (Lemay): Good morning, and thank you. My name is Art Lemay, and I'm the vice president for network development for Smilow Cancer Hospital at Yale New Haven. I adopt my prefiled testimony.

14 It's my pleasure to speak to you today 15 in support of the certificate of need application 16 filed by Yale New Haven Health and Hartford 17 HealthCare for the establishment of the 18 Connecticut Proton Therapy Center in Wallingford. 19 This proposal marks a historic collaboration 20 between the state's two largest health systems 21 that has been over four years in the making. Ιf 22 approved, the Connecticut Proton Therapy Center 23 will provide access to cutting edge life saving 24 cancer technology that's currently not available 25 in the State of Connecticut. Bringing proton

therapy to Connecticut will extend the scope of services provided by our already robust cancer programs, will bring extensive clinical expertise and resources together for the Connecticut residents without requiring our residents to travel out of state for this specialty treatment.

Yale New Haven Health's unprecedented strategic partnership with Hartford HealthCare for the delivery of proton therapy in Connecticut is evidence of our fierce commitment to the care of cancer patients in this state. Seeing this critically important project through to completion is one of the reasons why I continue to work beyond my planned retirement in early 2020. My colleague from Hartford HealthCare, Donna Handley, was also moved on to a different position since we began this work together four years ago, will testify to the same commitment to this project.

You've also received written testimony, and you'll hear from Lori Pickens, the senior vice president of oncology services and executive director for Smilow Cancer Hospital, and Kristi Gafford, the senior VP of the Cancer Institute operation for HartfordCare. Both have testified to their health system's respective cancer

1

2

3

4

5

6

7

8

9

10

programs and how their programs have evolved over the last decade. Dr. Kenneth Roberts and Dr. Andrew Salner have collaborated for years in the field of radiation oncology and have both supported this collaboration from the very beginning. Christopher Chandler from Proton International will discuss the evolution of proton therapy, its clinical efficacy, how it works, and who it benefits. And Dr. Nancy Mendenhall from the University of Florida Proton Therapy Institute who will give you an insider's perspective on the operation of the Proton Therapy Center.

13 Yale New Haven and Hartford HealthCare 14 were for many years monitoring the advances and 15 successes of proton therapy prior to our 16 collaboration. And in 2010, there were only nine 17 proton centers in the U.S., but the science and 18 technology was evolving in clinical research and 19 advancing rapidly. By 2015, five years later, 20 there were already 19 proton centers operational 21 in the U.S. and many more were in development. At 22 that time proton therapy was available or in 23 development in Massachusetts, in New York and New 24 Jersey. And still today Connecticut residents 25 needing this therapy are forced to either endure

1

2

3

4

5

6

7

8

9

10

11

the hardships associated with traveling long distances or forego this lifesaving therapy altogether.

Our journey together, Yale New Haven Health and Hartford HealthCare, began in 2016 when we were invited by the MetroHartford Alliance, an economic development organization, and the City of Hartford's Chamber of Commerce to explore a consortium of Connecticut hospitals to bring proton therapy into Connecticut. The group was asked to explore a novel proposal from a European manufacturer to bring both a research and clinical site into the state. While the hospitals concluded that it was not the right, the suitable technology at that time, the concept of collaborating among the Connecticut hospitals was actually studied and gained traction at least for two of the hospitals that proceeded to move forward.

In 2017, our two health systems entered
 into a strategic partnership to explore
 collaboration to develop the first proton center.
 This made sense recognizing that each health
 system brings to this collaboration clinical
 expertise, research capabilities, and other

1

2

3

4

important resources. Most important, both hospitals and both health systems were very focused on bringing this technology into Connecticut in the most cost effective, financially viable way without unnecessary duplication of services. We jointly engaged Proton International as a consultant to explore the patient demand in the state and assess the viability of a consortium model. We chose Proton International to do this work as consultants because of their expertise in developing and operating proton centers around the U.S.

Proton International confirmed after four months of work that what our two health systems had in mind had actually successfully been implemented in other centers across the country, and it was viable here in Connecticut. So in 2018, Yale New Haven Health and Hartford HealthCare began working together to develop a business model, identify a central easily accessible location in the state, and develop a selection process for a third-party with expertise in implementing, financing and operating proton centers. Ms. Handley will discuss this process in greater detail and tell you how and why we chose

1

2

3

4

5

Proton International to help guide us through this work.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

In conclusion, this proposal is all about bringing lifesaving proton therapy closer to home for patients in this state. It will directly benefit patients in Connecticut, and it will allow local basic scientists and clinical investigators to conduct research and further explore the benefits of the technology. If approved, our unprecedented collaboration will bring unmatched clinical expertise, a depth of experience in treating cancer patients, a relationship with an experienced developer and manager of proton facilities, and a coherent strategy for establishing and operating a first-of-its-kind proton therapy center in the state.

Thank you again for your time, and I'm
 available to answer any questions.

HEARING OFFICER MITCHELL: Thank you.
 THE WITNESS (Handley): Good morning,
 Attorney Mitchell, and members of the Office of
 Health Strategy staff. My name is Donna Handley,
 and I'm a senior vice president for Hartford
 HealthCare and president of Hartford HealthCare's
 east region. I adopt my prefile testimony.

Thank you for this opportunity to speak about our plan to establish a proton therapy center. Connecticut Proton Therapy Center in Wallingford is part of a joint venture with Proton International. First and foremost, I would like to extend my thanks on behalf of Hartford HealthCare, Yale New Haven Health Services and our partner, Proton International, for the extraordinary efforts that the OHS staff has made to keep the CON process moving during these unprecedented times. That may be the most commonly used word in our vocabulary, unprecedented.

1

2

3

4

5

б

7

8

9

10

11

12

13

15

16

19

20

21

22

14 Prior to serving in my role, my current role, I was the vice president of operations for the Cancer Institute at Hartford HealthCare. This 17 affords me additional insight into Hartford HealthCare's cancer services and how this service 18 can advance our shared goals of decreasing healthcare costs and promoting higher quality, better access and more value for healthcare consumers within the State of Connecticut.

23 The collaboration between Hartford 24 HealthCare and Yale New Haven Health Services for 25 the establishment of the Connecticut Proton

Therapy Center will lead to a historic partnership that will shape the future of cancer care in the State of Connecticut. It brings together the clinical experience and resources of the state's two largest health systems, as well as the expertise of our third-party vendor that has developed and operated proton centers both in the United States and internationally.

1

2

3

4

5

6

7

8

9

11

25

It is important to highlight Proton 10 International, another key player in the development and operation of Connecticut Proton 12 Treatment Center. After a thorough vetting 13 process, Hartford HealthCare and Yale New Haven 14 Health Services selected Proton International to 15 assist with our technology selection, financing, 16 and constructing, as well as the management and 17 operation of the facility. Proton International 18 was chosen for its reputation as an established 19 and experienced developer and operator of proton 20 centers throughout the country. Proton 21 International's experience and expertise will have 22 a significant favorable impact on the development, 23 operations, and ultimate success in the 24 Connecticut Proton Treatment Center.

This proposal is designed to provide

proton therapy services to all Connecticut residents through provider and self-referral. A vast majority of patients are expected to come from Hartford HealthCare and Yale New Haven Health Systems due to being the largest providers of comprehensive cancer care in the state.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

The Connecticut Proton Therapy Center will further the goals and objectives of the State of Connecticut as set forth in the Statewide Healthcare Facilities and Services Plan in a number of ways. This includes, but is not limited to, improving the health of Connecticut residents, increasing the accessibility, continuity and quality of health services, and promoting cost effective services while limiting the duplication of services. Encouraging collaboration among healthcare providers to develop healthcare delivery networks is also a guiding principle of the Statewide Healthcare Facilities and Services This partnership represents collaboration Plan. amongst providers at the highest level.

The proposed collaboration between Yale New Haven Health Services and Hartford HealthCare brings together the Academic Medical Center and several other teaching hospitals, a licensed

children's hospital, as well as an affiliation with the only other children's hospital in the state. Additionally, the Connecticut Proton Treatment Center will be involved with comprehensive cancer programs that are implemented by both health systems offering complementary diagnostic and treatment services necessary to support proton therapy centers.

The proposal before you today, if approved, would pave the way for a first of its kind in the state proton therapy center making this advanced lifesaving cancer treatment available for Connecticut residents at an affordable cost. We ask OHS to approve this proposal of establishing a proton therapy center in Wallingford for the benefit of the State of Connecticut.

I thank you for your time. I have with me today colleagues from Hartford HealthCare, Yale New Haven Health Services and Proton International, and we are also available to answer any questions that you have. Thank you. HEARING OFFICER MITCHELL: Thank you. THE WITNESS (Pickens): Good morning,

²⁵ Attorney Mitchell and members of the Office of

- 7

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

Health Strategy staff. My name is Lori Pickens, and I am senior vice president of oncology services for Yale New Haven Health Systems and the executive director of the Smilow Cancer Hospital. I adopt my prefile testimony.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

Thank you for the opportunity to submit testimony in support of the certificate of need application filed by the Hartford HealthCare Corporation and Yale New Haven Health Services for establishment of the Connecticut Proton Therapy Center. Like my colleagues, I am excited about this partnership between Hartford HealthCare and Yale New Haven Health Systems to bring cutting-edge lifesaving cancer technology to Connecticut.

In the interest of time, I will not be giving remarks today, but I am available to answer any questions you have about my testimony or this project. Thank you again.

HEARING OFFICER MITCHELL: Thank you.
 THE WITNESS (Gafford): Good morning,
 Attorney Mitchell and members of the OHS staff.
 My name is Kristi Gafford, and I am senior vice
 president of Cancer Institute operations for
 Hartford HealthCare. I adopt my prefile

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

testimony.

Thank you for the opportunity to submit testimony in support of the certificate of need application filed by Hartford HealthCare Corporation and Yale New Haven Health Services for the establishment of the Connecticut Proton Therapy Center. As you've heard from Lori and others, the establishment of this Proton Therapy Center represents an absolutely historic collaboration between the state's largest health systems and providers of comprehensive cancer services in Connecticut. I'm so pleased to be part of this, and am very eager to move forward with the development of the Connecticut Proton Therapy Center.

In the interest of time, I will not be giving my remarks today, but I am available to answer any questions you have about my testimony or this project. Thank you very much.

20 THE WITNESS (Roberts): Good morning, 21 Attorney Mitchell and members of the OHS staff. 22 My name is Ken Roberts, and I am a professor of 23 therapeutic radiology at the Yale School of 24 Medicine, and also director of pediatric 25 radiotherapy services at Yale, and also associate chief of radiation oncology at Yale New Haven Hospital. I have been practicing radiation oncology for almost 30 years. And I adopt my prefile testimony.

Thank you for the opportunity to speak today in support of the CON we have filed in partnership with Hartford HealthCare to bring equipment utilizing new technology to the state and establishing a proton therapy center in Wallingford. I would like to extend my personal thanks, and on behalf of Yale New Haven Health Services, Hartford HealthCare and our partner Proton International, recognizing the extraordinary efforts that the OHS staff has made to keep the CON process moving during these remarkable times with the COVID pandemic.

My remarks today will be focused on the evolution of proton beam therapy as a cancer treatment modality and the clinical efficacy of proton therapy as compared to other cancer therapies. And I have to say that I'm very excited that we are at the cusp of being able to bring to Connecticut what I believe to be an important cancer therapy modality.

From the perspective of being in the

1

2

3

4

5

6

field of radiation oncology for three decades, I've seen many significant technological improvements to radiotherapy that have made it more effective, targeted and safe with improved patient outcomes. I am excited to point out that I believe that proton radiotherapy particularly stands out as a major development in the field and continues to evolve with better scientific and clinical basis through our collective ongoing experience.

1

2

3

4

5

6

7

8

9

10

11 Allow me to simplistically point out 12 that proton therapy is a type of external beam 13 radiation therapy that uses protons rather than 14 x-rays, also called photons, as in conventional 15 radiation therapy, to treat and kill cancer cells. 16 Proton beam technology has been available since 17 the 1980s, but was in limited use due to the high 18 cost of implementation and initially few studies 19 documenting improved clinical outcomes. Yet its 20 promise to improve cancer therapy by the 21 characteristics of how proton beams are much more 22 focused than x-rays in their ability to deliver 23 radiation dose to a tumor has been well understood 24 by those of us in the field of radiation oncology. 25 The two hospital systems partnering in

this proposed proton therapy program have been very conservative with embracing this innovative technology such that there have been many years of discussing and observing the clinical and technological developments of proton radiotherapy that now brings us to the presence and well-timed Improvements in technology have crossroads. significantly reduced the cost -- improvements in this proton therapy technology have significantly reduced the costs of installation, and the number of proton beam therapy rooms have nearly tripled worldwide over the last ten years. Where there were a little less than a dozen proton facilities in the United States ten years ago, there are now, I believe, 36 proton centers in the United States. With this growth, as the number of proton therapy centers grew, more clinical trials have been conducted and hundreds of research papers published bolstering the evidence for efficacy and cost effectiveness of this therapy.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

There have been important technical enhancements in proton beam therapy since its introduction in the 1980s. The first commercially available proton delivery system was used in what can be characterized as a passive scattering

system to produce clinically useful proton beams. Special filters and collimators have to be physically placed in the beam path to further shape it for individual patient needs. Now, all new proton beam therapy systems are equipped with -- excuse me -- all new proton beam therapy systems are now equipped with a magnetic steering mechanism, as well as fast beam energy switching devices, to deliver individual proton pencil beams in which a distribution of spots of proton radiation energy may be individually tailored to appropriately overlap within a tumor target and better conform radiation dose to the shape and anatomic position of that tumor. This in turn importantly reduces radiation dose to nearby normal tissues. Pencil beam technology also reduces the time of treatment for patients for each session of therapy.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

¹⁹ In the United States medical ²⁰ marketplace there are five proton equipment ²¹ vendors that include Mevion, Ion Beam ²² Applications, also known as IBA, Hitachi, Proton ²³ International, and Varian Medical Systems. They ²⁴ have each worked out robust and sophisticated ²⁵ treatment delivery systems with an option of a

one-room configuration that has markedly reduced costs of proton therapy allowing for its enhanced diffusion in the medical marketplace with improved geographic distribution for improved patient access. Our team has selected the IBA ProteusOne proton therapy technology for the Connecticut Proton Therapy Center which is one of the most advanced compact systems available for providing proton beam therapy.

10 Allow me to get back to basic concepts. Proton therapy is a type of radiation therapy, a treatment that uses high energy ionizing beams to treat tumors by disrupting the tumor's DNA or genetic code in individual tumor cells. Radiation therapy using x-rays, again, also known as photons, has been long used to treat cancers and even noncancerous or benign tumors. Proton therapy is a newer type of radiation therapy that deposits energy from positively charged particles called protons. Proton therapy delivers more precise radiation doses to cancerous tissues with increased accuracy compared to traditional x-ray radiation treatments and with less collateral damage to nearby healthy tissues.

Compared to photon radiation treatment

1

2

3

4

5

6

7

8

modalities, proton therapy provides long-term benefits to the patient as a result of reduced radiation toxicity, fewer side effects, and reduced need for other medical and continuing care. Proton beam therapy may also allow for a higher radiation dose to some tumors increasing the chances that all the tumor cells are destroyed and improving cure rates. This particularly benefits pediatric patients as well as adults when there are tumors near vital organs.

Traditionally, radiation therapy is delivered with x-rays with an individual photon beam passing through normal tissue on its way to and from a target tumor. While increased radiation to tumor cells leads to better control of the cancer, increased radiation dose to normal tissue leads to higher likelihood of side effects. And finding the sweet spot between tumor control and minimal or acceptable risk of side effects is what we often refer to as finding the optimal therapeutic ratio.

22 Protons are charged particles with mass 23 which leads to differences in how they deliver 24 dose along their path. Compared to photons, when 25 protons enter the body they have a lower entrance

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

dose. As charged particles, the protons gradually slow down as they give up energy and deposit more dose as they slow down at the end of their path and tissue. The result is that protons deposit most of their energy over a small range that is known as the Bragg Peak. Importantly, unlike photons or x-rays, there is no exit dose with That is, no significant radiation dose protons. is delivered beyond the target as protons stop in tissue immediately after this Bragg Peak. This allows the sparing of normal tissues outside the target from radiation and leads to less total radiation dose to the body. While variable from patient to patient, the amount of radiation dose delivered to normal tissue may be reduced on the order of 50 to 60 percent when we use proton beam therapy over conventional x-rays.

While this is significant in its own right, it has been the cost benefit ratio with protons that has been the source of debate. We believe that now is the right time for a proton therapy center in Connecticut as the costs have been brought down and the benefits have been increasingly demonstrated in an important subset of patients who require radiotherapy.

1

2

3

4

A few comments on the clinical efficacy and benefits to patients. The American Society of Radiation Oncology evaluated the clinical efficacy data for proton beam therapy and developed a model policy to guide quality assurance and insurance coverage for proton beam therapy. It was stated that proton therapy is considered reasonable in instances where sparing surrounding normal tissue cannot, quote, cannot be adequately achieved with photon based radiotherapy, end quote, and can benefit the patient. Additional studies on proton beam therapy over the past ten years have further cemented its place in cancer therapy limited mainly by its availability. Like photon radiation therapy, proton beam therapy is often used in conjunction with surgery and/or chemotherapy to effectively treat cancers.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18 The improved therapeutic ratio of 19 proton beam therapy has been measured in some 20 instances of better cure rates for a few types of 21 cancers, but most of the time the benefits of 22 proton radiotherapy results from reduction in side 23 effects, a more difficult and often qualitative 24 rather than quantitative end point to measure. 25 With proton beam therapy the goal is to reduce

toxicity by reducing radiation doses to uninvolved normal tissues.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

Key benefits to proton therapy compared to traditional x-ray therapy are, one, less exposure time to radiation prevents injury to critical and developing tissues and organs. Two, proton beam therapy allows for a higher radiation dose to tumors and increases the chance that all of the tumors cells will be destroyed, thus improving cure rates. Three, proton beam therapy often results in fewer and less acute side effects such as lower blood counts, fatigue and nausea. Four, there's evolving data that late occurring side effects from proton beam radiotherapy are reduced relative to x-ray therapy. As an example, an example would be the reduced intellectual and cognitive impairments in children with brain tumors who undergo proton beam radiotherapy. Five, while more studies are needed, there has been scientific speculation that proton beam therapy compared to x-ray therapy would have a lower risk of causing secondary cancers, and there a host of preliminary studies supporting that. And finally, there is emerging data that lower side effects of proton beam radiotherapy translate

into lower hospitalization rates, reduced procedures to manage treatment toxicity, and improved quality of life for our patients.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

In terms of the target population, proton therapy is a benefit for treating patients whose tumors have not yet spread or for tumors that are located near vital parts of the body such as the eye, brain, spinal cord, heart and liver. Proton therapy benefits are most poignant for treating pediatric cancer patients who have many decades ahead of them after being cured, and developing tissues such as brain, bones and muscle are exquisitely sensitive to the effects of radiation therapy. Proton beam therapy can mitigate the risk of life-long effects over radiation such as neurological effects when treating brain tumors. And again, there's preliminary evidence that points to a reduced risk of secondary cancers.

Tumors where proton beam radiotherapy allows for higher doses of radiation and better cure rates include certain tumors at the base of the skull or near the spinal cord, eye tumors such as melanomas, liver or biliary tract tumors and unresectable sarcomas. Importantly, some patients require a second course of radiotherapy to the same region of the body, and in this situation protons are of particular importance to give patients a second chance at treatment while being better able to mitigate the high risk of complications from repeat radiotherapy.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

HEARING OFFICER MITCHELL: I'm sorry to interrupt you. I just want to ask everybody to make sure that they are muted. Sorry to interrupt during your talk. Go ahead.

THE WITNESS (Roberts): Thank you, Attorney Mitchell. And I'm actually almost done. In a number of common adult cancers such as certain head and neck cancers, lung cancers, esophageal cancers, lymphomas within the chest, breast cancers where regional node radiation is important, proton radiotherapy reduces complications of cancer therapy and improves the patient's quality of life.

In conclusion, thank you again for the opportunity to speak in support of this proposal to establish the Connecticut Proton Therapy Center and add proton beam therapy services to the complement of advanced cancer care available in

the State of Connecticut. On behalf of my clinical colleagues in both health systems, we are eager to move forward with this project on behalf of all cancer patients in our state. I thereby strongly urge OHS to approve our CON application. And I am, of course, available to answer any questions. Thank you.

1

2

3

4

5

6

7

8 HEARING OFFICER MITCHELL: Thank you. 9 THE WITNESS (Salner): Good morning, 10 Attorney Mitchell and members of the OHS staff. 11 My name is Andrew Salner, and I am director of the 12 Hartford HealthCare Cancer Institute at Hartford 13 Hospital, a part of Hartford HealthCare 14 Corporation. I have been a practicing radiation oncologist for more than 30 years and have been 15 16 part of the HHC system since 1982. Academically I 17 hold the rank of clinical professor at the 18 University of Connecticut School of Medicine. Т 19 adopt my prefile testimony.

Thank you for this opportunity to speak
about our plan to establish a proton therapy
center, Connecticut Proton Therapy Center in
Wallingford, Connecticut, as part of a joint
venture with Yale New Haven Health Services.
First and foremost, I would also like to extend my
thanks on behalf of Hartford HealthCare, Yale New Haven Health Services and our partner, Proton International, for the extraordinary efforts that OHS staff have made to keep the CON process moving during these unprecedented times.

You've heard my colleague, Dr. Kenneth Roberts, testify about proton beam therapy, how it has evolved as a treatment modality, the clinical efficacy of proton therapy for certain types of cancer, and its ability to significantly reduce debilitating side effects associated with conventional radiation therapy. My testimony today will focus on why we need to offer proton therapy in the State of Connecticut.

As proton therapy technology has evolved and its clinical efficacy has been studied, applications have expanded, and there are now many patients in Connecticut who would benefit from proton therapy as opposed to traditional photon based radiation. As more patients are determined to be good candidates for proton therapy, we as clinicians find ourselves referring these patients to proton therapy centers in the neighboring states of New York, New Jersey and Massachusetts due to the lack of availability of

1

2

3

4

5

this service in our home state.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

Connecticut Proton Therapy Center is a joint venture between Hartford HealthCare and Yale New Haven Health System, the state's two largest health systems and providers of comprehensive cancer services. The health systems have decided to locate the center in Wallingford as this is a central location in Connecticut for Connecticut residents roughly equally distant from our two centers in New Haven, the Smilow Cancer Hospital, and our Institute at Hartford Hospital, the health systems' most heavily utilized cancer treatment centers.

Currently the only existing proton therapy centers in the region are located in Boston, Massachusetts; the Francis Burr Proton Therapy Center at Massachusetts General Hospital; New York, New York, the New York Proton Center; Somerset, New Jersey, the ProCure Proton Therapy Center; and New Brunswick, New Jersey, the Robert Wood Johnson University Hospital.

Proton therapy is typically
administered five days per week, and a course of
therapy can range from one to nine weeks depending
upon the type of cancer, the location of the

tumor, and other patient related factors. Industry average for proton radiation therapy has been on the order of 27 daily treatments for approximately five and a half weeks.

In order to receive proton therapy, residents of Connecticut need to drive several hundred miles round trip on a daily basis or arrange for a week's overnight accommodations near the out-of-state proton therapy center. Often patients find the cost and extended travel required prohibitive and they're not able to access this potentially lifesaving treatment. When a patient is required to travel to another state for care such as proton therapy, they risk losing their family, community and provider support that often makes for a positive care experience and better patient outcomes.

Traveling out of state for proton therapy also interferes with the ability to provide coordinated multi-disciplinary care for patients given their need to be elsewhere for radiation therapy and considering the fact that many patients also should ideally receive concomitant systemic therapies such as chemotherapy. Receiving treatment out of state

1

2

3

4

can be complicated and costly in terms of reimbursement with out-of-network authorization and charges applying to commercial plans. Connecticut Medicaid needs to negotiate rates with out-of-state providers for proton therapy.

Incidentally, we are projecting that approximately 17 percent of the Connecticut Proton Therapy Center's patients will be Medicaid beneficiaries. And when proton beam therapy is not geographically convenient, many studies have shown that historically underserved populations are less likely to be referred to out-of-state proton beam therapy due to a variety of complex social barriers.

The economic, physical, and emotional hardships associated with out-of-state proton therapy impact pediatric patients and their families as well as adult patients, all of whom endure similar hardships with travel and lodging for many weeks of therapy. These challenges can be particularly difficult for the elderly population which is a significant and growing proportion of Connecticut's population and whose cancers benefit most from proton therapy. We have provided OHS with many letters of support for this

1

proposal from providers and patients alike that support the need for proton therapy services for Connecticut residents closer to home.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

For example, the director of Pediatric Neuro-Oncology at Yale New Haven Children's Hospital, Dr. Asher Marks, and the director of pediatric solid tumors at Yale New Haven Children's Hospital, Dr. Farzana Pashankar, wrote that their departments are seeing significant increases in the number of children diagnosed with brain tumors and a wide range of solid tumors. These types of tumors in children often benefit from proton therapy. In addition, Dr. Eileen Gillan, the director of neuro-oncology at Connecticut Children's Medical Center, plans to provide a public statement of support for the Connecticut Proton Therapy Center later today. You will also hear from the family of a pediatric patient who will speak to the benefits of having this technology closer to home.

The health systems have proposed a one-room proton therapy facility that can be supported entirely with volume from their own cancer programs, although the Connecticut Proton Therapy Center will be available to all

Connecticut residents and others in the region. The collaborative approach between Yale New Haven Health System and Hartford HealthCare to establish a proton therapy facility of modest size assures proper patient selection for proton radiotherapy as well as sufficient patient volume to make the Connecticut Proton Therapy Center successful and mitigate financial risk.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

The Connecticut Proton Therapy Center is expected to provide proton therapy services to 208 patients in the first year of operation ramping up to approximately 479 patients by year three. The capacity of the Connecticut Proton Therapy Center's one treatment room is approximately in the high 400s of patients per year. Most importantly, our projections for the Connecticut Proton Therapy Center are conservative and based on actual patients rather than assumptions around the need for this service in the Connecticut population generally.

Clinical experts from the health systems reviewed historic radiation therapy volumes from both systems organized by tumor site and estimated the percentage of each type of cancer that would be better treated by proton

therapy versus conventional radiation therapy. This methodology was also applied to those types of cancers treated at hospitals other than Yale New Haven Health Services and Hartford HealthCare hospitals based upon state tumor registry data.

A vast majority of Connecticut Proton Therapy's volume, approximately 80 percent, is projected to originate from the health systems, and in actuality, Yale New Haven Health System and Hartford HealthCare could fill all of the Connecticut Proton Therapy's capacity without referrals from any outside provider. This makes our projections both reasonable and entirely achievable.

15 Physicians working at the Connecticut 16 Proton Therapy Center will be credentialed to work 17 within the Yale Medicine physician group practice 18 with academic appointments to the Yale University 19 School of Medicine. Physicists at the Connecticut 20 Proton Therapy Center will have academic 21 appointments to the Yale School of Medicine as 22 This will form the basis for an active well. 23 clinical research program at the Connecticut 24 Proton Therapy Center giving patients access to 25 cutting-edge proton radiation therapy, attracting

1

2

3

4

5

б

7

8

9

10

11

12

13

the highest caliber professional staff, and potentially facilitating public and private insurance coverage for proton therapy as a matter of public policy for new and emerging medical technology.

The Connecticut Proton Therapy Center will also be a teaching site for graduate medical education at the Yale School of Medicine for trainees and students from the Yale School of Medicine, Yale New Haven Health System and Hartford HealthCare, as well as other academic institutions and hospitals to be worked out in the future.

The singular proton employment model will meaningfully merge the Hartford HealthCare and Yale School of Medicine faculties to be functioning as one collegial and noncompetitive group. In addition to the Yale School of Medicine's rich history of research and educational accomplishments, Hartford HealthCare institutions also serve as teaching hospitals and research institutions. The Connecticut Proton Therapy Center will be affiliated with the Smilow Cancer Hospital, a National Cancer Institute designated comprehensive cancer center, and a

1

2

3

member of the National Comprehensive Cancer Network. Association with the NCI and NCCN designated cancer centers has been an indicator of long-term economic success for proton therapy facilities.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

In addition, a robust integration of clinical research framework at the Connecticut Proton Center entails best clinical practices and the physics accreditation with Imaging and Radiation Oncology Core, Yale New Haven Health System, and Hartford HealthCare physicians and clinical staff will proudly contribute to the growing body of evidence supporting the clinical efficacy of proton therapy, its tendency to reduce long-term side effects of radiation, and its ability to improve the quality of life for many cancer patients. We are hopeful that as this technology evolves and more research takes place, applications for proton therapy will increase and this lifesaving treatment will be available to more patients for the effective treatment of more types of cancer.

Thank you again for the opportunity to speak in support of this proposal to bring cutting-edge proton therapy technology to the

State of Connecticut and in doing so advance cancer care for all Connecticut residents. Like my colleagues, I am eager to move forward with this project and am enthusiastic about the treatment and research possibilities that the Connecticut Proton Therapy Center will bring. I therefore urge OHS to approve our CON application. Thank you so much for your time today.

1

2

3

4

5

6

7

8

9

10

11

12

13

18

I have with me today colleagues from Hartford HealthCare, Yale New Haven Health System and Proton International, and we are available to answer any questions that you might have. Thank you.

HEARING OFFICER MITCHELL: Thank you.
MS. FUSCO: So our next two speakers
are our remote speakers. So Chris Chandler is
next.

Chris, if you can unmute.

¹⁹ THE WITNESS (Chandler): Good morning, ²⁰ everybody. There we go. Can you hear me okay? ²¹ MS. FUSCO: We can. ²² HEARING OFFICER MITCHELL: Yes, we can ²³ hear you. ²⁴ THE WITNESS (Chandler): Wonderful. ²⁵ Thank you very much. It's a great pleasure to

join my colleagues in support of this application. And good morning, Attorney Mitchell, and members of the staff. My name is Christopher Chandler. I'm the chief executive officer of Proton International. And I adopt my prefile testimony.

Again, thank you for the opportunity to speak in support of the certificate of need application filed by Hartford HealthCare Corporation and Yale New Haven Health Services for the establishment of the Connecticut Proton Therapy Center. Including the acquisition of the IBA ProteusOne proton therapy system, we are thrilled to be part of this collaboration, as has been described, between the state's largest health systems and providers of comprehensive cancer care, a very important and integral element to the success of the center which I'll speak to.

Prior to serving in my current role as CEO of Proton International, I've been involved in the development of several major proton therapy programs as vice president and general manager of IBA proton therapy early in my career. I also developed and launched and operated major proton facilities as a senior vice president of ProCure treatment centers. I have more than 35 years of

1

2

experience in the healthcare industry and have personally participated in the sale, financing, opening and the operations of more than ten proton therapy centers. I also am very pleased to be joined by colleagues at Proton International who have been involved in the development, design, installation and opening of multiple proton centers.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

I'd like to tell you a bit more about Proton International today and who we are and how we have helped make this lifesaving technology available and make it a reality for patients in other states and also internationally. We focus very carefully on what we call clinically relevant and financially feasible solutions for proton therapy. And note I mentioned "clinically relevant" first. That's the gatekeeper in our strategy for successful proton therapy centers.

¹⁹ Several key variables need to be ²⁰ present which we do have in this project: High ²¹ quality and dedicated clinical partners who ²² understand the need for proton therapy, the ²³ related clinical benefits and how to most ²⁴ appropriately use proton therapy, an overall lower ²⁵ cost solution compared to previous solutions in

the industry, a long-term lower cost financing solution, which becomes very important, and an equipment solution that is proven, clinically relevant and reliable, and finally, a very clear identification of the patients, as Dr. Salner had indicated, that will benefit using this facility from our clinical partners. And these are the most important variables if you look at financial feasibility. So that's really why we talk about clinical relevant and financially feasible facilities. All of these key variables and our experienced-based approach combine to give confidence, overall ensure that we can rely on proper reimbursement from payers, and I'll speak more to that as we go along.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16 We focus on treating clinically 17 appropriate patients that will benefit, assure the 18 physicians involved are well established in the 19 community and understand the science and the 20 appropriate cases are selected. And finally, 21 because we do not have to be unrealistic in the 22 numbers of patients we put through the system, 23 we're making sure that appropriately clinically 24 relevant patients are being selected to be 25 treated, and this is a key factor in

our (inaudible) --

1

2

3

4

5

б

7

8

9

10

HEARING OFFICER MITCHELL:

Mr. Chandler, I think when you're looking at your written testimony, you can hear it in the microphone a little bit.

THE WITNESS (Chandler): My apologies. My apologies.

HEARING OFFICER MITCHELL: That's okay. So the court reporter hears everything you're saying and of course that I do too.

11 THE WITNESS (Chandler): No problem. Thank you. I'll move it aside over here so that 12 13 doesn't happen again. In our experience, we've 14 really achieved a satisfactory level of 15 reimbursement based on applying the proper 16 clinical guidelines. And I think what's important 17 and why our approach really is different is we 18 don't create a financial plan and an Excel 19 spreadsheet and then determine how to make that 20 work. We work with excellent clinical providers, 21 and our focus is truly on the treatment of the 22 patient using the appropriate science and clinical 23 research to support all of our programs. And I'm confident, as you've heard this from the physicians already. You'll hear it again from

additional testimony that will be involved here in a minute.

We have a highly experienced team that's specializes in the development of proton therapy centers. We assist providers, like the health systems involved in this project here today, in developing business plans, evaluating the clinical programs, appropriate business assumptions, in order to provide a clear design, create a financing structure, select the technology, and be able to implement and open a successful proton therapy center including training of staff.

We've been involved in the development of three centers recently within the United States that are now operational. These three centers include the South Florida Proton Therapy Institute in Delray Beach, Florida; Proton International at the University of Alabama in Birmingham, Alabama, which is another NCI designated academic cancer center; and William Beaumont Hospital in Detroit. In addition to these, Proton International has active centers in Europe and eight centers that are currently under development in the United States and abroad. So we have a tremendous amount

1

2

of experience, I believe, in bringing these centers to fruition which helped instruct all of the centers that we work on.

As Dr. Salner indicated, the clinical partnership has selected IBA ProteusOne as the technology for the Connecticut Proton Therapy Center. And this was based upon improvements in the technology, the experience of the vendor, the imaging capabilities of the technology, its capabilities in intensity modulation, or as Dr. Salner referred to as pencil beam scanning. And I think that Dr. Mendenhall will speak with her experience to that as well because they use IBA technology at the University of Florida.

And I think Proton International, we found that the cost effectiveness of proton therapy that others have spoken to today really comes from the effect of fewer side effects, the ability to implement the treatment modality, as Dr. Salner also mentioned and Dr. Roberts, by improving the therapeutic ratio. Everybody understands that radiation to normal tissue is not a good thing. It causes significant side effects. And the ability to provide proton therapy in a cost effective manner for appropriate patients

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

allows us to reduce the side effects, reduce the overall cost to the patient, comorbidities to the patient, and also allows for additional concurrent therapies because there are fewer comorbidities, and these patients tend to tolerate the treatment better.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

25

I would like to thank you for the opportunity to speak in support of the program. I do have colleagues today with me from our building design, Peter Carbone, senior vice president for design and real estate, Charles Yoo, who's our director of finance and operations, and Kristen Powers who's involved in sales and marketing and project management. We're all available, as are our colleagues from the institutions to follow up with any questions you may have.

And I would like to just thank you very much for the opportunity to present today and to be a part of this project together with all of our colleagues. And we urge your adoption of the application. Thank you very much.

HEARING OFFICER MITCHELL: Thank you.
MS. FUSCO: So then our final speaker
is Dr. Nancy Mendenhall.

Nancy, if you can unmute.

THE WITNESS (Mendenhall): Good morning, Attorney Mitchell and members of the OHS staff. My name is Nancy P. Mendenhall. I'm a physician and currently the medical director of the University of Florida Health Proton Therapy Institute. I adopt my prefile testimony.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

I appreciate the opportunity to speak in support of the certificate of need application filed by Yale New Haven Health Services and Hartford HealthCare Corporation to establish the Connecticut Proton Therapy Center. As a physician with many years of practice, over 35, proton therapy has been the most exciting development that I've seen in my career. I think I can provide some perspective on this therapy and the technology and how the proposal you're facing can enhance the provision of excellent advanced care in the State of Connecticut.

¹⁹ Prior to becoming medical director at ²⁰ the UFH Proton Therapy Institute, I was a ²¹ practicing radiation oncologist since 1984 at the ²² University of Florida and served as the department ²³ chair for 13 years until 2006 and was involved in ²⁴ the conception of the proton therapy project at ²⁵ UF. And when it came to fruition in 2006, I

stepped down as department chair because I felt like the more important role I can play was in bringing on this new technology for the State of Florida.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

Proton therapy provides us as radiation oncologists with the ability to really do a better job of treatment. We can minimize radiation exposure to normal tissues. And if we can do this, that means less in the way of side effects and complications. And if we can lessen side effects and complications, we can escalate radiation doses and get higher cure rates, we can shorten treatment courses and provide more convenient, less costly treatment while all at the same time reducing complications and improving quality of life. Over the course of my service as medical director here at the Proton Center since 2006, I've been gratified to see this promise come to realization.

We opened in 2006. We were considered an early adopter, fifth in the country, first in the southeast. We have a 98,000 square foot facility which includes conventional radiation and three gantry-based treatment rooms as well as a fixed room for delivery of treatments to eye

cancer patients. We also house dosimetry simulation and administrative space in a clinic. It's a three-story facility comprised of high-density concrete walls that protect all patients and people from potential exposure. Each of the gantries is 200,000 pounds, and we have three of them. The cyclotron is 440,000 pounds. Some of the walls are 18 feet thick.

We have had an extremely successful relationship with our vendor, IBA, Ion Beam Applications, out of Belgium. And IBA is considered a worldwide leader. They've sold and operated more proton therapy facilities than any other vendor in the world. And I believe they are the vendor that you're working with for Connecticut. So based on my relationship, I can assure you that for us they've been an excellent partner, very reliable, very dedicated.

Since opening, we've had to undergo a number of technology upgrades because we were an early adopter, and we've had excellent support. We've had improved imaging guidance provided by IBA, safer floor designs around the treatment couch, and better proton delivery nodes. We've upgraded from double scattering, for example, to

1

2

3

pencil beam scanning, as Dr. Roberts had mentioned. And because we've been at capacity since even with our four treatment rooms since shortly after opening, we decided to expand our capacity and improve our technology by adding the ProteusOne in 2016, and this is the piece of equipment that you're considering at this time. This is a state-of-the-art application of proton beam scanning, pencil beam scanning. It provides more conformality of the high radiation dose to the target volume and therefore more sparing of normal tissues. And it's also very efficient. Ιt provides a faster delivery of the treatment which is important for many different reasons beyond simply operations. So I can endorse your choice of technology and your choice of a partner.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17 I would say that the affiliation 18 between the proton facility and the University of 19 Florida Health Systems with local hospitals and 20 physicians in Jacksonville has greatly contributed 21 to the operational success of the facility. I 22 think that the collaboration that's been described 23 this morning between Yale New Haven and Hartford HealthCare is excellent. You want to provide 24 25 maximum access to this technology to the maximum

number of patients, and I think this is exactly the kind of model that you need to guarantee operational success.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

We have now at UFHPTI treated about 9,000 patients since 2006, and this includes almost 2,000 pediatric patients who are very difficult patients who have come to us from all over the world. We've had patients from all 50 states. The major types of cancers that we've treated besides pediatrics include breast cancer, central nervous system, brain tumors, head and neck cancers, prostate cancer, lung cancer, esophageal cancers, liver cancers, mediastinal lymphomas, and a smattering of some others as well. About 40 percent of our patients are Medicare beneficiaries. And we have a philosophy of being, wanting to promote accessible care to all people. We avoid any disparity of care for lower socioeconomic groups and take pride in being accessible for all ethnic and racial backgrounds as well.

I would say that our success has been impacted by the founding vision that we would have a strong clinical research program concurrent with the clinical activities. 98 percent of our patients have been enrolled in an outcome tracking protocol, and about 40 percent have participated in clinical trials. We've been able to generate over 100 peer reviewed articles that deal with dosimetric comparisons, treatment outcomes, technical delivery issues, and I think this has helped inform the progress of the field, and it certainly made us aware of outcomes, made us able to give a better informed consent to our patients, and enabled us to identify errors to make improvements.

1

2

3

4

5

6

7

8

9

10

11

24

12 As a person who's been committed for 13 many, many years to clinical research as well as 14 clinical care and improving outcomes in patients, 15 I believe that proton therapy will be viewed as 16 the most cost effective radiation alternative as 17 time goes on and more data is generated. Fewer 18 side effects means lower cost to care for 19 complications, fewer recurrences means lower cost 20 for the care of recurrent disease, and better 21 quality of life means a happier, more productive 22 population of cancer survivors. I believe proton 23 therapy will produce all of these outcomes.

With respect to financial viability, I 25 would say that it has been a challenge for many

centers across the country. We've been very successful financially. We had no major grants. All of our financing came through borrowed money, and we've been able to make advanced payments, and we're regarded as being highly successful by our board and by the university. I think that the model that you've adopted will ensure operational success for your facility as well. I think it might be less challenging actually than it was for us with filling four vaults, but you have adequate patients and you have an excellent design.

1

2

3

4

5

6

7

8

9

10

11

12 So from my vantage point I think you're 13 poised for success. I think the facility is well 14 scaled, and you'll have plenty of patients, and 15 you'll be able to choose the most appropriate 16 patients who will benefit the most. I think 17 having both of the largest healthcare systems 18 involved is an excellent start. And I think my 19 understanding is that you're situated to be able 20 to provide anesthesia for your pediatric patients. 21 That's very, very important.

And one of the things I think is most important -- I've actually worked with Dr. Roberts for I don't even know how many years now. We've been involved in research studies in pediatric oncology for many, many years -- I think this commitment to the clinical research is really important. This is what will define the future for proton therapy and make it grow. It's also what will ensure the best outcomes for your patients. So I commend you on that.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

And then finally, I don't think I've said this yet. We've worked with IBA, so I believe they're a great partner. I have to say that Chris Chandler was involved from the outset in our project. I don't think we would have gotten the project done without Chris's involvement. And I think you just could not have a better partner.

Thank you so much for the time and the opportunity for me to speak in support of your project. I'm excited about it. I hope to welcome you to this field. And I'm happy to answer any questions that you might have now or later.

MS. FUSCO: Thank you, Dr. Mendenhall.
So that concludes our presentation.

HEARING OFFICER MITCHELL: Thank you.
I just wanted to double check how much time do we
have with Dr. Mendenhall because I understood that
she has other obligations.

1	MS. FUSCO: I believe, Dr. Mendenhall,
2	you're available until 1 o'clock, correct, or just
3	before 1?
4	THE WITNESS (Mendenhall): Yes, with a
5	short break.
6	(Laughter.)
7	HEARING OFFICER MITCHELL: I just
8	wanted to have a few moments to talk to my
9	colleagues about our questions. Is there anybody
10	that you wanted to have give public comment before
11	OHS asks their questions?
12	MS. FUSCO: No, I think everyone we've
13	spoken with is going to participate this
14	afternoon.
15	HEARING OFFICER MITCHELL: Okay. So we
16	are going to go off the record until about 11:35.
17	Does that sound okay?
18	MS. FUSCO: Perfect. Thank you.
19	HEARING OFFICER MITCHELL: Back on the
20	record at 11:35.
21	(Whereupon, a recess was taken from
22	11:20 a.m. until 11:38 a.m.)
23	HEARING OFFICER MITCHELL: All right.
24	So we are back on the record. OHS is going to
25	begin with their questions for the applicants. I

Г

just want to ask anyone who might testify who has not been sworn in, when you state your name just indicate that you haven't been sworn in and I will swear you in. I'm going to ask Lindsey to go ahead and start with our questions.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

Lindsey, before you start, just make sure that you indicate the subject matter for each question.

MS. DONSTON: The first question is just background information. What is the current legal status of the relationship between the applicants and Proton International?

THE WITNESS (Lemay): This is Art Lemay. And I can say that we have a letter of understanding under development, and we've been working towards the completion of a joint venture relationship. It is not final yet. We're waiting for the CON approval to proceed.

¹⁹ MS. FUSCO: This is Jen Fusco. Just to ²⁰ clarify, Lindsey. So the letter of intent has ²¹ been signed. We did submit a copy of that with ²² one of our completeness submissions which outlines ²³ the basic parameters of the relationship that the ²⁴ definitive agreements typically don't get ²⁵ negotiated and signed until after a CON is

approved just given the amount of time it takes to do that. So that's where we are.

MS. DONSTON: The next question is in reference to access to services within the region. Throughout the application and the prefile testimony it's emphasized that access for Connecticut patients will be improved by having a proton therapy center in Connecticut. Indicate how many patients within each of the applicant's systems have been referred for proton beam therapy in the last three fiscal years, if possible?

12 THE WITNESS (Salner): Hi, this is 13 Andrew Salner responding. We don't really track 14 that number of patients who were referred to other 15 centers, so I can't give you a precise answer. We 16 do track the pediatric patients who are sent to 17 other centers. And we attempted to reach out to 18 all of our radiation oncologists and referring 19 physicians to try and get a more quantitative idea 20 about how many patients have been referred over 21 the last number of years, and we did not come up 22 with a credible number. So I'm sorry to say we 23 can't really answer that question with as much 24 precision as you would like.

MR. CARNEY: Doctor, you said that you

1

2

3

4

5

6

7

8

9

10

11

25

1 had the number of pediatric referrals though. Did 2 you have that number to share? 3 THE WITNESS (Salner): I think that was 4 shared in the application; was it not? 5 MS. FUSCO: No, I don't think we shared the number of pediatric patients. 6 7 THE WITNESS (Salner): I don't have that off the top of my head, but I can get it for 8 9 you, Brian. 10 MR. CARNEY: Thank you very much. Ι 11 appreciate that. 12 HEARING OFFICER MITCHELL: I just want 13 to interject one other point. Attorney Fusco, if 14 you have any objection to this, let me know. We 15 could possibly look at some data through the 16 All-Payer Claims Database. I just wanted to take 17 official notice of that, and other databases to 18 determine who's actually gone outside of the state 19 for this type of service. Are you amenable to 20 that if we were able to present it to you so you 21 could comment on it? 22 MS. FUSCO: I think we would need it 23 presented to us in a way that we understand sort 24 of the universe of what's in the All-Payer Claims 25 Database, like my understanding was that it

doesn't capture a majority of the claims, so those things might be underrepresented. But as long as we could see the data and understood the parameters, I think we could comment on it. And I think too, you know, we could comment, to note that in terms of trying to put together those numbers an important thing to note is that there are plenty of patients that just forego the therapy altogether, right? So these would be numbers of people who actually decided they wanted the therapy and went out of state, you know, versus those who just decided to have conventional radiation. We'd be happy to look at them.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

THE WITNESS (Roberts): This is Dr. Roberts. Sorry to have a question back to you. Is this All-Payer's Database something that OHS has access to?

HEARING OFFICER MITCHELL: Yes.

THE WITNESS (Roberts): That's great. That's a great resource. I can tell you that we have outcomes, researchers at the Yale Cancer Center, and we've had some limited access to private payer claims datasets, but we were restricted from using that to look at this very question because it's considered proprietary, but

we'd love to see that information also.

HEARING OFFICER MITCHELL: So there are some challenges with the APCD, I will admit, but if there is a way that we could pull the data, and also, you know, as Attorney Fusco said, discuss some of the parameters and come to an agreement about that, we may be able to do that. I just wanted to throw it out there as a possibility.

MS. FUSCO: Absolutely. We appreciate that. Thank you, Attorney Mitchell.

HEARING OFFICER MITCHELL: All right. Lindsey, you can proceed.

MS. DONSTON: The next two questions also both relate to access to services within the region. So Question 3 is on page 8 of his prefile testimony Dr. Salner states, "It is likely as we work together that we will be able to embrace the referral process from nonsystem sites." Can you explain what that means and explain what the referral process would look like?

THE WITNESS (Salner): Sure. This is Andrew Salner speaking. Connecticut is a relatively small state, and there are a relatively small number of radiation oncologists who practice in the state. And Dr. Roberts and I know

1

2

3

4

5

1 everybody more or less in the state quite well, 2 and we have a very good collegial relationship 3 with that group of radiation oncologists. We 4 currently work with them on selected patients who 5 may need to come to one of our centers, for 6 example, for a specialized treatment. And we 7 would absolutely welcome referrals to the proton 8 center of appropriate patients from these other 9 sites. In contrast to other centers around the 10 country that have actually placed linear 11 accelerators that deliver photon therapy in proton 12 centers so that for those patients who don't --13 aren't considered a good proton therapy candidate, 14 that center could treat them on a linear 15 accelerator with photon treatment. We've chosen 16 not to do so. We felt no reason -- there would be 17 no reason to try and compete with all of our 18 radiation oncologists around the state who do a 19 great job at treating patients with photon 20 therapy. And in addition, all patients in 21 Connecticut are relatively close to a really good 22 photon treatment center. And so specifically if 23 we get referred a patient from a colleague whose 24 tumor doesn't -- there's not good evidence that 25 the treatment with protons would be advantageous,

we would be very anxious to refer the patient back to their referring radiation oncologist for photon treatment. Our job is to really see patients who we think are good candidates for proton therapy and to provide excellent care for them in the Connecticut Proton Therapy Center and then refer them back to their local community.

MS. DONSTON: Thank you. Ouestion 4 is according Ms. Handley on page 3 of her prefile testimony. She states "The CPTC will be available to all Connecticut residents through provider and self-referral." Can you please describe how the self-referral process works?

MS. FUSCO: Andy, do you want to talk about it or --

THE WITNESS (Salner): This is Andrew 16 17 Salner. If I may take the first step in answering 18 your good question. Self-referral to proton 19 therapy centers around the country has certainly 20 occurred where patients have heard about the new 21 technology, they're excited about it. They've 22 been diagnosed with cancer. They wonder if that 23 treatment might be appropriate for them. And 24 rather than seeing a radiation oncologist locally 25 or having their physician refer them, they make a

1

2

3

4

5

6

7

8

9

10

11

12

13

phone call themselves to the proton therapy center to be evaluated.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

We would have no problem in seeing patients who are self-referred, as we do now for cancer patients who come to us sometimes for a second opinion perhaps, or perhaps because they have had a relationship or a family member has had a relationship with one of our centers and wants to come and see us for a consultation. We would have no problem in seeing patients who are self-referred. Obviously, we would get all the pertinent clinical information about the patient, imaging and pathology, and we would see them in consultation as we would routinely at one of our cancer centers now. We would talk to their physician team because there's a lot of nuances in the care of these patients, and we would want to make sure that we understand what their clinical situation is and would be happy to consider treating them, if it's appropriate.

THE WITNESS (Roberts): Dr. Roberts here. I agree with those comments. We would certainly welcome self-referrals. And it would be part of our professional practice to give an independent evaluation as to how their cancer

1 ought to be treated, and if there is a place for 2 proton radiotherapy, and educate that patient as 3 to what their options are and the need for 4 collaboration with their other established 5 physicians.

THE WITNESS (Handley): I have nothing to add. I think that's exactly the response. So thank you.

HEARING OFFICER MITCHELL: Just a follow-up question. How often does that occur that someone will come and request a specific treatment versus having their doctor suggest it? It's kind of different than getting like a second opinion when you're going out to seek a --

THE WITNESS (Roberts): When there's a 16 new technology, a new exciting treatment option, 17 you know, I think we're aware that we're likely 18 going to see a good number of patients seeking out 19 opinions about proton radiotherapy, and we're 20 prepared to help those patients through their 21 journey and make sure that they have appropriate 22 treatment. But just because they're coming for 23 protons doesn't mean they're going to get proton 24 radiotherapy. We want all the decision-making to 25 be professional and based on scientific evidence.

THE WITNESS (Salner): I would add, this is Andrew Salner, there have been sort of a large number of patients when protons really became more accessible nationally there was sort of some evidence to suggest that it may have some benefits particularly in prostate cancer, and there were publications in the lay literature, for example, in I believe Time Magazine about the potential benefits of proton therapy. And there was a fairly large number of men with prostate cancer, newly diagnosed, who decided to self-refer just to learn more about it and see if their situation was amenable to proton therapy.

14 So I agree with Dr. Roberts. I think when there's a new technology that promises a 15 16 better result, whether that's a higher cure rate 17 or fewer side effects, or a combination of the 18 two, patients are interested in pursuing that. 19 And through their own research and discussion with 20 their peers and colleagues, they may know more 21 about it than their current physician in terms of 22 what the offerings might be. And so I think 23 self-referral is a part of it. It's probably going to be a relatively small part, but I think it's a part of it just the same.

1

2

3

4

5

6

7

8

9

10

11

12
HEARING OFFICER MITCHELL: Thank you. All right. So the next question actually regards Dr. Mendenhall's prefile testimony. It's on page 1 of her prefile testimony, the first page. And basically in her prefile testimony she states that proton therapy is an emerging cancer treatment modality. And so the question is kind of two parts. The first part is what do you mean when you say it is emerging, and then the second part is how does this statement relate to the effectiveness of proton beam therapy?

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

THE WITNESS (Mendenhall): Okay. So what I meant by "emerging" is that there's a compelling rationale for it. It makes a tremendous amount of sense when we as radiation oncologists look at the treatment plans that we can generate with proton therapy in comparison to the treatment plans that we have used and are using that are based on photon therapy. So we can see that there's going to be a whole lot less radiation dose to normal tissues. And so what I meant by emerging is that it takes time for us to prove that the clinical outcomes are going to be what we think they're going to be based on seeing the treatment plans.

And so we now have experiences that go back as far as 1990 from the first institution that had a clinically dedicated proton facility. So we now have data from that institution on patients that were treated quite a long time ago. At my own institution we now have data for a number of tumor sites where patients are out more than ten years. And so we want to see, we want to follow those patients and find out that in fact they have lower complication rates than what we've seen with x-rays and than what's reported in the literature.

And so what I meant by emerging is that the data is emerging. So now we know for sure that the children have fewer neurocognitive sequelae from proton therapy than what they had with conventional radiation. We now know for sure that there's a very significant reduction in second malignancies with proton therapy, overall a threefold reduction across all disease sites, all ages, all genders. And in some settings, for example, prostate cancer, that reduction in second malignancies at five years is a fivefold reduction.

Now, some of the other benefits are

1

2

3

4

5

б

more subtle, harder to measure, but there are ongoing studies. Every proton center in the U.S. is involved in gathering and analyzing data either within their institution or in a cooperative group setting. There are seven or eight ongoing comparative trials where patients were either put into cohorts or they're randomized to get proton therapy or conventional radiation. And what we want to do in these studies is confirm the degree of benefit when the treatment is applied over a very large number of patients and institutions. All this data is emerging, and I think it will continue to develop. And what we're seeing is increasing differences in outcomes with time. More and more improvements emerge the longer we follow the patients.

MR. CARNEY: Can I just ask a follow-up Dr. Mendenhall? You said you've been doing it since 1990. Has within the proton beam therapy, has the techniques and efficiency of the delivery of it improved? I mean, it's been going on for a while now since 1990. Has there been --

THE WITNESS (Mendenhall): Absolutely.
 And so the first clinically dedicated proton
 therapy facility opened in 1990 at Loma Linda.

1

2

3

4

5

6

7

8

9

10

11

There had been some proton therapy delivered with research equipment, physics research equipment at Massachusetts General and in a few other institutions. And so what we know from those experiences are that there was a significant reduction in second malignancy.

We know from the Loma Linda experiences where there was actually a clinically dedicated facility and gantry that could rotate around patients so that they could treat different kinds of cancers. We know that those outcomes in terms of disease control and toxicity appear to be better than the outcomes that were contemporaneously being reported with conventional radiation.

In order to prove that the differences you're observing with a single institution report are real, you want to confirm them. You want to see that other institutions can replicate those findings and that the overall population, as outcomes manifested in large databases like the National Cancer Database, you want to see that that data matches the single institution data that is being generated. That takes a lot of facilities operational and a lot of patience. And

1

2

3

so I mentioned that UF was the fifth in 2006. And so we came on board at the same time as MD Anderson Cancer Center in Houston, and the third facility is the only facility I know of that's actually closed.

So there were only two facilities, Mass General and Loma Linda, before 2006. And I think several people have mentioned that there is now three times as many facilities. In 2010 there were probably about ten facilities. It takes a number of facilities to treat enough patients of the same kind that we can see that those clinical outcomes are living at to what we predicted they would be based on the radiation dosimetry, the treatment plans. I hope that helps. I'm not sure.

MR. CARNEY: Yeah, definitely. I was also thinking like the pencil beam sort of technique, is that something newer to the whole proton therapy?

THE WITNESS (Mendenhall): Yes. And so pencil beam is newer. And I think it was first utilized in Switzerland at the Paul Scherrer Institute. And they, I forget exactly when they came on board, probably sometime after 2000, and

1

2

3

4

5

they have reported their pencil beam outcomes in several malignancies, base of skull tumors, for example, and those outcomes look to be excellent.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

Now, in the U.S. it's taken a little bit longer to bring that technology on board. I believe for us at UFHPTI. We got it in 2017. And so we don't feel like we have enough data yet to say for sure that the clinical outcomes are going to match the dosimetry outcomes, but the dosimetry outcomes certainly look better, and there's every reason to believe that the outcomes will be better with PBS. We have to wait, you know, we have to wait to confirm. There's no reason to think they won't be.

¹⁵ MR. CARNEY: Okay. Thank you. So you
¹⁶ need more data?

THE WITNESS (Mendenhall): It's always
 that way.

¹⁹ MR. CARNEY: Okay. Thank you very
 ²⁰ much, Doctor.

HEARING OFFICER MITCHELL: Can you just define for me the term, I believe that you said cognitive, is it sequelae, is that what you said? THE WITNESS (Mendenhall): I did. And what I meant by that was when we think about how a

child's brain functions, the pediatric neurologists measure brain function with a bunch of different parameters. The overall term is IQ, that the IQ is, there are a number of different types of processing and memory functions. And so when those functions are looked at after proton therapy, there's much less of a negative impact on the child's neurocognitive function. And when I say "neurocognitive," I mean the whole global IQ, memory, processing, all of that.

11 We collaborated with St. Jude Research 12 Center before they had a proton facility. So they 13 began to send us their patients for proton therapy 14 sometime probably around, I'm quessing it was 15 maybe 2009 or '10, and it took them five or six 16 years before they were able to get a proton 17 facility themselves. All of the children that we 18 treated for them were enrolled on protocols. And 19 the investigators at St. Jude compared the outcomes of those children that we treated with protons with the outcomes of the children they treated with conventional radiation, and the neurocognitive outcomes were better after proton therapy. So their IQ was better. They had less of a negative impact from radiation.

1

2

3

4

5

6

7

8

9

1

2

3

4

HEARING OFFICER MITCHELL: I was listening to you give your prefile testimony, and you had said that I believe since 2006 that you treated 9,000 patients with this type of therapy. The question that I have for you is this is in Florida, correct?

THE WITNESS (Mendenhall): It is Florida, yes, it's Jacksonville. It's part of the University of Florida. We have two campuses, one in Gainesville, one in Jacksonville.

HEARING OFFICER MITCHELL: Okay. Are there any other proton therapy centers in Florida?

THE WITNESS (Mendenhall): There are now, so I may forget the dates exactly. We opened 15 in 2006. There is a one-room facility that opened 16 in Jacksonville in the community, and I think, I 17 don't know, I don't remember the date exactly. 18 I'm going to guess, and please don't hold me to 19 this, but I'm going to guess it was around 2014 or 20 something like that. Also, there is a one-room 21 facility in Orlando, and recently a one-room 22 facility opened in Delray Beach. I believe 23 Mr. Chandler is involved with that facility. And 24 then finally there's another very large program 25 located at Miami Baptist Cancer Institute, and I

1 believe they have five treatment rooms. So right 2 now we have five proton facilities in Florida. 3 Sometime in the future there will be a sixth. 4 Mayo Clinic will put one in Jacksonville. Т 5 believe that's maybe scheduled for 2024. б HEARING OFFICER MITCHELL: Okay. To 7 the best of your knowledge, are all of these 8 programs, are they solvent? 9 THE WITNESS (Mendenhall): When you say 10 "solid," do you mean operationally? 11 HEARING OFFICER MITCHELL: "Solvent." 12 THE WITNESS (Mendenhall): Oh, solvent, 13 okay. To my knowledge, they all are. To my 14 knowledge, they're all treating at capacity as far 15 as I know. I've certainly not heard anything to 16 the contrary. And I'm aware that a couple of them 17 are already thinking about adding, a couple of the 18 small one-room programs are thinking about adding 19 a second treatment room. So there's not been a 20 problem with capacity. Now, I will say that COVID has had an impact on all of radiation oncology. 21 22 We think it's temporary, and everyone has had a 23 little bit of a drop, but, you know, it's nothing 24 major. 25

HEARING OFFICER MITCHELL: Okay. All

right. The next question is actually for you as well, and it relates to, let's see, page 7 of your prefile testimony. You basically stated in our complementary field of proton therapy you're looking for improved quality of life outcomes with equal or better cure rates to conventional x-ray therapy. And then on page 9 you said that the biggest hallmark of future success is that this program, CPTC, is structured to strongly support clinical research.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

So I have a number of questions for you with regard to those two statements. The first is can you define what you mean by "complementary field of proton therapy"?

15 THE WITNESS (Mendenhall): I actually, 16 I don't have the context in which I said that, so 17 I'm not sure exactly what I meant. I probably 18 meant that there are some patients that we think 19 are very, very well treated with conventional 20 photon based radiation. So we don't use proton 21 therapy for every patient that we see. And 22 sometimes we think, and this isn't necessarily an 23 issue of insurance coverage, sometimes we think 24 the better choice of treatment is actually x-ray. 25 So I'll give you an example. If we

1 have a patient with very early breast cancer, so 2 the only thing that needs to be treated is the 3 breast, we don't need to treat any lymph nodes, 4 it's often the case that we can treat the breast 5 with conventional radiation and have almost no 6 radiation at all to the lung or to the heart. And 7 right now with the current technology, even with 8 pencil beam scanning, the skin dose with 9 conventional radiation is lower than a skin dose 10 with proton therapy, so there's really no way for 11 us to have a better outcome with protons. So we 12 use a lot of proton therapy in breast cancer, but 13 it's for women who need to have their regional 14 lymph nodes treated or in whom our conventional 15 radiation plan would expose a lot of heart or lung 16 to radiation. So if we don't see a benefit for 17 using proton therapy, we recommend conventional 18 radiation, and sometimes it's because the results 19 might be equivalent, but in the case of breast 20 cancer we think the cosmetic outcome will be better with x-rays. So if that's the situation, 21 22 then proton therapy would be complementary in that 23 it would complement the full scale of radiation 24 technology that would best serve the patient. 25 HEARING OFFICER MITCHELL: Have we

reached the standard that you described where you state that you're looking for improved quality of life outcomes with equal or better cure rates to conventional x-ray therapy?

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

THE WITNESS (Mendenhall): So when I say quality of life outcomes, I'm referring very specifically to patient reported quality of life outcomes in contrast to physician reported toxicity or side effects. So when we think about how a patient and the success of a treatment, we're going to measure disease control. That's a very important thing. We're going to measure all of the toxicity that the physician or clinical team records in terms of side effects and the kinds of interventions that we use for those side effects.

17 So, for example, maybe we have to give 18 some pain medication, or maybe we have to give 19 some medication to help with the urinary function 20 or with the swallowing function or something like 21 that. So that would be an intervention. And I 22 would record that, and I would grade that as a 23 certain level of toxicity based on standard NCI 24 developed criteria for measuring the severity of a 25 side effect in an intervention. So that would be

my view of the patient's outcome from a toxicity and side effect perspective.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

The patient though has a different perspective on things. So let's say, for example, I'm going to switch to prostate cancer because I work in that right now and I'm involved in a trial where we're looking simultaneously at quality of life and toxicity and disease control. So let's say that with my conventional radiation, my photon based radiation, I do the very best job I can, but it's often the case that I'm going to expose most of the rectum that's behind the prostate to some low to moderate dose radiation. The side effect would be bowel urgency and frequency. The patient would need to go to the bathroom to evacuate frequently and wouldn't have a lot of time to do that. So there would be increased frequency and urgency. Now, if that's really bad, it could be as severe as incontinence, and that would have a major impact on that patient's quality of life.

Now, there's no intervention for that.
There's nothing I can do to solve that problem.
And so because there's no intervention, there's
not really a cost impact. It's not coded as a
severe side effect because I don't have an

intervention that can be graded. I might record that as very minor. The patient might say that is a very major impact on quality of life. So it's very important that we gather patient reported quality of life functional data as well as the physician recorded data.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

Now, on the other hand, let's say that that patient had some temporary rectal bleeding from the radiation that I gave him. And I thought that it was significant enough that I did something about it, I gave him suppositories, I did a Form 1 application, maybe I did a coagulation or something. It might go down as a grade 3 toxicity, but once I did that, that symptom would be over and gone. And so if you asked a patient what their quality of life was, they might say it's perfect. I might have recorded a grade 3 toxicity. So these patient reported quality of life outcomes are our ultimate qoal for cost of care. And for recording we also report toxicity and interventions, physician reported assessments. Does that help? HEARING OFFICER MITCHELL: It does, but

let me just -- I just want to probe just a little
 bit more because you did talk about improved

quality of life outcomes for patients, but you also talk about, you know, with equal or better cure rates to conventional x-ray therapy. And so I guess my question would be whether you feel that proton therapy offers equal or better cure rates currently when compared to conventional x-ray therapy.

1

2

3

4

5

6

7

25

8 THE WITNESS (Mendenhall): I absolutely 9 So at the risk of perhaps getting too much in do. 10 the weeds, when we give a certain amount of dose 11 with x-rays and we give exactly the same dose with 12 protons, we believe we're getting a little more of 13 an impact with the protons. And so it may turn 14 out to be, in fact, we've hypothesized this, it's the subject of -- it's one of the main points of a 15 16 major study right now -- we've hypothesized that 17 we are going to see improved disease control, same 18 dose with protons compared to photons. Now, we 19 don't know that yet because you need a 20 head-to-head trial to prove it, but we have a fair 21 amount of benchmark data to suggest that it may 22 happen. There's certainly no reason to think that 23 it won't be at least equivalent, but it may 24 actually be a little bit better.

And the other piece of this is that,

because we're less worried about side effects, we think that we're going to be able to more safely dose escalate with protons and give higher doses, dose intensify, give the dose in a shorter period of time, because we don't have to worry quite as much about the normal tissues. Much of the protraction, the stretching out of radiation forces over a period of six or seven or eight weeks it's because we're trying to protect normal tissues. And if we don't have to worry so much about them, we can shorten that course. One impact of shortening the course is that it costs That's a nice thing. It's less less. inconvenient for the patient, that's a really nice thing. But another impact may be that it will be more effective on the tumor. We have a lot of reason to think that might be the case.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18 So there's several ways that we may 19 actually achieve improved disease control with 20 protons. One is we think they are biologically 21 more effective, and we have a fair amount of data 22 that suggests that. Two, we may be able to dose 23 escalate. Three, we may be able to dose 24 intensify, shortening the course. So we're 25 confident, absolutely confident that the disease

control rates will be at least equivalent, but we think they're actually going to be better with protons.

1

2

3

4

5

б

7

8

9

10

11

12

13

14

15

16

17

18

HEARING OFFICER MITCHELL: So are you in the process of establishing this evidence to show that --

THE WITNESS (Mendenhall): Yes.

HEARING OFFICER MITCHELL: -- equal or better cure rates, or is this something that's already been proven?

THE WITNESS (Mendenhall): No, it has not already been proven. To prove something, you need a head-to-head comparative trial, and for high credibility that needs to be large scale. It needs to have a lot of institutions involved applying, you know, the competing treatments in different settings. It needs to be based on more than single institution data.

And so I was asked earlier about the early data. The early data coming out of Loma Linda suggested not only less toxicity but also better disease control. If we look back at it, the disease control in the tumor sites that were being studied and reported appeared to be significantly better than disease control rates

that were being reported contemporaneously with photons. But I think no one at that point in time had an explanation for why that might be. We've seen exactly the same thing at UF. We've seen disease control rates, for example, in prostate cancer that appear to be 10 to 15 percent better than what our most respected colleagues, our most respected colleagues are reporting with conventional radiation.

10 So, because the numbers of patients 11 involved are large, it's really begged the 12 question, and the radiation biologists have been 13 working very hard on this for the last five or six 14 years, and they now have some potential 15 explanations for why we might actually indeed see 16 higher disease control rates with protons than 17 photons. It isn't proven at this point, but it is 18 one of the hypotheses in the COMPPARE study which 19 I'm involved in where we're comparing the outcomes 20 of 1,500 men treated with IMRT, conventional 21 radiation for prostate cancer, versus 1,500 men 22 being treated with proton therapy for prostate 23 cancer.

24 A head HEARING OFFICER MITCHELL: trial, is that what you mean when you say

25

1

2

3

4

5

6

7

8

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

head-to-head?

THE WITNESS (Mendenhall): Yes, it's a large-scale trial fronted by in this case the Patient-Centered Outcomes Research Institute, and there are 51 institutions involved with it. And so, you know, it remains to -- it will take us five or six years to determine whether this is the case or not, but certainly there was enough suggested data that the hypothesis was accepted by a federal funding agency and deemed worthy to be tested in a prospective, comparative trial.

HEARING OFFICER MITCHELL: I just want to make sure I'm understanding correctly. In your opinion, are these trails as part of kind of the larger scale, I guess, as part of larger scale like research programs, are they part of just coming to that determination about proton therapy being, you know, having an equal or better cure rate when it's compared to conventional x-ray therapy?

THE WITNESS (Mendenhall): I think I'm not absolutely sure what the question is, but, you know, I think that as physicians there are certain times where we have enough equipoise that we want to do a head-to-head comparative study. There are

1 other times where we can see on paper that the 2 differences are so drastic that we don't think 3 it's ethical to do a head-to-head comparative 4 study. I think it's totally ethical to do a 5 head-to-head comparative study in prostate cancer. 6 And the reason is that we have excellent outcomes with conventional radiation. And so if we prove 7 8 that the outcomes are better with proton therapy, 9 those differences will still be relatively small. 10 They'll be small enough that I feel very 11 comfortable saying to a patient who I'm treating 12 with x-rays your outcomes are going to be 13 excellent. If I were dealing with a child with a 14 brain tumor, I wouldn't dream of asking the parents to have that child randomized between 15 16 conventional radiation and proton therapy because 17 I know from the dosimetry data and now the clinical data from St. Jude that that child 18 19 treated with x-rays would have an inferior 20 neurocognitive outcome. I don't have to do that 21 trial. I don't think it would be ethical. So I 22 think that in the disease site where we think the 23 differences are small, it's ethical and 24 appropriate to have these large-scale comparative 25 studies, but not in all areas. I hope that helps.

HEARING OFFICER MITCHELL: So let me just, I think this question might be best answered by Dr. Salner, and I just wanted to make sure that I'm clear. Is clinical research a large part of this application so that we can confirm that in fact proton therapy is equal or better to cure rates that might be --

1

2

3

4

5

б

7

8

9

10

11

12

13

14

15

16

17

18

19

THE WITNESS (Roberts): This is --HEARING OFFICER MITCHELL: --

conventional x-ray therapy, or is proton therapy currently a viable option for the treatment or cure of certain cancers? I think that's part of the thing that we want to make sure that we understand.

THE WITNESS (Roberts): This is Dr. Ken Roberts. I'll answer this. There are certain clinical situations, cancer situations where we think proton radiotherapy is the standard of care.

HEARING OFFICER MITCHELL: Okay.

THE WITNESS (Roberts): Okay. There are other instances where there's a gray zone for individual patients and we have to do a comparison of what x-rays of people will do versus protons, and then make a judgment as to how well we're going to spare radiation dose to normal tissues to

decide that protons are better.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

And then there are instances where there's such uncertainty, but there's the potential benefit of proton radiotherapy that we want to participate in clinical trials. And clinical trials will be an important component of our mission at the Connecticut Proton Therapy Center. But there are enough patients who benefit from proton just as a standard of care that will be a predominant clinical interaction of patients to be able to offer this therapy given where the science is now for proton radiotherapy. So I hope that helps.

HEARING OFFICER MITCHELL: Are you able to enumerate the types of cancer for which proton therapy is the standard of care?

17 THE WITNESS (Roberts): Well, 18 pediatrics is pretty clear. Not all pediatric 19 cancers need protons, but a good number of them, a 20 good number of solid tumors. But that's a small 21 proportion in epidemiologic terms of the types of 22 patients we'll be seeing. Many brain tumors, not 23 all, but many. Base of skull tumors. I'm just 24 anatomically going from head to toe. You know, 25 certain head and neck cancer patients will have a

benefit. Some of the studies have suggested 30 percent maybe of head and neck cancer patients will have a benefit. And those that have tumors that are close to the base of skull, near brain tissues that affect eye function, or those tumors that are more lateralized where protons just do a better job of reducing dose to the midline critical central structures like swallowing, taste and the saliva function.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

There are certain lung cancer patients. That's a very heterogeneous group of patients, but certain of them have a benefit.

Esophagus patients, there's been some very gratifying work recently of some large trials showing that because you're able to reduce the radiation dose to heart and lung when treating esophagus that that translates into lower side effects when treating these complex patients who often will get chemotherapy with radiation and a cohort will even get surgery, and so the surgical complications are reduced when proton is part of the combined modality therapy.

There are certain liver cancers that we can't treat with conventional x-rays but with protons, because you can spare some of the

uninvolved liver, you suddenly have a curative modality relative to the other types of treatments that might be available with embolization procedures or surgery. So there's a cohort of patients with liver cancers who suddenly we have curative treatments with the use of proton radiotherapy.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

There are certain circumstances where other gastrointestinal tumors are better treated with protons because of the ability to spare dose to normal tissues. For instance, a tumor problem in a young woman where you want to preserve reproductive function, in that scenario broadly, because we can reduce dose to the ovaries and uterus, we can preserve a critical part of life to that patient going forward.

There are sarcomas that are better treated with protons because of the ability to dose escalate, particularly those that aren't resectable by surgeons.

That's sort of a highlight of trying to answer that complex question. Cancer, it's a heterogeneous group of diseases to begin with, within a particular disease site its heterogeneity, and so oftentimes we're confronted with trying to sort out for a particular patient given that distribution of disease their anatomy to what degree does protons reduce dose to critical normal tissues and will be a benefit.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

THE WITNESS (Salner): Attorney Mitchell, this is Andrew Salner. If I can just add in to complement what my colleague has said. The other group of patients we think who seem to be benefiting now selectively from proton therapy are those patients who've had prior radiation therapy and who seem to have localized cancer that hasn't spread anywhere else in the body but they're not candidates for having their recurrent cancer removed. And it is possible with protons many times to actually retreat them with radiation and give a very limited dose of radiation just to the tumor, whereas if we use photon radiation the potential risk of re-radiation is that the surrounding normal tissue would get such a high dose that that tissue, that we would cause tissue necrosis or death of that tissue which frequently is a very bad thing for the patient.

So we've seen, one of the groups of
 patients that we've referred, for example, for
 proton radiation are patients with certain kinds

of head and neck cancers who have recurred in the head and neck but don't have any evidence of disease anywhere else in their body. And we've seen some really good results of patients who have come back to us after being treated with protons who seem to have good control of the tumor after their proton therapy.

1

2

3

4

5

6

7

8

9

10

11

12

16

17

19

I would also just make a comment about clinical research because I think you were getting at sort of are we trying to prove that it's good or do we already know that it's good. And I think it's both. You know, I think we already know that 13 it's very good for many tumor sites. But if you 14 think about the notion that there are thousands of 15 conventional radiation therapy centers throughout the country, some of which, like our centers, participate in clinical research, there's only 30 18 some centers that give proton therapy. So virtually every proton center has to make that 20 commitment to do some research to generate 21 information not only about tumor control but about 22 quality of life, as Dr. Mendenhall so beautifully 23 pointed out, you know, not only our perceptions 24 but the patient's perception about their quality 25 of life. Because it's only through understanding

that data that we'll ultimately be able to understand how best to take care of patients and advance the field.

1

2

3

4

5

6

7

8

9

10

11

12

13

So I think it's incumbent upon proton centers to participate in research, and we certainly have a commitment to it. Even in patients who where we already know it's a better treatment and we're treating them in, quote, standard proton treatment, we may want to understand more about their side effects, or we may want to understand more about their long-term outcomes, and we need to participate in research accordingly.

14 THE WITNESS (Roberts): And just for 15 completeness, I'd be very remiss if I didn't 16 mention a group of patients that actually I spent 17 a lot of my career involved with clinical trials 18 beside Dr. Mendenhall, not just pediatric patients 19 but young adults with lymphoma problems. You 20 know, we ages ago had a concept we don't have to treat these folks with very high doses of 21 22 radiation when in fact decades of follow-up have 23 shown that even moderate or low doses of radiation 24 given to large volumes of the body end up 25 producing significant problems with heart disease,

1 secondary malignancies. And, you know, we have 2 changed how we treat those patients by using more 3 chemotherapy, less radiation. But protons has 4 also been an evolving modality to help with 5 reducing the long-term side effects for 6 adolescents and young adults with lymphoma 7 problems who get cured and then are alive for decades, and the changes in how we give radiotherapy that includes proton radiotherapy we 10 believe reduces consequential late occurring side effects. So particularly patients with 12 mediastinal lymphomas, there are selective 13 patients who we believe benefit from proton 14 techniques to reduce normal tissue exposures. So 15 that was a little long winded, but I wanted to be 16 complete with how we see the role of proton 17 radiotherapy for our proposed center.

8

9

11

18

19

HEARING OFFICER MITCHELL: Thank you for your responses.

20 THE WITNESS (Chandler): Attorney Mitchell, this is Chris Chandler. I'd like to 21 22 just interject. The elegance of this whole model, 23 and I appreciate my colleagues and their clinical 24 excellence, but the elegance of the model too is 25 we take into account what are clinically

appropriate patients to treat, and that's why we're proposing a one-room facility and not a five-room facility because we want to make sure we tie, as I said in my opening statements, what's clinically relevant to what's financially feasible, and that's why one room is so important. Thank you.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

HEARING OFFICER MITCHELL: Thank you. All right. So we're going to move on. The next set of questions relates to the determination of need. And so basically in the response in the prefiled testimony and response to OHS issues, it was stated that updated incidence rates from 2011 to 2015 from the American Cancer Society Cancer Statistic Center show that Connecticut cancer incidence rate was I believe the tenth highest in the nation at 479.6 per 100,000 people in the population compared to a national incidence rate of 449.8 per 100,000 people.

And I just want, if someone can explain, I just want you to explain how that kind of large number relates to the need for this specific type of treatment, how does this incidence rate relate to the need for proton beam therapy? And you talk about it too with regard to

the volume, your methodology when you determine volume, but I just kind of want to make the correlation between the incidence rate for cancer and how people are determined to be clinically appropriate, and then I'll ask you some questions about volume.

1

2

3

4

5

6

8

9

11

7 THE WITNESS (Salner): Sure. This is Andrew Salner. I wish we knew exactly why Connecticut has a higher age adjusted incidence 10 rate of cancer in many cancer sites and overall than many other states. We don't really know. It 12 is associated with states that have higher 13 density, more industrial settings. It's also been 14 associated with states that have higher 15 socioeconomic status. We really don't understand 16 exactly why. But it does indicate that even 17 though our population is relatively flat that with 18 the aging of the population, because cancer 19 incidence increases with increasing age, it does 20 suggest the fact that over the next 15 to 20 years 21 our cancer incidence will increase significantly 22 in Connecticut as is happening in most states in 23 the country. And for that reason we need to be 24 prepared to have the capacity to care for that 25 patient population. Even if our cancer incidence

wasn't increasing and was remaining flat, we think that proton therapy is an important part of the armamentarium we need to take care of selected patients who would have better outcomes with proton therapy. But the fact that actually our cancer incidence rate will increase because of aging of the population and because it's already fairly high given these high age adjusted incidence rates sort of adds further armamentarium to the notion that proton therapy simply helps us to fill out all of the strategies we need to successfully treat cancer patients in the communities we serve.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

HEARING OFFICER MITCHELL: Okay. So the next question kind of narrows it down further. So if you could speak to the assumptions that you made when you projected volume for the center. I think you said that you were using actual numbers. Can you just talk a little bit about the methodology behind that?

THE WITNESS (Salner): What we did was we took a look at the literature produced by Dr. Mendenhall and many other experts in the field to make some assessments about what percentage of patients we think with various tumor sites and not only tumor sites but stages of tumors might benefit from protons. And we went through all of the institutions at Hartford HealthCare and Yale New Haven and then attempted to look statewide at what the need might be for proton therapy by tumor type. And Chris Chandler was helpful having been through this with many of the other institutions that he's helped in terms of developing proton programs. We tried to develop a conservative guess because that's really what it is as to what the number might be of patients who would benefit from proton therapy. That's how we went through it.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

HEARING OFFICER MITCHELL: The next question is how confident are you that you can meet the projected volumes?

17 THE WITNESS (Salner): I think we're pretty confident. We've allowed for a ramp-up 18 19 because obviously it's not going to be treating 20 400 patients on day one. So we've allowed for a 21 We have to educate our own staffs and ramp-up. 22 referring docs as to what the benefits of proton 23 therapy are. They already get that from the 24 literature they read and the meetings they attend, 25 but we have to gradually get people introduced to

protons and where it may be of value and where it isn't of value.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

And so we're feeling quite confident that the numbers we've projected are actually on the conservative side but are accurate in terms of where the proton volume might go, recognizing that if you and your colleagues were good enough to approve this application over this next period of time and we initiated planning construction, installation and ultimately establish the program, it's still two or three years away from starting. And there may be more indications. There could be It's possible. But we think that that's fewer. less likely. There may be actually more indications for protons. We'll see. But the program calls for a gradual ramp-up over several years of patients as we learn more about protons and as our colleagues who refer patients begin to feel more comfortable with referring patients for protons.

HEARING OFFICER MITCHELL: What's the maximum volume capacity that can be achieved at the center?

THE WITNESS (Salner): The center, if treating in two shifts, which many proton centers

around the country do, we think that we can treat somewhere in the upper 400s, close to 500, but maybe not quite, maybe 490 patients or so per year.

HEARING OFFICER MITCHELL: So you're right at that, based upon the information that you've provided us, it looks like you're right at that year four?

THE WITNESS (Salner): Yes, we would be maybe at 470 some patients or somewhere like that.

HEARING OFFICER MITCHELL: So what happens after you exceed that maximum volume capacity?

THE WITNESS (Salner): I think we would continually be evaluating the need for additional capacity in our state even from day one, looking at the numbers and determining whether additional capacity is needed or not, whether there are any geographic barriers for patients in Connecticut to get to Wallingford, recognizing that Wallingford is right off of Route 91 and other highways and should be relatively proximate for most residents of Connecticut. And if it appears at any time that we think that a one-room facility is not going to provide all the capacity needed, we would

1

2

3

4

5

6

7

8

initiate discussions amongst ourselves and with all involved as to whether we should increase capacity by adding a second facility or a second room to the existing facility.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

THE WITNESS (Roberts): During the experience of setting up our center, we'll also be looking for improved efficiencies. I think in our modeling patients are being treated every 17 minutes, on average. And we might be able to improve on that to help with capacity. We might be able to sort out treatment schemes that are shorter that also allow us to treat more patients. But we honestly thought that the conservative and responsible plan to present to you for the CON application was a one-room facility knowing that there's some uncertainty as to actually how many patients we'll see, but we thought we were pretty responsible.

THE WITNESS (Lemay): This is Art Lemay. Let me just also comment. We spent a lot of time talking about the size of this center, and I think both health systems were very concerned about being fiscally responsible and not building in excess capacity that may or may not be needed. So, depending on treatment approaches, the

research, the technology, a decision can be made, and we will see the volumes escalate either faster or slower, but we will also be prepared to act at that time. So we chose not to add two machines into our proton center. We chose to go with one so as to avoid unnecessary expense, yet we could expand, if we needed to, on that site or somewhere else.

1

2

3

4

5

6

7

8

9 THE WITNESS (Salner): Okay. This is 10 Andrew Salner. I would just add to what Dr. 11 Roberts and Mr. Lemay just said, and that is Dr. 12 Mendenhall mentioned some studies showing efficacy 13 of shorter radiation courses. We've seen shorter 14 radiation courses become more standard when we 15 treat breast cancer and prostate with photons. We 16 don't know yet if shorter radiation courses will 17 be more of a standard approach with protons, but 18 theoretically if they would that would result in 19 the need for future treatment slots overall, if 20 you will, so that we can increase the number of 21 patients being treated. So we'll have to wait and 22 see how that plays itself out as the research 23 becomes available.

THE WITNESS (Roberts): And then lastly, just to amplify what Mr. Lemay's comments
There's a history in the field of certain were. proton centers being built too large and then were not fiscally sound, and we certainly did not want to be in that situation. We also wanted to make sure that we didn't have so much capacity that we were then in an uncomfortable situation of having to stretch what we thought were the indications for proton radiotherapy. We wanted to be very much sure that what patients we select were appropriate for protons. And so again, after lots of discussions, believe me, we settled on a one-room concept knowing that the burden of doing that was going to necessitate running two shifts. And we're fully and professionally prepared to do that.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16 THE WITNESS (Chandler): And this is 17 Chris Chandler from Proton International again. Just one comment from our side. This is the niche 18 19 that our company understands how you build 20 clinically relevant successful proton centers from 21 experience. And we believe that the one room was 22 the right way to go with this. That number is a 23 capacity number. We could treat more if the 24 hypofractionation elements come into play, as the 25 doctors were indicating will open in two or three

years, so a lot can change between now and then. But the focus, in our mind, is treat what's clinically appropriate, do it in a way where we know the center will be successful financially, and, as Dr. Roberts indicated, we don't have to wake up one day and try to push patients through that aren't appropriate and relevant. So we think one room is conservatively the way to go, very successful, we'll have plenty of patients. And our actual experience in our centers that have opened recently in Birmingham, Alabama and South Florida bear this out that those volumes are reasonable and attainable.

1

2

3

4

5

6

7

8

9

10

11

12

13

14 And if you look over the history of 15 centers that have opened, you can see that going 16 from zero to 40, 50, 60 patients a day has been 17 achieved in essentially all the centers. The 18 issue where you get into trouble is some of these 19 areas didn't have the appropriate clinical 20 relationships, they built too big, and, you know, 21 they just didn't have the demand. And so we're 22 very cautious about coming to you with what we 23 think is a valid, appropriate and proper 24 application that we can deliver on clinically. 25 And if we deliver on it clinically, then by

definition it will support itself financially. HEARING OFFICER MITCHELL: Thank you. All right. This question is a little bit duplicative. And basically we wanted to understand which pediatric cancers proton beam therapy is approved for. I know that you all enumerated the types of cancers for which proton therapy is the standard of care. And because of the description of some of the, I guess the fact that the use of proton therapy minimizes side effects, that it will probably be an approach that would be best suited for children if it's clinically appropriate. Can someone speak to the types of pediatric cancers that it would be used for?

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16 THE WITNESS (Roberts): Dr. Ken 17 Roberts. Well, the most common childhood 18 malignancies, Leukemia, and we wouldn't treat it 19 with protons for that. CNS brain tumors are the 20 next large category, and those are highly 21 appropriate for proton radiotherapy. You then get 22 into pediatric cancers being a collection of very 23 rare tumors, but there are a number of different 24 There are sarcomas, which are broken down types. 25 into rhabdomyosarcoma and the semantics are

cumbersome but non-rhabdomyosarcomas. Many of those, but not all, are appropriate for protons depending on their anatomic site and how much radiation dose is required for that given circumstance and the need to reduce side effects.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

There are bone tumors. Many of those are treated with chemotherapy and surgery, but there's a cohort where radiotherapy is important. And a number of those, depending on the anatomic site, are best treated with proton radiotherapy. The concept is also of the benefit of radiotherapy is largely due to how old the patient is and whether they're still growing and developing, because we do a much better job of reducing what we call developmental side effects with proton radiotherapy that just helps their growing tissues.

There are certain Hodgkin Lymphoma patients that are in the pediatric group that do benefit from protons but not all patients with that diagnosis.

There are are probably patients who with certain types like Wilms' tumor, which is a kidney tumor, or nephroblastoma where a lot of times there's not a big benefit to protons and that we would just treat with conventional x-rays.

And you can then get into other rare types of pediatric tumors that there's a benefit. Does that help?

5 HEARING OFFICER MITCHELL: That's б helpful. Thank you. All right. So the next set 7 of questions, but actually the last question that we'll do before we take a break, this is actually for Mr. Chandler, and it's based on his prefile 10 testimony. He stated that we have drawn, and this is a quote, "We have drawn on our collective 12 experience and designed the CPTC as a single 13 gantry lower cost facility that can thrive by 14 treating a reasonable number of proton relevant 15 patients. Proton International offers small 16 proton facilities that are lower risk and more 17 financially feasible than some of the larger centers that have been built nationwide and encountered financial difficulties. A one-room facility like CPTC is built under a lower cost and operational structure that can withstand reimbursement pressures. Structuring a financing solution that is low cost, long-term, and does not demand unrealistic throughput assumptions, will allow the CPTC to focus on providing proton beam

1

2

3

4

8

9

11

therapy services to clinically appropriate patients."

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

So two questions for you, Mr. Chandler. If you could, would you define what you mean when you use the term "cost." And then when you use the term "lower cost," specify what you were using as a comparison.

THE WITNESS (Chandler): Sure. And in general, that really refers to -- and I think Dr. Mendenhall mentioned earlier in her testimony -there were early centers. The first two were Loma Linda and Mass General. Then there were some early adopters, the University of Florida and MD Anderson, who did very well. And they did very well because I believe they were associated and affiliated with clinical excellence, understanding of how to use the proton therapy particle, everything we've talked about this morning.

There was a grouping of centers that developed in the middle after that that were large four and five-room centers. Some were affiliated well with the right academic and clinical partners, some perhaps were not. When I use the term "cost," I'm referring to the cost of those kind of middle level centers that developed, and

these were very high cost centers, four and five-room treatment centers north of 150, 200, \$250 million in those centers.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

When I refer to "lower cost," I'm referring to the fact that we want to reduce all the capital expenditures, reduce the operating expenses of our centers, and then try to get to the point where you need less revenue to break even and operate efficiently. And the whole premise around that was to go back to treating the right kinds of patients where we don't have to manufacture, quote, the demand for a patient to put him through the center because we need the volume. And by doing that, you can create a more successful center, in my opinion, because you're focusing with your clinical partners on the appropriate use of proton therapy.

18 With respect to the financing, and when 19 I use the term "lower cost" in financing, these 20 mid-level centers, and, you know, I can speak from 21 experience because we did this at ProCure, and 22 these centers early on were not developed with --23 they were developed with very short-term high-cost 24 financing, more typical of private equity 25 financing and things like that. So those centers

needed a lot of volume quickly to be able to be financially feasible. Those volumes, because they were such large expensive centers, did not show up, and it caused an issue in the industry.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

Now, it wasn't an issue of whether proton therapy was clinically important or useful. It was a business model issue. It was a business model that just didn't work. So the idea was to come back and say, well, proton therapy is important, but how can we structure a business model around it, it will give it a better chance to work. And not to be too simplistic with it, but, you know, if you buy a home and you have a 10 year mortgage versus a 30 year mortgage, your mortgage is higher on a 10 year mortgage. Well, most of those proton centers were developed under 10 year terms of financing. So, you know, not only have we gone to reduce the capital expenditures, but we have extended the financing term out to 30 years and tried to lower the cost of financing using access to the tax exempt municipal bond market. So hopefully that's responsive to your question.

HEARING OFFICER MITCHELL: It is. I
think this is a good time to take a break. But

1	let me just turn to my colleagues. I just want to
2	make sure Brian and Lindsey don't have any
3	follow-up questions.
4	MS. DONSTON: I don't.
5	MR. CARNEY: I'm good.
6	HEARING OFFICER MITCHELL: All right.
7	And then, Attorney Fusco, anything that you wanted
8	to add before we go to our break?
9	MS. FUSCO: Just to let you know that
10	Dr. Mendenhall is going to be leaving, it's 1
11	o'clock, if that's okay. Correct?
12	HEARING OFFICER MITCHELL: I think
13	that's fine. I don't think we have any other
14	questions.
15	MS. FUSCO: Okay. Thank you so much.
16	And thank you, Dr. Mendenhall.
17	HEARING OFFICER MITCHELL: All right,
18	everybody. So we're going to go off the record.
19	We're going to come back at 1:45, and then we'll
20	finish up with OHS's questions.
21	(Whereupon, a recess for lunch was
22	taken at 1:00 p.m.)
23	
24	
25	

Γ

1 AFTERNOON SESSION 2 1:45 P.M. 3 HEARING OFFICER MITCHELL: All right, 4 everybody, we are back on the record. I just want 5 to check over at the board room and make sure б everybody is okay on that side. Let me know if 7 you need more time. 8 MS. FUSCO: We're all set. We have 9 everyone we need. Thanks. 10 HEARING OFFICER MITCHELL: All right. 11 So Brian, I'm going to give it over to you. 12 MR. CARNEY: Okay. Good afternoon, 13 everybody. Enjoyed your lunch? It's feeling a 14 little bit like winter out today. 15 So the next set of questions I have are 16 all sort of financial related, capital 17 expenditures, the financial worksheets. 18 MS. FUSCO: This is Jen Fusco, Brian. 19 So we have Gerry Boisvert from HHC is remote, as 20 is Fred Sorbo. The Yale New Haven finance folks 21 are in another conference room, and I think they 22 may come in here to answer those questions, if we can just grab them. And Chris Chandler as well. 23 24 MR. CARNEY: Okay, great. Do you need 25 some time to do that?

1 They are right around the MS. FUSCO: 2 corner. 3 MR. CARNEY: Okay. Sure. 4 (Pause.) 5 MS. FUSCO: Thank you. We're all set. 6 Sorry, one more minute. 7 HEARING OFFICER MITCHELL: No worries. 8 Before we start again, is there anybody who has 9 not been sworn in that has been brought into the 10 room? 11 MS. FUSCO: No. Tom was sworn in. 12 Mario, you were sworn in as well. So we should be 13 all set. Fred was sworn in remote and Gerry. 14 Okay, now I'm all set. Thank you. 15 MR. CARNEY: Okay. So there's been 16 some internal discussion about the costs of the 17 proposal relative to the number of patients that 18 are going to be treated in this project. So total 19 capital expenditure for the proposal is \$72 20 million. On page 72 of the application you state 21 that Connecticut Proton Therapy Center intends to 22 secure public bond financing to fund the project. 23 Further, you state that the public bond financing 24 will be a private placement management by Loop 25 Capital Management with the issued bonds able to

be traded and information available on the Electronic Municipal Market Access system.

Can you please sort of walk us through how this private placement management works for the bonding?

MS. FUSCO: Chris Chandler would be the appropriate person. Chris.

8 THE WITNESS (Chandler): Sure. Happy to do that. Thank you for the question. 10 Obviously, as I mentioned earlier, the ability to access the tax exempt municipal bond market is an 12 important part of the project. So, in general, we 13 established the joint venture management company 14 that we've referenced before between PI, Yale New Haven and Hartford HealthCare. That will be CPTC, 15 16 if you will. We will draft, in cooperation with 17 our placement agent, Loop Capital, which is an 18 investment banking firm out of Chicago, a general 19 memorandum that explains and outlines the details 20 of the opportunity to invest in. We structured it as a tax exempt filing. We use a tax exempt bond 21 22 conduit called the Public Finance Authority out of 23 Wisconsin which allows us to access the tax exempt 24 municipal bond market.

The offering is made under all the

25

1

2

3

4

5

б

7

9

appropriate security regulations and requirements. We typically structure it as a senior debt and an subordinated debt offering. A senior debt offering is offered to large institutional investors who are interested in these bonds. They typically tend to be in the tax exempt market, kind of high yield long-term bonds that are attractive to municipal investors.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

17

18

19

The senior bonds that I've just referenced have a security package with them that's basically the assets of the CPTC entity and the technical revenue streams from the CPTC entity. And those assets are pledged, if you will, as security against the bonds.

¹⁵ Go ahead. Sorry. Do you have a ¹⁶ question?

MR. CARNEY: Yes. What's the anticipated time frame for repayment of that debt obligation?

THE WITNESS (Chandler): Normally they're structured as a series of tranches. You might have some shorter term and some longer-term bonds. We push it as long as we tend to have an average term of about 28 years or so, I think, 27, 28 years. It just depends ultimately on where we

1 end up. My colleagues just indicated to me that 2 it's a 30 year term that we ultimately get to as 3 we average out the different tranches. 4 MR. CARNEY: 30 years. 5 THE WITNESS (Chandler): Yes. Sorry, 6 qo ahead. 7 MR. CARNEY: Go ahead. 8 THE WITNESS (Chandler): I was just 9 going to say and the senior debt has that security 10 package. The subordinated debt investors, and 11 that's where PI and the institutions provide some 12 capital into the subordinated debt, and they're 13 buying the same security as the senior debt 14 investors. It's just junior to the senior debt in 15 the waterfall, but they have the same security 16 package. It's just in a junior position. 17 MR. CARNEY: Okay, not as secure. 18 THE WITNESS (Chandler): Correct, 19 correct. And because of that, it carries with it 20 a slightly higher interest rate. 21 Interest rate, okay. MR. CARNEY: What 22 legal entity will be responsible for repayment of 23 this debt obligation? 24 THE WITNESS (Chandler): The actual 25 operational joint venture is responsible for

operating the center and generating the revenues to repay the obligation. The bonds are actually secured to the PFA, public finance initiative, public finance asset program. And so we provide all of our securities to the PFA asset program, and then they're responsible ultimately for the repayment of the bonds. If these bonds are nonrecourse, which I should have mentioned in my opening statements too, so the risk to the parties is related to the subordinated debt. The subordinated debt, if you will, is at risk. The senior debt, if for some reason the entity was unable to repay the debt, those bonds are basically a project finance structure, and they're secured only by the assets that I mentioned earlier.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17 MR. CARNEY: Okay. So that was kind of 18 like a follow-up question. So in the event that, 19 you know, maybe it's unlikely, but in the event 20 that CPTC were to become insolvent, the question 21 is who would be responsible for repayment of the 22 debt. And I guess what you're saying is the 23 assets would be sold to fulfill the senior debt, 24 and the subordinate debt would be out of luck? 25 THE WITNESS (Chandler): Correct. And

I think that it may not be that the assets would be sold. Likely what would happen is the bond holders with step-in rights probably tell Proton International we appreciate all you did but you didn't do a good job and we would be out of luck. And when you have an asset like this, it typically would go back to the clinical institutions and work with them to come up with a strategy to keep the center going. Typically in the past when these -- and there have been some issues with the larger centers that have had some problems like this, and they've gone into a forbearance mode where they work with the parties to try to figure out what the problems are.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

24

25

MR. CARNEY: So basically legally like the Yale System or the Hartford HealthCare System would not really be on the hook?

THE WITNESS (Chandler): Correct. They would not have any risk, other than the subordinated debt investment they make.

MR. CARNEY: Okay. And what's the likelihood of this being approved, you know, the bonds to be issued at that amount?

THE WITNESS (Chandler): We're still very confident in it. I think Proton

International pioneered this effort in accessing a municipal bond with our projects in Birmingham and 3 Delray. Since then I believe there's been four or 4 five additional centers using this finance mechanism. So it's been well received. I can tell you that in conversation with investors they 7 like our model, they like the one-room approach, they like the experience we bring to the table. And even in the COVID environment you can imagine people are concerned. However, there's a tremendous amount of capital sitting out there 12 looking for a way to go to work, and these 13 long-term bond structures are really very 14 appealing to the institutional investor. So we're 15 very confident in fact that we'll continue to do it.

1

2

5

6

8

9

10

11

16

17 We also have very good relations with 18 the largest investors that have participated in 19 these before. We continually have conversations 20 with them, talk to them about how to structure 21 these things so that they'll be amenable in the 22 public markets. And again, that's why, when we go 23 back to my opening comments, this has to be based 24 on excellent clinical partners that understand how 25 they want to use proton therapy and have

identified the patient pool carefully. And you can imagine these kind of senior investors don't take these things lightly. So if we showed up and we didn't have a well thought out plan, the probability of investment would be lower. But because we come to them with experience, a well thought out plan, strong clinical partners, a clear identification of where the patients will come from, you know, and an independent feasibility study before we make the offering, our experience has been very positive, and we don't see any reason why it wouldn't continue to be.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

MR. CARNEY: Okay. And just say there wasn't the interest, so would it be more of a delayed effect or an adjustment of the rates to encourage the participation, or how would that work?

18 THE WITNESS (Chandler): Yeah, I think 19 that's a very good observation. There have been 20 indications in the past in the bond market, not 21 with Proton International, but with other projects 22 where the initial offering was not guite as well 23 received and it took a little longer to get it 24 They got it done, but they would have an done. 25 interest rate adjustment for the perceived risk or

126

things like that. And we try to avoid that. So far we've been able to close our transactions based upon how we assumed they would be because we go to the table with kind of a preplanned strong program with strong clinical partners.

I would also mention, and you may be asking this in a minute, but I'll just jump in real quick because it's related to the financing, these are big numbers. I mentioned earlier, well, these are lower costs. Well, believe it or not, they are lower costs compared to what we used to deal with.

MR. CARNEY: All relative.

14 THE WITNESS (Chandler): All relative. 15 And when you look at the total capex number versus 16 the total finance number, it jumps guite a bit. 17 Well, that's because these municipal bond 18 investors are taking essentially the risk. You 19 asked me before if this doesn't work who has to 20 pay the note back, and the answer is really 21 nobody. So that risk gets priced into this. And 22 it also, there's always, you know, a tradeoff, 23 right, for what you do. It's really good that we 24 can get this kind of money on a nonrecourse basis, 25 but they require us to put up a debt service

1

2

3

4

5

б

7

8

9

10

11

12

13

reserve fund and capitalize the interest during the development period. So, you know, they can pay the interest on these bonds during the couple of years that we're developing the center. We have to take all the funding down up front. So that's why the cost of this financing, you know, it looks like it's significantly -- it is, it's a lot of money, but that's what it's for, it's to fund the capitalized interest and things like that.

1

2

3

4

5

6

7

8

9

10

11 And finally, we're being very 12 conservative as we bring things to you in our 13 application. But what we're doing is, as we're 14 becoming more aware of the costs, we're going to 15 minimize every area we can to tend to reduce the 16 costs. Ultimately that reduces the capitalized 17 interest and things like that. So we're confident 18 that over time as we finish the building design, 19 as we select the contractor, as we understand more 20 about whether there's going to be site costs we're 21 not aware of yet and our contingencies will fall 22 away, and ultimately we'll do everything we can do 23 to reduce the overall cost of the project.

MR. CARNEY: Okay, fair enough. Thank
you, Mr. Chandler. I appreciate it.

THE WITNESS (Chandler): Yes, sir. My pleasure.

3 MR. CARNEY: My next question has to do 4 with some financial projections you provided me on 5 Exhibit E on page 19, 17, and I think you also 6 provided the same table in the prefiled testimony. 7 It's called the CPTC Programmatic Financial 8 Projections. It's on page 5, I think, of the 9 issues portion of the prefiled. 10 MS. FUSCO: Brian, this is Jen. If you 11 could just clarify. Is it a proforma, is it one 12 of the financial worksheets? 13 MR. CARNEY: It's a table that you 14 provided with the application. 15 MS. FUSCO: Yeah, here we go. So just 16 for Gerry Boisvert's reference who's remote, 17 Gerry, it's on page 5 of the hearing issues 18 responses. It was also part of the CON filing. 19 It's the programmatic breakdown. 20 MR. CARNEY: All set, Jen? 21 MS. FUSCO: Yes. 22 MR. CARNEY: Okay. So CPTC 23 programmatic financial projections were provided 24 showing financial solvency for the program in the 25 third year of operation. Please walk me through

these numbers and explain why this is the more appropriate way to determine financial feasibility.

1

2

3

4

5

6

7

8

9

10

11

13

15

16

17

18

19

24

25

Chris, do you want to start MS. FUSCO: with the Proton piece, or do you want us to answer for the health systems?

THE WITNESS (Chandler): If you would answer for the health systems, and then -- I'm struggling. In all of the open documents I have to find it, so I'll find it while you guys are answering. I apologize for that.

12 THE WITNESS (Newman): This is Tom Newman from Yale New Haven Health. So I'll 14 respond to the Yale New Haven programmatic financial projections that we had for each of the three years. And so while the program breaks even in year three, Yale New Haven, in particular, as I'm speaking to you, has losses in each of those years. And what that represents is our estimate 20 of those cases that we currently provide care for and other procedures that would be moved to the 21 22 proton therapy joint venture, and that would be 23 the gap assuming not -- that we wouldn't backfill. So it's a conservative gap from that perspective. MR. CARNEY: So the significant driver

for the incremental losses is due to a reduction in revenue from the sort of transfer of patients out of traditional treatment to proton therapy?

THE WITNESS (Boisvert): Our contribution from the Yale New Haven side, and Hartford's contribution from their perspective Gerry can speak to.

> MR. CARNEY: Okay.

THE WITNESS (Boisvert): Our response would be the same as Tom's. It's a similar situation.

12 MR. CARNEY: It looks like the profits 13 are I guess in each your cases would be 24.5 14 percent of the profits of CPTC in 2024 would be 15 reflected in your financial proforma and 16 nonoperating revenue. The figure was like 945,000 17 or something like that. I guess my question is, 18 you know, the incremental losses are over a 19 million dollars and they continue throughout the 20 whole projections. That's a little concerning, I 21 think, to the agency, you know, especially given 22 recent losses with COVID, that you would be taking 23 on a project that's going to lose, each system would lose an additional sort of million plus per year. How can you sort of respond to us about

24 25

1

2

3

4

5

6

7

8

9

10

that?

1

2

3

4

5

б

7

8

9

10

11

12

13

THE WITNESS (Newman): I guess I'll start. Again, this is Tom Newman from Yale New Haven. I think what I would say is that the way we calculated this impact was conservative and that these were the estimated revenues associated with patients who would be contributed to this process. We have a robust cancer program that is frequently at capacity, and we would continue to expand and fill those voids over time. And we believe that as our cancer centers continue to grow that that capacity will be reabsorbed by the system.

14 MR. CARNEY: A couple times we sort of 15 talked about sort of a break-even point with the 16 funds that, you know, the amount of contributions 17 that would be put in by, you know, each system and when and if or would there ever be sort of a 18 19 break-even point for those contributions, and you 20 guys didn't really sort of have a response as far 21 as, you know, that time period. It looks like the 22 bonds are going to be issued for 30 years. So I'm 23 wondering is it going to be that long a time 24 period before you're sort of at a break-even point 25 for the commitment that the systems are putting

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

into this project?

THE WITNESS (Chandler): This is Chris. Maybe I can help a little bit with that. And a couple of different points too. And I don't want to speak to the institutions' numbers. They have those in front of them. But from the perspective of when we operate the center, and let's say we're doing well in the center, we'll generate between 2 and \$3 million a year, including management fees, from the center. We're still in the process of negotiating the management fee structure and the numbers and the amount, but the center will generate free cash flow. As you well know, when you have a tax exempt structure, you don't distribute profits, but the entity would own access to the profits pursuant to fair market value contracts and things like that. So the intention here is to through a management fee structure, a fair market value management fee structure, share the revenues that go back for the services performed by the institutions and by Proton International. So really we think within four or five years, based upon the management fee revenue that they'll share, they'll be able to reach breakeven points just specifically from

their respective subordinated debt investments. So that's really that structure there.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

The other aspect that it's hard to bring out in these kinds of things is the general halo effect around proton therapy centers, and I wish Dr. Mendenhall was still on, but in all of my experience and all of the experience we've seen in centers we've actuality built and opened, the clinical partner that's involved sees a significant amount of additional services from, as mentioned earlier, we don't treat every patient that shows up at the door with protons. Sometimes they get traditional radiation. Oncology patients, you know, they need concurrent therapies. Often they have surgeries or chemotherapy. So this really is a holistic approach to the best treatment, possible treatment of care for the patient, and it's very hard to pigeonhole every piece of revenue that might come back to the individual parties.

MS. FUSCO: I think Tom has one more thing to add too, if that's okay. THE WITNESS (Newman): Just to restate

MR. CARNEY: Okay. Thank you.

²⁵ what I said and to emphasize, I think, that the

combination of the just under million dollar impact, that this is really not considering, our projections did not consider the backfill, as I said earlier. So we would assume there would be backfilling, as well as what Chris mentioned, the halo effect and other revenues generated in our programs as it relates to these patients.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

And also the real driver of this is it's the right thing for patients. In collaboration with our providers and operating partners, the mission is just that. It's really in the interest of patient care. And, you know, we feel it's the right thing to do whether there was an annual loss impact or not. And the organizations are both, not to speak for Gerry, but sizable enough to absorb this loss if that were the worst-case scenario.

MR. CARNEY: Okay. Thank you.

THE WITNESS (Boisvert): This is Gerry. Just to confirm all of what Tom said, this really is about clinical care. And while we've presented the economic loss that is possible from, without backfill, from the shifting from one modality to another, ultimately it's the right thing for patients. And we will adjust our operations, you

know, find efficiencies in various pockets, ultimately hope to make up those dollars either by backfilling or other efficiencies elsewhere, but we have the financial strength to easily adopt this model.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

MR. CARNEY: Okay. Just kind of following up on this sort of same thing, you've kind of answered most of it for me, but given that the recent newspaper articles are reflecting information like Yale New Haven Hospital System is expected to lose an unprecedented \$400 million due to COVID, you know, is the timing of this good for a proposal that's going to sort of add to the burden with incremental losses of more than a million a year, you know, your system is going to be able to absorb sort of the additional debt right at this time? Maybe you can speak to that. THE WITNESS (Newman): Sure. Thanks for that question, and it's a good one.

Obviously, the economic pressures in the wake of COVID have been significant, and we continue to recover. The oncology program has really been least affected throughout the COVID pandemic, and many of the volumes stayed very close to where they were, what we call baseline. So that's all adding to the strength and support of this component of what we provide.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

From the operating side, you know, we're a couple of years out before this center would be built, so we fully expect to be back to baseline and growing again before, well before the center opens.

And from a capital perspective, as it relates to our investment, in the upcoming year we assume and have built into our prioritization of capital for the upcoming year the expectation that we will be doing this.

So as much as we've been conservative in the impact of our financial projections in the upcoming year and our recovery, we've included this as a priority.

MR. CARNEY: Okay. Good on that answer? Anything from the other side?

¹⁹ MS. FUSCO: Gerry, do you have a
²⁰ comment on Hartford's behalf?

THE WITNESS (Boisvert): No. It's the same challenge in terms of we are recovering nicely. And, you know, it's an unfortunate loss, you know, both in terms of lives as well as activity, but we know that people are going to

continue to get sick. We feel good about our volumes and our position going forward. This is, you know, COVID, even though it's dragged on way too long and will continue to drag on, will come to an end. And we're figuring out every day how to adjust to battle the disease and get everything back on track.

MR. CARNEY: All right. So my apologies. One final sort of COVID related question. So given the effect of the global pandemic on net revenue for fiscal year 2020 for all hospital systems within the state and the future uncertainty of the result of the current increases going on with COVID infections, please indicate whether you have made any adjustments in planning of your projects to minimize losses. If you have, elaborate upon those adjustments.

THE WITNESS (Newman): So we certainly -- from Yale New Haven this is Tom Newman. From a Yale New Haven Health System perspective, we have had a lot of lessons learned from the first round of COVID. And as we look and are currently preparing and as our experience with COVID cases continues to grow in the second wave on a daily basis, we don't intend to voluntarily

1

2

3

4

5

close programs down as we did in the initial phase. So our expectation and plans are to continue to provide that care in a safe environment for our patients as long as they're willing to come and receive that care. And should it get to a certain point, then we would have to talk about what services we would need to adjust should those volumes reach a certain level.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

MR. CARNEY: I guess of course too that would be affected too if state government imposed sort of kind of a similar thing as before about not doing elective surgeries.

THE WITNESS (Newman): Correct.

MR. CARNEY: Do you guys have the final tally for the impact of COVID on fiscal year '20?

THE WITNESS (Newman): I don't have that.

18 THE WITNESS (Boisvert): Speaking for 19 Hartford HealthCare, we're still in the middle of 20 discussing things with our auditors, et cetera, so 21 we don't yet have a finalization. A lot of the 22 federal rules have continued to change from the 23 spring, and so it's too early to publicly present 24 a number because we're still working with our 25 auditors as we all understand how the changing

rules might have impacted us.

MR. CARNEY: Micheala, should we ask for a Late-File at this point? I know our executive director is going to be highly interested in sort of seeing these, the financial worksheets updated to the best of your ability to show us the impact. I think utilizing the same years that you submitted earlier with just sort of an update. So I would appreciate if you could provide those updates for the two health systems and for the center itself.

HEARING OFFICER MITCHELL: I just want to echo that. It goes without saying that this is an expensive project. And so that is one of her main concerns. And I think that in order for us to make an informed decision, we have to know what the financial status for each system is, especially if the system is projecting, even though it's a conservative projection, is projecting that there will be a loss. So I don't see any way of getting around that. And I think that the question would be if we requested Late-Files for updated financials how long would that take.

THE WITNESS (Newman): So we expect our

1

2

3

audit to be completed and issued just before Christmas. That's usually the timing of our audit report.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

MS. FUSCO: Attorney Mitchell, would we be looking more to do it on a short-term basis or to the best of our ability now understanding that audits aren't complete, but, you know, whatever we could give in the next two weeks. Is that what you'd be looking for versus --

HEARING OFFICER MITCHELL: I think that she wants as close to actual as possible. And I'm thinking that she may want to know what was the actual for fiscal year 2020 projected out until 2022.

MS. FUSCO: Gerry, from an HHC perspective how long would that take, same timing?

17 THE WITNESS (Boisvert): We're on a 18 similar schedule as Tom at Yale New Haven. We 19 would have to caucus to see if there's something 20 that could be done in the next couple weeks as an 21 example. Again, the rules are changing from the 22 federal government. Today additional guidance 23 came out which has to be absorbed. So it 24 continues to be a rapidly changing situation. So 25 the finality that you're looking for and we're

looking for is probably not totally available, but we can make our best efforts to respond as quickly as possible.

1

2

3

4

5

6

7

8

9

10

15

16

17

18

19

20

21

22

MS. FUSCO: Attorney Mitchell, if you're amenable, I mean, I would suggest that we take this down as a Late-File and then we caucus as a group tomorrow and get back to you with sort of the time frame. Would that work? And then we can agree upon what we can provide when and come up with a time frame for submission.

HEARING OFFICER MITCHELL: I think that works. Let me just, Brian, as he knows a lot about the financials, let me just ask Brian. Was there anything that you wanted to say about that?

MR. CARNEY: That seems reasonable to me. I would like to, if it is possible, to get like sort of the summary version of information provided to me about the bond financing in writing as opposed to trying to get it off the transcript that Chris provided. I think that would be very helpful to sort of understand.

THE WITNESS (Chandler): Yes.

MR. CARNEY: I tried to absorb most of
it, Chris, but I'm not sure I got all of it, but I
tried.

THE WITNESS (Chandler): I'd be happy to do that, yes.

3 HEARING OFFICER MITCHELL: All right. 4 So what we'll do is we will -- so the record is 5 going to remain open anyway for a week to receive 6 written comments, if anybody has any. And so we 7 can confer tomorrow after everybody has had time 8 to talk about it and figure out the parameters for 9 the Late-File in terms of what should be included 10 and the time frame for producing the information. 11 MR. CARNEY: We had the estimate of 12 pediatric referrals too, Micheala, to add to the 13 list. 14 HEARING OFFICER MITCHELL: Thanks. 15 Attorney Fusco, did you get that too? 16 MS. FUSCO: I did. So the estimate 17 of --18 HEARING OFFICER MITCHELL: You're able 19 to provide --20 MS. FUSCO: -- pediatric referrals, 21 yes. 22 HEARING OFFICER MITCHELL: Brian, was 23 that your last question? 24 MR. CARNEY: Yes. 25 HEARING OFFICER MITCHELL: Okay. And

1 then also, Lindsey, did you have anything 2 additional? 3 No, I didn't. MS. DONSTON: 4 HEARING OFFICER MITCHELL: I'm going to 5 turn it back over to you, Attorney Fusco. Is 6 there anything additional that you wanted to add? 7 MS. FUSCO: No, I think we're in good 8 shape. I mean, we'll keep it open for the public 9 portion. We have a few folks prepared to testify. 10 And I don't know, I mean, if we would have 11 anything we'd need to respond to after that, 12 probably not. So now while we're here, we'll 13 thank you guys for all your time and effort on 14 this if we don't get to wrap up later. But no, we 15 appreciate this. This has been a very well run 16 and informative hearing. And I know it's 17 difficult, and there are even more challenges with 18 all of us being different places, so thanks so 19 much for bearing with us. And most of us, or a 20 good number of us will still be here through the 21 public portion, and we'll be in communication, as 22 needed. 23 HEARING OFFICER MITCHELL: We 24 appreciate the applicants being so organized. 25 This was easy for us. So thank you.
MS. FUSCO: We tried. We tried hard. We appreciate it.

1

2

3

4

5

6

7

8

9

10

11

HEARING OFFICER MITCHELL: The other thing I wanted to mention is so we're going to go off the record unless, Attorney Fusco, you have people that want to render public comment now. We're going to go off the record and then we'll come back on at 4 for people who have public comment that they want to render.

The other thing too is that I think at 3 o'clock, I'm not sure if Leslie Greer is still 12 on, but at 3 o'clock there's going to be a 13 registration period for people who want to render 14 public comment. So we'll kind of do it in the 15 order that people present themselves. And I know 16 that there were two people that you wanted to go 17 in tandem. Can you just remind me who those two 18 people were?

19 MS. FUSCO: It was Dr. Eileen Gillan 20 and Matt Somberg. She's a physician, and he's a 21 patient's parent.

22 HEARING OFFICER MITCHELL: Got it. 23 MS. FUSCO: Thank you very much. 24 HEARING OFFICER MITCHELL: So we have 25 those two. We'll let Dr. Dillan and Mr. Somberg go first.

1

5

б

7

8

9

10

11

12

13

14

15

16

24

25

2 MS. FUSCO: "Gillan," I'm sorry, with a 3 "G." Sorry.

4 HEARING OFFICER MITCHELL: Gillan, got it. Thank you.

MS. GREER: I'm here, Micheala. HEARING OFFICER MITCHELL: I'm sorry. Leslie, thank you. Okay.

And then one last thing, Attorney Fusco. Did you want to make a formal closing statement so that I don't forget it when we do the comments?

MS. FUSCO: I don't think we need to. And we appreciate the opportunity, but I think unless anything comes up in the public comments, we should be good, but thank you.

17 HEARING OFFICER MITCHELL: I thank everybody for their time. I will wait to hear 18 19 back from you, Attorney Fusco, on what you guys 20 think you can provide and then the time frame. 21 And then what I'll do after I do hear from you, is 22 I'll issue a formal order with the time frame and 23 everything that we've agreed upon.

> Fair enough. Thank you. MS. FUSCO: HEARING OFFICER MITCHELL: All right.

1	Thanks, everybody, for your time.
2	(Whereupon, the technical portion of
3	the hearing concluded at 2:25 p.m.)
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	

Г

PUBLIC COMMENT SESSION

4:00 P.M.

HEARING OFFICER MITCHELL: So it's 4 o'clock, and we're going to go back on the record. I just want to make sure everyone is here.

All right. So again, we're back on the record with the public portion of Hearing 19-32339-CON, involving Hartford HealthCare Corporation and Yale New Haven Health Services Corporation's application to establish proton therapy services by acquisition of new technology to the state and acquisition of a CT simulator.

My name is Micheala Mitchell. I'm the hearing officer for the hearing today. Also in attendance are Lindsey Donston, who is an analyst working on the application with me, and Brian Carney, who is the team lead for the certificate of need team. In addition to that, we do have Leslie Greer, who is our consumer information rep, who has been signing everyone up for their participation in public comment this afternoon.

I'm just going to ask all participants
 to the extent possible to enable the use of their
 video cameras when commenting during the
 proceedings. Anyone who is not commenting should

1

2

3

4

5

mute their electronic devices. And also just in case they're not muted, make sure all televisions, telephones and other devices that are not actively being used have been silenced.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

We're going to call individuals in the order in which they signed up to speak. If I miss anybody, please utilize the raise hand function and let me know. I will make sure that I get to you. So far I think we have six people who have signed up to speak. I just want to ask everyone, before you give your comments, please make sure that you state and spell your name for the purpose of accurate transcription. We are now starting to transcribe public comments.

Speaking time is going to be limited to about three minutes. I don't want you to be dismayed if we stop you at the conclusion of your time. We want to make sure we give everybody the opportunity to speak, and we want to be fair. If people are ending their statements around that three-minute mark, I'll give you a little bit of extra time to make your final statements.

Additionally, if you know someone who wanted to make a statement and they couldn't be here today, please let them know that we encourage

1 submission of any further or additional written 2 comments to OHS by email. I'm going to hold the 3 record open for public comment until November 25th 4 of 2020. Our email address for that purpose is 5 CON comment, C-O-M-M-E-N-T, at ct.gov. While we 6 prefer to receive written comments electronically, 7 you also have the option of mailing comments to 8 the office. Our mailing address is P.O. Box 9 340308, 450 Capitol Avenue in Hartford, 10 Connecticut. The zip is 06134-0308. 11 I want to thank everybody for taking 12 the time to be here today and for your 13 cooperation. I know that we did say we're going 14 to let Dr. Gillan qo first, but I do understand 15 that we have the mayor for the Town of 16 Wallingford. Let me just ask Dr. Gillan, do you 17 mind if the mayor just makes some comments briefly 18 before you go? 19 (No response.) 20 HEARING OFFICER MITCHELL: Dr. Gillan? 21 DR. GILLAN: That would be fine. I'm 22 sorry for that. 23 HEARING OFFICER MITCHELL: It's no 24 problem. Not to worry. All right. So we are 25 going to start with, I think that we did have the

mayor for Wallingford. Is it Mr. Dickinson?

MAYOR DICKINSON: That is correct.

HEARING OFFICER MITCHELL: Okay. You can go ahead and give your public comment. You're able to do so. Just make sure you state your full name for us.

MAYOR DICKINSON: All right. Good afternoon, Attorney Mitchell, members of the Office of Health Safety staff. My name is William Dickinson, W-I-L-L-I-A-M, D-I-C-K-I-N-S-O-N. I serve as mayor in Wallingford. And with me is Steve Civitelli, director of the Wallingford Health Department, and Tim Ryan, director of our Wallingford Economic Development Department.

We salute the thoughtful joint effort of Yale New Haven Health Services and Hartford HealthCare Corporation to establish the Connecticut Proton Therapy Center. Proton therapy, as you are aware, is very important for cancer care delivery, research and education. Connecticut, as a state, lacks this form of cancer care. Wallingford's central location in Connecticut and its proximity to major transportation options, such as major state highways and rail service, will assist the

1

2

3

4

residents throughout Connecticut to more easily access this cancer care.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

This application has the full support of Wallingford. We thank you for providing this opportunity to encourage approval of the Connecticut Proton Therapy Center application for a certificate of need. Thank you very much.

HEARING OFFICER MITCHELL: Thank you, Mayor Dickinson.

Let me just ask Mr. Ryan. I know you're with Mayor Dickinson. Did you want to make a separate comment?

MR. RYAN: I think the Mayor speaks for all of us, and we are all in resounding support of this application and this project. Thank you.

HEARING OFFICER MITCHELL: Got it. All right. So we're going to go ahead and move on to Dr. Eileen Gillan.

19 DR. GILLAN: That's correct. Thank 20 you. Good afternoon, Attorney Mitchell and the 21 members of the Office of Health Strategy staff. 22 My name is Eileen Gillan. I'm a pediatric 23 oncologist at the Connecticut Children's Medical 24 Center. Thank you for this opportunity to speak 25 in support of this proposal to bring proton

therapy services to the state and specifically the benefits that will accrue to our patients and their families. Matthew Somberg, the father of Cooper, who is one of my patients and underwent proton therapy in Boston on two occasions, will speak after me about his family's experience.

First of all, allow me to give you some of my background as a pediatric oncologist. I have been practicing in Connecticut Children's Medical Center since it opened in 1996. I am the medical director of the pediatric neuro-oncology program and the founder of the survivorship and cardio-oncology programs. Within these three subspecialty areas I have seen the type of damage that radiation has done to our patients, and I wanted to speak to that today.

First, I would like to share my experience with our pediatric neuro-oncology patients. The standard of care for pediatric patients requiring brain or spine radiation is unequivocally proton therapy. Currently greater than 90 percent of our neuro-oncology patients are referred to the proton center at Mass General for proton radiation therapy. This is the standard of care for this patient population. Those patients

1

not referred include patients who have no chance of cure and those families who do not have access to this care due to social or financial reasons.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

Late effects, as you know, was spoken about today, or long-term side effects from cancer treatment are seen in the majority of our patients. I have seen many of these patients survive with life-long debilitating radiation late effects in my survivorship clinics. These late effects are accentuated by the child's growing tissues. Currently greater than 85 percent of all pediatric cancers are successfully treated, and patients are now survivors with a normal life expectancy. Unfortunately, radiation late effects are often cumulative throughout the rest of their lives and lead to a diminished quality of life with associated physical, emotional and financial burdens for these patients and also to our society.

Clinical studies. The use of proton
 therapy for pediatric brain and spinal tumors is
 especially important and is supported by many
 clinical studies, most importantly, neurocognitive
 function. Proton radiation therapy allows
 improved neurocognitive function after treatment

when compared to traditional photon therapy. This has been shown in several studies in which the proton group exhibited superior long-term outcomes in categories of IQ, perceptual reasoning and working memory when compared with the photon group. Unfortunately, those patients who receive traditional radiation therapy exhibited significant decline in these functions, including IQ. This decline in IQ can be avoided somewhat by the use of proton therapy. There is also a decrease in brain hormone dysfunction. This can lead to poor linear growth, thyroid and sexual dysfunction.

These late effects can often be avoided by proton therapy. Proton radiation therapy to the spine also delivers less dose to the vertebrae of a growing child, and thus there's less spinal growth abnormalities and thus leading to an improved quality of life for these young patients.

In addition, side effects. The organs adjacent to the spine, which is irradiated, infections to the thyroid gland, the heart, the gonads, are also affected by the proton therapy. In addition, traditional radiation scattered to the heart can lead to significant cardiac damage

1

2

and is increased in patients who have photon therapy.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

Finally, secondary cancers in children may develop from underlying genetic syndrome. Radiation to adjacent normal tissues harboring this predisposition may promote secondary malignancies. Due to the nature of proton therapy, less radiation will be delivered to this tissue leading to improved quality of life.

In conclusion, proton radiation therapy is considered the standard of care in the pediatric patient population, particularly in neuro-oncology. The use of proton therapy leads to decreased neurologic sequelae, a decrease in neuroendocrine and also cardiac dysfunction, among other benefits.

The proposed Connecticut Proton Therapy Center will allow patients throughout Connecticut to benefit from the greater control of their cancer and less treatment related effects that are associated with proton therapy.

Now I'd like to introduce Matthew
 Somberg who's son Cooper has had treatment at the
 Boston Proton Center on two occasions. His story
 will tell the parent perspective. Thank you again

1 for allowing me to address this committee. 2 HEARING OFFICER MITCHELL: Thank you. 3 DR. GILLAN: You're welcome. 4 MR. SOMBERG: Good afternoon, everyone. 5 My name is Matthew Somberg. Hello to the members 6 of the Office of Health Strategy staff. 7 I'm a resident of Glastonbury, 8 Connecticut, and I want to thank you for the 9 opportunity to speak for a few minutes this 10 afternoon. I speak to you as a parent and as a 11 Connecticut resident. As Dr. Gillan mentioned, 12 our youngest son, Cooper, at ten months old had an 13 emergency surgery for what turned out to be a 14 cancerous brain tumor, an ependymoma. We have no 15 prior medical knowledge or medical experience in 16 our family, and literally overnight we were turned 17 on to a new world. 18 The surgery was incredibly complicated, 19 and there were a lot of complications after the 20 fact, and we lived in the ICU at Connecticut 21 Children's for three months. And during that time 22 we learned that his tumor was an ependymoma which 23 is cancerous. And as Dr. Gillan mentioned earlier 24 and as was explained to us at that time, our 25 treatment options were very limited. Chemotherapy

is not something that is effective on this type of brain tumor. Our options were to pursue something like chemo, which would probably have no result, or try to pick ourselves up and move out of state to a proton beam center so that our son could receive treatment.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

We have two older children. At the time they were five years old and three years old. And for our family to pick itself up and relocate for months at a time for our son to receive treatment it's not something that's easily done. So one of the things that we noticed when you pick yourself up and you move out of state is that it has a multiplier effect on your family.

15 While we were at the proton beam center 16 in Boston, we saw people who came from all around 17 the world, people from Europe, people from 18 California, people from Texas because the 19 treatment is so effective and so powerful. But we 20 also saw the impact that this had on families, 21 spouses that had to separate themselves because 22 they couldn't afford or were not in a position for 23 both spouses to travel with their children, 24 families that were divided up where maybe one or 25 two siblings would travel with the parent and the

other sibling would be left behind. We were fortunate where we were able to leave our older two children with grandparents, but to this day our older two children still feel some sense of abandonment from having been left behind because we had to choose to leave the state to provide treatment for our son out of state.

1

2

3

4

5

6

7

8

9

10

11

12

13

15

16

17

18

19

20

21

22

24

25

When you do have to pick up and travel elsewhere and you're being cared for, you have to reintroduce the patient to all new caretakers, new doctors, new nurses, people that have no familiarity with the patient. This has happened to us twice where we've had to travel and live up 14 in Boston for proton beam therapy. I cannot imagine the difference in the experience had we been able to stay in our own home in Glastonbury and travel every day to Wallingford for treatment. I cannot imagine how wonderful that would have been for our family to stay intact during those I cannot imagine how wonderful it would times. have been for our older two children to have their parents still home with them every night to put 23 them to bed. And I can't imagine even more recently how we had to pull our son out of school for three months and live in Boston where he could actually go to school after receiving treatment in the morning and continue on with a sense of normalcy for him. So we know and believe how powerful and how effective this proton beam therapy is. I'm very proud to live in this state. I feel this is a state that has tremendous resources, tremendous schools, tremendous universities. It's surprising to me that we don't yet have a facility like this here to treat the citizens of Connecticut.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

So I pray every day that our son will not have to go through treatment again, but I can't imagine what a difference maker it would be for him to be able to receive that treatment here in Connecticut and go to sleep at night in his own bed.

¹⁷ So I thank you so much for the ¹⁸ opportunity to speak this afternoon from a ¹⁹ parent's perspective and from a family's ²⁰ perspective, and I certainly hope that in the ²¹ not-too-distant future we can have a wonderful ²² facility like this here in the State of ²³ Connecticut. Thank you.

HEARING OFFICER MITCHELL: Thank you,
 Mr. Somberg. How is your son now?

1 MR. SOMBERG: So this is our three guys 2 here (showing photograph). So he's in first 3 grade. Right before the call today, we had his 4 teacher conference on Zoom. And I'm a little 5 bias, but his teacher said he's the most 6 pleasurable kid they have in the entire class. So 7 thank you for asking. 8 HEARING OFFICER MITCHELL: Thank you. 9 DR. GILLAN: I agree with that. 10 HEARING OFFICER MITCHELL: All right. 11 Thank you, Dr. Gillan, and also Mr. Somberg. 12 DR. GILLAN: You're welcome. 13 HEARING OFFICER MITCHELL: We're going 14 to go to Mr. Les Yonemoto. 15 Mr. Yonemoto, are you okay? Do you 16 need any assistance? 17 DR. YONEMOTO: Hello. Can you hear me? 18 HEARING OFFICER MITCHELL: Got you. 19 We're ready. We can hear you well now. 20 DR. YONEMOTO: Yes. For some reason I kept the video going, so embarrassing for an 21 22 electrical engineer that I used to be to have this 23 problem. But anyway, I'd like to thank you for 24 this opportunity to speak. I would like to 25 introduce myself and my experience with proton

therapy and my support for this project. I'm Leslie, the other Leslie, Yonemoto, L-E-S-L-I-E. Yonemoto, Y-O-N-E-M-O-T-O.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

I'm a radiation oncologist that started with proton therapy way back in 1992 at Loma Linda University when it was the first hospital based proton center, had the first gantry, had the first capability of high capacity and with four treatment rooms. And in addition to the medical research, patient care and teaching that I did, I assisted in increasing the volume of the facility from 30 patients a day to over 150 patients a day as the director of operations. Since Loma Linda was the only facility of this type in the nineties and early 2000, I participated and developed multiple medical facilities with proton therapy, including University of Florida, MD Anderson Cancer Center, and University of Pennsylvania. Ι had helped various proton centers, and I worked at Loma Linda University Proton Therapy Center, Hampton Proton Therapy Institute, ProCure, Oklahoma Proton Therapy Center, and San Diego Proton Therapy Center.

I want to express my support for the
 Connecticut Proton Therapy Center as the others

have discussed. I especially want to give my support and second the testimonies given by Dr. Roberts, Salner, Mendenhall and Gillan. This is a wonderful technology. And I'd also like to give my support for my old friend, Mr. Chandler, and support for his company Proton International.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

I have treated over 2,500 patients with proton therapy and personally seen the benefits of improving cancer control and lessening the side effects with my patients, and there is an improved quality of life for not just the patients but the family that takes care of them as we just heard. It's more cost effective to cure the cancer than provide palliative care. So the citizens of Connecticut will be well served with the proton center, especially since it's locally accessible and would be run by Dr. Roberts and Salner and Mr. Chandler. Thank you for your consideration of this valuable project.

HEARING OFFICER MITCHELL: Thank you,
 Mr. Yonemoto.

I'm going to again open the floor. Is
 there anybody who has just joined us? I see that
 it looks to be 20 more people that have logged on.
 Is there anybody else that wants to give public

comment?

1

2

5

6

7

8

9

10

11

12

13

14

15

16

17

18

(No response.)

³ HEARING OFFICER MITCHELL: Did I miss
⁴ anybody?

(No response.)

HEARING OFFICER MITCHELL: It's very quiet. Okay. So this is what's going to happen at this point. I am actually going to stay on until 6 o'clock -- I think that's what our hearing notice said -- in case there is anybody that wants to give public comment. Others are able to stay on if they'd like to observe. We're going to keep everything recording. We're going to ask the court reporter to stay until 6, and until then the hearing is going to be adjourned.

I just want to ask again is there anybody else that wants to make a public comment regarding this application?

19

(No response.)

HEARING OFFICER MITCHELL: All right.
So for the time being, I'm just going to go ahead
and mute myself. I'm going to stay here. You're
welcome to stay or leave, if you'd like. We are
adjourned until somebody else comes back, and we
will stay until 6 o'clock. Thanks, everybody.

(Whereupon, the hearing adjourned from 4:22 p.m. until 5:45 p.m.)

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

HEARING OFFICER MITCHELL: Hi, This is Micheala Mitchell again. I'm everyone. the hearing officer for Hearing No. 19-32339-CON. I just wanted to extend the opportunity for anybody who may have jumped on to make a public comment before we go off the record. These are the last 15 minutes for the hearing. If there's anybody on who wants to send in a written comment or knows somebody who may have wanted to make a public comment during the hearing and they couldn't do it, they can still submit a written comment that would preferably come to us by email at CON comment, that's C-O-M-M-E-N-T, at ct.gov. An alternative is that comments can be mailed to us at our mailing address at P.O. Box 340308, 450 Capitol Avenue, Hartford, Connecticut, zip code is 06134 - 0308.

When I come back on at the final time of 6 o'clock, I'm not going to offer anybody else an opportunity to speak. But I just wanted to thank everybody who has hung on for this last hour and a half to see if anybody was going to show up with me. And I want to thank you all for your time, especially, Lisa, our court reporter, and Leslie Greer, who has been with us for most of the day. And we will be in touch with the applicants sometime tomorrow to finalize the information that is required by OHS with regard to the financials and the numbers for pediatric volume. If there's anything else, unmute yourself and let me know. otherwise, at 6 o'clock we're going to go ahead and adjourn the hearing. Thank you.

1

2

3

4

5

6

7

8

9

10

11

23

24

25

(Whereupon, the hearing adjourned from 5:47 p.m. until 6:00 p.m.)

12 HEARING OFFICER MITCHELL: All right, 13 everyone. This is Micheala again, Micheala 14 Mitchell, obviously, the hearing officer. It's 6 15 o'clock. We're going to go ahead and adjourn the 16 hearing. Please keep an eye out on the docket for 17 updates with regard to the Late-Files and the 18 closure of the hearing record. And thank you 19 again for your participation. I hope everybody 20 has a good night and that you stay safe.

(Whereupon, the above proceedings
 concluded at 6:00 p.m.)

CERTIFICATE FOR REMOTE HEARING

1

2

3

4

5

б

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

I hereby certify that the foregoing 166 pages are a complete and accurate computer-aided transcription of my original stenotype notes taken of the Hearing held by Remote Access in Re: DOCKET NO. 19-32339-CON, CONNECTICUT PROTON THERAPY CENTER, LLC, HARTFORD HEALTHCARE CORPORATION AND YALE NEW HAVEN HEALTH SERVICES CORPORATION SEEKING APPROVAL FOR THE ESTABLISHMENT OF PROTON THERAPY SERVICES BY ACOUISITION OF NEW TECHNOLOGY AND ACQUISITION OF A COMPUTED TOMOGRAPHY ("CT") SIMULATOR, which was held remotely for the State of Connecticut, Office of Health Strategy, before MICHEALA MITCHELL, Hearing Officer, on Wednesday, November 18, 2020. Wallel Lisa L. Warner, CSR 061 Court Reporter BCT REPORTING LLC 55 WHITING STREET, SUITE 1A PLAINVILLE, CONNECTICUT 06062

1	I N D E X
2	
3	WITNESSES: (SWORN ON PAGE 10)
4	ARTHUR LEMAY DONNA HANDLEY
5	KRISTI GAFFORD
6	KENNETH ROBERTS
7	CHRIS CHANDLER
8	GERRY BOISVERT THOMAS NEWMAN
9	MARIO DONINI FRED SORBO
10	SUSAN MANNING EXAMINERS: PAGE
11	Ms. Donston 63 Hearing Officer Mitchell 71,78
12	Mr. Carney 75,118
13 14	LATE-FILED EXHIBITS LATE-FILE DESCRIPTION DISCUSSED ON PAGE 1 Pediatric referrals 65 2 Updated financials 140
15	
16	PUBLIC COMMENTS
17	MAYOR WILLIAM W. DICKINSON, JR. 151 TIM RYAN 152
18	DR. EILEEN GILLAN 152 MATTHEW SOMBERG 157
19	DR. LESLIE YONEMOTO 161
20	
21	
22	
23	
24	
25	