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STATE OF CONNECTICUT

OFFICE OF HEALTH STRATEGY

Docket No.: 20-32376-CON

Proposal: Acquisition of a Computed

Tomography ("CT") Simulator and

Technology New to the State (Statute Reference 19a-639)

Applicant: Danbury Proton, LLC (Danbury, CT)

Public/Administrative Hearing held via Teleconference, on April 1, 2021, beginning at 10 a.m.

Held Before:

MICHEALA MITCHELL, ESQ., THE HEARING OFFICER

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(Begin: 10 a.m.)

THE HEARING OFFICER: Good morning, everyone. This hearing before the Health Systems Planning Unit of the Office of Health Strategy is identified by Docket Number 20-32376-CON and is being held on April 1st of 2021 to establish proton therapy services in Danbury, Connecticut, by acquisition of new technology and a CT simulator.

On March 14 of 2020 Governor Ned Lamont issued Executive Order 7B which in the relevant part suspended open meeting requirements to ensure the continuity of operations while maintaining the necessary social distance to avoid the spread of COVID-19. The Office of Health Strategy is holding this hearing remotely.

We ask that all members of the public to mute the device that they are using to access the hearing and silence any additional devices that are around them.

This hearing is being held pursuant to

Connecticut General Statutes Section 19a-639a in

accordance with the provisions of Chapter 54 of
the Connecticut General Statutes.

My name is Michaela Mitchell. Victoria

Veltri, the Executive Director of the Office of
Health Strategy has designated me to serve as the
Hearing Officer in this matter.

Also in attendance are my colleagues, Brian Carney and Roy Wang, who are here to assist me in gathering facts related to this application. We also have with us Ms. Leslie Greer who is our consumer information representative.

The certificate of need process is a regulatory process, and as such the highest level of respect will be accorded to the party in this matter, also to the members of the public and to our staff. Our priority is the integrity and transparency of this process, and we ask that decorum be maintained by all present during the 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 portable which is accessible on the Office of Health Strategy's CON webpage.

In making its decision HSP, which is the Health Systems Planning unit, will consider and

1 make written findings concerning the principles and guidelines set forth in Section 19-639 of the 2 3 Connecticut General Statutes. 4 Danbury Proton, LLC, is a party to this 5 hearing. There are no interveners. 6 At this time I'm going to ask Mr. Carney to 7 read into the record those documents already 8 appearing in HSP's table of record in this case. All documents have been identified in the table of 9 10 record for reference purposes. 11 MR. CARNEY: Good morning. My name is Brian Carney of 12 the Office of Health Strategy, Health Systems 13 Planning Unit. 14 THE REPORTER: This is the Court Reporter. I'm having 15 a lot of feedback. 16 THE HEARING OFFICER: All right. So I'm just going to 17 ask so that if anybody is having feedback, we make 18 sure that you use the chat function. 19 Is anybody else experiencing feedback? 20 going to actually ask counsel for the applicant, 21 are you having any feedback? 22 MR. HARDY: Good morning, Attorney Mitchell. Yes, we 23 are hearing feedback there. I think we're still

hearing feedback.

THE HEARING OFFICER: So I'm just going to ask everyone

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who is not speaking to mute themselves. I'm actually going to mute myself when others are speaking, too. It may be an issue with the microphones.

Okay. Brian, if you wouldn't mind just repeating what you said?

MR. CARNEY: Sure. I'd like to enter into this record at this time the table of records Exhibits A through R.

THE HEARING OFFICER: I just want to double check with Attorney Hardy. Any issue hearing Mr. Carney at that time? Was there still feedback?

MR. HARDY: No feedback that time. Thank you.

THE HEARING OFFICER: Okay. So I'm just going to go ahead and intermittently mute myself. I think I want everyone to mute themselves if they're not speaking during the hearing, and that will probably minimize the feedback.

If anybody else is experiencing feedback just make sure that you use the chat function. We do monitor that through the hearing. It minimizes interruptions if people are testifying or talking, and we'll make sure that we address any issues in that fashion.

So -- I muted myself.

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Let me just ask. Attorney Hardy, just for the record did you have any objections to the exhibits in the table of record?

MR. HARDY: No objection to the exhibits.

THE HEARING OFFICER: Okay. So we will proceed in the order established in the agenda for today's hearing.

We'll stop for a 45 minutes at one o'clock for lunch. I'm going to reserve the right to allow public officials and members of the public to testify outside of the order of the agenda as necessary. I'd like to also advise the Applicant that we may ask questions related to your application that you may feel that you've already addressed, and we do this for the purpose of ensuring that the public has knowledge about the proposal and also for the purpose of clarification.

I want to reassure you that we read your application complete with its responses and prefiled testimony.

As this hearing is being held virtually, I'm going to reiterate that all participants to the extent possible should enable the use of video cameras when testifying or commenting during the

proceedings. Anyone who is not commenting or testifying should mute their electronic devices including telephones, televisions and other devices not being used to access the hearing.

Again, we're going to monitor everyone during the hearing. To the extent possible I ask
Attorney Hardy to use the raised-hand function to make an objection or a comment, and I'll address you -- but if we don't immediately recognize you, you may unmute your device and address me directly.

And again, I also advise people that we're not going to stop the recording for this hearing. So participants in the hearing should mute their devices and disable their cameras when we go off the record or take a break, otherwise whatever you say is going to be recorded. So you just want to make sure that you're being very careful. If there's something you don't want to be on the recording, make sure you mute your device.

I'll also continue to give a warning to the Applicant and to the public to let them know one minute prior to us going back on the record after we've taken a break so everybody can be all settled in.

Public comment taking during the hearing shall go in the order established by OHS during the registration process which commences at three o'clock. I'll call each individual by name when it's his or her turn to speak, and each member of the public will be limited to three minutes of speaking time.

At this time I would like all the individuals who are going to testify on behalf of the Applicant to be identified by Attorney Hardy, after which I will swear them in.

MR. HARDY: Thank you. So the witnesses who will testifying this morning are Mr. Stephen Courtney, Dr. Michael Moyers, Dr. Lionel Boucher, Mr. Drew Crandall, Dr. Andrew Chang, Ms. Deborah Hickey, Mr. Donald Melson, Mr. Steve Coma, Dr. Leslie Yonemoto and Mr. Robert Marckini.

THE HEARING OFFICER: Perfect. So that's everybody that you identified in your prefiled testimony.

Right?

MR. HARDY: That is correct.

THE HEARING OFFICER: Okay. So I'm going to ask
everyone that Attorney Hardy mentioned to raise
their right hand so that I can swear them in.

1 STEPHEN COURTNEY, 2 MICHAEL MOYERS, 3 LIONEL BOUCHER, 4 DREW CRANDALL, 5 ANDREW CHANG, 6 DEBORAH HICKEY, 7 DONALD MELSON, 8 STEVE COMA, 9 LESLIE YONEMOTO, 10 ROBERT MARCKINI, 11 called as witnesses, being first duly sworn by the 12 Hearing Officer, were examined and testified under 13 oath as follows: 14 15 THE HEARING OFFICER: All right. So at this time we're 16 going to go ahead and turn it over to Attorney 17 Hardy for the presentation of the applicant's 18 testimony. 19 MR. HARDY: Thank you, Attorney Mitchell, and 20 Mr. Carney and Mr. Wang. 21 Are you able to provide me with screen 22 sharing license? 23 MR. CARNEY: Yes. One second. Let me get to that 24 here. 25 THE REPORTER: And this is the Court Reporter. As a

1 gentle reminder, if people could just identify 2 themselves when speaking it would be greatly 3 appreciated. 4 THE HEARING OFFICER: Perfect. Also when you make your 5 statement just make sure that you adopt your 6 prefiled testimony as well. 7 MR. CARNEY: Okay. Attorney Hardy, you should be a 8 cohost now and be able to share your screen. 9 MR. HARDY: Okay. Is my screen now showing? Okay. 10 Very good. Our first witness is Mr. Stephen 11 Courtney. 12 THE WITNESS (Courtney): Thank you, Attorney Hardy. 13 Good morning, Attorney Mitchell and OHS 14 staff. My name is Steve Courtney and accept my 15 prefiled testimony. 16 It's a pleasure to be here, and we look 17 forward to answering any questions OHS may have. 18 If ever there was a team that could answer even 19 the most arcane questions on proton therapy, this 20 is it. 21 I will introduce you to our speakers very, 22 very briefly, as you have their CVs. In the order 23 of presentation, myself an architect, Danbury 24 Proton Managing Director; Dr. Michael Moyers,

medical physicist, Professor and Chairman,

Department of Medical Physics, Shanghai Proton and Heavy Ion Center; Dr. Lionel Boucher, Vice
President, physicist with Mevion Medical Systems;
Mr. Drew Crandall, our Danbury Proton Community
Engagement Director; Dr. Andrew Chang,
pediatrician and radiation oncologist with Proton
Doctors Professional Corporation; Ms. Deborah
Hickey, Brotherhood of the Balloon, Director of
Operations; Mr. Donald Melson, our Danbury Proton
finance director; Mr. Steve Coma, Hilltop
Securities Managing Director; Dr. Leslie Yonemoto,
radiation oncologist with Proton Doctors
Professional Corporation; and finally, Robert
Marckini, Brotherhood of the Balloon, Founder.

We will endeavor to keep our testimony in the five-minute range that you have outlined for us, but there will be a couple of them including my own that will be a little bit longer.

Throughout our brief comments we will -there will be three common themes; one, the
efficacy of proton therapy in terms of cure and
quality of life; two, the treatment costs, long
view; and number three, the Connecticut need for
at least two treatment rooms.

Next, I'll start with this graph which shows

the accelerating growth of proton therapy in the last 30 years. I became director of operations of the one design firm with proton therapy capability in 2005, 15 years into this development.

Really just as proton therapy began to gain steam I was a relative late comber -- late, late comer to the typology compared to Doctors Moyers, Yonemoto and Chang who were involved with Loma Linda in the 'nineties, the foundational years.

This is cutaway model of the center they built and managed at Loma Linda.

The next proton center -- next -- came online at Mass General Hospital in 2001, 11 years after the Loma Linda project had begun treating patients.

Next.

In 2006 two new centers came online, the first of my involvement. These used a round rotunda that was first used at MGH as kind of a design marker. All these facilities were three to four treatment rooms centers, this center at MD Anderson.

Next.

And this facility at the University of Florida, Jacksonville. Dr. Nancy Mendenhall

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was -- was and is the medical director here.

Next.

Next was designing the UPenn center in Philadelphia with four treatment rooms and a research bay, one of the largest facilities in the world.

While we were building the UPenn facility we also did a prototype design for standalone proton therapy operator ProCure. Chris Chandler, CEO of Proton International was part of that organization. We built four centers and designed one for the Detroit market in that area before the 2008 recession stopped more development.

Next.

After the recession we did, in fact, build a facility on that site using a new IBA compact system.

Next.

Before that last project in Detroit I founded our design firm SCI.X. This project in Flint, Michigan, was our first commission.

Next.

The last project I was in -- involved with the previous firm on this that was with a newly FDA approved Mevion compact proton therapy system in St. Louis.

Next.

In our new firm SCI.X, we began to work more and more with the truly smaller Mevion system.

This is a study of the three main systems in the market at the time, and it's very clear how much more compact the Mevion system is.

With Mevion we did a series of projects around the globe. Here is a two-room study that we did in Singapore.

Next in Malaysia. This facility anticipated a second room from the start. This is typical for Mevion systems. The first -- the first facility that was done that I pointed to earlier in St. Louis has recently completed their second room.

Here, next.

Here in Orlando, Florida, we conceptualized a second room. The second room had not been anticipated, but with the use of high-density shielding we were able to shoehorn it into the site.

Next.

This facility design was for a two-room center from the beginning.

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Next.

Proton International is the developer for this potential project in Germany. Again, a Mevion project.

This Thailand site was extremely tight and could only be accomplished with the compact Mevion system.

Next.

I apologize for this rather dense graphic, especially at this scale, but in general the yellow blocks to hospitals are those outside the Hartford Yale health systems. That represents a patient bed population of about 3,739 in Connecticut; and an additional 3,677 is in New York in the three New York counties in our primary service area that also contain the three hospitals from the Connecticut health system Nuvance in -- in New York, in those New York counties.

That totals a bed capacity of 7,416, which correlates obviously to the population in those areas. And -- and that obviously is significantly higher than the Hartford Yale bed count of 5,177, which you see on the map.

There are approximately in Connecticut 2,500 patients per year that are primary candidates for

proton therapy. These, the two rooms that we're now considering can together only treat around 800 per year and that's at 16-hour day operations in both facilities, far under the patient need for just Connecticut alone, not recognizing New York or New Hampshire, or Vermont or beyond.

Next.

This is a rendering of the Danbury project facility. This project is, as they say, shovel ready to go. From this angle it appears it's almost an non-building with its general footprint into the existing hillside.

Here it's a little more prominent from the southwest.

Next.

And next.

And here a view of the porte cochere, the entrance.

Next. And here the entrance with radiant paving which will be used to melt snow and minimize -- (inaudible).

THE HEARING OFFICER: So I think for some reason I think we lost the sound. Mr. Courtney, if you could just unmute yourself? For some reason we lost the sound.

1 THE WITNESS (Courtney): All set? 2 Next. 3 This is a cross-section of the treatment A second vault can be added to the left. room. 5 Essentially we excavate all that dirt and add in a second room. 7 Next. 8 This is a treatment room entrance with its 9 patient's customizable window view. 10 Next. 11 In the treatment room itself we use warm 12 materials and a faux external window to take a bit 13 of the bunker feel away from -- from the facility. 14 Next. 15 Okay. This is an important view, as 16 50 percent of our patients will be treated in a 17 second eight-hour shift. This makes for an 18 efficient use of capital, and accommodates the day 19 worker who can drop by for their 15 minutes of 20 treatment before going home. 21 Next. 22 I'm seeing something else here. 23 My screen just got messed up. Can you hear 24 me?

Yes, I can hear you.

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THE HEARING OFFICER:

THE WITNESS (Courtney): And you can see the next slide, healthcare sustainability?

THE HEARING OFFICER: That's healthcare sustainability, yes.

THE WITNESS (Courtney): Okay. Very good. Quality -quality patient care involves a complicated system
of elements. Sustainable operation starts with
the physical plant that considers the long view
such as tapping geothermal energy on the site to
heat and cool the building, even though the
payback is seven to ten years at best.

No fossil fuel use except for emergency generation which helps the local air quality.

We close -- we -- we really work at close sourcing the proton therapy equipment and the building materials which minimizes the trucking and all the associated pollution that comes from that.

We do community responsible design by reducing the parking and the heat -- heat island effect that parking cause. We negotiated with the City a reduction in parking.

We build only what is needed. No grand or excess square footage in the facility, reducing our carbon footprint overall. We used a green

roof for plant and animal diversity, including pollinators, and again not mowing or -- or using power equipment to maintain that except for only two times a year.

We exceed the fresh air requirements for the occupants, way above what code requires, all the more understandable with the pandemic. We use low volatile organic compound materials, which is key for staff that live in this, this building for years. And not to forget our workers, it's an inclusive and safe worksite because their health is a concern of ours as well.

Looking forward to your questions and our next speaker is Dr. Moyers.

THE WITNESS (Moyers): (Inaudible.)

Oh, can you hear what I said?

MR. HARDY: Now we can, Dr. Moyers. Thank you.

THE WITNESS (Moyers): Oh, okay. I'll start over.

Good morning, Attorney Mitchell and OHS staff. My name is Michael Moyers, and I adopt my prefiled testimony.

Thank you for this opportunity to testify in support of the application of the Danbury Proton to establish a proton therapy center in Danbury.

I'm a PhD Medical physicist that started working

in radiation therapy over 40 years ago in 1979. Since 1990 I have concentrated on various aspects of proton beam therapy while continuing to work with X-ray electron beams and implanted radioisotopes known as brachytherapy.

I've spent 15 years at Loma Linda University where I honed my skills in proton therapy, and then began teaching and helping other proton centers around the world get started. A copy of my curriculum vitae contains my experience in this field, and it's attached.

Since 2013 I've been a professor and Chairman of the Department of Medical Physics of the Shanghai Proton Mevion center, which consists of 22 physicists, 24 therapists, 5 information-technology engineers, 2 nurses, and 1 administrator.

I'm on the board concerning patients in Connecticut as a medical physicist for Danbury Proton upon its approval.

Today I'd like to mainly address two topics.

The -- the first topic is to provide some history of proton therapy. Proton therapy is often labeled as an emerging technology. For a technology to be classified as emerging it's

typically characterized by novelty, rapid growth, significant impact, and sometimes uncertainty and ambiguity. The label of emerging technology does not necessarily mean that it is new or improving.

In the case of proton therapy, the potential benefits of proton beams for radiation treatments were known by 1946. After various physics and animal experiments were performed, the first patient treatments with proton beams began in 1954 in Berkeley, California.

The next facilities to begin treating patients with proton beams were in Uppsala, Sweden, in 1957; and in Boston, Massachusetts in 1961. Many other facilities around the world then began their own research treatment programs, but the number of patients treated per day at each facility ranged from zero to a maximum of 12.

In 1990 the first hospital-based proton facility begin treating patients in Loma Linda California when I served as a physicist and assistant professor at the university medical center.

The equipment in this facility was approved by the FDA and treatments were reimbursed by Medicare. Within two years this clinical facility

was treating 50 patients per day. By 2003 the average number of patients being treated by this one facility in four treatment rooms was 150, with the maximum number of patients treated in one day being 173.

By the year 2000 proton therapy had transitioned from a research environment to routine clinical practice. Personally I became aware of the power of proton and other ion beams for treatment during 1979 while I was writing a term paper on heavy particle therapy for one of my classes for my master's degree.

After the paper was completed I was wondering why all patients receiving radiation treatments were not treated with ion beams, and then sought out a job where I could perform these types of treatments. I later discovered that the main reason protons are not used for more patient treatments was not lack of efficacy, but rather a lack of computing power.

Between 1979 when I learned of proton beam therapy and 1990 when I started working at the first clinical proton therapy facility three major events happened. All of these events involve computers. The first event was the availability

of fast computers with a large amount of memory to reconstruct the anatomy inside a patient using computed tomography, also known as CT. This is an essential task for taking advantage of the benefits afforded by proton beams, because without it the targets cannot be defined and critical vulnerable tissues cannot be avoided.

The second event was the development and implementation of three-dimensional treatment planning programs and interactive display monitors where different possible treatment scenarios could be simulated and compared.

The third event was control of the accelerators and beam transport lines by computers. Previously the beam parameters inside the accelerator and beam transport lines had to be adjusted manually before and during each patient treatment. This arduous task, referred to as tuning, meant that more time was spent preparing the beams than were used for treatment.

In addition, treatment sometimes had to be paused while changes were made, but with the advent of high-speed computers and local networks this preparation could be programmed to perform much faster than humans could react, thereby

increasing the efficiency of facilities.

Next slide.

The second topic I'd like to address today is startup consideration. Be certain starting any new radiation facility is a significant undertaking, especially for one that utilizes a beam of protons. On the other hand, steady developments in technology together with standards in educational resources created for the dramatic upward trend in demand for proton therapy make the establishment of today's proton therapy centers more readily achievable than ever before.

In particular, there are a number of guidelines and standards that have been produced to help launch new facilities, standards for manufacturers concerning equipment safety requirements have been produced by the international record technical commission.

Guidelines for mastering dose have been produced by the International Commission on Radiation Units and Measurements.

Recommendations for commissioning facilities accounting for uncertainties in treatment planning and delivery and performing quality assurance have been produced by the American Association of

Physicist Medicine.

Standards for transferring information
between various computers and equipment have been
produced by the Digital Information Communications
and Medicine Working Group.

And recommendations for staff training and facility credentialing have been produced jointly by the American College of Radiology and American Association of Physicists in Medicine.

In addition, the book entitled, Practical
Implementation of Light Ion Teletherapy, which I
also co-authored, details many procedures needed
to plan, start and operate a proton facility.
These standards, guidelines and recommendations
are all readily available to ensure safe and
accurate treatments for patients in Connecticut.

Next slide.

Although proton therapy will be new to the state of Cali -- state of Connecticut, it's relatively late introduction will allow the State to realize the benefits of previous advancements in proton equipment technology as well as treatment planning types.

In the future research and development in areas such as ultrahigh dose rate rotational

delivery may further optimize patient treatments.

This research and development applies, not only to
beam delivery and the symmetry equipment, but also
the clinical trials of patients.

We also anticipate further development of treatment planning capability that could be optimized using Danbury Proton as a test bed.

With Connecticut's high demand for cancer radiation treatment within its patient population, its first-rate medical practitioners and institutions, the State may serve a very valuable role in helping develop these advanced treatment techniques.

Next slide.

I'll thank you again for considering the use of this technology for the patients in Connecticut and the surrounding areas. If you have any technical questions, please do not hesitate to ask me at any time. Thanks.

MR. HARDY: Thank you, Dr. Moyers.

Our next witness is Dr. Lionel Boucher.

THE WITNESS (Boucher): Good morning, Attorney Mitchell and OHA. I adopt my prefiled testimony.

My name is Lionel Boucher. I'm the Vice
President of Technical and Clinical Fellowship at

Mevion Medical Systems. I'm also a PhD physicist and I've been involved in Mevion compact proton therapy systems for the past 15 years.

Mevion is -- was established in 2004.

Next slide.

And is located in New England just outside
Boston. This, the company was founded from a
group from MGH and the Harvard proton centers that
believe that proton therapy should be much more
closer to conventional photon therapy.

We are the inventors of compact proton therapy. We cleared our system through the FDA in 2012 and we were clinical in 2013.

Next slide.

Our vision continues to be to provide superior proton therapy to as many cancer patients as possible, and that's an important vision that drives all of the work that we do in our company.

Next.

Mevion's background is very simply, we are a single focus, single passion, proton therapy. A lot of our employers in New England -- a lot of our employees in New England -- actually staff had interaction with proton therapy. They had to have

patients in the family receive proton therapy, so this passion for us is very important.

Next slide.

The market has been completely transferred through this invention of compact proton therapy where proton therapy used to be a large football field sized facility with high capital and operational costs and generally poor and difficult financial performance.

Compact proton therapy today is much more similar to conventional radiation therapy. With project deployment and operational costs that are similar to conventional radiation therapy, and that are a successful financial performance.

Next slide.

The market, as you saw from earlier testimony, the market of proton therapy in the USA is growing rapidly. The access is growing rapidly with about 41 in all proton centers clinical today, and 21 centers under active development.

Next slide.

What is very interesting, in 2020 we have seen more single-room proton centers either under development or clinical, than the large proton centers. So this compact proton therapy has truly

transformed the proton therapy market.

Next slide.

And what is remarkable about these compact proton therapy centers is they are all clinical and financial success. Proton therapy is always a clinical success, but with this compact access it's also a financial success.

Next slide.

Proton therapy is becoming the expected tool of leading centers for radiation therapy through guideline -- the National Comprehensive Cancer Network is continuing to increase the use of proton therapy and the ASTRO also, which is radiation oncology associations, and also the proton guideline that increases all this access.

Next slide.

What makes this compact Mevion proton therapy different is this right size and right technology. This is the lower capital and productional cost than the large proton centers. This is a smaller footprint which provides opportunity to integrate with an existing radiation oncology.

This also provides a higher footprint. As Mr. Courtney mentioned, this ability to operate 14, 15, 16 hours as the demand increase, the

higher beam activity -- beam ability, and this next generation intensity moderated proton therapy which also increase the amplification that proton therapy can be used for.

Next slide.

The compact proton therapy comes from a miniaturization of technology and we are followed; we are all experiencing today this miniaturization of technology just through the cellphone that we all have with us. Similarly -- next slide.

Proton accelerators have also been miniaturized. The miniaturization is with (unintelligible). We started with 250-ton accelerators at the office proton centers in Boston. And today we have proton accelerators with similar capabilities of about 15 ton.

Next slide.

We have smaller accelerators. We are able to integrate it into one single room. This is the enabling of compact proton therapy. This ability to miniaturize and take the proton accelerator technology and integrate everything into one single room.

Next slide.

Which our environment -- which our

environment is very similar to conventional radiation therapy. So although you have this complex technology carved in the wall, the clinical space is very similar to conventional radiation therapy.

Next slide.

The same time this intensity modulated proton therapy, which is not the standard of care in proton therapy, is increasing the -- the use of proton therapy for other applications, for multiple applications. This is a technique that corresponds to printing the dose that's necessary to treat the tumors that is now widely used through all the proton centers.

Next slide.

Similarly this image guidance which is the standard of care in radiation therapy is also the standard of care in proton therapy such that the tumors and the radiation can be very precisely located, and the precise proton treatment can be delivered.

Next slide.

So compact proton therapy, and more specifically, Mevion proton therapy is used by leading institutions. And this is just a few

examples of the Mevion proton centers in the U.S. that are -- and some of them international, that are both clinical and also under development.

Remarkably a lot of the NCI comprehensive cancer centers are adding proton therapy to -- in their (unintelligible), not only NCI comprehensive cancer centers, but also smaller community hospital. An example, in Mercy Hospital in St. Louis next to Barnes-Jewish Hospital, which is an NCI comprehensive cancer center. They want to provide proton therapy to their patents, provide this access, and as such they are now offering proton therapy services.

I want to thank you for the time here in testifying for -- in support of the Danbury Proton Centers and would welcome any questions.

Thank you.

MR. HARDY: Thank you.

Our next witness is Mr. Drew Crandall.

THE WITNESS (Crandall): Good morning, Attorney

Mitchell and OHS staff. My name is Drew Crandall

and I adopt my prefiled testimony.

I am the community engagement director at

Danbury Proton. I have deep family and community

and professional roots in Connecticut. My family

has been in Connecticut since the 1600s. Prudence Crandall, on the left of your screen, is the official state heroine for her courageous stand against racism and slavery in the 1830s. I'm not a direct descendent, but I'm part of the same family. I participated in the grand opening of the Prudence Crandall museum in Canterbury in 1984, and have been the family spokesperson at many Prudence-related events ever since.

My father Robert grew up in West Haven and enlisted in the U.S. Navy Submarine Service immediately after Pearl Harbor. During World War II he served on the USS Baya, a diesel submarine made by Electric Boat, in Groton.

On the bottom center of your screen there;

I've always had an acute interest in health care
because I'm one of Bridgeport Hospital's miracle
primi babies. I had about a 1 percent likelihood
at birth of living and being healthy.

During my high school years I lived in the Weatogue section of Simsbury. While at UConn in Storrs I played drums in the basketball pep band -- and all I can say about the women's team is, go Huskies.

I served in the First Company Governor's Foot

Guard part of the Connecticut State Militia for six years. Professionally I have decades of experience helping Connecticut healthcare systems, hospitals, urgent care centers, practitioners and healthcare related nonprofits with their media relations and community affairs.

Several years ago my firm received a national award from the American Cancer Society for a grassroots community based campaign that we developed.

Next slide, please.

I serve on the core leadership team of
Danbury Proton. Over the past 40 years I've
served on many boards including the Better
Business Bureau of Connecticut, where I served as
chair for two years.

In my experience the Danbury Proton team is exceptional. Each of us has our areas of expertise and experience, and we work together extremely well. Since the beginning our team has had a passion to make a positive difference for both health care and economic perspectives. Local and state businesses are being engaged, and that will continue and increase should OHS choose to approve our CON application.

Next slide.

That shows our -- our Connecticut focus, which has been delivered from the beginning.

Next slide.

Over the past year the response has been positive. As a matter of fact, the enthusiasm for this project is very high.

Next slide.

I studied 25 letters of support that we received from men across the Northeast who had prostate cancer and chose proton therapy. These men traveled an average of 1,343 miles each way to have proton therapy. To me this speaks volumes about access.

Can you imagine having to travel an average of 1,343 miles each way to have cancer surgery or chemotherapy? Or for that matter, traditional X-ray radiation?

Next slide, please.

Here are some of the comments about the quality of the therapy and the prospect of having a proton therapy center in Danbury from these 25 men.

Proton therapy was the best medical decision of my life. I am pleased that you are planning a

proton therapy center in Danbury.

I have nothing but complete confidence in the efficacy of proton radiation. I am happy to help in any way to see Danbury Proton become a reality.

I'm a living example of the fact that proton therapy works and preserves the quality of your life. It is the least invasive of all treatments.

While waiting for proton therapy each day I encountered many parents and their young children who had brain cancer. They were getting the proton therapy because of proton's precise non-damaging beam for spots as delicate as the brain.

Please rush the opening of Danbury Proton to give people who live close by the opportunity to save their lives with less side effects than other treatments, as there were no proton facilities in Connecticut at the time I had to travel 3,000 miles from home.

Connecticut needs such as center. I would much preferred to have stayed local with my family for this treatment, and there are thousands of men in the tri-state area who would not be so fortunate as me. Good luck with Danbury Proton.

I understand that a proton therapy treatment

center is being planned for Danbury. This would be great for the people of the surrounding area. I went through proton treatment in Boston. Having a center in Danbury would have meant an hour commute with very little cost, and I would not have had to give up my support folks. I hope that Danbury moves forward with proton radiation.

I am originally from the Litchfield area and look forward to visiting the new proton treatment center in Danbury. If you choose proton beam therapy you can relax knowing that you have made the correct choice.

I hope the residents of Connecticut and nearby states have the opportunity that I had to choose proton therapy to treat their cancer conditions. The number one hurdle preventing proton therapy for most patients is the distance a patient must travel to get therapy.

A proton center in Connecticut would be a huge benefit to the residents of Connecticut and also in nearby Westchester and Putnam Counties. It would be an outstanding addition to life in Connecticut.

It's too bad that New England has only one treatment unit at Massachusetts General Hospital.

I do not regret going to Houston, but if we had a center nearby it would have been great.

Next slide, please.

We have received over the past year what -what I would describe to be a 360-degree circle of
support. From witnesses you can tell, public
comments, letters, media coverage, local and state
government officials, community and business
groups, healthcare providers, potential employees,
existing and potential suppliers; and here are
just some snippets of some of the feedback we've
received.

Nidia From Danbury said, we hope to be part of this wonderful much-needed facility.

Lara from Danbury said, I am interested in employment. I have been a radiation therapist for 22 years.

Alex from Danbury said, hi. Very exciting news that this facility is coming to Danbury.

Susan from Sandy Hook said, this looks very exciting. Would love to learn more. I've been working in healthcare for almost 15 years.

Ilene from Danbury said, this is amazing and so much better for people to preserve the good.

Robert from Danbury said, welcome to the

neighborhood. We would love to talk to you about ways we can partner together.

Michael from Brookfield said, I would love an opportunity to earn your business.

Joyce from New Milford said, I'm interested in staying updated as a possible employee at your organization.

Miranda from Danbury said, I hope your certificate of need application gets approved. I think your facility would be great for the area and bring lots of jobs.

Jessica from Danbury said, we look forward to seeing this project unfold and we are excited that proton therapy is coming to local cancer patients.

Next slide.

This past year we didn't let the coronavirus discourage us or slow us down. We have a good and noble mission, and we are looking forward to filling it should OHS say yes to our CON application. Thank you for this opportunity to share today.

MR. HARDY: Thank you, Mr. Crandall.

Our next witness is Dr. Andrew Chang.

THE WITNESS (Chang): Hi. Good morning and thank you for giving me the opportunity to share, Attorney

Mitchell and Board. My name is Andrew Chang, and I am a radiation oncologist and I adopt my prefiled testimony.

So I was asked to share a little bit about my experiences as a radiation oncologist in the world of proton therapy. I've been involved in proton therapy since I was at Loma Linda a little over 20 years ago where I worked with several of the individuals who initially started the proton center, including Doctors Yonemoto and Meyers who are on the -- Moyers who are on the call today.

My particular area of research and training has been focused on two areas that we are seeing utilization of proton therapy. The first is in the pediatric population.

This was a study I published amongst the -for our pediatric radiation oncologists throughout
the country where we were starting to see the
growth of proton therapy in the early 2010s.

I remember 20 years ago when having a conversation with Dr. Yonemoto about proton therapy there were two in the country, and when I was interviewing for jobs at the time I remember some advice he gave me of saying, you know, don't talk about proton therapy. Other places don't

really want to hear about it because everybody thinks it's only for a very limited number of patient populations.

Well, we've certainly seen that change over the last one or two decades, as Steve Courtney showed earlier, because between just about 2000 and the 2010 period there was growth from two centers in the United States to ten centers, and continuing growth beyond that for the next decade of tripling to 30 centers.

Part of the reason why is we started seeing a lot of the benefits of proton therapy that were only hypothesized come to fruition. And so one of the areas where we saw a large growth and a quick adaptation of proton therapy was the use of treatment for pediatric tumors.

Pediatric tumors are one of the areas because primarily the pediatric body is very sensitive to radiation therapy, in particular the side effects that radiation causes. And so as we get better and better at curing cancer the mentality in the United States has shifted and only -- away from cure at all costs, to cure while preserving high quality of life. Proton therapy is one of the tools that is -- is very crucial to being able to

do that indeed.

This paper was one where between 2010 to 2013 there was ten centers -- or sorry, eleven proton therapy centers that were treating pediatric patients at the time. And in just that four-year period we saw a growth from 465 patients in 2010 to 722 patients in 2013, to over close to a thousand patients in 2014.

Since then we've updated the paper, but it was hard to do a comparison directly because in the next five years that we published the update the numbers of centers have more than doubled, but certainly the number of pediatric patients have increased dramatically.

During this time period as well we started seeing quite a bit of patients that are coming from outside the United States, to us in the United States for proton therapy. Part of the reason is in planning a center, the amount of time it takes for construction, planning and development is on average anywhere from five to eight years. Because many of the benefits were far away from patients in outside counties many of those patients were then being sent to the United States for proton therapy treatment.

Just by itself, when I started asking this question in 2012 and 2013 it was 19 and 22 percent of the pediatric patients treated in the United States were coming from outside the United States. That number has held steady through the next decade of about 25 percent.

One of the big drivers of this was from the United Kingdom where patients -- where the NHS were sending approximately 120 patients to the United States every year for proton therapy, of which I treated about half, and another half went to a different center.

Next slide, please.

So this is kind of the poster child of why patients and physicians recommend proton therapy. This is an example of a ten-year-old girl -- it was about 15 years ago, with a tumor called a medulloblastoma where the cancer cells get into the fluid that goes from the brain into the spine.

And so to treat these patients -- and they have a very good rate of cure -- we have to give radiation to the entirety of the fluid in the brain and spine.

The colors that you're seeing are an equivalent idea of where the radiation is going.

On the left is how we treated patients with a medulloblastoma with standard radiation, X-ray radiation for the last seven decades. With the advent of proton therapy being able to be used though what you're seeing on the right; we can stop the radiation to just the area of the fluid that needs that radiation.

And so on the right there you can see what this does is stop the radiation from going to the normal structures that don't need radiation such as the heart. And in these cases these children, if they survive their cancers they get heart attacks in their twenties and thirties. So being able to eliminate that is of great importance for, not only for the quality of life, but the survival for these patients.

Likewise, just for quality of life as well, being able to avoid her bowels meant that she did not get the nausea during the radiation. Being able to avoid her thyroid and her breast tissue means that she's not at increased risk of thyroid and breast cancer 20 years down the line.

Likewise, being able to stay off of her ovaries meant that I was able to preserve her ability to have children in the future, whereas

with X-ray radiation that was not something we typically thought about. For that reason most of these children with these tumors now, if having proton therapy available, they are able or recommended to get it.

As some of the others have mentioned, one of the greatest downsides of protons, though, is the access to that technology. For this particular tumor the reason I showed this is this is a tumor where we know we need to start radiation within 30 days after surgery. And it's very unfortunate that a lot of times I would get calls from these patients' families. They've had surgery a week ago, two weeks. They're just being hit with this diagnosis of cancer and a brain tumor. When they start doing their research and say, yes, we would like to get proton therapy.

But then to be able to travel and transplant a family for two months while a child is sick and start radiation within that 30-day period is very, very difficult. And so having centers that are spread throughout -- throughout the regions where cancer is occurring makes it much more feasible that these children will be able to get access to a technology they otherwise cannot get.

Next slide, please.

This is another one, a pair of patients that were actually treated a colleague -- by a colleague of mine at a center that had very similar tumors. On the bottom left there's a tumor -- and right next to the kidney. And you can see the kidney that's drawn out in the white there.

One patient was treated at the beginning of the year just before he has got his proton therapy center, which was under construction -- available and needed radiation. So they treated with X-ray radiation. And the other patient, a very similar -- again, 16-year-old at the end of the year happened to have the diagnosis in a very similar location and was able to use proton therapy to treat that tumor.

One of the things that was very interesting about this is we often think about the side effects from radiation exposure as something that occurs many years or -- or decades afterwards, but in this particular patient you can start seeing the actual effects of radiation, unnecessary extraneous radiation on the normal tissues very shortly after.

If you go to the next slide we have CT scans of this patient twelve months after radiation, from each one. You can see on the top left picture the tumor with an arrow pointing to it. And then just above and to the side that white circle is the kidney.

Twelve months later, you go down to the picture on the bottom left you can see that kidney is shrunken and shriveled up as compared to the kidney on the patient's other side, again that circle.

Whereas as with the patient that received proton therapy, the right-hand pictures, the kidney again is about normal at the start of treatment. At the end of treatment it is shrunken a little bit, but substantially larger and still functional as compared to the patient that got x-ray radiation.

Well, what this patient -- now he's six years after these treatment -- both of these patients are six and six and a half years after treatment -- are seeing is that kidney function of the patient that got the IMRT X-ray radiation is severely compromised such that now he's going to be on medications to control his renal

hypertension, or high blood pressure from that kidney damage for the rest of his life. And when one thinks about what can be done to prevent that with the use of a separate technology, the -- the possibilities are -- are great in being able to prevent future illnesses that come up.

The next slide shows one of the areas that we're seeing growth of proton therapy. I know when I was at Loma Linda we had a lot of patients that we treated with prostate cancer, and I remember getting patients occasionally coming back for followup and the wives would ask, hey, I've gotten diagnosed with breast cancer now. My husband got prostate cancer. Can you not treat my breast cancer with proton therapy?

And unfortunately for the many years at first our answer was always no because of a simple difficulty of our machine at that time was only able to treat a limited size of radiation, something about this size. That was unable to treat the entirety of the breast for breast cancer.

Well, with the growth in proton therapy as well as the evolving technology that has made it a much more feasible on a larger size, we started

realizing, yes, these women with breast cancer especially women with left-sided breast cancer is something that can benefit greatly from the use of proton therapy.

And an example why is the picture I've got here. We're showing a patient on the left getting treated with x-ray. And as you can see, it's going across the chest and the lungs, but the important part is that circular structure right behind the left breast is the heart, and the most critical part of the heart that is exposed to radiation is the artery that runs right in the front of it is called the anterior descending artery. That is the one that is involved in the majority of heart attacks.

And that's exactly why women who have breast cancer, especially left-sided breast cancer that get treated and have a good outcome and survival of their cancers develop heart attacks at a much higher rate than the general population just because of that exposure of radiation to that one artery that sits in front for breast cancer.

Well, with proton therapy what we've been able to start doing is carving that radiation around that heart, and in essence we do see the

rate and the risk of heart attacks and heart disease in these women to that of the baseline community, that is those who did not get radiation.

Other ways we're looking at doing this is treating only the area where the cancer was, rather than the entirety of the breast. A lot of our research now in proton therapy is, in addition to the pediatric population, the breast cancer population.

This growth in utilization and the realization of the benefits of sparing of the heart is such that between 2017 and 2018 there was a sevenfold increase in the number of women with breast cancer treated with proton therapy. That is only going to continue to grow as more and more centers become available and this -- this technology becomes accessible for women with their breast cancer and being able to stay off of that.

So that my ends my testimony in kind of sharing on the clinical side what it is that I see in the growth of proton therapy, not only what we can do now, but where we're going to be in five and ten years from now.

I thank the committee for giving me this

opportunity to share. Thank you.

MR. HARDY: Thank you, Dr. Chang.

Our next witness is Dr. Deborah Hickey.

THE WITNESS (Hickey): Good morning, Attorney Mitchell and OHS staff. I am Deb Hickey, and I adopt my prefiled testimony.

I am the Director of Operations for the Brotherhood of the Balloon running the day-to-day processes of our 10,000 member organization consisting of men who have all had proton therapy for prostate cancer. We have members from all 50 U.S. states and 39 countries. They represent all operating proton centers in the U.S., as well as four in Europe and Asia.

The Brotherhood of the Balloon, also known as the BOB, allows former and current prostate cancer proton patients to share information, learn from each other, ask questions and receive from us the latest information on prostate cancer, proton therapy, the healing process, preventing a recurrence, and much more through our 20-plus page monthly newsletter.

Many of our members actively promote proton therapy in many ways and are willing to share their personal experiences of treatment. In fact, we have nearly 54 of our proton patient reference lists with the names and contact information for hundreds of our members who volunteer to speak with newly diagnosed men and their family members about their personal experiences of treatment and life after treatment.

Our members are enormously enthusiastic about their experiences and typically jump at the chance to spread the word. In fact, I think Drew may have quoted a few of them earlier. One of our members once said, proton therapy is the only cancer treatment with a fan club.

The advantages of proton therapy over conventional radiation are well established and have been experienced firsthand by thousands and thousands of our members. In my prefiled testimony I focused on the overall cost effectiveness of proton and the critical importance of considering initial cost versus total cost of treatments for prostate cancer.

I mentioned in my testimony that the initial cost to treat prostate cancer with protons is -- is higher than IMRT, however this doesn't capture the total cost to private insurers and Medicare of treating with other forms of treatment.

In focusing on IMRT if you consider follow-up costs and hospitalizations for treating higher levels of impotence, rectal issues, incontinence and other side effects that are more prevalent with IMRT due to healthy tissue being exposed to radiation, as well as the cost of diapers for incontinence, ED meds for impotence and over-the-counter medications for pain and discomfort, those costs add up. As such when you compare overall costs from proton versus IMRT, proton becomes comparable and often less costly when you consider total cost.

Here's an example. Our founder Bob Marckini is my father. He founded the BOB after he was

Here's an example. Our founder Bob Marckini is my father. He founded the BOB after he was treated with proton therapy for his prostate cancer back in 2000. That was more than 20 years ago, and hasn't seen his urologist since then, and that is not uncommon among our membership.

Finally the cost of proton therapy is coming down as there are advances being made through the use of hypofractionation which cuts the treatment time in half by treating patients with higher daily doses in fewer fractions, and the results from trials have been extremely positive.

And it's likely that hypofractionation will

become the standard treatment protocol in the near future. That means initial costs for proton will be comparable to IMRT and total costs will be less. When these perspectives are considered it's not entirely accurate to characterize proton therapy as being significantly more expensive than IMRT.

In fact, the collective and extensive experience of our group and several thousand former prostate cancer proton patients suggests that proton therapy costs more initially, however following treatment most proton patients require zero follow-up medical attention, thereby incurring zero additional medical costs.

Thank you.

MR. HARDY: Thank you, Ms. Hickey.

THE WITNESS (Melson): Good morning, Attorney Mitchell and OHS staff. My name Don Melson, and I'm the Finance Director of Danbury Proton. Having been born and raised in Connecticut I'm pleased to be here today to discuss the cost benefits of the Danbury Proton -- that Danbury Proton will bring to Connecticut residents as well as the financial viability of the center.

Our next witness is Mr. Donald Melson.

I adopt my prefiled testimony.

As background for the last 30 years I've held senior financial roles in well-known life science, biotech and medical technology companies in the Boston area. Prior to my current role, I was the Chief Financial Officer of Mevion Medical Systems between 2013 and 2018.

In my role as CFO I was exposed to all aspects of the company's technology, competition, customers as well as the economic outcomes of those customers. After leaving Mevion I joined Danbury Proton as I viewed the business was poised for success due to the favorable site demographics, single-room design and a particularly strong management team.

I will now turn my attention to the cost effectiveness of proton radiation, my first slide.

And as you heard, proton radiation's major benefit versus photon or x-ray radiation is that it minimizes the secondary effects of radiation dose on healthy tissue while effectively radiating the tumor. Though the initial costs of photon treatment may be less than the current costs of proton radiation, the long-term, total long-term costs of photon radiation, including subsequent

treatment and care, loss due to income/workplace contribution, not to mention patient suffering can exceed the cost of protons.

Another benefit of proton's lower radiation impact is that radiation dose intensity can be increased in the tumor versus that of photons. Also called hypofractionation, this evolving technique opens the door to fewer treatments, hence lower costs and a shorter, less intrusive treatment period.

Finally, single-room proton systems are the most efficient and risk reduced method to build proton radiation capacity within the state. Early proton centers were very large, expensive multi-room centers costing in excess of \$200 million. Because of the size and cost such centers were frequently underutilized contributing to financial instability.

Alternatively, multiple single-room centers are less expensive and can be situated near the local populations they serve. Single-room centers can also be scaled up as demand grows by adding another room. The benefit of this is matching cost to demand.

Moving to my next slide I will address the

financial feasibility of Danbury Proton center.

As with most enterprises, a significant key to a successful business venture is location.

Danbury Proton's proposed facility provides convenient access to Connecticut residents in the heavily populated southwest region of the state.

In fact, the population density within 25 miles of the facility is just over a million people, including 98 percent of the population of Fairfield County.

Increasing that radius to 30 miles are five of Connecticut's top ten most populated cities. If you increase the radius even further to 50 miles, the population expands to over 17 million. Given the high density pop -- high population density, the expected incidents of proton radiation candidates and the scarcity of local proton radiation centers, Danbury Proton expects that it will have more than sufficient demand in it's primary service area.

Successful reimbursement is the second driver of financial success. Danbury Proton expects approximately 52 percent of its patients will be covered under Medicare, Medicaid or TRICARE,

38 percent will be covered under commercial

insurance programs, and 10 percent will be private payers.

While Medicare has generally covered proton radiation since its FDA approval in 1988, commercial insurance plans have varied in their coverage while insurers are now increasingly covering the cost. Commercial insurance coverage has been supported by high profile lawsuits as well as certain state legislatures that have passed laws that encourage coverage by insurance carriers.

The efficient use of capital and operating resources is the third driver of success. As mentioned, single-room systems are efficient through their low relative cost and scalability, however the size of the single-room facility also matters. Danbury Proton's Mevion facility has the smallest footprint in the industry, and therefore the lowest cost of construction. Mevion's systems are also known for their efficient usage of utilities and other overall operating costs.

In summary, proton radiation is a highly cost efficient therapy and, in my opinion, the Danbury Proton proposal has a high probability of

financial success. I urge the Office of Health Strategy to approve this project.

MR. HARDY: Thank you, Mr. Melson.

Our next witness is Mr. Steve Coma.

THE WITNESS (Coma): Good morning, Attorney Mitchell and OHA staff. My name is Steve Coma. I'm with Hilltop Securities, and I adopt my prefiled testimony.

Don has had, you know, a number of the points in terms of financial feasibility. My job is to raise the financing to build and initially operate the project. Similar to what Don had expressed, one of the ways that we want to accomplish that with the market is that we're going to use tax exempt financing that we will market to third-party investors, as there is precedent for that in the market.

A number of facilities have been financed that way, and from a marketing perspective we need to do several things -- one, demonstrate that we have a strong team.

You've heard from a number of the project participants already. We've done the same thing on the finance side, putting on our team folks that have a tremendous experience in this area

already. Just to highlight a couple, Orrick

Herrington will be bond counsel. They are the

largest bond counsel firm in the country and have

financed a number of these projects.

Mevion, you've heard from. Butler Snow, actually the attorney that we're working is -- is a proton therapy, you know, patient or user and a strong advocate for the project.

Dave, next slide.

As Don had highlighted, you know, we will market to investors, you know, in a similar fashion about the financial feasibility that Don had mentioned; the things that we like and the things that we'll highlight with investors.

Obviously Connecticut with the dense population, single-room therapy is extremely important.

Some of the features that Don had mentioned are critical to investors. We want to have the highest utilization with the smallest initial cost, and going with the single-room project has the ability to expand. It will be very, very favorably viewed by investors.

The no-affiliation restriction, a number of the facilities across the country have had very strong affiliation agreements at the outset. That has not helped financially. So from a marketing perspective we would like not to have that, those initial affiliations and we're set up to proceed in that manner currently.

And then the financials that Don had mentioned, from a feasibility perspective the team has been working with IHS and Kaufman & Broad in terms of feasibility reports, and we have a strong projected financial feasibility with debt service coverage in excess of two tenths, which is very strong.

David, next slide.

From a market perspective obviously last year with the advent of COVID, you know, it was a very difficult spring from a financial markets perspective, but the markets have entirely healed. Interest rates are, as I'm sure you're very aware, at very attractive levels and those are directly applicable to what -- what we're going to do.

The market for, at least taxes and bonds are taxes at mutual funds, and certain large investors. We will not sell this to retail investors. And they have had a tremendous amount of influence, people putting more and more money to work with the funds. And so the funds are

anxious for projects like these to have the opportunity to invest in.

And while we will be careful and prudent in our marketing strategy we are very comfortable and confident that -- that we will successfully place this project. And David, with that, that's -- that's my testimony.

MR. HARDY: Thank you, Mr. Coma.

Our next witness is Dr. Leslie Yonemoto.

THE WITNESS (Yonemoto): Good morning, Attorney

Mitchell and OHS staff. My name is Leslie
Yonemoto, and I adopt this prefiled testimony.

I'm a radiation oncologist that started in proton therapy in 1992 where Dr. Mars taught me everything I needed to know about proton therapy physics, and later worked on proton therapy with Dr. Chang and met Mr. Marckini and Ms. Becky and Mr. Courtney. It's good to see all of them.

We've been working on proton therapy for 20 to 30 years, which is unique. Most folks haven't worked that long, especially when you consider the centers such as the University of Florida and University of Pennsylvania started in 2006 and 2008.

Anyway, I have -- I'd like to go to the next

slide that will help explain what proton therapy is about. This is a slide that I developed 25 years ago and used to help explain the development and operations of several proton therapy centers that I've been involved with including University of Florida, Indiana and University of Pennsylvania, Brookview centers and others.

It's a rather busy slide but the idea is why proton therapy is unique. If you look in the center of the slide where it says, tumor volume, that's our target. That's what we want to get with a dose of something; dose of radiation, dose of chemotherapy in order to eliminate those tumor cells.

The circle around it is the body. So if the tumor is in the middle of the body, that is our target. The body is in the way. The body creates side effects to get to the tumor. You don't get a side effect from getting rid of the tumor. You get side effects from giving dose or harming the body that doesn't have the tumor.

So on the left side of the graph it says the sort of dose. That means how much radiation that part of the body got. You can consider it like a medication like in milligrams, the higher the

number the more milligrams or more dose, or more effects that medication or radiation has.

And on the bottom of the graph shows the depth. How far in the body did we travel to get there? Now if this is a medication there isn't any depth. The whole body gets medication. You take a medication, a chemotherapy drug or you take a pill of anything including ibuprofen, it would travel throughout the body, but radiation is different. It loses its steam as its goes through the body.

So if you look on the left side of the graph that says beam direction, consider that a flashlight being beamed into the body from left to right, and that's how radiation works. It goes into the body and then usually exits out the other side.

But at the very top of the graph you'll see it says it says, ortho or orthovoltage of 0.2 MeV as million electron volts. That's the technology that was available in the 1930s and '40s and '50s, and '60s, and in order to get the desired dose which is a hundred percent at the tumor volume, which you see in that graph going to the depth of 20 centimeters, it shows the tumor volume getting

a hundred percent of the dose, I have to give over 200 percent of the dose on the way in.

So if I create harm to the tumor at 20 centimeters on the way in, then creating harm almost twice as much on the way in. Then if you follow the graph as it goes to the right, it continues to harm the tissue on the way out, not a hundred percent but at least 50 to a hundred percent.

So that's the way radiation works. It creates harm on the way in and harm on the way out depending on the amount of dose that you give. This is not unlike chemotherapy or any other medication, you want to give the dose to the tumor volume, but other parts of the body as an innocent bystander -- as one of my mentors called it, it also receives a dose.

If you think of it as chemotherapy it knows cancer is at the roots of the hair, but chemotherapy reaches the hair and causes hair loss. There may not be cancer in the gut, but chemotherapy goes there and causes nausea, vomiting and diarrhea. The same thing for radiation.

The before-and-after tumor volume on the

graph here represents areas where there isn't cancer, but you have to harm it in order to get to the tumor. So that's the physics of radiation therapy that Dr. Mars has taught me, and I developed this graph.

So as you see on the lines again, the top lines are in orthovoltage. While we improved our technology and went to cobalt 60, a gamma-ray emitter that's like x-rays, it increased the energy to 1.5 MeV, which is a higher dose. And the reason why that was adopted is because, as you noticed, it reduced the amount of harm on the way in. It reduced the amount of dose, serum dose -- and now that the technology trumped.

And then in the 1970s and so, we developed LINACs. And we've got this six-four, six-eight MV LINAC, which was adopted because it reduced the amount of dose on the way in, and it was actually easier to control also. There are other characteristics also, but the main one is that it reduced the amount of dose on the way in.

And then the higher energy machines came out with 25 MeV -- or actually we usually used 18 to 23 -- has even further reduced the dose in there. And that's the limit of the LINAC technology, and

that's what we use today. 95 to 99 percent of all cancers use this type of technology for radiation therapy. And again we treat anywhere from 50 to 60 percent of all cancer patients with the thousands of LINAC machines throughout the country.

Well, the bottom line there was the protons at 250 MeV, that characteristic shows two important things. One is the entrance dose, or the dose harming the tissue on the way in is significantly less than x-rays.

X-rays, they're also called photons. So the reason why I put the "H" there in the photons in upper left, distinguished from protons, they're very much different. Photons are x-rays. A proton is a particle, but with this particle we can go to high energy and it reduces the amount of harm or dose on the way in.

And if you follow the red line to the tumor volume and you see to the right of it, there is no dose -- after you hit the tumor volume, there's no harm to the tissue there. Whereas the other lines you see up there, the LINAC, the cobalts and orthovoltage does radiate and give dose to that part of the body.

therapy. It's irrefutable on how this works. So with proton therapy we're still using this now that we have -- in research. Now that we have over 30 centers, we're going to have more and more data showing that this type of technology reducing the amount of tissue that's harmed on the way in and in giving no harm to tissue behind the tumor will result in two things; one, less side effects, which decreases the overall cost of the health care; and with less side effects we can go and try to increase the dose to the tumor volume and increase the chances of controlling the cancer there.

So it gives us two big advantages. Hopefully more dose, more tumor volume kill, less dose to the normal tissue, i.e., less side effects, the two things that we would like to do in anything in medicine, especially with cancer.

I appreciate your time and I support this project. I've been working on this over -- David and I have been working out over a decade on this.

So thank you.

MR. HARDY: Thank you, Dr. Yonemoto. Our last witness is Mr. Robert Marckini.

THE WITNESS (Marckini): Good morning, Attorney

Mitchell and OHS staff. I'm Bob Marckini, and I

adopt my prefiled testimony.

My focus and that of our organization, as I mentioned earlier, is promoting proton therapy for prostate cancer. How did this all start? Well, about 23 years ago I drove my brother, my older brother to the hospital. He had been diagnosed with prostate cancer and he did what his urologist and most urologists recommend, and that is he had -- he agreed to do -- have a radical prostatectomy, or surgery and his prostate removed.

He walked into the hospital, the picture of health and then about five hours later I was with him in the recovery room -- and it scared me to death. He looked like he was near death and he had lost five pints of blood and he had some other complications, many of which didn't show up until a few months later.

I knew I was at risk at the time because my
PSA was rising, and I made a promise to myself at
that time and that was it. If I'm ever diagnosed
with prostate cancer I'm going to find something a
lot better than -- than surgery.

Next slide, please.

So when I was diagnosed, being what I refer to as a, quote, recovering engineer, I was comfortable wallowing in technical detail. I initially interviewed doctors representing all the various specialties that are treating prostate cancer. And I became more confused after doing that because each doctor told me that I was the poster boy for what he or she had to offer.

I did lots more research, internet, library, so on and so forth, but the heart of my research was interviewing formal patients. The smartest thing I ever did. I interviewed literally hundreds of former patients, and what I heard from them was quite a bit different representing each of the treatment protocols.

Proton therapy sounded too good to be true. At that time there was only one proton center in the country and that was Loma Linda University Medical Center in Southern California. And I traveled 3,000 miles across the country to be treated there. I was there for eight weeks with my wife.

It was, for me, one of the most extraordinary experiences I -- I've ever had. I learned through

my interviews and then through my personal experience that proton therapy cures cancer, and at least as well as any other treatment option, but it leaves the patient with a much higher quality of life after treatment.

I, while I was in treatment I became friendly with several other fellows that were technically oriented, scientists, chemistry professor, physicists and so on. And at that time we decided to form a group so that we could stay in touch with each other and compare notes about side effects and PSA progression after treatment, and that sort of thing.

I jokingly refer to that group as the Brotherhood of the Balloon -- and please don't ask me to explain where that name came from -- but the group became much larger than I had ever expected. It exploded in size and as Deb mentioned earlier, We have 10,000 members, 50 states, 39 countries, and representation from all US proton centers, and several overseas.

We've been told by several people that we are the largest group of its kind, men who have been treated -- in patients who have been treated with a specific -- with a specific disease that were

treated with a specific treatment protocol.

So our mission, the Brotherhood of Balloon's mission has evolved into a three-part mission, to keep our members connected with each other and educated, to promote proton therapy, and to promote giving back to the institution that saved our lives, and equally important preserve the quality of our lives.

How do we do this? We have a monthly newsletter. As Deb mentioned, we have periodic reunions around the country. Now we have a website, a Facebook page, Uplog, Power Point, patient reference lists, my books. These are the ways that we promote proton therapy.

And as far as giving back is concerned, we do it through our newsletter and occasionally a fundraising campaign to different parts of the country.

How are we doing in these three areas? Our members are highly educated and well informed. They're all ambassadors for proton therapy. Newly diagnosed men who are discovering proton therapy through our website, Facebook page, my book. And routinely our members are giving presentations using our Power Point presentation at Rotary Club

meetings, Lions Club meetings, church meetings, senior communities and so on.

And as Deb mentioned, one of -- one of the patients that we had spoken with said that they chose proton therapy because it was the only treatment option that had a fan club. So I think we've done a pretty good job at achieving our mission and we still work at it.

Recently the National Association of Proton
Therapy awarded me the honor of the lifetime
achievement award for the work our group had done
promoting proton therapy worldwide. We routinely
support the establishment of proton centers around
the country, including the proposed Danbury
center. I know a bunch of our members have
written letters of support and will also be
attending hearings, public hearings.

Next slide, please.

My book has become an important part of the proton story. As I said earlier, when I was diagnosed I had great difficulty finding the best treatment options, an option for me. So I decided I was so enamored with proton therapy and what it did for me that I -- I decided to write the book that I thought would -- basically the book that I

wish had been available to me when I was diagnosed 20 years ago.

If you go to Amazon and do a search under prostate cancer, you will find there are 4,000 books on that subject. My first book was in the top five for about ten years and my current book is in the top one or two. It's currently number one in that search. It's distributed to proton centers and proton centers that give them to patients, and it's had a significant impact in the decision making process.

You can see the topics that my book covers here. I won't go into them in detail, but I would be happy to answer any questions later on. But fundamentally the book addresses men's greatest fears, firstly dying from prostate cancer and then the side effects, loss of bladder control, loss of sexual function, bowel control -- and perhaps one more.

If they choose radiation, secondary cancers from the radiation treatment is something that men fear, particularly now that younger and younger men are being diagnosed with prostate cancer and are gravitating toward proton therapy.

At one point that -- and I think it's come

out already in some of the presentations, that all radiation oncologists, physicists, scientists agree on is the only safe radiation dose to healthy tissue is a zero dose, and from my perspective proton comes closest to that goal with regard to any other form of radiotherapy for prostate cancer.

Next slide, please.

Okay. Something that has -- I -- I have found very important is to talk to patients and hear and listen to patients with regard to their experience of proton therapy for prostate cancer. And we actually have done a number of surveys of our patients and our members.

Initially we did the surveys, but since then independent third parties have done surveys and the results are always the same. And this is sort of a conglomeration of the results of said multiple surveys. You'll notice that the percentages are all in the high 90s, and these are patients that were treated at all proton centers in the country.

Experience was excellent to outstanding.

They felt they made the best treatment for the decision for themselves. They would make the same

decision again. That's -- that's significant.

They recommend proton therapy to others, and

almost all of them reported no recurrence of their

prostate cancer. And -- but they also reported

high scores with regard to urine control, bowel

function and sexual function.

Now you have to ask the question, how would surgery, brachytherapy, or IMRT patients respond to these same questions? I don't think the answers would be the same. We know this for a fact because we talk with them all the time.

Next slide, please.

So I'd like to thank you for the opportunity to speak today. I'd like to summarize -- my contention is that based on my 20 years of research and experience, that proton therapy cures prostate cancer at least as well as any other major treatment option, and it scores Betty at -- better at all the other categories with regard to side effects.

Over the years I've found patients have become more and more informed, and self referral is much more common than it was in the early days that I started studying this disease. I'm convinced that proximity to a proton center is a

huge factor for patients who want proton therapy, but can't travel for various reasons.

The Danbury area is a superb location to fill the void in the Northeast, the area that I'm most familiar with, especially considering Danbury's proximity to major population centers.

And add to that the clinical leadership provided by two of the brightest stars in the proton world, Dr. Leslie Yonemoto and Dr. Andrew Chang, two extraordinary physicians and experts in the field that I've had the pleasure of knowing for most of the past 20 years. That's a winning combination.

And finally, you certainly have Deb's and my support for this venture, and the support of our entire organization. I urge the State of Connecticut to support this effort.

Thank you very much.

MR. HARDY: Thank you, Mr. Marckini.

And with that, Attorney Mitchell, that completes our testimony this morning.

THE HEARING OFFICER: All right. Thank you, attorney Hardy.

I'm just going to ask, are there any public officials that are present that want to provide a

1 comment? A VOICE: The video? 2 3 MR. HARDY: Oh, I'm sorry. Attorney Mitchell, if we have time. We just 4 5 had one video we wanted to conclude with. 6 THE HEARING OFFICER: Okay. Has that been submitted as 7 evidence? Are you --8 MR. HARDY: It has been, yes. 9 THE HEARING OFFICER: Okay. All right. All right. 10 So I'll go ahead and allow it. I remember 11 looking at a video, so okay. All right. 12 MR. HARDY: Let me get my screen back up. 13 THE HEARING OFFICER: I'm going to ask everybody to 14 unmute themselves. 15 MR. HARDY: Well, I apologize. It appears the video is 16 not there for us. My apologies, but there is a 17 link in the -- that was submitted along with all 18 the other record materials. 19 THE HEARING OFFICER: All right. Thank you, Attorney 20 Hardy. If you're able to establish the correct 21 link we can allow you to show it later on before 22 the end of the hearing. 23 MR. HARDY: Thank you. We'll work on that. 24 THE HEARING OFFICER: Okay. Let me just ask, are there 25 any public officials that want to make a comment?

1	You can unmute yourself and let me know.
2	
3	(No response.)
4	
5	THE HEARING OFFICER: All right. So I don't hear
6	anything yet. So what we're going to do is we are
7	going to go off the record for about 20 minutes so
8	that I convene with Brian and my colleague Roy, so
9	we can look at the questions we have, see which
10	ones were answered and then we'll come back with
11	our questions at twelve o'clock. Okay?
12	MR. HARDY: Yeah. Excuse me, Attorney Mitchell? Can I
13	just have two scheduling requests?
14	THE HEARING OFFICER: Yes.
15	MR. HARDY: I noticed that Mr. Marckini I know has a
16	hard stop at one o'clock.
17	THE HEARING OFFICER: Right.
18	MR. HARDY: And then Dr. Moyers needs to return to the
19	hospital. So to the extent you may have questions
20	for Dr. Moyers, if we could get them towards the
21	front that would be appreciated?
22	THE HEARING OFFICER: Got it. Will do. I think I did
23	have a couple questions for Dr. Moyers. Okay.
24	Let me just ask, just for a point of clarification
25	if we get back to Dr. Moyers first at noon would

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Τ-

that be okay in terms of scheduling?

THE WITNESS (Moyers): That's fine.

THE HEARING OFFICER: All right. Thanks everybody. So we will go off the record for about 20 minutes, and I'll give you the announcement about a minute before we go back on so that everybody is all set and in their seat. Make sure that you mute yourself and you turn off your camera, because we are not going to stop recording.

Thanks, everybody.

(Pause: 11:41 a.m. to 12:01 p.m.)

THE HEARING OFFICER: All right. So we are back on the record. I do want to ask before we go into the questions that we developed prior to the hearing -- there is one question that I want to ask Dr. Moyers before he leaves.

And it's based on the presentation presented with the slide that starts with the year 1990. It talks about the increase in the number of patients treated with this type of therapy. And I think that the part that we're missing in terms of being able to do our analysis is we do see the increase in the number of programs. We also see -- I'm

getting feedback.

THE REPORTER: This is the reporter. I'm getting some feedback as well.

THE HEARING OFFICER: Right. I'm just going to ask everybody to mute just for a second until the question has been answered, and then Dr. Moyers you can unmute.

I think I really am interested in, in addition to the number of people that are being treated using this mode of treatment. Is there a correlation between the number of people treated and the efficacy of this type of treatment? Like, what were the outcomes?

Can you talk a little bit about that?

THE WITNESS (Moyers): As far as the outcomes I -- I think I should leave that to the physicians that examined the patients before and after the treatments, and do those.

As -- as far as number of patients, you -- well, maybe you can ask that part of the question again?

THE REPORTER: Dr. Moyers, is it possible you could get closer to your microphone? I believe the background noise is coming from your microphone.

Thank you.

THE WITNESS (Moyers): It's -- it's on my mouth, my microphone, so --

THE HEARING OFFICER: That's okay. So basically what

I'm asking is the slide that was presented during

your presentation talked about the number of

patients treated from 1990 on, and noted an

increase in the amount of patients that were

treated. So we also note, too, I guess from 2000

on that the number of these types of centers also

increased.

And I think that we are looking for some correlation between the increase in the number of patients treated and the efficacy of this type of treatment, if you have it?

THE WITNESS (Moyers): Yeah, I -- I think the increase with any new facility, part of it is for the -- I would say the first year is in training, getting all the staff going and -- and trained during the first year.

But in the second year they increased, it's probably due to getting the word out to the -- the patients. They have to learn the facility exists and -- and they're referring doctors to let them know that if -- if you've heard the other people talk, a lot of patients find the facility on their

own, but -- but those that have referring physicians, that -- that network of learning that exists and in teaching other physicians that it's a good treatment, I think that determines how it comes out.

THE HEARING OFFICER: Thank you. And I think that was all of the questions that we had specifically for you, Dr. Moyers, in case you have other pressing things that you needed to do.

THE WITNESS (Moyers): Okay. If you have any other questions just send them to me. Or you can give them to the team members and they can transfer it.

THE HEARING OFFICER: Will do. Thank you.

THE WITNESS (Moyers): Okay. Thank you.

THE HEARING OFFICER: All right. So these next set of questions are questions that we preprepared and we kind of went through and determined whether or not they were answered during the presentation that the applicants presented.

I'm going to just note, Attorney Hardy, if there's anyone that you feel is most appropriate to answer the question, you can designate them. It doesn't have to go to a specific person, but we have grouped them by category. So these first couple of questions relate to demonstration of

need.

So the first question is, please discuss the methodology used to determine the need for proton therapy services in Danbury, Connecticut.

Specifically, how do you deduce that -- well, let you guys answer that question first and then I'll go to the second part of that question.

MR. CARNEY: I think probably the person to start with may be Mr. Courtney.

THE WITNESS (Courtney): Certainly. Actually the correct answer is, various ways. The -- there are population based. There are tumor registry based. There are essentially interviews in the market. There are a number of ways to really calculate what -- what the need might be. That's why we looked at the patient bed count of the various facilities; who was not going to be readily served by the Hartford and New Haven health system.

We were frankly quite surprised how -- how many -- how much population was not going to be connected, if you will, to those, to those institutions. And one of the things that we learned, and as Mr. Coma pointed to, facilities that exclude, but through these kind of affiliations their surrounding market really end

up hurting, not only themselves, but there their patients.

We in fact think that proximity is a huge issue and that population is -- is the driver. And even if there is a patient that's typically, say, served by Hartford or New Haven that's in our market, they may choose to actually get their -- their treatment with us, and we'll be working very closely with the Hartford or New Haven health system.

So we're -- this is a proximity-based evaluation primarily.

THE HEARING OFFICER: All right. So I just note you actually brought up something that I was going to ask a question about later, and this pertains -- you brought this up just now, but this pertains to Mr. Coma's testimony.

So I noted that you said that your project does not have affiliations due to limitations on patient referrals -- and how does an affiliation limit that? So I just wanted to see if you can expand upon that since you brought that up.

THE WITNESS (Courtney): Actually, I would like

Dr. Yonemoto to take that question because he does

it so well. He understands better -- better than

most the significance of this question.

Les?

THE WITNESS (Yonemoto): Sure. Now let me understand.

Is the question about affiliation with the

different medical organizations and such?

THE HEARING OFFICER: Right.

THE WITNESS (Yonemoto): Yes. Well -- you know,
they're not much different than any other facility
that's freestanding and not part of an affiliate
organization. We provide a niche and a need to
reach out to these patients to provide services.

What we do is we prevent -- we provide access to others that somehow affiliations may not be the best way for them to access medical care that they're not part of an integrated system, but would like to be part of a system that is independent and can affiliate with other folks that are not part of the usual affiliation or service line.

So that's no different than any other freestanding nonaffiliated center, and we're quite familiar with that. We have worked, including Dr. Chang and myself, with many nonaffiliated centers providing the need. We don't see that as a detriment, but as complementary like all

freestanding centers are. And we work with affiliated centers as much as we can and provide services along with them.

THE HEARING OFFICER: Okay. Thank you.

I'm going to go back to Mr. Courtney on the need analysis.

So you said that you used a number of ways to determine need used, population based tumor registry based, interviews in the market. Is there any one methodology that you use that you can point to that you believe best determines that there is a need for this service through your proposal?

THE WITNESS (Courtney): Certainly. The thing that

drove us and really drove us to Danbury was

because of our national, and actually

international history in this particular market.

We -- we've looked at throughout the United States, of the MSAs, or the geographic areas that are missing proton therapy facilities. The Danbury -- the 50-mile radius around Danbury was the -- the highest need area in the whole United States, at which underscored the need to be there and the viability of the center.

In some ways development is location,

location, location, and this is -- is the highest need in all of the United States.

THE HEARING OFFICER: Okay. Thank you. And then there was a sub-part to that question -- just trying to go back to my questions here. So it looks like in your prefiled testimony -- and it may not specifically be yours. Let me just double check.

But on Bates or OHS page 4 of the prefiled testimony the question is based on the statement that was made that 17 percent of patients are being treated at New York Proton Therapy, like their facility.

And I guess the question is, how was the assumption made that most of the 17 percent of patients are from Connecticut? Does that make sense? Let me just go back --

THE WITNESS (Courtney): Oh, yeah. No, I understand.

No, that's a very good question.

Yes. First of all, that data is coming from, you know, a relatively new center. So their numbers are going to definitely be going up, but when they indicated that 17 percent of their -- their patient base was from Connecticut and New Hampshire --

THE HEARING OFFICER: New Jersey.

THE WITNESS (Courtney): -- New Jersey, we knew that there were very few coming from New Jersey.

That was kind of a residual because that that institution was working with the ProCure facility and there were a few patients left that were kind of in that, in that queue, if you will.

And -- and additionally there are, between that facility and the Mevion facility at Robert Woods Johnson there are five treatment rooms. So they have plenty of capacity locally in New Jersey. So there would be very little reason to send people to -- to Harlem in New York for treatment.

On the other hand, Connecticut patients have no place to go. And so you know, it's was very easy to make the assumption that the largest part of that, that population is going to -- coming from Connecticut.

And of course, most of those Connecticut residents are folks that are probably in the Fairfield County area, the Gold Coast that have access to -- to that facility. Most people in Connecticut don't even know proton therapy exists yet.

THE HEARING OFFICER: Thank you. All right. So the

1 n 2 p 3 p 4 i 5 s 6 o

next question that I have is, again in the prefiled testimony it's going to be Bates OHS page 5. It states that a single treatment room is inadequate to fulfill the need for the entire state of Connecticut, and that the authorization of a second room in Danbury will still leave substantial need unmet.

How do you arrive at your conclusion that the demand for proton therapy services in Connecticut could support two separate facilities, and two separate rooms?

THE WITNESS (Courtney): Sure, yeah. The next -- the key is how many treatment rooms you have and essentially how many treatments you can make. And the number of patients is not a fixed item per se. Where both facilities are talking about operating at 16 hours a day, they have a higher amount of patients just based on a fewer number of treatments assumed for their patient mix.

With hypofractionation we should be able to increase the actual number of patients that we -- that we service over time. The -- but that's not your question.

I forget what your first part of your question was.

THE HEARING OFFICER: Not a problem. So in the prefiled testimony it says that a single room is inadequate to fulfill the need. And so the question goes to, how did you arrive at your conclusion that demand for proton therapy services in Connecticut could support two treatment rooms, let alone two separate facilities?

THE WITNESS (Courtney): Sure. The -- the number of cancer patients that will present themselves annually approximately in Connecticut are around 20,000. And 60 percent or so of those patients, all depending on what -- what kind of things they have, if they have throat cancer, you know a good 80 percent of them will get radiation treatment.

But 60 percent of those would be normally in radiation oncology as part of their treatment, and -- and about 15 to 30 percent of those patients are eligible typically for proton therapy.

Which gets you to around to 2,500 patients that are just a subset of the overall -- overall radiation requirement. And then you have two facilities that can only accommodate maybe 800 patients per year. So you're nowhere close to the bottom need of 2500 people for the state, and

that's just for Connecticut.

That's not taking anybody -- any of the overflow from Massachusetts, which happens every -- every week. They -- they turn away people. That's not taking any overflow from the New Hampshire, Maine, Vermont and -- and the millions of people in the West, in our market in New York.

THE HEARING OFFICER: Just for clarification when you say, overflow, do you mean people who are appropriate for the type of treatment, but they don't have a capacity? Or are these people that are being turned away for clinical reasons?

THE WITNESS (Courtney): No, it's -- it's overflow.

They -- they've documented for years their need to ration proton therapy at MGH. They try to drive them away with high prices. They charge 300 percent over Medicare. Even that doesn't drive the demand away.

And so they -- essentially they have to every week sit down and look and see, okay. Who are we not going to treat this week?

THE HEARING OFFICER: Do you have any evidence that indicates the amount of people that are turned away from other facilities that Connecticut

patients might be going to?

THE WITNESS (Courtney): Yes, that was in our official -- our first submission with the CON, the research and the reports that they had given them then.

And frankly, I don't recall the numbers off the top of my head, but yeah, they have -- it's -it's famously known for being under capacity.

From our point of view we also are -- are surprised that they really haven't extended their hours significantly. And we, we are going to -- it's not easy to do a second shift. Its -- it's difficult to staff. You know people, you know, would rather not.

But we, we want to make this treatment available to as many citizens as we can.

THE HEARING OFFICER: Thank you. Okay. So I'm going to go ahead and turn it over to my colleague, Roy.

MR. WANG: Thank you. So the next questions and sub-questions is in the category of quality. So first, please discuss the cancer types that Danbury Proton proposes to treat at its facility.

And specifically, which types of cancers will represent the highest percentage of patient volume? What is the efficacy for each type of

1 cancer to be treated? And then lastly, has the 2 Food and Drug Administration approved the use of 3 proton therapy for these cancer types? 4 I'd be happy to reread the sub-questions of 5 that larger question. 6 A VOICE: Dr. Yonemoto? THE WITNESS (Yonemoto): Yes. I think the last 7 8 question was about FDA approval, or clearance for 9 proton therapy? 10 MR. WANG: Correct. The various cancer types that will 11 be treated. 12 THE WITNESS (Yonemoto): The FDA has cleared proton 13 therapy back in the 'nineties for all cancer 14 types. Similarly to the over 2,000 LINAC 15 accelerators out there, it's the same indications. 16 You can treat the same as the conventional 17 radiation. 18 So the FDA approval has been -- or clearance 19 as they like to say has been around for decades. 20 That's never been an issue for proton therapy. 21 The -- I think your one question is ethics --22 oh, the types of cancer treated with proton 23 therapy? 24 MR. WANG: Correct. And then just what was the highest 25 percentage of patient volume?

THE WITNESS (Yonemoto): The -- in my world, we, as radiation oncologists as part of the oncology team in medical, surgical and radiation oncology, we see approximately 50 to 60 percent of all cancer patients get radiation therapy, and they're typically treated with X-ray therapy, similarly to the graph I show there where I showed the LINAC being the primary modality of giving the radiation.

I don't know of any place that uses cobalt anymore -- but anyway, that's the use for all -- almost all the patients that are treated with radiation therapy.

Proton therapy as per that graph could be substituted for arguably most of those cases, but not all. So in terms of potential indication, the way I think about it, if it's indicated for X-rays, saying it's probably indicated for protons. Just -- and with that technology I can use the advantage of lower entrance dose and no exit dose.

So that's how I think about protons is it's the same as I need to get a certain amount of radiation to the target volume, which is a tumor, and reduce the amount of dose and damage on the

way in and on the way out.

So on a 30,000-foot view, yes, if it could be treated with X-rays, then it could potentially be treated with protons. Saying that, the most common cancers are breast cancer, lung cancer and prostate cancer. They represent half of all cancers in the United States, and next are colorectal, lymphomas and such.

But similarly, that's the same statistics in terms of radiation therapy. Most of us as radiation oncologists, we treat breast, lung and prostate cancer, and it's usually about half our patients or practice, similarly to the volume of the number of patients. So proton therapy does the same. Most of our patients would be breast, lung and prostate cancer.

As Mr. Marckini and Ms. Hickey had mentioned, there's an overwhelming number of patients that are prostate cancer patients that has discovered proton therapy. In expanding what Dr. Moyers was talking about, about the expansion, at the time we were there in the early 'nineties, for us old folks we noticed that's when the Internet started and the ability to do searches on data instead of having to find scientific papers at such. Now

they can look up that.

And we went and, you know, put our data on the Internet and then people saw and found this, like Mr. Marckini and such. And that's how -- part of the expansion.

So in terms of the efficacy, one of the things that we did in the 'nineties is we did an NIH sponsored protocol, a clinical trial with proton therapy and prostate cancer showing that if we give more dose to the tumor, or the prostate which contains the tumor, we would get a higher control rate of the cancer, and showed that. It was a positive study and it was published in the Journal of American Medical Association.

Things like that in terms of efficacy have shown what we know as a truth. I mean, radiation oncology is typically if you give more dose to the cancer cell you tend to control it better.

Similarly to any other medications and things like that, there's a lot to be said that oftentimes giving more dose of the drug or medication tends to get a better efficacy.

And there's plenty of scientific papers out there. We can provide lists and such. It's expanding rapidly by the number of centers that we

have now. The more centers, the more scientific papers -- and that's one of the points I like to bring up is, we intend to be research oriented.

We have participated in clinical trials. We were doing it decades ago. Dr. Chang is part of the clinical trial group. So we are -- just because we're not part of an integrated system doesn't mean we're not clinically, you know, oriented towards clinical trials. We are. We plan to do both clinical and scientific studies.

Does that answer all your questions?

THE HEARING OFFICER: I'll just interject. I just want to make sure that we got the response on the types of cancer that are going to represent the highest percentage of patient volume.

And so I was hearing you -- I heard you say breast, lung and prostate cancer represent half of all cancers in the U.S. and those are probably the ones that most oncologists treat, most in their practices.

And so I guess the question is, would that translate to proton therapy as well, that those are going to be the highest percentages of the types of cancers that you'll treat?

THE WITNESS (Yonemoto): Yes, that's correct. It would be similar to the other, you know, conventional centers that proton therapy will treat those three mostly. And I think that prostate would be the number one, then lung and breast cancer and that's kind of similar to what our practice is.

One big note is that, although pediatric cancers are a small percentage of all overall cancers in the United States, most of the pediatric cancers that get radiation therapy are being steered towards proton therapy, as you know with Dr. Chang's presentation.

That's a very big deal because the extra dose into normal tissue that doesn't have cancer affect children significantly more than adults.

MR. CARNEY: The is Brian Carney.

So Attorney Hardy, I'm not really sure we have this information, but I think it would be helpful for OHS in our analysis if we were to receive a breakdown of the projected volume for the three years by cancer type. I think that would be immensely helpful for us to take a look at.

And I just had one other additional question, too, because the other proposal was a little bit

different as far as prostate goes. Do you know, is prostate covered by commercial health insurance currently for proton therapy?

THE WITNESS (Yonemoto): Sure. I can answer that.

Back when I was treating prostate cancer in the

1990s it's covered by Medicare, CMS, and many

commercial insurers, and it continues to this day.

The difference is, is just the insurance companies have more scrutiny and spending more time on, you know, vetting the applicants in terms of coverage, but that's all -- all modalities of therapy, not just protons.

THE WITNESS (Melson): Excuse me. This is Don Melson.

I want to contribute some information. We did report -- provide you with information about cancer types in our responses to some of your earlier questions.

Our models include 35 percent prostate,
20 percent lung, 15 percent breast, 10 percent
head and neck, and then 5 percent each for central
nervous system, other chest, other pelvis and
other abdominal.

MR. CARNEY: Yes, I think I have that. I think that's just for one year. So if we could get that for the three projected years, that would be great.

MR. HARDY: So I think Mr. Carney, we can. We can put that together and submit it.

MR. CARNEY: Thank you.

MR. WANG: If I might? Just one last follow-up with the new information. This is Roy Wang, OHS.

Would anyone like to add any additional information on the efficacy of proton therapy on those different cancer types that Mr. Melson just mentioned?

THE WITNESS (Yonemoto): Well, I -- I mentioned the prostate cancer, which we wrote we participated in the first clinical trials in '95 to '98. And there's been subsequent trials showing that there's more control with more dose to the prostate.

Dr. Chang mentioned the efficacy with breast cancer. We're not really trying to increase the cure rate, so control rates per se, because it's fairly good control rates of any radiation or proton, but to reduce the side effects, the cardiovascular events that occur from radiating the coronary arteries, and that's very hard to do a randomized protocol to see if that would harm someone.

So we used the commonsense protocol, well, if

we don't treat it, it won't get a side effect type thing. So it's -- the efficacy is difficult to place on a randomized protocol, per se, in -- in that type of scenario.

And for lung cancer, it's -- it's highly evolving. We're getting more into the stereotactic radiation therapy and such, where they're actually putting more dose, and the proton is ideal for that. There are papers out there. We can submit those, but it's rapidly changing. Right?

I hate to start quoting things that may not be, you know, relevant in a year or two.

MR. WANG: Thank you very much.

THE WITNESS (Chang): This -- this is Andrew Chang. I also wanted to also answer a little bit more about that to one of your questions, about the FDA approval.

So as Dr. Yonemoto mentioned, the FDA has approved the use of proton therapy for the treatment of all malignancies, so it's not a concern. One of the things that I would like to point out, though, is I think one of the themes we've been seeing, of those of us who've been working in proton therapy for the last several

decades is the continued expansion and evolution of the use of proton therapy for more and more indications.

And part of that is, as more users of the, in essence, a tool -- proton therapy is just another tool for us as radiation doctors, we find better and better ways of using these tools. And so things that we hadn't thought about before we are starting to use it more frequently.

For instance re-irradiation patients that have had radiation already for one cancer and having a cancer come back in an area, standard radiation, X-ray radiation has a hard time treating it.

And so we're starting to see quite a bit of secondary radiation being preferentially referred to a proton center, because otherwise a standard radiation, X-ray radiation would not be able to treat. And those patients might have been going to hospice, for instance. That we can now say, this is something we can treat. So a growing expansion of indications.

Now that being said, there's also another big expansion that is currently being investigated for noncancerous utilization. Examples of that

include the examination of proton therapy for the treatment of seizure activity in the brain; use of proton therapy for the treatment of heart attack prevention in patients that have abnormal heart conductivity issues.

So for these indications those are noncancerous at all, but are being studied in a few centers that I would say those are not FDA approved because those are being examined -- it could be in five or ten years from now that that suddenly becomes a new standard and becomes FDA approved.

But for the treatment of cancer itself proton therapy has been FDA approved, but there's a whole other set of indications that we're, as a community in the field we're just starting to research as well.

THE HEARING OFFICER: Just for clarification,

Dr. Chang, this proposal doesn't cover those kind

of experimental seizure and the heart attack

prevention types of --

THE WITNESS (Chang): That's correct.

THE HEARING OFFICER: Okay.

THE WITNESS (Chang): I was just saying that. So -but to answering the question about FDA for cancer

it is approved, but there are things that proton therapy is not FDA approved for, and those are experimental and that's not what we're anticipating doing.

THE HEARING OFFICER: Got it. Okay. Any other -THE WITNESS (Boucher): Can I add?

THE HEARING OFFICER: Yes.

THE WITNESS (Boucher): I just wanted to add a simplification, because it's very important. It's about retreatment. What we are seeing in proton therapy -- and I have seen that for the past ten years, increased use of proton at our centers, the centers that I work for -- for retreatment.

A good example is New York proton centers has 41 percent of their treatment that are retreatment, a patient that most likely had no other options of treatment than proton therapy. Some of the centers that have been mentioned in St. Louis that work very closely. Washington University has also about 40 percent of their patients are retreated.

So when you talk about application, these are the application. The retreatment covers a wide range, and most likely 30 to 40 percent of the patients treated will likely need retreatment.

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MR. CARNEY: This is Brian. Just so that means -following conventional radiation therapy as well, that's what you're referring to, the retreatment? THE WITNESS (Boucher): That is correct, yes.

MR. CARNEY: Okay. Thank you.

THE HEARING OFFICER: Okay.

THE WITNESS (Courtney): I just might add that the reason that is, is because with the conventional radiation a lot of healthy tissue has already been impacted. So they can't go back without causing major side effect issues, whereas they can go to proton therapy because those health tissues are now not going to be treated again.

THE HEARING OFFICER: Thank you.

All right. We're going to move on to access to services within the region. And the next question is, according to the application Exhibit C, Bates page 1297, Danbury Proton -- this is a quote, Danbury Proton has no existing referral arrangements with area providers and intends to maintain an open affiliation policy in order to allow for patient referrals from many sources.

The first question with regard to that statement is, describe your expectations for the patient referral process at Danbury Proton Center. MR. HARDY: I think maybe Dr. Yonemoto can speak to an intake process in comparable settings.

THE WITNESS (Yonemoto): Yes, I can. We started this process back at Loma Linda back in the 'nineties where most may -- 90 percent of the patients were outside of our usual referral network within the university. And that was reaching out with the usual ways of information, publishing papers, outreach, things like that.

We helped other centers including the ProCare centers with the same process essentially. It's like any other freestanding center that's not affiliated with an integrated network. We go and reach out to the individual physicians in -- with personal and integrated meetings and such.

We go to the usual community outreaches. We go and obviously do our research and publish our papers. We go and do the usual advertising, you know, to reach the community with the -- nowadays it's the search engine optimization. And it's highly effective.

Just like Mr. Marckini mentioned, once you have information in front of you a lot of people see the benefits like we're presenting today and self refer, and then after initial information

distribution a lot of the physicians self refer -not self refer, but refer patients.

We're not saying we're not going to have providers referring to us. It's just that we won't have the ready base when we first start, but we'll go and work on that, and to build on that referral base.

It's not, we don't have a referral base, or we don't want one. It's just that we'll have to work to build that up, and we have.

THE HEARING OFFICER: Since you were talking about self referrals, this is a great segue into the next question. Because according to the application of the same page, it's Bates page 1297, you anticipate that 60 to 70 percent of patient capacity will come from self referrals.

So can you just talk about how you reached that percentage and how that process works?

THE WITNESS (Yonemoto): Yes. It's mostly based on experience that we had over at Loma Linda and the ProCare centers, and our reaching our colleagues that have similar experiences that are not affiliated with a major center that has already a built-in referral base.

THE HEARING OFFICER: So --

THE WITNESS (Yonemoto): And that's -- oh, excuse me.

THE HEARING OFFICER: No, you keep going. I'm

listening.

THE WITNESS (Yonemoto): And it's fairly well known especially within our proton therapy communities and in our conferences. We discuss this as a part of the strategy of getting this technology and these wonderful treatments to patients, because it is relatively unknown.

It doesn't, you know, have this large notoriety like any other cancer treatments. In fact, radiation therapy is not as well-known as a surgery or chemo. People realize that now you go to the radiation part, and you've got proton.

So -- but once the information is disseminated and reached the patients, that's why these numbers are so high.

And we expect with time, like many centers, that as the -- even as the physician population will start to realize the benefits and then the referral process would be going.

After we realized that radiation oncology is less than 1 percent of the physician population -- so many physicians are not familiar with our specialty. And within the radiation oncology

community, only 1 or 2 percent are proton physicians.

So we even have an educational need for even in our own community. So that's -- that's why communications and outreach is so important, and we do that all the time.

THE HEARING OFFICER: What does a self referral look

like for somebody who's been diagnosed with cancer

and is not coming to you through a referral from

their doctor?

How does that go from start to finish?

THE WITNESS (Yonemoto): Well, we saw this happening long ago at Loma Linda when the Internet was born, or it became popular in the 1995, '96 era, that people started to call in and asking what -- what's -- what is this?

And so we would set up a whole center just like MD Anderson has. It's -- we all have a process that when an inquiry comes in that we process it through a system and protocols to inform the patient of what we have.

We tend to go the extra mile by trying to get information to them immediately, not call in and we'll send a brochure. We tend to try to spend the time and initial call to educate a patient

about cancer radiation therapy, types of radiation, proton therapy, similar to what we're doing today in terms of giving information about why this is something that may be of interest, especially to a patient that's been diagnosed with cancer.

And so the next step would be seeing if they would like to come in for a consult with one of the physicians, or oftentimes an outreach, like, would they like to see, like, Mr. Marckini's book that is extremely helpful for the folks with that. And we have other resource materials that we can send, but we encourage them to come in and see one of the physicians where we can do a consult.

Now the duty of Danbury Proton is they don't have to travel like Mr. Marckini 3,000 miles to do the consult. With a nearby center they can drive to it and then hear about it firsthand, have then a full consult with the radiation oncologist to, you know, determine if this is, you know, appropriate for that patient, and what to expect.

It's a full consult with all the expectations you would have in terms of knowing what the patient's disease is, what their treatments have been and how we can participate in their care.

THE HEARING OFFICER: All right. Out of the 60 -- well, maybe this is an inappropriate question.

Let me just make it broader.

What proportion of self referrals do you expect would be appropriate for treatment?

THE WITNESS (Yonemoto): Well, there's two ways to answer that. One is during the initial contact phase there we can screen patients that may not be proton cases in the first place. Like leukemia is not treated regularly by radiation therapy including proton therapy. So those, we kind of refer them to other centers that may be more appropriate.

So the ones that do show up, the chances that they are appropriate candidates is very high, because we try to discourage people taking the time and effort and expense to see us if we didn't think that they had a cancer that was amenable to proton therapy.

So in terms of percentages, I would say

90 percent of the folks we see typically qualify
because we screen to make sure that they are good
candidates before they show up.

THE HEARING OFFICER: All right.

The next question is, will you charge an

office visit or a consultation fee for
self-referred patients, that 10 to 20 percent that
do eventually come in even if they're not
appropriate for proton therapy?

THE WITNESS (Yonemoto): That I'd would have to maybe get some help on -- I'm not familiar with the billing, but I do know, you know, typically with any physician office including radiation oncology, X-rays, and I assume protons would be -- yes, we do charge an office visit and consultation charge.

And those are fairly set by the insurance company and CMS on their rates and such. You know, that's being a highly regulated industry. Those are pretty well set.

And in fact, I believe we could run into problems if we don't charge or undercharge, or overcharge. There's a lot of parameters that we have to follow. And I'm sorry, I don't know if we could not charge someone. I'd love to, but I -- I don't have that answer.

THE HEARING OFFICER: I guess my question would be, for example, if somebody who's self-referred goes in -- well, even before they go in. Maybe they have a conversation with somebody at the office.

Then they're screened to be possibly appropriate.

So they come in for their consultation, and they're one of that, kind of, 10 or 20 percent of people may be inappropriate for this type of treatment.

I'm just wondering if they're going to be -if their insurance is going to cover it because
they self refer? We all know that there's a lot
of different requirements for insurance companies
to cover for certain types of treatment.

So we're just trying to get an idea of how this is going to affect people in terms of cost and access?

THE WITNESS (Yonemoto): Yes. Actually, thank you for the clarification. Most -- almost all the self-referral patients that I've seen, and typically seen in most practices are covered by the insurance companies, and CMS also.

It's, a lot of times, it's considered a second opinion. So those are typically covered by most insurance companies for -- at least the consultation, because that is something that is done quite frequently -- not just for protons, but for, say, surgery. You want a second opinion with a different surgeon. It's just the same process.

THE HEARING OFFICER: Do people usually seek out this

type of therapy as kind of like a second line of treatment? Because I'm thinking -- if I'm thinking like it's a second opinion, maybe they've been told that they need -- that either they can't be helped or maybe that they're inappropriate for more conventional radiation therapy, and I'm not a professional. I just want to make sure I understand.

THE WITNESS (Yonemoto): Yes. Well, the dynamics I think has changed dramatically in the last two decades because of the access to information, the Internet, social media and all these other ways to communicate information.

And yes, the -- typically most patients have seen another physician before they see us. Mostly the patient says, you know, they would see someone that does the biopsy, either a surgeon or an interventional radiologist. And then they talk to their primary care doctors and such.

And then they would ask what are, you know, what's next? What are my options? And a lot of them will check the social media and the Internet about their options. And if they -- they typically, a lot of them come across proton therapy when they're talking about radiation

therapy. And that's how the majority of the patients come in. That's typical for us.

THE HEARING OFFICER: Do many doctors recommend proton therapy for their patients?

THE WITNESS (Yonemoto): Oh, yes. Yes, they do. They, like I mentioned before, we're only less than 1 percent of the physician population. So they tend to say, well, you need radiation therapy and, we'll let the radiation therapist, or you know, radiation oncologist help determine what type would be best.

And so we're referred to -- some centers have both, you know, protons and conventional. Some will have only conventional. Some will have protons, but if I feel someone needs conventional I will send them to that.

We obviously treat to the -- or recommend what's best for the patient.

THE HEARING OFFICER: Thank you.

Dr. Chang you wanted to say something?

THE WITNESS (Chang): Yeah, I was going to answer some of those specifics, as well as Dr. Yonemoto mentioned with the increasing access to information it unfortunately in one way has made everybody Dr. Google.

So as soon as anybody has anything they'll type in Google, you know, what's the treatment for this? Even if they've been seen by a physician it's rare that a patient will not even look up what condition they have.

And if they find something that they don't -have not been recommended, oftentimes they'll call
up or just send e-mail inquiries as to whether
they're a candidate. That -- that's part of the
reason we often have a first screening just to
rule out patient -- and unfortunately I get calls
like this on a daily basis. People saying, you
know, I've got this cancer. It's spread
everywhere. Can proton help me? The answer is,
unfortunately no.

And -- and that screen just helps patients not waste their resources and time trying to gather medical records, or traveling out to us to get treatments that are not going to be helpful for the overall situation.

But for many more candidates, that referral process then goes through a very regulated -- a system of collecting medical records and interfacing with the physicians.

The reason we've got this built up is

Dr. Yonemoto and I are part of a group of physicians that cover several different radiation facilities, including many proton centers in the United States. So I'm the President for our group, and through that we have a fairly robust insight into how referrals come.

I -- we see thousands of patients every year between all of our centers and we have metrics that break down the numbers of patients that find us through, you know, various search engine optimization, through whether it's Facebook or Google, or Microsoft Bing, or whatever the case may be; versus those who are referred by friends and family, those who come to us through organizations such as the Brotherhood of the Balloon.

And diving into it we believe -- and it's pretty fairly stable throughout all of our centers, that anywhere from 50 to 60 percent of the patients are -- are self referred. Many of them aren't necessarily even from radiation doctors.

One of the most common cancers, or the most common cancer in men in the United States is prostate cancer, and pretty much any patient will

tell you that as soon as they've been diagnosed the first thing they're told is because the diagnosis is by a urologist, they're told they're a surgical candidate and they should have surgery.

It's usually when they go searching themselves, they say, oh, radiation is an option. Then they'll see a radiation doctor whom they contact. At that point they might do more research into radiation because there is a variety of radiation techniques and tools.

And then someone will say, hey. There's also a proton tool, and so will contact a proton center. That's oftentimes how the patients who self refer are someone who's just looking for information for themselves and seeing it as a potential option.

So yes, we certainly have metrics that are able to count on a very granular basis where patients are coming from, referrals from the community, our affiliations with the various healthcare systems that we work with regularly and for each of our centers we have them broken down. And part of that is for our internal reference purposes. Right?

If we see, for instance, that geocaching for

web searches on Google is going to work well for getting people information they need, then we can divert more dollars to education that way.

If we have patients that are being referred quite regularly for second radiation from a healthcare system -- for instance, one of our major centers in San Diego, we get a lot of patients from Orange County. There's several hospitals there that send their patients here.

And so then we'll put on more educational seminars for them to inform the physicians and the community there what the benefits are, and likewise what -- what are not benefits so that those doctors don't call us on odd cases that would not be good patients and not give false hope, unfortunately, to other patients.

So those are all things that we as a group have developed over 20-something years of doing this, and in a variety of centers.

THE HEARING OFFICER: How are self-referral patients

then transitioned? If they're appropriate

candidates for proton therapy how are they then

transitioned for follow-up care after proton

therapy treatment? What happens after that?

THE WITNESS (Chang): It depends on the patient a lot

of times. For most patients who have radiation, regardless if it's proton radiation or X-ray radiation, most patients for followup go back to their primary oncologist, and that's usually the medical oncologist who's giving the chemotherapy.

I describe it to our patients as the medical oncologist is oftentimes the quarterback and they will oversee the entire care. Most radiation patients will come to us back on a yearly basis just for followup making sure that there's no other issues that crop up, but are primarily followed by the medical ecologist.

THE HEARING OFFICER: Is it the same kind of procedure for people who are referred to you by an oncologist?

THE WITNESS (Chang): That's correct.

THE HEARING OFFICER: Okay. I think right now is a good time to actually stop and take a break. It's almost one o'clock.

Before we break, though, I just want to defer to Attorney Hardy and also Leslie Greer. I'm not sure if she's still on, but just to see if there are any public officials that need to make comment.

I'm just going to open up my screen here.

1 Yeah. Thank you. The public officials MR. HARDY: 2 that I'm aware of that intend to speak intend to 3 do it in the --4 THE HEARING OFFICER: Afternoon? 5 MR. HARDY: (unintelligible) -- yeah. 6 THE HEARING OFFICER: So what we'll do now is we are 7 going to take a break from 1 until about 1:45. 8 I'm just going to make the announcement to just 9 make sure that you turn your camera off and your 10 mic off, because we're still going to record. 11 And we'll come back and we'll finish up OHS's 12 questions. And we'll kind of go off so people who 13 want to speak can register at three, and then 14 we'll go into the public comment portion of the 15 hearing. 16 Thanks everybody. 17 18 (Pause: 12:59 p.m. to 1:46 p.m.) 19 20 THE HEARING OFFICER: So we're back on the record. 21 going to go ahead and turn it over to Brian Carney 22 who is going to go through the remainder of the 23 questions. 24 MR. CARNEY: Good afternoon, everybody. We had a good 25 lunch.

So the first question is kind of somewhat related to with those sort of same access of service area. The application, the same page we referred to before, Exhibit C, Bates page 1297, states that, Danbury Proton has initiated discussions with Nuvance Health towards a potential association for patient referrals from its Connecticut and New York-based facilities.

So my question is, what progress has been made, if any, with Nuvance in regard to this potential association?

MR. HARDY: Good afternoon. I think Steve Courtney may be the right starting point for that.

THE WITNESS (Courtney): Actually Drew Crandall might
be the better response, but we a in conversation
with him. He's had the most recent conversations
with them just before, you know, a couple of weeks
ago when we were preparing for this organization
to see if they were ready to make, you know, a
definitive conversation about things.

They continue expressing interests, much as we get from everyone. We did get a bit more from them at ECHN. Their president of their cancer program actually provided a support, as you may have seen.

We're also in conversations, from an economic point of view, with the New York Medical College in Valhalla. The chancellor there reached out to us. We didn't reach out to him -- and very interested with working with their -- them in placing, you know, residents at our facility which is -- which will be nice as well.

Again what we anticipate -- and Dr. Yonemoto has referred to this as well as Dr. Chang many times, is once -- once the market knows that's there, that you're real, you have a CON approval, you've broken ground, there will be all kinds of interests in performing associations, if you will.

We -- we are going to steadfastly avoid anything that ties us up, if you will, that that makes us exclusive to any healthcare system, because again we're there to treat the region and we do not want to exclude anyone from any facility. Whether they're private physicians or tied into hospital practices, we want to be available for all.

MR. CARNEY: Okay. Thank you.

The next one I think I pretty much know the answer, but I'll just ask anyways. I don't think you're currently affiliated with any research

facility or medical school within Connecticut at this time?

THE WITNESS (Courtney): No, we -- we have not. We certainly intend to speak to UConn. I -- I've actually been remiss a bit in that. Nancy Wyman is a close friend and I know she has very stong connections there as well, and that will be of interest to the kind of research we're looking at.

The medical college in New York is obviously interested in that research connection as well.

And frankly, every patient that comes into our facility, we'll be asking them if they're interested in being part of a clinical trial.

The more data we can gather from our patients as -- as they come back over the years is very, very instructional. Just like Bob not having to go to his urologist, we actually encourage them to at least keep -- keep in touch with the doc that cured them of their -- of their cancer once in a while. And particularly if they're on clinical trial that follow-up treatment is very, very important so that we can take down that data, particularly that quality of life data that we think is so important.

MR. CARNEY: Okay. And just finally, you did mention

another, another health system has reached out to you in the form of ECHN.

How about individual physician providers in the area? Do you have any ongoing, sort of you know, relationships with the existing physicians in the Danbury area?

THE WITNESS (Courtney): We have not reached out. The Independent Physicians Association in Connecticut is 7,000 members strong. It's one of the reasons why we have a hefty marketing budget in our project, because we plan to actually visit as many of those independent physicians as we can.

Obviously, not all of them are oriented towards radiation oncology, but a good number are. And so those independent practices will be very important to us, and important to them as well.

MR. CARNEY: Okay. Very good. Thank you. My next question is sort of related to financial feasibility. So I'll begin.

The proposal has a capital expenditure in excess of \$80 million. Explain how the proposal will be funded? I guess we'll start with that.

I've got some sub questions, too. But --

MR. HARDY: Dave, you want to jump in on that one?
You're muted, Steve.

THE WITNESS (Coma): And that was such a brilliant insight before I unmuted such.

The planned financing mechanism is to use taxes on debt, which there's substantial precedent with that with some of the other facilities and in our markets generally.

The municipal market, as you guys probably well know, specializes in a public-private partnership and, you know, facilities that are primarily for the public good. And so market investors are well versed in projects like this and this technology.

Basically we would -- we would do a couple things. We would prepare an offering statement and then market to institutional investors, many of which you've heard of, Nuveen, Invesco, Franklin, Pacific Investment Management; all have been investors in similar type facilities.

And then project participants are also planning on contributing. Mevion, for -- for instance, and some of the other project participants will also be purchasing debt that will take a subordinate position in -- in the transaction. And the expectation is the combination of the institutional investors with

the -- with the largest part -- portion of the offering and then the subordinate investors will provide a hundred percent financing for the transaction.

MR. CARNEY: Would those institutional investors represent private equity investors?

Is that the same?

THE WITNESS (Coma): It's typically not private equity.

It's institutional investors that have big

municipal mutual funds. So Nuveen would be a good

example. So they have a big tax exempt -- many

tax-exempt mutual funds, high-yield. So for

unrated transactions all the way through, you

know, very high investment grade.

And there are a number of institutions like that, so -- and we market just to the institution. We would not sell this to individual retail investors just given the, you know, the initial risk of the transaction that's not investment-grade.

But the institutional investors, like I said, have extensive experience in similar transactions. There's about, you know, by our count ten other facilities, ten other proton centers have been financed using the tax-to-debt markets.

And then many, many hospitals, senior living facilities; we just did a financing in the fall for a series of AIDS clinics. So the market is familiar with these types of transactions, and the risks -- and are, you know, very good at evaluating the strength of the -- of the transaction and the investment.

MR. CARNEY: Okay. So if I'm clear, there's no private individual investors that are part of the 8-million-dollar funding?

THE WITNESS (Coma): Correct.

MR. CARNEY: And the institutional investors that you're talking about are not lined up just yet.

Right?

THE WITNESS (Coma): Correct. We've introduced them to the project -- the process just to, you know, as we would prepare, you know, an official offering document. Counsel helps prepare that and it contains, you know, another voluminous description of the project, description of the -- of the actual bonds that we're going to sell.

And then it would be the -- the feasibility study would be incorporated as part of that. So they could review financial projections and the -- and the third party, third-party's view of the

1 transaction. And then we present that to 2 investors and then they make an investment 3 decision once they've had the opportunity to 4 review that, that. 5 THE REPORTER: Could that last speaker identify 6 themself? I'm sorry. I just have Steve on the 7 screen. 8 THE WITNESS (Coma): Sure. Last name is Coma, C-o-m-a. 9 And I'm with Hilltop Securities. 10 MR. CARNEY: So that, just the 80 million would be 11 split up amongst different institutional 12 investors, more or less? 13 THE WITNESS (Coma): Exactly right. Yeah, exactly 14 right. 15 MR. CARNEY: Okay. All right. Thank you very much. 16 The next question I have relates to cost 17 effectiveness. Bates OHS page 15 of the prefiled 18 testimony states that, although the initial 19 expense of proton radiation therapy is currently 20 more than comparable to photon radiation therapy, 21 that expense is offset by long-term savings 22 associated with fewer side effects and 23 quality-of-life impacts for the patients receiving 24 it.

So my question is, have there been any sort

of financial studies that have been completed that have been able to quantify these long-term cost savings? I mean, it makes sense that, you know, with fewer side effects and, you know, not getting some other type of cancer could potentially lower, you know, overall costs or long term.

But are there any particular studies that have actually quantified a number to provide, like, hard evidence of that, of that amount?

THE WITNESS (Courtney): I'm not certain where to start that, that response because all of us are attuned to that in some fashion or another. My initial though was maybe to get Deb to respond, because she had done such a nice job of looking at that particular piece and had also submitted some more recent studies for that in this lattice -- latest submission that we gave to you.

The biggest trick there is time, because the -- we need, you know, 10, 15 years, you know, to see what those side effects might be causing problems for. The immediate short-term things are more clear, but the long-term ones are -- are you need to wait, and those studies are -- are in process.

We -- we do know that the younger you are the

more important it is, because if you have cancer when you're 40 and you're cured of your cancer, you don't want your -- your cure mode to impact you, you know, 20 years down. You're still a young person at 60.

So the younger you are the more important it is that really you avoid that excess radiation, what we call radiation pollution. It's, you know, it's just -- it's just radiation that's not doing you any good. As a matter of fact, it can only hurt you.

But there are studies and we can point to the ones that are ongoing. I can't remember specifically if the -- the more recent studies that we sent to you which were about 215 -- because these, these are ongoing. They keep coming. You know, every week we get a new one.

And so -- and in all of them, none of them point to the fact that the alternative methods are going to be less expensive. It's definitely with proton. And again, with the advent of hypofractionation and actually being able to take the number of treatments for, say, prostate that -- which is normally around 44. And if you can cut that in half, all the sudden you can treat

two patients in the amount of time that you used to treat one patient. So obviously the costs come down for treatment.

And in conventional radiation you have -- you have no option for hypofractionation because it just -- it treats too much healthy tissue coming in and out, but because we can limit where the radiation is on protons. I can increase that dosage and shorten the period of time for treating and not hurt healthy tissue.

THE WITNESS (Chang): This is Dr. Chang. I was going to add that probably one of the strongest studies that specifically looked at the financial impact came from the MD Anderson group that is currently at the University of Texas. And they made a proposal to the University of Texas healthcare system -- which has about 130,000 employees there -- to say, allow us to treat with proton therapy and do case cost analysis for the entire case of treatment with the patients that are treated with protons.

And so specifically in this particular case I was looking at head and neck cancer, as this is Dr. Frank's primary area of treatment. And in doing so over a period of April of 2016, for the

next three years they tracked the numbers of patients they were able to treat with protons compared to their equivalent patients that were treated with X-rays.

And in that time period they did see a total cost savings in just that three years -- so we're not talking about long terms, but in those three years of patients that were treated with protons, having a lower overall cost by 21 percent.

When they looked at the amount of money that was spent on additional visits to the emergency room, pain control, the need of placement of a feeding tube as compared to half of those that did not need placement of a feeding tube. And because of those cost savings the University of Texas system has now approved that all patients that would qualify for proton therapy for head and neck cancers will get treatment with protons.

If I'm able to share a screen, I'm happy to show the slides that he presented and showed these cost savings were, just in that three-year period, accurate.

MR. CARNEY: Yeah. I mean, maybe. Maybe you could share that with us, Dr. Chang, like, as a late file? Or would that be possible?

THE HEARING OFFICER: Yeah. What I was going to suggest is, so at the end what we generally do is we have a discussion with counsel to determine whether or not there should be late files submitted. So it may be one of a few late files that we're going to ask for.

And so if there's just like a short summary that you could provide in addition to the study, it would be helpful to us.

THE WITNESS (Chang): Okay. Yeah. It's just -- it's like five slides here, and then he broke -- breaks it down by the costs from these various different areas, aside from the radiation; the emergency room visits, the internal medicine visits, the laboratory tests, the pharmacy and diagnostic imaging.

And when all calculated, it was savings if you accounted for all the extra visits that were saved from not going to the emergency room, not needing pain medications, not needing a feeding tube placed.

So I'll send those over to you.

THE HEARING OFFICER: Thank you, Dr. Chang.

THE WITNESS (Chang): You're welcome.

MR. CARNEY: All right. My next question is actually

for Mr. Courtney based on his prefiled testimony.

Mr. Courtney, on page 89 you state that, assuming both treatments rooms are approved it will prevent a state monopoly for the service, which when combined with billing transparency will serve to keep healthcare costs down in Connecticut and likely improve competitive quality for patients.

elaborate on your statement and specifically address how two new proton therapy facilities combined with billing transparency would serve to help keep healthcare costs down in Connecticut?

THE WITNESS (Courtney): Certainly. Well, as you know throughout the healthcare industry transparency has become a crucial element, and there's lots of hope for that -- although so far the customer, if you will, the patient has not responded significantly to the information that has been made available.

So that the transparency piece is -- is, I think, to some extent a hope that patients respond to that. More often they respond to other considerations than, you know, with somebody's treatment being \$5,000 less than someone else's.

But I do think over time those, that transparency consideration will make -- make a difference.

In terms of monopolies are not -- there's just a capitalistic commonsense notion there that if there is just one facility in the state there's not a lot of control over what -- what might happen there.

Massachusetts has a case in point. MGH charges an arm and a leg, frankly, for the treatments that they -- they give there. And they have absolutely no motivation to change that in any fashion. There's no competition to MGH, and politically they've been able to keep others out.

So it's -- that's -- that's something that not only contributes to the cost of the facility, but we think it will impact the quality as well. You know, more and more patients are asking, you know, what were the results?

Well, how did you do? You know? You know, on your prostate cancer how did they do? Your breast cancer, how many of your patients did well and how many didn't? And we think that kind of transparency might be more significant than price transparency.

MR. CARNEY: And just one quick followup. So would the

approval of both proposals lead to any direct reduction in the cost for proton therapy services? And if you think so, explain how that would occur? Or would it be more of a limiting of increases?

THE WITNESS (Courtney): These, these services are negotiated with the Medicare provider, if you will, the -- and I would expect that they will have very similar pricing structures.

But it's certainly -- if we didn't have two facilities there would be less energy around having those numbers be as reasonable as possible.

The same thing with the commercial carriers as well.

MR. CARNEY: All right. Thank you very much.

That's all the questions that I have.

THE HEARING OFFICER: I think I had a couple of followup questions, but I just wanted to ask some of them. You all did answer, but I just want to go back and make sure that I got everything.

So I just want to understand for the record.

If proton therapy -- I think somebody said there
was 41 percent retreatment of patients in proton
therapy, and I'm just trying to understand if this
is a type of therapy that is routinely offered to
patients as a first kind of line of defense when

somebody gets a diagnosis of cancer, for the cancer types that you all are anticipating will be treated.

THE WITNESS (Yonemoto): (Unintelligible.)

THE REPORTER: This is the Court Reporter. I've got some feedback here.

THE HEARING OFFICER: Okay. I think it's me. I'm going to mute myself. I see Dr. Yonemoto is going to answer.

THE WITNESS (Yonemoto): There we go. Thank you.

Most re-treatments is now, by definition, after prior radiation, therapy and retreatment means in the same area that was given radiation before either with X-rays of protons.

And when they retreat -- the normal tissue, what we call, remembers the prior treatment and the side effects go up accordingly like it -- that's what kind of restricts us in terms of how much radiation we give in the first place. If we give additional there's more chance of an increased severity and incidence of side effects. Using protons reduces that.

It's typically not something you initially talk to patients about when you first see them.

You just say, let's just try to get this cured or

controlled in the first place. And then the referral back, or if you're following them and you see that the disease hasn't been controlled, or a new site of cancer or a different cancer in the same area occurs, then we approach them about being part of the multidisciplinary team of medical oncology with chemo; we'll have the surgical colleagues and radiation.

And we tend to use protons for that because whenever you do a retreatment it's more complex and more fraught with side effects, and try to minimize that. So yes, we don't mention at the beginning. We do mention if it reoccurs or another cancer occurs in the same area.

THE WITNESS (Chang): I wanted to clarify what

Dr. Yonemoto is saying, is that's a specific

reference to reradiation.

But if -- I understand your question as well, as aside from those patients, is proton therapy also a first-line treatment for cancer? And it is, yes. It is also a first-line treatment. But for those who did not get it or for those who have had cancer come back, it can -- at that point it becomes the last line treatment because of its precision, but that precision also makes it a very

good first-line treatment for those who have access to it.

THE HEARING OFFICER: Thank you both.

I think this question is actually for you,
Dr. Chang. You were talking about the UK actually
sending patients here. Can you tell me for what
time period that was occurring, or if that's
something that's still occurring and why that
happens?

THE WITNESS (Chang): Sure. So the UK being a system that recognizes that any long-term side effects caused by treatment is something that the society is going to, in essence, pay for literally with a national healthcare system for the entirety of the patient's life.

Their timeframe is much longer than that of the typical patient in the United States where unfortunately if someone who is 60 years old and has a side effect in five years, that commercial insurer is not paying for that side effect and it becomes a Medicare taxpayer responsibility at the time.

Before the United Kingdom any patient that has any side effect at any time point the entire system pays for it. And so they're very much

focused on that specific question, what is the -not only the quality of life for the patient, but
what is the financial cost throughout the system?

And as such they recognize that at the very beginning the greatest benefit are those in the pediatric population, because if cured of cancer that's decades worth of side effects that can be avoided.

And so realizing that, they started saying that we are going to identify patients that are going to benefit most from proton therapy and start sending them to places that can provide that treatment for them.

And so initially the first patients that
were -- this program was instituted was, I
think -- I believe in two thousand and -- I think
2010 or '11, with a very specific area of
diagnosis, particularly brain tumors under -- in
patients under ten years of age. And every year
they would add to that and grow the indications
and their program was able to grow and support it.

At first those patients were sent to Paris
where the closest proton center was, but because
of cultural differences and language and stuff
they realized it was easier to send to the United

States where the culture background and language was easier on the patients that were traveling.

And so they started sending them out to us.

In that time period the United Kingdom was also planning to build their own proton centers, but because of the, again, time in planning and developing these centers, not to mention the physical limitations of London and Manchester, and just securing a site that could build the center, it took them many years.

The plan was always that they would help provide that treatment to the patients in the United States until such time that those centers were built in the United Kingdom themselves. And so they started the first center in Manchester at the Christie Hospital -- I believe it was 2018 or '19. With the COVID years, the years are blending together now. I can't remember exactly when it was, but until about 2018 or '19 those patients then were -- started being able to be treated back at home instead -- in essence and not having to transplant their families.

So it was between about 2010 or '11 when it first started for six and a half, seven years.

That numbers -- grew until the last portions of

2 3

the years. So about 120 patients per year they're sending out to the United States, and now that's substantially decreased now that they have their -- their first center in Manchester.

There's still a few that come out. I -- I've actually got a patient right now from the United Kingdom with me in San Diego that I treated a few years ago that they can't get treatment still. So they're out here with me. And then a few patients, for instance, from Poland that are out here, as Poland is looking at building their centers. The same with Australia, but it takes many years.

The system initially was set to say, let's find out the patients that will benefit greatest, meanwhile their physicians at home are able to learn the indications that are benefiting most for those patients and training their doctors, and their doctors came to the United States, and their physicists came out to -- to get training in it such that when their system has now opened they're able to keep those patients at home.

THE HEARING OFFICER: Thank you.

THE WITNESS (Yonemoto): My note, too, in that context,

Michaela, that Canada's does not have its own

1 facility. And so they are sending their patients 2 here as well. 3 THE HEARING OFFICER: Thank you. 4 All right. The next question is for 5 Mr. Crandall. Mr. Crandall, in your testimony you 6 quoted that you talked to 25 men -- I quess in 7 the, I don't want to assume northeastern area of 8 the U.S. Is in northeastern? 9 THE WITNESS (Crandall): Yes, it is. The 25 letters of 10 support are posted on our website on the results 11 page. 12 THE HEARING OFFICER: How did you arrive at the 13 average 1,343 miles each way to travel for proton 14 therapy? Only -- I'm asking that only because I 15 know there's therapy centers in Massachusetts and 16 New York. How did you get --17 THE WITNESS (Crandall): Sure. 18 THE HEARING OFFICER: Basically let me just be more 19 precise. Over what period of time were they 20 seeking treatment, because that might also be 21 relevant? And then just your methodology that I 22 know will help me? 23 THE WITNESS (Crandall): Sure. I went through all 25 24 letters, and I looked at their hometowns and where 25 they're sending them for proton therapy. And then

I went on Google maps and typed in their home and the location of the proton therapy facility.

And that's how I got all the numbers. So it's like something like over 33,000 miles divided by 25, and that's how I get 1343.

THE REPORTER: I'm having real difficulty getting those numbers. I'm getting a lot of feedback. This is the Court Reporter.

THE HEARING OFFICER: I'm going to ask if you wouldn't mind repeating, Mr. Crandall. I'm going to mute myself because it seems like maybe it's my computer, so.

THE WITNESS (Crandall): Sure. What I did is I looked at each of the 25 letters of support and the men gave us their hometown and state. So then I started where they went for proton therapy, and I went on Google maps for all 25 of those letters of support. I typed in their hometown and then the city where they had proton therapy. That gave me a one-way trip to the -- the proton therapy center.

And so I -- I calculated all 25 men, how -- how many miles they went to get their therapy, and it was something like 33,000 miles altogether divided by 25 equal to 1,343 average.

1 The actual distances they traveled ranged from 20 miles to 3,000 miles, but the average over 2 3 the 25 men was 1,343. 4 THE HEARING OFFICER: Do you know from what time period 5 they accessed treatment? Did that also vary? 6 THE WITNESS (Crandall): Well, there their number of 7 treatments fluctuated, so their lengths of stay 8 out of town varied, but other than that I didn't 9 actually compile the timelines. I was more 10 interested in the -- the travel distance. 11 THE HEARING OFFICER: I don't want to make an 12 assumption. I'm not sure if I have this right. 13 And I'm thinking Mr. Marckini was one of them? 14 THE WITNESS (Crandall): Yes. Yeah. 15 THE HEARING OFFICER: All right. And I just don't know 16 if Mr. Marckini is still here, but I think he said 17 he was treated about 20 years? 18 THE WITNESS (Crandall): Correct. 19 Now in those letters of support I think most 20 of the men gave me the year they had treatment. 21 So if it would be helpful to you I can re-crunch 22 the numbers based on, you know, any of the men who 23 shared letters of support where their therapy was 24 the past five years or ten years. 25 If you would like me to that, I would be

1 happy to. 2 THE HEARING OFFICER: So what I'll do after we go 3 through all of the questions -- which is pretty --I only have a couple more. I'm just going to 4 5 confer what the team and we'll circle back and see 6 what we need. And then we'll talk to Attorney Hardy about it. 7 8 THE WITNESS (Crandall): Sure. 9 THE HEARING OFFICER: Thank you, though, for your 10 responses. 11 THE WITNESS (Crandall): You're welcome. 12 THE HEARING OFFICER: All right. Let me see what else 13 I have. 14 I just want to make sure -- the Court 15 Reporter, can you hear everything well? I am not 16 muted, so I just want to make sure you're hearing 17 me okay. 18 THE REPORTER: I hear you well -- but I believe you 19 were right. I was getting a lot of feedback when 20 you had you microphone on. 21 THE HEARING OFFICER: All right. 22 THE REPORTER: I'm getting it now, as a matter of fact. 23 THE HEARING OFFICER: I'm going to mute right now until 24 I get to the next question. 25 THE WITNESS (Courtney): Attorney Mitchell, while

you're doing that I can certainly add something to the miles question in terms of distance. I think what you'll find is there are a significant distances that had to be traveled early on in proton therapy, and it's certainly not that kind of average now.

I think a more accurate representation of that is a study that we included in our initial package to -- to your board from St. Louis which talked about -- and they tracked very precisely the distances patients traveled to -- to access, not only their proton services, but their photon services.

And the average treatment -- or the average distance people would travel to St. Louis in this case, and again, there were not a bunch of facilities around that they had a choice about -- was 87 miles.

THE HEARING OFFICER: Thank you. So this is just kind of a clarification question for Mr. Melson.

Mr. Melson, were you able to hear me well?

For some reason it flashed on my screen that I was muted.

THE WITNESS (Melson): No, I can hear you.

THE HEARING OFFICER: Okay. Perfect. So the question

that I have, it goes towards your statement about insurance coverage about the initial coverage of proton therapy in 1988, and then the fact that insurance companies weren't covering it as much, and now they're increasingly covering it.

Are you able to quantify how, how this change occurred in terms of the numbers, in terms of how it's increasing? Because that can be just a little. It can be a lot. I'm just trying to get an idea of how insurance companies are looking at this type of treatment, and how they're evaluating it.

THE WITNESS (Melson): Well first of all, I have to say that I'm not an expert in insurance coverage.

That said, I have done research on the subject -- and you can tell. This is on the Internet -- that if you look at various Insurance programs and the types of -- of radiation, proton radiation that is covered fluctuates, you know, from company to company to company. And that was just with several large insurers and I think one of them was Aetna.

In addition there was a lawsuit brought in nine -- 2019 against United Health which opened the way to coverage for proton. And there have

been several States, Virginia and a couple of
others which have actually legislated their
preference to use protons in -- in the appropriate
cases.

Does that help?

THE HEARING OFFICER: Yes, thank you.

THE WITNESS (Boucher): I might be able to add -- this
is Lionel Boucher -- to add a little more
information as it relates to Medicare and Medicare
administrative contractors.

So Medicare coverage is managed by the Medicare ministry -- administrative contractors, and when they started, they've been covering proton therapy since 2001. I lot of these Medicare administrative contractors who come back had local coverage determinations for proton therapy, and what we have seen over the past five to eight years is see these local coverage examinations expanding the coverage of proton therapy.

We'll see also -- we have seen also some of the local coverage examinations being removed, giving access to proton therapy to Medicare patients based on the physician's -- physician's need, or the patient need based on the physician. 1 | 2 | 3 | 4 | 5 | 6 | 7 |

So we are seeing -- we have continued to see this evolution of the Medicare case. We see that also in private payer. Recently one of the private payer just assists on that, in covering -- coverage for the -- now I apologize. I don't remember which one it was -- but coverage for either case or level, and we can provide that.

So we are seeing this increased coverage indication definitely on the Medicare case, but also in the private case.

THE HEARING OFFICER: Thank you.

Just one last question for you all, and it goes back to Mr. Boucher about -- it goes back to your testimony. And during your testimony you kind of give us an overview of the development of compact proton therapy, and you were talking about the number of proton therapy centers.

I think that we're up to, I want to say, 41 in the U.S. at this time. And you said that the development of this has been very successful. And I just want you to talk to me about what you mean when you talk about it being successful.

How do you quantify success?

THE WITNESS (Boucher): Well -- you may want to mute yourself.

So the success for me is always first from a clinical standpoint, and I can make this statement based on publications that have been published based on the increased numbers of institutions joining the multi-institutional registry that exists. So increased numbers of all of these institutions, increased numbers of patients receiving proton therapy. And I see that when I travel, and I see pediatric patients being treating like other patients. And I see that when they do have customers.

I see that when I talk to physicians about technology, that are telling me, like, I mean, proton has changed a lot of the way I'm managing these patients. I feel like at least 25 percent of the patients I've seen can benefit from proton therapy.

So I -- I quantify that, the qualifications is first for a clinical standpoint, and also after the number of publications that have significantly increased.

For the financial standpoint it's, you know, we have seen several large proton centers multiroom -- 200 million, 250, 300 million in those going through refinance. None of them have

ceased operations. There's only one center that ceased operation, but not from a financial standpoint. So that's the University of Indiana. It's -- it's for other reasons, because of technology.

But none of the centers have -- have ceased operations, but they went for refinance because they were -- their operation was being drained down, or brought down by the heavy investment that they had put in the payments.

So refinancing, none of the single-room centers have required refinancing. So today we have 20 to 30 proton centers; 20 -- 15 to 20 are single room, and none of these single-room compact centers require refinancing.

The success is really, for me, in looking at how proton centers, compact proton centers are operating from a financial standpoint, and none of them have required funds.

THE HEARING OFFICER: Thank you. I don't think I have any other questions. I'm going to ask Brian and Roy if you have any follow-up questions that maybe I might have missed?

MR. WANG: I do not.

THE HEARING OFFICER: Okay. So what we'll do now,

Attorney Hardy, if there's nothing else that you want to present, what we'll do is I'm going to have a conversation with Brian and Roy offline, and we'll talk about some possible late-file documents that we'll request from you.

I think that we can go off the record until about four when we take public comment. And at

I think that we can go off the record until about four when we take public comment. And at that time when we go back on the record we'll just talk about some of the documents that we're going to require and we'll figure out the time constraints for them.

Let me just ask you, is there anybody that you want to have give public comment or any additional testimony that you would like us to hear before we go off?

- MR. HARDY: So we don't have any additional testimony.

 I was able to (unintelligible) video.
- 18 THE HEARING OFFICER: Oh, okay.

- 19 MR. HARDY: It's a minute twenty.
- 20 | THE HEARING OFFICER: That's fine.
- THE REPORTER: I'm having difficulty understanding the speakers.
 - MR. HARDY: If you give me (unintelligible) play that.

 So that's all we have by way of testimony and we are aware that (unintelligible) tend to make

1 public comment later this afternoon. 2 MR. CARNEY: Okay. Attorney Hardy, you should be all 3 set. 4 THE HEARING OFFICER: Before you start sharing, I just 5 want to make sure I've got it right that, Aubrey 6 and Grace Eline are going to testify first? MR. HARDY: Yes. Thank you. So (unintelligible) line 7 8 them up to be ready to go (unintelligible). THE HEARING OFFICER: Okay. All right. I'm going to 9 10 mute myself. 11 THE REPORTER: Are we off the record? 12 THE HEARING OFFICER: We're not off the record yet, no. 13 THE WITNESS (Courtney): I can't hear the music that is 14 with it, but that's okay. 15 Here we take the roof off the building. You 16 can take a peek inside. You can see the CT sim as 17 well as the Mevion gantry. 18 We put the roof back on and then we peel away 19 the earth here, we cut the building in half. 20 Then we go into X-ray view which shows all 21 the internal systems, the mechanical/electrical 22 systems. All the construction documents are ready 23 for this. We can actually start construction next 24 week. 25 And that's our all-important evening view.

THE HEARING OFFICER: Mr. Courtney, thank you for narrating for us. Appreciate that.

All right. So at this time I'm going to double check. Attorney Hardy, anything else that you want us to know before we go off?

MR. HARDY: No, just in terms of when we go over the late-file information. I would like to note that we would like to supplement the record.

THE HEARING OFFICER: Oh, okay. Sounds good. All right. So we're going to go off the record until four o'clock.

(Pause: 2:32 p.m. to 4:01 p.m.)

THE HEARING OFFICER: All right. So we are going to go back on the record. My name is Michaela Mitchell.

I'm the Hearing Officer in this matter. I just want to take care of some administrative stuff with Attorney Hardy before we get to the public comment, and then we can go ahead and proceed with that.

So Attorney Hardy, there are two late files that we are going to be requesting from you, and once I tell you what they are you can let me know how much time you need.

So we're interested in seeing the study that Dr. Chang cited. It was a Texas study regarding the cost savings for the use of proton therapy versus more conventional therapies. And then just kind of like a brief summary of results. It doesn't have to be that long, just summarizing the points that he was making with regard to the slides.

And then in addition to that, the second item that we wanted you to produce for us is a breakdown of projected volumes for years 2023, 2024, and 2025 by cancer type. So when you provide the volumes just make sure that you provide the methodology, or you have your clients provide the methodology that they use to actually arrive at those numbers.

And then the last two things that I wanted to mention before you tell me how much time you might need is, I wanted to take administrative notice of our APCD, which is our all payer claims database that allows us to take a look at data, at claims data regarding certain services in the state.

I don't know that we will absolutely use it, but if there's anything that we use in the decision we'll make sure that we present it to you

and give you an opportunity to comment on it beforehand. So I wanted to take administrative notice of that.

And also wanted to administratively notice the Connecticut Proton Therapy Center application which is 19-3239 CON.

So Attorney Hardy, do you know about how long

about it might take for you to produce this information? Do you need a week or two?

MR. HARDY: Yeah. Thank you, Attorney Mitchell. We can provide the requested materials by next Friday, which is April 9th. We certainly have no issue with the matters that you wish to take administrative notice of, as you indicated.

We would like to file a written response to the letter submitted as public comment by Yale New Haven Health and Hartford Health, which we will include with our April 9th filing.

THE HEARING OFFICER: Okay.

MR. HARDY: And I wanted to thank you and your staff for accommodating us today particularly with regard to the slides this morning. That was very helpful, and so thank you for that.

THE HEARING OFFICER: No problem. So I think we're all set. We're going to get everything by April 9.

If you need an extension, let me know.

And then I was wondering about a thing that I thought that I needed -- but I think we're all set. I'll remember it if there's anything that I need to and before we go off the record.

So I just wanted to make a brief comment about how we're going to proceed with the public portion of the hearing.

So we'll call the names in order of how people signed up, or how people registered. If we miss anyone, please utilize the raise-hand function. It's our practice to let administrative -- not administrative, to let administrative officials and public officials go first.

So we have three that are on the list, and I'll actually read the entire list so that if there's anybody that we missed that's here that wants to speak, I just want you to utilize the raise-hand function and we will get to you and make sure that you get on our list.

The speaking time is going to be limited to three minutes. Don't be dismayed if we stop you prior to the conclusion of your statements. I'll give you a warning to let you summarize. We just

want to make sure that we give everybody the opportunity to speak, and we want to make sure that we're fair so that everybody gets the same amount of time.

Additionally, we strongly encourage people to submit any further written comments to us either by e-mail or mail no later than -- we're going to go to April 8th of 2021.

Actually, you know what? I'm going to change that. We're going to go to April 9th of 2021, because we're going keep it open anyway to receive additional information from the Applicants. So if anyone wants to submit any written comments they can do so.

Our e-mail address is C-O-N -- like certificate of need -- it's CONcomment@CT.gov. So you can send those in to us. Again, our contact information is on our website. If you need to take a look at that we're also going to also post the recording on the website. The recording and the transcript are going to include all public comments.

I just want to thank everyone in advance for taking time to be here today and for your cooperation.

Everyone should make sure that all of their devices are muted while other people are speaking. If not, I may have to go in and mute you. But if you're having any problems just make sure that you utilize the raise-hand function. I will acknowledge you as soon as I can.

So the list that I have is as follows. I have -- please forgive me and also feel free to correct me if I mispronounce your name, but I have Mayor Cavo, Representative Callahan, Senator Kushner, Aubrey Eline, Grace Eline -- Brad, and I think it's G-U-T-E, Gute. Marshall Rankowitz, Rich Obarowski.

I believe that this is Mr. McInerney. And then I have Dr. Salner, Dr. Andy Salner.

Is there anybody else that I have missed that's not on the list? Please utilize the raise-hand function.

I see Ken -- got it. Representative -- is it Gucker? Is that how you say it?

You can unmute yourself.

- MICHAEL RELL: I can say Representative Gucker will be joining shortly.
- 24 THE HEARING OFFICER: Okay.

MICHAEL RELL: He is in another meeting right now. He

just sent a message that he will be joining.

THE HEARING OFFICER: Thank you.

So I'll have him go, if he's here, after Senator Kushner.

All right. So we will go ahead and get started with Mayor Cavo.

MAYOR JOSEPH M. CAVO: Thank you, Michaela. I appreciate that. And good afternoon, ladies and gentlemen. And it's my pleasure to be here today to testify on the certificate of need for Danbury Proton.

Distinguished members of the Office of Health Strategy, and Hearing Officer, it is my pleasure to testify today in support of Danbury Proton's certificate of need application. The proposed Danbury Proton technologically advanced facility will establish, not only the City of Danbury, but also the State of Connecticut as pioneers in the healthcare industry.

Countless people will benefit from this endeavor both directly and indirectly including residents of Danbury and the Greater Danbury region, and the best of all, the patients from the Northeast who will have easy access to the revolutionary conceivably life-changing and

life-saving proton therapy.

It is our anticipation that the Danbury
Proton will be a world-class top-rate facility
that will have significant short and long-term
economic research and development, and academic
benefits. Given this opportunity, if approved,
Danbury Proton will be a leader in the field of
computed tomography.

This state of the art facility will bring good paying construction jobs and employ over 30 permanent medical and administrative professionals. We also expect countless opportunities for local vendors and an important addition to our property tax revenue.

The city of Danbury has long been the home to various esteemed healthcare facilities. We proudly support the healthcare industry, and we're excited to welcome Danbury Proton as a new part of our business and medical family.

I admire the Danbury Proton team's good and noble mission, as well as their vision and perseverance to Connecticut's cancer patients and their families who too often struggle to find cutting-edge technology close to home.

I applaud and fully support Danbury Proton's

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vision, and I urge you to do the same by approving the Danbury Proton certificate of need application, and I thank you for your time.

THE HEARING OFFICER: Thank you, Mayor Cavo. I appreciate your comments.

We're going to move on next to Representative Callahan.

REP. PATRICK CALLAHAN: Thank you, Michaela and thank you to the members of the Office of Health Strategy for allowing me to speak today. I've been on the other side of the Zoom hearings for many weeks now, as Senator Kushner has, where we're usually the questioners and not the testifiers -- but having read through and researched all the information regarding Danbury Proton, I'm certainly happy to come here today to support their application for the certificate of need.

It's a great location -- as you know, the next closest facility is Boston. The location at the intersections of 84, Route 7 and 684, a short distance away, makes this very accessible -- not to mention Danbury Airport is a hop, skip and a jump for people to reach the facility.

The draw up of the construction plan is

looking innovative and will create many jobs in the area. We have Western Connecticut State
University which has the number one nursing
program in the state close by. We have -- after
reading your website, the need and the number of
people that can be treated with this innovative
and very low invasive treatment is -- just would
be such a great addition to the gap in the
healthcare services that we have here in Danbury.

We have Danbury Hospital and New Milford
Hospital and Nuvance Health, but there is a gap
for this type of targeted treatment and we
certainly have a need for it.

Reading the testimony of people who've been treated this way with the proton treatment is just heart wrenching, but also usually the stories end with a smile because it's been so successful.

So -- not to mention the revenues, as Mayor Cavo just eloquently stated.

It's a win-win for the Danbury area and I would urge this, the Office of Health Strategy to approve their certificate of need. And I'm sure you'll hear more from our Senator Kushner and Representative Gucker, and I certainly appreciate you taking the time to listen to me today.

THE HEARING OFFICER: Thank you for your comments
Representative Callahan.

We will move on to Senator Kushner.

SEN. JULIE KUSHNER: Thank you, and thank you for allowing me to participate here today.

Like my colleagues before me have shared, there are so many benefits to our community and the State of Connecticut that Danbury Proton will bring.

I did write a letter of support, and I don't know if that's been received. If not, I'll make sure that that will be received as my written comments, but I don't want to repeat what the others have said. I will just say that as a longtime resident of Danbury we have a great quality of life here, and we have wonderful resources in Danbury Hospital and in the state university mentioned by Representative Callahan.

But this Danbury Proton would really put us on the map as a center and a focal point for advanced technology in health care, and I think that's really important to our part of the state as well as we can attract people from over the border of New York to come into Connecticut for this, what's been called, revolutionary therapy.

On a personal note, you know, we all have members of our family -- I have a brother who struggles with cancer. And any time there are innovative strategies, innovative technologies, new forms of treatment we're so really eager to see these opportunities extended to everyone.

Being located in an urban area like Danbury I think brings a lot of good to our community and to those in our community who wouldn't be able to afford the long trip to Boston or to, you know, other far distant places. It makes it really available, and I think there's an element of equity in that being that we are a very diverse community that has certainly struggled in terms of our economic base as well.

So I feel really excited about the idea of
Danbury Proton, the new job, the location. And as
has been mentioned, you know, frankly it's really
convenient for people who would bring relatives
there. Family for treatment would have the
benefit of going nearby to the mall and, you know,
having a place to spend time. And I think that,
you know, there's a lot to be gained from locating
this in Danbury, Connecticut.

So I hope you will approve the certificate of

1 need, and I know that it will be very beneficial 2 to our community to have this great resource 3 located right here in Connecticut. 4 Thank you so much. 5 THE HEARING OFFICER: Thank you, Senator Kushner. I do 6 wish your brother well with his prognosis. 7 SEN. JULIE KUSHNER: Thank you. 8 THE HEARING OFFICER: You're welcome. 9 Do we have Representative Gucker yet? 10 11 (No response.) 12 13 THE HEARING OFFICER: No. All right. So I'm going to 14 move on to Bill Finch who's, I believe, the former 15 Mayor of Bridgeport. Is that correct? 16 BILL FINCH: Hi, Michaela. Yeah. It's Bill Finch 17 here. I'm representing the National Electrical 18 Contractors Association today, and I want to thank 19 you just for the time to make some brief remarks. 20 Obviously, our members are very involved in 21 Western Connecticut and the Greater Danbury area. 22 We're looking forward to participating in this 23 project, if that works out -- but certainly our 24 members are very active in the community and are 25 concerned about fighting cancer, and all of our

families have been touched by it.

So we think this is a valid project and we hope that the commission grants the certificate of need primarily because we have families, too, and we want the best for all the families in the Greater Danbury area.

We respect the work of the Commissioner. And NECA, the National Electrical Contractors

Association and their partner, the IBW strongly support this project. And any way we can move it forward just by our brief remarks here today, we'd like to try to lend our hand.

THE HEARING OFFICER: Thank you for your comments,

Mr. Finch.

BILL FINCH: Thank you.

THE HEARING OFFICER: Representative Gucker?

Mr. Rell, I noticed that you -- you actually alerted me that Mr. Finch was here, and I'm trying to keep an eye on everybody that's coming, but I know that you'll know the minute that Representative Gucker comes.

Would you mind sending me another message if you see him pop in and I don't notice him?

MICHAEL RELL: I sure will. No problem.

THE HEARING OFFICER: Thank you.

All right. So we're going to move on to Aubrey and Grace El-me [phonetic]. Am I saying that correctly?

AUBREY REICHARD-ELINE: Don't worry. It's okay. It's E-line [phonetic]. Don't worry. Eline.

I don't know how it's put in, so don't worry. You're doing a good job.

THE HEARING OFFICER: All right. So you guys can go ahead and give your comment. I'm going to give you three minutes apiece.

AUBREY REICHARD-ELINE: Okay. Perfect. Thank you so much. Hi. I'm Aubrey Reichard-Eline. I'm Grace's mom -- and you never want cancer in your home, in your vocabulary, and you absolutely don't want it with your child.

Cancer came into our home with our, at the time, nine-year-old daughter Grace. And it, you know, obviously cancer changes everybody's lives, but especially with a child it changes everything. You know it affects the child, but it also affects the entire family.

We first learned about proton radiation the few days after Grace's tumor was found. Grace had to have chemotherapy and then radiation. And to us, radiation was just radiation until we learned

more about it.

And Grace's tumor was in her brain, and we learned that proton radiation was different than photon. And it was less impactful to the tissues around, you know, where the tumor was.

So to us, having our, you know, talking about cancer in our daughter's brain, having proton radiation, having it be the least impactful, you know, portion of her treatment, and having that option was absolutely imperative to it. You know, a young brain being formed and it was absolutely imperative that we had that type of treatment versus what the other one, what the other options were.

For Grace, where we got our treatment was at Rutgers Cancer Institute in New Brunswick, New Jersey. And the cancer center was -- made it a fun experience, which I know sounds really weird when you're talking about cancer, especially with a child.

But they were beautiful, amazing staff. They played music and they had lights. So for our nine-year-old daughter it was -- it made it a fun experience. It took some of the scary out of it.

She also had to have a mask that they used to

bolt her to the table. So she did not move to receive this precise treatment, which is super scary -- but the center painted it. Grace's mask was actually the first one that they painted like Wonder Woman.

And now everybody there gets their -- they get to pick and they get their mask painted, which was, you know, again, when you're talking about pediatric cancer, it's not fun, but it was a way of easing the scary part of it.

The most important thing that I want to speak to is the location of the center. It was close to home for us, so we didn't have to travel. We had to travel 30 minutes. We didn't have to move somewhere for the 30 days of Grace's treatment. We could have it close to home so Grace could, at that point, go back to school. She'd leave school early, go to her treatment and then could resume her after-school activities, which was amazing.

We didn't have to leave. We could stay in our home so that, you know, my husband and Grace's brother didn't have to have that disruption of us leaving and moving out for a month for her treatment. So having that option of having something close to home was amazing.

Also Grace was able to, on days that she didn't feel well, she was able to come home and sleep in her own bed, lounge on her own couch and feel comfortable. So that close to home and that proximity of care was huge for our family, not only because of the ease of traveling -- the mental aspect of it was huge that there wasn't, you know, this disruption, not only to Grace, but to our entire family. So that that close-to-home care was imperative.

Also from a cost perspective we were, you know, renting a hotel room for a month. So all of that factored into why we think it's really important and why we're here today to speak to, you know, having access to care close to home, both from a cost perspective plus the, you know, disruption to the family is, you know, imperative to have that close access to care for families, especially when you're, you know, dealing with a child.

Grace was nine, but there's kids a lot younger that get proton therapy. And you know, having access to proton therapy where it's less invasive and less damaging to the tissues around these sensitive areas in these growing children is

so important.

So that's why I'm here to say I would approve this, and if I think about the number one reason to approve it, it's for the kids. It keeps them, you know, intact and close to home and gives them access to, you know, less disruptive care.

So thank you so much for having me here, and I'm going to turn it over to Grace, which is really where my cancer journey started.

GRACE ELINE: Hi, everybody. My name is Grace Eline and I am twelve years old.

So when I was nine years old I was diagnosed with germinoma, a germ cell brain tumor. And before my diagnosis I went through a bunch of tests, scans, and different types of appointments to determine which type of tumor I had and what my treatment plan was going to be.

And once we found out my treatment plan, it was to have four rounds of chemotherapy administered at the Valerie Fund Center at Newark Beth Israel Medical Center. And then I had 24 rounds of proton radiation at Rutgers Cancer Institute of New Jersey.

And after my treatment I was very eager to help different children like me who were going

through their own cancer journey, specifically having the proton radiation. So I've been a pediatric cancer advocate for many different reasons. I was a keynote speaker at the 10th annual Child Cancer Caucus, and I was also a guest at the 2019 State of Union. And I was so honored to represent pediatric cancer as the President pledged \$500 million for this much needed pediatric cancer research.

And I share this because my heart goes out to all the children in Connecticut who are facing childhood cancer and who need this very much important proton therapy. So I would -- I mean, it just means so much to have proton therapy close to your home, especially if after a long day of proton therapy.

If you just don't feel good having that comfort of proton therapy close to your home, I mean, it made all the difference for me and I know that it will make all the difference for the children.

So please approve the Danbury Proton's application for the certificate of need, and I know that it will help children all over the state of Connecticut. And thank you so much again for

1 having me here today. 2 THE HEARING OFFICER: Thank you both for your comments. 3 Let me just say, Grace, you're so eloquent in 4 you're speaking and talking about what you've been 5 through. 6 GRACE ELINE: Thank you. 7 THE HEARING OFFICER: Let me just ask you really 8 quickly, how are you feeling? 9 GRACE ELINE: I'm feeling very good right now. 10 NED, or no evidence of disease, and I've been 11 cancer free for over two years now. 12 And I mean, I feel great. 13 AUBREY REICHARD-ELINE: We're coming up on -- actually 14 April 9th is the anniversary of us finding Grace's 15 tumor. So we're very fortunate we're in the place 16 that we are right now, because we know it can be very different. So we feel very fortunate and 17 18 compelled to pay it forward. 19 THE HEARING OFFICER: That's wonderful news. 20 well. Thank you so much for your comments. I 21 just want to ask one other question. You all are 22 residents of New Jersey. Right? 23 AUBREY REICHARD-ELINE: Yes. 24 GRACE ELINE: Yes. 25 THE HEARING OFFICER: Okay. All right. I just wanted

1 to make sure I kept it in perspective -- but thank 2 you so much for your comments and your time. 3 AUBREY REICHARD-ELINE: Thank you. Thank you. Thank 4 you, everyone. 5 THE HEARING OFFICER: So we're going to move on to a 6 Representative Gucker. 7 THE REPORTER: This is the Reporter. I'm not hearing 8 any testimony. 9 THE HEARING OFFICER: Yeah, he's muted. Let's see if I 10 can help him out. 11 There we go. 12 REP. KENNETH GUCKER: Terribly sorry. I think that it 13 was my turn and I was in the other room 14 actually --15 THE HEARING OFFICER: That's okay. That's okay. 16 you ready to go forward with the comments? 17 REP. KENNETH GUCKER: Absolutely. Number one, I want 18 to thank you for having this meeting. And I think 19 this is a terribly important area that we should 20 be looking at here in Connecticut, not only as a 21 economic driver but also just for the health, 22 safety and well being of the people in our 23 community. 24 One of the things that unfortunately I had to 25 deal with as a state rep is my mother is a cancer

survivor. My mother had to travel long distances out of, you know, down to Yale and other places to, you know, deal with her breast cancer.

You know, had we had proton technology here in Danbury, she could have taken the ten-minute drive from the town of New Fairfield to my home, to Danbury, and it would have been a lot better for her, a lot easier for her because, you know, it's not just so much getting the therapy and the treatment, but it's the drive and the time, and then the after times. You know, the ill effects that go along with, not only having the radiation treatments, but then also having the chemo treatments.

From what I'm understanding by sitting down with the owners and the proponents of this, the ill effects aren't there. The ill effects are more targeted. You know, it's more of a holistic right on the spot, we can treat this location where we have, when we have this affliction, as opposed to having to treat the entire body, which then leads to a lot of side effects that aren't there.

So I'm a wholehearted supporter of that, just from even the experiences I've had with cancer

myself and not knowing how she was going to come out of it. I mean, luckily she's been cancer free now for the last year and a half. So it worked. But she paid -- she paid a heavy price, and I think with this kind of therapy being here in town she wouldn't have had to suffer so much.

She wouldn't have had to be ill so long. She wouldn't have had to have gone through as much as she did.

But even beyond that, we talk about here in Connecticut with, you know, opportunities to bring in more, you know, better, better suited things for Connecticut. We are right here on the cusp of the border of New York, in Danbury to be able to build this.

We could bring in patients from not only all through Connecticut, but through Westchester County. New Jersey is not that far away, as you see. Pennsylvania, it actually is a mile -- is an hour and a half away. You know, to where if they don't have proton treatments in those areas, people will be traveling to Connecticut.

And if we want to get into the economic drivers of it, just the building of the facility is going to keep our building trades going for

quite a while. They have an innovative method of how they're going to build this, which is fantastic. It's actually very energy efficient, very environmentally sound.

Being underground, being sheltered and being in the area where this piece of property, quite honestly, couldn't be used for much more than anything else. You know, you cannot put residential development there. You can't build anything other than proton energy there. Being that it's in the flight path of the Danbury Airport, you know, so the restrictions of even that. This is a perfect spot.

You know, here in Danbury, where we're going to talk about we have, you know, a world-class hospital around the corner. We can have world-class treatment for cancer right here in Danbury, and we can keep building up that, that end of it.

I mean, it's a great idea. I cannot speak more highly for how good this would be economically, health-wise, convenience-wise, and you know, when opening it up, an opportunity to folks to be able to get this therapy that they normally wouldn't have to.

They wouldn't have to suffer like my mother did with the chemo and with the radiation, and the other things that could go in here and actually have this, this therapy. It's wonderful.

And now if you can use this for fixing gallstones I'll be in there tomorrow, because I need to get gallstone surgery soon. So -- but no, honestly it's fantastic.

You know, economically, jobs-wise and also health-wise where the health is where I'm more about -- and environmentally. It's an environmentally sound project as well.

So thank. I don't know if you have any questions or any other things I need to address.

THE HEARING OFFICER: No, I do not. Thank you.

REP. KENNETH GUCKER: I tend to speak off the cuff.

THE HEARING OFFICER: No, that's okay. Thank you so much for your comment.

So the next person I have -- I think he stepped away from his computer. It's Brad Gute. I think it's G-u-t-e.

So I see you came back. Did I did I pronounce your name correctly? Can you spell it for me?

BRAD GUTE: Thank you. Yes, my name is Brad Gute, and

I live on Long Island. And ten years ago I was diagnosed with prostate cancer and began to do my research.

I met with robotic surgery doctors. I met with IMRT radiologists. That's the traditional radiology. And I was introduced to someone who had -- who lives in the New Mexico area, and he had gone to Loma Linda University for proton beam radiation where that's kind of the founding spot of the proton beam radiation.

And he was so happy with his results. I continued to do some more homework and studying, and I determined that this sounded like the best course of action, even if I did have to travel.

At that time 10 years ago the nearest center was in Philadelphia, which is about a three-hour drive for me. And since the treatments at that time were 44 treatments over about a 2 and a half-month period, I certainly wasn't going to drive six hours a day.

So I was going to rent a place there and just stay there -- but it was in the winter and it's cold out in the winter. So I decided to go to California and be treated at Loma Linda University where it all started.

I actually call it -- and some, I didn't coin this phrase, but I called it a radiation vacation because it was painless. I was able to golf every day. I was able to function beautifully, and here I am ten years later and it is gone.

My urologist told me just the other day -- I just happened to go for my annual physical. He said, you're past ten years now. Your PSA levels are perfect. He said, the odds of it returning, while he can't guarantee anything, the odds of it returning are very slim.

I met a bunch of people who came there from all over the country and other countries, because that was one of the few spots available here in the United States at the time. And as far as I know -- because I've kept in touch with a number of them, they are all fine.

This, this procedure -- this proton beam radiation is so precise that it does 99 percent of the damage at the site and very minimal damage going in, and no damage through the site. So it is the most wonderful procedure I believe that anyone can have.

And I also understand that it's being used on many different cancers now. Prostate cancer, I

believe, was the number one use for proton beam therapy, but I won't extend my time too much more.

This is state of the art. I think you guys will do as, as people have said in the past, wonderfully economically -- but more important, this is going to save lives and help people very much.

Thank you.

THE HEARING OFFICER: You're welcome. I just want to thank you for your comments and let you know I'm glad you're doing better.

BRAD GUTE: Thank you.

THE HEARING OFFICER: You're welcome.

All right, so we'll go to Mr. Marshall Rankowitz.

MARSHALL M. RANKOWITZ: Thank you. So twelve years ago
I was diagnosed with prostate cancer and I lived
two miles away from where the Danbury Proton site
is expected to be built. I live in Ridgefield,
Connecticut. I've lived there more than 30 years.

So I'm now 72 years old. I was 60 at the time of diagnosis. I also, like Brad, I did a lot of research on where to go to get treated. I went through all the options. Proton therapy ended up as my number one choice.

The hospitals I had to choose from at the time were Mass General, MD Anderson, and Loma Linda. I went to Mass General first, but Mass General at the time was really favoring children's cancers -- and neck, neck and head cancers primarily.

And I was basically told, if you have prostate cancer you'll be knocked out on days when machinery is not working. So it, you know, the oncologists were kind of discouraging me from coming there. And to make a long story short, I also, like brad, ended up at Loma Linda.

And really the only thing I wanted to say that it's different from Brad is -- because my experience was the same as his. I was treated over 45 treatments over nine weeks. I felt terrific during the treatments. I had no side effects during the treatments.

I worked a full day. I should have mentioned to you, I'm in the financial industry. So I found an office out in California. Basically I worked from six in the morning until one in the afternoon. I ran over to the hospital. I was in and out of the hospital every day in 30 minutes, and then I exercised every day.

During the treatments you can function.

Obviously, I was able because -- financially capable of going away for nine weeks, but if this was local it would open the doors for so many people who basically could take a half an hour out of their day, get treated and still function wonderfully. So to me that's the most important thing I can say.

I wish it was available when I had cancer.

My oncologist didn't even know what proton therapy
was twelve years ago, but I think everyone knows
now. There are centers going up all over the
country. I believe very strongly that it is the
radiation of choice when you have a defined tumor.

You know, that is the right thing to use if you're going to use radiation. So I just wanted to say those things. I wish Danbury Proton well. I hope this thing happens and it will be a big boon for our area, and for really the people who live here, most important.

Thank you.

THE HEARING OFFICER: Thank you very much for your comments, Mr. Rankowitz. I'm so glad that you're feeling better.

MARSHALL M. RANKOWITZ: Thank you.

THE HEARING OFFICER: You're welcome.

Next we have Rich, I believe it's Obarowski.

RICHARD OBAROWSKI: Perfect pronunciation. Thank you very much for allowing me to speak. Marshall Rankowitz is a good friend of mine, so some of the things that you heard him say I'm not going to repeat.

My wife and I have been residents of New Fairfield for 34 years. We've raised two boys who are now 36 and 39 and married. We're just waiting for the grandchildren.

I retired from a career of engineering operations and quality assurance in 2016. In 2018 I was diagnosed with prostate cancer. It's a hell of a decision to make when you find out you have cancer.

I talked in depth with Marshall and I did a lot of research. I read the Harvard School of Medicine's Prostate Disease and Treatment book. I read Rob Marckini's, You can beat Prostate Cancer Without Surgery -- and went in to see my urologist with a lot of information.

And so he said to me, if you were younger than 55 I'd recommend surgery. If you are over 70 I'd recommend radiation. At 66 I was in the

middle.

I said to him, what do you think about proton beam radiation?

He said, radiation is radiation. He was not obviously versed in this.

I saw him within the last six months. I asked him if he knew about this project. He said he did not. So the word is not out there about this therapy.

I had more choices than Brad and Marshall did when I went to Mass General. And like Marshall said, their focus is pediatric, neck and brain. They were going to fit me in two and a half months after I was there, and that was literally what they said, fit me in. Was not feeling good about them.

My second choice was ProCure in Somerset, New Jersey. My wife and I went down there and it's not their official model, but their unofficial model is high tech, high touch. They're very, very sensitive to their patients. Everybody we met there was concerned about my well being and my wife's wellbeing.

So I started my nine-week journey down there with that little bit of an intricate way of doing

it. I would drive down on Monday, as Brad and Marshall said, fully functional. Get treated Monday afternoon, stay over Monday night in a hotel. A Friend of mine from Florida would call me every Monday night and we talk about Monday night football. Tuesday I'd be treated and drive back.

Wednesday I got four of my buddies who rotated through driving me back and forth on Wednesday for my treatment. Thursday, Jen and I, my wife, would drive down; I'd get treated. Thursday night was date night, and Friday she would drive me home.

The one side effect I did feel during the therapy was fatigue. So the idea of doing that two-hour drive on Friday was not within my capability. Other than that I was fine.

So it did take a toll on logistics, but I did have a great support network and that's one of the things I want to say. Building the center here would so much reduce that stress on family and friends of commuting for treatment.

I am now two years cancer free. I have zero -- let me repeat, zero side effects. It's amazing. I talked to about 20 guys, most of which

who are total strangers. And they talk about the intimate problems you could have with this surgery, and they all share that with me. And I had -- I'll say it again, zero side effects.

I am a very proud cancer survivor; totally support proton beam technology and totally support proton in Danbury because it's going to bring a lot less stress to families who need this treatment.

Again, thank you for having me.

THE HEARING OFFICER: Thank you for your comments. I'm glad you're feeling better as well, Mr. Obarowski.

All right, so we are going to go to Mr.

Daniel Mack-er-nin-ee [phonetic] -- McInerney.

Got it.

DANIEL W. McINERNEY: That was very good. My name is

Dan McInerney. I'm the business manager for the

International Brotherhood of Electrical Workers,

IBEW, Local 488. We serve most of Western

Connecticut and have many, many, members who live
in Danbury and the surrounding area.

I'm in favor of the certificate of need for Danbury Proton. Just listening to all of these heart wrenching stories of the people who have already gone through this and how much better it

would be to be in a local area such as this is compelling.

Most families have lost loved ones to cancer.

I'm no different. Most of my members are the same way, and a facility like this can give hope to those who have really been stricken with this cancer.

Our members work on these types of facilities and hope that they or their families never have to use them, but knowing that they're in the area has to give them some type of comfort if they had to use them. Not only that, this would definitely be a tremendous economic driver for the local area.

I would urge you all to support the certificate of need for Danbury Proton. Thank you very much.

THE HEARING OFFICER: Thank you for your comments.

Okay. So we're going to move on to Dr. Andrew
Salner.

ANDREW SALNER: Thank you, Attorney Mitchell and OHS officials for giving me the opportunity to speak.

I'm Dr. Andy Salner. I'm the Medical Director of the Hartford HealthCare Cancer Institute at Hartford Hospital, and a member of the Yale New Haven Health and Hartford HealthCare team that

also has a CON pending for a proton therapy Center.

I would first like to start by agreeing with many of the speakers this afternoon who argue for having a proton center here in Connecticut. I totally agree with Grace and her mom, and the other speakers that in order to access this lifesaving technology we need to have a center right here in Connecticut.

I wanted to speak briefly about the importance of referral relationships in establishing and maintaining any healthcare service, including proton therapy services, and also wanted to clarify for OHS what it means to be an affiliated proton therapy center and what that means for patients.

Referral relationships are crucially important in the treatment of cancer. Cancer treatment is usually multimodal, meaning that patients are receiving multiple treatments even at the same time, including chemotherapy and radiation therapy at the same time.

Referral relationships are part of providing the most effective treatment for the patient, maintaining good coordination of care for the

patient during their treatment. Physicians who already provide cancer services in the state have established referral relationships as patients are referred to us for traditional radiation therapy and other cancer treatments. These patients are often treated jointly with their medical teams where these physicians are within the health systems, or referred from other health systems or independent practices and hospitals.

Also to clarify for the record, a proton therapy center that is affiliated with a healthcare system is not a closed referral facility. Affiliations are not exclusionary, meaning a center like the one we have proposed will not exclude patients referred by nonsystem providers or even self-referred patients.

Our facility that's proposed, like most freestanding proton centers in the United States, will be affiliated with the healthcare system and accept referrals from all providers and systems within the state as well as self-referred patients.

Thanks so much for the opportunity to make my comments.

THE HEARING OFFICER: Thank you.

Is there anyone else that wants to make public comment before we go to closing statements for the applicant?

If so, you can. I'm going to go ahead and ask if you wouldn't mind unmuting yourself and just announcing your name?

I don't see any hands raised.

(No response.)

THE HEARING OFFICER: So I think that's it. I'm just going to make a quick announcement regarding any written comments. Again, I'm going to leave the record open until April 9, at least, to receive written comments.

Those written comments can be sent to CONcomment@CT.gov. And that's again by April 9 of 2021, and then we're also going to be receiving all late-filed documents and a response by Attorney Hardy to written comment that was submitted by Hartford HealthCare and Yale who are the applicants for CPTC.

So with that being said, I'm going to go ahead and turn it over to you, Attorney Hardy, if you'd like to make a closing statement?

1 Thank you, Attorney Mitchell. MR. HARDY: 2 I really don't have a closing statement 3 because I don't think I can improve upon the 4 statements that have been given this afternoon by 5 patients who have treated with proton therapy and 6 have survived cancer. 7 The importance of bringing that therapy close 8 to home for patients and families is the key, and 9 I'm happy to let this rest with the testimony of 10 the patients this afternoon. 11 THE HEARING OFFICER: All right. I do thank everybody 12 for their participation. Also with the feedback 13 that you experienced when I was speaking, I'm so 14 sorry about that. 15 We are going to go ahead and adjourn for 16 today. I'll leave the record open at least until 17 April 9 of 2021. 18 Attorney Hardy, if you need any additional 19 time, please feel free to reach out to me and we 20 will accommodate you as best as we can. 21 Everybody have a great weekend. 22 23 (End: 4:49 p.m.) 24

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1 STATE OF CONNECTICUT (Hartford County) 2 I, ROBERT G. DIXON, a Certified Verbatim Reporter, 3 and Notary Public for the State of Connecticut, do hereby certify that I transcribed the above 199 pages 4 of the STATE OF CONNECTICUT OFFICE OF HEALTH STRATEGY, PUBLIC/ADMINISTRATIVE HEARING, in Re: DOCKET NO: 5 20-32376-CON, ACQUISITION OF A COMPUTED TOMOGRAPHY ("CT") SIMULATOR AND TECHNOLOGY NEW TO THE STATE, 6 (STATUTE REFERENCE 19A-639) BY DANBURY PROTON, LLC (DANBURY, CT), on April 1, 2021, via teleconference. 7 I further certify that the within testimony was 8 taken by me stenographically and reduced to typewritten form under my direction by means of computer assisted 9 transcription; and I further certify that said deposition is a true record of the testimony given in 10 these proceedings. 11 I further certify that I am neither counsel for, related to, nor employed by any of the parties to the action in which this proceeding was taken; and further, 12 that I am not a relative or employee of any attorney or 13 counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action. 14 WITNESS my hand and seal the 30th day of April, 15 2021. 16 17 18 19 2.0 21 Robert G. Dixon, CVR-M No. 857 22 My Commission Expires: 23 6/30/2025 24 25

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