STATE OF CONNECTICUT

OFFICE OF HEALTH STRATEGY

VOLUME III, BEGINNING WITH PAGE 229

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)

BEFORE HEARING OFFICERS:

DR. DEIDRE GIFFORD, Executive Director of OHS

DANIEL J. CSUKA, ESQ., OHS Staff Attorney

STEVEN LAZARUS, CON Program Supervisor

DATE: May 2, 2024
TIME: 9:00 a.m.
VIA: In Person/Remote

REPORTER: ALEXA A. BUDIHAS, RPR/CRR

APPEARANCES

FOR THE APPLICANT:

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(The hearing began at 9:00 A.M.)

MR. CSUKA: Good morning, everybody.

ALL: Good morning.

MR. CSUKA: Danbury Proton, LLC, the applicant in this matter, is not currently a provider of healthcare services in Connecticut but proposes to establish a proton therapy center in Danbury, Connecticut.

In its application, Danbury Proton represents that its proposal includes the acquisition of a proton beam accelerator, which is equipment utilizing technology not previously used in Connecticut, as well as a CT simulator for treatment planning purposes. The anticipated capital cost for Danbury Proton's project is approximately $96 million.

Today is May 2nd, 2024. My name is Daniel Csuka. I'm a staff attorney with the Office of Health Strategy. To my side is Dr. Gifford, who will introduce herself now of.

DR. GIFFORD: Good morning, everyone. I'm Deidre Gifford, and I'm the Executive Director of the Connecticut Office of Health Strategy.

MR. CSUKA: Thank you. Although I am here to assist and provide legal counsel, Dr. Gifford will be the one presiding over this matter. She will rule on

all motions and will issue a decision that includes findings of fact and conclusions of law upon completion of the hearing.

This is a hybrid hearing. By that, I mean it is being held in person and electronically via Zoom, in accordance of Section 1-225a of the Connecticut General Statutes. Any person who is participating orally via the electronic component of this meeting should make a good-faith effort to state his or her or their names and titles at the outset of each occasion that such person participates orally during an uninterrupted dialogue or hears questions and answers.

Sign-up for public comment has started and will continue until 12:00 p.m. If you would like to supply commentary, please sign up either in person, in the hallway, or in the Zoom chat box. You can also submit written comments to CONcomments@ct.gov for up to seven days after the hearing today.

For anyone attending remotely, unless you are actively participating in the hearing either as one of the applicant's witnesses or as a member of the public providing comment at the designated time, please mute the device that you are using to access the hearing and silence any additional devices that are around you.

This public hearing is held pursuant to

Connecticut General Statutes Section 19a-639a(f)(2). Although this does not constitute a contested case under the Uniform Administrative Procedure Act, the manner in which OHS conducts these proceedings will be guided by the UAPA provisions and the Regulations of Connecticut State Agencies beginning at Section 19a-9-24.

I will be asking questions of the witnesses as well as Dr. Gifford. Either OHS -- other OHS staff members are also here to assist us in gathering facts related to this application and may also be asking the applicant's witnesses questions.

At this time, I am going to ask each of the OHS staff persons up here to identify themselves with their names, spelling their last name, and OHS title. So, I'm going to start with Steve.

MR. LAZARUS: Good morning. Steven Lazarus, L-A-Z-A-R-U-S, and I'm the CON Program Supervisor.

MS. FAIELLA: Good morning. I'm Annaliese Faiella, F-A-I-E-L-L-A, and I'm the Zoom team lead.

MS. McLAUGHLIN: Good morning. I'm Yadira McLaughlin, OHS Planning Analyst, M-C, capital L-A-U-G-H-L-I-N.

MR. CSUKA: Thank you. Also present is Faye Fentis over in the corner, who is another OHS staff

member that does assisting with the hearing, logistics, gathering of names and providing miscellaneous other support.

The certificate-of-need process is a regulatory process and, as such, the highest level of respect will be accorded to the applicant, members of the public, and our staff. Our priority is the integrity and transparency of the process. Accordingly, decorum must be maintained by all present during these proceedings.

This hearing is being transcribed and recorded, and the video will also be made available on the OHS website and the CON account. All documents related to this hearing that have been or will be submitted to OHS are available for review through the CON portal, which is accessible on the OHS CON web page.

In making a decision, Dr. Gifford will consider and make written findings in accordance with Section 19a-639 of the Connecticut General Statutes.

Lastly, I wish to point out that by appearing on camera in this hybrid hearing, you are consenting to being filmed. If you wish to revoke your consent, please do so at this time by exiting the Zoom meeting or this hearing room.

So, I'm going to start by going over the exhibits and items of which we are taking administrative notice, and then I will ask if there are any objections.

The CON portal contains the prehearing table of record in this case. At the time of its filing a couple days ago, the exhibits were identified in the table from A to M. That's "M," as in Michael.

The applicant filed a few more documents yesterday that are not included in that table. We're going to mark the PDF presentation as Exhibit N, the compilation of support letters as Exhibit O, and the single support letter as Exhibit P. And we will update the table of record accordingly after the hearing.

Does anyone from OHS have any additional exhibits that they want to enter into the record at this time?

MR. LAZARUS: Not at this time. Thank you.

MR. CSUKA: Thank you. Counsel for the applicant, can you please identify yourself for the record?

MR. HARDY: Good morning, Attorney Csuka. David Hardy, along with Makana Ellis, from Carmody, Torrance, Sandak & Hennessey.

MR. CSUKA: Thank you. So, do you have any

objections to the exhibits that we have just gone over?

MR. HARDY: We do not.

MR. CSUKA: Okay. Thank you. So, all are identified and marked as exhibits and are entered as full exhibits.

(Applicant Exhibits A through P admitted as full exhibits.)

Attorney Hardy, do you have any additional documents that you wanted to enter before we get started?

MR. HARDY: We do not. Thank you.

MR. CSUKA: In terms of administrative notice, we're going to be taking administrative notice of the Statewide Healthcare Facilities and Services Plan and its supplements; the Facilities and Services Inventory; OHS Acute Care Hospital Discharge Database; All Payer Claims Database Claims Data, Hospital Reporting System, that's HRS, Financial and Utilization Data; and Community Health Needs Assessments.

Obviously, some of those are more relevant than others to this, but you should know that we're taking administrative notice of those databases.

We're also going to be taking administrative notice of the following CON dockets. One is Docket Number 20-32376 -- excuse me -- 76-CON, and that's

Danbury Proton's first application docket; and Docket Number 19-32339-CON, and that's the one where Connecticut Proton Therapy Center, Hartford HealthCare, and the Elder Human Health Services sought to establish proton therapy in Connecticut.

Attorney Hardy, do you have any objections to those administrative notice -- administratively noticed dockets or documents?

MR. HARDY: No objection.

MR. CSUKA: Thank you.

(Administrative Notice taken of the above-mentioned documents.)

So, as the hearing progresses, we may also take administrative notice of other information, including prior OHS decisions, agreed settlements and determinations that may be relevant but which have not been identified as of yet. The applicant will, of course, have an opportunity to respond to those if one of those should come up.

We will proceed in the order established in the agenda for today's hearing. I would like to advise the applicant that we may ask questions related to your application that you feel you have already addressed. We will do this for the purpose of ensuring the public has knowledge about your proposal and for the purpose

of clarification. I want to reassure you that we have reviewed the docket and will do so again before issuing a decision.

As this hearing is being held in hybrid fashion, we ask that all participants attending via Zoom enable the use of video cameras when testifying or commenting remotely during proceedings. All participants and the public should mute their devices and should disable their cameras when they go off -- when we go off record or take a break. Please be advised that, although we will try to shut out the hearing recording during breaks, it may continue; if the recording is on, any audio or visual that has not been disabled will be accessible for all participants. That includes inside this room.

Public comment taken during the hearing will likely go in the order established by OHS during the registration process; however, we may allow public officials to testify out of order. As I mentioned earlier, registration for public comment has already begun, and comment is currently scheduled to start at 12:00 p.m.

If the technical portion of this hearing has not been completed by 12:00 p.m., we may postpone public comment until the technical portion is complete.

The applicant's witnesses should remain available after public comment, as OHS may have additional follow-up questions based on the public comment.

Attorney Hardy, are there any other housekeeping matters or procedural issues that you would like to address before we start?

MR. HARDY: No, not at this time.

MR. CSUKA: Thank you. So, Attorney Hardy, would you like to make an opening statement or an opening presentation?

MR. HARDY: Thank you, Attorney Csuka. And good morning, Dr. Gifford, and all OHS staff.

I first wanted to express our sincere gratitude to OHS staff for working very hard and very diligently and efficiently to get us to this point in the process.

We have a lot of ground to cover, so what we intend to do is have Stephen Courtney, the Managing Director of Danbury Proton, be our first witness. He'll give an overview of the presentation we intend to make this morning, again, with witnesses and topics they intend to address. We will try to be as brief as possible. We want to talk about what you want us to talk about, and so we look forward to the question-and-answer session.

Also in the category of time-saving, since this application is unopposed, I'll waive making a closing argument so we can focus on the facts and the witnesses that are here today.

MR. CSUKA: Thank you. Can you please identify all the individuals in the room by name and title who are planning to provide opening remarks?

MR. HARDY: Certainly. So, our first witness will be Stephen Courtney, Managing Director of Danbury Proton. We also have with us Mister -- or Dr. Lionel Bouchet, who will be providing remarks. We have Dr. Leslie Yonemoto, who will be providing remarks. We have Mr. Duke Crandall and --

MR. HARTY: Jack Harty.

MR. HARDY: -- Jack Harty.

MR. CSUKA: Thank you. So, I'm going to swear all of them in first, and then I'm assuming some of the people attending remotely also be making remarks, so I'll swear them in separately.

MR. HARDY: Correct.

MR. CSUKA: So, if you could all please raise your right hand, I would appreciate that.

Do you solemnly swear or solemnly and sincerely affirm, as the case may be, that the evidence you provided in your prefile and the evidence that you

shall give or have already given in this case shall be the truth, the whole truth, and nothing but the truth, so help you God or upon penalty of perjury?

ALL: I do.

(STEPHEN COURTNEY, DR. LIONEL BOUCHET, DR. LESLIE YONEMOTO, DUKE CRANDALL, AND JACK HARTY, having been duly sworn by DANIEL J. CSUKA, ESQ., OHS Staff Attorney, testified as follows:)

MR. CSUKA: Thank you. So, now we can turn our attention to the witnesses who are attending remotely. Have they all joined us at this point?

Or if you'd prefer, Attorney Hardy, we can start until they --

MR. HARDY: Yes. So, we have Dr. Andrew Chang on the Zoom. We have Christopher Gonzalez on the Zoom. We have Daria Chylak on the Zoom, Don Melson on the Zoom, and Mr. Steve Coma on the Zoom.

We're missing one witness, but certainly we can proceed with the swearing in of these witnesses.

MR. CSUKA: So, the witnesses who are attending remotely, if you can all please raise your right hand.

Do you solemnly swear or solemnly and sincerely affirm, as the case may be, that the evidence you provided in your prefile and the evidence that you

shall give or have already given in this case shall be the truth, the whole truth, and nothing but the truth, so help you God or upon penalty of perjury?

ALL: (Yes. I do. Yes.)

MR. CSUKA: Thank you.

(DR. ANDREW CHANG, CHRISTOPHER GONZALEZ, DARI CHYLAK, DON MELSON, DR. MICHAEL MOYERS, AND STEVE COMA, having been duly sworn by DANIEL J. CSUKA, ESQ., OHS Staff Attorney, testified as follows:)

MR. COURTNEY: Dr. Moyers did join us. Just in time.

MR. CSUKA: Was he sworn in? I didn't --

MR. COURTNEY: Yes.

MR. CSUKA: Thank you. So, to the witnesses, I just want to start by saying that we have read and are familiar with all 161 pages of your prefiled submissions. We -- well, I'm not sure if everyone in this room has reviewed what was submitted yesterday, but I have reviewed the presentation that was submitted yesterday.

If you plan to make any additional opening remarks today, that's fine; but since there are 11 of you, please try to limit your comments to only summaries and new information that may not have been provided up to this date.

When giving your testimony, make sure that you state your full name and adopt any written testimony that you have submitted on the record prior to testifying.

So, Attorney Hardy, you can now proceed with your witnesses' testimony.

MR. HARDY: Thank you. We'll call Mr. Stephen Courtney.

And if I may, I'll share my screen. We have a presentation that will help narrate the witness' testimony.

MR. CSUKA: Sure. Mr. Hardy, is the green light on?

MR. COURTNEY: Yes, it is.

MR. CSUKA: Okay. Great. Thank you.

MR. COURTNEY: Good morning, Dr. Gifford, Attorney Csuka, and Mr. Lazarus, and OHS staff. It's a pleasure to be here. And I accept my -- my name is Stephen Courtney, and I accept my prefiled testimony.

My first slide, if we could, is essentially a list of all our speakers. And I had intended actually to spend some time talking about my association with all these speakers over the years, some of which have been over 35 years -- next slide -- and a bit about what they were going to say.

But we got a reminder memo from Attorney Csuka yesterday that said, It looks to me like, with 85 slides, you're going to go way too long. I was -- and I must admit, I had not timed myself. And when I did, I was a major violator of the five-minute expectation.

MR. CSUKA: I just -- I don't want to stop you. I just want to make sure that -- are we on the correct slide? Who's controlling the slides? Let's start there. Okay.

So, Attorney Hardy, you're not having any issues, are you?

MR. HARDY: Sorry. Let me do this.

MR. COURTNEY: So, the first slide, while he's trying to pull it up, is a list of all our speakers, people I've been working with over all these years.

So, as I was saying, I did some major slide surgery, if you will, last night, on my presentation and will -- I will not go into detail about the speakers. You have all their prefiles. You know who they are and what they represent. And I'll just say that this team's experience with proton therapy is extraordinary, and they'll be happy to answer any question you might have about proton therapy. They know what they're doing.

We're still not getting slides handled here for some reason.

MR. HARDY: The sharing feature has been paused. Let me try it again.

MR. COURTNEY: I'll keep going, though, given our timeline here.

The next slide, if you ever get to see it, is simply a graph of the proton projects that have come online since they started coming to us in 1990. And what you'll see, if you ever see the slide, is that the progression in the years since 2008 have been fairly consistent and it's been a pretty steady state of new projects coming on.

The next slide, which you still haven't -- oh, the one just above where you are now is also -- I won't spend a lot of time on it since it doesn't want to come up. But it's amazing things that can happen in 66 years. And in the proton therapy space, the technology has evolved significantly. Okay. So, let's stop on this one. We'll go with this one.

What you see at the top of this --

MR. CSUKA: Attorney Hardy, can you put that in slide-show view?

MR. HARDY: Yeah, I just did. There seems to be a lag between when I --

MR. COURTNEY: Oh.

MR. HARDY: -- when I do that and when it appears.

MR. COURTNEY: The timeline across the top you can't read, but that's okay. We blow up each section as I go along.

The first ten years of proton therapy that -- out of the labs of Harvard and Berkeley and things like that actually started at Loma Linda Hospital in California. There was also a small ocular unit down at Davis, UC, Davis, in the first ten years.

Our Dr. Moyers, who's online, was a physicist primarily responsible for that project coming online. Dr. Yonemoto was chief of staff there and ran the facility, and he also had his -- Dr. Chang as a pediatric oncologist there as well.

So, the heart of our clinical team have been in proton therapy since the very beginning. They're undisputed proton therapy pioneers in this space.

The next ten years have brought about seven new centers, if we can -- yeah, you did it. Very good. This is when my own proton therapy experience develops.

I started -- I was working as the director of operations of an architecture firm in Boston that had had the only expertise in designing proton therapy

facilities. And I was involved in the Houston project, MD Anderson; Jacksonville; Oklahoma City; Philadelphia, Chicago; Hampton, Virginia.

The next slide, if we go to the next five years, things really took off. We had 11 new centers in that five years. In 2013, Mevion introduced its compact single-room proton therapy equipment and changed the course of the industry in significant ways. All the red "Ms" are the projects that have Mevion equipment.

I was fortunate enough to work with Mevion at that stage. I got to meet Dr. Bouchet, and I really became a champion of their system compared to the other systems.

Most projects on this timeline, whether we designed them or consulted or in some way were involved -- an example is Dr. Moyers, on the Memphis facility, St. Jude's, was actually contracted to review the shielding design others had done to make certain it was being done correctly. Dr. Yonemoto is -- testified at other CON hearings in other parts of the country, et cetera. We touched just about all 50 projects in some fashion.

In the next decade, 20 more centers came on, four of them Mevion systems. And I won't go into it,

but a new piece of equipment was developed and went into the (inaudible) facility. It took them seven years to actually get it operating, and that system was also used now at Mass General's new facility that they added.

In the last four years, 11 more centers have come. And as you can see by the timeline, in '21, there were -- oh, there was only one center that came on, so Covid took a significant bite out of the development of proton therapy.

This year, we're expecting two more projects that are not shown on this chart -- Charlottesville, North Carolina, and Milwaukee, Wisconsin. Those are both Mevion systems as well.

Next slide shows very graphically why we love Mevion systems in terms of its required architecture. It's much, much, much smaller bulk space that's needed; and, therefore, your cost structure is lower, which helps everything all around.

On the next slide, we'll get into a little bit of a conversation about patient needs. These are the hospitals that you're all familiar with in Connecticut.

The next slide shows the ones that are affiliated with Hartford and Yale, including the

prospect hospitals that have been recently approved to be acquired. I know that it's still cooking, but we assumed that that was going to happen.

And the next slide, it shows the -- in yellow the other hospitals in Connecticut that are not part of those two systems, including the four Nuvance facilities in western Connecticut.

And the next slide shows the other three Nuvance facilities in New York, plus the other New York hospitals that are in -- in our service area, if you will.

In round numbers, almost a thousand Connecticut patients would benefit from proton therapy, as established by your agency in the Wallingford CON approval. At best, about approximately 800 patients per year could be treated with the two proton facilities in the state, still leaving an unmet need of that 900.

The Danbury team thinks the 900 was vastly underestimated and that it's easily double the thousand patients that would really benefit from proton therapy. Our number is actually close to 3,000.

And that is, as I said -- that's what we're going to be able to do is treat 800 of those patients, and that's assuming 16-hour-a-day operations. These

are not just, you know, 8-hour-a-day operations. That's going to be necessary in terms of patient slots.

This would make the weekly decisions of who not to treat very difficult given the limited treatment sites. Both Mass General Hospital and Memorial Sloan Kettering, the next ones closest to us, are running at full capacity now.

I'll move quickly through this next slide, which talks about our patient focus. We -- we're pretty excited about this fairly new platform. I spoke about it in great detail in my prefile testimony, so I won't spend time here, given we're trying to trim this up.

Next slide just shows the portal that people can use. It makes it easy for people to ask for things that they need, because people have a hard time asking for it and makes it easy for people that want to help to know what kind of things they can do for that patient. It gets -- it treats the patient in a holistic fashion. Memorial Sloan Kettering has started using that platform as well as a bunch of other folks.

The next slides I'm going to quickly go through. I was going to spend some time on the aesthetic design and how that relates to patients, but I'll just say that it essentially is a nonbuilding.

It's really about the patients. It's about healthy space. It's tucked into a hill. It's almost invisible, and that's -- that was very much by design.

And we'll just flash through to the next slides again. And I did want to spend a little time on the patient treatment rooms, because we are doing that differently than some to try to deinstitutionalize the space. We want to introduce warm materials, which people do that often. But the thing that's really innovative here is we introduced a faux window that gives the illusion that you're not in a bunker, you know, underneath earth. And so, we're hoping that will make a difference on the patient comfort.

And our last evening shot, this is important because, again, we are planning on treating 16 hours a day, five days a week, and how the facility presents itself in the evening in a safe manner is very important for our patients as well.

And that concludes my very quick thoughts.

And next, Drew Crandall will be speaking for us.

MR. CSUKA: Thank you, Mr. Courtney.

MR. HARDY: I did offer questions. I didn't know if you were going to do questions in between or just do it at the end.

MR. CSUKA: I was planning to hold it at the end.

MR. HARDY: Very good.

MR. CRANDALL: Good morning, Dr. Gifford and members of the OHS strategy staff. My name is Drew Crandall, and I adopt my prefile testimony. I am the Community Engagement Director for Danbury Proton.

First slide, please. I have deep family, community, and professional roots here in Connecticut. Prudence Crandall, the official heroine, I'm a distant relative of; and my father, Robert Crandall, grew up in West Haven, and he served in World War II on a Groton-made diesel sub. I'm one of Bridgeport Hospital's miracle babies. I had a 1% chance of living and being healthy, so I consider myself very blessed by the healthcare that has been provided here in Connecticut.

I was a UCONN student at Storrs. I played drums in the UCONN men's basketball pep band, so, go, Huskies. I served in the First Company Governor's Foot Guard, part of the state militia, for six years. Professionally, I've owned a business for 36 years here in Connecticut, and one of my firm's sweet spots is healthcare. So, we've provided assistance to a lot of health organizations across the state.

Next slide, please. I've served on many boards the past 45 years, and in my observation, the Danbury Proton team is exceptional. It's a UCONN Huskies championship-style team. Each of us has areas of expertise and experience, and we work together extremely well.

Next slide, please. Since the beginning, our team has had a passion to make a positive difference here in my home state of Connecticut, both from healthcare and economic perspectives. Local and state businesses are being engaged, and that will continue and escalate with the approval of our CON application.

Next slide. Over the past four years, we've had a 360-degree circle of support. We've submitted many letters of support on the OHS CON portal. This morning, I'd like to share excerpts from three of the letters in particular.

First, the Webster family in Wethersfield. They have been on Fox 61 TV featured several times. And this is a letter -- I'll take brief remarks from that letter.

"We are writing to express our enthusiastic support for the establishment of Danbury Proton. As the parents of an 11-year-old daughter who recently was declared NED, no evidence of disease, after a

year-and-a-half-long battle with bone cancer, we feel that we have a good understanding of why local proton therapy in our state is needed.

"The significance of proton therapy and cancer treatment cannot be overstated. We were grateful to have been given the opportunity to travel to Boston for proton therapy; however, we know that option is not open to everyone. We wholeheartedly endorse this initiative and commend the dedication and vision of all those involved in bringing Danbury Proton to fruition. Thank you for your dedication to this important cause."

From the Connecticut Cancer Foundation: "Our mission is to financially assist Connecticut cancer patients and their families with basic living needs and to fund cancer research. Given CCF's intense passion for, focused experience with, and extensive network of Connecticut cancer patients and cancer treatment providers, we applaud and enthusiastically support Danbury Proton's good and noble mission to bring revolutionary proton therapy cancer treatment and research to Connecticut.

"This advanced treatment is growing rapidly across the United States and around the world. It's about time that we have it here. Connecticut

cancer patients and their families need access to proton therapy locally. Let's get it together and make it happen, the sooner the better. Signed, Jane Ellis, President and Executive Director of the Connecticut Cancer Foundation."

And then from Dan DelGallo, President of Business Development and Cancer Services for ECHN: "I am in support of the Danbury Proton Therapy CON. Access to cutting-edge technology and advances to radiation oncology services are welcomed options for residents in the state of Connecticut. Proton therapy has been relatively inaccessible for most patients in Connecticut; therefore, access to additional resources of advanced radiation oncology treatment will likely be embraced by patients and residents across Connecticut.

"I am asking for your support of more accessible advanced radiation oncologic care and approval of the Danbury Proton CON."

The Danbury Proton team is eager to bring proton therapy cancer treatment to Connecticut. For me, it's a bucket-list situation. My maternal grandfather died of cancer. My mom died of cancer. Cancer was a contributing factor in my dad's death. I have a cousin who died from cancer and a brother-in-law who died from cancer.

We are looking forward to fulfilling our mission as soon as OHS approves our CON. Thank you for this opportunity to share today.

MR. HARDY: So, our next witness will be Dr. Michael Moyers, who is on the Zoom. Muted. Dr. Moyers, you're muted.

DR. MOYERS. Okay. Can you hear me now?

MR. CSUKA: Yes.

DR. MOYERS: Okay. Thank you for this opportunity to testify in support of the application of the Danbury Proton -- to establish a proton therapy center in Danbury. This presentation was about eight minutes, so I guess I'll skip my background.

If you can go to the next slide. Today I would like to mainly address two topics. The first topic is to provide some history of proton therapy. Proton therapy is often labeled as an emerging technology. For technology to be classified as emerging, it's typically characterized by novelty, rapid growth, significant impact, and sometimes uncertainty and ambiguity.

The way we have emerged in technology does not necessarily mean that it is new, unproven, or experimental. In fact, more than 320,000 patients have now received treatment at more than 100 proton

facilities around the world.

Go to the next slide, please. And I think I'll have to skip this one too.

Personally, I became aware of the power of proton as a means for treatment during 1979 while writing a term paper on heavy charged particles for one of my classes for my masters degree. After the paper was completed, I wondered why all patients receiving radiation treatments were not treated with (inaudible) beams and (inaudible) to perform these treatments. I later discovered that the main reason protons were not used for more patient treatments was not lack of efficacy but rather a lack of computing power.

Between 1979, when I discovered proton beam therapy, and 1990, when I started working at the first clinical proton therapy facility, three major events happened. All these events involved computers.

The first event was the availability of fast computers with a large amount of memory to reconstruct anatomy inside a patient and computed tomography, also known as CT. This is the essential path for taking advantage of the benefits afforded by pro ton beams. Without it, the targets cannot be defined and critical 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.

And the third event was control of 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 use in treatment. In addition, treatment sometimes had to be paused while changes were made. At the advent of high-speed computers networks, this preparation could be programmed and perform much faster than humans could react, thereby increasing the efficiency of the facilities.

Next slide. Okay. The second topic I'd like to address today is startup concerns. To be certain, starting any new radiation treatment facility is a significant undertaking, especially for one that utilizes a beam of protons. On the other hand, study developments in technology, together with standards and educational resources created for the dramatic upward trend of demand for proton therapy, make the

establishment of today's proton therapy centers more readily available 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 and performance have been produced by the International Electrotechnical Commission, or IEC. Guidelines for measuring dose have been produced by the International Commission on Radiation Units and Measurements, or ICRU. Recommendations for permission (inaudible) accounting for uncertainties in treatment planning and delivery in performing quality assurance have been produced by the American Association of Physicists in Medicine, AAPM.

Standards for transferring information between various computers and equipment have been produced by the Digital Imaging Communications in Medicine Working Group, known as DICOM. The recommendations for staff training and facility credentialing have been produced jointly by the American College of Radiology and the American Association of Physicists in Medicine.

In addition, a book entitled "Practical Implementation of Light Ion Beam Treatments," which I

co-authored, details many procedures 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 Connecticut, its relative late introduction will allow the state to realize the benefits of previous advancements in proton equipment technology as well as treatment planning techniques.

Despite proton therapy currently being a standard clinical treatment, in the future, treatments may be further optimized by performing research in (inaudible) for example, delivery techniques that utilize high-dose rate number of (inaudible) beams. Research and development may be applied not only to the beam delivery symmetry equipment but also the clinical trials with patients.

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

With Connecticut's high demand for cancer radiation treatment within its advancing population and its first-rate medical practitioners and institutions,

the state may serve a very valuable role in helping develop these advanced treatment techniques.

Next slide. Thank you again for considering using this technology for the patients of Connecticut and the surrounding areas. If you have any technical questions, please do not hesitate to ask me at any time.

MR. CSUKA: Dr. Moyers, before you turn your mic off, I don't think you adopted your prefile testimony. Do you adopt your prefile testimony?

DR. MOYERS: Yes.

MR. CSUKA: Okay. And also, one quick question before we move on to the next witness. What is your relationship to Danbury Proton?

DR. MOYERS: I'm -- since there's no income coming in right now, I guess I'm acting as a consultant at the present time.

MR. CSUKA: Okay. Thank you.

DR. MOYERS: Been working with them for quite a few years, trying to get this together.

MR. CSUKA: Okay.

MR. HARDY: Thank you, Dr. Moyers.

Our next witness is Dr. Leslie Yonemoto, who's here today.

Mr. YONEMOTO: Good morning, Dr. Gifford and

staff of the OHS. I'm Les Yonemoto, and I adopt my prefile testimony information. I only have one slide, so --

In the -- what I'd like go is give a rationale for proton therapy based on pure physics and biology. As a radiation oncologist, I treat patients with cancer, and radiation oncology treats about 60% of all cancer patients. We have 1.9 million people a year with cancers in the United States.

The cancer therapies, I call them MRS, are the standard therapy. And this medicine -- chemotherapy therapy, immune therapy, hormone therapy, "R," is radiation, which we're talking about today, and surgery, some cancers need one, most need two or three of these modalities as part of it.

In terms of radiation therapy, we try to do what we all do as physicians, is to do the least amount of harm and the most amount of good. Well, proton therapy follows that aim. In terms of radiation oncology, we try to adopt the way of disturbing less normal tissue and killing more cancer cells, just like anything else with surgery or chemotherapy.

So, the slide that I have there is a representation of what proton therapy does and how it relates to radiation oncology. On the left side of the

graph is absorb dose, similar to chemotherapy. The more dose you give, the more effects you have, both in cancer killing and side effects.

On the bottom of the graph, the X-axis shows the depth into the body, how far in does the dose get distributed. Similar to a medication like a chemotherapy drug, it gets distributed through the body. Radiation is the same way. And it's the same kind of idea of more dose, like milligrams for medication, for us, it's (inaudible.) The more dose, the more effects, both cancer killing and side effects.

So, on the left side of the graph, where it says "absorb dose," we have a beam that's coming from the left and going to the right and shows the effects of radiation. The standard radiation is called X-rays or photons. And over the years, the X-rays have changed so that they reduce the amount of dose on the way into the body and on the way out.

So, the way the graph looks is, in the center, where it says "tumor volume," is our target. We're trying to get a certain amount of dose, whether it's chemo or radiation. We want -- that's what we're prescribing. But to do that, we have to go through the body, just like chemo or surgery. There are normal tissues disturbed.

So, going from left to right, as you see the absorb dose, we almost give over twice as much dose in the normal tissue to reach the tumor and then continue on to treat the tissue behind it that doesn't have cancer, but we can't stop the beam. That's just the X-ray. That's why you can put a film on the other side and just see what you just did, imaging.

So, over the years, we changed the machine and upgraded it and had more technology. So, in the 1930s, '50s had (inaudible) voltage, cobalt, 1960s and '70s, and the LINACs, 6 to 8mv, in the '70s, '60s. And now the modern LINAC goes up to 18 to 23 megavolts. Megavolts.

So, what that means is, with that technology improvement, we're reducing the amount of dose on the way in, reducing the harm and side effects of the tissues going into the body. And that's revolution. Nobody -- well, hopefully, nobody is using voltage or cobalt machines anymore or voltage. They're using the modern LINAC and estimates there's 4,000 in the United States treating 60% of all of the cancer patients.

What's different, as you see on the red line, is protons. It's a particle, so it has different characteristics. Same damage to normal tissue and cancer, depending on the dose, just like a medication.

But the difference of the physical characteristic is that it reduces the amount of radiation on the way in by at least a half compared to the X-ray or proton machines.

And what's really great, it stops. Once you hit the tumor, it stops. The tissue behind the tumor does not get any radiation and side effects. You can think of a radiation beam going to a sinus tumor going into your head, X-rays would go out the back into the brain. The protons will come in and stop and not hit the brain but to the effects to the tumor and the sinus between the eyes, as one example. And this has only been around recently because of the technology that's -- Dr. Moyers has talked about. Even though it first started in 1954, it took -- this is before CTs, this is before cell phones, and all this other stuff. Now it seemed reasonable that we should have that.

And one of the things I'd like to impress is radiation is like a medication. If I say take 30 tablets of this medication, bad idea to take it all at once. But if you spread it out, it helps reduce the side effects.

Same thing for radiation. Most radiation therapy is given daily Monday through Friday over one to two months. Very difficult for patients to travel

to for a daily basis if it's any distance. In Connecticut, it is distance. You have to go to Boston or you have to go to New York. We'd like to have it here so that the patients can get it.

And in my experience as a radiation oncologist, a lot of patients, even with regular radiation, do not get the treatment that they need and deserve simply because it's not conveniently close. And that's why we are stressing not just one but multiple proton centers in the state of Connecticut.

I appreciate your time and attendance. Thank you.

MR. CSUKA: Thank you.

MR. HARDY: Thank you, Dr. Yonemoto. Our next witness is Donald Melson. He is testifying via Zoom.

MR. MELSON: Good morning, Dr. Gifford and OHS staff. My name is Don Melson, and I'm the Director of Finance for Danbury Proton.

Having been born and raised in New Britain, in fact, my childhood home was less than two miles from where you are today, I'm pleased to be here to discuss the cost benefits that Danbury Proton will bring to Connecticut residents as well as the financial viability of the center. I adopt my prefiled

testimony.

As background, for the past 30 years, I've held senior financial roles with well-known life science, biotech, and medical technology companies in the Boston area. Prior to my current role, I was Chief Financial Officer of Mevion Medical Systems from 2013 to 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. As you have heard, proton radiation's major benefit versus photon, or X-ray radiation, is that it minimizes the secondary effects of radiation dosed to the healthy tissue while effectively radiating the tumor.

Though the initial cost of photon treatment may be less than the current cost of proton radiation, the total long-term cost of photon radiation, including subsequent treatment and care, lost income/workplace

contribution, not to mention patient suffering, can exceed the cost of protons.

Another benefit of protons' lower secondary radiation impact is that the radiation dose intensity can be increased to the tumor versus that of photons. Also known as hypofractionation, this evolving technique opens the door to fewer treatments and 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 their size and cost, such centers were frequently underutilized, contributing to financial instability.

Alternatively, single-room centers are less expensive and can be situated in 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 now address financial feasibility of the Danbury Proton Center. As with most enterprises, a significant key to successful business venture is location. Location is also key to providing access to all residents requiring this

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

In fact, the Connecticut population density within 25 miles of the facility is over 1.3 million people, including 98% of the population of Fairfield County. Within 30 miles of the facility are five of Connecticut's top-ten most populated cities. If the radius is expanded further to 50 miles, the total population is approximately 15 million. And at a 75-mile radius, the population is approximately 18.7 million.

Given the high density -- high population density, the expected incidence of proton therapy candidates, and the scarcity of local proton radiation centers, Danbury Proton expects it will have more than sufficient demand in its primary service area.

Successful reimbursement is a second driver of financial success. Danbury Proton expects approximately 52% of its patients will be covered under Medicare, Medicaid, or TRICARE, and 38% will be covered under mutual-insurance programs, the remaining 10% by private payers.

While Medicare has covered proton radiation

with few exceptions since the FDA approval in 1988, commercial insurance plans have varied in their coverage, though insurers are increasingly covering the cost.

Commercial insurance coverage has been supported by high-profile lawsuits, some of which have resulted in large judgments against insurers who did not cover the use of proton radiation in appropriate cases.

For example, in 2022, a judgment of $200 million was levied against UnitedHealthcare in Nevada. In addition, the Tennessee, Oklahoma, Oregon, and Virginia State Legislatures have passed laws that encourage coverage by insurance carriers.

The third -- the efficient use of capital and operating resources is the third driver of success. As mentioned, single-room systems are efficient due to their low relative cost and scaleability. 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 Systems are also known for their efficient use of utilities and other operating costs.

Because of the efficiency of this design, the proposed Danbury Proton treatment center has a low

break-even point on a cash basis. Even though the center is expected to generate a $2.4 million loss on a book basis in its first year at 60% capacity -- that's 280 patients -- on a cash basis, excluding depreciation, the center will actually be cash positive from operations.

In fact, the center could withstand a 30% shortfall in first-year patient volumes -- that's 146 versus the capacity of 338 -- or 42% of total full-scale capacity. The center would still maintain positive cash-basis earnings and be able to meet all of its financial obligations, including maintaining a $7.9 million dollar restricted cash balance required under expected debt covenants.

In summary, proton radiation is a highly cost-effective 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 Daria Chylak. She is also testifying via Zoom.

MS. CHYLAK: Good morning, Dr. Gifford and OHS staff. My name is Daria Chylak. I'm an independent consultant for GlobalData, and I adopt my

prefile testimony.

I have worked as a researcher and a consultant on several proton therapy projects since 2018 while working on a healthcare consulting team at IHS Markit and GlobalData. And my academic ground, I have a Masters of Public Health and a Masters of Science in Bioinformatics.

Opening a proton therapy center in a high-population area can have a significant impact on the surrounding region, influencing many aspects of healthcare delivery and economic activity in the area.

Increasing access to advanced cancer care and increasing the options patients and their care teams have in treatment pathways can lead to better health outcomes. Specifically, research has shown proton therapy treatment can decrease long-term complications, reduce recurrence rates, and improve overall survival rates, especially for cancers in sensitive or hard-to-reach areas of the body.

Although opening a new center involves significant investment and resources, there are clear benefits for local and regional economies once the facility is in operation, such as creating high-paying skilled jobs and attracting related services like medical supply companies.

Proton therapy centers often become hubs for clinical research and innovation. This can facilitate partnerships with universities, pharmaceutical companies, and research institutions, potentially leading to new breakthroughs in treatment and unique collaborations with other researches.

New proton therapy centers can also serve as a training ground for medical professionals. This helps cultivate a skilled workforce that shares ideas and expertise across the country, improving the standards of care for cancer nationally. In the long term, this can only improve our understanding of cancer and lead to improved health outcomes and improved public health policies relating to cancer care.

Establishing a new proton therapy center and improving patient access to cancer treatment can set a precedent for other regions to follow, potentially leading to more widespread adoption of this technology.

Next slide, please. Overall, in our feasibility study, we have concluded that the environment in Connecticut is favorable for the concurrent operation of two proton centers with one delivery unit at each center. This is due to the location in the northeast. Danbury's in a high-population density area with large urban venters

nearby. A significant population provides a base of potential patients, including a high proportion of older adults who are more likely to require cancer treatment.

The single-room configuration is beneficial in that it's less expensive to build, staff, and maintain. And there's a higher probability of operational stability and success.

Site location and accessibility is crucial. Danbury is near major transportation routes, near public transit, and near major hospitals and medical centers.

Recent peer-reviewed published research has shown promising evidence that proton beam therapy can provide improved patient outcomes compared to conventional radiation therapy.

There are still some gaps in the knowledge. There's a need for more randomized control trials, which are seen as the gold standard and the most scientifically rigorous for evaluating medical interventions. But the general growth in proton therapy and increased interest in this treatment suggests that the evidence base will continue to grow.

I thank you for the opportunity to provide my testimony. I welcome any questions.

MR. HARDY: Thank you, Ms. Chylak.

Our next witness is also testifying via Zoom. Christopher Gonzalez.

MR. GONZALEZ: Thank you so much for your time this morning. I'll try to keep my presentation brief for the sake of time. My name is Christopher Gonzalez. I am the President of Apollo Healthcare.

A little background before my -- the inception at Apollo Healthcare. I trained at the University of Texas and the (inaudible) cancer center, specializing in medical dosimetry. Most people might not know what that is because most dosimetrists don't show up to your kindergarten class and tell you what they do.

But in layman's terms, dosimetrists are --

THE COURT REPORTER: Excuse me. I'm sorry.

MR. GONZALEZ: -- fulfill the prescriptions of the doctors and --

MR. CSUKA: Mr. Gonzalez, could you hold for one second, please?

THE COURT REPORTER: He's very muffled to me. Is anybody else having trouble understanding him?

DR. GIFFORD: A little bit.

(Mr. Gonzalez's microphone was adjusted.)

MR. GONZALEZ: So, as I was saying, I'm a

medical dosimetrist by trade. I have been a clinician on the dosimetry side for about -- since 2014, I'm sorry. And then I quickly got into the business side of radiation oncology since the inception of Apollo Healthcare.

Next slide. So, at Apollo Healthcare, we now represent about 40% of the proton centers within the United States. And when I say "represent," we are a contractor for the centers to help patients get access to proton therapy through their insurance companies.

And I can say throughout my time, the further it's gone, which is -- it's not good for our business but good for patient access, where proton therapy through the commercial carriers have increased access nationally without us having to do a deal or, quote/unquote, fight with insurance companies.

So, when we started Apollo Healthcare, I would say about -- it was roughly around 70% of our denials for proton therapy were getting denied. I mean, our submissions were getting denied.

Now that's flipped. Our up-front submissions are mostly getting approved mainly because most of the payers, including the large payer in Connecticut, which is Anthem Blue Cross, have changed their medical policies drastically, which is a good thing for

patients to be approved.

And so, now we're seeing multiple disease sites that we were normally having to appeal to get approved are already getting approved on first-pass submission. So, that would include all of your CNS tumors, all pediatrics, all skull tumors, head and neck. Now things are -- other disease sites such as breast are coming more online in terms of getting approved as well.

So, the utilization of protons isn't just because of a geographical location. There was always a restriction based upon the payers. But the trend now is payers are I guess -- we're seeing it develop. That's the best way of saying it. And a lot of these disease sites are on par with the access that regular radiation therapy would get.

And then, lastly, Medicare itself for y'all's region or, for that matter, every region in the United States, I wouldn't say covers almost every disease site but about 95% of the disease sites Medicare covers, and it's normally at 100% depending on the location of (inaudible.) But in theory, we've never had any issues with Medicare approving proton therapy thus far.

So, lastly, I did want to say is, with regards to this area and the centers that we do

represent at Apollo, capacity has always been now a new issue with proton therapy centers where patients are -- we are hitting capacity at a lot of these centers; hence the need for more centers in that region, mainly because before we were having issues that we had a center that we couldn't get patients approved on these private-insurance companies, so the capacity was always kind of maybe at 60% or 70%.

Well, now that insurance companies are covering proton therapy, which is great, it's kind of like squeezing another rubber band around a balloon; something else pops up somewhere, and, again, most of our centers are having capacity issues. And, unfortunately, that capacity metric is very hard to capture because a lot of patients end up getting regular radiation, and it's hard to capture that data.

But from an anecdotal standpoint, most of our centers are at capacity at this point. With that said, I wanted to keep it short, and thank you for your time.

MR. HARDY: Thank you, Mr. Gonzalez.

Our next witness is Steve Coma. He's also testifying via Zoom.

MR. COMA: Thank you. Can everyone hear me okay?

MR. CSUKA: Yes.

MR. COMA: Awesome. Well, thanks to the committee for their time this morning. My name is Steve Coma. I'm a Senior Managing Director at Hilltop Securities. I have been in the business for about 40 years, as you can tell by my hair color. And I look forward to testifying today. I adopt my prehearing testimony.

You know, I will be very short, as others have said. My primary role in the transaction is to find financing. And I am confident, given current market conditions and the structure of this project, that we would be successful. I can't see the slides that the committee is looking at, but I can take you through them quickly.

The first slide -- you know, one of the primary reasons that we have a high degree of confidence is Steve and his staff have assembled a very strong team. To structure these transactions successfully, you need excellent legal counsel as well as financial advisers, and we have both. We plan to use Orrick Herrington as bond counsel. They're the largest bond counsel firm in the country and have financed numerous projects similar to this. We just thought we (inaudible) that's the counsel that represents me and prepares the offering document or the

official statement.

We have DAMG Worldwide as a financial adviser, with Steve on the team, and importantly we have LendLease as a primary contractor, obviously an extremely well-known name.

Next slide. The project -- as the committee probably is well aware, this is not the first time that the bond market has potentially financed a facility like this. There have been successes and failures. Actually, that works very much to our advantage. We can highlight the strengths of this project and eliminate areas of weakness if either the market is identified or producements are identified.

Obviously, the dense population of Connecticut where the center is going to be located is a huge strength. The fact that it's a single-room therapy, you know, a smaller initial transaction, we can build in demand, don't overbuild where we would have excess capacity. No affiliation restrictions.

While that seems somewhat counterintuitive, a number of the facilities have had affiliations and those affiliations have not ended up being as substantive as hoped. So, this gives us flexibility to search for patients, you know, on a broader basis.

And then the financials. We've spent a fair

bit of time on feasibility with this. Obviously, that will be updated, but financials certainly highlight a strong project.

For the committee's, you know, perspective, the investor base for this are large institutional, primarily tax-exempt mutual funds and similar large institutions. We do not sell this to individual investors. While we are very confident in the project, we want to make sure our investor base is very sophisticated and has experience with these projects. All potential participants already have experienced financing proton therapy. Were I could have had this conversation with the committee, you know, two years ago, my confidence wouldn't be quite as high.

But with the Fed stabilized, even though they didn't cut rates yesterday, they cut them consistent. That has been a very positive sign for the bond market and institutional investors, and currently demand for projects like this considerably exceed supply. Obviously, that puts us in a stronger position to negotiate appropriate terms and put in place successful financing.

And that's all I have.

MR. HARDY: Thank you, Mr. Coma.

Our next witness is Lionel Bouchet, who is in

person today.

MR. BOUCHET: Good morning, Dr. Gifford, OHS staff. My name is Lionel Bouchet, and I adopt my prefile testimony.

So, I represent Mevion Medical Systems, the manufacturers. I've personally been in proton therapy for almost 20 years, really with a vision that proton therapy should be provided access to as many patients as possible.

So, Mevion was formed in 2004 by members of the Boston community, the New England community, MGH, Harvard, M.I.T., with a very specific goal, is reducing the complexity of proton therapy.

We've been FDA-cleared since 2012. We've been leading the proton therapy market since 2013, really developing that next generation of proton therapy.

Next slide. So, we have organized here just outside Boston, and our vision is to provide superior proton therapy to as many cancer patients as possible.

And we've heard from a lot of people here about the concept of access. Access was limited because of the size, because of the complexity of the proton facilities, and was limited to only a few people that were local to the proton centers. So, the concept

of equity of care in proton therapy has always been the reason of sort of why we have been pushing and developing these proton therapy centers.

If we go to the next slide, you will see that Mevion, in the compacted versions, the miniaturizations, has changed the market. We go from the very large centers where the accelerator is distributing to multiple rooms of about several hundred million dollars of investment, football-field-sized facility, MGH, these kind of facility, University of Pennsylvania and others too.

Proton centers are much more similar to accelerators. They are integrated. They can be integrated within an existing facility. They can have a support staff that are very similar to promotional therapies. And the operational success has been proven, where some of the large centers have had financial difficulty, the compact centers, the Mevion centers, their experience than that the proton centers are successful.

You've seen the history. This is a very long history, because it is complex. And today we have -- when we go to next slide, we have seen since 2020 multiple single-room centers being developed in the U.S. than multi-room centers, because, again, this

concept of access, concepts of being able to integrate within an existing radiation therapy, existing radiation therapy.

And if you want to go to the next two slides, here, what proton therapy becomes is a tool in the toolbox. It's a tool in the toolbox for radiation therapy, as Dr. Yonemoto said, is about delivering radiation very precisely, sometimes small. The more you can do that, the more you can control the tumor.

So, how have we achieved that? When we go to the next two slides, you'll see that it's a question of miniaturizations. We've seen that and we've experienced that. And I'd like to show that with the evolution of the miniaturization of technology that is with us today, with all of us, the miniaturization of cell phone -- miniaturizations of our cell phones.

And we've done the same thing with phototechnology, where the proton therapy accelerators or generators used to be 250 tons. Today it's just 50 ton. It's the diameters of about two-feet diameters, where we accelerate the proton and (indiscernible) come out of the -- you see on the right, the accelerator on the left, just the size.

With the smaller size, what we do is we can put everything into one single box, single room. So,

that single room is, if you want to go to the next slide, this is three stories. You've seen it. But the Mevion is a clean environment, very similar to conventional radiation therapy.

And the Danbury project is doing a great job, when we go to slide 68, to really develop a environment that is pleasing to the patient. And that's very important.

So, we develop that staff radiation therapy can actually use, but here they're going even further, but it will be normalization for the patient.

So, the technology continues to evolve, and we are excited with this project just being an hour and a half away from a factory, from a manufacturing of the amount of where we build the system. And we continue to evolve technology to be more and more precise. And here is the development that we are doing, combining the imaging, combining more precise beam options to be able to deliver radiation more precisely, more efficiently.

So, a patient -- some of the centers are treating maybe 40 or 50 patients a day very successfully. We are doing that because we are keeping (indiscernible) to very standard radiation therapy.

So, today in the U.S., we have -- Mevion has

about 20 centers or 20 default centers. We have about 12-plus centers (indiscernible), several also in development.

We're very excited for opportunity of this project. We do see that importance of access. We very often have patient coming to a factory, patient that have been treated with a machine, sharing their experience, and we hear the same thing, is proximity of care is important.

The journey is a difficult -- it's a long journey, a longer journey. And each journey, as Yonemoto said, can take five, six weeks; and five, six weeks of travelling can be very difficult for equity of care. So, we're excited for this project.

Thank you for your attention.

MR. HARDY: Thank you. Our next witness is Jack Harty.

MR. HARTY: Good morning, Dr. Gifford and members of the OHS staff. My name is Jack Harty, and I adopt my prefile testimony.

I'm the Facilities Director for Danbury Proton, and I come before you today to speak about the unique designs and construction considerations included on the Danbury Proton therapy facility.

I've been in the healthcare construction

industry for over 30 years with an emphasis on radiation-generating devices and facilities and have had the opportunity to visit and study other existing proton therapy centers and the different systems they use.

Prior to joining Danbury Proton, I spent ten years at Mevion Medical Systems, helping to design and construct every one of the Mevion sites currently in operation while developing concepts and designs for over 200 other locations word wide.

Until the introduction of the Mevion system, proton centers required large, bulky rooms, concrete vaults to house the proton accelerator and individual treatment rooms. Those systems required massive amounts of space and concrete to construct and, once operational, would consume large amounts of electricity and fossil fuels to operate.

The Danbury Proton Center examined these costs and the impact to the environment with an eye towards determining what contributions we could make in addressing the current climate-change situation we're in, while at the same time minimizing the impact to the area, while providing a safe, comforting space for our patients as they are battling their cancer diagnosis.

To accomplish our goals, Danbury Proton

selected the Mevion system as our primary treatment device, capitalizing on the reduced size of the vault and minimal support system space requirements, as Steven noted in his presentation.

We then considered the impact to existing surrounding area of the site and elected to construct much of the facility underground, embedding it within the natural topography of the site to allow for better interior environmental controls while maintaining the existing grades and flow of the land to preserve the field-like appearance of the former farm.

Covering the building with a green roof of metal grasses allowed us to preserve the natural habitat and biodiversity commonly on site and minimized water runoff that eliminating green spaces would cause.

For the operational systems of the facility, we elected to invest substantially in renewable-energy sources utilizing a geothermal heat pump system to provide required heating and cooling of the facility while allowing the building to operate without the need for fossil fuels.

We also put in exterior window glazings that adjust automatically to shade the building from the temperature gains usually encountered with large glass walls.

And for the exterior of the site, we chose to use L.E.D. down-lighting to safely promote illumination of the site while almost eliminating any light pollution that would negatively impact the local area and its nocturnal plants and animals.

Finally, we recognize that patients affected with a cancer diagnosis require more than just a direct treatment of their disease, and we offered to provide additional spaces to accommodate the more holistic side of patient needs.

To accomplish this, we included a significant amount of building space to allow our patients to maintain their dignity and privacy while they travel their cancer journey, providing spaces for their support people to be on site with them during treatment days and provide an office of support personnel to assist them in finding resources to help them access and recover from their treatments.

I'd like to thank you again for considering this unique facility and technology, and I look forward to helping to bring the benefits of this facility to Connecticut cancer patients. Thank you.

MR. HARDY: Thank you, Mr. Harty.

Our last witness is Dr. Andrew Chang, and he is testifying via Zoom.

DR. CHANG: Good morning. Thank you for giving us a chance to present some information about our involvement with the Danbury Proton project. My name is Dr. Andrew Chang, and I'm a radiation oncologist by training. I adopt my prefile testimony.

I have been involved in proton therapy for the last several decades with a primary focus on the clinician treating pediatric cancers and breast cancers.

And the reasons that the pediatric population is particularly seen as beneficial for receiving proton therapy is because the pediatric body is very sensitive to the exposure of radiation to the normal developing tissue.

Pediatric patients are impacted not only in slowing down the growth and development of (indiscernible), but in addition are the patients that, if cured of their cancer, are expected to live long enough such that the long-term side effects of radiation, such as second cancers or impact on organs, will show up and can impact that patient's life 10, 20, even 30 years after their treatment.

It's for that reason that, once proton therapy started becoming more widely available in the early 2010s or so that we saw a very quick uptake in

the numbers of patients that were being sent for proton therapy in the pediatric population.

It was for this reason that my work with all of my colleagues at that time, ten proton centers in the United States, looking at the volume of patients that were being treated with proton therapy -- and as shown on this slide here, there was a pretty big uptick in those patients being sent.

In addition, one of the things we saw was that other countries that did not have access to proton therapy were likewise sending patients to the United States for proton therapy. And in 2012, there was about 19% of all the patients treated with proton therapy in the United States actually came from outside the United States.

At its peak, the United Kingdom, before they had built their first proton center, were sending about 120 patients per year to the United States for us to treat, and I treated about half of those patients.

Next slide. This is kind of the poster child of what we think about and why we look at the benefits of proton radiation therapy in these patients. This is an example of a 10-year-old girl that had a brain tumor that we typically would treat with surgery to the main tumor in the back of the brain there, as well as

chemotherapy, and then radiation to the entire fluid of the brain and spine.

With that treatment, we know it does a very good job of curing these patients with the estimated survival in the 80%-to-85% range, but they would develop long-term side effects as a result of the radiation exposure in combination with chemo that they would receive.

In particular, as you can see on the picture on the left, that light green is the radiation from standard X-ray radiation that's exiting the body of this child, and these patients will develop heart disease even as soon as five to seven years after the radiation exposure to the point that the most common cause of death in these patients, should they survive their cancers, is heart attacks in their 30s and 40s.

With the use of proton therapy, not only are we able to avoid things like the heart completely, as shown in the picture on the right, but the radiation stops before it gets to the bone marrow. And for children like this receiving chemotherapy, what that means they are not needing the transfusions or the hospital admissions for low blood counts that we saw in the standard X-ray radiation before we had access to being able to use proton therapy.

Some other kind of side benefits we see from that is avoiding the bowels. It means less nausea for these patients under treatment. Without radiation exposure to the thyroid and breast, like this young girl, that would mean there's no increased risk of second cancers, of breast cancer or thyroid malignancy. And, likewise, being able to avoid the fertility organs means this why would will be able to preserve her ovarian function and her ability to carry children in the future.

Next slide. While most side effects from radiation we think about occurring years to decades after radiation, this is a particularly striking case of two patients that were treated by a colleague of mine, both 16-year-olds, with a tumor in the right back area. And this colleague of mine had treated one with X-ray therapy before he had a proton center available to him. And nine months later, he had a proton center built at his facility in Oklahoma and was able to use proton therapy when another patient, another 16-year-old male with the exact type of tumor, occurred in that area.

And what's striking is, on the next slide, you can see, within 12 months, the child that had the X-ray therapy, the IMRT radiation, the kidney that's

adjacent to it on the bottom slide 12 months later is shrunken and damages compared to the kidney on his other side, was the patient that had the proton therapy, that kidney is a little bit smaller in the back but for the most part relatively normal and still functional.

These patients were actually treated by my colleague, Sameer Keole, the new president of ASTRO this year. And he still follows these patients. And he told me just last year that these patients were treated in 2011, 2012, they're both still alive, but the patient that had the IMRT radiation is now on kidney medications that he's going to be on for the rest of his life because of that damage to that kidney.

Next slide. One of the largest areas of growth in adoption of proton therapy in the past few years has been that with breast cancer. In the United States, breast cancer is the most common cancer among woman, and we know that, with the great screening that we do now, we catch most of these breast cancers earlier and earlier, and as such, we have very good cure rates for many woman with breast cancer.

But, as a result of that, what we see is that the side effects from the breast cancer radiation catch up to these womans, and typically, the biggest concern

about breast cancer treatment with radiation is increased risk of heart disease.

And this is particularly for woman with cancer on the left breast because of the heart, that sits just behind the left breast. And the big artery that is most often clogged in heart disease sits right in the front of that left heart.

And you can see in the picture on the left that heart, which is sitting right behind that left breast, gets that full dose of radiation, or very close to a full dose of radiation, with X-ray or photon radiation; whereas with proton therapy, we can stay off of that heart almost completely.

And it's for that reason we started seeing a very large uptick in the numbers of patients with breast cancer that are being sent particularly for proton therapy. In fact, in some cases, like the University of Maryland Photon Center, the most common cancer that is treated by proton therapy is breast cancer. And that's because of the risk after about seven years, increasing heart attacks and heart disease occurring in the woman with left-sided breast cancer. That can be completely avoided in the use of proton therapy.

Next paragraph. One of the more striking

studies to come out recently was a randomized study in the mid-2022 where patients with cancer that spread to the brain, particularly in breast cancer or lung cancer, were found to have increased survival when treated with proton therapy to the entire brain and spine axis.

This was particularly striking because this is the first study in a little over 20 years that has seen an increased survival in these patients when treated with normal radiation.

This was started by our colleague of ours at Memorial Sloan Kettering when he noticed that, just like the pediatric population, there's less radiation to the spine, they can tolerate more chemo and their blood counts start doing better. He said, Can we do the same thing for adults with the tumor on the brain and spine?

And not only did he see they tolerated the therapy just as well as limited radiation but that these patients had increased survival. And so, he instituted this randomized study that was early because of the survival benefit that saw substantially greater length and duration of survival in these patients that were able to receive proton therapy.

Next slide. Some of these things that I've

been talking about, about side effects that occur after months or years, also lead to not only improvement in the patient's quality of life but, likewise, what is not often considered is the cost of the side effects that we have to care for in these patients, right.

It's hard to calculate how much not having a heart attack saves the institutions or -- that 16-year-old patient, what is the cost of the medication for the rest of his life for his kidney disease?

Well, the group at MD Anderson has paid attention to this and said maybe we should not just look at the cost of proton therapy but the cost of the entire care for a procedure. And in particular for this picture, it's the cost of head and neck cancers. When treated with radiation, these patients need less use of a feeding tube. And not only is that a quality-of-life issue for these patients, but as you can see in this picture, when the patient needs a feeding tube with X-rays, which is about twice as often as proton therapy, the cost jumps up.

And at the end of the treatment course, you can see in the blue versus the orange, the cost differential between proton therapy and X-ray therapy is only a few percent as a result of the other interventions needed.

This analysis was further expanded on the next slide, where Dr. Frank said, Look, what if we took a look at the entire cost of care not only in just particular things like a feeding tube, but what if we looked at the cost of care for pharmacy and medications for pain control, the use of laboratory testing and in hospital admissions?

And you can see this graph here looking at the cost of the entire care versus the cost of radiation itself. And you can see the radiation for the protons is, indeed, more expensive, but everything else less.

And that led to the startling finding that, when utilizing proton therapy, these patients with head and neck cancer actually had a lower overall cost of care. On the next slide, you can see for the cost savings are 21% lower for proton therapy as compared to patients that were treated with X-rays.

This led to the university -- this led to the entire University of Texas system approving proton therapy for patients with head and neck cancer.

As more and more of this data comes out, and there's going to be another one by Dr. Frank, a randomized study coming out in the next month, we're starting to see not only the improvements in the cancer

control with use of the proton therapy but decreases in side effects and, leading to that, the cost savings to healthcare systems as a whole.

Because of that, we're -- or as has been mentioned by a few of the others, we're starting to see capacity constraints. I, myself, am a radiation oncologist in San Diego, California. And I can tell you that my meetings mostly nowadays are figuring out how to triage patients, because we have more patients than we can treat, and we have to figure out who is the greatest benefit.

When we start seeing that at other locations -- and we do see that at other proton centers when I talk to my colleagues about, can we send patients to your center because I'm full. And, for instance, just at our annual National Association Proton Therapy meeting a month and a half ago, the big presentation from the Memorial Sloan Kettering group and the proton center in Harvard was about how do they triage patients, because they're full and they have a waiting list as well. The next closest one, Boston, they're very full with patients, and their machine is going to be undergoing a multiyear upgrade soon, so they're going to be losing 70% of their capacity to treat patients.

And I think that leads us to the big question of how do we get more of these centers access to -- have patients have access to the machines? And with the location there in Danbury, it provides a very convenient overflow to not only the patients in Connecticut but from the surrounding areas as well.

Thank you for giving me this opportunity to share some of the clinical background and how I see it, having been involved in protons for the last few decades and seeing the growth of this space and what changes have come as a result of that. Thank you very much.

MR. HARDY: Thank you, Dr. Chang.

So, that concludes the direct-testimony portion of our presentation.

MR. CSUKA: Thank you. I think it makes sense to take a break at this point. We've all been sitting for quite a while now. So, let's come back want to say 20 minutes, 30 minutes?

DR. GIFFORD: 20 minutes. I do have some questions for your witnesses that are remote, so if they could stick around for the questions.

MR. HARDY: Certainly.

MR. CSUKA: So, let's take 20 minutes. We'll come back, let's say, 11:00, and we will pick up where

we left off.

Again, public comment sign-up is continuing until 12:00. And anything that's said in this room may be picked up by the mics, anything you say may be picked up by the mics, so just be careful of that fact. Thank you.

(A recess was taken from 10:39 a.m. until 11:00 a.m.)

MR. HARDY: We're ready.

MR. CSUKA: Can we go back on? Thank you. Welcome back.

For those just joining us, this is Docket Number 23-3267-CON. It's Danbury Proton's application for the Acquisition of a Technology New to the State Plus a CT Scanner.

We had the applicant's presentation earlier this morning. Now we're going to continue on to some of the questions that OHS has.

The plan is to begin public comment at 12:00. So, for anyone listening in or in the area who wants to participate, please sign up before 12:00, and they will likely take you in the order in which you appear.

Elected representatives, we may have to go a little bit out of order in order to accommodate their schedules. But the plan, again, is to begin at 12:00

and then probably break for lunch, because I don't think we're going to get through all of OHS' questions before noon. And then we'll come back and we'll wrap things up.

So, does that sound okay to you, Attorney Hardy?

MR. HARDY: It does. Thank you.

MR. COURTNEY: The only qualifier I might give there is Dr. Chang was hoping that he was done at noon so he could get back to his patients. So, if we had specific questions for people on the line, if we could move those before 12:00 as opposed to having them wait until after all the public --

MR. CSUKA: Okay. I think that's doable. We'll do our best to direct them to specific individuals. There are 11 of you, so --

MR. COURTNEY: Yes.

MR. CSUKA: -- so, you know, we'll do our best is all that I can say.

So, I think Dr. Gifford wanted to start by asking some questions about the presentation that was given earlier. So, I will turn the mic over to Dr. Gifford.

DR. GIFFORD: Thank you very much. And I want to say thank you to all of the witnesses for both

your carefully prepared application and your thoughtful testimony. It's very helpful for the Office of Health Strategy as we consider this application. So, thank you.

I actually -- my first questions were for Dr. Chang, so hopefully that comports with his need to see patients.

First of all, I just want to establish for the record, Dr. Chang, that the cost/benefit data that you showed on your slide beginning at Slides 82, 83, and 84, is unpublished data. Is that accurate or -- just I'm noting provided by Steve Frank at the bottom, so I just wanted to confirm that this was provided by a peer and not published in a peer-reviewed journal.

DR. CHANG: Thank you for the question and the kind words. There have been updates published in a couple of different versions now. This was the summary slides he originally provided to me a few years ago. And there have been published reports -- there's been published portions of this since then, and I'm happy to provide those as well. I'll get the papers from him if that would be helpful for you.

DR. GIFFORD: Yes. Thank you.

DR. CHANG: Sure.

DR. GIFFORD: Okay. So, my other questions,

which I believe are for you, Dr. Chang, but whoever from the team wants to respond, have to do with the clinical indications for proton beam therapy.

First of all, in the application, you provided the ASTRO model policy as the template for clinical practice guidelines.

Is that the closest thing we have to a clinical practice guideline for proton beam therapy?

DR. CHANG: So, I would say there's probably three major ones. ASTRO's is one of them. Astro is our society of radiation oncology in general. And they have an updated one, actually, that came out fairly recently. I'm not sure if that's the updated one that's included in there. But, yes, in essence, they split it into group ones and group twos.

The other two big policy groups would be the NCCN, and that is more of an oncology standards rather than radiation in general. So, that -- NCCN is a group that gives general guidelines for surgery, chemotherapy, and radiation in there. And in there, it does site specific ones that were -- where proton therapy has a particular advantage.

The last group would be for the National Association of Proton Therapy that also has policy guidelines that will address similar clinical cases.

But, yes, those are the named three, ASTRO being one of them.

DR. GIFFORD: Okay. And I believe that ASTRO model policy was included in your application but not the other two; am I correct there?

Okay. So, if there's relevant information to my question for that clinical indications in those other two guidelines, then it might be appropriate to provide those to us.

DR. CHANG: Sure. The NCCN one is fairly comprehensive. And I think part of the reason we didn't include that is there are literally hundreds of pages per disease site and about 40 disease sites, so it wouldn't be necessarily helpful to submit all of that for specific questions.

DR. GIFFORD: Okay. All right. So, in the ASTRO model policy, as you mentioned, they divide cancer types into group one and group two cancers. I'm trying to get a better understanding of your assessment of need based on those two groups.

And so, can you give us -- can you describe for us, either you, Dr. Chang, or another member of the team, of the estimated number of cases that Danbury Proton would be treating in a year, how many of those are from the group one cancers, and how many would be

from the group two?

DR. CHANG: So, I think I would defer that to another member of the team who did the numbers specifically for Danbury modeling.

I would say that in my center in San Diego, approximately 70% of the patients would be in group one, many of those being reirradiation. And that's a growing area of treatment where I tend to see a lot of referrals from my colleagues in the X-ray practice. And that's because about 10% of all patients that we treat have local recurrence only that have had radiation before and are still curable because it hasn't spread. But the difficulty is once an area has received radiation, coming in and getting a second course of radiation is particularly difficult to do.

And so, we see a lot of head and neck and brain tumors that have this -- that fall into this category where they've been treated once, it's only come back right where it started, and it's hard to give any more radiation, standard radiation, then they get referred to a proton center. That makes up probably 40% of my head-and-neck patients, are reirradiation. And so -- and reirradiation is one of the group one -- major group one indications.

I would say, again, in total at our center in

San Diego, about 70% would fall into that group one. As for the numbers specifically for Danbury, I'd have to refer to one of my teammates who would know those numbers better.

MR. COURTNEY: I can say that the numbers are evolving as we speak.

DR. GIFFORD: You probably want to turn on a mic.

MR. COURTNEY: It is on.

And Dr. Yonemoto -- I'll have him speak next, but I was just at the national conference, as he said, a month and a half ago. Even the ASTRO recommendations were being updated as to what's one and two. As more and more modalities -- they're realizing how valuable it is, it's really changing that significantly.

So, for example, we had an awful lot of proton -- I mean prostate patients anticipated when we initially applied, and we essentially stuck with that for the time being for this application. But that's -- that number is going to be significantly down or breasts are going to be significantly up. It's definitely changing.

Les, you want to talk about that?

DR. YONEMOTO: Sure.

DR. GIFFORD: Dr. Yonemoto, if you could

comment in particular on the changing approach to prostate cancer.

DR. YONEMOTO: Yeah. One of the things that -- I don't have the exact number. I don't think we actually did the percentages.

But the way I think about it is half of all cancers are treated in the United States, including with radiation -- breast, lung, and prostate cancers. With that, protons have been used as level-one indications for all three in the national guidelines also.

DR. GIFFORD: I'm sorry. When you say level one, you mean group one?

DR. YONEMOTO: Yeah. Group one. Excuse me. Yes.

DR. GIFFORD: Okay. But those cancers don't appear on that list.

DR. YONEMOTO: Well, in terms of, you know, retreatments and -- so, there is a category of those that let you treat those patients.

Now, the reason why I mentioned that half the patients of cancer are those three is you get a lot of retreatments with them and a lot of other indications that come back into group one because of that, because there are adjacent structures and things like that.

DR. GIFFORD: Thank you.

DR. YONEMOTO: So, I'm trying to impress the volume is high that -- following group one.

The other is that the group-one indication has always increased over the last few years, several years, that as more papers come out and more -- frankly, more centers, you know, until, you know -- 2010, there was only ten of us, you know.

Now there's over 40, we would have more papers coming out, and the group-one indication should increase. But I don't have the exact number of what we predict in Danbury. But I expect it's going to be exactly -- not exactly but close to the same as San Diego because the cancers are the same.

DR. GIFFORD: So, is there anything that you can point to in the published literature that describes that percent of these more common cancers that would be eligible for proton beam?

DR. YONEMOTO: As a group one? I don't. I don't know if Dr. Chang knows. I don't recall that. Sorry.

DR. GIFFORD: Okay. Because estimates -- obviously, we are very interested in the projected need for the state of Connecticut for this type of therapy.

So, then, the projected need is evolving is

your -- is what you're saying and --

MR. COURTNEY: Yeah. At the conference, for example, Memorial Sloan Kettering said at their proton facility they're treating now 42% retreatment, and that involves all of these other primary cancers. But, so that -- that number is changing things dramatically.

DR. GIFFORD: I see.

MR. COURTNEY: And that's a public record as I understand it.

MR. BOUCHET: I may be able to help with the literature because I've been following literature for --

DR. GIFFORD: You might want to restate your name.

MR. BOUCHET: Lionel Bouchet, PhD, physicist and everything else.

A lot of the nations have looked at what percentage, nations -- you know, France did, Italy, Sweden did a great job at looking at the percentage of radiation therapy patients with their -- so, they looked at literature. And the convergence is between 10% and 15%.

And these are actually not new data. They are data from the past ten years, actually ten years ago. So, this 10% to 15% of data about ten years ago

published by this country, convergence was between 10% and 15%.

What we are seeing since then, we are seeing an increase in percentage, right. So, the Mevion centers, which I have visited, typically treat between 10% and 20% of their patients with proton therapy, and it's what the physicians are saying as value base, a value base.

So, there is an evolution. We are continuing to see data come in. MD Anderson has been fantastic for head and neck. We have the esophagus -- excuse my French, I can't say that word -- esophagus trial that was a phase-two trial, and some data coming out here that we all have heard but we don't know yet the data that are coming out (indiscernible.) So, we are seeing a growth of the publication of data coming out because there are more and more centers.

So this group one, usually from ASTRO, they are all plenty of referrals, right. You look at the documents, group one, tons of reference that Dr. Chang talked about, the NCCN and a lot of different -- a lot of different referrals, published referrals for all of this group one. So, this group one are pretty established.

I have heard a percentage of group one

patients that are treated with proton is actually quite small in the U.S. So, I don't have a number, but I think -- I should message someone. The medical director, executive director of NAPT gave me a number two weeks ago, and I just don't have it yet. But that percentage is very small.

So, the questions that I ask myself when you ask the question is what group-one populations of cancers within the state of Connecticut, right. That's --

DR. GIFFORD: Well, exactly, because those are for the most part fairly rare cancers in group one. Take away the retreatment, the rest of the cancers are fairly rare, both the adult and the pediatric cancers. And I see you eyeing Dr. Yonemoto. So, that's why -- hence the question.

I believe your application references that you used IHS Markit to estimate the percent of the group-two cancers that would be appropriate for proton beam? Did I misread that, or is there something -- is there something there that you want to point us to?

MR. COURTNEY: Daria, could you comment on that?

MS. CHYLAK: Yes. Sure. IHS Markit is the previous company for our group at GlobalData. So, we

used to be employed by IHS market, and the life sciences consultant group was purchased by GlobalData.

But can you ask the question one more time? I know you're asking about a specific item.

DR. GIFFORD: I should -- let me get you the page reference from the application. That might be helpful.

MS. CHYLAK: Great.

DR. GIFFORD: And if the team can help me look, I know I saw it recently.

MR. LAZARUS: Page 29 of the application?

MR. CSUKA: So, we're looking at Bates number page 29 of the application, and the application is Exhibit A.

MR. HARDY: I'm sorry. Does that -- number page 22 of the application itself?

MR. CSUKA: 21.

MR. HARDY: 21. Okay. Sure.

DR. GIFFORD: For any members of the public who might be with me, I'll just read it.

It says, "According to a report of IHS Markit, the estimated radiation of eligible patients for whom proton therapy is appropriate range from 14% to 30%. A figure of 20% is also in line with estimates provided by proton therapy equipment manufacturer IBA

world wide."

So, I was just asking the data that was behind that estimate from IHS market.

MS. CHYLAK: Yes. So, if you look at the response to public hearing issue number -- I don't have the number in front of me, but one of the last large documents that was submitted by our team, there is research -- let's see if I can pull it up -- there are research studies that provide those 14% and 30% numbers. And they're cited there in that document. I believe it's in Section 4.2, Proton Therapy Demand in Connecticut.

DR. GIFFORD: Are you guys tracking where that is so we can follow up? Okay. Are you finding it?

MS. CHYLAK: And the copy that I'm looking at, that's on page 37, Section 4.2, called Proton Therapy Demand in Connecticut.

DR. GIFFORD: Okay. Thank you. So, as long as we have it, I think I can move on.

MR. BOUCHET: I think Chris Gonzalez may have some specific data from his experience that he may be able to share. Is Mr. Gonzalez online?

MR. GONZALEZ: Yes. Can you all hear me? Okay. Great. I would also like to mention the

definition of eligibility.

So, between that -- term can be interpreted two ways, from a clinical standpoint versus a patient access standpoint in terms of eligibility. But for the region of Connecticut, the Medicare-approved contractor, which is NGS for the region, does have a proton-therapy-specific LCD policy. That policy is L-35075.

And essentially, the proton therapy policy in terms of eligibility is defined as any patient that is a radiation therapy patient is eligible for proton therapy. So, it's not a -- so, that's -- in terms of access, that's why people in layman's terms say, well, if you have Medicare, you can get proton therapy.

But it does not define eligibility by a specific disease site. It defines it actually by where the target, meaning where the -- where we're treating a patient.

So, you know, not always -- for example, breast cancer, you can have a mediastinal, let's say lymphoma or a breast cancer variance in a similar region, but from a histology standpoint, they're different. But what we're actually treating is in that region. So, the definition of the potential use of a patient isn't because someone has breast cancer or,

let's say, lymphoma. It is defined by how close that target is to critical structures in the LCD policy.

So, and lastly, the policy doesn't recommend one disease site over the other; it recommends based upon other literature for those disease sites.

So, I always like to mention eligibility can be viewed in two different ways. Some people say, well, if you're a radiation candidate, if you're a proton candidate from a clinical standpoint. If you ask an insurance company, and they will redefine eligibility not because of medical necessity, because they may or may not have included it in that -- in their own medical policy. So, two different definitions.

DR. GIFFORD: Yeah. And I think you're pointing to one of the reasons for my question, which is the need in the application is calculated based not on those clinical variables that you're talking about but by diagnostic type. And then there's an estimate of what percent of those diagnoses would be eligible for proton therapy, and that's what I was trying to get a better handle on.

MR. GONZALEZ: And I did want to point out, between all these organizations -- between ASTRO, even CMS and NCCN -- their group-one versus group-two

categories are all different. It's ambiguous.

So, you'll have some, for example, CMS' group-one category for reirradiation tumors is actually in CMS' policy a group two, but for ASTRO it's a group one, and NCCN it's a group one. So, I did want to point out their syllabus -- not syllabus -- their rubric between all organizations are exactly the same.

So, you kind of end up in a -- you know, it depends who you ask and where you ask, the organization. But by and large, they all kind of even out at some point based upon resupporting literature.

So, the more conservative I would say policy is normally NCCN, but then you have different maps across the United States. You know, you think Medicare shares the same policy, but every map has a different -- which there's five of them -- have different policies. And the NGS map, which is the (indiscernible) region, is the most conservative as well too.

And even in the conservative light, it still, you know, approves about 95% of radiation candidates for proton therapy.

DR. GIFFORD: Thank you. Anything else on that issue before I move on? All right.

MR. CHANG: Yes. Dr. Gifford, I have looked

up several of the references that you were requesting about cost effectiveness.

Should I just send that to the team to get over to your team for the actual manuscripts? Is that the best way to do that?

MR. HARDY: Yeah. If we could make a late filing of those materials, we'd be happy to do that.

MR. CSUKA: Yes, Doctor. We're going to keep track of what are called late files.

MR. CHANG: Okay.

MR. CSUKA: And then those will be supplied to your counsel, and then your attorney will provide them after the hearing.

MR. CHANG: Okay.

MR. CSUKA: So, there's no rush. You'll have plenty of time to do than.

MR. CHANG: Okay. I just pulled up the five or six articles, so I'll bundle them together and send them along.

MR. CSUKA: Okay. Thank you.

DR. GIFFORD: I wanted to move on and ask some questions about the location, your proposed location.

We noted in the application that you estimate a significant percentage of the patients would be

New York residents and that your primary service area encompasses both New York and Connecticut.

Can you tell us a little bit more about why you chose Connecticut as a location for this facility?

MR. CSUKA: I said earlier that people who are testifying online should say their names. I think it also makes sense for people present to also say their names.

MR. COURTNEY: Sure. Stephen Courtney.

I have been, since -- and Les and I have been trying to bring proton therapy to Connecticut since 2011. We first started -- we got interviewed by Hartford Hospital, Dr. Salner and his team. About three times we reported to their board.

We tried a number of years to work with Yale in bringing them a facility. LendLease, Mevion, and our firm also proposed a turnkey solution on a couple different sites that Yale had as well. And it just was going nowhere.

But we suspected that certainly some -- someone in the middle of Connecticut was going to provide it. So, they'd been talking about it for years.

When we look at the United States as a whole, the largest hole demographically for proton therapy

centered around Danbury, Connecticut. So, that necessarily does go into New York, as well, but it was essentially the biggest need in the United States. So, we said that's the place we should look at doing a facility, and that's where that came from.

In terms of the day-to-day selection process and referring to your issue you identified, who the facility chooses to treat is a difficult one, especially as we anticipate, even with 16 hours a day, we're going to have to turn away people.

And so, the cases that are the most clinically needy are the ones that we hope to take. And it -- all patients being equal, if there was a Connecticut patient, we would obviously want to take the Connecticut patient since that's our location.

But I think Dr. Yonemoto could speak to that decision-making process that we'll essentially have to be making every Monday of who we treat.

DR. GIFFORD: Before you do that, can I just follow up on your statement about Danbury, Connecticut, being the center of need?

MR. COURTNEY: Yep.

DR. GIFFORD: Because Danbury is located between two -- I think we're up to -- is it 40 -- how many --

MR. COURTNEY: 50, actually, counting the small --

DR. GIFFORD: In the United States.

MR. COURTNEY: Yes.

DR. GIFFORD: Okay. So, we have two and soon-to-be three of those in the New York, Connecticut, Massachusetts area.

So, can you say more about -- was it based on the demographics, cancer rates? What was the data behind identifying Danbury specifically as a place of highest need? And if there's a place that you can point us to in the application where that data resides, that would be helpful.

MR. COURTNEY: The data was simply population. It was the radius population around Danbury. It was no more complicated than that.

DR. GIFFORD: Okay. Thank you.

In terms of selection --

MR. CSUKA: Before we get to that, actually, I have another question.

So, you're projecting that 66% of the volume will be coming from New York. So, why did you select Connecticut over New York I guess is a more refined question.

MR. COURTNEY: As I said, we'd been trying to

bring it to Connecticut for years. I was a 16-year resident of Tolland myself. I'm Connecticut-centric. My wife went to UCONN. My daughter went to UCONN.

We -- just -- it's a businessman's decision to support the state that they're most familiar with, certainly. I know now with Northwell's proposed takeover of Nuvance, they will be very interested in sending patients to our facility because they can't get access to Memorial Sloan Kettering. So, we'll be asked to look at some very difficult cases to say "no" to.

MR. CSUKA: Thank you.

DR. YONEMOTO: Les Yonemoto, radiation oncology.

As for the explanation about the triage or list of how we select, I defer to Mass General Hospital's proton center. They published an article in I think Journal of Clinical Oncology -- I can go and provide that -- that details their selection criteria of how they triage the patient selection. And it's very reasonable, and it makes a lot of sense. Instead of trying to remember exactly each step of the criteria, I can provide that paper.

MR. COURTNEY: It's actually part of the record already.

DR. YONEMOTO: Okay. Yeah. It's in there.

It's typical based on need. You know, like the group one, they don't have any other options. Then you move on from there. And of course pediatric is always high on the list. But it's all in that criteria.

DR. GIFFORD: Sorry. We're just following up on the location question.

So, just so we completely understand, you looked at population per square mile, I guess, is what you're saying, population density, and then compared that to the availability of existing proton beam therapy centers, and that's how you picked the Danbury location?

Was there a study that your company performed or anything else that you could refer us to?

MR. COURTNEY: All that was confirmed by our feasibility consultant initially, which was IHS, as was referred to, that's now GlobalData.

They're actually in the process of updating all -- our larger study, which we'll need for the bond placement. But we're sure the information is going to be the same.

DR. GIFFORD: Okay. So, no additional documents?

MR. COURTNEY: No.

DR. GIFFORD: Okay. Thank you.

I wanted to ask -- I believe it was Mr. Melson who mentioned that Medicare covers proton beam therapy with few limitations.

Am I correct that for group two it's covered under the coverage with evidence-development category for Medicare, or is that no longer the case?

MR. COURTNEY: I think Chris is better to answer that because he's got a national perspective on that.

DR. GIFFORD: Okay. Sure.

MR. COURTNEY: Chris?

MR. GONZALEZ: Sorry, everyone. I had to unmute. Could you all repeat the question again?

DR. GIFFORD: With respect to Medicare coverage -- and you and one of your colleagues had mentioned that Medicare covers proton beam therapy with few limitations.

It was our understanding from the application that it covered for group two under the coverage with evidence-development category --

MR. GONZALEZ: Correct.

DR. GIFFORD: -- that the provider needs to meet certain standards?

MR. GONZALEZ: That's correct. Yes. So the coverage with evidence-development clause, or CED, is

normally fulfilled when the centers themselves host or participate either in a clinical trial or a clinical registry; where right now, almost every proton center does participate in some either clinical trial or registry.

So, it does fulfill the need of the group-two indications, hence why you still see, for example, prostate cancers normally in group two across the board for all Medicare -- for all MACs; but yet we've never not treated a prostate patient because of that -- because they fall in group two, because normally almost of our, in this example, prostate cancer patients are on a registry or some sort of trial that fulfills the group two.

So, in theory, once you meet group two, it bunches you into group one by getting someone on a trial or a registry.

DR. GIFFORD: I see. And maybe this is a question for you.

What do we know about Danbury Proton and their participation in clinical trials or registries?

MR. COURTNEY: What we know is we want every patient to be involved, if at all possible. It's obviously their choice, but it's important to the industry that we are able to track and collect data so

that we can show really the veracity of the treatment.

DR. GIFFORD: Okay. But you won't have an academic affiliation, necessarily. So can you tell us a little bit more about how that would work in terms of clinical trials and --

MR. COURTNEY: Sure. It depends on what you mean by "affiliation."

DR. GIFFORD: Yeah. Just -- go ahead.

MR. COURTNEY: We've been in conversation with UCONN -- UCONN Dempsey Hospital, for example. We've been in conversation with Hala Medical College in New York. They're both very interested in working with us on the research that we both were planning.

DR. GIFFORD: Okay. And I don't believe you submitted any formal representations in that regard yet; is that right?

MR. COURTNEY: No. Until you have a CON, you're not real.

DR. GIFFORD: Yeah.

MR. COURTNEY: And that really -- we're very interested, but, you know, you don't exist yet, so --

DR. GIFFORD: Okay.

MR. COURTNEY: Yeah.

DR. GIFFORD: Thank you.

MR. GONZALEZ: I did also want to mention

that most of these trials are participated through what's called PCG, which is our proton collaborative research group. So, that allows centers that are not necessarily, like, for example, stand-alone centers that aren't associated with, you know, a university hospital or some sort of, you know, research institution. I think Andrew Chang can attest to that, as well, too.

And I think the last thing I wanted to mention, the same methodology of CED, coverage with evidence development, is also what is adopted by the commercial insurance companies. So, they have those same clauses. For example, Anthem Blue Cross of Connecticut will have a group two, which is, again, just like guideline. It's not a hard-and-fast rule, and it will have a disclaimer -- if this patient is on a, you know, a clinical trial or registry, they qualify for a CED, hence why you do see group-two patients getting approved now for proton therapy from commercial insurance, not just Medicare, because it's the same kind of methodology that most centers are using.

MR. COURTNEY: Andrew, did you have something to add?

DR. CHANG: Oh, sorry. I was going to say the same thing that Chris just brought up on the

question about clinical trials came up.

Yeah, when Dr. Yonemoto and I worked together with the proton therapy collaborative group, PCG, to run these clinical trials, initially we started it because, at that point, there was only a handful -- there were seven proton centers in the United States, and there was a need to develop these trials. And so, the PCG was founded specifically along proton therapy trials.

I'm the vice president and treasurer for the organization right now and sort of the P.I. for the breast cancer trial, which we started in 2013, actually about to close for that.

So, yes, the majority of proton trials -- previously you had them run through the PCG. As more centers have come out, now we're starting seeing dedicated proton trials being run through, like, the NRG through other national groups. But initially, there was not interest because we were a small subset of the oncology world.

DR. GIFFORD: Dr. Chang, before we lose you, I wonder if I could take advantage of your clinical expertise, and if you could summarize for us -- you talked a lot about the reduction in side effects from proton beam therapy because of the more targeted nature

of less surrounding tissue damage, et cetera.

Can you talk about the survival advantages, if any, that have been documented with proton beam therapy? I understand the evidence is still under development and is fairly limited.

But are there cancers for which there has been a documented survival benefit? Can we unmute Dr. Chang?

DR. CHANG: Sorry. I couldn't unmute myself.

Yes. Initially, the studies that we utilized for proton therapy were specifically for cancer that could not be treated with standard radiation. And because in the, you know '50s and '60s and 1970s, the number of centers were limited to, in essence, scientific research accelerators where we move the physics aside and treated for just a few patients, Harvard Cyclotron lab being one of those.

So, we would only be able to treat about 10 to 12 patients a day on these research machines, so we had to be very selective on what cancers that were treated. And so the ones that could not be treated with standard radiation were the ones that were initially proton therapy utilized for. And that's why you see in, like, the group ones the chordomas of the base of the skull, those simply could not be treated

with standard radiation; and so proton therapy, in essence, was the only survival-definitive cured method. So, those, for instance, are increased survivals.

With more access, the thought came to be, well, in addition to survival, can we then treat patients where we can get equivalent survival but lower the side-effect profile? And so, in essence, increasing the therapeutic index by having the same survival but improving the quality of life; which, in general, for oncology, that's where we've gone for the last 40 years, right.

We don't really do mastectomies for breast cancer anymore. It's lumpectomy and radiation or small surgery. That's because the survival is the same but the idea is less aggressive treatment. You don't have as big of a surgery. There's not the cosmetic -- decreased cosmetic outcome for many woman.

Similarly, for sarcomas. We don't, you know, take off the arm anymore for a large sarcoma. We would do a smaller surgery and then radiate. So, the survival didn't change, but it's toxicity reduction.

Proton therapy falls into that same general category and paradigm of cancer treatments, is can we get the same survival with a lower cost, in essence, of patient toxicity.

That being said, there are still other cancers that we do see documented survival, and that's why I brought up the slide about the disease for breast cancer and brain cancer -- sorry, breast cancer and lung cancer that spread to the brain and spine.

For that type of diagnostic -- or that type of disease, for the last 30 years, we have not changed survival at all. It's been always palliative treatments and trying to get the average survival of 6 to 12 months.

Kudos to my colleagues at MD Anderson that said, maybe since we have this access to protons, we can keep giving them the good systemic therapies that they need but let's see if we can sterilize all the spinal fluid. So doing that with protons, we suddenly saw an increase in survival, something we haven't seen before.

And I think what we're going to see is that there are specific cases where proton therapy can increase -- improve the survival. That's one of them that's come out. But I would say most of the studies are really -- most of the utilization of protons has not been trying to improve survival but it's to optimize the survival with the lowest toxicity possible.

DR. GIFFORD: Thank you.

MR. COURTNEY: I think it's important, too, that you stalk about survival. In the left breast case, yeah, the cancer didn't kill the person, but the heart complications did.

DR. GIFFORD: Mm-hmm.

MR. COURTNEY: So, to the fact now that I can get rid of that complication, doesn't that change the formula?

DR. GIFFORD: A few of you mentioned -- sorry, I forgot who it was, but a couple witnesses mentioned that previous proton beam facilities had struggled financially and some of them had been unsuccessful but that more recently they were managing to be successful financially.

Is there any documentary evidence that you can provide us with covering the overall financial stability of these places around the country?

MR. COURTNEY: Single-room certainly made a big difference. But even in that case, it hasn't been foolproof.

The only thing that's been foolproof is the single-room Mevion system. And that's the key, and it's why we've been behind them since they came out. It makes all the difference because you're able to

reduce your capital stack. You're able to reduce your operating cost.

You know, we have one engineer on site. A competitor has three engineers on site. They're working all night to recalibrate the thing. Our guys, it's Maytag man, he's bored out of his mind. It really makes a difference what equipment is used.

DR. GIFFORD: Okay. And are there -- are there any trade publications or anything that you can point to that describes this difference in -- it would be helpful to have that evidence in the record if you have it.

MR. COURTNEY: Yeah. I don't know -- we can Google it and see if there's any -- Lionel knows all the facilities, and he has the data for all the facilities. And he can certainly -- you guys have a paper of some sort that addressed this?

MR. BOUCHET: So, there's a few publications sharing the experience up to two years, right. Washington University did a publication about two years' experience on running proton therapy. I think, in response, the financial success is -- it's not even success. It's stability.

DR. GIFFORD: Right.

MR. BOUCHET: Stability. Right. I mean, a

lot of the centers are not for profit. That is anecdotal. You know, there's no data, no documents. So, aside from the experience published after two years in 2016 by Washington University, everything else is more anecdotal.

DR. GIFFORD: Thank you.

MR. CSUKA: You may have just answered this, but there's a statement in the response to Complainant's Letter One that none of the existing 16 Mevion proton facilities has had any financial difficulty.

And my question was, what is that based on? There was no real source for that. Is that anecdotal or something other than that?

MR. BOUCHET: Well, again, it's anecdotal, but we started the first centers in 2013. We just opened one last year. It was in December. We have one or two to be opened. So, I mean, you know, so it is anecdotal. We always like to say we never had customers that had to refinance or go bankrupt.

So, at least from a -- from a market experience, Mevion is in a position that we can say that none of the Mevion centers have had to refinance, have had to go bankrupt. But that's a factual statement that can only be verified by the

understanding of where the Mevion centers are.

Does that answer your questions?

MR. CSUKA: It does, yeah.

DR. GIFFORD: How many of the 50 centers in the U.S. are Mevion?

MR. BOUCHET: So, in the U.S., there's about a dozen Mevion centers, all singular rooms. actually, we have one that is two rooms, Washington University, that has expanded to a two-room center.

MR. CSUKA: And to the best of your knowledge, has the financial support and backing that has been developed for those other facilities been equivalent to what you're projecting will happen here?

MR. BOUCHET: I don't have that level of detailed informations. So, a lot of the centers, all the centers with similar data, NCI cancer centers, and so the way they finance in general, this kind of financing done through -- through their standard operation capital.

We have a few centers that are private that are a physician group. Usually have used debt financing, so Mevion is not -- it's usually debt financing. These Mevion centers have done debt financing.

MR. CSUKA: Okay. Switching gears a little

bit, I also noticed that there's a statement in a few locations that proton beam was beginning to be used in noncancerous conditions.

Is it the intention of Danbury Proton to begin using it under these circumstances, or is Danbury Proton planning to limit the use of proton therapy to only cancerous conditions?

DR. YONEMOTO: I can get into that one. Les Yonemoto, radiation oncology.

In the cancer world and the radiation oncology world, I should say, we treat both cancerous and noncancerous diseases. And our intention is to be part of that priority list, including noncancerous diseases.

I personally treated over 400 patients with age-related macular degeneration, a noncancerous disease, and I have papers on that. So, that's one example of a novel therapy for that. Protons and radiation therapy treats a lot of different benign diseases, and we'll include that as part of it. It's just that with radiation oncology, most applications and such don't really mention it too much because it's -- the focus is cancer.

MR. COURTNEY: I might mention, too, that Dr. Moyers in China has just recently started doing

much of what you guys did down in Loma Linda with ADM as well -- I mean -- age-related macular degeneration.

DR. YONEMOTO: Right. Age-related macular degeneration.

Well, actually, one of the first things that was used was protons for age-related -- being a malformation, a blood disorder in the brain, back in the 1960s with Harvard Cyclotron treating that, because you can see that on plain film, X-rays. This is before CT scanners were invented. And you can measure a distance of where to stop the protons.

So, and then next was eye diseases and things like that. So, yeah, a lot has happened in the last decade or two in terms of the feasibility of proton centers.

MR. CSUKA: Thank you.

MR. COURTNEY: I will add that this is a very research-interested group.

Dr. Moyers, how many patents do you have now? Seven, eight, nine, ten?

DR. MOYERS: Hello?

MR. COURTNEY: There you are. How many patents do you have, Dr. Moyers?

DR. MOYERS: It's around 20 now.

MR. COURTNEY: Oh. Sorry. Underestimated.

But we're very -- these guys are pioneers.

DR. YONEMOTO: Research is definitely part of this. There's no question about -- research has always been a part of this, and it comes with the center, especially since we're registering everybody and we're going to be participating in clinical trials. It was something we didn't have even second thoughts about participating in that.

Dr. Moyers, years ago, and continues to, is a mentor in terms of colleague and papers and patents and such. So, it just kind of shows the depth of experience in terms of research that we perform.

MR. CSUKA: So, we've talked a lot about the benefits of proton beam therapy.

Are there any circumstances in which conventional radiation would still be the more preferred modality?

DR. YONEMOTO: Well, there's many ways to look at that question. The first reason why there's I think 4,000 LINACs that are treating over 95% percent of the patients is, one, access and availability, that they're everywhere; and rightfully so, because if you're going to treat 60% of the cancer patients, you have to be available, have access to it.

Saying that, since radiation therapy is

typically given over one to two months of daily treatment, the X-rays or the LINACs that produce X-rays by default are the preferred method because they can access it.

For protons, it's not the preferred method because of nonaccess. You have to be near a center and be able to come in for a daily treatment, which is a significant hurdle for many patients.

As I put on the first slide of X-rays and protons, the biology of the beam is the same whether you treat it with protons or X-rays in terms of both cancer-killing and side effects. So, the other end of the question is both modalities can treat cancer in the (indiscernible.)

It's just that we find advantages with protons in many cases. And a lot of them are equivalent. Like, one example is right-sided breast cancer. It's far away from the heart. The advantage of protons isn't there, right, but it can treat it and have the same efficacy and side effects as X-ray. But since it's not near the heart, then maybe that's one of those reasons why protons could treat it, but it's a -- X-rays can do a better job because it's more accessible to the patient and the patient will probably get the treatment.

There are so many patients that I know of that don't get this -- any type of radiation because of the logistics of getting to a center. So, I'm trying to answer both sides of that question. I hope that was sufficient.

MR. CSUKA: It was. Thank you, Doctor.

It's probably a good place to pause questioning. We do have some other questions, but I do want to turn our attention to public comment.

I don't know if we -- so, Attorney Hardy, you had emailed over a number -- not a number but some people that you anticipate would be speaking. So, we will likely take them first. But I'm just going to sort of go over what public comment is for anyone else who's tuning in.

So, this is the public's opportunity to provide their thoughts on a particular project. So, public comment sign-up has been all day, since we started the hearing, and it will end right now. If you have not signed up, please do so immediately either in person -- I don't see anyone here -- or through the Zoom comment function. And Ms. Fentis just confirmed that no one else has signed up.

So, typically, the order in which we go is elected and appointed officials, clinical professionals

and executives, and then individuals who have signed up.

So, Attorney Hardy, do you want to sort of take the wheel on this a little bit?

MR. HARDY: Yeah. So, today's a very challenging day in terms of having the legislators be able to Zoom in because there are marathon sessions going on today with the legislative session.

So, I have word that Representative Farley Santos should be able to log in at some point within the next half hour and word that Mayor Alves of the City of Danbury will be able to log in at 12:30. But that's the only information I have at present in terms of situations where we might want an accommodation in terms of taking people out of order.

MR. CSUKA: Okay. I don't have the list of names that was -- that you emailed over yesterday, so I frankly don't know who else is on that list.

Do you have that available to you?

MR. HARDY: I do. So, we had listed Deborah Hickey. I see she is on the Zoom. We had listed Aubrey and Grace Eline. I'm not seeing them. Dan McInerney. I don't quite see him on there. Miguel Fuentes and Bill Fench -- I don't see either of those at present on the Zoom.

MR. CSUKA: Okay. You said one of the individuals you did see, though?

MR. HARDY: Yes. Deborah Hickey.

MR. CSUKA: Okay. Ms. Hickey, are you available?

MS. HICKEY: I am. Can you hear me?

MR. CSUKA: I am -- I can. Oh, boy. So, typically we limit people to about three minutes, but since you're apparently the only one who's here right now, feel free to take your time.

MS. HICKEY: That makes me feel better. I'm going to try to keep it under ten minutes.

So, good afternoon, everybody. Dr. Gifford and OHS staff, thank you for the opportunity to speak in support of the Danbury Proton therapy center.

I am Deb Hickey, and I run the Brotherhood of the Balloon organization. Please allow me to explain who we are and how we came to be. But quickly, since I joined this Zoom a bit late, I'm not sure if you covered the public hearing issue statement that proton therapy is considered experimental, though I'm sure at this point you're convinced that that is an inaccurate statement. And the following story will help clarify that. And, again, I'll try to get through this very quickly. But I'm just going to tell you a brief

history of the Brotherhood of the Balloon so you'll understand.

My father, Bob Marckini, was diagnosed with prostate cancer in 2000. A few years earlier, he watched his older brother suffer debilitating side effects following a prostatectomy. And at the time, my father vowed to himself, and he knew that prostate cancer was hereditary, he said if he were ever diagnosed, he'd find a different treatment option.

Now, my father, a retired engineer, recovering engineer, as I like to call him, is a researcher. He doesn't make any decisions without first doing a lot of research. So, following his diagnosis a few years later, he spent months talking to and meeting with physicians, including several radiologists, to educate himself about the various treatment options for prostate cancer. And he spoke with nearly 60 former patients representing each treatment option he looked into. He read studies. He read articles and everything he could find online.

Meanwhile, one of his best friends, Larry, was vacationing in Grenada about six months after he'd undergone a prostatectomy for his prostate cancer. Larry and his wife were out for a walk one day and struck up a conversation with a guy who had just

finished a jog.

Larry learned that the guy that had just finished the jog had been treated for prostate cancer a month prior. Dumbfounded, Larry said, Well, what kind of treatment did you have? thinking, How could this guy be jogging? Here I am still learning how to walk because I have so much pain and I'm wearing a diaper. Turns out the jogger had had proton therapy.

Larry knew that his friend Bob had recently been diagnosed, so he told him about it. He said -- when he got home, he said, This guy said he never felt a thing and is living the same life he was living before he was treated.

So, after that conversation and learning as much as he could about protons, my father ultimately decided to visit Loma Linda University Cancer Center in California, where the only proton center in the country was located at that time.

Shortly thereafter, he decided that proton therapy was the best option for him because it was painless, noninvasive, and would allow him to maintain his quality of life, which was the most important thing to him. So, he and my mother flew to Loma Linda, where they'd spend the next couple of months.

And while back home we all thought he was

sickly and bedridden, my father was golfing every day after his 15-minute morning treatments and spending his evenings touring the area and eating his way through all the local restaurants. My father later referred to his treatment time as a radiation vacation.

After his first -- after his treatment ended, my father volunteered to keep six patients connected through email. They planned on sharing PSAs and other updates and information. And by the time my father was actually packing up to leave California and head home to Boston, there were 19 men in the group.

When my father sent out the first email to this group of men, he jokingly titled it "The Brotherhood of the Balloon," as Loma Linda used a rectal balloon to reduce rectal toxicity and enhance immobilization. My father also did not intend for the abbreviation, the BOB, to correspond with his first name. That was just lucky.

Some months later, there were 100 men in the group, and my father thought, How on earth am I going to keep 100 men connected? because the emails and the friendly communication had become pages of information, the latest news on prostate cancer and proton therapy as well as general health information he thought the group would find valuable.

And later, he began including humor and trivia and other things he thought the guys would enjoy. And they did, because they started responding, and they started asking questions.

And then the other proton patients and prospective proton patients got wind of the group, and they wanted to join. And they started sending separate emails with questions, and some were then requesting phone calls.

It became a lot. In fact, it became too much, which my father sort of did to himself, but he decided it was just too much. So, he called his old friend at Loma Linda, Dr. Lynn Martell, who at the time was the Director of Patient Services, and he told Lynn that he planned to shut down the BOB because it was taking too much of his time and energy, more than he'd ever anticipated.

But by that time, Dr. Martell knew that patients were loving this organization, they were loving this group. They were staying connected with each other, they were staying informed, they were sharing information with family and friends, and they were so appreciative of Bob's, my father's enthusiasm, his knowledge about proton therapy and prostate cancer, and his willingness to answer questions via email and

phone.

So, Loma Linda offered to help financially. And since my father was retired and the stock market wasn't doing too well -- excuse me -- he accepted. So, he could now hire someone to create a membership database by which he could keep all of the member information organized and categorized, and he could even search for member contact information and other statistics.

He then also hired someone to build a web site to post information about proton therapy and have a section where members could access a private-member resources section, which included archived newsletters and other resources.

A few years later, around 2006, still running the BOB, my father wrote a book called "You Can Beat Prostate Cancer -- and You Don't Need Surgery to Do It." The main purpose of the book was to help newly diagnosed men navigate their way through the often very confusing treatment decisionmaking process.

In it, he included information on prostate cancer awareness, prevention and detection, the pros and cons of each treatment option, the advantages of proton therapy, the importance of speaking with former patients before making a treatment decision, and the

importance of becoming your own health advocate.

He found a small publisher, and eventually the book worked its way up to the number two position in the search results on Amazon for a search for prostate cancer as well as 400-plus five-star reviews.

And by this time, the BOB Tales Newsletter, called Bob Tales, was in full swing, about 10 to 15 pages sent out monthly, and my father had established a three-part mission for the BOB: One, to keep members connected; two, to promote proton therapy; and, three, to give back to the institution that started it all at Loma Linda.

The newsletter and our website were also promoting BOB reunions led by Loma Linda that were happening all over the country, and eventually our members started forming their own local BOB groups and member unions.

At this point, around 2010, my father was completely overworked and overwhelmed. So, he called me. I was the director of marketing for a search engine optimization company in Boston, and he knew I had the experience to take some of his work off his shoulders and perhaps build upon what he'd started.

So, long story short, I came aboard. And by 2011, 2012, we had a Facebook presence, a blog, a

PowerPoint presentation for our members to use themselves in their own communities to educate others about protons. We had a number of patient reference lists, including the names and contact information for some of our members who volunteered to communicate with newly diagnosed men, share their personal experiences of treatments and their outcomes.

And we began fund-raising campaigns for proton research at Loma Linda. And by the way, those efforts eventually led to the Robert J. Marckini Endowed Chair for Research for Loma Linda, and our group has raised about $14 million to date.

It's also important to note we initiated multiple surveys among our thousands of members across multiple proton centers over the years. And results from our last survey showed that 98% rated their treatment experience as excellent to outstanding, 99% reported that they felt they made the best treatment decision for themselves, 97% would make the same treatment decision again, 97% had recommended proton therapy to others, 97% reported no recurrence of their prostate cancer. And there were also high scores reported on urine control, bowel function, and sexual function.

At around 2018, 2019, my father began writing

the second edition, an updated version of his book, which was published in 2020. That book now holds the number two position out of 6,000 books on Amazon on a search for prostate cancer, and patients are reporting that the book was a major factor in their treatment decision. Some say it was the deciding factor.

Also note that many of the proton centers buy the book in bulk, and they give it to their patients when they request information about proton therapy for prostate cancer.

So, fast forward to today, we have more than 10,000 BOB members who have all undergone proton therapy for prostate cancer or they're currently undergoing proton treatment, and the vast majority of them are doing great. They come from all 50 U.S. states and 39 countries. They represent more than 40 operating proton centers in the U.S. as well as several in Europe and Asia.

I also want to point out that many of our members were treated more than 20 years ago. My father at this point was treated 24 years ago. He hasn't seen his urologist since. He hasn't needed medications for any side effects ever. His quality of life is superb. He's 81. He swims a mile every day at his golf club's pool. He's still working about ten hours a day because

he's still passionate about this ministry we call the BOB.

Newly diagnosed men and their family members, they're finding our organization in search engines through the National Association for Proton Therapy and others in the proton community from our members and other ways. We receive hundreds of emails each month, and we do our best to respond to each one, but it's very difficult.

Our monthly newsletter now is about 25 pages. It contains the latest news and information on proton therapy and prostate cancer as well as information on the healing process and preventing a recurrence.

There's a member spotlight section where we highlight our members in a variety of ways, a health section where we include information focused on men's health, a section called "On the Lighter Side," which includes a monthly brain tease they're we developed to keep our members engaged and in contact with us, and they absolutely love it. We pick a winner each month who receives a signed copy of "You Can Beat Prostate Cancer."

And there's a lot more. The advantages of proton therapy are now well established in the medical community, and the advantages have been experienced

first hand by thousands and thousands of our members who are normally enthusiastic about their experiences, and they typically jump at the chance to spread the word about protons through any means possible.

They volunteer to be included on our former patient -- proton patient reference list. We now have 55 lists categorized by treatment center, pre-existing health condition, country, state, et cetera.

Our members use our PowerPoint presentation to educate and inform their local community groups about proton therapy. Many of them forward or print our newsletter for friends, family, and acquaintances. Some share it with their urologists, some with their dentists and other physicians, and many print and drop them off at local libraries and churches.

One of our members once said that proton therapy is the only cancer treatment with a fan club, and I believe that that's true.

So, given the undeniable benefits of proton therapy, particularly as it concerns to the patients' overall quality of life, it's no surprise there's a phenomenon of self-referral among proton therapy patients. When presented with treatment options or life-and-death decisions and given at least some limited time for exploration, patients will

understandably devote and prioritize their time and resources to independently research the best treatment course available. And time and time again, this process has led patients to proton therapy.

So, this phenomenon, coupled with Danbury's location and proximity to major population centers and the outstanding clinical leadership of Dr. Les Yonemoto and Dr. Andrew Chang, along with support from Chief Physicist Michael Moyers, who is extremely known well for the anticipated utilization of the Danbury therapy proton center. Thank you.

MR. CSUKA: Than you, Ms. Hickey.

Attorney Hardy, is anyone else here?

MR. HARDY: I don't see any others on our list having appeared on the Zoom.

MR. CSUKA: Okay. So, we do have I believe you said the mayor who plans to make a statement at 12:30.

MR. HARDY: Correct.

MR. CSUKA: I think it makes sense to jump back into some more questions until that point.

MR. HARDY: Sorry. Breaking news. Representative Farley Santos is logging in momentarily, so I don't know if you want to break and come back and take him as the first -- up to you, obviously.

MR. CSUKA: Do you happen to know what "momentarily" means? That can mean a lot of different things.

MR. HARDY: It said "two minutes" two minutes ago, so --

MS. FAIELLA: He is right here.

MR. CSUKA: Great. So, that's Representative Santos?

MR. HARDY: Yes.

MR. CSUKA: Okay. Representative Santos, are you available? There you are. Can you hear us?

REPRESENTATIVE FARLEY SANTOS: Hi. Were you calling on me?

MR. CSUKA: Yes, I believe so, if you're Representative Santos.

REPRESENTATIVE FARLEY SANTOS: That's right. I am. I'm sorry. We're in the middle of session here, so we're trying to get to a nice, quiet spot to discuss this with you.

I'll be very brief. I think the delegation submitted a letter of support for this application. I think this is something that Danbury for sure could benefit from, along with our residents, right. And there are some stories that have come to us from folks who have had to have cancer treatments and have had to

go a further distance, right, to have those services that they required.

This not only would be addressing some of those issues, it would be an economic development issue, as well, for Danbury. And I think that it's progress that is needed in that corner of the state.

I think it would serve a need for a broader base of the community. And now that they've done a lot of work not just on the design of the facility but the kind of treatments that they're going to have, along with also acknowledging some of the concerns that were brought up in the past and addressing those as well.

So, I have full faith in their operation of this facility, and I hope that all of you will understand the need for this within the Danbury community and would support their application. Thank you.

MR. CSUKA: Thank you, Representative, and thanks for taking the time. I know things are really hectic over there right now.

So, I think now we can do some questions, and then -- as we wait for the last person to jump on at 12:30. So, I was going to continue with mine unless you had any additional questions.

DR. GIFFORD: I do, but please keep going.

MR. CSUKA: So, I have some questions about the open-affiliation policy. What -- so, the team that you have developed here, what is their experience with nonaffiliated facilities?

MR. COURTNEY: Les, you want to talk to this subject?

DR. YONEMOTO: Les Yonemoto with radiation oncology.

In the medical world, we have restrictions on using facilities and nonrestrictions depending on hospitals and facilities, as you know.

Our intent, our goal is to be an open model where any radiation oncologist that is certified can use the facility for any of their patients, similar to any other -- you know, not just for radiation but other centers are open centers too. We don't want to close it to any physician or patients. It's, I think, that simple.

Obviously, they have to be certified radiation oncologists, and there will be another radiation oncologist such as myself, or doctor-trained, to help oversee the direction to make sure of quality. Most of the radiation oncologists coming out here are well trained with all the modalities, so --

DR. CHANG: I'm happy to share a little bit

about that as well. Our center in San Diego is likewise an open model where physicians in the community are able to bring and treat their patients at the center.

In reality, what we've seen -- in San Diego, there's three large healthcare systems, and really it's mostly -- it's a commitment from one institution would be the ones that primarily would bring those patients over.

For instance, in our case, it's our partners at UC, San Diego, where they've dedicated physician time to be at the center, and so they have their doctors spending anywhere from one to three days at the proton center seeing the patients and treating the patients.

As an open model, we also welcome the other healthcare systems to bring patients, like the Scripps physicians to come over. And they did at first, and they did enough to get credentialed at the center, but it was really dabbling -- they would just spend maybe half a day every couple of weeks. And after a short period of time, they just decided it would be easier for them to refer their patients to the center.

And so, I think it really comes down to the intentions of the other systems, whether -- how much

they want to use the facilities. And I think that's something I've seen similarly happen at other facilities that are open. You'll have groups that are committed to using it and then will dedicate the time and resources and personnel to do so, and then you'll have those dabble as well and then just find it easier to refer.

I think it's similar how a stand-alone surgical center might function. They would open a facility, and then surgeons can come in and get credentialed and certified to operate in those facilities. And it tends to find -- or play out that a few groups will utilize the centers more than other groups, but all are welcome. And I see that model as how it really works once a proton center gets opened up.

DR. GIFFORD: A follow-up to that comment. So, in your application, you talk about actively recruiting physicians who would bring their patients to the facility and say that there are very few physicians that have high levels of experience with this type of treatment for reasons of, you know, it being a less widespread technology.

So, can you just talk to us a little bit more along the lines of what Dr. Chang was saying about who

the clinicians would be?

I don't know, Dr. Yonemoto, if you would be practicing at Danbury Proton or, if you know yet, to your earlier point, Steve, you know, about -- chicken-and-egg kind of question. But can you just tell us more about how you intend to assure that you have adequately trained clinicians at the facility?

DR. YONEMOTO: Oh, yes. Les Yonemoto.

Like most facilities, there's usually a medical director or someone in charge. That's part of it. And I hope to be that person. My intent is to be that. My intent is to practice there.

But with over 50 -- 40, 50 proton centers, there's a wealth of people with experience with protons now that actively recruiting people with the experience is not a big problem I see.

The other is, we're used to training folks. That's why I used to be a training residency director at the only proton center for many years. So, that's not an issue.

The planning of a radiation -- you know, our plan is sort of agnostic to what beam you use. So, the beam -- as the plan looks better with protons, we're all trained on how to make the plans look better where you put more dose on the cancer and less on the normal

tissues. And a lot of that's due to the planning.

There's a dosimetrist that we have here that will have experience in using protons, and that's the key person that helped, you know, design the plan with the physicist and the physician but takes the lead on making the plan the best possible plan, whether it's protons or X-rays.

So, that's -- that's -- there's plenty of supply like that. We obviously want to recruit the best, and the credentialing is no different than credentialing at a hospital or anywhere else. You know, they have to be licensed and board-certified and have references and such. I don't see it's much of an issue. You only need one or two physicians to keep the center going.

DR. GIFFORD: Okay. I apologize if you stated it. Are you actively practicing in Connecticut?

DR. YONEMOTO: No, I'm not.

DR. GIFFORD: So, you're not licensed yet in Connecticut?

DR. YONEMOTO: No. I will be, hopefully soon.

MR. CSUKA: I think that's enough on the open affiliation.

But a related question is, you said in your

response to the completeness letter that you intend to initiate discussions with existing proton centers in New York and Boston. And you re- -- that word is not going to happen right now -- reiterated that earlier.

You know, what are your feelings on potentially affiliating with CPTC, that's Connecticut Proton, in the event they were to approach you down the road? Would you be open to that, or would you be limiting yourself to New York or Boston?

DR. YONEMOTO: Oh, we'd love it. We'd love to work with them. We would encourage it. We'd push it. We want to work with them. I was in support of their facility at the, you know, last --

MR. CSUKA: Okay.

MR. COURTNEY: I might comment, too, just -- just having -- Steve Courtney -- just having come from the National Proton Conference. It's frankly a big club. All the facilities are doing great work. They're doing clinical surveys -- I mean studies. They're working together. Jacksonville now has two facilities already. Mayo Clinic's building another facility there. They're all going to be working together.

We will definitely be communicating and working with the Wallingford facility as well as the

MGH's and New York, New York's and Massachusetts. All of these are frankly going to get more facilities. There has to be more facilities. We just can't treat everybody.

So, there will be a lot of cooperation between all the groups. A little bit of flourishing, you know, between Danbury and Wallingford will totally disappear.

MR. CSUKA: Attorney Hardy, has that other individual signed on yet?

MR. HARDY: I don't see him, no.

MR. CSUKA: Okay. I think we're going to -- I think we can probably be done within the next, like, half hour or so, so I think it makes sense for us to keep going rather than, you know, break for lunch for a long period of time and then come back for a short period of time.

MR. HARDY: Makes sense.

MR. CSUKA: So, Dr. Gifford, do you want to ask some questions?

DR. GIFFORD: Yes. I wanted to ask about access in particular for individuals covered by Medicaid in Connecticut. As you know, part of our statute requires us to consider that access in terms of need.

And your witness -- your public comment --

MR. CSUKA: I think --

MR. COURTNEY: Sounds like a politician logged on.

DR. GIFFORD: Okay. I'll defer to the mayor. If you are not the mayor, could you mute yourself, please?

MR. CSUKA: Mayor, can you hear us?

MAYOR STEVE COMA: I can hear everybody okay. I've just been waiting. I apologize. I can mute myself until you're ready.

MR. CSUKA: No. I think we're ready for you, so feel free to make whatever statement you would like.

MAYOR STEVE COMA: Well, thank you everybody, so much, for the opportunity for my testimony on this, and Executive Director Gifford.

My name is Steve Coma, and I proudly serve as the Mayor of Danbury. And for the last four years in my capacity as an elected official and resident of Danbury, I've had the opportunity to follow Danbury Proton Center's journey from the beginning, and I've been excited about the prospect of this project finally coming to fruition.

This project is just about shovel ready and, if approved, it could break ground immediately, like

tomorrow, allowing us to experience new healthcare and revolutionize cancer treatment in Danbury and Connecticut.

As the CEO of the greatest city in Connecticut, Danbury Proton Center would be an exciting transformational new addition to our community and our business community. It would create 100 well-paid, high-skilled local construction jobs and over 30 permanent medical administrative jobs. We also expect opportunities for local vendors, which represent a very important portion of the Danbury property tax revenue.

We're always on the lookout for opportunities that will benefit our local economy and our community, bringing new, good-paying jobs and bringing cutting-edge healthcare and technologies to our city.

These initiatives are also personal for me. After receiving treatment for two years, last year my father passed away from pancreatic cancer at 63 years old. Cancer affects everyone in some way, and our families, like mine, knowing that there's cutting-edge treatment options in our backyard, makes a big difference.

Danbury Proton, the pioneer in the healthcare industry, their life-changing, lifesaving services will provide significant benefits to the residents of

Danbury and its surrounding communities, and patients throughout the northeast will soon have access to this revolutionary proton therapy. It would be an honor if Danbury Proton called our city home, and I am committed to making that a reality.

So, thank you all so much for your time. I will stay here unless there's -- you need me not to. But Danbury Proton has our full support.

MR. CSUKA: Thank you, Mayor. You don't need to stay on, but you're welcome to.

And I believe that's it for public comment. Is that correct, Attorney Hardy?

MR. HARDY: That's correct.

MR. CSUKA: Okay. So, anyone who didn't get an opportunity to speak today is free to submit written comment up to seven days after today. The email address again is CONcomment@ct.gov. And you can submit that directly to that email, and it will eventually get uploaded to the portal.

I'm going to turn back to Dr. Gifford now, who's going to ask a few more questions.

DR. GIFFORD: Thank you, Mayor, for your testimony.

So, getting back to Husky/Medicaid here in Connecticut. So, we've heard about the challenges of

daily treatment, and we understand that that can be especially challenging for people with limited means, particularly those who lack -- who rely on public transportation or who lack family supports for things like child care, et cetera. Not everyone has the -- of course the luxury to travel and to receive this treatment.

So, can you just tell us a little bit more about experience with supporting individuals with Medicaid to receive this treatment? How in particular do you see Danbury Proton providing support such that we have equal access to this treatment for people that are covered by Medicaid?

And as part of that, if you want to talk about the coverage policy here for Husky here and how that relates to your response.

MR. COURTNEY: I think it might be good to start with Andrew Chang. Andrew, you guys have a charity policy, obviously. How's it working there in San Diego?

DR. CHANG: So, the majority of our patients who are on Medicaid are our pediatric population. We have -- 19% of our patients we treat are pediatrics. And especially where we're located in Southern California, those family members also crossing over

from Mexico into our region are placed on emergency Medicaid. In addition, we have patients that come from Nevada and New Mexico, so we have to work with out-of-state Medicaid as well.

So, the support systems we have are, first we look with -- we're familiar with the local children's hospital that provides housing support with a lot of their own housing. In addition, we have a variety of other support systems, such as relationships with American Cancer Society, that provides local housing or a stipend for local housing for adult patients with Medicaid who cannot afford the trip.

We have also worked with various transportation groups in the area to provide transport to and from housing, so a few of the hotels near us will have shuttle services for the daily transport. We have vouchers with Southwest Airlines to provide travel to and from their home as well as the -- it's called, like, Uber Health or something like that. I can't remember exactly their name. But they have a section where we are able to utilize their services to do patient transportation for, you know-- across nonacute assistance, so patients that just need to get to and from their hotel that we work with.

Those have all been very helpful in providing

additional support for the patients who don't necessarily have the financial resources to be able to stay, especially like an expensive city like San Diego.

There's also the charity program that you mentioned, Stephen, for patients who don't have any insurance at all to still -- if they need therapy -- again, this primarily goes for patients that come from Mexico, Tijuana -- where they get surgery, and they'll come up for proton therapy. And we have a review group that consists of the oncologists, the surgeons, and the radiation doctors that will triage those patients, as well, along with our standard triage process for patients.

The -- I think the biggest difficulty has been working with Medicaid from out of state who have different rules on which patients they'll send and what support we can provide to those patients.

I'm not familiar with the Connecticut area more to be able to speak much more on that, but that's how we do it in Southern California. And I think that is growing as well. We have partnerships helping Stanford, UCSF, build centers in Northern California. So it will be easier for those patients to get access, because currently there's no proton centers in Northern California, so they have to fly down south. And

California, you know, we're a state of 40 million people, and we only have Loma Linda and us in San Diego, so we're happy to see more centers coming up to provide more access.

DR. GIFFORD: Thank you, Dr. Chang. So, will there be -- I'm trying to understand the relationship of that response to Danbury Proton.

So, there's not a formal relationship between Dr. Chang's center and Danbury Proton, or is there one that I've missed?

MR. COURTNEY: Not a formal one, no.

DR. GIFFORD: Okay.

MR. COURTNEY: We have gotten proposals from them to assist us in our operations.

DR. GIFFORD: Okay. So, with respect specifically to the questions around access for Danbury Proton, do you have any analogous plans to those that Dr. Chang described?

MR. COURTNEY: That's certainly in the plan, certainly. We certainly -- part of our mantra is, you know, to turn no patient away from a financial point of view, by any means. So, no, it's a big part of what we hope to accomplish there.

There is, you know, a population that is in that area that we hope to serve as well. The

transportation side of it is important. There are various transportation organizations -- or organizations in Connecticut that are very helpful in that regard. You know, in the public health side of things, there are resources there in terms of transportation.

One of the keys of running a smooth operation is getting patients there on time. And so, to the extent that we spend money on that, that's also what we anticipate doing. We have a written charity policy already developed. I think that was submitted as part of the record? So, that speaks to the charity side of things.

DR. GIFFORD: Okay, which is different from Husky.

MR. COURTNEY: Yes.

DR. GIFFORD: Okay. And 5% of poverty level, that would be eligible for charity care? Just remind me what's in the policy? You can come back to that while you get your big notebook there.

So, on a similar line, you, at our request, kind of quickly went past the WiTT test slide in your presentation. Can you say a little bit more about what that is and why it's needed?

MR. COURTNEY: Sure. I think it is something

that OHS would more broadly be interested in. I frankly just discovered it at the National Proton Conference just a month and a half ago. And Memorial Sloan Kettering was championing that particular platform. The developer of that platform had some life situations in terms of battling cancer himself and wanted to find a way to more effectively impact the total patient.

I mean, every facility has a patient liaison and that sort of thing, but this platform he was able to develop gives a patient a place to say what things would be nice for them, whether it would be walking the dog or giving them some transportation, coming over and cleaning the dishes, mowing the lawn.

Yet most people really have a hard time asking people to do things, so this platform, you just list these various things that would be nice to have happen by somebody, and then on the other side of the coin is there are a lot of people that would love to help a person but have no idea how to do it. And so, it facilitates the people that want to help. They can go to the registry and say, Oh, Saturday, I can go and mow the lawn or whatever the request is. So, it puts -- excuse me -- it puts the need out there more easily for the patient and puts the response out there more

easily for the would-be helper.

DR. GIFFORD: I see.

MR. COURTNEY: It can involve money as well. As a matter of fact, Memorial Sloan Kettering said essentially that 95% of the requests that were honored had some kind of monetary component, whether it was bringing over ice cream this afternoon or something.

But -- so, it's little bit of a blend of a GoFundMe and a registry. It's pretty exciting, really, because it addresses the whole patient, and not just the patient but the family needs, which, as you know, the patient doesn't have cancer, a family has cancer.

DR. GIFFORD: Okay. Thank you. And I just -- I want to go back because something Dr. Chang said struck me a little bit about the number of facilities in California. There's Loma Linda, San Diego, none in Northern California.

So, can you just explain again how that relates to your assertion that Danbury, Connecticut, is the place where one is most needed based on population, given that we have one in New York, one in Boston, and one to be built in Wallingford, and there's only two in the whole state of California?

MR. COURTNEY: The whole state of California is very big, so if you look at the -- you know, the

larger density, it's simply a matter of population density.

DR. GIFFORD: Right. And proximity.

MR. COURTNEY: Lionel and Mevion is trying to correct that problem in Northern California right now. They are developing a center with Stanford.

DR. GIFFORD: Okay.

MR. BOUCHET: A lot of the limitation -- Lionel Bouchet -- a lot of the limitations that we have seen at for proton centers is because the construction costs have been tremendous.

So, we have a partnership with Stanford to bring proton therapy within Stanford Health. That was a project started some 20 years ago. UCSF the same way. It's just the cost of this very large construction. The partnership with Stanford has been very (indiscernible) because we are going to bring it directly on their campus, so that integration is important. So, why no more -- more proton, it's here. Danbury is a much, much -- a lot of patients, a lot of population.

DR. GIFFORD: Understood. Thank you.

MR. HARDY: I have located the charity care parameter if you'd like me to read that.

DR. GIFFORD: Yes.

MR. HARDY: And so, this is Exhibit N, as in Nancy, to our original application. So, it provides, where income is 200% of the federal poverty limit or less, that qualifies for free care; then at less than 225%, a 60% discount; less than 275%, a 40% discount; less than 300%, a 20% discount; less than 400%, a 10% discount.

DR. GIFFORD: Thank you very much.

MR. CSUKA: In some of the materials that you sent over yesterday, you made reference to the Mevion S-255th and how it's likely to receive FDA clearance in 2024.

Is there any chance that Danbury Proton would, in a sense, move to instead install one of those instead of the planned --

MR. COURTNEY: Yes and no. We've designed the facility so we can easily add a second treatment facility. That's all been approved by the city and the planning process.

And so if, in fact, what happens that we expect, that we'll be quickly running out of patient slots, we will probably add a fifth to that as our second machine.

It does have to get FDA approved. It is unique in that the patient positioning is not laying

down and the seated position is going to be challenging. So, it may not make FDA approval or be ready for treatment very quickly, and we didn't want to frankly wait around for that for our current installation. And, frankly, having both systems might offer some advantages in the future.

MR. CSUKA: Thank you. And I think this probably goes without saying, but I didn't see it anywhere in the record, so I'm going to ask it anyway.

Does Danbury Proton plan to seek either ACR or ASTRO accreditation?

DR. YONEMOTO: Yes, we would like to. In order to do that, we'd have to have some established time frame of operations, and then what they do is they retrospectively look at our records and see if it meets the national standards. But the short answer is yes.

MR. CSUKA: Okay. Thank you. I think that's the main substantive questions. There were some other sort of late-file sorts of things that I wanted to go through.

Actually, let me first ask, Annaliese, Yadira, do you have any questions you wanted to ask?

MS. FAIELLA: All set.

MR. CSUKA: Do you? All set?

So, as we were going through all the

materials that were submitted, there were just some sort of deficiencies that I noticed as I was going through.

So, for instance, on page 28 of the application, there was one paragraph there that had some figures and percentages, but there was no source provided. So, I would like to ask for that source to be provided.

The same sort of thing for page 29, the first two full paragraphs. No source was provided for the facts and figures put there.

And let's just start with page 28 first. Again, that's Bates page 28. And you might -- you know, somebody here might be able to say what these figures are based on. If not, you can go and do some digging and then get back to us.

MR. HARDY: Yes. Certainly. We can provide that.

MR. CSUKA: For page 28, it's the first full paragraph, need and demand within the service area. And I think actually we touched on it earlier. Dr. Gifford may have asked some questions about that.

So, I'll include that as part of the late file order, that application page 29. Again, it's the first two full paragraphs starting with "an estimated

1,317,745."

So, page -- actually, page 36 we addressed.

MR. HARDY: I do know the 1,317,745 Connecticut residents is in the GlobalData report.

MR. CSUKA: Okay. So, this may all be based on the GlobalData report? Because up above you referred to the Connecticut Cancer Plan. So, it sort of blends a little bit? So, if you can just --

MR. HARDY: Yeah. We'll confirm that either way.

MR. CSUKA: On page 41, you made reference to a second primary service area in New York, and then you said -- I think it wasn't your intent to list the towns and cities that make up that New York PSA, but only a map, which was sort of grainy, was provided. So, if we could receive the towns and cities, just a list of them as you did for Connecticut, that would be helpful.

And lastly, page 57, Bates 57, there was a chart that was provided, and as the source it says "compiled sources." I wasn't sure what that referred to. So if you can confirm that, that would be helpful as well. Oh, actually, I just -- I apologize. I just found that you -- "compiled sources" is a defined term on page 50, so we'll ignore that one.

So I think -- so, we'll send those out just

so that you have them and they're easier to respond to.

There were also some other late files that were discussed in the course of today's hearing. I don't recall who said they would provide the -- I think it was Dr. Chang who said he would provide the publications for slides 82 through 84, as well as the NCCN policy, and I believe there was another policy as well. I didn't catch what the acronym for that was.

MR. BOUCHET: NAPT.

MR. CSUKA: NAPT.

DR. GIFFORD: Not the 400-page one.

MR. BOUCHET: Right. The NAPT does a very good job at summarizing the NCCN, and I would recommend using those.

DR. GIFFORD: As long as it cites their original --

MR. BOUCHET: It does cite. It's a fantastic site. That's cited and updated regularly. They just -- wherever a proton is mentioned, it's provided information.

MR. CSUKA: Attorney Hardy, do you want to take a minute off the record to discuss how long you might need to get those late files to us?

MR. HARDY: Sure.

MR. CSUKA: Or if you have something in mind.

MR. COURTNEY: Seven days will be fine. We don't need it, right?

MR. CSUKA: We'll put that in the order that's issued tomorrow as seven days. If you need more time for any reason, that's fine. And that will line up nicely with the public comment period, which also ends in seven days.

Attorney Hardy, I know you said in the interest of time you're willing to forgo providing a closing statement. We are ending earlier than I think -- certainly I anticipated, so if you do want to make a closing statement, feel free.

MR. HARDY: Yeah. I would just, again, thank staff for your assistance in this process and for a good hearing today.

You know, my takeaways from the presentation and the experts that you've heard from today is that this project meets the core objectives of the CON review program in that it will help reduce an unmet need and will increase access to this leading technology and reduce overall cost.

So, of course we're asking that the agency approve this very important project. Certainly, as you're considering your decision, we would be happy to address any specific issues or concerns you may have

after today's hearing.

We want to reiterate that Danbury Proton is willing to accept, as conditions of approval, any of the conditions that have been incorporated into the approval of the CPTC Center and of course would welcome any discussions needed to facilitate that approval for the project.

MR. CSUKA: Thank you. So, thank you to everybody who attended remotely and in person. We really appreciated having you all here.

And, again, as I mentioned earlier, written public comment can be submitted up to seven calendar days after today. And for now, the hearing is adjourned, and we will close the record at some point in the future. Thank you very much.

DR. GIFFORD: Thank you very much to all of you.

THE COURT REPORTER: Mr. Hardy, did you need a copy of the transcript?

MR. HARDY: That would be great. Thank you.

(The hearing was adjourned at 12:59 p.m.)

EXHIBIT INDEX

STATE OF CONNECTICUT

I, ALEXA A. BUDIHAS, a Licensed Professional Reporter/Commissioner within and for the State of Connecticut, do hereby certify that I stenographically recorded the aforementioned hearing on May 2, 2024, in person and via Zoom.

I further certify that the witnesses were first duly sworn by DANIEL J. CSUKA, ESQ., OHS Staff Attorney,to testify to the truth, the whole truth, and nothing but the truth concerning his knowledge in the matter.

I further certify that the within testimony was taken by me stenographically and reduced to typewritten form under my direction by means of computer-assisted transcription.

I further certify that I am neither counsel for, related to, nor employed by any of the parties to the action in which this hearing was taken; and further, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action.

WITNESS my hand this 12th of May, 2024.

ALEXA A. BUDIHAS, RPR/CRR
My commission expires 4/30/29