STATE OF CONNECTICUT

OFFICE OF HEALTH STRATEGY

Docket No.: 20-32390-CON

Proposal: ESTABLISHMENT OF CARDIAC SERVICES

PUBLIC/ADMINISTRATIVE HEARING

In Re: Norwalk Hospital Association Certificate of Need, Application to Establish Elective Percutaneous Coronary Intervention Services, "PCI," at Norwalk Hospital

DATE: April 22, 2021

TIME: 10:01 A.M.

PLACE: (Via teleconference)

Reporter: Robert G. Dixon, CVR-M #857

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(Begin: 10:01 a.m.)

THE HEARING OFFICER: Good morning, everyone. This public hearing before the Health Systems Planning Unit identified by the Docket Number 20-32390-CON is being held on April 22, 2021, regarding the Norwalk Hospital Association certificate of need application to establish elective percutaneous coronary intervention services, or PCI, at Norwalk Hospital.

On March 14, 2020, Governor Ned Lamont issued Executive Order 7B, which in relevant part suspended in-person open meeting requirements to ensure the continuity of operations while maintaining the necessary social distance.

To avoid the spread the COVID-19 the Office of Health Strategy is holding this hearing remotely.

We ask that all members of the public mute the device that they are using to access the hearing, and silence any additional devices that are around them. This public hearing is being held persaunt to Connecticut General Statutes 19a-639a, and will be conducted in accordance with the provisions of Chapter 54 of the Connecticut General Statutes.

My name again is Michaela Mitchell. Victoria Veltri, the Executive Director of the Office of Health Strategy has designated me to preside as the Hearing Officer over these proceedings today.

In addition to myself, my colleagues Brian Carney and Jessica Rival are here to assist me in gathering facts related to this application. Also on the line is our consumer information representative Leslie Greer, who will assist in gathering names for public comment.

The certificate of need process is a regulatory process, and as such the highest level of respect will be accorded to all of the parties and members of the public, and our staff --

[Interruption.]

THE HEARING OFFICER: Hold on one moment.

I want to make one announcement about muting yourselves. Please make sure that you're muted.

Our priority is the integrity and transparency of this process. Accordingly, we're going to request that decorum be maintained by all present during these proceedings.

The hearing is being recorded and will be

transcribed by BCT Reporting, LLC. All documents related to this hearing that have been or will submitted to the Office of Health Strategy and will be available for review through our CON portal, which is accessible on the Office of Health Strategy CON Webpage.

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

The Norwalk Hospital Association is a party in this proceeding; and Stamford Health, Incorporated, has been designated as an intervener with full rights in this proceeding.

At this time I'm going to ask Mr. Carney to read into the record those documents already appearing and HSP's table of record in the case.

MR. CARNEY: Good morning. Brian Carney for the Office of Health Strategy Health Systems Planning Unit.

At this time I'd would like to enter into the table of record Exhibits A through S.

THE HEARING OFFICER: All right. I just want to make a quick note that we did receive a few additional submissions which were Exhibit T. It was Attorney

Monahan's appearance. And then also we added Exhibit U a few moments ago, and that was the public comment.

I'm going to ask attorneys for the Applicant if there's any objection to the inclusion of these exhibits into the record?

MR. TUCCI: Good morning, Hearing Officer Mitchell. This is Ted Tucci. And on behalf of the Applicant we have no objection to the supplemental exhibits.

THE HEARING OFFICER: Okay. I'm going to turn to the Intervenor's counsel for any objections?

MR. MONAHAN: Intervenor's counsel has no objection to the supplemental exhibits.

THE HEARING OFFICER: All right. Thank you, Attorney Monahan. All right. Thank you, Brian. I appreciate that.

So we are going to proceed in the order established in the agenda for today's hearing. As always, the Office of Health Strategy reserves the right to allow public officials and members of the public to testify outside of the order of the agenda as needed.

I'm going to advise the Applicants that we may ask questions related to your application that you might feel that you've already addressed, and

we do this for the purpose of ensuring that the public has knowledge about your proposal, and also for the purpose of clarification if we have questions about something that we read. I want to reassure you that we read your application complete in its responses and your prefiled testimony.

As this hearing is being held virtually we're going to ask that all participants to the extent possible and able to use the video cameras when testifying or commenting during the proceedings. Anyone who is not testifying or commenting will mute their electronic devices, including any telephones, televisions, and other devices not being used to access the hearing.

We're going to monitor participants during the hearing. To the extent possible we just ask that counsel for the parties, counsel for the Applicant and counsel for the Intervener raise hands to make an objection.

I'll address you. If I don't, it's okay to unmute yourself and address me directly.

All participants, again make sure that you mute your devices and disable your cameras. When we go off record or take a break we are not going

to stop the recording. The fear of stopping the recording creates, you know, concern that we may not turn it back on properly when people are testifying. So we're going to record everything. So just make sure that you mute your device or disable your camera when we go on break, off the record.

As we did before we started the hearing, I'm going to provide a warning to everyone that we're going to go back on the record so that everybody can get back in their places and turn their cameras on as appropriate.

Public comment is going to go again in the order established by OHS. I'll call each individual by name when it's his or her turn to speak. At this time I'm going to ask all of the individuals who are going to testify on behalf of the Applicant and the Intervener to raise their right hand so that I can swear you in.

J O H N M U R P H Y,

A R S H A D Y E K T A,

D A V I D L O M N I T Z,

K A T H L E E N S I L A R D,

R O H I T B H A L L A,

J O N A T H A N B A I L E Y,

S C O T T M A R T I N,

M A R K W A R S H O F S K Y,

called as a witnesses, being first duly sworn by Hearing Officer, were examined and testified under oath as follows:

THE HEARING OFFICER: Thank you.

MR. MONAHAN: Attorney Michaela Mitchell?

THE HEARING OFFICER: Yes.

MR. MONAHAN: I don't know -- am I too far away for you to see my hand if it -- it's raised given what you said?

THE HEARING OFFICER: No.

MR. MONAHAN: And I did have -- I didn't want to interrupt your instructions and prehearing statements, but I did have a question about administrative notice of docket numbers, if I may raise them?

THE HEARING OFFICER: Okay.

MR. MONAHAN: May I do that before the hearing and testimony begins?

THE HEARING OFFICER: Absolutely. Go ahead.

MR. MONAHAN: The Intervener respectfully requests that the Docket Numbers of CON which were two Norwalk Hospital decisions 12-31793-CON; the final decision of that docket number be admitted into the record for administrative notice as it is a public document on the precisely same issue involving the same applicant.

Similarly, the second one is the Norwalk Hospital application of 04-30286-CON for the same reasons, both of which have been referenced or alluded to, even though without the docket number in testimony of the Applicants and in the submissions in the -- before the prefiled testimony.

And then finally, because the objection to our request as a petitioner was grounded in part on a very specific reference to our reiterating arguments in a prior proceeding just last year and not too long ago, I believe it is appropriate that that reference be properly identified in the record as the Greenwich Yale New Haven application Docket Number 20-032342-CON.

And those are the three docket numbers that are on the public docket of this agency that I request administrative notice be taken.

THE HEARING OFFICER: All right. So Attorney Tucci, do you have any response to this request?

MR. TUCCI: Thank you, Hearing Officer Mitchell. This is Ted Tucci, one of the counsel for the Applicant.

And we have no objection to OHS taking administrative notice of prior dockets. I would just note for the record we want to make sure that with respect to the docket number concerning the Greenwich Hospital application, Docket Number 20-32342-CON, that the Stamford Hospital appeared as an intervener in that proceeding.

So we would just want to make sure that all of the materials including late files and any other materials that were submitted by the Intervener in that process were part of the administrative notice of that record.

THE HEARING OFFICER: Any objection, Attorney Monahan?

MR. MONAHAN: Absolutely no objection.

THE HEARING OFFICER: All right. So we're going to go ahead and take administrative notice of those three dockets.

Anything else, Attorney Monahan?

MR. MONAHAN: No, not at this time. Thank you.

THE HEARING OFFICER: You're welcome.

Anything else, Attorney Tucci?

MR. TUCCI: No, thank you, Hearing Officer.

THE HEARING OFFICER: Okay. So the last thing I'm going to mention is just a reminder to everyone 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.

At this time I'm going to allow the Applicants to proceed with their testimony.

Before you begin one other thing is if you use any acronyms make sure you define what they are before you use them just for the benefit of the public, and also clarity of the record.

And I'll turn it over to you, Attorney Tucci.

MR. TUCCI: Thank you, Hearing Officer Mitchell. And good morning to you and good morning to members of the OHS staff.

My name is Ted Tucci, and along with Lisa Boyle and Connor Duffy, we represent the Applicant in the CON proceeding that brings us here this morning on behalf of Norwalk Hospital Association.

We're prepared now to present the direct testimony of the Applicant's witnesses. We're going to begin with the testimony of Dr. John Murphy, and then we'll proceed through our witnesses in order.

THE HEARING OFFICER: Thank you. I'm ready for you, Dr. Murphy.

THE WITNESS (Murphy): Good morning, Hearing Officer Mitchell. My name is John Murphy. I'm the President and CEO of the Nuvance Health. It's nice to see you again. I'm also a practicing physician and neurologist, and I hereby adopt my prefiled testimony.

There are a few points I'd like to make in the few minutes that I have. The first of which is elective PCI, or percutaneous coronary intervention. At Norwalk Hospital it's an important part of our vision for healthcare delivery within Nuvance Health. Our goal is and has always been to deliver high-quality care that is accessible, affordable, patient centered and delivered as close to home and family as possible.

We currently offer a broad range of cardiovascular services within Nuvance Health. It was actually the first Institute that we created,

as it represents the leading cause of death in America. Elective PCI at Norwalk Hospital in our view is a missing link in -- in our service delivery to patients in this community and our ability to provide them with life-saving care and to keep their hearts healthy.

The existing regulatory system prevents patients with cardiovascular disease to access this life-saving care at their local hospital, their hospital of choice, yet there's no corresponding advantage in terms of cost or quality, and we do believe that that regulatory system needs to understand and modify its position as a result.

We are firmly committed to play a role in controlling the escalating healthcare costs that confront the State -- and the nation, for that matter. Fee-for-service medicine is giving way to value-based care and we are willing to be held accountable for the quality and the cost of that care.

We want to be part of this solution. We salute the State for its position really in leading health systems and hospitals towards the adoption of alternative payment models, and your

office really has led the way.

As part of our agreed settlement, as a matter of fact, we committed to increase the number of patients receiving care under alternative payments models and risk-based contracts of one kind or another, and we have been diligent in our pursuit of that settlement and those times.

We already provide primary PCI, as you know, at Norwalk Hospital. We have the team, the facilities, the equipment and the experience. I think it's important to remember that in the decade that I was born medical knowledge was said to double every 50 years or so. In the decade I was in medical school in the eighties that changed, and medical knowledge doubled every seven years.

In the decade in which we live today it is said that medical knowledge doubles every 73 days. We believe that the regulatory framework needs to embrace that reality and evolve as such.

Here at Norwalk Hospital we are ready, willing and able to perform elective PCI. I thank you sincerely for your consideration of this application and I respectfully ask that your office approve it.

Thank you.

THE HEARING OFFICER: Thank you, Dr. Murphy.

MR. TUCCI: Thank you, Dr. Murphy.

This is Ted Tucci, counsel for Norwalk Hospital. And the next witness who will be presenting direct testimony is Dr. Mark Warshofsky.

THE WITNESS (Warshofsky): Thank you, Hearing Officer Mitchell and staff of the Office of Health Strategy for the opportunity to testify in support of Norwalk Hospital's application today.

My name is Dr. Mark Warshofsky. I am -- I'm the System Chair of the Nuvance Health Heart and Vascular Institute, and a practicing interventional cardiologist. I adopt my prefiled testimony for the record.

This morning I will tell you a little bit about Nuvance Health's approach to providing cardiovascular care for our patients and to provide some background for the reasons that we would like this application approved.

Nuvance Health approaches cardiovascular care in a systemwide approach. We do this in a number of ways. We have a systemwide collaboration with multidisciplinary experts within our system that

participate in clinical councils. We are participating in numerous national registries which help us to compare ourselves to national standards.

And Danbury Hospital has recently gone through a program assessment and affiliation with the Cleveland Clinic. Norwalk Hospital is currently undergoing an assessment of our cardiovascular program by the Cleveland Clinic Heart and Vascular Institute, and we anticipate a formal affiliation later this year.

That affiliation focuses on quality and best practice, and it -- we've already started to push out a lot of the care pathways and guidelines that we have developed with the Cleveland Clinic.

The safety of performing PCI without cardiac surgical backup is not in question. That has been proven by multiple randomized studies that are easily viewed in the -- in the literature, and that's largely due to improved interventional techniques such as coronary stents, coronary covered stents, new technologies, techniques and new medications to make PCI much, much safer for percutaneous intervention; much, much safer than it was several years ago.

The -- the current estimates of the need for coronary artery bypass surgery in the setting of a PCI are about two patients in a thousand, all the way down to a few patients in 10,000. And I think it's important to restate the Norwalk Hospital is already performing PCI on STEMI patients.

This is really the sickest cohorts of patients. They present suddenly to the emergency room. They're in need of emergent care, and that life-saving care is provided by our physicians at Norwalk Hospital.

I also think it's important to note that while we're calling this an elective PCI application, many of our patients who fall into that category are not truly elective. They're patients who have been admitted to the hospital who are in need of urgent procedures to prevent heart attacks or to minimize heart attacks, and that life-saving care really should be available as well at Norwalk Hospital.

We have sufficient current volume to support this program. We are currently performing PCI on approximately, for the FY '21 year, projected to be about 80 patients with STEMI presenting to Norwalk Hospital.

And if you look at programs around the state and nationally, programs that are doing PCI for patients presenting with STEMI, their ratio of elective PCI to STEMI patients is over four to one. And I think that using those 80 STEMI patients as a surrogate for what the volume could be and probably should be at Norwalk Hospital, we would be well over the 200 cases that the literature suggests that we should have if we are to perform PCI without surgical backup.

I think it's also important to note that, you know, geographic distance doesn't necessarily equate to geographic isolation, or is a sufficient measure for geographic isolation. We all know we have bad weather that comes up. We have storms. We have terrible traffic with accidents. The inability of family to -- to be with their loved ones during a stressful experience -- and even pandemics, unfortunately, really I think should make us question the wisdom of transferring patients to another hospital without necessity.

I think also the use of valuable EMS resources to perform those transfers when they could be doing other necessary activities is something that we really should think about.

There is a redundant -- the redundancy involved in terms of work being performed on the part of the receiving hospital, and that redundancy is not just extra work, but it also introduces the chances for medical errors and patient harm.

I think that -- certainly I have no doubt that if this application is approved Norwalk Hospital will operate a high-quality elective PCI program that's going to serve the patients of Norwalk Hospital and the surrounding communities in a way that will allow for actually improved care for the patients of the community.

Thank you.

THE HEARING OFFICER: Thank you, Dr. Warshofsky.

MR. TUCCI: This is Ted Tucci, counsel for Norwalk Hospital. And the next witness who will be speaking in support of the application Dr. Arshad Yekta.

THE WITNESS (Yekta): Good morning. And thank you, Hearing Officer Mitchell and staff of the Office of Health Strategy for the opportunity to testify in support of the Norwalk Hospital application today.

My name is Dr. Arshad Yekta, and I'm an interventional cardiologist, and I'm also the

Director of the Cardiac Catheterization Laboratory here at Norwalk Hospital. I hereby adopt my prefiled testimony for the record.

In regards to our history here at Norwalk Hospital, we have been offering primary angioplasty coverage for approximately eleven years when we started our program back in July of 2009. Since then we've offered 24/7 coverage in our cardiac catheterization laboratory for the sickest of patients that come into the hospital who are on death's door.

We have a very well staffed and well-stocked cardiac catheterization laboratory here. We offer equipment that may not be available at even many other advanced institutions. We are able to perform percutaneous intervention. We have the latest in technology in terms of stents. We also perform coronary imaging to ensure that we provide high quality care.

We have a new cardiac catheterization laboratory which we are building out, and will be completed in May and be starting to be used at the end of May. Additionally, we offer support devices like intra-aortic balloon pumps and Impella devices, which as well are very -- are at

the forefront of cardiology care today.

In addition we have an on-call cardiologist who's on call 24/7. We also have thoracic surgeons, and vascular surgeons are also on call 24/7 to offer any support which would, if at all, would be necessary can also help in the function of the cardiac catheterization laboratory.

At this time we function as a cardiac catheterization director, and the one thing that we have is we have a core group of dedicated physicians. We have a core group of dedicated staff who have been here, and who've really shown dedication to our -- our STEMI program and to our diagnostic angiography program as well.

We have a very robust education system. We -- as in many advanced tertiary care centers, they offer education and teaching. We do the same. We offer cath conferences monthly. We have STEMI meetings -- or I'm sorry, meetings in regards to all our cases. I review every single coronary intervention which we perform at the hospital -- and to make sure that we offer the highest quality of care for all of our patients.

In addition to that, we -- we train our staffs on a regular basis weekly to make sure that

they understand anything that is going on at the forefront of cardiology, to make sure we are well suited to deliver any types of care that's needed to all of our patients.

In terms of why I feel like, you know, at a hospital of our size, you know, we -- we all know that there -- there have been -- there, as volume does increase we have shown that there are also improved measures of outcome. And as Dr. Warshofsky mentioned, we have a very -- actually an intermediate volume of patients presenting with acute myocardial infarction.

If you extrapolate that out to patients who would be presenting with non-ST elevation, myocardial infarction or elective PCI, I feel like our volume would be the middle ground.

The one benefit that we have here is that we would have cardiac catheterization laboratories available. And with that being said, we would be not be a very high-volume center, but we'd fall in that middle-of-the-road center, intermediate volume. And I feel like that's kind of the ideal ground where we're able to provide high quality of care, personalized -- personalized care to these patients and offer a lower incidence of

complication for these patients.

In terms of why we also have to understand that acute coronary syndrome is not a binary diagnosis; a continuum of diagnosis. You have patients who present with, you know, stable angina, with unstable angina, myocardial infarctions and acute ST elevation myocardial infarctions. But you know we understand that this is not a binary, or there's not distinct cutoffs in between these diagnoses. So currently we're only able to provide care for patients that present with the acute ST elevation myocardial infarction.

And I strongly believe that if we think in this manner we actually cause harm to many patients which present with other diagnoses.

For example, it's been adopted by many the of guidelines including -- including the American College of Cardiology, the European Society of Cardiology; that early invasive strategy should be employed in patients who present with acute myocardial infarction, in particular if they have elevated risk, and they should undergo angiography within 12 to 24 hours.

In addition, patients who present with high

risk acute myocardial infarction who are not STEMI may need to have angiography done within two hours.

Unfortunately, these metrics are very hard to accomplish if we don't have the capacity to perform these procedures here at Norwalk Hospital. As you know, we're in a very congested area and the ability for us to transfer patients in a timely manner is hindered by many obstacles including traffic, weather, EMS services, and also the coordination it takes to actually transfer a patient can also -- also be very time consuming.

In addition to the -- the fact that transfers can take some time, they also pose many hinderances. There's an issue in terms of medical records. Medical records oftentimes between institutions are not shared. So oftentimes these records are printed. Imaging is likely unavailable. In addition, there is a change of providers. Not only are the cardiologists different, but in addition the nursing staff is different, the hospitals are different, the health staff may be different.

And this really -- what -- what this -- what this does is it causes an area for errors in -- in

medical records, medical -- medical administration errors and increased risk of infection. So we feel like transfers should be avoided if possible.

In addition, followup for these patients becomes disjointed. Now all the sudden you've given them two cardiologists, two hospitalists. So they become a little bit confused as to how followup will also be employed.

Lastly, the whole area -- era of COVID-19 has really shown us that transfers can become difficult in addition because of multiple things. First of all, during COVID we did realize -- we did see according to many studies that have been published that elective cases had to be held. Even semi-urgent cases were being delayed.

In addition to that, the availability of cath labs and cath lab staffs became limited. So even if the transfer was available -- a transfer was necessary, it may not be available to the patient.

So in conclusion, I strongly believe that if elective PCI were to be able to be performed at Norwalk Hospital I think it will improve quality of care, decrease length of stay for the patients. It will decrease the cost for these patients, but most importantly, it will increase patient

satisfaction, and we will do this without increasing the risk of cardiac events.

And the other issue is -- is that I feel like in the area we are, we'll be able to deliver care to patients who may not be able to achieve it otherwise. Thank you.

THE HEARING OFFICER: Thank you, Dr. Yekta.

MR. TUCCI: Hearing Officer Mitchell, this is Ted Tucci, counsel for the Applicant. And the final witness who will be presenting testimony on behalf of the Norwalk Hospital Association is Dr. David Lomnitz.

THE WITNESS (Lomnitz): Thank you, Hearing Officer Mitchell and staff of the Office of Health Strategy for the opportunity to testify in support of Norwalk Hospital's application today.

My name is Dr. David Lomnitz. I am Chief of the Section of Cardiology at Norwalk Hospital, and a practicing cardiologist. I adopt my prefiled testimony for the record.

I'd like to use my time at this hearing today to highlight two important issues that are in my prefiled testimony. The first issue of great concern is the underutilization of the appropriate use of PCI. We know that this is a significant

problem. We know it exists throughout medicine, that things that have been proven to be beneficial aren't always done.

Data from the New England Journal of Medicine shows that up to 30 percent of people who are clearly appropriate for PCI do not get PCI. We also know that the outcome for those patients is worse than those that receive PCI. In summary for that -- is that patients do worse. They have higher mortality and higher morbidity.

What is also known and also very concerning is that patients who are at highest risk for underutilization of appropriate use of PCI are racial minorities. This is an issue that plagues us in medicine, not just in cardiology, but in other areas as well, and is certainly highlighted by the COVID-19 crisis.

So why does this happen? We don't really know for sure, but we do know when it comes to PCI there is a clear association with the underutilization of PCI when appropriate with patients coming to hospitals that do not have the elective PCI capability, and don't have full invasive cardiac service available.

We know this to be true, not only in the

United States which has been repeated in multiple studies, but is known internationally to be the case. Patients who don't go to hospitals with full capacities tend to be the ones at risk. So what does this mean? Can this be addressed?

Interestingly, there was a study in New York City that was able to show the same finding, that these patients going to the hospitals without these services available were not receiving the care at a much higher rate.

If proximity to a hospital that has those capacities for invasive interventions were the solution, certainly New York City with its high density of hospitals that -- with and without would certainly be the first and most capable of tackling this issue, yet they aren't.

The authors of that study which is in my prefiled testimony and is published in the Annals of Internal Medicine, the authors suggest that the factors are much more complex. I think we have to be humble as physicians to recognize what we know and what we don't know, and these authors suggest that there may be factors social, economic, language barriers and other factors that play an important role.

So what is the solution? What can we do to minimize this impact? I think that from the data it's clear that if we can increase access to high-quality care, that patients will be less likely to be underserved and underutilized in these appropriate procedures. I think Norwalk Hospital is in an ideal position to do it.

I don't want to repeat Dr. Warshofsky and Dr. Yekta's testimony. I think they did it very well, that the hospital and the network is highly committed to providing a high-quality program and to follow the highest standards.

I think certainly the high rates of primary angioplasty speaks to a very high burden of disease in our area, and certainly raises the question of underutilization in our community.

I'm also very proud of Norwalk Hospital, a place that I've worked for the last 20 years, is extremely committed to the best care for all of its patients in its community, and all patients who arrive here, but specifically very committed to providing care to underserved communities, particularly racial minorities and the uninsured.

We have a very tight association and work closely with Americares, which is a clinic that

provides care for the uninsured, Norwalk Community Health Clinic that also provides health care for uninsured; and in our estimates which are in the OHS table six, projections that at least 20 percent of those receiving elective PCI will be patients who are either on Medicaid or uninsured.

I think that the commitment of Norwalk Hospital will certainly help, not only Norwalk Hospital and Nuvance's commitment to try and improve care, reduce the issues of racial disparity -- but I think it's a commitment that all physicians in the United States are acutely aware of and trying to make a positive impact.

There's another issue that I want to highlight from my prefiled testimony. That is what, you know, we deem sort of the fractioning of care, or dual pathways. I've been practicing at Norwalk Hospital for the last 20 years. I think Dr. Warshofsky spoke very well with regard to the problems that occur acutely when you transfer a patient from one health system to another, and so are the pitfalls that -- that can occur.

I want to talk about some of the things that can occur that aren't necessarily clearly obvious initially, but over time become clear, or

unintended consequences of these actions. What we see is that patients are not uncommonly -- who live in our area are seeking cardiac care in other health systems. This could be because when they arrive at Norwalk Hospital they spend a brief amount of time here, then were transferred out. They ended up staying with physicians at those health systems.

Now you've created a dual pathway where that patient is now having health care delivered in more than one setting where the communication, either by EHR or by other methods is not ideal by any standards.

Oftentimes those patients will arrive at Norwalk Hospital, and we -- while we try our best and do our due diligence to try to get those records, this is often a challenge even during work hours, but certainly on off hours.

I think those patients have higher rates of having tests repeated unnecessarily because of this issue. They're more likely to be admitted to the hospital because for -- for being conservative. They want to ensure that nothing falls through the cracks, when if all that information were available that might have been an

unnecessary mission to the hospital.

The other issue I think is that patients that do follow with us -- and there are many -- are confused, and I think this is understandable. If a patient came to Norwalk Hospital and all of the sudden was put in an ambulance and sent to another hospital for their cardiac care, they come to us -- and they come to me in particular, and they'll say, if I have a problem where should I go? Should I go to Norwalk, or should I go somewhere else directly? Should I bypass that step?

This is very worrisome for us. We know that cardiac conditions can be something that can deteriorate within seconds to minutes. We want those patients to seek care locally. If not, important time can be wasted and bad outcomes can follow.

Patients understandably may not follow that, and they -- and they are confused and they're -- and they may end up at hospitals and the delay may cost them, not only mortality, but morbidity.

In addition, we all know that not every -- every chest pain patient will have a cardiac condition. They may end up at other hospitals

not -- without their primary care doctors, without the flow of information for the -- for conditions that may be noncardiac such as a gallbladder problem or pneumonia, et cetera.

I think this, this displacement is exactly what we don't want to happen due to the inefficiencies, the lack of communication and ultimately poor, poor care that's more costly.

Thank you for your time.

THE HEARING OFFICER: Thank you, Dr. Lomnitz.

Attorney Tucci, does that conclude your presentation on behalf of the Applicant? Or is there anything that you wanted to add?

MR. TUCCI: Good morning, Hearing Officer Mitchell. Ted Tucci.

That concludes the presentation of the direct testimony on behalf of Norwalk Hospital. I did want to alert you, Hearing Officer Mitchell, that at some point in the proceedings we've been informed that State Representative Perone may be available for public comment.

Our best information is that currently the State Representative is engaged in a legislative meeting, but if and when Representative Perone becomes available we will just notify you of that

fact. If that's acceptable?

THE HEARING OFFICER: Absolutely. Thank you.

All right. I'm going to turn it over to you Attorney Monahan.

MR. MONAHAN: Thank you, Hearing Officer Mitchell. The Intervener would like to present witnesses, and the first witness is Kathleen Silard, President and CEO of Stamford Health, Inc.

THE WITNESS (Silard): Good morning, Hearing Officer Mitchell and members of the Health System Planning Unit and Office of Health care Strategy staff. My name is Kathleen Silard. I'm the President and CEO here at Stamford Health, and I hereby adopt my prefiled testimony.

As you know, Stamford Health is an independent not-for-profit healthcare system and I'm very proud of the 3600 employees who devote their work to the commitment of patient-centered care and have enabled us to become a best in class provider of health services to our entire community regardless of their ability to pay.

At Stamford Health we really live our commitment to addressing healthcare disparities and provide a community benefit through participation in and financial support for

community-based initiatives and collaborations.

In fact, even though we're only the fifth-largest healthcare organization in the state, we're the second largest provider of uncompensated care to the most vulnerable in our community.

While I have a great deal of respect for my professional colleagues at Norwalk Hospital and Nuvance Health, Stamford Health strongly opposes the systems application as it simply fails to meet the guidelines and principles that have been established by our General Assembly in our certificate of need law.

Moreover, upon reading the prefiled testimony submitted by the Applicant -- Applicant, I realized that I was effectively reading a request by Nuvance Health System that this agency remove, as Dr. Murphy stated in his prefiled testimony, the regulatory barrier imposed by the CON law.

I feel compelled to remind everyone that Connecticut is a CON state until the General Assembly decides that it is not, and the legislative policy of demonstrating an unmet need is and has been a core principle of the CON law from its very inception.

In addition to unmet need the CON law seeks to avoid duplication of services and unnecessary increases in healthcare costs while at the same time supporting the promulgation of high-quality care.

I respectfully urge that OHS see this application for what it plainly is, a request by the petitioner to have OHS aid in its expansion of a system, as opposed to an application that must comport with controlling CON law in order to be granted.

If this agency abides by the principles that are set forth in statute it should be clear that there is no demonstration of unmet need. There is no shortage of access to elective PCI programs in this geographic region and the region at issue. And there is no valid reason under CON law to grant permission for duplicative services which will only aid in the dilution of quality and the increase of costs associated with elective PCI programs in our region.

Thank you, and I'm happy to answer any of your questions.

THE HEARING OFFICER: Thank you, Ms. Silard.

MR. MONAHAN: If I may? Hearing Officer Mitchell, we

do have a second witness we have prepared. And that is Dr. Rohit Bhalla.

Okay. And Dr. Bhalla, will you adopt your prefiled testimony, and then proceed? Thank you.

THE WITNESS (Bhalla): Good morning, Hearing Officer Mitchell and the members of the Health System Planning Unit staff. My name is Rohit Bhalla, and I'm Senior Vice President of Clinical Affairs and Quality at Stamford Health. I hereby adopt my prefiled testimony for the record.

I am testifying today on behalf of Stamford Health in strong opposition to the application submitted by Norwalk Hospital Association, this authorization to establish elective percutaneous coronary intervention service for the hospital.

My comments focus on the crucial role of evidence-based guidelines in improving the quality and safety of healthcare. The standard of using reviews of research and scientific evidence to identify which practices lead to optimal patient outcomes while reducing excess utilization dates to 1970, when the Institute of Medicine now known as the National Academy of Medicine founded.

Best practices are reviewed by experts in professional medical societies who incorporate

these findings into clinical practice guidelines. We know from a litany of quality improvement efforts that adherence to clinical practice guidelines improves health outcomes, reduces patient harm and reins in inappropriate healthcare utilization.

The 2014 guidelines and annual volume standards on PCI pertinent to today's hearings represent the consensus of not one, not two, but three professional societies; the Society of Cardiovascular Angiography Intervention, the American College of Cardiology and the American Heart Association.

Increasingly policymakers, regulatory agencies and payers are calling for tight adherence guidelines to maintain compliance and to receive payment for services. The Centers for Medicare and Medicaid Services, or CMS incorporates clinical practice guidelines recommendations in its provider conditions of participation and coverage.

For example, 42 CFR 42.8 CMS establishes evidence-based volume standards for organ transplantation services. It requires hospitals to perform an average annual minimum of ten

transplants as a condition of Medicare participation.

In its national coverage decision on transcatheter aortic valve replacement, CMS established the requirement that existing centers for transcatheter aortic valve replacement programs maintain an average annual volume of 300 PCI cases and 20 TAVR procedures.

The federal government also utilizes clinical practice guideline recommendations and evidence-based facility volume standards in its decisions on what services it will cover. For instance, the Affordable Care Act mandates coverage with no cost sharing for evidence-based preventive screenings, such as screening mammography and screening colonoscopy -- because these have demonstrated a connection between early detection and better patient outcomes.

Professional and certifying organizations such as the American Board of Internal Medicine Foundation initiated the Choosing Wisely campaign. This program promotes adherence to best practices to reduce inappropriate utilization of procedures and tests with limited patient benefit.

More than 80 specialty provider organizations

including the Society for Cardiovascular Angiography Interventions and the American College of Cardiology --

THE REPORTER: I'm just having a little difficulty hearing you. This is the stenographer. If you could speak up please? I'm just hearing a little background noise. Apologies for the interruption.

THE WITNESS (Bhalla): No problem.

THE HEARING OFFICER: That's okay. I think it's the papers. It might be on -- I don't know if you have a microphone, but I do hear the papers moving.

THE WITNESS (Bhalla): Okay. I'm not shuffling anything, but perhaps this -- I -- I will -- repeat what I just said, and please let me know if you want me to go through prior comments.

Professional and certifying organizations such as the American Board of Internal Medicine Foundation initiated the Choosing Wisely campaign. This program promotes adherence to best practices to reduce inappropriate utilization of procedures and tests with limited patient benefit.

More than 80 specialty provider organizations including the Society for Cardiovascular Angiography Interventions and the American College

of Cardiology actively participated in this campaign.

I lay out the above discussion to illustrate the rich history and value of evidence-based medicine is properly accepted as the gold standard in healthcare as it improves patient care, reduces harm and lowers healthcare costs by discouraging unnecessary service.

Guidelines are derived from exhaustive research reviews -- not only the latest study, and from the contribution of experts in their fields who devote countless hours and resources to the betterment of giving care. Stamford Health supports the use of clinical practice guidelines and urges OHS to continue to be guided by science, and not by the business desires of health systems. Our patients deserve no less.

Thank you.

THE HEARING OFFICER: Thank you, Dr. Bhalla.

MR. MONAHAN: Hearing Officer Mitchell, I'd like to introduce Dr. Scott Martin. If we may proceed with our next witness?

THE WITNESS (Martin): Hi, Officer Mitchell. Thank you for allowing me to speak. I'm Dr. Scott Martin. I'm an interventional cardiologist and the

Director of Intervention Cardiology here at Stamford Health.

I accept my testimony into the record?

MR. MONAHAN: Yes, you adopt --

THE WITNESS (Martin): I adopt my written testimony.

MR. MONAHAN: Dr. Bhalla spoke about the importance of clinical guidelines in all medicine, and we're fortunate that on this topic at hand we have a number of guidelines to look at, the most pertinent being the 2014 multi-societal guidelines.

There were a number of others, you know, 2013, 2016, 2017 that are, I think, all in the record that adopt the same volume standard. All the professional societies that are involved including this, the Interventional Cardiologists, the Society for Coronary Angiography Intervention, the American College of Cardiology which represents all cardiologists, and the American health -- Heart Association which represents, you know, everyone involved in cardiac care including physicians and public health experts and a wide range of others -- came together to review all of the pertinent information and evidence and decided what's safest and the best practice in -- in

regards to finding an elective PCI.

And the benefit of that is that we don't have to review every little study because the group of experts has done that. So I, you know, I saw in the Applicant's submissions their studies looking at transfers across the Outback in Australia, or transfers of ICU patients in Iowa.

I don't think that's really pertinent, because we have our societal guidelines that look at all the pertinent data and come up with the recommendation. There their -- their recommendations are highlighted in bold in my testimony here.

The clinical competence guidelines state that in order to maintain proficiency while keeping complications at a low level, minimal volume greater than 200 PCIs per year will be achieved by all institutions. And they go on to say that new programs offering PCI without on-site surgery are inappropriate unless they clearly serve geographically isolated populations.

In the application the Applicant originally estimated that their PCI volume would be between 128 and 155 per year, depending on the year, and that clearly doesn't meet the guidelines.

And they have since formed a new estimate, you know, based on our objection, I think -- and with the recent uptick in some primary PCI numbers, but I think it's hard to swallow, honestly. I'm sure they've put significant time and effort into coming up with their application and to expect that their volume has jumped 50 percent, you know, since that time is -- is hard to understand from my standpoint.

You know, there they talked about how the -- the number of elective PCIs often correlates with the number of primary PCI, and that's true to some extent. You know, because they're based on the same, some of the same factors, you know, population density and, you know, prevalence of disease. But they don't -- there's no clear link, and there's no study looking at that.

You know, some centers, referral centers like Columbia University have dramatically more of elective PCI than they do higher PCI, because people choose to go there and there's transfers and referrals there. Other places are predominantly driven by, you know, who was brought there by EMS. So it's -- it's not a clear correlation where we have 80 primary PCIs one year

and you're going to necessarily have two or three hundred total PCIs.

I think what's a better predictor in general is -- is how many cardio caths you do, because in -- in general about 40 percent of your cardio caths will generate PCI, because not everybody needs a stent. You know, often we do these procedures and patients are best treated medically, or we do that procedure and they require bypass surgery. Or we do the procedure and it's complicated, and we have to stop and think it over and talk it over.

So not every cardio catheterization ends up with a PCI, and if you look at the volume of nonprimary PCI cardio catheterizations, it's not a big number. It ranges from 83 to 105 over the last couple of years. And if you look at the transfers out, you know, where people get PCI in another center, it's not a big number.

And so I think the original application estimates are reasonable, and those are all less than 200 PCIs per year.

You know, I -- I think the -- it's -- it's a stagnant market in terms of PCI. You know the population is aging. There are more diabetics.

So could that lead to more cardiac disease in the future? It's possible, but on the other hand we have more and more evidence over the years that other than primary PCI all of our elective PCIs are not necessarily life-saving procedures.

There they do treat symptoms. They do help people live better lives sometimes, but in -- in contrast to the Applicant's suggestion that PCI is underutilized, you know those are studies from 1999 and 2003.

If you look at more recent studies, there's been a strong push that PCI is -- is overutilized, and the appropriate use criteria were invented, not to drive people to get more PCI, but in fact the opposite, that there was a strong intention that we were doing too many.

I -- I wish it was otherwise, because it's my job. I would love to be doing more, but you know, if you look at regional and statewide and national trends it's at best stagnant. And so I think it's very unlikely that they're going to get to 200 PCIs per year, which is what the guidelines suggests is the -- suggests in terms of outcomes and safety.

And even if they did, in a stagnant market

the only way to do that would be pulling from all the surrounding full-service elective PCI programs which has the potential to hurt there everywhere.

Thank you.

THE HEARING OFFICER: Thanks, Dr. Martin.

MR. MONAHAN: And Hearing Officer Mitchell, I would like to introduce John Bailey as our next witness.

And you can proceed to address the Hearing Officer.

THE WITNESS (Bailey): Thank you, and good morning, Hearing Officer Mitchell and the team from the OHS planning office. My name is Jonathan Bailey. I have the privilege of serving as the Senior Vice President of Operation and Chief Operating Officer for Stamford Health.

I'd first just start off by saying that Stamford Health is deeply committed to the communities that we serve. I believe this has been absolutely underscored by our response to the COVID-19 pandemic through that initial wave of COVID that -- COVID infections that hit this community incredibly hard, and has been ongoing as we have now taken a role back in saving our communities, having now administered more than 100,000 vaccines this week to the communities of

low -- Lower Fairfield County.

There are five points that I'd like to specifically call out from my testimony this morning. Because we are gravely concerned at the recent interests at health systems to establish low-volume percutaneous coronary intervention, PCI programs without on-site cardiac surgery programs in Fairfield County, despite the fact that there are already four existing PCI programs in the area with on-site cardiac surgery, and all four of those programs are within the clinical practice guidelines established on travel range.

My first point is that the Applicant's proposal is inconsistent with the statewide healthcare facilities and services plan. As my colleagues have shared, and has been stated within the state facility plan, that the most recent professional consensus statement addressing elective PCI without on-site cardiac surgery establishes an annual minimum threshold of 200 PCIs, and provides a sole exception for those facilities serving underserved areas or those that are geographically isolated. Neither of those situations apply in the case before us today.

We are an organization, as you've heard from

Dr. Bhalla, that strongly believes where professional standards and clinical guidelines exist we must follow them, because we know they are the foundation for which we can achieve improved clinal outcomes and reduce unnecessary harm.

The projected PCI volume as stated in the original application here by the applicants never reached that 200 annual PCI threshold. It was only after the OHS public hearing issues list that the Applicant now has claimed that it will be able to meet that minimum PCI volume, and that these new projected PCI volume or cases are derived through a methodology that, frankly, is without basis and definitely ignores regional, statewide and national trends.

My second point is that the application fails to establish clear public need for a low-volume PCI program in the proposed service area, and fails to take into account the existing full-service cardiovascular programs in the region.

Simply stated, there is no unmet need. Stamford Health's well-established program, which we are proud has been recognized for our

high-quality outcomes, is located merely 10 miles, or an 18-minute drive from Norwalk Hospital. And we have ample capacity to continue to meet the needs of the community.

This simple fact negates the Applicant's assertion that for patients in the Norwalk Hospital service area, the option to receive elective PCI is not available to them -- and to quote the Applicants, they must be transferred out of their community.

In fact if you look at the data, every primary service area town is within a 30-minute drive of the service area defined -- of Norwalk Hospital, and frankly four of the five towns defined have more than two -- or have two or more hospitals within that 30-minute range.

It is clear that there is no geographic isolation that exists in the Applicant's primary service area. The desire of a health system to restrict patient care to its own facilities does not constitute unmet need.

My third point is that Norwalk Hospital's cardiac catheterization utilization volume in trend do not support the projected volume in the application, and go against the national and

statewide projections.

The Applicant's historical data that they have submitted in their application demonstrates declines in both cardiac catheterization and primary pre -- PCI procedures pre-COVID. In fact, Norwalk Hospital's cardiac catheterization volumes declined more than 18 percent; and their PCI volume, primary PCI volume declines by more than 16 percent between FY '17 and FY '19.

Despite these historical declines the Applicant projects a dramatic increase in PCI and cardiac catheterization procedures without providing any empirical evidence to support its assumed capture rate, or it's assumed annual growth rates. This downward trend is projected to increase -- or to continue post pandemic.

SG2, a very well-known healthcare consultancy group was cited by the Applicant in their application, projects that the Applicant's service area service towns will generate 1.7 percent fewer PCIs between FY '19 and FY '24.

Despite these projections the Applicant originally projected a staggering 195 percent increase in cardiac catheterizations, and a 43.6 percent increase in primary PCIs between FY

'20 and FY '23, while elective PCIs are presumed to increase 10 percent annually with no basis as to where that volume will come from. Further, Norwalk Hospital fails to provide any recognized basis for its newly revised method of applying a multiplier to its primary PCIs to derive its elective PCI volume.

My fourth point is that the Applicant's proposal will negatively impact the financial strength of the overall healthcare system in this state. The Applicant's proposed PCI program is duplicative of those offered by the existing full-service cardiovascular programs and will result in unnecessary increases in expenses for the statewide healthcare system.

The restated financial worksheet submitted by the Applicant, worksheet A documents that Norwalk Hospital projects incremental operating expenses of 1.03 million, 1.3 million and 1.6 million respectively for the next three years.

And further as Dr. Yekta mentioned in his testimony, that Norwalk Hospital is building a new cath lab which we also would recognize will have significant increased expenses to the healthcare system.

Given the ready access to existing providers in the region these incremental operating and capital expenses represent the very unnecessary, frivolous spending that the CON regulations and the statutes and the healthcare policies seek to avoid.

Finally, Norwalk Hospital does not provide any evidence for the -- that the proposed elective PCI program will improve quality, accessibility or cost-effectiveness of healthcare delivery in the region.

The application contains no statistics or outcome measures that would indicate that the services that are currently being provided in this region lack quality elective PCI care or are outside of the distance of the 30-minute drive as defined by the clinical practice guidelines. Instead the Applicant, as Dr. Martin mentioned, offers links to various articles that we believe are frankly irrelevant to the application.

As a reminder, Norwalk Hospital previously applied for the ability to perform elective PCIs in the hospital, and OHS denied them before. There is no compelling basis for OHS to reach the different conclusion than it has previously.

We believe that the OHS/CON goals remain very relevant and pertinent to the situation presented to this application.

Improving access to high-quality health services, minimizing duplication services, facilitating healthcare market stability and helping to contain healthcare costs are critical to the healthcare future of the great State of Connecticut.

Thank you and I'm happy to address any questions you may have.

And I failed to mention, even though I did write it up -- to my remind myself that I do -- I do adopt my prefiled testimony as written.

THE HEARING OFFICER: Thank you, Mr. Bailey.

Do you have any additional witnesses, Attorney Monahan?

MR. MONAHAN: The Intervener has no additional witnesses.

THE HEARING OFFICER: All right. Anything else that you wanted to present before we go to the cross-examination phase?

MR. MONAHAN: Nothing from the Intervener, Hearing Officer.

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

think what we're going to do, I think we should take about a ten-minute break here before we should start cross-examination.

I just want to make sure the attorneys are amenable to that? We'll go to Attorney Tucci first.

MR. TUCCI: Yes. Thank you, Hearing Officer Mitchell.

That is fine.

THE HEARING OFFICER: Okay. And also Attorney Monahan?

MR. MONAHAN: That is absolutely fine.

THE HEARING OFFICER: All right. So we are going to stop for about ten tenants. We will come back on the record at 11:25. I'll give everybody a little bit of notice before we start recording again -- or not recording, but before we start the proceedings again. Thank you.

MR. MONAHAN: What is the order of the cross-examination?

THE HEARING OFFICER: According to the agenda we're going to start with the Applicant's examination of the Intervener.

MR. MONAHAN: Thank you.

THE HEARING OFFICER: All right. See everybody in about ten minutes.

(Pause: 11:13 a.m. to 11:26 a.m.)

THE HEARING OFFICER: All right. We're going to go back on the record.

At this time we're going to start with the Applicant's cross-examination of the Intervener.

MR. TUCCI: Good morning, Hearing Officer Mitchell. This is Ted Tucci, and I ask for as our first witness on cross-examination Kathleen Silard.

May I proceed?

THE HEARING OFFICER: Yes, you may. No worries.

CROSS EXAMINATION (Silard)

MR. TUCCI: Ms. Silard, this is Ted Tucci. Good morning.

THE WITNESS (Silard): Hi. Hi, Mr. Tucci.

MR. TUCCI: I appreciate your permission to allow me to speak with you this morning.

BY MR. TUCCI:

Q. Now you've been in an executive position in Stamford Hospital for about the past 20 years. Correct?

A. Correct.

Q. And you were trained originally as a nurse?

A. Yes.
Q. You obtained your BS in nursing in 1979?
A. That's correct.
Q. Would it be fair to say that the focus of your efforts and involvement in the healthcare delivery system for the last 20 years or so have been primarily involved in the administration and management of hospitals and healthcare systems?
A. My primary roles have been leadership roles. That's correct.
Q. Yes. As opposed to the delivery of frontline care?
A. I have not been at the bedside, no. That's -- that's evident.
Q. In your prefiled testimony you noted that you would be in the presentation of your remarks deferring to the administrative and clinical expertise of the other Stamford Health witnesses who spoke here this morning with respect to the subject matter of their testimony.

And you would agree with me that the subject matter that brings us here today is the broad subject matter of cardiovascular

care. Correct?

A. Correct.

Q. And in particular what we're focusing on here is the guidelines, requirements and standards that apply to the interventional cardiovascular procedure that is known as percutaneous coronary intervention, or PCI.

Right?

A. Correct.

Q. And it would be fair, would it not, to say that you did not consider yourself to be a subject matter expert in the area of cardiac care and cardiovascular care. Correct?

A. I am not a subject matter expert like the other experts that are here with me today.

Q. Right. And that's one of the reasons why you took care to note in your written testimony that you were deferring to their expertise and their knowledge of the depth of the subject matter relating to cardiovascular care.

Correct?

A. Certainly as it relates to the science and the interpretation of the guidelines.

Q. Right. And so you would agree with me that

you did not consider yourself to be a subject matter expert with respect to the various clinical guidelines and standards that have been discussed here this morning that apply to the interventional cardiology procedure known as PCI. Right? You're not an authoritative expert on that. Right?

MR. MONAHAN: Object, asked and answered.

THE HEARING OFFICER: All right. That's correct. If you can move to a different line of questioning, Attorney Tucci?

MR. TUCCI: Sure. Happy to.

BY MR. TUCCI:

Q. You also noted in your written testimony and in your comments to Hearing Officer Mitchell this morning that you took care to note that you have great respect for your professional colleagues at Norwich Hospital and with the Nuvance Health System.

Would it be correct to conclude that of your own knowledge you certainly don't have any basis to question the professional qualifications, skills and competence of the interventional cardiology team at Norwalk Hospital?

A. I have no -- no issue or question about the competency of the -- the clinic -- clinical team. I don't know that. My issue is around if the application meets the CON statute as it is currently in effect in the State of Connecticut.

Q. Okay. We'll get to that. And you would agree with me that you don't have any basis to question the adequacy or status of the interventional cardiology or cardiac catheterization facilities that currently exist at Norwalk Hospital. That's not something that you're equipped to express an opinion on?

A. I have no knowledge of their facilities or the adequacy of them.

Q. Now you are aware of your own general knowledge. Are you not? That the current state of play in the healthcare landscape in your area is that when a patient comes to Norwalk Hospital and presents with ST elevation, a STEMI profile, that is at serious risk of heart attack -- that the medical professionals at Norwalk Hospital perform urgent PCI on that patient.

You know that to be true. Right?

A. That was stated today, yes.

Q. And the opposition in part that Stamford Hospital has raised here to the certificate of need request, and in your position as an Intervener is that those doctors at Norwalk, Norwalk Hospital who are currently doing primary PCI procedure should not be allowed to do PCI on patients who present with less intense cardiac symptoms.

Correct?

MR. MONAHAN: Object to the form of the question. I don't think that's an accurate representation of the testimony.

MR. TUCCI: Well, I'm asking the Witness.

BY MR. TUCCI:

Q. Isn't that so? You know. You know for a fact that Norwalk Hospital doctors perform PCI procedures on people who are in imminent danger of dying of a heart attack. Correct?

A. I know that they perform procedures. It's not -- the characteristics of, or the competency or the clinical acumen of the physician is not in question in my testimony.

It's the establishment of a program that

will be underperforming.

Q. Right. And the procedure we're talking about here is percutaneous coronary intervention. Correct?

A. We -- yes, we stated that.

Q. Right. And that procedure is currently being performed at Norwalk Hospital -- to your knowledge. Right?

A. Emergency, yes.

Q. Yeah. And so the question is whether or not Norwalk Hospital should be allowed to do that procedure on patients who present with less severe symptoms. Isn't that right.

MR. MONAHAN: Object to the form of the question. The application speaks for itself.

MR. TUCCI: Well, that's not an objection to the form, Hearing Officer Mitchell. I think I'm entitled on my cross-examination to understand the basis for the Intervener's opposition to the application.

THE HEARING OFFICER: So I'm going to ask Ms. Silard, what is the basis of your understanding about why Norwalk Hospital should or should not be able to perform elective PCI?

THE WITNESS (Silard): Because the current CON law requires that -- that the approval would only be

provided if there was demonstrated unmet need, not -- not provided in this, in this hearing, that there would not be a duplication of services, which the application clearly demonstrated there would be.

And that there would be an improve -- an improvement in quality, not demonstrated. And that there would be reduced costs -- or no increased costs, pardon me, and that is also not demonstrated.

That is the premise of my objection.

MR. TUCCI: Thank you, Hearing Officer Mitchell.

May I continue?

THE HEARING OFFICER: Yes.

BY MR. TUCCI:

Q. So Ms. Silard, really what we're talking about here is, and as I understand the gist of your testimony, your firm statement to the Office of Health Strategy is to affirm the importance of making sure that applications for CON approval apply with the controlling CON law.

Right? Isn't that the substance of what you're talking about here?

A. That is what I said.

Q. And you would agree with me as you stated in your written prefiled testimony at page 2 that you're not a legislator. You're not a legislator. Correct?

A. No, I am not.

Q. And you're obviously not a lawyer. Correct?

A. I am not.

Q. And you would agree you're not a representative of an executive agency of the State, like the Office of Health Strategy. Correct?

A. Correct.

Q. I assume you do not consider yourself to be an expert in the interpretation and application of legal requirements for CONs. Is that true?

A. I'm not an expert, but I do know them. I've read them.

Q. All right. Now one of the things that I think you have communicated on behalf of Stamford Health here this morning is your belief that it is a worthy goal to strive for -- and I think I'm quoting from your prefiled testimony, to strive for, quote, the secure access to quality care for all

Connecticut residents.

You believe that's a worthy goal of the healthcare delivery system in Connecticut.

Correct?

A. Yes.

Q. And under the current healthcare delivery system that we have in your area a patient who has received all of his or her cardiac care from the doctors at Norwalk Hospital is currently not able to get care from his or her interventional cardiologist to do elective PCI at Norwalk Hospital.

Correct?

A. That was what was stated.

Q. If -- if a reasonable basis could be shown to support a conclusion that there was an unmet need four Norwalk Hospital's service area patients to have elective PCI done at their hospital of choice, and doing so wouldn't be an unnecessary duplication of service in the area, would you continue to oppose this CON application?

MR. MONAHAN: Object to the form, because that is not one of the principles stated in the CON statute. And I think the Witness has stood on her

testimony that she's going by the principles as stated, not on a hypothetical situation which I think that is what has been proposed.

MR. TUCCI: Well, Hearing Officer Mitchell, two things. First of all, I think I'm entitled on cross-examination to ask hypothetical questions.

And I wasn't asking the witness a legal opinion because she's not qualified to give a legal opinion. I simply asked a factual question about whether or not if a patient who wanted to get elective PCI at Norwalk Hospital should be allowed to get that if it could be shown reasonably that doing so would not create unnecessary duplication of services in the service area.

I'm asking whether she agrees that that's a reasonable proposition or not. That's all.

THE HEARING OFFICER: I'm going to allow it.

THE WITNESS (Silard): I would -- hypothetically if Norwalk application was not a duplication of services, did meet unmet need and met the cost and quality parameters as recommended in CON law, then I would not object, but none of those have been met.

BY MR. TUCCI:

Q. All right. So what do you think about the concept of patient choice? Do you think that's an important consideration to be taken into account in a healthcare delivery system?

A. Yes.

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

THE HEARING OFFICER: I just wanted to confirm. So no more questions for Ms. Silard -- because Ms. Silard left.

MR. TUCCI: She left, Hearing Officer Mitchell, because she's a very astute witness and realized I had no more questions for her.

MR. MONAHAN: I have no redirect for Ms. Silard.

THE HEARING OFFICER: Okay. All right. So Attorney Tucci, you'll let me know who you want -- or let Attorney Monahan know who you'd like to cross next.

MR. TUCCI: Yes, Hearing Officer Mitchell. I'd ask for Dr. Bhalla.

CROSS-EXAMINATION (Bhalla)

BY MR. TUCCI:

Q. Good morning, Dr. Bhalla. This is Ted Tucci.

Can you hear me all right?

A. I can. Good morning, Mr. Tucci.

Q. Good morning.

Now your role at Stamford Health is in the area of clinical affairs and quality assurance. Correct?

A. Yes.

Q. And you're not a cardiologist. Correct?

A. Right.

Q. Don't practice and not trained as an interventional cardiologist?

A. No. My -- my board certifications are in internal medicine, prevention medicine and public health.

Q. Now as I understood the general sum and substance of your written prefiled testimony submission, you -- you are, as a general proposition, confirming your views that the existence of and adherence to clinical practice guidelines, as a general proposition, is an important thing.

Do I have that right?

A. Yes.

Q. Okay. And you're aware, are you not, that with respect to the performance of PCI

procedures without on-site surgical backup, there have been published over the course of a number of years various statements and consensus documents and other documents that could be characterized as guidelines with respect to the subject of PCI.

Correct?

A. Yes, with -- with respect to the -- to not having on-site cardiac surgery, that's consistent with the 2014 guidelines that we discussed.

Q. Well, yeah. There's lots of different guidelines that have been published over the years. Right?

A. Correct.

Q. And some of those guidelines have come from SCAI, the Society for Cardiovascular Angiography and Intervention. Right?

A. Correct.

Q. The American College of Cardiology, ACC, and the American Heart Association. Right?

A. Yes.

Q. Now as I read your prefiled testimony I did not see any discussion or analysis in your prefiled testimony that interpreted or

applied the various requirements contained in those different policy or consensus statements.

Am I correct about that?

A. My testimony stated that the application is inconsistent with current guidelines. The guidelines that were referenced speak to a consistent adverse signal associated with poor outcomes in institutions that do less than 200 PCIs annually as stated in the guidelines.

Q. Do you consider yourself to be an expert with respect to the various consensus documents and guidelines that have been published in the area of cardiology with respect to performance of PCI without surgical backup?

A. My expertise is in quality of care, safety of healthcare, and healthcare delivery.

Q. So the answer would be no?

MR. MONAHAN: I'll object to that, to the argumentative response by Mr. Tucci.

MR. TUCCI: Well, I'm just trying to draw a conclusion from the Witness' testimony.

BY MR. TUCCI:

Q. Do you agree with me that you're not an

expert in that particular area of clinical guidelines? You're not a cardiologist. Correct?

A. (Unintelligible.)

THE HEARING OFFICER: Yeah, I was going to say I was going to allow it for the purpose of clarification. I'm just going to ask both counsel, whenever there's an objection raised to allow me to respond to the objection. Thanks.

BY MR. TUCCI:

Q. Doctor, can you respond?

A. I am not a cardiology expert, but I reviewed many different guidelines for different areas of clinical care.

Q. All right. So with respect to your general familiarity with clinical guidelines and their application in medicine as a general proposition, would you also agree that as a general matter it's important for that clinical guidelines be updated when necessary?

A. I think the guidelines should be updated when there's material change in the body of evidence that supports a change in practice.

Q. And would you agree that in some instances a

material change in the body of evidence could be as a result of advancements in medicine and the advent of new technology relating to the provision of that service?

A. Yes.

Q. Again, given your focus in your role with respect to quality assurance, I know you feel strongly that quality and safety are important factors that need to be accounted for in the delivery of healthcare to patients.

Correct?

A. Yes.

Q. Would you also agree that in today's world in the delivery of health care, that cost and value of healthcare delivery are components that should be taken into account in considering how best to get health care to the people of the state of Connecticut?

A. Yes.

Q. And in fact, you talked about that in your prefiled testimony. Don't you? You -- you referred to, in fact, some specific initiatives that the Office of Health Strategy has undertaken in the past several

years to do just that, to promote the improvement of healthcare value. Right?

A. Yes, adherence to guidelines such as the ones from 2014 are associated with improvements in care, reduction in harm and reduction in inappropriate use.

Q. And so would you agree that where it's reasonably clear that minimum quality standards are being met, that it's also a desirable goal to make sure that the health care that is being delivered is being delivered as cost effectively and cost efficiently as possible.

Right?

MR. MONAHAN: Object to the form of the question. I'm not sure very candidly, with the question -- if I may? In whose judgment is it reasonably clear?

THE HEARING OFFICER: Did you want to respond to the objection, Attorney Tucci?

MR. TUCCI: Thank you, Hearing Officer Mitchell.

BY MR. TUCCI:

Q. I'm asking about this witness who is a physician who's in the area of quality assurance about what his judgment is about the balance between quality and cost?

A. Mr. Tucci, you -- you said, minimal quality standards. My testimony pertained to consensus guidelines from three different societies. I'm not sure what you mean by minimal quality standards.

Q. Okay. I apologize. It may be my ignorance in using the wrong terminology. My question is really very simple. All other things being equal, assuming that health care is being delivered at the appropriate level of quality and safety, would you agree that it is also important to ensure that that quality and safe care is delivered as cost efficiently as possible?

A. Yes, if you mean that the appropriate level of quality of care equates with following professional consensus guidelines.

Q. Okay. And so for example, in today's world where we're looking to control healthcare costs, one way that the overall cost of health care could be reduced and delivered more efficiently is to eliminate the running of duplicative tests.

Right?

A. Yes.

Q. And one way that the cost of health care could be streamlined and made more efficient would be to eliminate the emergency transport of patients if it was not otherwise necessary to do that. Right?

MR. MONAHAN: Object to the form of the question.

THE HEARING OFFICER: Response, Attorney Tucci?

MR. TUCCI: Well, I'm -- Attorney Mitchell, I'm at a loss to understand what the objection to the form of the question is, so (unintelligible).

MR. MONAHAN: The form (unintelligible). Hearing Officer, if I may? I will state why the form is, in my view, inappropriate.

THE HEARING OFFICER: Absolutely, yeah.

MR. MONAHAN: The Witness has been testifying repeatedly to the context of the consensus document and the consensus requirements, yet the questions seemed to tail off back into isolated instances or hypotheticals without connecting the Witness' prior statement.

So I want there to be -- the form of the question to me suggests a gap and, perhaps confusion on the record about the continuity of this Witness' testimony.

THE HEARING OFFICER: Attorney Tucci?

MR. TUCCI: Thank you, Hearing Officer Mitchell.

I don't think there's any gap at all. I'm asking this witness who is a physician who is expert in the subject of quality assurance to give the Hearing Officer and OHS the benefit of his view on strategies that exist to balance both quality and cost.

That exists generally in medicine and it can be applied specifically to the facts of this hearing.

THE HEARING OFFICER: Okay. I'm going to allow a few more questions on this issue as long as they're not unduly repetitive.

MR. TUCCI: This will be the last one, Hearing Officer.

THE WITNESS (Bhalla): Can you repeat your question?

BY MR. TUCCI:

Q. Doctor, my question is if we're talking about achieving the goal of delivering health care as cost efficiently as possible, would you agree that where circumstances are appropriate avoiding the unnecessary emergency transport of a patient from one facility to another would be one strategy to help bring down the cost of health care?

A. One who's focused solely on cost, that would

be correct, but the guidelines for 2014 clearly state that in the interests of quality and safety, transfer is unnecessary if it can be achieved within 30 minutes. That's a situation where quality and safety outweigh any cost consideration.

Q. All right. Doctor, you concluded your prefiled testimony with this statement. I'm going to quote it to you.

On behalf of Stamford Health you indicated that Stamford Health, quote, encourages OHS to continue to be guided by science and not the business desires of health systems.

That was what you wrote in your prefiled testimony. Do you recall that?

A. Yes.

Q. So with respect to the performance of elective PCI, if it could be reasonably concluded that the performance of elective PCI could be done safely at Norwalk Hospital without surgical backup, do you agree that that's an important factor that OHS should be guided by, that -- that scientific factor?

A. My comment pertained to the reasonableness of

the volume that's being proposed.

Q. I didn't ask you about what your comment pertained to. I'm asking you now, you said in your testimony, your sworn testimony you submitted to OHS that OHS should be guided by science and not business desires.

Didn't you say that?

A. Yes.

MR. MONAHAN: May I object to the argumentative tone? And the Witness gave a very reasoned answer to the question to explain his answer.

And while Mr. Tucci may not be pleased with the answer, I don't think that tone responds to the Witness appropriately.

THE HEARING OFFICER: I'm going to sustain.

MR. TUCCI: Thank you, Hearing Officer Mitchell.

I apologize for my tone. My wife often reminds me that I need to be careful about that. So let me just reask the question, because I think it's fair cross-examination.

And I believe that, Hearing Officer Mitchell, the purpose of cross-examination is not to elicit explanation, but to elicit direct answers to specific questions, which is all I was attempting to do.

BY MR. TUCCI:

Q. So Doctor, if the evidence showed and it could be reasonably concluded that it was safe to do elective PCI procedures on patients at Norwalk Hospital even though there is no CABG surgical backup, do you agree that that is a factor that OHS should take into account?

A. Yes, if the safety is predicated on volume, which is what the basis of safe -- the ability to do this procedure safely is, that a volume over 200 PCIs annually. It should be -- that's what the guidelines say.

Q. So to modify my question then, if there was a reasonable basis to conclude in your view that that volume threshold was reasonably attainable, you would think that you would agree that that's an important factor for OHS to be guided by in terms of being able to do elective procedures without surgical backup. True?

A. Yes, if it was reasonably attainable.

Q. And if it was reasonably attainable, then you would agree with me that Stamford Health's business desire to retain elective PCI

procedures that formerly were transferred from Norwalk Hospital is -- would be a less important factor for OHS to consider even though it might result in Stamford Hospital losing some elective business.

Right?

MR. MONAHAN: Objective to the form. Calls for speculation about what OHS may consider.

THE HEARING OFFICER: Attorney Tucci, any response on the objection?

MR. TUCCI: Respectfully Hearing Officer Mitchell, it doesn't call for speculation at all. It states a factual premise and asks the Witness if that factual premise is proven by the evidence, what his reaction to it is.

THE HEARING OFFICER: I'm going to allow it.

THE WITNESS (Bhalla): My area is not the business interests of Stamford Health. It's clinical affairs and quality. In general it's shifting volume from -- from one center to another will result in of dilution of procedures across the region.

MR. TUCCI: Thank you very much.

Those are all my questions.

THE HEARING OFFICER: Thank you, Dr. Bhalla.

THE WITNESS (Bhalla): Thank you.

MR. TUCCI: Hearing Officer Mitchell, I'd request Dr. Bailey be available for cross-examination.

MR. MONAHAN: And just for clarification, can Mr. Bailey and Dr. Martin -- I don't know if you were going from one or the other?

MR. TUCCI: Yeah. No, I apologize. That was my mistake. Thank you, Mr. Monahan. I meant Mr. Bailey.

CROSS EXAMINATION (Bailey)

BY MR. TUCCI:

Q. Good morning, Mr. Bailey. Can you hear me okay?

A. I can. Good morning.

Q. And good morning to you. Now back on September 25 of 2020 you testified in opposition to the Greenwich Hospital CON for the approval of elective PCI. Correct?

A. That is correct.

Q. And you're here today opposing the Norwalk Hospital CON request for approval to do elective PCI. Correct?

A. That is correct.

Q. In your prefiled testimony at page 2, at the bottom of page 2 -- and I'm just going to quote a portion of it.

You indicate, I am testifying today on behalf of Stamford Health in strong opposition to the application submitted by the Norwalk Hospital Association seeking authorization to establish elective percutaneous coronary intervention services at Norwalk Hospital.

Do you recall submitting that written prefiled testimony?

A. I do.

Q. And are you aware that large portions of the prefiled testimony that you submitted in opposition to the Norwalk CON application are word for word the same thing that you said when you opposed the Greenwich PCI application?

MR. MONAHAN: I'm going to object. Are you saying -- I don't mean to be too picky. Is it similar in substance, or are you saying verbatim?

BY MR. TUCCI:

Q. I'm asking you -- I'm asking the Witness. I think it was very clear, are you aware that

the portion of your testimony that I just quoted in virtually word for word is the same testimony that you gave when you opposed the Greenwich PCI application?

It's a very simple question.

A. I guess I can ask to clarify. Are you asking about the words you just quoted being the same that were actually submitted in the previous, so whatever 40 words, that quote you just stated?

Q. Well, Mr. Bailey, I assume you read your written prefiled testimony that you submitted here in this proceeding. Right?

A. That's correct.

Q. And so I'm asking -- my question then is, are you aware that significant portions of the written prefiled testimony that you've submitted in this hearing substantially mirror the same testimony that you gave in writing in the proceeding seven months ago?

That's all.

A. So let me answer your question this way. I did not do a side-by-side page turn comparing the two. So I'm hard-pressed to be able to answer/address your question to your --

probably your satisfaction.

But I would say in general, no I would not agree with you that it they are substantially the same. In fact, I believe there are significant additional points that I point to in this overall submission.

Only I believe in ten points -- and if you would compare that to what I submitted before with the Greenwich application, there was nowhere close to ten points given in these. No, I disagree with your assessment of that.

Q. All right. Thank you very much. So I assume you would have no problem with the Office of Health Strategy taking administrative notice of your prior testimony and looking at it in comparison with your testimony today.

Correct?

A. I believe our attorney has submitted that as prefiled in his opening comments. I think that that's already been stated.

Q. All right. Now you -- among the points that you have raised in opposition to the CON application is a point that you made in your written testimony and that you reiterated

orally here today. Your believe that the Norwalk Hospital application has not adequately taken into consideration the other full-service cardiovascular programs in the region. Correct?

A. That is correct. I believe that is the missing statement -- or missing assessment.

Q. All right. Now you acknowledge, do you not, that there are no elective PCI programs in the Norwalk Hospital service area?

A. Can you clear -- when you're saying, service area, you, you're talking their primary service area? Or the adjacency as defined by the State?

Q. Well, I think the question was very clear, Mr. Bailey. And I'm actually -- if you need clarification perhaps you could go to page 11 of your prefiled testimony?

A. Yeah, I'm on page 11.

Q. Let me direct you to Roman seven.

Do you have that in front of you?

A. That is correct.

Q. While the Applicant states -- I'm quoting, while the Applicant states that there are no elective PCI programs within its proposed

service area.

Do you see that written statement in your prefiled testimony?

A. I do.

Q. You agree with what -- as a matter of fact, you agree, do you not, that there are no elective PCI programs within the Norwalk Hospital primary service area? Correct?

MR. MONAHAN: I object. You're asking him if he stated -- I think you used the words, he referred to the, what the applications state -- but maybe I misunderstand what you say.

MR. TUCCI: I'll ask the question again, Hearing Officer Mitchell.

BY MR. TUCCI:

Q. The Norwalk Hospital's application stating that there are no elective PCI programs within its primary service area, is that an accurate statement?

A. Yes, that is an accurate statement.

Q. Now the four, the four programs that you indicate that OHS should be concerned about, those full-service cardiovascular programs, one of those programs is Stamford Hospital. Correct?

A. That is correct.
Q. And the other full-service cardiac programs would be Danbury Hospital which is part of the Nuvance system. Right?
A. Yes.
Q. St. Vincent's Hospital, which is part of the Hartford HealthCare system. Correct?
A. Yes.
Q. Bridgeport Hospital, which is part of the Yale system. Correct?
A. Correct.
Q. And so as I understand the gist of your testimony, what you're concerned about is the creation of what you would view to be unnecessarily duplicative elective PCI services in the face of these existing four system programs that are in the region. Right?
A. I believe you've articulated my point, yes.
Q. And the -- in intervening in the proceeding here today Stamford Hospital, would it be fair to say, is advocating that OHS should maintain the status quo with respect to the ability to have elective PCI services performed in the region as you've described

it. Right?

A. I would characterize what I'm advocating for, as is Stamford Health is advocating for -- is that the State continue to enforce the already established regulatory requirements and follow what is prescribed within the state facilities and services plan.

Q. The current state of play in the area in which Stamford Hospital operates is that patients who go to Norwalk Hospital and who otherwise qualify for and need elective PCI procedures, you're here on behalf of Stamford Health advocating that those patients continue to be transferred to some alternative care center.

Correct?

A. I -- I would characterize what I would say is I advocate that the State continue to follow the consensus guidelines, which I believe Dr. Bhalla and Dr. Martin have articulated. A clinical perspective --

Q. Mr. Bailey, excuse me. I didn't ask you about consensus guidelines. I asked you a question that simply calls for a yes or a no answer.

And the question is, is your position on behalf of Stamford Health that a patient goes to Norwalk Hospital today who otherwise medically qualifies to receive elective PCI should get transferred to an alternative care site that is approved to perform PCI, an elective PCI? Yes or no?

MR. MONAHAN: I'm going to object. That is a slightly different question, and the question has been asked and answered.

THE HEARING OFFICER: I just want to make sure I'm clear. Let me just let Attorney Tucci respond, and I just want to make sure I'm clear on the objection.

But go ahead, Attorney Tucci.

MR. TUCCI: Yeah, Hearing Officer Mitchell. I'm simply again attempting to understand the basis for the Intervener's opposition.

And I did not ask the Witness a question about the Witness' opinion or view regarding standards or guidelines, or what have you. I'm asking about circumstances relating to the actual delivery of healthcare. I don't think that's a hypothetical question. I don't think it calls for speculation.

And it appears I'm having difficulty getting answers to basic factual questions.

THE HEARING OFFICER: Let me ask Attorney Monahan, how is the question different? I think you said that that was one of your objections.

MR. MONAHAN: Because this Witness is not a clinician, and this Witness has couched every answer in relation to that type of factual question with the basis of his expertise which goes to the policy and the procedures that surround why patients are transferred, not purely to the clinical needs.

And that question --

MR. TUCCI: (Unintelligible.)

MR. MONAHAN: And that -- let me finish. And that question included a hypothetical that the PCI would be reasonably be able -- would be able to be performed. And based on what this Witness has said, that is not his testimony in light of the standards that govern elective PCI.

MR. TUCCI: May I be heard on that objection, Hearing Officer Mitchell?

THE HEARING OFFICER: Yes.

MR. TUCCI: If the position of counsel for Intervener is that the Witness who's currently under oath and is testifying, and is not a clinician, and is not

qualified to speak about clinical issues relating to cardiovascular care, then I would move to strike his prefiled testimony in all areas where the Witness has given opinions about how to interpret the professional guidelines of various societies, and what those standards are, and expressing opinions as a non-physician about what appropriate care and safety guidelines are for the delivery of cardiovascular care.

Move to strike.

MR. MONAHAN: Well, I'm told I can be heard.

THE HEARING OFFICER: Go ahead. Go ahead, Attorney Monahan.

MR. MONAHAN: Ms. Mitchell, we all know that this application involves clinical and nonclinical expertise. It involves public policy, legislative issues, administrative action, cost savings across the board.

Not only doctors are qualified to testify in this proceeding, and indeed I don't know how many physicians, with all due respect, are sitting on the OHS panel. So if that question was if that objection had any merit then we would only have to have physicians listening to this and presiding over this hearing.

This Witness has every right to testify. If Mr. Tucci wants to hear the basis for his, this Witness' opinion, why doesn't he just say, please give me the basis for your opinion?

THE HEARING OFFICER: What about the motion to strike all of his prefiled testimony that relates to --

MR. MONAHAN: I object to that strenuously. It would be an egregious error, and it would be -- I think an absolute injustice.

THE HEARING OFFICER: So I'm just going to say with regard to the motion to strike, I mean, this is an administrative hearing. So when we look at the record we weigh all of the evidence accordingly.

And with regard to the objection, I'm going to allow Attorney Tucci to just go ahead and ask the question once more. And then I'm going to ask the Witness just respond to the question as directly as possible.

MR. TUCCI: Thank you. Mr. Bailey, I'll try to state the question as simply as possible.

BY MR. TUCCI:

Q. Is it Stamford Health's position that patients who otherwise receive care today at Norwalk Hospital and who qualify for elective PCI should continue to be required to go to

alternative care sites to get that care?

A. Yes, our position is that they should continue to follow the established guidelines.

Q. In your Prefiled testimony you generally speak about the Norwalk Hospital CON proposal and it's potential impact or threat to the existing four, four full-service programs in the region as you defined it.

Is it your opinion that the Norwalk Hospital CON request threatens the ability of the four regional programs we've discussed to continue to meet their PCI volume thresholds?

A. Can you point me to just -- just to point me where you're at in my prefiled testimony so I can refresh my memory where you're reading from?

Q. You can take a look -- I wasn't reading, but you can take a look at page 13 of your prefiled testimony.

A. Sure. Okay.

And I hate to ask you to restate the question. I was combing through my paper just reviewing that.

Q. Well, sure. Why don't you focus on page 13,

Mr. Bailey. And you have a chart there. Right? And right below the chart I'll read portions of your prefiled testimony.

Partially quoting, quote, the only way for Applicant to achieve its projected volumes is to divert patients from existing providers already serving the market.

There you're referring to the four system programs that you identified earlier in your testimony. Correct?

A. That's correct.

Q. And then later on in your written remarks you have a sentence that begins, recent efforts to increase elective PCI programs.

Do you see that sentence?

A. Yes, that's correct.

Q. And you go on to state in that sentence that these efforts to expand elective PCI, quote, all -- among other things, quote, all threaten the ability of existing programs to continue to meet PCI volume thresholds, end quote.

Have I read that accurately?

A. You have.

Q. And so my question is, is it your testimony

that the Norwalk Hospital CON request raises a serious threat to the ability of Stamford Hospital, Danbury Hospital, Bridgeport Hospital, St. Vincent's Hospital to continue to meet what you believe to be adequate PCI volume thresholds?

A. I believe that based on the fact that the market has already seen declines, as I stated in my written testimony and as I gave in my introductory comments, and the fact that there is a continued projection of decline in the service area that we know for at least the Norwalk Hospital service area -- that yes, the only way for those volumes to be met would be to have a declining impact, a negative impact to volumes that are going to other facilities within -- within this 30-mile radius.

Q. Do you mean that you believe approval of this CON would pose a threat to those four programs to meet minimum volume thresholds?

A. So I -- I believe that the question you're asking me would cause me to speculate about what exactly -- how those volumes would go and the total number of cases by certain

geographic regions, by certain hospitals.

So I'm not sure I can answer your question with a, cause them to go below the threshold number.

But what I can answer for you is, that yes, I do believe it would have negative and adverse impacts on their volumes, and it could potentially impact there, their overall threshold volumes.

Q. So even though -- so you can't speculate, but you believe that potentially could impact.

Correct?

A. I believe I answered the question on that, yes.

Q. All right. Let's turn to some numbers, please. Please look at the CON application page 15 and 16?

A. Just allow me, if I can, to get that application, because I don't have it in front of me?

MR. MONAHAN: Can you read me the pages of the application?

MR. TUCCI: CON application pages 15 and 16.

THE WITNESS (Bailey): I have them in front of me.

BY MR. TUCCI:

Q. All right. If I could just direct your attention to the bottom of page 15 and then over to the top of page 16. I want to ask you a few questions about the data that appear there.

A. Yeah, I've got it. Yeah, I've got it.

Q. So at this portion of the application Norwalk Hospital has listed patient transfer data for a period of August 1, 2019, to March 19th of 2020 for patients that were transferred from Norwalk Hospital because they required some type of follow-up cardiac clinical care.

Do you see that?

A. I do see that.

Q. And the data that Norwalk Hospital presented showing that during that seven-month or so period, 13 patients who presented to Norwalk Hospital ended up being transferred to Bridgeport Hospital, which is part of the Yale system.

Right?

A. I see that noted here.

Q. And to state the obvious, Bridgeport Hospital in the Yale system have not intervened to

oppose this CON application. Right?

A. I -- I believe that to be factually true based on what Hearing Officer Mitchell opened up with her comments.

Q. And the data further show that during that seven-month period there were 55 patients who were required to go to St. Vincent's Hospital, or who elected to go to St. Vincent's Hospital because they couldn't get cardiac care at Norwalk Hospital.

And you would agree with me as a matter of fact that St. Vincent's as part of the Hartford Health system did not request intervener status to oppose Norwalk Hospital's request for elective PCI.

Correct?

A. I -- I honestly can't speak whether they requested it, but I -- I do know that they were not granted an intervener status based again on what Hearing Officer Mitchell stated.

Q. Okay. And during the same seven-month time period a total of six patients who could not receive follow-up coronary cardiovascular care at Norwalk Hospital ended up going to

Stamford Hospital. Right?

A. I see that's what's stated here, yes.

Q. One of the things that you have talked about is the PCI procedure data that has been the subject of this application, and you -- you included some information concerning Stamford Hospital's experience with PCI procedures in your prefiled testimony.

Correct?

A. I'm not sure I know exactly what question you're asking about. What we've cited in our prefiled testimony about Stamford Hospital's procedure volume?

Q. Okay. Well, I'm asking about your prefiled testimony and --

A. Yeah, yeah.

Q. And in particular to assist you, I'd ask you to go to page 12 of the testimony you submitted?

A. Okay.

Q. And you put a chart in your prefiled testimony at the top part of the page which you've described with the label, regional PCI trends. Do you see that?

A. I do.

Q. And it shows for example in fiscal year 2019 that the total inpatient and outpatient PCI procedures done at Stamford hospital were 477. Right?

A. I would -- I would agree with you, yes.

Q. And you also reported for fiscal year 2020 a total of your inpatient and outpatient PCI procedures at 388. Right?

A. Yes.

Q. And 2020 was the year that all of us were required to stay home starting in March when the pandemic hit. Do you agree with that?

A. I do agree that was when the pandemic hit.

Q. All right. And so if we look back at the experiential data from the seven-month period that we talked about earlier in terms of patients from the Norwalk service area, from August of 2019 to March of 2020, you agree with me that there were a total of six patients who ended up going to Stamford Hospital for some form of further cardiovascular care.

Right?

A. That's correct.

Q. And as a matter of simple math, if that

experiential data was consistent throughout the course of time, the reduction of six or ten, or twelve PCI procedures coming from the Norwalk service area would not have in any way a material impact on Stamford Hospital's ability to maintain a high-quality PCI intervention program.

Would you agree with that?

A. The way I answer you question is --

Q. Well, I asked you -- I'm sorry, sir.

I asked you a very simple question that is based on the numbers that we've all just talked about. And so I'm asking you very simply, do you agree, yes or no, that a reduction going forward of as many as a dozen cases, let's just say, from what your existing volume trends are for PCI would not have a materially adverse effect on your health systems' ability to maintain volume thresholds?

MR. MONAHAN: May I object to the interruption of the Witness' answer -- and allow the Witness to answer as he sees best to answer that question?

THE HEARING OFFICER: I'm going to direct him to answer the specific question yes or no. If there's any

followup, then Attorney Monahan, you can make that followup.

MR. MONAHAN: Okay. Thank you.

THE WITNESS (Bailey): So to answer your question based on the math you presented, then no. That would not have a material impact based on the math you presented.

MR. TUCCI: All right. I'm now trying to move along here, but I want to cover some of the other sort of highlighted areas that I understood from your written prefile and your remarks under oath here today.

BY MR. TUCCI:

Q. And as I understand it, a fair characterization of one of the other concerns that you have raised is that the Office of Health Strategy should be concerned about a declining PCI volume and what you characterize as the region.

And for purposes of our discussion we'll talk about the region meaning the four full-service programs that we talked about earlier. Am I right that that's one of the concerns that you raised?

A. It is absolutely correct.

Q. Okay. Do you believe that within a geographic -- have you seen, do you believe that within a geographic region that there may be factors that apply to particular institutions, or a particular location within that region that could influence procedure volume in a way that may be different when you look at the region as a whole?

A. I -- I'm sorry. I have no idea what the question actually -- is trying to ask me to provide a opinion on it.

Q. All right. Okay. Let's look at your chart on page 12, sir.

Do you have it in front of you?

A. I do.

Q. You've defined the region that you would like OHS to focus on to be comprised of Bridgeport, Danbury, St. Vincent's and Stamford Hospital's. Correct?

A. That's correct.

Q. You've shown for fiscal years 2016 through fiscal year 2020 what the actual volume numbers are for PCI for those different institutions. Correct?

A. Yes.

Q. And you're asking OHS to draw conclusions about what you believe are regional trends shown by that PCI volume. Correct?

A. I believe what I'm trying to do here is to demonstrate that there is a decline that has been noted here that falls in line with what has also has been projected in the state as well as other national trends.

Q. When you look at the region as a whole. Correct?

A. Yes, when we look at the region whole -- holistically here I think we've -- we've cited the -- I've cited the percentage decreases.

Q. All right. Now, sir, I'd ask you to look at your chart at the top line for Bridgeport Hospital.

Do you have that data in view?

A. I do.

Q. Would you agree with me that for fiscal year 2016 Bridgeport Hospital reported a total PCI inpatient/outpatient volume of 288?

A. That's correct.

Q. In fiscal year '27 [sic] Bridgeport Hospital had a total PCI volume of 349. Correct?

A. That's correct.
Q. In 2018 Bridgeport Hospital reported a total inpatient/outpatient PCI volume of 390. Correct.
A. Correct.
Q. In 2019, for that fiscal year Bridgeport Hospital reported a total inpatient/outpatient PCI volume of 489. Correct?
A. Yes, that's correct.
Q. So from 2016 to the four-year period ending in 2019 is a matter of simple mathematics, sir, do you agree that the PCI volume at Bridgeport Hospital part of the region that you've defined increased by 200 cases?
A. I would agree it's increased by 201 increases, as I reported.
Q. Thank you.
Moving along, sir, again I think one of the sort of major topic areas that you presented was a concern about the granting of the CON application potentially having an adverse effect on the financial strength of what I think you characterized in your prefiled testimony at page 6 as the overall

healthcare system in the state.

Is that, in fact, a concern that you have expressed to the Office of Health care Strategy?

A. Yes, it is in fact a concern.

Q. Can you point me to any data in the 13 pages of your prefiled testimony that shows how allowing elective PCI at Norwalk Hospital will jeopardize the financial health of any Hospital in Connecticut?

A. I -- I do not have any, any data in my -- that points to an impact on a hospital, but I do believe and what my point is here is that the impact is to the statewide health system.

And when we increase operating expenses as stated and proposed by Norwalk Hospital here at 1.08, 1.3 and 1.6 million; anytime a healthcare system increases costs in their operating basis or capital, it has a deleterious effect on the overall cost of the healthcare system holistically.

Those costs are passed on elsewhere and it has impacts that are oftentimes hard to immediately define.

Q. All right. Mr. Bailey, I'm a little confused

by that. I'm not a chief operating officer, but I did note that you noted that if this CON were approved that Norwalk Hospital would experience some additional cost. That's the point you were making. Correct?

A. That's the point I am calling out that was based in their worksheet that they submitted.

Q. Right. And that would be the costs associated with providing more services to patients than Norwalk was previously allowed to provide because of CON restrictions. Right?

A. That's correct.

Q. So presumably if Norwalk Hospital is providing services that it was previously not allowed to provide, you would agree with me as a basic elementary manner they would be able to charge for those services, at least a portion of it?

MR. MONAHAN: Object to the form.

THE HEARING OFFICER: Attorney Tucci?

MR. TUCCI: Yes?

THE HEARING OFFICER: I just wanted to see if you had any response to the objection.

MR. TUCCI: No, I don't, because I think it's fairly

clear that when -- the question I'm asking the Witness who is -- I think has financial expertise, is that you're investing cost and providing services, the idea is you're going to generate revenue and revenue offsets cost.

THE HEARING OFFICER: Attorney Monahan, any response?

MR. MONAHAN: Well, I believe that Attorney Tucci introduced the concept of charges, which was not the thrust of what the testimony was, and what the answer to the question was. So I think the thrust of the questions that led up to that and the answers dealt with increased costs for services that would be duplicating others.

So I think there -- I think that there was -- the charge is, I believe, was an inappropriate form of that question and followup to the line of questioning that is being presented.

MR. TUCCI: Hearing Officer Mitchell, I'm sorry. I'm trying to really make this as simple as possible. The Witness testified about cost, and that we reported that there would be increased cost.

I'm simply asking a basic elemental question about the concept of increased costs associated with allowing more procedures to be done, and if more procedures are being done, therefore revenue

is generated. I don't think that's a controversial concept or one that's hard to understand.

THE HEARING OFFICER: All right. I'm going to allow it.

THE WITNESS (Bailey): Would you mind restating your question?

MR. TUCCI: You know what? I'm going to move on.

BY MR. TUCCI:

Q. All right. Now I am going to spend some time on this next topic, Mr. Bailey, because I think it's one that you have provided some extensive discussion around. And that's the issue of volume projections. Right?

You would agree that the substance of your testimony here today is that you would like OHS to conclude that the projected volume figures that Norwalk Hospital has presented are not backed up by what you describe as empirical evidence. I believe you use that term at page 10 of your prefiled testimony.

A. Yes, that's correct.

Q. That is right?

A. That's correct.

Q. All right. And I assume as part of your preparation for coming here today to testify you reviewed Norwalk Hospital's response to the OHS hearing issues which set forth information concerning recent utilization.

Did you review that?

A. I did.

Q. And in reviewing that you would agree with me, would you not, that those responses reported empirical information for fiscal year 2021, actual to date and projected showing annualized volume of 108 cardiac cath cases and 82 primary PCIs?

That's what the empirical information is that was set forth in the response that my client submitted to OHS.

Would you agree with that?

A. Before I answer your question I'd just like to be able to be able to point you to the information so that I, as being under oath as you pointed out, I answer it correctly.

Q. Sure.

A. So you're referring to the table Norwalk Hospital cardiac cath, the piece how the cases trend. I don't have a page number on

it -- where it has FY '21 annualized 108 plus 92 adds up to 190?

Q. Yes.

A. I see that.

MR. TUCCI: Hearing Officer Mitchell, if you could just give me a moment? I need to locate another document.

THE HEARING OFFICER: Absolutely.

THE WITNESS (Bailey): I'm going to take a moment to get a drink of water if that's okay?

THE HEARING OFFICER: That's okay.

(Pause: 12:35 p.m. to 12:37 pm.)

THE HEARING OFFICER: I'm just going to note that my colleague Brian Carney was having some technical problems, and he is trying to assess the hearing again.

So I'm just going to ask that we wait until he is back because he controls a lot of the functions related to muting and monitoring individuals who want to speak when I can't see them. So I'm just going to ask that we hold on just for another minute or two until he's back.

(Pause: 12:37 p.m. to 12:41 pm.)

THE HEARING OFFICER: Okay. So we can go ahead and resume. I'm just thinking before you continue with your questions, I'm wondering if both counsel would be amenable to taking a break at one o'clock?

MR. TUCCI: That's perfectly fine.

THE HEARING OFFICER: Okay. I just didn't want to interrupt your flow if you wanted to continue on.

But is that okay, Attorney Monahan?

MR. MONAHAN: Absolutely okay.

THE HEARING OFFICER: Okay.

MR. TUCCI: Hearing Officer Mitchell, I'm ever the internal optimist. I only have a little bit longer for Mr. Bailey.

THE HEARING OFFICER: Okay.

MR. TUCCI: I was thinking I might be able to wrap up the last cross-examination. I'm not sure I can do it precisely by one.

So maybe what makes the most sense to do is just finish with Mr. Bailey and then take a break when we're done with him. And if that's acceptable?

THE HEARING OFFICER: That works for me. What about

you, Attorney Monahan?

MR. MONAHAN: That works for me, too.

THE HEARING OFFICER: Okay. All right. So you can proceed when you're ready.

MR. TUCCI: Thank you.

BY MR. TUCCI:

Q. All right, Mr. Bailey. We're back.

A. Yes, we are.

Q. And we were chatting before the break about the data, empirical information presented in Norwalk Hospital's responses to the OHS public hearings list -- public hearing issues, and I'd ask you just to go back to that page.

And I want to direct your attention to the graph pertaining to Danbury Hospital cardiac cath and PCI case trends.

Do you see that?

A. I do see that.

Q. And this is a particular set of data reported for fiscal years '17 through '20, and then fiscal year '21 for approximately the first six months. Right?

A. That's what it states, yes.

Q. Right. And of course you know that Danbury

Hospital is approved to provide both primary PCI services to patients, but also elective PCI services to patients. Right?

A. I do know that.

Q. And looking at the various data that's reported as Danbury Hospital's actual case experience, I want to go through each of the fiscal years with you and look at primary PCI and elective PCI in each of these years and talk to you about what that empirical information shows.

So focusing your attention on fiscal year 2017 you would agree with me that Danbury Hospital reported 88 primary PCI cases in 2017, and a total of 329 elective PCI cases in that same fiscal year. Correct?

A. Yes, I see that written in the chart there.

Q. So in looking at the relationship between the number of primary cases versus the number of elective cases, there are about four times as many elective cases. Right?

A. I am following that simple math, yes.

Q. Okay. And for 2018 we'll do the same thing. Do you see that Danbury Hospital reported 63 primary procedures and a total of 302

elective procedures?

And you would agree with me that the ratio there is approximately five times as many elective cases as primary PCI cases.

Right?

A. I am following your math, yes.

Q. And for 2019 the data show that Danbury Hospital's actual experience was 79 primary PCI procedures for patients, as compared with 367 elective PCI procedures performed on patients in that fiscal time period.

And again, we're talking roughly about five times as many elective cases as primary cases. Right?

A. You're on FY '19?

Q. Yes.

A. Yes, I would. That's probably more around four times that volume, but yes.

Q. I apologize. I'll go with your rounded number. Agreed.

And again, to complete the exercise with regard to the fiscal year 2020, what that data show is that Danbury Hospital performed primary PCI procedures on 76 patients, as compared with elective PCI procedures for a

total of 339 patients.

And again, we're roughly in that approximate four times ballpark right?

A. Yes. I'm following your math, yeah.

Q. Do you believe that the trending data for Danbury Hospital showing the relationship between the number of primary PCIs and elective PCIs roughly mirrors the experience that you note to be the case at Stamford Hospital?

A. I have not done the math to do a comparative analysis. I cannot answer your question.

Q. Well, have you, in getting ready for this hearing that we're here for today, did you take a look at what Stamford Hospital's breakdown was in terms of the number of primary cases versus elective cases?

MR. MONAHAN: Asked and answered.

MR. TUCCI: No, it hasn't been asked and answered. It's the first time I've asked the question, Hearing Officer Mitchell.

THE HEARING OFFICER: I'm going to allow for it.

THE WITNESS (Bailey): So certainly we looked at our most recent data of elective PCIs, and we've also looked at our primary PCIs, as we do on a regular

basis as just doing business.

I have not done the math. I would not be able to cite, you know, what I believe was your original question, was whether this follows a similar trend. Quite frankly, it simply did not do the math to know if that is the case.

BY MR. TUCCI:

Q. That's fine. Let me break it down a little bit more. Let's go.

Let's go to page 12 of your prefiled testimony.

Do you have it in front of you?

A. I do.

Q. You reported data for Stamford Hospital in the chart. Correct?

A. That is correct.

Q. And the data you reported concerned the actual performance of PCI procedures in Stamford Hospital, for example, in fiscal year 2017?

A. Correct.

Q. Right? You reported it and you reported it based on whether the procedure was done inpatient or outpatient, but nevertheless you reported a total number of PCI procedures

performed at your institution at 592. Correct?

A. That is correct.

Q. How many were elective? And how many were primary?

A. I -- I do not have that answer. I don't have that, that information.

Q. When you're sitting in Stamford Hospital do you have that data available?

A. I do not have it in front of me at the moment.

Q. Where it is?

MR. MONAHAN: Hearing Officer, if there would be a request for a late file we certainly can prepare it, but we do not have it here in front of us.

THE HEARING OFFICER: If they don't have it, you know they can't produce it at this moment. Maybe we will file a request for a late file, but that is going to be up to me after I determine what we need from the team.

I'm going to ask that we move on.

MR. TUCCI: So I'll continue.

BY MR. TUCCI:

Q. So Mr. Bailey, you've indicated that in getting ready for today's hearing you didn't

do the math in terms of a breakout between the number of primary cases done at Stamford Hospital versus the number of cases done electively for percutaneous coronary intervention. Right?

A. That is how I answered that question, and there's no reason for which I would do that calculation.

Q. Have you ever been involved in or done a similar calculation in the past?

A. I -- can you -- are you speaking about PCI procedures? Or are you just talking about doing a ratio?

Q. Yeah. No, it's very simple. I don't mean to overcomplicate this. My question is very simple.

At any time in the past have you ever been involved in, or do you know of any existing breakdown showing in a fiscal year how many primary PCI cases Stamford Hospital did and how many elective PCI cases Stamford Hospital did?

A. I have not -- I have been in any previous conversation where we calculated a ratio of what our PCI is. I've never -- I have not

seen any data in front of me to their doing that -- or doing this calculation. We have no, again -- we go back to we don't have basis on why we would do that calculation.

Q. All right. You obviously agree with me that you did participate in and testify as an intervener in opposing the Greenwich Hospital CON for elective PCI. Correct?

A. That's correct.

Q. And in your, in Stamford's Health's capacity as an intervener in the Greenwich Hospital CON request for elective PCI, Stamford Hospital submitted a late file in that proceeding showing a breakdown in 2017 of primary versus elective PCI procedures, showing that you did six times as many elective PCIs as primary.

Are you aware of that?

A. I don't have my -- I don't have my prefiled test -- or the testimony or the transcript in front of me from that hearing. So --

Q. Are you aware that in 2018 Stamford's Hospital experience was that it did 51 primary PCIs and 335 elective PCIs, or six

times as many elective as primary?

A. Again, I don't have the data in front of me. So it's impossible for me to be able to answer your question. I'm sorry.

Q. Are you aware in 2019 Stamford Hospital reported doing an actual number of 65 primary PCIs, and a total of 337 elective PCIs, or approximately five times as many elective procedures as primary?

MR. MONAHAN: Hearing Officer, may I just? And I'm not doubting what is being read, but can we just -- can I just understand what it is that Attorney Tucci is reading from so that we can understand where the numbers are coming from?

MR. TUCCI: I'm reading from --

THE HEARING OFFICER: I believe this -- oh, go ahead.

MR. TUCCI: Hearing Officer, I apologize. I didn't --

THE HEARING OFFICER: No, no, no. I believe that this is from the Greenwich hearing, prefiled testimony from that -- but go ahead, Attorney Tucci.

MR. TUCCI: Yes, your understanding is correct, Hearing Officer Mitchell.

THE WITNESS (Bailey): So again, Attorney Tucci, I don't have the information in front of me on any of the years that you might cite. So it's

impossible for me to answer your question.

BY MR. TUCCI:

Q. What about fiscal year 2020, last year? Do you know what those numbers were?

A. I do not.

Q. Well, let me refresh your memory.

In 2020 your institution reported doing 54 primary PCIs and 255 elective PCIs, again approximately five times as many elective procedures as primary procedures. You don't recall that?

A. I don't recall the specifics of the data.

MR. TUCCI: I have no more questions for this Witness.

THE HEARING OFFICER: All right. So let me just ask --

MR. MONAHAN: May I have --

THE HEARING OFFICER: Oh, go ahead. Was that you, Attorney Monahan?

MR. MONAHAN: Yes. I apologize. I was raising my hand.

THE HEARING OFFICER: No, that's okay. That's okay.

MR. MONAHAN: Do I have the opportunity to just ask a couple of questions on redirect?

THE HEARING OFFICER: Yes.

MR. MONAHAN: Thank you.

REDIRECT EXAMINATION (Bailey)

BY MR. MONAHAN:

Q. Mr. Bailey, there were a number of questions about the charts in your testimony, your prefiled testimony in this matter on page 12 in connection with the regional PCI trends.

Do you recall that line of questioning where I made an objection, it was overruled and then you were asked to answer the question?

A. I do recall.

Q. Was there a point during that line of questioning that you had any reason to describe something greater than what was in that chart in the section seven as a whole?

A. Yeah. So I believe what I was trying to get to, section seven which really speaks to the aspects of the full-service cardiovascular programs in a declining market is when we -- it's impossible to really separate out all the full-service programs in and of itself.

And then when you're looking at multiple full -- multiple hospital systems applying for bringing in low-volume PCI programs

without the on-site cardiac surgery, it's impossible to fully comprehend the ripple effect that could occur in a situation where there would be deleterious effects on the volumes at hand. And so while --

MR. TUCCI: Objection. Move to strike. This Witness is not qualified to give that testimony. It's pure speculation. He's offering an opinion without any qualification or basis to give it.

He's not a cardiac expert. He's now giving a prediction or an evaluation, or an opinion that could only be given by an expert in the field.

Move to strike it.

THE HEARING OFFICER: Attorney Monahan?

MR. MONAHAN: Attorney Mitchell, with that motion to strike if that's the basis for a motion to strike there's nearly every single written prefiled testimony that will receive a similar motion on the Applicant's side.

This is a chief operating officer of Stamford Health care. He crosses the lines between clinical data analysis, financial data analysis, market analysis, and he receives information from a number of different experts. This is not a trial where there has been a designated expert on

a particular minute narrowminded scope.

So the fact that I have asked this Witness to embellish on the testimony that he has presented to you in my view is fair for you to hear based on his experience in his role at Stamford Health.

MR. TUCCI: Hearing Officer --

THE HEARING OFFICER: I'm going to allow it. No, I'm going to allow it briefly. As this is an administrative hearing, you know, I do -- we're going to look at all of the evidence and I'll give it the appropriate weight based on everything we hear. So I just want to hear what he has to say.

THE WITNESS (Bailey): Thank you, Hearing Officer Mitchell.

So just to wrap up my comment on that, is when at any point in time in this situation or others where services are coming in and they are going to be duplicative, or areas where multiple systems are coming in on an effort, and now we've got services that are already at commercial volume objectives; those will have a compounding factor on them that will have a negative impact on healthcare organizations -- and I'll keep it as a broad aspect.

There are four already existing programs in

this geographic region that provide these services. And they will have, based on previous experiences I've seen as these types of things play out, where they will have a negative impact on their volumes. And that can have -- I just want to cite this example. I do have it in my written testimony, so it's not new information.

But we have a type of program under an aspect relative to CMS's national coverage decision. We are to retain a 300 volume, PCI minimum volume. So there are aspects that may not be on the forefront awareness of these types of impacts, but as an organization why we are so concerned, reducing our volume may have downstream impacts that may not be overly apparent when looking at it at just the surface.

MR. MONAHAN: Thank you.

THE HEARING OFFICER: Followup, Attorney Monahan?

MR. MONAHAN: I have no other questions of the Witness.

MR. TUCCI: Recross, please, Hearing Officer Mitchell?

THE HEARING OFFICER: Yes, very briefly.

MR. TUCCI: Yes, very briefly. And following up just on the point that the Witness was making, Hearing Officer Mitchell.

RECROSS-EXAMINATION (Bailey)

BY MR. TUCCI:

Q. Mr. Bailey, please look at page 12 of your prefiled testimony?

A. I have it in front of me.

Q. In page 12 of your testimony you present some projections by the healthcare consulting group called SG2. Correct?

A. I do.

Q. And the projections that you present are SG2's estimates regarding projected PCI volume going forward for the primary service towns of New Canaan, Norwalk, Weston, Westport and Wilton.

Right?

A. That's correct.

Q. And you show what the actual PCI volume is in 2019, and you show what SG2 projects the PCI volume to be going out a five-year period or so to 2024. Right?

A. That's correct.

Q. And for those four towns what you're consulting expert shows is that in 2019 there were a total of 303 PCI cases. Right?

A. That's correct.

Q. And in 2024 your consultant suggests that the total volume of PCI cases will be 298. Correct?

A. That's correct.

Q. A difference of five less. Sir?

A. Yes, five less.

MR. TUCCI: Thank you.

MR. MONAHAN: No other questions.

THE HEARING OFFICER: No other questions? Okay. So it looks like everybody is done with Mr. Bailey. I just want to make sure we're all set before we take a break?

MR. TUCCI: Yes. Thank you, Hearing Officer, on behalf of the Applicant.

THE HEARING OFFICER: Okay. And also Attorney Monahan?

MR. MONAHAN: Yes, we are ready to take a break.

THE HEARING OFFICER: All right. So we are going to take a break until 1:45. I'll give everybody the notice that we're going to go back on around 1:43. And then for the hearing reporter I'm going to send you a list of witnesses for both sides.

(Pause: 1:01 p.m. to 1:50 p.m.)

MR. TUCCI: Hearing Officer Mitchell, I think we're back now and ready to proceed.

THE HEARING OFFICER: Perfect. So you were going to ask additional questions of the Intervenor's witnesses, Attorney Tucci?

MR. TUCCI: Yes. I would ask to call Dr. Scott Martin, please.

THE HEARING OFFICER: Okay.

CROSS EXAMINATION (Martin)

BY MR. TUCCI:

Q. Dr. Martin, good afternoon.

A. Good afternoon.

Q. Can you hear me all right?

A. Yes.

Q. Okay. Do you have your prefiled testimony in front of you?

A. I do.

Q. If you could look at the first page of your written submission, please?

A. Okay.

Q. Now one of the things that you say in your prefiled testimony, I'm just going to read the quoted language to you. It begins at the

bottom of the first page.

Stamford Health's interventional cardiology program offers the latest in leading-edge minimally invasive approaches to cardiac care.

You strongly believe that to be an accurate statement. Correct?

A. Yes.

Q. And you've heard the earlier testimony concerning the number of patients that have been treated at least during the seven-month period from 2019 to 2020 who originate from the Norwalk Hospital service area.

And you'll recall that at least in that period it was at least about six patients that ended up actually receiving care at your institution. Correct?

A. If you're referring to the transfers from their hospital to ours, yes.

Q. Yes. And if those patients elected to stay at Norwalk Hospital because Norwalk Hospital was permitted to do elective PCI procedures you would agree that Stamford Hospital is still going to have a state-of-the-art interventional cardiology program.

Correct?

A. Yes, I would agree. I, you know, the transfers -- it's been about one per month historically for Norwalk for quite a while.

You know, I don't think that taking that away would provide any imminent existential threat to our program, but -- and I believe the application is, you know, positing that there would be many more patients getting PCI at Norwalk Hospital from those direct transfers.

Q. I understand that's your point of view, but I'm focusing now on what effect this may or may not have on your program, and on Stamford Hospital.

And you'd agree with me just as a matter of sort of simple reality, which I think you've acknowledged, that whether or not that that volume from the Norwalk Hospital service area is or is not part of your work, Stamford Hospital is still going to be doing hundreds of PCIs annually.

Right?

A. Well, I think there's two separate issues. You know, the patients coming in direct

transfer is potentially a lot less than the patients who end up here from your service area.

If you were counting only the patients who are direct transfers out of your hospital, then your PCI per year would be far less than 200. You're obviously coming up with patients who are going to get PCI from somewhere and not -- not just people directly transferred out.

Q. Well, Doctor, that wasn't my question. I understand. We're going to get to your view of the volume and the numbers in a minute, but for right now my question is -- you know for a fact that Stamford Hospital does hundreds of primary and elective PCIs annually.

Correct?

A. Yes.

Q. And you also know for a fact because you've told me that your experience shows that you get about one transfer a month of a patient who originates from Norwalk Hospital primary service area.

Correct?

A. No, one a month, one patient per month from Norwalk Hospital transfer. I don't know where the primary service area is. They come from your hospital.

Q. I understand your point. Okay. I got it.

Am I correct in understanding that the primary substance of the testimony that you've offered both in writing and orally here today is your belief that the Norwalk Hospital's proposed elective PCI program in your view has not presented sufficient information to demonstrate that volume and quality guidelines that you think apply would be met.

Is that true?

A. Yeah, that's my view, and -- but it's taken from the application. The de facto numbers that are posited are all less than 200 on the application.

Q. I understand. You're telling us you've reviewed the application, and based on your review of the Norwalk Hospital CON application you believe that the application fails to present sufficient information to demonstrate that the applicable professional

guidelines for elective PCI without surgical backup have not been satisfied.

That's your view. Right?

A. Right.

Q. And in writing your prefiled testimony you took care to attach to your written submission the different guidelines of various professional societies and organizations that in particular you wanted to bring to the attention of the Office of Health Strategy.

Correct?

A. Yes.

Q. You included them as exhibits so that they could be readily referred to by the Hearing Officer and by OH staff to look at what the substance of those different guidelines and standards have said over the years in the documents that have been promulgated.

Right?

A. Right.

Q. Okay. Do you agree with the statement that PCI has become widely practiced and is an integral component of cardiovascular therapy?

A. Yes.

Q. And in fact, you attached Exhibit C to your prefiled testimony and that's precisely what the ACCF/AHA/SCAI 2013 update says on page 439. Correct?

PCI has become a widely practiced and integral component of cardiovascular therapy.

You don't disagree with that?

A. Yeah, I -- I'd have to look at it to see if it says that exactly, but I believe it.

Q. All right. Do you agree with the general proposition that the development of coronary artery stents has dramatically altered the practice of coronary intervention, and that the initial stents available markedly reduced the need for PCI related emergency coronary bypass surgery?

A. Yes.

Q. And that's because that's what the information is that was also reported in the 2013 report that we referred to earlier.

Right?

On page 440.

A. Yeah, I mean I know it to be true outside of the guidelines, but -- but yes. I mean, that's --

Q. You don't view that to be a controversial medical proposition, that the development of stenting has markedly reduced the need for emergency coronary bypass surgery. Correct?

A. Correct. You know, the development and then advancement of stenting -- and this is -- this is not news. You know this was in the 'nineties to early 2000s. It's markedly lower than the need for emergency bypass surgery.

Q. All right. And I want to focus your attention in particular on the 2013 update that we've been discussing, the clinical competence statement that was issued by the three professional organizations.

In particular, I direct your attention to page 442 of the July 23, 2013, document.

A. Okay.

Q. Do you see the reference on page 442 that talks about overall institutional system requirements?

A. Yes.

Q. And you are familiar generally, are you not, with what the overall institutional system requirements are for a procedural success

when it comes to doing interventional PCI procedures?

A. Yes.

Q. And part of what is discussed in the 2013 competence statement is a reference back to the earlier 2011 guidelines that contain some recommendations. Right?

A. Correct.

Q. And those recommendations from the 2011 statement are summarized on page 442.

Correct?

A. Are you -- you're talking about the bulleted bit at the end here?

Q. The three bulleted points that appear at the bottom of page 442?

A. Yes.

Q. And the first point of the 2011 guideline talks about primary PCI being reasonable in hospitals without on-site cardiac surgery as long as there's appropriate planning for program development that's been accomplished.

Right?

A. Yes.

Q. And of course you're aware that primary PCI is currently performed at Norwalk Hospital

without on-site cardiac surgery, and that's because there has been appropriate program development that's been accomplished to allow that to occur?

A. Yes.

Q. Now the second bullet talks about elective PCI. And it says elective PCI, you know, could be considered in hospitals that don't have cardiac surgery backup as long as there's appropriate planning for program development that's been accomplished, but also rigorous clinical and angiographic criteria that are used for proper patient selection.

That's one of the three guidelines that we're talking about here in the 2011 document. Right?

A. Yes.

Q. And you know that the Norwalk Hospital CON is in excess of 900 pages in length. I assume you've taken some time to go through it?

A. Yes. If you -- if you want to refer to something specifically I -- I would have to review it now.

But no, I have looked through it.

Q. And in your review of the materials submitted by Norwalk Hospital you would agree, would you not, that the hospital has specifically stated what the clinical and patient selection criteria are that it would propose to apply to govern selection of patients who are appropriate for elective PCI?

That's in there. Isn't it?

A. I believe so, yes.

Q. And the 2011 guideline goes on to state, primary or elective PCI should not be performed in hospitals without cardiac surgery backup, without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital.

And you know for a fact that's in place. Don't you? Because there, there are appropriate transport guidelines to get patients from Norwalk to Stamford in the event that there's a need for cardiac surgery backup.

Correct?

A. Yeah. I don't know that there's a plan with Stamford, because I don't recall ever getting an emergency surgery patient from Norwalk,

but I -- I'm sure there's a plan somewhere. I -- I don't have that.

Q. All right. So Doctor, you've expressed a number of concerns relating to the data reported with respect to projected PCI volume going forward, and so on.

And as I understand it, the big thing that you're concerned about is the issue of whether or not it's reasonable to conclude that Norwalk Hospital can achieve a minimum patient threshold of approximately 200 PCIs on an annual basis.

That's the issue that you're most concerned about. Right?

A. Yes.

Q. Because the number is stated as one of the various components of the elements that these professional societies have identified as important. Correct?

A. Correct.

Q. Do you agree with the idea that you also need to exercise reasonable and appropriate caution against an overemphasis or preoccupation with specific volume recommendations?

MR. MONAHAN: I object to the form -- only because I don't understand. If the Doctor understands it, he certainly can answer it, but I'm not sure I understand the question.

BY MR. TUCCI:

Q. Well, Doctor, do you get what I'm asking you?

A. Can you just repeat it?

Q. Sure. Do you agree with the concept or idea that in considering this notion of volume thresholds for the safe performance of PCI, that there ought to be an exercise of an appropriate degree of caution against preoccupation or overemphasis with specific volume recommendations?

Do you think that's a reasonable approach to take?

A. I don't think so. You know, if you look at the guidelines they say a minimum volume of 200 PCIs a year to be initiated. And it's pretty clear that, you know, it goes on to say a multiple of volume and partial service PCI centers that use PCI expertise increase costs, and have not been shown to improve access.

I think it's pretty clear that the 200

is not, you know, something to be taken lightly.

Q. I might direct your attention to page 451 of Exhibit C, the document you attached to your testimony. Do you have it in front of you?

A. I do.

Q. The paragraph, the first full paragraph in the second column of the ACCF/AHA/SCAI clinical competence statement reads as follows.

Quote, it is the opinion of our writing committee that the public, policymakers and payers should not overemphasize specific volume recommendations recognizing that this is just one of many factors that may be related to clinical outcomes, end quote.

Have I read that accurately?

A. Yes. You know, if you go back to the paragraph before --

Q. Let me direct your attention -- let me direct your attention?

MR. MONAHAN: Hearing Officer?

THE HEARING OFFICER: So yeah. I hear you, Attorney Monahan. I'm going to let you go ahead and make your objections.

MR. MONAHAN: Yeah. I believe there was a selective sentence the Doctor who is an expert in reading this was I believe attempting to put that sentence in a context and was cut off, and I think he should entitled to answer the question.

THE HEARING OFFICER: So here's what I'm going to say about it. I know that, Attorney Tucci, I didn't give you an opportunity to respond, but rather than go back and forth about whether or not he has the opportunity to do it now, I'm going to give you the opportunity to follow up with Dr. Martin after Attorney Tucci asks some questions.

So if that's something that you feel that he needs to bring out and it's something that Attorney Tucci believes is a yes or no question, then you can go back and follow up.

MR. MONAHAN: Thank you.

BY MR. TUCCI:

Q. All right. Doctor, let me direct your attention to, again page 451 which includes the second full paragraph in that column which reads, quote, the relative benefit of mor favorable outcomes in facilities with higher volumes must be weighed against the potential decline in access resulting from

minimum volume standards for regionalization of care.

Do you disagree with that finding?

A. No, I think that's accurate and reasonable.

Q. There again, I want to focus on volume requirements since it appears to be a major point of your contribution to these proceedings. Do you think it's reasonable that when we look at the criteria that the various professional societies have identified, that appropriate weight be given to all of the criteria that have been identified?

A. I -- yeah, can you be more specific? I'm not sure what you're asking.

Q. Yeah. So we talked a little bit ago about three of the guidelines and requirements, you know, patient selection, rigorous patient selection, appropriate policies and procedures. Those, those are important as well. Aren't they?

A. Certainly.

Q. It would be a challenge to have a safe elective PCI program without surgical backup if you didn't have really good patient

screening to make sure you were only doing elective PCI on the proper patients at a facility without immediate surgery backup.

Right?

A. Correct. And you know, similarly you need the proper equipment. You need a cath lab and you need nurses. Yeah, those are the other requirements, and I agree that all the requirements should be met.

Q. Okay. Do you have any concern about using the volume standard as a metric or requirement, you know, when it is equated to be a measure or predictor of quality?

Does that cause you any pause?

A. I think there have been multiple studies that show that doing a procedure more does coordinate with quality. But you know, I think within -- within reason it doesn't really give you pause. I think that's reasonable.

I, you know, if I -- if I had to go for an elective PCI, I would rather have it done with a provider of an institution that did quite a number of them rather than did very few.

Q. Right, but it's a question of degree. Isn't it?

A. There's always a question of degree, sure.

Q. Yeah. So when the committee who wrote the 2013 competence update document says on page 452, quote, the writing committee cautions against focusing on specific volume recommendations and emphasizes that procedural volume is one of several variables to consider when determining operator competency; volume is not a surrogate for quality and should not be substituted for risk-adjusted outcomes or other measures of quality.

Do you agree with that?

A. Sure, you -- you could have somebody who does a high-volume of procedures and has poor, poor outcomes.

But you know, in this 2013 document it does roll back. You know, the 2011, you know, the context is in 2011. They recommended that providers have -- bring in 75 procedures -- bring in 400 procedures at each site and on-site cardiac surgery.

So this 2013 document was in that, in

that setting and was relaxing those guidelines from 75 per operator and 400 per center and on-site cardiac surgery without the more.

But you know it is a question of degree. I mean, if we're going to relax it from 200, are we going to relax it to 10? You know, there is a standard here and it's for a reason.

Q. Right. And so what you've just described could be reasonably thought of as we had an approach that we as professionals thought made sense in 2011, and now looking at it two years later we've evolved our thinking based on looking at new information and new data, and new science that tells us what we think is reasonable.

Right?

A. I -- I think that's correct and I, you know, I can see where this is going that, you know, now it's, you know, this is from 2013, 2014. Have things changed since then? The answer is, no.

If you look we've updated, you know, the guidelines in 2016, 2017, and they all

reaffirm this 200 number.

There's really been no study that that's, you know, randomizing patients to low-volume centers because people don't -- that would be ludicrous. And nobody is going to compare their 50 PCI per year program to the Cleveland Clinic or Columbia.

Q. All right, Doctor. Well, I appreciate very much that you may be able to see where we're going, but I still need to get there.

A. Very well.

Q. So let's talk about these evolving standards that we've been discussing and how things may or may not have changed as more and more professional input has happened since 2013.

And you would agree that there has been more guidance that's been issued over the course of the last seven years. Right?

A. Yeah. I, you know, I think we -- we include exhibits from I think 2016 and/or 2017. And -- and certainly these guidelines do come out when things change.

You know, you may -- I don't know if you were going to bring it up or not, but there was recent guidance from one of our societies

regarding potentially, you know, guidance for PCI ambulatory surgical centers, that that was prompted by Medicare CMS approving payment for such a PCI.

And you know, you saw that when -- when there's a need there's a guideline document to come up with. So with regards to, you know, surgery, in regards to PCI without on-site surgery there's been no change and no need to update the guidelines.

Q. Well Doctor, since you brought it up -- it's a little bit out of order, but if you could enlighten us I'd be interested to hear your views and understanding regarding that recent policy promulgation relating to having PCIs done in an ambulatory surgical center, which obviously by definition doesn't include surgical backup to do bypass surgery. What's your sense of how we evolve to get there?

THE HEARING OFFICER: I'm going to interject. We're not talking about ambulatory surgical centers. It's not part of the application. I just want to keep it focused on this application.

MR. TUCCI: We don't need to belabor the point, Hearing Officer Mitchell. Thank you very much. I'll move

on.

BY MR. TUCCI:

Q. So Doctor, are you with me?

A. Yes.

Q. I want to ask you some more about sort of what your views are regarding sort of the general state of interventional cardiology in the world we're in today.

Do you agree with the idea that performing PCI without on-site surgical backup is something that's gained greater acceptance as the years have gone by in the United States?

A. Yes.

Q. And that is a view that is expressed in Exhibit B, the 2014 update on percutaneous coronary intervention without surgical backup. That was done by the three professional societies we've been discussing.

And that, for the record, appears on page 2621 of the document.

A. I agree, yeah.

Q. Yeah. Thank you. You're familiar with the New England Journal of Medicine?

A. Yeah, I've heard of it.

Q. And at the risk of stating the obvious, obviously the New England Journal of Medicine is an authoritative source in the medical field. Correct?

A. Yes.

Q. In the course of preparing for your testimony both in its written form and oral, did you have occasion to look at an article published in New England Journal of Medicine in May of 2012, the title of it being, Percutaneous Coronary Interventions Without On-Site Cardiac Surgical Backup?

A. I have it here in front of me now. So I have seen this before, yes.

Q. Yeah. Do you recall that that article had some discussion that specifically addressed the question of volume when it came to doing PCIs without on-site cardiac surgery backup?

A. I -- I believe you, but can you direct me to where -- where you want me to look at that?

Q. Sure. I'd ask you to focus on page 8 -- 1818.

A. My -- what I have in front of me goes up to 1801.

Okay. I have it in front of me.

Q. You're familiar with the term "nonprimary PCI?"

A. I'm sorry. Non-what?

Q. Nonprimary PCI?

A. Sure. And in this context that's elective PCI. You know you can divide it up in different ways, but you know it's elective PCI for our purposes.

Q. And the New England Journal of Medicine article when it's discussing volume considerations says, and I quote, nonprimary PCI is eight times as common as primary PCI according to a national registry data, and there was a strong association between PCI volume and outcome.

Are you familiar with that national registry data?

A. I -- I believe it. I -- I have -- I haven't looked at the national registry data in terms of the frequency of primary versus nonprimary PCI, but I think that that sounds logical.

Q. I guess my point is this, Doctor. Do you have any reason to quarrel with the notion that from an experiential standpoint elective PCI is performed eight times more than

primary PCI is performed on average?

A. I think nationwide that that rings true.

Q. All right. And the New England Journal of Medicine goes on to state -- make the following statement, and this is a paragraph in the left-hand column down toward the bottom.

If the privileges of sites that perform primary PCI were expanded to include nonprimary cases, the resulting increase in volume would enhance hospital, operator and team experience, and would theoretically improve the quality and safety of all PCIs performed.

Is that a statement you generally agree with?

A. Yes, but if you -- the next sentence is, removing the requirements raises countervailing concerns; proliferation of sites which nonpriority PCI can be performed for some existing high-volume regional centers and the low-volume programs with adverse implications for quality.

Q. Right.

A. And I think that's the -- the objection

that's being raised here.

Q. Right. These things all have to be balanced out. Don't they?

MR. MONAHAN: Object to the form. If you're asking him what his interpretation is, you can ask that.

MR. TUCCI: Yeah. That's exactly what I'm asking you.

BY MR. TUCCI:

Q. Do you agree that these things all have to be balanced out to make sure that there's an appropriate balance maintained so that quality exists in both high-volume centers and centers that do a lower volume of PCI? Isn't that the goal?

THE HEARING OFFICER: I'm going to let Dr. Martin answer it. Dr. Martin, you're already answering -- so go ahead.

THE WITNESS (Bailey): Yeah. The goal is to have high quality everywhere. I'll agree to that.

BY MR. TUCCI:

Q. All right. In your written testimony you conclude by saying that the concern that you're bringing to the fore is that the Norwalk application will -- and I'm quoting, redirect patients from existing full service, full-service providers, end quote.

And then you go on to say, quote, with no clear public benefit.

Is that your view?

A. Yes.

Q. Do you agree that allowing a patient to remain with a provider of choice is something that could be viewed as a public benefit?

A. Sure.

Q. Do you agree that not requiring a patient to travel to get needed care when the circumstances don't require it can be a public benefit?

A. I -- I think that's a tougher one because you know it depends. Saying that circumstances requirement is really what is at issue here.

Q. I understand that, but I'm asking you to assume the circumstances don't --

A. All other things being equal, you're better off, you know, patients are better off having a choice and being able to do things closer to home. I'll agree with that.

Q. Okay. And I assume you'd also agree that if that was the case it would be a public benefit not to have to pay the cost of having an ambulance transport a patient from one

institution to another, or have a duplicate testing run because the medical record systems don't talk to each other.

Right?

A. So I -- I don't propose to be an expert on cost of health care, but what I will say is that places that have centralized health care, you have this hub and spoke system where not every hospital duplicates every service and they, you know, that's -- that's done as part of a cost-saving measure.

So I -- I would argue that transferring to a higher level of care is not necessarily, you know, a higher cost proposition for the healthcare system as a whole.

Q. Well, let's try it this way. In a world where the goal is to provide and maintain a high level of quality when medical care is provided by institutions such as Stamford Hospital and Norwalk Hospital, would you agree with the notion that finding ways to deliver that care more efficiently and reduce the cost that consumers have to pay for that care, if it can be achieved would be a public benefit?

A. I agree that's a public benefit. I just don't know that not transferring patients is -- is a net cost saver.

MR. TUCCI: All right. Thank you, Doctor. That concludes my questions.

THE HEARING OFFICER: Any followup for Dr. Martin, Attorney Monahan?

MR. MONAHAN: Yes, if you just give me one moment I do have a followup.

REDIRECT EXAMINATION (Martin)

BY MR. MONAHAN:

Q. Dr. Martin, without going through every article that was referenced by Attorney Tucci, is it fair to say that he selected segments of different articles and asked you to read them, and agree or disagree?

Is that a fair statement?

A. Sure.

Q. Okay. Having studied the literature both in terms of your general practice as an interventionist, and having studied all the literature in connection with this application for this PCI program, and having

studied all the literature for the application for the Greenwich/Yale New Haven PCI program; when you examined these various articles that come up with different improvements, studies, examinations, does it alter your view at all that the best standard in terms of minimum threshold still stands in the 2014 consensus document by the three expert agencies that we have talked about?

A. No, I think the 2014 document still stands.

Q. Isn't it a fact that guidelines are in fact studied, examined -- even debated, and that is why there is a number? There are a number of literature pieces that come out.

And it is, as Dr. Bhalla testified earlier, these consensus groups that come together to pull all that together, to come up with a gold standard best practice.

Is that a fair statement?

MR. TUCCI: Objection to the leading, and the speech.

MR. MONAHAN: I'm following up, Attorney Michaela, on the very questions that he was giving segmented and without context. This is my ability now to give context to what was omitted from the question.

THE HEARING OFFICER: All right. I'm going to go ahead and allow you to ask those questions, Attorney Monahan, but just not -- I would rather hear Dr. Martin testify in his own words rather than --

MR. MONAHAN: Certainly.

THE HEARING OFFICER: Yeah.

BY MR. MONAHAN:

Q. Certainly. So based on everything you've read, what do you view today as the best standard in terms of minimum threshold for elective PCI in your professional opinion?

A. Well, my --

Q. For facilities?

A. -- my professional opinion is shaped by the expert consensus guidelines which are still, you know, has been reaffirmed really again and again, that at least 200 is a minimum standard.

Q. And with all of the other advancements, additions, improvements, has there been any document that you know or that's been demonstrated or shown to us by the Applicant that has superseded, eradicated or abolished that threshold?

A. No.

MR. MONAHAN: I have no other questions.

THE HEARING OFFICER: All right. Any followup, or any additional questions for the Intervener's Witnesses, Attorney Tucci?

MR. TUCCI: Nothing further. Thank you, Hearing Officer Mitchell.

THE HEARING OFFICER: Thank you. I'm going to go ahead and turn it over to you, Attorney Monahan, for questions for the Applicant's witnesses.

MR. MONAHAN: Can I just have a moment to put some binders away?

THE HEARING OFFICER: Absolutely.

MR. TUCCI: Hearing Officer Mitchell, I'm just going to step out briefly while Mr. Monahan is getting ready.

THE HEARING OFFICER: All right. So what we can go is we can go ahead and take a five-minute break, if that's okay with people?

We'll go on the record at 2:35 rather than just have the dead air while people are waiting around in case anybody needs to use the restroom or make a call.

MR. MONAHAN: Thank you very much.

THE HEARING OFFICER: You're welcome.

(Pause: 2:30 p.m. to 2:35 p.m.)

THE HEARING OFFICER: All right. So we'll go ahead and I will hand it over to you, Attorney Monahan.

MR. MONAHAN: Yes. I'd like to call Dr. Murphy as a witness for cross-examination.

THE WITNESS (Murphy): Okay. I'm all set.

CROSS-EXAMINATION (Murphy)

BY MR. MONAHAN:

Q. Hello, Dr. Murphy. How are you?

A. Hello, Mr. Monahan. Good, thank you.

Q. Dr. Murphy, you submitted prefiled testimony in this matter. Correct?

A. Correct.

Q. And you know, without going through your whole curriculum vitae, which is obviously very impressive, you are a physician. Correct?

A. Yes, correct.

Q. Am I correct that you do not specialize in any area of cardiology?

A. That is also correct.

Q. In connection with your role at Nuvance, what

is your role at Nuvance in connection with Norwalk Hospital?

A. I'm the Chief Executive Officer of the entire system including the various hospitals.

Q. Is it fair to say that you have the final say when it comes to a decision at Norwalk Hospital if there's a disagreement between you and the CEO of the Norwalk Hospital?

A. That's probably true.

Q. In your prefiled testimony you made it quite clear that you see a regulatory impediment or barrier to the application that you had submitted. Correct?

A. Correct.

Q. And am I correct in assuming that the fact that you had applied for this as Norwalk Hospital twice before in the years past and had been denied by the office, the predecessor of OHS, the Office of Healthcare Access, that that contributed to your view of there being a regulatory barrier?

MR. TUCCI: Objection to the form. Objection, your Honor -- objection, Hearing Officer. No foundation.

The question assumes that, you know,

Mr. Murphy was in charge of Norwalk Hospital at that time.

MR. MONAHAN: I'll establish the foundation very clearly. If Dr. Murphy does not know of that, I think I can get that established on the record.

THE HEARING OFFICER: All right. I will say in terms of this type of hearing the evidentiary rules don't apply, but it probably would be helpful to have that on the record. You know he may not be able to answer if he wasn't, so.

THE WITNESS (Murphy): Well, I was aware of it. And you know, as was the case that Danbury Hospital where it was previously denied, it was ultimately overturned. The State permitted it.

So I would say the fact that it was previously -- the application was denied had no material bearing on our decision to file again.

BY MR. MONAHAN:

Q. And on page 2 -- do you have your testimony in front of you?

A. I can get it. Just give me a second.

Go ahead.

Q. At the very top of the second page of your testimony it's a carrier sentence, but you establish a sentence about establishing an

overview of Nuvance Health, a systemwide network vision and demonstrating how the application and the establishment of an elective PCI service at Norwalk Hospital is essential to furthering that goal.

Do you see that?

A. I do.

Q. Okay. The next sentence, I'd like to understand if you could explain to me -- what is the long-standing state restriction that you have put out as a regulatory barrier that you foresee as a potential problem that you would like OHS to overcome and approve?

A. The requirement that on-site cardiac surgery backup be present at the same site where the elective PCI is taking place.

Q. So is that -- and it's only because I don't understand. Perhaps I don't understand your answer. Is that because you are required to transfer from Norwalk Hospital patients who do not need primary PCI, but if they need -- if they want elective PCI they need to be transferred to others.

Is that the barrier?

A. The barrier is if, you know, in -- in our

view in an ideal world if patients wanted or needed elective PCI and they wanted to have it here, they could have it here.

That even if this site did not offer cardiac surgery at Norwalk Hospital, that they -- they should be permitted to have that procedure here since, in fact, primary PCI is being done and we have the talent and the expertise, the facility, et cetera.

Q. Okay. I understand that that's your goal, but what I'm trying to understand is what's the regular barrier from you doing that?

A. Well, we don't have cardiac surgery on site here.

Q. Okay. And why is that a problem for you?

A. Because that's the requirement.

Q. And do you understand that that is -- look. Let me put it this way, or ask it this way.

You described this as a state restriction and as a regulatory barrier. Are you asking OHS to change any particular regulation?

A. We are asking to be permitted to do elective PCI here at Norwalk Hospital, and that the State approve the application.

Q. You do understand that the Office of Health Strategy has no ability in this proceeding to change or make a regulation. Correct?

A. I understand that.

Q. Okay. You also understand that the Office of Health Strategy is -- while it certainly is under the statutory principles open through all applications to listen to all claimants of all sizes, systems, nonsystems, whatever it may be.

Their goal is not to -- their mission is not to grant a vision of a system, but to uphold the state law as defined in the principles and guidelines of CON. Correct?

A. Well, I don't know that upholding the state law they can approve an application, or not. I don't know the details regarding the -- the applicability of the enforcing state law in that process.

Q. Okay. So as you sit here -- and I recognize that, unless I've missed something on your resume where you're also a JD, I'm not asking you for a legal opinion.

But is it your understanding that OHS can act independently of statutory principles

and guidelines guiding this decision?

MR. TUCCI: Objection, Hearing Officer Mitchell.

If I may be heard?

THE HEARING OFFICER: On what basis?

MR. TUCCI: The objection is that his understanding of legal matters is not relevant. I've tried to refrain from objecting here, but I don't think this line of questioning about what Dr. Murphy may or may not understand about the legal implications of CON regulations is at all relevant to or helpful to OHS in deciding whether or not this application should or should not be granted.

THE HEARING OFFICER: Attorney Monahan?

MR. MONAHAN: Well, it was the lead introduction to this Witness' testimony that he put forth as the premise of his testimony, and then filled in the strength and the vision of the heart and vascular center and talked about a request to remove -- not consider, remove regulatory and state barriers.

I think it is a fair question to ask the CEO of this system whether he has a sense of the distinction between the role of this Hearing Officer, this body, with all due respect, and the State Legislature.

If he doesn't know he can tell me he doesn't

know.

MR. TUCCI: Hearing Officer Mitchell, may I be heard briefly in response?

THE HEARING OFFICER: Yes.

MR. TUCCI: The only point that I'm making is that Mr. Monahan asked the Witness what his understanding or belief was to explain the concept of a barrier or a regulatory barrier, and the Witness answered him three times.

So I don't know what else he's asking this Witness to explain other than what he's already explained, and I'm not sure why we have to keep going over this. That's my point.

MR. MONAHAN: The only question that has been unanswered is whether the Witness understands that state statutes govern the operation of this OHS decision-making process and the stringent review needed? Or whether he has no idea that that's the case? He can tell me either way.

THE HEARING OFFICER: So I'm going to allow for that last question that you asked, Attorney Monahan.

And then, Dr. Murphy, are you able to answer that last question?

THE WITNESS (Murphy): Yes. I -- I have confidence that the Office of Health Strategy can interpret

statutes, supply guidelines and approve applications. And -- and that that blend of activities is what we're here for.

And the fact that we don't have a cardiac surgical program is, in fact, a barrier for us that we are asking you to consider as you examine our application.

BY MR. MONAHAN:

Q. Thank you. Now one of the statutory principles -- and I'm asking if you're aware of this is whether the -- in determining whether your application has merit is whether the results of the Office of Health Strategy's examination of the relationship of the proposed project to the statewide healthcare facilities and services plan; are you aware of that as a tenet or principle, or concept that guides this proceeding?

A. I realize that the Office of Health Strategy does have to at least understand, if not respect the principles articulated in that, that policy or statement -- or plan.

Q. Okay. And in addition to that statement in the legislative provision that I just read, the Office of Health Strategy has indeed

published a statewide healthcare facilities plan.

Are you aware of that?

A. Not in -- with any specificity.

Q. Are you aware that the current statewide plan published by the Office of Health Strategy on page 39 of its 2012 publication, which is still in force and which has been cited in a number of CON applications as final decisions, states as follows.

Connecticut hospitals seeking authorization to initiate an elective PCI program without on-site cardiac surgery capabilities will be required to meet the conditions required in the ACCF/AHA/SCAI practice guideline and to demonstrate clear public need for the program.

The guideline states that it is only appropriate to consider initiation of a PCI program without on-site cardiac surgical backup if this program will clearly fill a void in the healthcare needs of the community.

And further, the guideline notes that the competition with another PCI program in

the same geographic area, particularly an established program with surgical backup may not be in the best interests of the community.

In advance of filing this application were you aware of that established guideline by this agency?

A. Well, I know that the -- two comments, Mr. Monahan. First of all, I'm not worried about OHS's ability to properly do its job. I have full confidence in the people who work there. So the fact that they understand what the state facilities health plan says, I'm sure that they will adhere to it and follow it.

And in addition to the 2012 facilities plan which you have identified, I'm sure you're also aware of the supplement that was published in 2020 which specifically addresses this issue and the need to call and bring together a task force to examine this particular question.

So the 2012 guidance and plan that was published has clearly been brought back for further examination and discussion.

Q. I appreciate that, and I am well aware of that task force, and I appreciate you bringing that out into the record.

However, I also appreciate the fact that you say that you will respect the ability of the Office of Health care Strategy to adhere to its own published guidelines.

Now the fact that there's a task force studying, you are not purporting to tell me that that task force has somehow superseded or already modified, or eliminated this guideline. Are you?

A. I'm not privy to the thinking of OHS and how it interprets the task force, or for that matter where the task force is in its work. I'm simply drawing attention to the fact that I inferred that you were offering the 2012 plan as if it were poured in concrete and never changing.

And I simply wanted to draw attention to the fact that I believe OHS is aware of the fact that guidelines evolve and need to be reexamined, and it will do its job properly in the context of the task force. The timing will be left to OHS, not to me.

Q. Okay. And there's nothing you know that I don't know about the timing having already been completed on that. Is there?

A. I don't know what you know, and I don't know where the task force is in terms of its work.

Q. Are you on the task force?

A. I am not.

Q. When the original application for this CON was filed who on your staff did you put in charge of pulling it together?

A. It was a team.

Q. Okay. But was there a lead person on the team?

A. Well, I would speak to Sally Herlihy or Mark Warshofsky as the key contacts as far as I was concerned.

Q. Okay. When we talk about -- excuse me, the original application there, and as is common with CON applications there is an attestation filed.

And the attestation in this case in your application were filed by -- excuse me, Peter Cordeau who, of course, is the President of Norwalk Hospital, and Stephen Rosenberg, who I understand is the Chief

Financial Officer of Nuvance.

Is that correct?

A. Yes, it is.

Q. Okay. And just for the record, those affidavits attest that all the facts contained in the submitted certificate of need application are true and correct to the best of their knowledge?

And if you need to see it to corroborate what I'm saying you can, but I think Attorney Tucci will attest that I have read it correctly.

A. So you're asking if I knew that they were attesting -- what's the question again?

Q. That they were attesting to my affidavit to the truth and veracity to the best of their knowledge about to the facts recited in this application?

A. Yes.

Q. Okay. Now one of the facts that was recited in the executive summary was that there was no capital expenditure associated with this application. Is that an accurate statement?

A. Yes.

Q. So there is also a statement in here that the

hospital will not incur -- excuse me, the program can be implemented -- and I'm reading from page 16 of the original application -- that the program can be implemented immediately upon approval of this proposal as the facilities and staff to provide the service are already in place at the hospital, and there is a demonstrated need for the service in the hospital's community.

Do you believe that to be true and correct?

A. Yes.

Q. Now subsequent to the filing of this application and in response to the Office of Health care Strategy to complete these questions there was a revised financial worksheet that was submitted. And in that financial worksheet -- and I'm referring to the Applicant Norwalk Hospital Financial Worksheet A, there is a specific request for the Applicant to provide projected incremental costs associated with the project.

And while I have highlighted certain costs -- and I don't know that I've covered

every single one -- for fiscal year 2021 the estimated incremental cost by Norwalk Hospital is $1,084,000. The projected annual cost for fiscal year 2022 was $1,317,000. And the projected annual cost for fiscal year 2023 was $1,583,000.

Were you aware of those incremental costs being supplemented or added to the application?

A. Well, I'm -- I'm sure what you're stating is true.

Q. And I'm asking if you were aware that in fact what Norwalk had originally reported in its original application which you deemed to be true and correct based on its knowledge at that time was actually several million dollars incorrect, and it was only after some later analysis that the additional costs surfaced?

MR. TUCCI: Objection, Hearing Officer Mitchell. Objection. It misstates the evidence and comes fairly close to being scurrilous.

THE HEARING OFFICER: Okay. Any response to that, Attorney Monahan?

MR. TUCCI: I can explain the basis for my objection.

It's a strong objection I'd like to explain.

MR. MONAHAN: But I --

THE HEARING OFFICER: Hold on one second, Attorney Monahan.

MR. TUCCI: The basis for my objection is that counsel asked the witness five questions ago or so about facts contained in the executive summary. And he specifically asked the Witness about facts relating to capital expenditures associated with the application. And the Witness gave an answer that had to do with capital expenditures.

Now counsel is focusing on incremental costs which is a different thing than capital expenditures, and attempting to draw a comparison between the two as if they're both the same and then accusing Norwalk Hospital of misrepresenting information. I object.

MR. MONAHAN: That is absolutely a misstated objection. The paragraph that I read from indeed at first was no capital expenditures. The second paragraph that I read dealt with, the program can be -- and I'll read it again.

The program can be implemented immediately upon approval of this proposal as the facilities and staff to provide the service are already in

place at the hospital, and there is no demonstrated need for the service in the hospital community.

As I will be able to show in this financial statement there were FTEs that needed to be added. They were operating costs that had to be added that were not capital costs. So I take great offense to what was called as a scurrilous objection.

THE HEARING OFFICER: All right. So can you help for the record? Just make the distinction between the capital costs and the costs that were on the worksheet, and then help us understand where you're going with the line of question?

MR. MONAHAN: Where I'm going with the line of questioning is we are now talking with the CEO of the Nuvance System who has premised this entire application on the need for Nuvance System to move forward to develop this vascular system, this vascular program, to gain approval on this application and to overcome long-standing existing regulatory barriers.

What I am saying is, regardless of the team that he put in place there is an application -- and this is the first of several that I will be

able to show that the initial application, which in appropriate manner should be complete to the best of the Applicant's ability -- has been altered and modified and supplemented right up until the 15th the day of the prefiled testimony to try to augment the problems that occurred in the deficiencies in the original application.

And if this Witness has no knowledge as the lead person, he can tell me that.

THE HEARING OFFICER: All right. I'm going to -- Dr. Murphy, I'm going to let you respond to that to the best of your knowledge.

THE WITNESS (Murphy): Let me first reassure you, Mr. Monahan. And I'm -- I'm certain that you didn't mean to be offensive by implication.

We operate on a principle of integrity so that I am 100 percent confident that any question that you ask of us will be properly answered. I have, you know, I have the good fortune of being surrounded by a lot of smart people here today to whom I can defer for the specifics regarding why were these incremental costs added.

But in your characterization you said that the document was altered. I think that that isn't -- is not accurate. It was in fact

supplemented, but we didn't alter anything. We found additional information and provided it truthfully, and that is the basis -- integrity is the basis upon which all of our actions are guided.

So if you want me to provide for you someone else to answer the question with specific detail I can certainly make that happen if Hearing Officer Mitchell would like me to do that.

MR. MONAHAN: No. Dr. Murphy, I appreciate that. And believe me in no way -- and I'm sorry if in the spirit of the proceeding like this if the tone comes across -- there was no way I intended to in any way be offensive towards you, or toward the integrity of you or your team.

In fact, I really want to be clear about that. So I apologize if it came across that way.

So if you may? And bear with me, I'd like to ask you a few more questions about your testimony.

BY MR. MONAHAN:

Q. Right now you have -- and maybe even upon hearing the testimony of others -- but I suspect you have a very good sense that elective PCIs, to the extent that Norwalk Hospital cannot do elective PCI's right now,

they are transferred to at least four different hospitals and maybe more.

But those include Stamford Hospital, Bridgeport Hospital, St. Vincent's Hospital, and of course your own Danbury Hospital.

Correct?

A. Yes.

Q. I'm sorry. That was a yes?

A. Yes. I'm sorry.

Q. Okay. I'm sorry.

Am I correct that it is the case that there is no instance in which those four hospitals within the 30-minute guideline standards have at all said to you, we can't take another PCI, elective PCI patient?

In other words, there is access available at those four hospitals for elective PCI patients who presently would need to be transferred in the absence of this application being granted.

Is that correct?

A. Yes, it is. I believe it is.

Q. Okay. Now one of the reasons you've put forth in your testimony as supportive of keeping patients close to home, you know,

closer to the hospital -- perhaps of their choice, is because of the -- without quoting exactly, but some of the difficulties associated with transfer and communication with medical records, or transmission of medical records.

Is that correct?

A. Yes.

Q. Okay. If we go -- and bear with me for a minute while I look through these. Okay.

Attorney Tucci referred to these numbers in the original application in the project description where he talked about there are about 155 cardiac transfers from the hospital, being Norwalk Hospital to other acute institutions for cardiac clinic care.

And he did reference 46.2 percent being transferred out of 119. 55 being transferred to St. Vincent's, 38 to Danbury, 13 to Bridgeport, and 6 to Stamford, and 5 to Yale New Haven, and even 2 to New York Presbyterian.

I've read those numbers. Obviously it would never hurt to check them, but I represent to you that I've read them from

your application.

My question about that is, let's take the transfer to Danbury Hospital. Of those 38 transferred how many of those 38 transferred to Danbury Hospital, and of course without any disclosure of any type of identifiable information -- but how many of those transfers resulted in an adverse outcome or harm to the patient as a result of Norwalk's inability to communicate in an appropriate manner with Danbury Hospital on medical records?

A. I -- I do not have the specifics here. So it would be speculative for me to offer a response.

Q. Okay. But do you know of any that happened?

A. If you want me to guess, tell me. If you want facts, I don't have them.

Q. If you don't have facts I don't want you to guess. I just didn't know whether you knew it was zero, or you knew it was some amount. You just don't know the amount?

A. Yeah. As I said, unfortunately I -- I can't provide you with a response, because I -- you don't want me to guess and I don't have the

facts.

Q. Okay. Similarly in the transfer to Danbury Hospital of those 38 patients how many incidents resulted in adverse outcomes to a patient that would need to be reported to the Department of Public Health because of harm arising from the transfer from Norwalk to Danbury?

A. Yeah. Unfortunately, Mr. Monahan, I'm going to have to provide the same answer. I have not studied the nature of the transfers on an individual patient level. So I -- I really can't provide you with a meaningful response.

Q. Okay. Well, the reason -- and I appreciate that, and I certainly wouldn't expect that every detail worked its way to your desk.

However, given that you have referenced in your testimony the -- what you, you know, you call the downside or what I'm saying, describing as the downsides that you describe of transfer, and from one facility to another even within the 30-minute period.

And in the inability to, you know, perhaps ideally coordinate through medical records, it seemed to me -- I was just trying

to understand whether you think this is a prevalent problem, or whether this is a possibility but hardly ever occurs?

A. Well, I've been practicing medicine -- medicine for 35 years. And you know, I've transferred lots of patients in my life. And stuff happens, and it happens more often in general than it does when you keep the same patient within the same four walls of the hospital.

So I think you know, it's -- it's instinctively I think sensible to realize that sending somebody out of your institution someplace else invites some degree of risk, but I -- I can't specifically answer the questions that you've posed, unfortunately.

Q. Okay. No problem. So you've made it as a general statement as a possibility, but you have no data to back that up as you sit here today?

A. Other than 35 years of experience.

Q. Now at some point in time there was an estimate in the original application made by Norwalk Hospital of projected elective PCIs over a series of projected years that fell

well short of the -- and I will get to the expert document in a moment -- but the 200 facility threshold, that minimum threshold that has been the subject of discussion in this hearing today.

Do you recognize that?

A. Yes.

Q. And in that original calculation of -- if you give me one moment, please?

In that original calculation which is in the utilization section on page 36 of 52, of your original application, the Norwalk Hospital projected based on fiscal years -- I believe they cited a table, or you cited a table of fiscal year 2017, 2018 and 2019, and perhaps an annualized fiscal year 2020.

And for '17, '18 and '19 when one adds up Danbury Hospital we come up with a total of 73, 71 and 61 in those three successive years of PCIs. Does that make sense to you? Or do you want to look at those numbers?

A. I -- I see the numbers. I -- I'm happy to address a particular question if you have it.

Q. Sure.

A. You know, if you want a more educated answer

there are individuals who I suspect you will be calling for cross soon that may be able to offer a greater degree of precision.

Q. I appreciate that, and my questions are not going to sort of get into the sort of the nitty gritty of the calculation.

But what I am wondering is, when you see the projected volume in the table below, do you see, you know, fewer numbers -- or lesser numbers. Do you see that?

A. I -- I lost you a little bit, Attorney Monahan, I -- in terms of -- what is falling off?

Q. There's two tables in OHS table four?

A. Yeah.

Q. And then the projected numbers that -- for utilization by service -- yes, is for primary elective PCI, if this were granted would be for fiscal year '20, '21 and '22, a total of 62, 128, and 141.

Do you see that?

A. Yes.

Q. If you add the primary and elective PCI numbers together?

A. Yeah.

Q. Okay. In general, again knowing you didn't author every answer to this, but did you know that those were the projections going in? Do you remember if you knew?

A. No. Honestly I do not know that I looked at or examined with this degree of detail the difference between the actual and the projected -- or for that matter, whether Danbury was included in the system numbers or not.

Q. Okay. Let me ask you, were you aware at the time that this application was being filed that the consensus document from the three leading cardiac societies and groups who had reiterated their minimum threshold in 2014 of 200 minimum procedures for facilities without backup surgery, and that that had not been changed?

Did you have any sense that those projections were below that threshold?

A. I -- I have discussed the -- the numbers with, certainly with Dr. Warshofsky. It's someone that I'm confident -- and we respect the guidelines of 200. I'm confident that we will exceed them.

I don't know whether or not if your question is, well, then why did you submit the application if your number was below 200? I -- I don't know, but you can certainly ask Dr. Warshofsky about the differences and whether or not COVID, for instance, is factored into '20 at all.

But I will tell you that our more recent numbers, particularly those from this year annualized look at 80 primary PCIs. And if you do the extrapolation I'm very confident that we will exceed, substantially exceed the 200 number as a threshold.

Q. All right. When did it come to your attention in your office that there was a desire or a need, or a request to change that calculation?

A. No one came to me with an expressed desire to change a calculation.

Q. I'm just going back to what you said you had conversations with -- I believe it was Dr. Warshofsky, and maybe others.

But is there at some point sometime before you filed your testimony that someone said to you in words or substance, e-mail,

hey. Our projections are below 200. We need to rework them, or words to that effect?

A. Never.

Q. Okay. So is it the case that from the original filing of those projections below 200 to this very day you had no knowledge of the modification from below 200 to a projection in excess of 200?

A. Again, I -- I was not --

MR. TUCCI: I'll object to the form. Excuse me, Hearing Officer. I'll object to the form as to modification. That's a mischaracterization of what the Witness has testified to. He's testified to a supplementation.

MR. MONAHAN: Well, I'll withdraw. Whether we call it a supplementation, you know, a change, a modificate -- whenever appropriate word, the numbers changed.

BY MR. MONAHAN:

Q. What I'm trying to understand is, Dr. Murphy, when did you first become aware that the numbers were being supplemented?

MR. TUCCI: Hearing Officer Mitchell, I have to renew the objection. There was a premise in the question that, quote, unquote, the numbers

changed. There is simply a gross mischaracterization of the evidence.

If you are looking at the information that was submitted in Norwalk Hospital's responses to OHS public hearing issues list, it provides updated cardiac cath and PCI case trends through fiscal year 2021 based on FP1-6, meaning the first six months of the year.

So those, that's the additional information that was presented. It's not a change.

MR. MONAHAN: Well, rather than that -- my request is rather than have Attorney Tucci testify about the change, what I'm asking is whether Dr. Murphy had knowledge that there would be a change, whether it's in the numbers, the calculation, the methodology, but something to get those numbers from below 200, over 200.

THE HEARING OFFICER: I'm going to allow that question.

THE WITNESS (Murphy): No. The answer is no.

BY MR. MONAHAN:

Q. Okay. So when you gave your testimony on August -- excuse me, April 15th, and submitted it, you did not know that there had been a supplement to those numbers?

A. Correct.

Q. You've heard a lot of talk about the 2014 consensus document regarding the three organizations that published guidelines, consensus guidelines in 2011, and then in 2014, and remain steadfast at the facility minimum threshold of 200 PCI services as a minimum threshold for elective PCI at a facility without surgical backup.

Correct?

A. Yes.

Q. Do you respect that, those three entities as expert entities in the promulgation of guidelines and best practices in connection with cardiac care?

A. Well again, I think at the outset I hope I made it clear I am not a cardiologist. I don't pretend to be one, and I have no reason to be suspect of these guidelines or the consensus statements.

But I don't know the totality of other guidelines and I don't want to get, you know, caught in -- in a paragraph or a sentence here about something that may be in the documents. But you know, in general, I -- at least in my field I read them and to the

extent that they're appropriate, follow them, but I also recognize that individual patient circumstances, some things aren't followed to the letter.

Q. Who doesn't follow them to the letter?

A. No, I'm saying if you're applying a guideline, a consensus guideline in the field of neurology to a particular patient, there are times and circumstances where the guidelines are less relevant.

Q. Right. So if for instance in these guidelines -- and maybe you know enough about what has been said and read, and maybe you've read them yourself, even these consensus guidelines provide an exception to the 200 minimum threshold when a hospital may be in an isolated area, unlike the area you're in where you have at least four hospitals with full cardiac backup.

You understand that there is that exception?

A. Yes, I do.

Q. And you agree that that exception does not apply to you?

A. I just want to be careful that I -- I answer

fully here, that I get the sense that the premise of your question is, we're looking for an exception to come in under 200 cases, and that's not in fact the circumstance here.

Q. And if you didn't know that there was -- and I'm really, really just trying to understand based on what you said, the chronology here. If you did not understand as of the time you penned your signature to the testimony on the 15th that there was not a supplement to the projection, when did you learn that now there was a supplement where we -- where Norwalk Hospital was projecting numbers above the 200?

A. Yeah. Attorney Monahan, you -- you may not fully appreciate the nature of my job. I'm running seven hospitals in 85 communities and I am not looking at this with a fine-toothed comb to see whether supplemental data has been submitted.

I rely on my team. They are enormously talented, filled with integrity and deeply honest people. So if there's some supposition that somebody is playing a game, that it won't fly.

I do -- I do not recall any specific time where somebody said, do you realize that data was submitted? I've been through CON submissions before and there are all kinds of answers to questions that are provided on an ongoing basis, and then additional questions appear.

So I'm used to this continuum of communication and data exchanges. So there's nothing about this that feels odd to me, nor was anything brought to me as, you know, there's some signal submission here that you need to know about.

And I don't have any particular recollection of any particular conversation where someone said, you need to be aware that supplemental data was provided to the Office of Health Strategy in this particular application.

THE HEARING OFFICER: With that, that was a very specific response with that. I'm just going to ask Attorney Monahan if you wouldn't mind moving on, because Dr. Murphy has indicated a couple times that he really was unaware of the update and the numbers.

MR. MONAHAN: Absolutely.
THE HEARING OFFICER: Perhaps there may be somebody else that has more knowledge about that?
MR. MONAHAN: I can certainly do that. Thank you, Dr. Murphy, for your patience in that questioning.
BY MR. MONAHAN:
Q. Dr. Murphy, am I correct that there is a large cardiology group called Cardiology Associates of Fairfield County, in the region that you, that Norwalk Hospital operates in?
A. Yes.
Q. And isn't it the case that Cardiology Associates of Fairfield County are community physicians who have every right to refer cardiac patients to various hospitals of their choice.
Correct?
A. Correct.
Q. So if you were to be granted this application -- regardless of the methodology that I will ask another witness about -- that gets you theoretically over the 200, you cannot control the referrals of those cardiologies.
Correct?

A. That is correct.
Q. Okay. So to the extent that your volume depends on complete recapture of all of the transferred elective PCIs out of Norwalk to every other hospital, that is not an assumption that you control. Am I correct?
A. Again, the nature of the question -- a complete recapture, I don't believe that that's built into our numbers, that that assumption is built into our numbers.
Q. Okay. So I should ask Dr. Warshofsky about that?
A. I think you can ask Dr. Warshofsky, or Dr. Lomnitz. I -- I suspect that they would be better informed that I am.
Q. Okay. All right. I just have a few more questions.
I believe it's in the testimony of one of the doctors, Dr. Murphy, that there's a new cath lab in process that you're building for Nuvance -- or is there a new cath lab that Nuvance is building?
A. Yes, sir.
Q. And just, does that cath lab bear in any way with respect to Norwalk Hospital?

A. Yes.
Q. And approximately when was that construction? Do you know?
A. I -- I'd be guessing again. It's -- it's nearing completion, but I don't know when it actually started.
MR. MONAHAN: Okay. Dr. Murphy, I really appreciate your time with me and your patience.
And I have no other questions.
THE HEARING OFFICER: Attorney Tucci, do you have any followup for Dr. Murphy before Attorney Monahan moves on?
MR. TUCCI: Hearing Officer Mitchell, if I could just do some brief redirect with Dr. Murphy?
THE HEARING OFFICER: Okay.

REDIRECT EXAMINATION (Murphy)

BY MR. TUCCI:
Q. Dr. Murphy, can you hear me okay?
A. Yes.
Q. Dr. Murphy, on behalf of Norwalk Hospital as the Applicant in this CON proceeding are you asking the Office of Health Strategy to ignore or change any of its regulations?

A. No.

Q. You were asked a question about whether you had ever received a call from one of the other friendly competitor health systems in your area, say, for example from Stamford Hospital or Bridgeport, or St. Vincent's saying to you communicating to your system in effect, we can't take another PCI patient.

And Mr. Monahan asked you what you thought about the concept of there being access to PCI services in the region.

Do you understand the difference between capacity and access?

A. Yes, I do, but I thought the question that Attorney Monahan was asking me was, had I ever received a phonecall?

That was what I was answering.

Q. Right. And the answer is -- I take it your experience has been you have not gotten a call from a competitor saying, don't send us another patient?

A. Correct.

Q. So the conclusion to be drawn from that is that your competitors perhaps have capacity to take patients.

Does that necessarily equate to whether or not your patients will get quick access to elective PCI care at those institutions?

A. It does not.

Q. You were asked about questions relating to transfers of Norwalk Hospital originated patients to Danbury Hospital. Now Norwalk and Danbury are part of the same integrated network platform of care.

Correct?

A. Yes.

Q. And as part of that integrated network of seamless care, do the two institutions share an integrated medical record?

A. Yeah. Yeah, so -- yeah, I recognize that there are certainly differences between, at least in my view, in the risks between transferring to a sister institution and, if you will, foreign institution, or one that is outside of the network because you don't have access to the same EMR.

You don't have access to the same imaging systems. You use a different formulary. You don't have the cellphone number of the interventional cardiologists to

whom you can rapidly communicate critical information. You may have a different system in place if the patient doesn't speak English.

So there are significant advantages to in-network transfers that don't exist when you leave the system. But -- so I didn't know where Mr. Monahan was going with his questions, and I wasn't sure that was an answer he was looking for.

I didn't know the facts he was asking about regarding the specific outcomes of intra-system patients leaving Norwalk Hospital.

Q. Doctor, one more question? I would like, if you would bear with me -- if you could refer to a couple of pages. The first is page 36 of Norwalk's Hospital CON application.

If somebody can provide that to you. And then I'd ask you to look at the Norwalk Hospital Responses to OHS public hearing issues list, the document dated April 15, 2021. In particular, they're not marked, but there's a third page that shows at the top a chart entitled, Norwalk Hospital

cardiac cath and PCI cases, Trend through FY '21?

A. Yes.

Q. Can you put those two pages side-by-side?

A. Okay. Yeah.

Q. Focusing first on page 36 of Norwalk Hospital's CON application. Looking at table four under fiscal year 2017, it lists the number of primary PCIs actual volume at Norwalk Hospital.

But what is that number?

A. Twenty -- 2017 was 73. 2018 was 71. 2019 was 61.

Q. All right. Now, direct your attention, please, to the document that Norwalk Hospital provided to OHS on April 15, 2021. Look at the chart at the top of that page.

A. Okay.

Q. What is the number reported on that chart for fiscal year '17?

A. 73?

Q. The same number as reported in the original application. Correct?

A. That is correct.

Q. What is the number for fiscal year '18?

A. 71.
Q. The same number reported in the original application. Correct?
A. Exactly the same number.
Q. Fiscal Year '19, what is the number reported there?
A. The same as it was, 61.
Q. All right. Now let's look at fiscal year '20. What number is reported there?
A. The second sheet, it's six-zero.
Q. Okay. And then you said you've had experience in being involved in the submission of CON applications over the course of your many years involved in health care.

Correct?
A. Yes.
Q. In your experience, is it unusual or not unusual for an applicant to submit updated data to reflect the applicant's most recent experience concerning the particular service at issue?
A. Yes, I -- I think it is typical.
Q. The column that you see on the third page there reflects the fiscal year '21 actual

primary PC numbers of 41 at least through what's characterized as FP1-6. Right?

A. Yes.

Q. In your experience in the world of health care is it unusual for hospital systems to look at their actual experience over a part of the year and then project an annual experience based -- an annualized experience based on that actual experience?

MR. MONAHAN: Okay. I'm going to -- may I object?

THE HEARING OFFICER: On what basis?

MR. MONAHAN: I was -- after probing this, I was cut off from the questions because Dr. Murphy had indicated that he had no real involvement in this, and I should defer my questions to others.

And now we're getting into a more detailed discussion of the very tables that I was heading towards that I'm now being -- that I was told that I could not go into, and I don't think it's appropriate. It's going beyond the scope of direct. I was cut off by the very objections of Attorney Tucci.

THE HEARING OFFICER: Attorney Tucci?

MR. TUCCI: Yes. Thank you, Hearing Officer Mitchell. It's obviously not beyond the scope of the direct.

It's precisely in line with the scope of the direct.

Nor am I asking the Witness to do anything other than testify about his general experience as an experienced chief executive officer of a hospital institution about how hospitals in the normal course of business project lines of business. That's all I asked him.

THE HEARING OFFICER: So I think we are getting a little bit into the details of the numbers. I think that it would probably be more appropriate to have the other witnesses with more direct knowledge about how those numbers came about, respond to those questions.

MR. TUCCI: Thank you very much, Hearing Officer Mitchell.

I have no further questions on redirect for Dr. Murphy.

THE HEARING OFFICER: Thank you.

MR. TUCCI: And would you mind if we just took a short break?

THE HEARING OFFICER: Yeah. We're running a little bit long, so we're going to keep it --

MR. TUCCI: Five minutes?

THE HEARING OFFICER: Yeah. Let me just ask. There

was somebody that was going to be testifying from the Legislature? Is that person available?

A VOICE: Not at this time.

THE HEARING OFFICER: No? Okay. All right. I just wanted to make sure that they were not waiting around.

Okay. So we'll go back on the record about 3:43, 3:46.

THE WITNESS (Murphy): Am I excused?

THE HEARING OFFICER: Let me just -- I don't know that we have any questions from OHS. Let me just ask.

THE WITNESS (Murphy): I can wait. No, no. I -- I don't want to pressure anybody.

THE HEARING OFFICER: So Dr. Murphy, I'm thinking our questions may need to go to the other witnesses. Let me just confer with Ms. Rival and Mr. Carney.

I think our questions go to the other witnesses. Correct? Then we can let Dr. Murphy go? Jess is nodding.

MR. MONAHAN: Would that be the same for Ms. Silard?

THE HEARING OFFICER: I think so too. Yeah, I think we're all set with --

MR. CARNEY: Attorney Mitchell, I think we have one question for Dr. Murphy, that I was aware of.

THE HEARING OFFICER: All right. So why don't we take

a five-minute break.

And then let me ask Attorney Monahan. Do you mind if we ask our question of Dr. Murphy? I know we're kind of getting into, you know, I don't like to interrupt people while they're doing their cross because you kind of get --

MR. MONAHAN: I have no objection. I you need to step out of order, that's fine.

THE HEARING OFFICER: Okay. All right. So we'll come back in five minutes. Then after, after we ask your question, Dr. Murphy, you can go.

And then also Ms. Silard can also go, too.

MR. MONAHAN: Thank you.

THE HEARING OFFICER: Thank you. All right. So let's just come back on the record at 3:40.

(Pause: 3:35 p.m. to 3:50 p.m.)

THE HEARING OFFICER: All right. We're going to go back on the record. Is everybody ready?

MR. TUCCI: Yes, for the Applicants.

THE REPORTER: The Court Reporter is ready.

THE HEARING OFFICER: Okay, Applicants.

And the Intervenor is ready also?

MR. MONAHAN: Yes.

THE HEARING OFFICER: All right. So Dr. Murphy, I did confer with my colleagues and we had one question for you based on your prefiled testimony. I'm going to pull it up, and I'll read it.

It says on page 31 of your prefiled testimony you stated that unnecessary transfers also reduced Norwalk Hospital's ability to coordinate care and manage its cardiovascular patient population. While some patients may be transferred to Danbury Hospital for elective PCI, other patients are sent out of network -- sent to out of network providers that may not know the patient's histories, et cetera.

So I've heard you talk about this in questioning by Attorney Monahan, but we have just a couple more questions for you. And we wanted to know first -- and I'll just do them one by one. What are some of the reasons why a patient would be transferred to an out-of-network provider versus maybe Danbury Hospital?

THE WITNESS (Murphy): Well, it could be that a relationship that exists. It could be a patient preference, a preference of the physician, a preference of the patient, a preference of the family member. There are a number of

circumstances that would influence the ultimate destination.

THE HEARING OFFICER: Do you know about what proportion of patients are transferred out of network?

THE WITNESS (Murphy): I -- I do not know the answer to that question.

THE HEARING OFFICER: And then I think one of the things that we wanted to know is if you could help us understand how these out-of-network transfers hinder Norwalk Hospital's ability to participate in alternative payer models?

THE WITNESS (Murphy): Sure. As you know, the alternative payment models really are moving away from fee for service where the patient shows up and whatever services they receive they get billed for, to a different model which is fee for value -- which both the quality outcome and the cost of that care, the responsibility and the accountability shifts to the provider. And those payment models have been in place and are growing in popularity.

And they are believed -- certainly the state and federal governments believe that it is through those value-based arrangements that we will ultimately improve quality and reduce the cost of

care.

So what happens is if you send somebody from Norwalk Hospital for an elective PCI to another facility. It's conceivable that that other facility doesn't participate in that particular insurance plan, let's say, or while the hospital may, the cardiologist may not, an anesthesiologist may not. They may have a different formulary that doesn't anticipate the particular insurance.

Or for that matter, in some circumstances based upon, you know, where the patient goes, if it goes out of state there can be state plans that become a problem.

And as I'm sure you're aware, Hearing Officer Mitchell, the -- the whole notion of surprise billing, you invite that possibility at times when somebody shows up to do an emergency procedure. After the procedure is done, you know these patients don't really have the opportunity really to shop for services.

They get a big bill and the patient is exposed to significant out-of-pocket expenses or co-pays, or you know, major financial exposure because those coordinated efforts do not take place.

And you know, the whole notion of a bundled payment, for instance, is there's an impetus for the institution that has signed up for that bundled payment to say, we're going to take care of that patient. No matter what it takes we'll be held accountable for the quality outcomes as well as the cost.

So it forces us to be as efficient with the services that we provide as we can be. We lose control over all of those decisions when the patient leaves the network.

THE HEARING OFFICER: Okay. And then is there a way to quantify how these transfers might hinder participation in EPNs?

THE WITNESS (Murphy): I'm sure there is. I -- I couldn't give it to you, you know, as I sit here with any degree of confidence, but there's no question when -- if you look at, you know, we have tens of thousands of patients who are in at-risk models, and we -- and the State knows this and has encouraged us to continue to increase our participation in those alternative payment models.

When the patients do leave the system we do find that that is in fact where the expenses take off and that is a significant exposure that is

difficult to manage when you're in a bundled payment.

We also have challenges sometimes in getting the data back on what the quality outcome was, the -- a different EHR system. It has different ability -- abilities to report back on particular outcomes.

So it is -- it's cumbersome. It's -- it's awkward. It's inconvenient, but I will tell you that it represents potentially a quality concern, but undoubtedly a financial concern.

THE HEARING OFFICER: All right. Thank you, Dr. Murphy, for those responses.

Let me just check in with Mr. Carney and Ms. Rival.

Any additional questions from us you think that maybe I might have missed?

MR. CARNEY: That was the only one I had.

THE HEARING OFFICER: All right. Jessica, we're all set? Okay. So that was it from us. I'm just going to follow up again with Attorney Monahan and also Attorney Tucci.

Any followup for Dr. Murphy?

(No response.)

THE HEARING OFFICER: If not, hearing nothing I think we're all set, Dr. Murphy.

THE WITNESS (Murphy): Okay. Thank you very much.

MR. MONAHAN: May I just ask one -- I'm sorry. One last question.

THE HEARING OFFICER: All right.

MR. MONAHAN: Just on an EPN question.

RECROSS-EXAMINATION (Murphy)

BY MR. MONAHAN:

Q. On how many EPNs do you participate in? And how much money is at risk, as you just described?

A. How much money is at risk? We have --

Q. Mute -- you're on mute. I'm sorry.

A. Pardon me. We have about 40,000 patients who are currently under some form of risk arrangement.

I -- I don't know that the total sum of dollars based on, you know, there are -- there are Medicare participants. There are commercial participants. There are even some Medicaid pilots that we're looking at, some national, some state specific, but it would

be hard for me to give you a solid number, Attorney Monahan.

MR. MONAHAN: Thank you, I appreciate that. Okay.

THE HEARING OFFICER: Attorney Tucci, any followup?

MR. TUCCI: No, thank you, Hearing Officer Mitchell.

THE HEARING OFFICER: All right. Thank you again, Dr. Murphy.

THE WITNESS (Murphy): Okay. Thank you very much.

THE HEARING OFFICER: All right. So I'm going to turn it over to you, Attorney Monahan.

MR. MONAHAN: Before we do that, Hearing Officer Mitchell, are there any group questions for the CEO and president Ms. Silard? Or may she be excused, I think, from the panel?

THE HEARING OFFICER: Right. So, no. We don't have any questions for her.

MR. MONAHAN: Just so there's no -- she may be excused?

THE HEARING OFFICER: Yeah.

MR. MONAHAN: Okay. Thank you very much.

THE HEARING OFFICER: You're welcome.

MR. MONAHAN: Doctor -- I want to pronounce it correctly. I apologize. Warshofsky?

Warshofsky, I call Dr. Warshofsky for cross-examination.

THE WITNESS (Warshofsky): Good afternoon.

MR. MONAHAN: Good afternoon. Really hopefully just a few questions.

One is there, there were a number of questions regarding different medical literature from this whole application process, and in connection with that there were references to the 2011 consensus document by the -- and I want to get the exact acronyms, ACH -- excuse me, the American Heart Association, the --

Give me one moment, please. I just want to get my -- okay. I apologize.

CROSS-EXAMINATION (Warshofsky)

BY MR. MONAHAN:

Q. There were several discussions about the literature and guidelines published by the ACCF, AHA and the SCAI consensus documents in 2011, 2013 and then in 2014.

And my question is, do you recognize and see the 2014 best practices -- or recommendations, I should say, of that consensus group from 2014 as a current state -- excuse me, a current guideline that is not superseded, not eradicated, and not

abolished?

A. Yes, I see the 2014 guideline as current. And -- and I would emphasize that it's a guideline, not a policy.

Q. Thank you. Would you -- and I believe you may have heard testimony from today on this. In connection with the fact that elective PCIs presently at Norwalk Hospital are transferred because you can't do that, they are sent to other hospitals for that procedure.

Do you, as you sit here, believe that there is sufficient access were those four hospitals to accommodate the transfer of any elective PCI patients that you have encountered to date?

A. No, I don't believe that.

Q. And what is the basis for your belief that those four hospitals cannot accommodate the elective PCIs that you would be transferring them to date?

A. Well, I -- I guess it would depend on how you define sufficient access, but I look at this from the patient standpoint. And then I would be quite upset if I were a patient or a

family member of a patient to be transferred for something that really is not necessary.

So although ultimately the patient may receive the, what we're terming an elective PCI, the fact that they had to endure a transfer and that the family may or may not have been able to go visit them at the receiving hospital, for me is not sufficient access.

Q. Well, I understand. I appreciate your personal opinion, but right now you understand under the law you cannot perform an elective PCI at Norwalk Hospital.

Correct?

A. Correct. Under the law we cannot.

Q. So that if a patient says to you, oh, I'm disturbed by this. Are you telling me that you're saying, well, then you had no access?

Or are you saying they have access, and now here are the places you can go within the 30-mile/30 minute time period?

That's my question. Can they get the procedure done within a timely manner even though you can't do it?

A. What I am saying to the patient is, I am

sorry. At this time we're not able to provide this service for you here at Norwalk Hospital. We'll have to transfer you. Where would you like to go?

And they may say to me, but my neighbor got the same procedure here. And I would say to them, but your neighbor came in with a STEMI. And we were able to do that, but we're not able to provide, quote, unquote, elective PCI for you.

Q. Okay. And then you wouldn't abandon them. You'd send them to one of the four hospitals.

Right?

A. No, we would not abandon them. We would find a place to care for them. That's correct.

Q. Okay. And you have been able to find a place. There has been satisfaction of that need. Even though you don't like it, there has been satisfaction of that need for you to get those patients to those other hospitals?

A. I mean, Attorney Monahan, you know, we're -- the way you describe this it sounds like an ideal world out there, but you and I know that there are nights when it's cold, when it's freezing, when it's snowing, when the

traffic is backed up.

And so you know, it's not something that's always done very easily. And as I think I mentioned earlier, in the midst of a COVID pandemic sometimes you do get an answer where you know what, we're just too crazy right now. We can't take that patient.

Q. All four hospitals at the same time have said that to you?

A. I didn't say that.

Q. Well, what I'm really trying to understand, Doctor -- because you seem to be saying that there is a restriction, and I don't want to put words in your mouth. But you're under oath, and I want to know whether there are four hospitals within your region that you can transfer elective PCI patients to.

Are you telling me that you are unable to transfer patients in need of those elective services to any one of those four at any given time?

A. If you're asking me, is there capacity in the area to say, okay, somebody somewhere can do this PCI? I would say that there is capacity.

Q. Thank you.

A. But when you think about access, that's a different story. And I think access is limited at times, certainly.

Q. All right. Well, I suppose we can let the Office of Health care Strategy decide whether capacity and access, how to judge that under the legislative standard whether there's an unmet need.

And lastly, were you in charge of creating the methodology, or retaining the methodology for both in the original application and in the prefiled testimony answers to questions supplementing the projections of elective PCIs?

A. I participated in that process. I wouldn't necessarily say I was in charge of it.

Q. Can you point me to any benchmark studies, statistical sampling methodology or outside consultant that you used to come up with that analysis that led you to the supplement?

A. No. There was no outside entity that led us to that. It was really an evolutionary process.

I think as Dr. Murphy described earlier,

it's pretty common in CON applications. And we, when we looked at our FY '21 numbers we certainly were interested to see that the annualized number was about 80, a little bit over 80 STEMIs, which when we think about it -- and again, we talked about this a little bit earlier, whether it's a four-to-one ratio or an eight-to-one ratio, we would be well over the 200 threshold.

And I -- I believe that's borne out even by Stamford's own numbers, which I think had less STEMIs than Norwalk, but had -- certainly I think over 200 PCIs.

Q. Okay. And you said you were a participant. Who were the other participants in putting that methodology together?

A. Well, I don't know about -- I don't -- I don't understand what you mean by methodology. We -- we looked at our numbers and they are what they are.

Q. I guess I'm sorry if I'm -- who is the we?

A. The team, our strategy team, Sally Herlihy. I think you heard her mentioned, her name earlier. Kelli Stock who is the Vice President for the Heart and Vascular

Institute at Nuvance, and some of our finance team as well.

MR. MONAHAN: Excuse me, Ms. Mitchell. May I have one moment?

THE HEARING OFFICER: Yes.

MR. MONAHAN: Okay. No more questions. Thank you.

THE HEARING OFFICER: All right. Any followup, Attorney Tucci?

MR. TUCCI: No, thank you, Hearing Officer Mitchell. No questions.

THE HEARING OFFICER: All yours. All yours, Attorney Monahan.

MR. MONAHAN: Thank you. If Dr. Yekta Is available? Hi, Doctor.

THE WITNESS (Yekta): Hello.

MR. MONAHAN: One minute to turn some pages.

CROSS EXAMINATION (Yekta)

BY MR. MONAHAN:

Q. Doctor, similarly -- well, first of all, what is your -- and I apologize. And I know you said this in your testimony, but what is your specialty?

A. I'm an interventional cardiologist.

Q. And do you recognize the 2014 consensus document that I referenced just before the previous testimony as the most current consensus document with a recommendation of a best practice of a minimum threshold of 200 PCIs for a facility without on-site surgery?

A. So yes, that document from 2014 does relate to elective PCI stents, also is without cardiothoracic surgery backup.

And in response to your numerical comment, it does state that it is recommended and is -- again, it is a guideline that 200 PCIs should be strived to achieve, but there was also a comment in there about if labs are unable to get to that 200 threshold, annually they can have, quote, unquote, stringent systemic and process protocols in place with close monitoring of critical outcomes and additional strategies that promote adequate operation of catheterization laboratory; staff expertise throughout -- through collaborative relationships with larger volume facilities which is --

So again, my point in emphasizing that is that the number of 200 is there, but it

also acknowledges that 200 may not be an absolute number that has to be present for all facilities.

Q. How long have you been with Nuvance -- I apologize. How long have you been in your position?

A. In my --

Q. Your current position?

A. I've been there for about two years now, approximately two years.

Q. Have you had any experience before today in or surrounding the CON process for the State of Connecticut?

A. I have not. I have not been part of the CON application prior to this process.

Q. And aside from the written testimony you provided, did you participate in any type of research or calculations, or any type of work that went into the actual substance of the application?

Or any supplemental bylines?

A. No. One of the reasons why I wore my scrubs today is thinking I wasn't a numbers person. So I was not involved in the numerical evaluation of the program or the -- or the

PCI volumes.

Q. Okay. And lastly, do you have -- and I think you just answered it, but just to be sure, do you have any experience in extrapolation of data -- well, let me just point you to your testimony.

You do refer to extrapolating transfer data to an annualized projection when compared with current primary guideline trends, fiscal year 2021. And the fact that transfer data doesn't capture all eligible permutations to go elsewhere for elective PCIs shows that there is more than sufficient volume for Norwalk Hospital to support a primary and elective PCI service in accordance with national guidelines.

And that's on page -- it's not numbered but let me get it.

It's at the bottom of page 4 of your written testimony.

A. So if you don't mind, just repeat from where you read to --

Q. Sure. On the bottom of that page I read from the fifth line up starting on the word "extrapolating."

A. Okay.

Q. And the reason -- well, I'll let you read it and then I'll ask the question.

A. Sure. All right.

Q. The reason I ask the question is, as you just explained that you're not a numbers person, how is it that you -- you started voicing then and have voiced an opinion on extrapolation and volume trends, and things of that sort?

A. Because one of the things, you know, in my position, you know, we have had numerous inspections here at Nuvance in regards to what our transfer volumes have been in addition to the data in terms of our primary PCI volume.

So if you, you know, as an organization we've come to realize -- the realization bringing those numbers together, that we should be able to achieve more than 200 PCIs. And this is just inpatient volume that we're talking about. We're not even including any outpatient elective PCI.

So that's where we came to put that data, or that -- where I extrapolated from

that data.

Q. Okay. And then if you -- the same question asked before. When you say, we, was there a group of you that put your heads together to do that?

A. Was there a group? So there is a group of -- of people here and the data is sometimes, you know, as I'm presented to the data -- but I'm not part of the -- the committee that formulates that data, so I can't really help you there, but I'm not really part of that group specifically.

Q. Okay. Thank you.

I do have one more question and I want to go back to the completeness responses which deal with the transfer of elective, present transfer of elective PCI cases from Norwalk Hospital.

I'm looking at page 6 of 7 on the completeness questions. And this -- it's number six and it says, provide the number of patients within the primary service area that are transferred from Norwalk Hospital to Danbury Hospital. And of those patients transferred, provide the number of patients

who received an elective PCI post transfer.

Do you see where I'm referring to? And I'll give you time to get there.

A. I do.

Q. And there's an OHS table one, patient transfers from Norwalk Hospital to Danbury Hospital and post transfer elective PCIs.

Do you see that?

A. I do.

Q. Do you see that it's approximately -- well, at 34 percent. Of all these patient transfers it's about a one third percentage -- or one third of the total transfers that end up having elective PCIs.

Do you see that?

A. Roughly.

Q. What's the explanation for that?

A. I'm not part of any of these cases, so I can't explain that to you. I mean, I don't know how you -- how you want me to answer that question.

I mean, I -- I don't know how to answer that question. You know, pieces are done on an individual basis, so when a patient gets transferred and cardiac cath and if they

decided to get an elective PCI, it's on a case-to-case basis. So I can't do any of those. So I can't explain that.

Q. Okay. Are you often part of the decision to make the transfer?

A. Oftentimes, yes.

Q. And do you often get involved in the decision to make transfers of patients from Norwalk Hospital to hospitals other than Danbury Hospital?

A. We always ask the patient what their preference is, and if they decide to. Again we don't try to convince patients to go one way or the other. If they have a strong preference for one hospital or the other, we do. I certainly acknowledge that.

Q. And I'm not asserting that you don't. I was just trying to understand if -- just the way you're structured if that's -- if that is what, you know, it's not just Danbury that you're focused on.

It could be any of the hospitals that can absorb a transfer from Norwalk Hospital. You could be involved in that process?

A. I can be involved, but you know, the one

thing is a patient, you know, once the patient meets the physician oftentimes they want that physician to be their provider.

So I do not provide services at other hospitals outside of Danbury Hospital and Norwalk Hospital. So it would have to be a change in their cardiac care if they were transferred. So they have to see different interventionalist, different cardiologist, different hospitalist, different nurse, different PCA.

So that is part of that equation.

Q. And do you often deal with the community physicians that -- or the community cardiologist that may be the attending physician for any of these patients?

A. Of course. I think that's a natural part of my job to deal with referring physicians.

Q. Okay. So -- and in those cases is it your experience that the attending physician provides some continuity of care with respect to the patient and their transfer to a different hospital?

A. So are you in reference to the general cardiologist that you're talking about?

Q. Yes.

A. Yes, absolutely. So I mean, they do provide some continuity of care, sometimes in the hospital, but sometimes not in the hospital as well.

MR. MONAHAN: Thank you for your time and I have no other questions.

THE HEARING OFFICER: Followup, Attorney Tucci?

MR. TUCCI: No questions for Dr. Yekta. Thank you, Hearing Officer.

THE HEARING OFFICER: All right. Thank you, Dr. Yekta.

THE WITNESS (Yekta): Thank you.

MR. MONAHAN: Just one moment, please?

Dr. Lomnitz, if I may?

CROSS-EXAMINATION (Lomnitz)

BY MR. MONAHAN:

Q. Hello, Doctor.

A. Hello.

Q. How are you?

A. Good, good. How are you?

Q. Okay. Thank you.

And Doctor, sir, I understand your chief of cardiology at Norwalk Hospital. Am I

correct.

A. That's correct.

Q. Okay. One of the, you know, the questions you've heard over and over again is -- and I'd like to ask you as a cardiologist is, do you view the consensus document published in 2014 by the three societies that I have mentioned that recommends the 200 minimum threshold for facilities that do the elective PCI that do not have surgical back up -- do you view that and see that as the existing consensus guideline that has not been abolished, retracted or in any way vacated?

A. Well, you know, I have experience with clinical epidemiology and -- and the statistics and the guidelines have a different level of evidence. The highest level of evidence comes from randomized clinical controlled trials, prospective.

The lowest form of evidence comes from registry, and the reason for that is that when you rely on registry data there's lots of confounders that can trip you up. And the people who wrote the guidelines were very wise because they're not relying on

randomized controlled trials that determine that 200 was the number. What they were relying on was registry data.

So in the interests of making sure that any program that is doing PCI is doing it in the highest quality fashion, should do it and meet their standards, which not only includes following data, but making sure that there's good quality assurance programs, oversight, and the like.

And I think that the 200 PCI number comes from a signal from registry data that comes from the early 2000s. And I think that in our case we -- we believe we're going to be over 200. I'm confident we'll be over 200, but what I can assure you is our commitment to a high quality program.

We are in partnership with Cleveland Clinic, considered by U.S. World News and Report the number one cardiac hospital in the nation. They'll be working with us with our network in Danbury and with us in Norwalk. And I can assure you that no one here wants to be associated with anything but the highest quality program.

Q. And I certainly respect that for you, Doctor. And what -- I guess, what I was trying to understand is in the world of evolving medical literature, medical guidelines and the studies, at some point medical guidelines, I suppose, will or do change, but the medical recommendation of that consensus group as of today, at 200 thresholds -- in addition to the various studies that you've talked about, but that number still is in place and hasn't been displaced by the cardiology community?

A. I think as part of a holistic approach, that is part of the holistic approach. It's not the only approach to determining a quality program.

Q. Fair enough. In your testimony, you refer to there being a regulatory barrier preventing Norwalk hospital from obtaining an elective PCI, or the ability to perform elective PCI for its patients.

If you need me to refer you to the page, it's the second page of the document.

What did you mean by, regulatory barrier? It's down near the bottom of

page -- under section one. It's about four lines up.

A. Well, I think that, you know, it's clear that Connecticut requires a certificate of need for certain services. Elective PCI at a hospital without surgical backup falls under that, and we currently don't have a CON for that service.

Q. Okay. And that's what you see as the barrier at this moment that you are having to overcome in this application?

A. That's why we're here.

MR. MONAHAN: I have no other questions. Thank you.

THE HEARING OFFICER: Any followup, Attorney Tucci?

MR. TUCCI: No thank you, Hearing officer. No followup for this Witness.

THE HEARING OFFICER: All right. Anything additional, Attorney Monahan?

MR. MONAHAN: Well, as far as cross-examination? No. And I don't -- I didn't know whether closing remarks on the agenda means closing remarks from lawyers, or that's just closing remarks by the panel.

So nothing else for me, but I do have one request to make before the end of the hearing.

THE HEARING OFFICER: Absolutely. I'll give you a chance. I'm actually going to ask that we take a little five-minute break so I can confer with my colleagues, because we have a few questions that we want to ask that some of the attorneys in this hearing didn't touch on -- and some of them, actually you did.

So we just want to make sure that we are ticking off the list of questions that we have, what's already been discussed, and we want to make sure that we get the other things that have not been discussed.

So maybe if we could have five minutes until 4:40? We'll come back and we'll ask our questions, and then we'll go to closing statements.

Let me just ask, is there anybody here that has signed up for public comment? Anybody from, you know, any public officials, anything like that?

(No response.)

THE HEARING OFFICER: Okay. No. Okay. So we'll come back on at 4:40.

(Pause: 4:33 p.m. to 4:53 p.m.)

THE HEARING OFFICER: All right. So we are going to go back on the record. We're going to start with OHS's questions.

I think we're going to request some late files. I will see if there's anybody that wants to render a public comment. If not, I'll make an announcement about that, and then we'll go to closing comments.

All right. So Brian, you want to take it away?

MR. CARNEY: Sure. Good afternoon, everyone. Thank you for answering my questions.

The general question for the applicant to begin with, let me just preface it by saying, you know, a lot of the information has been submitted through the application, through prefiled testimony and heard today in testimony, but I just want to sort of ask, like, sort of one more time to get, sort of, your top reasons for the request for this proposal. So let me go ahead and ask the question.

So given that elective PCIs are scheduled procedures, the volumes you have reported on page

7 of the prefiled testimony show mostly declining volumes and there are four other elective PCI-capable hospitals in the area. Why is there a need for a new elective PCI program at Norwalk Hospital?

So again, maybe you give me the top three, you know, five reasons why you think it's appropriate?

A VOICE: Would Dr. Murphy or Dr. Warshofsky like to answer this question?

THE WITNESS (Warshofsky): Hi. Yes, here I am. So thank you for that question. I think that what we have seen in terms of volumes for PCI in our system, has actually been increasing volumes for PCI not dramatically, but certainly we have seen some increasing volumes.

And when we look at the last six months of this fiscal year we have seen certainly an increase in our STEMI volumes and an increase in other volumes, volumes related to cardiovascular disease. We have recently brought on two cardiologists to our group in Norwalk largely because we saw a need that was not met, and that has led to increasing volumes for electrophysiology and for other procedures within

our cath lab.

And -- and so when we think about kind of overall volume trends, we -- we have to be careful not to make that a reason to not look at more specific areas and specific needs.

And I think the other reason -- or one of the other reasons that we're making this application is because we know that we can deliver this care safely. And the thought of transferring patients without a real true need to transfer them is not good medical care, frankly.

And when we think about elective PCI -- and you mentioned that elective PCI was a scheduled procedure, I think again I would emphasize that the patients that we're talking about are -- or at least I would say a majority of the patients that we're talking about are not patients who are well, and scheduling something like an office visit -- they are patients who are admitted to the hospital who are in need of, actually an urgent procedure and some of them are scheduled and some of them are not scheduled.

And most of the transfer patients, unfortunately for them they are not scheduled. They're added on, because they're coming as an --

as an add-on to the receiving hospital's schedule.

So they tend to be done later in the day and -- and actually have a much poorer experience overall, I would say, than one who, let's say, is admitted to the hospital and is scheduled for the first case the next day.

MR. CARNEY: Okay. Thank you, doctor. Kind of in coordination with that, I know you gave the initial estimates in the application and the prefiled testimony. Those numbers have increased. I'm still not fully clear on the exact numbers you are projecting now and how you arrived at those numbers.

So if you can -- and if not -- and we probably would need to get this in writing as well -- describe in detail the methodology you used to arrive at the new projection that Norwalk Hospital performed well in excess of 200 PCIs and cite evidence to support your findings.

THE WITNESS (Warshofsky): Sure. So again, I want to emphasize that we were conservative on our initial estimates. We are certainly cognizant of the fact that many patients who could be -- could undergo a cardiac catheterization to look for coronary artery disease, who are in Norwalk's service area

or sometimes even in Norwalk Hospital don't undergo that particular procedure because if they needed a PCI they wouldn't be able to get it at Norwalk Hospital.

So the numbers of diagnostic cardiac caths are, I would say, pretty, pretty grossly under what would be happening if we did have an elective PCI program.

That the numbers again for the last six months of this fiscal year in terms of STEMI are, I think, very informative. The data that I would say to back up the estimates of over 200 cases -- which and again, this is kind of an evolutionary process for me in terms of seeing the data and -- and learning, frankly, a little bit about those ratios that are reported in the literature; whether they be the, you know, eight-to-one ratio that the Seaport trial reported on, or even our own State's data that would say the ratio is at least, you know, a three-to-one, four-to-one ratio, if not more.

So when we think about the burden of coronary disease in the Norwalk service area and we look at the numbers of patients who are presenting with STEMI, and extrapolate that based on what we know

is in the literature on estimates -- or actually, not estimates, but real data when you compare the numbers of elective PCI versus the numbers of STEMI, that's where we get that number from.

MR. CARNEY: All right, Doctor. Let me just follow up with that, because Dr. Martin had said something a little bit different, in fact, stating that cardiac caths were a better indicator of who would require a PCI.

So is there any documented evidence to confirm the relationship between either, you know, cardiac caths or primary PCI to that of projected elective PCI volume?

THE WITNESS (Warshofsky): You know, some of it depends on -- on the population and -- and what one is getting a cardiac catheterization for. Some cardiac catheterizations are not done for acute coronary syndromes in anticipation of PCI.

Some are done for valvular disease in the rate of PCI in those patients certainly would be much lower, but I want to go back to what I was saying before because I want to make it clear. It is really frankly disingenuous to say because Norwalk Hospital's cardiac cath volume is low, that that's a reason that their PCI volume would

be low.

And again, the reason for that is if we have an inpatient here who we have a high suspicion is going to need a PCI, we won't even do that cardiac catheterization here unless the patient really says, you know what? I'll undergo the two procedures. I want to have it here. So those patients are transferred out before they even have a cardiac catheterization.

And similarly on the ambulatory side, if there's a patient in the office with a markedly positive stress test that you anticipate is going to need a PCI, those patients are done at another hospital and leave the -- and leave the community.

MR. CARNEY: All right. Attorney Mitchell, we're going to talk about the late files later. Okay. All right.

THE HEARING OFFICER: Yes, we will.

MR. CARNEY: Next question. Page 37 of the application you provide projected utilization by service. Describe how you determined these projected cardiac cath volumes were expected to increase more than twofold between 2020 and 2021?

It looks like only just table five. It's the bottom of page 37. Cardiac caths go from 83 to

203.

THE WITNESS (Warshofsky): Okay. We're just pulling that up.

MR. CARNEY: Okay. Sure.

THE WITNESS (Warshofsky): Yeah. This is Dr. Warshofsky. So you know, again that goes to a couple of things. One is we are seeing increased volumes in general with our cardiologists, new cardiologists here, increased utilization of their services.

And exactly what I was saying a couple of minutes ago which was that right now the patients who are in need of a PCI, or who are thought to be in need of a PCI are not having a cardiac catheterization done here, and that I would say is the majority of cardiac catheterizations that we do.

The majority of cardiac catheterizations that we do are done looking for coronary artery disease in anticipation of stenting.

MR. CARNEY: So they're not having it done at Norwalk because they're saying basically, well, if I need a PCI, an elective PCI, I won't be able to have it down there. Is that what you're saying?

THE WITNESS (Warshofsky): Exactly.

MR. CARNEY: Okay. And you said you hired two new cardiologists?

THE WITNESS (Warshofsky): Yeah. Actually, Dr. Yekta has been with us a couple of years and most recently we brought on Dr. Menendez.

MR. CARNEY: Okay. Thank you.

Let's see. So page 7 notes that while Norwalk Hospital anticipates performing more than 200 PCIs per year it is important to consider that the volume standard for PCI programs of 200 annually has been questioned recently in the literature.

I know you've touched on this a little bit, but please elaborate on the statement as to why institutional volumes have been questioned specifically?

THE WITNESS (Warshofsky): I just want to make sure that I understand the question. Are you asking whether I believe that 200 number is relevant, important? Or are you asking a different question?

MR. CARNEY: Yeah, the statement was that basically that 200 number is sort of being questioned in some recent years in the literature, that it may not be the number, the appropriate number.

So I just wanted you to follow up on that, you know, your opinion about that.

THE WITNESS (Warshofsky): Sure.

A VOICE: Excuse me, Mr. Carter. Just before Dr. Warshofsky answers. I didn't catch the page reference.

MR. CARNEY: Page 7. Sorry, page 7.

A VOICE: Of the application?

MR. CARNEY: Page 7 of the prefiled testimony.

THE WITNESS (Warshofsky): Yeah. So again, I think Dr. Lomnitz pointed out that that -- that number is a number that is not based on randomized clinical trials, or really any clinical trial per se trying to look at that.

The strength of the relationship between volume and outcomes really was much more -- was much stronger in -- in the, what we call the plain old angioplasty era where we didn't have coronary stents. Since that time that relationship really has been, I would say, weakened and questioned much more.

And when -- when you think about it just in terms of common sense, if you will, to think that a program that's doing 190 PCIs is, you know, materially worse in quality than a program doing

205 PCIs, it just, you know, goes against common sense. Right?

We -- we all know that quality is related to many more things than any absolute number. So although, again in this stage of looking at our volumes and through, you know, the exercises that we've been through I'm confident we will exceed that number, but I think that number really does need to be taken a little bit with a grain of salt.

MR. CARNEY: And one final question, Doctor. How do you describe sort of the relationship between operator and institutional volumes? The two do different thresholds. How do they interrelate?

THE WITNESS (Warshofsky): You know operator volume, the numbers for recommended volumes have been decreasing over the years. I think you've heard the recommended volume for PCI operator on the most recent recommendations is 50 per year.

MR. CARNEY: Fifty, agreed, 50.

THE WITNESS (Warshofsky): Yeah. It used to be 75. The -- the two go hand-in-hand to some degree in that, you know, the -- the volume data for operators is relatively weak when it comes to looking at any specific number, but we do know

that there is a weak overall directional association.

Our physicians who are working in our STEMI program in Norwalk will certainly maintain those minimal volumes -- and I'm thinking offhand. I think all of them will be working at fairly high-volume centers in addition to Norwalk Hospital.

MR. CARNEY: So the Danbury, too, with the library?

THE WITNESS (Warshofsky): Danbury and other centers as well.

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

THE WITNESS (Warshofsky): You're welcome.

MR. CARNEY: I think that's all I have, Michaela.

THE HEARING OFFICER: Okay. Let's see here. So page 8 of the prefiled testimony states that the ability to offer elective PCI at Norwalk Hospital will reduce the cost of care by eliminating unnecessary transfers and enabling timely medical interventions.

How will this affect overall healthcare costs and consumers' out-of-pocket costs.

THE WITNESS (Warshofsky): I -- I may ask to phone a friend on this one, but I will just say this. You know, that certainly when we think about length of

stay for a patient, when you think about them coming into a hospital and then getting worked up, and then the decision is made to transfer them. And then they're getting reworked up at the receiving hospital and getting put on for the next day for cardiac catheterization, I think we can all see how that increases the overall length of stay in -- in any particular hospital for that patient.

The cost of an ambulance ride with EMS services I think is significant, and you have to add that onto the, you know, the equation in terms of cost for our healthcare system. And you've got to backfill that EMS service for a patient who may need it.

And so we're -- we're kind of overall increasing the cost of care throughout many things. There's a lot of ripple, ripple effects and unintended consequences, as -- as with a lot of things.

I'm going to see if Dr. Murphy has anything to add to that?

THE WITNESS (Murphy): Thanks, Mark. I do think that was a comprehensive answer, and an excellent one. The only thing that I would add, Hearing Officer,

is that once again you have to recognize that we, let's say, within our system have worked very hard, A, to come to an agreement with the payer, whomever that payer might be, Medicare or commercial payer or even potentially Medicaid and say, listen. We're responsible for the entire episode of care from soup to nuts.

We have coordinated who's going to do what in what sequence, what tests will be done, which tests won't be done.

And to the extent -- to the extent that we've spent more than we've agreed to, the onus is on us. That's a problem for us that there isn't this notion that, well, it's not my problem. It in fact is.

And to the extent that we can generate high-quality care cost efficiently, everybody wins. When the patient is transferred out of the system there is no -- there may be no such relationship and the receiving hospital can do what it wants, follow a different protocol. And again, having transferred lots of patients for many years, what inevitably and unfortunately happens is the tests get repeated oftentimes.

Somebody says -- at least in my field, you

know what? We can't find the film. Or these MRIs don't run on our machines, or I can't find the software. So just run the -- the MRI again, or -- or do the EKG or do the echo. Or do whatever the particular imaging study is, or let's rerun the labs.

Or as Dr. Warshofsky said, you know, that was yesterday. We were booked. It was a late case. We didn't realize it was Friday. All of the sudden now it's Monday morning, and the renal studies, the renal functions have to be repeated.

So there is this inevitable result, in my view, that tests get repeated that otherwise would not have been repeated, that the patient now is at an institution that may or may not be part of his or her insurance plan, and he or she is now responsible for significant bills where they were under the impression that if they had a heart attack, God forbid, that they were covered.

Not only do they then have to then contemplate the issue of the facility itself may be out of network -- and I don't have out-of-network coverage, but so too may the doctor or the doctors, plural, that that entire team is going to have the opportunity to bill that

patient.

All of those services would have been covered on the bundled contract that existed at the home institution. None of those services are going to be covered potentially at the receiving institution if it's a transfer.

So the consequences, the financial consequences are substantial to the patient no matter what kind of insurance they have, if it's a nonparticipating provider both in terms of coinsurance, co-pays, maximum out-of-pocket expenses.

And that's the reason so many companies in America, and for that matter, the State of Connecticut itself has spent so much time and reached out to so many healthcare providers to say, listen. We want you to sign up for these bundles of care so that we can begin to control costs while improving outcomes.

We as a health system have subscribed to that. That's not equally true across the county, or for that matter the State, but we believe it's -- it's our responsibility as providers to try to contemplate and coordinate cost-efficient high-quality care, and transfers fly in the face

of that effort.

THE HEARING OFFICER: Thank you for that. Just a follow-up question. So you've explained it to me so that at least I can understand how, how this could increase costs.

But is there a way or have you been able to quantify the cost savings that would occur if these transfers were eliminated?

THE WITNESS (Murphy): Well, it would be difficult for -- for me to sit here, because as you know I don't have the access to free schedules of other institutions.

But I can tell you that from the payer's perspective, that payer being either the state government, the federal government, or the employer, they're all migrating to -- to this notion either of saying, there's going to be an accountable care arrangement where they call it the Medicare shared savings program, as you know, or the next generation ACO; or what is becoming even more popular, the bundled payment coordinating care initiative out of Medicare did it.

We participated in 22 of those bundles. Now the commercial market and the employers are moving

more and more to these episodes of care because they have found that's where most of the expense lies. When somebody gets really sick and needs these life-saving but expensive interventions, it's very important that the care be coordinated.

So they have told us basically by virtue of having to pay the bills that this is where the savings are. These have to be priorities, and given the fact that cardiovascular is the leading cause of death we feel it's incumbent upon us to be responsible and to be able to offer bundled cost-effective, high-quality accessible services to people that live in our area including those who have no insurance whatsoever.

Again, I can tell you having sent lots of patients to some quaternary centers, if you don't have insurance you're out of luck when you try to go someplace else.

THE HEARING OFFICER: Thank you. All right. I think that is it for that question. I do have another question. Let's see here.

So I think we asked this. I was listening to Dr. Warshofsky's testimony and I think that he was talking about -- and Brian, my colleague Brian Carney may have touched on this -- but I just want

to make sure that I've got it.

So I think that there was a discussion of a four-to-one kind of ratio used to determine or project how many PCIs might be needed. And I think I wanted to ask Dr. Warshofsky if there's any literature that goes along with that? I think Brian may have asked you this, but I didn't cross it off my list.

THE WITNESS (Warshofsky): Yes, he did. And I -- I mentioned our own, you know, New York State -- sorry, not New York state. Connecticut's data, the NCDR data that was presented earlier.

THE HEARING OFFICER: Yeah?

THE WITNESS (Warshofsky): With several of our hospitals throughout the Norwalk/Southern Fairfield County area. And also if we look at that Seaport trial, that mentioned I believe an eight-to-one ratio.

And I think that that has -- that that ratio has come down somewhat over time, but even today using, whether it be Stamford's numbers or Danbury's numbers, we know that that ratio is -- is around four to one and sometimes higher.

THE HEARING OFFICER: Okay. Thank you for that.

And then I think the other question that I

had for you is if there's any data that you could share with us about how COVID has impacted the ability to transfer patients out of Norwalk to other hospitals who may be requiring elective and you can't perform it there?

THE WITNESS (Murphy): Yeah. So you know, I cannot give you specifics about the transfers out of Norwalk Hospital for elective PCI during COVID. What I will say about COVID is that, as you know, patients have delayed coming in for acute problems, and a lot of those acute problems were heart attacks. We received patients much later on in their disease process.

I think that the notion to a patient who did, let's say, decide to come in during COVID, the notion of saying to them, okay. Well, you know, you were -- you got over your fears of coming into a familiar hospital, but now we're going to transfer you away from your family to a less familiar hospital, or a completely unfamiliar hospital -- I think would not go over well.

And -- and again, I want to emphasize also how incredibly busy the hospitals were throughout the state during COVID. And the thought of taking transfers during that time was daunting because

everybody is running on fumes taking care of very, very sick patients.

And the thought of then admitting a transferred patient and going through all their data all over again is -- is just horribly difficult to think about doing during that time.

THE HEARING OFFICER: Okay. And just a followup? Do you believe that where the hospitals were, there was a surge and they weren't able to take patients as readily as they would pre-COVID? Do you think that that's something that's might be an anomaly? Or something that's ongoing?

THE WITNESS (Murphy): Oh, I think it's ongoing. I think that, you know, I'm not an infectious disease or epidemiologist, but I -- I do know that we are not through this pandemic yet, that we are seeing hospitalized patients still.

We're seeing very sick hospitalized patients, and so I think it is an ongoing problem. I don't know what we're going to be facing next year as it relates to COVID, but I certainly wouldn't be surprised if it was affecting our healthcare system in some way.

THE HEARING OFFICER: Okay. Thank you for your responses.

I have a question for Dr. Lomnitz. So Dr. Lomnitz, you indicated that there is an underutilization of PCI, that about 30 percent of the people who need it don't get it.

30 percent of the people who are appropriate don't get it. And I just wanted to understand if that 30 percent, how does that relate specifically to Norwalk Hospital's primary service area? Was that just kind of like a national percentage?

THE WITNESS (Lomnitz): Yeah, that's a good question. That -- that's -- those studies, and there's lots of studies that are concerned about underutilization of care that can improve people's lives and decrease mortality, and PCI is certainly one of them.

Those studies are based nationally and that's -- that's, you know, we have to assume until proven otherwise that we're no different. And what was -- I hopefully highlighted was the concern that people whose primary hospital do not have elective PCI are more likely to be underserved compared to those that do go to hospitals that have elective PCI capability.

THE HEARING OFFICER: Okay. Thank you. I think that that is all the questions that I have for the

Applicant. I did have a few follow-up questions for the Intervenor's witnesses.

Thank you, Dr. Lomnitz.

THE WITNESS (Lomnitz): Thank you.

THE HEARING OFFICER: So the next couple of questions are for Dr. Martin, if he's still available?

MR. MONAHAN: He is.

THE HEARING OFFICER: So Dr. Martin, you testified that update in the numbers, the volume numbers or projections by the Applicant were -- and I'm quoting you, hard to swallow.

What do you mean by that?

THE WITNESS (Martin): I mean, I'm sure they took great care in making this application, and they had plenty of time to do it. And then to update the numbers based on a brief uptick in primary PCIs just seems spurious to me.

THE HEARING OFFICER: What do you mean by when you say, brief uptick?

THE WITNESS (Martin): So that there, they list their numbers for primary PCI from 2016, '17, '18, '19, '20. And typically those numbers are 60 to 70.

And then based on partial year having a few more primary PCI than other years, they upped their estimate. I think based on partial numbers

fiscal year 2021 I believe they estimated 80-some for PCIs based off a partial year.

And then based on that you use this multiplier that really there is no literature about it. You know it is true that nationwide, you know, back in the Seaport time this eight-X multiplier was typical nationwide, and now it's more like three or four times as many nonprimary, you know, elective PCIs as there are primary PCIs nationwide -- but that varies widely by institution.

It's driven by -- by practice patterns where facilities that get outside referrals, or people choose to go there. Tertiary centers will have a much higher number of elective PCIs.

For example, Cleveland Clinic publishes their numbers every year, and it's typically 25 to 30 times as many elective PCIs as primary PCIs.

Whereas other centers that are not referral centers where people are not choosing to go to, the number may be much lower. And nationwide the average, it is about 4 elective PCIs per primary PCI.

THE HEARING OFFICER: So you said that -- I believe and correct me if I'm wrong. I think you said since

2003 there were studies that showed elective PCI is over utilized, that you know practitioners are doing too many.

Can you elaborate on that?

THE WITNESS (Martin): Sure. You know, the appropriate use criteria were established by CMS mainly as a response to an understood overuse of primary PCI. In the American Heart Association's -- what's it called?

A VOICE: Choosing wisely.

THE WITNESS (Martin): Choosing wisely program. They actually, you know, how to take elective PCI as something that's over utilized. There were a couple of big trials that I think I mentioned in my written testimony that show that for -- for a lack of PCI patients who are not in the hospital with a heart attack, that for most of those patients medical treatment was just as good as PCI in terms, of, you know, and then we like to say that PCI is a life-saving procedure. I would like that to be true, and sometimes it is.

If you come in with a heart attack, we open your artery. It's a life saving procedure. It dramatically improves your rate of survival, but if you're seen in the office and have a stress

test and have some chest pain, we bring you in, do PCI, and that's what a lot of these patients are.

It doesn't, you know, in -- in the big studies it did not show improvement in survival. And even in terms of symptom improvement was not significantly better than medicines alone.

THE HEARING OFFICER: When you say, medicines alone, is that what you mean by medical treatment?

THE WITNESS (Martin): Correct.

THE HEARING OFFICER: Okay. And one other thing -- actually, not one other thing. So there was another thing that I heard you say that you know in terms of PCI, that we're in a stagnant market.

What do you mean by that?

THE WITNESS (Martin): You know, so that nationwide the number of PCI is actually, you know, despite a growing population it's not gone up over the last 5 to 10 years at least.

I don't -- I don't have the numbers in front of me, but you know, it peaked some years ago. And you know, all the projections, you know, from -- from the consultant groups and the nationwide numbers are that there's not a significant increase year over year. That the numbers are basically flat to slight decline over

the years.

And a lot of that is driven by this, you know, this understanding that PCI may have been over utilized in the past.

THE HEARING OFFICER: All right. And then the last question for you is that, you know I've heard a lot of discussion about giving the different factors and the guidelines the appropriate weight. And so whether the Applicant is going to be very close to 200, over 200, there, there it sounds like their argument is there are also other things also to consider in terms of a quality program that OHS should look at and focus on when making the decision.

And so I heard you say you talked about how the guidelines indicated previously that the threshold institutional volume was 400; that was reduced to 200. It hasn't been reduced since then. So it's just like the guide. You know I'm just trying to understand so that I can make a recommendation to the Executive Director about how she should go.

And can you just explain for me why? Why? Why is the 200 operator volume threshold? Why do you believe, or based upon what you've read, why?

Why should we stick with that hard and fast?

THE WITNESS (Martin): So I -- I don't think a number set in stone. You know, you, you're balancing reality versus, you know, what's optimal. And I think what might be optimal would be, say, a thousand -- you know might be a better number, honestly.

You know, if we all did 200 PCIs per year per operator and a thousand in the center, you probably would get, you know, better outcomes than what's available right now, but that's not the reality in the US.

It is in some other countries, but here that, you know, we -- we train more in retro cardiologists. We have hospitals all over the place that decide they want to have a cath lab. You know, we have to, you know, the states, they have to -- I have to, have to just deal with reality.

And so I -- I think it's with that compromise what our societies have come up with is that 200 is a good number. I think clearly ten is not a good number, no. I think in, you know, in 400 it can even be too high because it was unreasonable and that no, you know that not enough places would

meet it.

So you know, could -- could that number be 150 or 250? I, you know, I don't think there's any magic about the number, but it's -- it's a parsing reality with what's -- what's optimal in terms of patient care and patient outcomes.

MR. CARNEY: This is Brian Carney. Just to chime in Dr. Martin? By 200, you're speaking specifically about institutional volume. Correct?

THE WITNESS (Martin): Yeah, that's -- that's, you know, what our guidelines suggest, is -- it's the reasonable number to use and it was a minimum.

MR. CARNEY: Okay, thank you.

THE HEARING OFFICER: All right. I don't believe I have any additional questions. I'm going to defer to Jess, Jessica Rival.

MS. RIVAL: Good afternoon. My first question is for Dr Warshofsky.

Hi, Doctor. On page 45 of the application there are some assertions about the Cleveland Clinic. Could you give us some detailed examples to explain how Norwalk Hospital's affiliation with the Cleveland Clinic will affect cost and quality measures related to the proposed elective PCI services?

THE WITNESS (Warshofsky): Sure. So as you know, and as was mentioned earlier, the Cleveland Clinic is -- is really regarded as -- as essentially the top cardiovascular institution in the country, and probably the world. They do thousands of interventions per year.

And what we've established with them is a very close affiliation in Danbury Hospital after a programmatic assessment. And that programmatic assessment is currently ongoing in Norwalk Hospital, and that will lead to an affiliation with the Cleveland Clinic as well.

That program is -- is one that focuses on quality, and it's a collaborative effort. It will be a collaborative effort between Norwalk Hospital and the Norwalk Hospital Cath Lab staff, and the Cleveland Clinic staff. It goes beyond just physician relationships and physician interactions. It -- it goes to nursing and operational leader interactions.

And it really covers everything from things like, what are the best care pathways for patients? What are the best order sets? How can you decrease, decrease costs by opportunities in the supply chain? How can you decrease costs by

maintaining high quality, lowering adverse event rates, which can lead to prolonged hospitalizations?

Discussing cases with the Cleveland Clinic, and deciding what might be the best approach for a particular patient; in the unfortunate circumstance of an adverse event, reviewing those cases with the Cleveland Clinic so that we can get their insight into what they may have done differently, or just get their insight into what -- what their thoughts were on the case.

It -- we -- we have regular meetings with them where we look at case reviews, as I mentioned, but also compare ourselves to the Cleveland Clinic. They actually generate a report card for us that looks at our data and tells us really how we're doing compared to the Cleveland Clinic.

So it's -- it's a constant effort and focused with them. And again, it goes beyond just the physicians. It -- it certainly includes the physicians and that's a major focus, but it -- it really encompasses the whole episode of care, you know, and care across the continuum of cardiovascular disease. The cath lab and PCI

programs are obviously a huge focus of that.

MS. RIVAL: Thank you very much. My next couple of questions are actually for the Intervener.

The first one is the applicant states on page 15 of the application that Norwalk Hospital's primary service area includes the towns of Norwalk, Westport, Wilton, New Canaan, and Weston, Connecticut.

Are these towns covered by Stamford Hospital's cardiac program?

THE WITNESS (Bailey): I guess -- at this point, Jess, I guess it's good evening. We're now past five o'clock. So it's gone from good morning to good evening.

So I can address that. So to make sure I heard your question correctly, Jessica, is that you're asking if those five different towns listed as the Norwalk service area, whether we consider those in our overall service area?

MS. RIVAL: Correct.

THE WITNESS (Bailey): We do. We look at both service areas as primary services -- service area as well as our secondary service area based on where patients do seek care from Stamford.

So when we look at the service area of

Norwalk for sure, and then secondarily as we go out a little bit further.

MS. RIVAL: My next question is, do you have at your disposal the numbers as far as how much Stamford Hospital's PCI volume is derived from these towns?

THE WITNESS (Bailey): I do not have that at my disposal. You're asking how many PCI volumes that we get from the different, those five different towns? I don't have that readily available.

I'm sorry.

MR. MONAHAN: We certainly can provide that in a late file, if OHS would like that?

MS. RIVAL: Yes, please.

And lastly, does Stamford Hospital have the capacity to perform additional PCIs at this time?

THE WITNESS (Bailey): And Jess, that's a great question and we appreciate the opportunity to address that.

I'm sorry. We've got some team members coming in. Sorry. We're going to lock one of the doors here real quickly. Sorry about that interruption.

But your question was, do we have the capacity to continue to grow? And we do have the capacity to continue to grow. As I mentioned in

my comments, we do have that ample capacity as we looked at our ability to continue to expand and meet whatever needs are within the community.

We've evaluated that and would certainly be able to satisfy any appropriate needs.

MS. RIVAL: Do you know about how many additional PCI's could be performed, say, at Stamford Hospital in a given year?

THE WITNESS (Bailey): I would probably defer to my colleague Dr. Martin to more specifically address that, if he has that information.

MS. RIVAL: Sure.

THE WITNESS (Martin): Sure. So with current staffing and facilities, you know, we can certainly increase PCI volume by 50 percent. We could do that without a problem, and potentially more if we have the space to grow if we needed to in the future.

THE HEARING OFFICER: Just for the clarity of the record, 50 percent of what?

THE WITNESS (Martin): So our current volume last fiscal year was 300 and --

THE WITNESS (Bailey): 380, something like that.

THE WITNESS (Martin): So that's 190 -- so another 190 per year I think would easily be doable with

current staffing and the facilities.

MR. CARNEY: Yes, 388 is the total for '20, FY '20.

MS. RIVAL: Okay. Thank you very much.

THE HEARING OFFICER: Dr. Martin, can I ask you one other question? When you were giving your testimony you also said that you had to maintain a minimum threshold of 300.

Can you explain more about that?

THE WITNESS (Martin): Sure. I -- I think Jonathan mentioned that, but --

THE HEARING OFFICER: Oh, it was Jonathan? Okay.

THE WITNESS (Martin): But anyway, I can speak to that. The CMS rules for having a TAVR program. It's a transcatheter aortic valve replacement which is a valve replacement procedure that we do; require, you know, a higher volume than -- than just continuing to do PCI, because it's a specialized procedure.

And -- and that 300 per year volume is -- is required to be paid by CMS for the -- for the valve procedure.

THE HEARING OFFICER: Overall, 300?

THE WITNESS (Martin): 300 PCIs yearly, correct. And then are also -- there are a number of other requirements, like how many of the TAVR procedures

you do and certain staffing and -- and equipment resources.

MR. CARNEY: Can I just ask a followup? This is Brian Carney. So Doctor, what happens if you fall below that 300 minimum?

THE WITNESS (Martin): Well, the risk would be that you would stop getting paid into the TAVR procedures and effectively have to shut down the TAVR program.

You know, I don't think we would be under any scrutiny right now for the volume because of COVID, but if going forward we were routinely less than 300 we would risk losing that program, and the, you know, the ability to treat the patients locally with TAVR.

MR. CARNEY: Great. Thank you.

THE HEARING OFFICER: This is the last question for you, Dr. Martin, I promise.

What is the TAVR program?

THE WITNESS (Martin): So the aortic valve is the valve that lets blood out of your heart when it pumps out to your body.

THE HEARING OFFICER: Yeah.

THE WITNESS (Martin): And it's pretty common as you get older the valve stiffens up, and in some

people it narrows and -- and fails, and that can be deadly. And historically that would be treated by cutting the chest open, cutting out the valve and replacing it with a new valve.

Over the last 15 years a procedure where that's done from the inside, you know, going in through the groin and taking a new valve to where the aortic valve is and replacing it from the inside. Basically the new valve crushes old valve out of the way and pops open.

It has become the preferred treatment for most patients with aortic stenosis, the newer valve there. And you know, we -- we started the program here just shortly before I got here six or seven years ago, and then it's had significant growth over the last several years.

THE HEARING OFFICER: All right. Thank you.

MR. MONAHAN: (Unintelligible.)

THE HEARING OFFICER: I'm sorry. Go ahead, Attorney Monahan.

MR. MONAHAN: Sorry to interrupt, if you were about to speak, Ms. Mitchell.

THE HEARING OFFICER: That's okay.

MR. MONAHAN: My oversight, but in one of your questions about the cardiac issue -- and I can't

exactly -- saw the two shoulders move. It was Dr. Martin and Dr. Bhalla, and I do believe Dr. Bhalla had a responsive statement to make in response to one of your questions.

Would it be possible that he could address it? He remembers the question -- if he can address it for you?

May he have permission to come to the table?

THE HEARING OFFICER: Oh, yes. I thought he was coming. Yes, that's fine, Dr. Bhalla.

THE WITNESS (Bhalla): Hi. It's Dr. Bhalla. I just wanted to follow up on my colleague Dr. Martin. You mentioned -- talked about the 200 criteria, that question you asked, had asked about. And I just wanted to reiterate that in terms of that number, for any quality and safety parameter, procedural parameter, some cutoff does have to be chosen.

And i just do want to reiterate from the guidelines that what's written in those guidelines that we've talked about from 2013, it's in operational labs performing less than 200 procedures annually that are not serving isolated or underserved population. The question, and that any laboratory that cannot meet satisfactory

outcomes should be closed.

And their rationale from a quality and safety perspective is that that was the number that was consistently associated with -- with worse outcomes.

And to the point that was raised that Dr. Martin brought up choosing wisely which I had mentioned in my testimony, I think it's noteworthy that the single practice that the Society for Cardiovascular Angiography mentioned put forth for potential inappropriate utilization is the statement in their Choosing Wisely campaign, which is avoid PCI in asymptomatic -- asymptomatic patients with normal or only mildly abnormal or adequate stress test results. And they put that recommendation for this part of the Choosing Wisely campaign.

We've been talking about the timeframe of the guidelines from 2014. This was put forward by the SCAI in 2014, but in this kind of period that has come after 2014 they've reiterated this statement in 2016 and they reiterated it again, in 2018 just to underscore the potential for over or inappropriate utilization.

THE HEARING OFFICER: Thank you, Dr. Bhalla.

All right. I don't think we have any more questions from the agency.

Double checking, Brian and Jessica, nothing else? Okay. Everybody shaking their head, no. All right. So thank you.

All right. So I'm just going to ask is there anybody here that wants to give public comment?

(No response.)

THE HEARING OFFICER: All right.

Leslie, did anybody sign up? I just want to make sure we're not missing anybody.

MS. GREER: No, Michaela. Nobody signed up.

THE HEARING OFFICER: Thank you. Okay. So what I'm going to do with regard to public comment is I'm actually going to leave the record open.

I usually leave it open only for a week, but in this case I'm going to leave it open for two weeks, because I'm going to ask for some information from both the Applicant and the Intervener in the form of late files.

So anyone who wants to submit public comment, if you know somebody that wants to submit public comment and they haven't done so, they can do it

in writing. That would need to be sent to the Office of Health Strategy. I believe that the e-mail address is CONcomment@CT.gov.

Did I get it right, Leslie?

MS. GREER: It's actually OHS@CT.gov.

THE HEARING OFFICER: Oh, it's OHS@CT.gov. Say that again for me, Leslie?

MS. GREER: OHS@CT.gov. We would get it either way at the CON, but we've tried to eliminate that mailbox.

THE HEARING OFFICER: Oh, my goodness. And I keep resurrecting it. Okay. Thank you. All right. So anyone who wants to submit public comment can do that by May 6th.

So in terms of late files, I just want to go over that and one other thing, and then I'll let both the Applicant and the Intervener make closing statements.

In terms of late files for the Applicant I wanted you to provide to us the methodology for your updated volume projections, including data sources and calculations. So just kind of explain that to us so we can understand how you came up with them, and that would be for the next three fiscal years.

And then for the Intervener information that we would be looking for from you are the number of elective and primary PCI procedures derived from Norwalk's primary service area for the last three fiscal years.

Let me just -- I'm going to go ahead and turn to Attorney Tucci for a timeline for a production of the methodology. Is a week okay?

MR. TUCCI: Yeah. Attorney Mitchell, if I could just ask for ten days? I have some other conflicts and commitments.

THE HEARING OFFICER: Got it. Okay. So you want ten calendar days?

MR. TUCCI: Yes, please.

THE HEARING OFFICER: Okay. Let me just look. That date is going to be what day here? Let me just pull up my calendar.

All right. So we are at the 22nd. The ten-day mark is going to be on May 3rd. Is that okay? Did I get that right, everybody.

MR. TUCCI: Yes, thank you very much. Appreciate that.

THE HEARING OFFICER: And then also Attorney Monahan, are you going to be able to get your information in by May 3rd?

MR. MONAHAN: Yes.

THE HEARING OFFICER: Okay. And then what I'll do is I'm going to give both the Applicant and the Intervener a week to send a reply to the information that's submitted to OHS.

So if there's anything that you wanted to note with regard to the submissions, you're going to have an opportunity to do that. So that is going to be due on a week from May 3rd. So that's going to be due on May 10th.

Is that enough time for everybody? I don't want to get anybody in a jam.

MR. MONAHAN: It's fine for the Intervener.

MR. TUCCI: And yes for the Applicant.

THE HEARING OFFICER: All right. So I'm going to go ahead and correct myself, too, that we are going to leave the record open to May 10 -- that any public comments that people want to send it.

One other thing, since we're looking at a lot of data I wanted to take notice of the all-payer claims database and the OHS in-patient discharge database.

We do run numbers from that sometimes when we have applications for PCI. If there's anything new that we're going to introduce, we're also going to give counsel the opportunity to make

comment on anything that we propose to add to the record.

So we just want to make sure that we double check the numbers and look at it from what we have in-house. Sometimes it may not be the most up-to-date data, but we're utilizing more of our data as much as we can to take a look at what we're receiving from applicants who are going to do that as well. So I'll just go ahead and take notice of that.

Is there any objection from counsel on that? As long as I give you guys an opportunity to reply or respond to any data that we want to submit, we want to include into the record that we generate in-house at OHS.

MR. TUCCI: On behalf of the Applicant, that's perfectly fine.

THE HEARING OFFICER: Thank you, attorney Tucci.

MR. MONAHAN: No objection from the Intervener.

THE HEARING OFFICER: Okay. All right. So at this time I'm going to go ahead and ask counsel for the Applicant and for the Intervener to make closing statements. So because this is the Applicant's -- because it's their application, I'm going to ask the Intervener to go first and then the Applicant

to have the last set of comments.

So Attorney Monahan, if you wouldn't mind going first?

MR. MONAHAN: Certainly, and I appreciate that.

And you've heard a lot today. We have all have heard a lot today, and read a lot. I'm just going to make some brief summary comments.

On behalf of Stamford Health, Inc, I think what I would like to just impress upon the Hearing Officer and the OHS staff is that we believe that this, we are in a period of time where we have to take stock in the fact that we are a CON state. We have CON statutes, and we have them until we do not.

I know that there is talk and there has been testimony about different variations of the views of quality and cost, and so on, but the principles and guidelines of the CON statute are what we are bound by -- and indeed what we submit, as you know full well, OHS is considering, and considering well and thoroughly as it hears all this information.

We believe that the desire of -- especially as we become, and candidly, a system, a state -- a state that has more systems than smaller community

hospitals -- we think it's important as was made clear by our CEO that the desire of a system and even the desire of a patient to be close to home, or to be close to their favorite hospital does not necessarily and does not in fact constitute one of the core principles, which is unmet need. And we think that we have to, in this kind of setting, go to the core principles of our CON law, one of which is unmet need.

I do not think there was one person on either side of the table here today that acknowledged that there is a lack of access of elective PCI. There are a number of hospitals that are able to provide that with full surgical backup and so we believe that one of the cornerstones of CON is not met in this case.

The second thing is, in the event that this application was granted it may be sort of a natural followup to what I just said, but it would be a duplication of a service that is already being provided and satisfying of a need. And as you've heard from witnesses, there is plenty of additional capacity or access.

I believe whether one calls it access or capacity, we may be dealing with semantics. The

point is, can the service be provided to the people who need it with the highest quality care possible? And there has been no evidence submitted by the Applicant that that is not the case. We are a system in the state for elective PCI where we can provide high-quality service to all who need it.

The third thing I'd like to raise is just clearly -- and again, as a core principle we're always dealing with providing the best care possible for all of our residents in the state of Connecticut, and quality is an important issue. Now for that reason -- and I think, you know, focusing back on what Dr. Bhalla has emphasized, while we have a number -- and it's becoming the nature of medicine.

I heard actually testimony from the Norwalk people about how the study of medicine is accelerating and there's new things happening all the time, which really highlights the point that Dr. Bhalla was saying, is that we need to have experts come to consensus to reach agreement on a best practice.

And again, not being a clinician, when I was given examples as I prepared for this about how

best practices formed things like when women should get mammograms every year, when people should start getting colonoscopies, what the best practices are; the fact that we start with best practices, yes, they may change over time, but in this case the best practice is unanimously recognized.

Even though there's poking at it and examination and debate, the best practice in place is that 200 minimum PCI volume for the facility. And we believe to go below that is to lean toward less optimal care and worse outcomes based on those three expert consensus studies.

The other thing I would like to point out is that I do believe -- and I appreciate there will be late files in this. I do believe that there is a distinction between empirical scientific study that projects numbers that are real, especially numbers that are real in connection with a declining market, whether we look locally, statewide, or nationally in the elective PCI world.

And what I believe has happened in this application -- and this is, again no disrespect to anyone involved, but there is no evidence that the

mechanism to come up with these projections that were well below the 200 benchmark, and now suddenly many more above -- it has no empirical basis that we have seen.

And we do not think an off-the-cuff estimation is the way to somehow get past this critical quality requirement.

So in closing, what I'd like to just suggest and say is, number one, we appreciate the fact that we have had the opportunity to present a very full hearing. We appreciate the fact that the Office of Health Strategy has heard testimony, and I'll daresay heard counsel who have I think both vigorously tried to represent their clients and allow as much information in as possible.

I would as a last point state that in being consistent with the Office of Health Strategy charge under the CON laws we feel strongly that that statewide healthcare and facility plan has meaning.

It has precedent. It has been used and relied on, and while others -- and I believe Dr. Murphy did, in fact, point out that there may be task forces looking at things, and of course that's natural. There is a study and a facilities

plan that took a long time to put in place. It is still consistent with the consensus expert report that is in place, and we believe it should be honored.

So for those reasons I thank you for the opportunity to present to you this closing remark, and I appreciate the fact that you allowed our witnesses to testify as fully as you did.

THE HEARING OFFICER: Thanks Attorney Monahan.

Attorney Tucci?

MR. TUCCI: Thank you, Hearing officer Mitchell.

It's been a long day, and I want to say this. On behalf of Norwalk Hospital as the Applicant, we appreciate the extraordinary patience of you as the Hearing Officer and of OH staff in allowing a full area of this hearing.

The second thing I want to say is, we're going to keep our remarks in closing very brief, especially in light of the fact that we've been here so long. And I think the last thing that you need to hear is more lawyer argument from me about statutes and magic numbers, and all this other stuff.

So I'm going to cede a very brief amount of time to Dr. Warshofsky who's going to actually

tell you about what's really going on on the ground in medical science, which I think is really the most important thing for OHS to consider in this application.

THE WITNESS (Warshofsky): I want to thank everybody for their time. I certainly appreciate it.

I want to first say, just if it helps, based on 2020 it looks like a little less than a tenth of patients that had PCI at Stamford Hospital came from Norwalk, from the city of Norwalk. So hopefully that helps.

I really want to bring this back to the patients. We've talked a lot about data. We've talked a lot about laws and CONs, and all that, but I do want to bring this back to the patients. And we know that providing PCI without cardiac surgical backup, which is really an antiquated term even at this point, is safe.

We know it's safe and we can quibble about 190 versus 210, but I do feel that we have the expertise in our system to provide this care, particularly with a partnership with the Cleveland Clinic safely and efficiently, and with high value for patients.

I think that when we, you know, I would not

trivial -- trivialize the transfer of patients and what it means to patients and their families. You know, we say, okay. It's only, you know, 10 miles away to this institution, or -- or 20 miles away to that institution. Many of our patients' families take public transportation.

To think that they can just all of the sudden hop over to another hospital to be with their family member is, I think, you know, not really seeing what's happening on -- on the ground, and in terms of those who are -- who are caring for patients on the front line and what they're seeing.

And I think when we think about what we've been through over the past year with COVID and looking into going into potentially another season with variants and -- and vaccines not being as effective maybe as we'd like them to be, the thought of transferring patients between institutions is frightening.

At worst -- I mean, at best, you know, transferring a patient is inconvenient. At worst, it can lead to medical errors, and certainly redundancy of care and increased costs.

I think that our STEMI patients, whether it's

65 or 80 per year, whatever that may be, you know, these are patients who have come to know Norwalk Hospital, not because of any marketing campaign or anything like that. They've come to Norwalk Hospital because they have really presented with life threatening -- a life threatening episode, a heart attack that needs emergent care, and we provide that care for them.

The thought that we could not care for patients who come in with unstable coronary syndromes that do in fact need urgent care, it just doesn't make really any sense at all at this point. And I think that those patients are coming here with a STEMI who know that this is the closest place for them, who know that this is their community hospital; really speak volumes and really say to us that there is a need in our community.

And whether it's a 4-to-1, 6-to-1, 20-to-1 ratio, that our volumes for PCI are going to be more than adequate to meet the standard. So again, I -- I want to bring this focus back to the patients, back to our community because I really do think that those patients deserve to have this program at their hospital, at Norwalk Hospital.

So thank you.

THE HEARING OFFICER: Thank you. So just in closing, I just want to thank both the Applicant and the Intervener for presenting all of the testimony today, and I also want to thank OHS staff.

We're going to leave the record open for the receipt of the late files and the replies, and also any public comment. I hope that everybody has a great day and we will be in touch shortly.

Thank you.

(End: 6:04 p.m.)

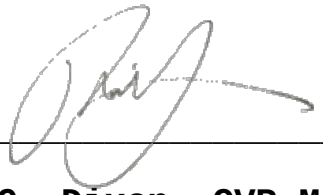
STATE OF CONNECTICUT
(Hartford County)

I, ROBERT G. DIXON, a Certified Verbatim Reporter, and Notary Public for the State of Connecticut, do hereby certify that I transcribed the above 291 pages of the STATE OF CONNECTICUT OFFICE OF HEALTH STRATEGY PUBLIC/ADMINISTRATIVE HEARING, in Re: NORWALK HOSPITAL ASSOCIATION CERTIFICATE OF NEED, APPLICATION TO ESTABLISH ELECTIVE PERCUTANEOUS CORONARY INTERVENTION SERVICES, "PCI," AT NORWALK HOSPITAL, on April 22, 2021, via teleconference.

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; and I further certify that said deposition is a true record of the testimony given in these proceedings.

I further certify that I am neither counsel for, related to, nor employed by any of the parties to the action in which this proceeding was taken; and further, 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 and seal the 27th day of April, 2021.



Robert G. Dixon, CVR-M No. 857

My Commission Expires:

6/30/2020

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