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1 {York Stenographic Services, Inc.}

2 HIF057.140

3 HEARING ON ``MEDICAL RADIATION: AN OVERVIEW OF THE ISSUES''

4 FRIDAY, FEBRUARY 26, 2010

5 House of Representatives,

6 Subcommittee on Health

7 Committee on Energy and Commerce

8 Washington, D.C.

9 The Subcommittee met, pursuant to call, at 10:03 a.m.,

10 in Room 2123 of the Rayburn House Office Building, Hon. Frank

11 Pallone, Jr. [Chairman of the Subcommittee] presiding.

12 Members present: Representatives Pallone, Eshoo, Green,

13 Schakowsky, Barrow, Christensen, Castor, Sutton, Waxman (ex

14 officio), Whitfield, Shimkus, Myrick and Gingrey.

15 Staff present: Steve Cha, Professional Staffer; Ruth

16 Katz, Chief Public Health Counsel; Elana Leventhal,

17 Professional Staff; Eric Flamm, FDA Detailee; Alvin Banks,

18 Special Assistant; and Chad Grant, Legislative Analyst.

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Mr. {Pallone.} The Subcommittee is called to order and today we are meeting to discuss the topic medical radiation and the overview of the issues.

By now, I am sure many of you have read or at least heard of the New York Times article series on medical radiation errors. The patient's stories highlighted in those articles are heartrending and they have raised huge concerns and questions for me as well as for many of my fellow members in the House of Representatives. I actually was just reading now today's New York Times where there is a front page story about a group, a radiation oncology group in Melbourne, Florida that raised a lot of the issues. I mean the article today raised many of the issues that we are going to bring out today but particularly disturbing was the fact that this group practice apparently had the physicians who were not present, who were actually overseas and were billing on the assumption that those physicians were present and I guess had to be present under the rules and yet they were not. So those are some of the problems that are highlighted in today's New York Times and have been in a whole series.

I want to start, however, by saying that medical radiation undoubtedly saves lives. It has reshaped the world of diagnostics and has offered patients less invasive

alternatives for treating complex and life-threatening conditions. Personally, I don't want to express any concern that in having this hearing that we are sending the message that medical radiation is bad. I want to assure you that that is not the case. It is important that patients do not stop going to their scheduled treatments or getting their CAT scans when they need them, and we are not here today to make the statement that medical radiation should not be used.

But we are here today to learn more about the field and to examine what the driving factors are when things go wrong. Due to the dangerous nature of these technologies, when things do go wrong the effects on patients are horrendous. As mentioned, the benefits that we as a society have gained from these advances are enormous but we often forget the fact that we are still dealing with something that is toxic to the human body. When it is delivered correctly, a single CAT scan can deliver as much radiation as 300 chest x-rays. With the operating technology as powerful and dangerous as this it is even more crucial that quality and safety are always front and center, but tragically, as highlighted in these New York Times articles, this is not always the case. A procedure with such a small margin of error should be stringently overseen and monitored but these critical steps appear to be lacking in many cases.

With all the advances the industry has made, these technologies have become more complex and complicated to operate. It is shocking to me that in many States individuals who operate these devices do not need to be licensed and are therefore not regulated at all in terms of education and expertise. Even in States where there are licensing requirements, the requirements to report errors and the penalties for making errors are basically nonexistent or not enforced. Now as a result, we have no idea how often these errors occur and have no good data on where the weaknesses in the system truly are.

I understand Mr. Barrow has legislation that deals with training and possibly accreditation as well so, you know, obviously when we have these hearings we are looking at the possibility of legislation and Mr. Barrow's is certainly one of those that we would be looking at. I think part of the problem could be the fact that no single agency has authority over the entire spectrum of issues related to medical radiation and because of this things are more likely to fall through the cracks and I am eager to hear from our witnesses today about this and what problems it presents.

In addition to the lack of oversight from a regulatory perspective, there also appears to be very little guidance to physicians on the appropriateness of use of these

technologies especially with respect to radiation dosage and lifetime exposure of radiation. One of our witnesses today will go into more detail on this issue but for example, dosing for the same CAT scan can vary by huge amounts between and within facilities. In addition, there are questions as to the appropriateness of use of these scans.

I know from personal experience that health care providers are very quick to order yet another CAT scan without talking to patients about the health risks let alone the cumulative effects of multiple scans. When I say my own experience is from my mom. My mom passed away last December and the reality--not this December but the previous one, and I remember she had pancreatic cancer that when we were going around to different hospitals and we ended up I think at four different hospitals, every time I would go to a new hospital I would bring the scan with me, you know, the disc I guess. And I would give it to them and they would say well we can't use that and I would say well why, and they would say well, you know, our machines don't operate that way of maybe it is a good idea to have another one and I wasn't concerned. I mean frankly I wasn't addressing it from a cost perspective although that is a big factor but I was worried about the health implications and, you know, frankly most no one said to me that there was a problem. It was always like oh that

is not a problem, you know, she can have it done again and nobody actually would use the previous one. I was never able to get them to use the disc that I had brought with me. They always had a reason why they couldn't use it and maybe there was a good reason but it just seems that maybe the lack of interoperability or, you know, one of those things that needs to be addressed.

Many in Congress have questioned the overuse of medical imaging but for the most part those conversations has centered on cost implications. I have to wonder though if there are not also health implications as well and I am eager to hear from our witnesses today about the issue and what is being done to study the long term cumulative effects of medical radiation.

Our witnesses today are all intimately familiar with these types of technologies, the possibilities they hold and the dangers they can present and I would like to welcome especially Ken Mizrach who is--where is Ken? Oh he is on the next panel I guess, who has traveled here from my home State of New Jersey and also Mr. Parks, whose son's story was featured in one of the New York Times articles, and we appreciate your taking the time to speak to the committee on this very important issue, and I think we are going to have some interesting conversation.

Before I recognize Mr. Whitfield though I did want to say that, you know, just reading today's New York Times article there are so many different factors here. You know, how much radiation, what type of technologies are used, whether we should have doctors present, how long they should be present, whether they should be nearby or there the whole time, and it is a very complex issue and I don't need to be simplistic about it but we should also get to the bottom of it. So with that, I will recognize my colleague from Kentucky, Mr. Whitfield.

[The prepared statement of Mr. Pallone follows:]

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Mr. {Whitfield.} Well, thank you, Chairman Pallone, and I also want to thank the witnesses for being here today to help educate us on this particularly important subject matter.

Medical radiation involves both radiation therapy and medical imaging. The medical community uses radiation therapy to treat cancerous tumors including brain cancer, breast cancer, lung cancer and prostate cancer just to name a few. They use medical imaging like CT scans and mammograms to find those tumors and identify other problems. It is clear that the overwhelming majority of Americans who receive radiation therapy and medical imaging benefit greatly and thousands of lives are saved each year because of these treatments and procedures.

This hearing will also however focus in part on tragic events associated with radiation therapy. These events raise legitimate questions that we need to explore and my hope is that the members of the committee and the public will listen to the witnesses who are experts in this field and not proceed with preconceived notions. We must examine the issues associated with radiation therapy and medical imaging and if there are problems to be addressed we need to work with the manufacturers and the health care providers to do

so. However, as we examine these issues it is important that no one comes away from this hearing thinking radiation therapy and medical imaging are too dangerous to use because too many lives are at stake.

I am particularly interested to hear from the manufacturers how these lifesaving technique devices work. I am also interested in hearing from the various provider groups on the training associated with operating these complex devices and how the different professional societies develop criteria so these devices can be operated safely. Radiation treatment is a complex issue and so we welcome the witnesses here today and are excited that you can help educate us on what if anything and what steps we need to take.

And I would yield back the balance of my time.

[The prepared statement of Mr. Whitfield follows:]

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Mr. {Pallone.} Thank you.

The gentlewoman from Ohio, Ms. Sutton, is next for an opening.

Ms. {Sutton.} Thank you, Mr. Chairman, and I appreciate you holding this hearing today. It is an important and complex issue that deserves our attention.

All of us know someone whose life has been saved by medical radiation whether a tumor was discovered with a CT scan and treated before it grew into something unmanageable or whether someone we love beat prostate cancer through the help of radiological seeds. There is no doubt that medical radiation has allowed people to stay on this earth with their loved ones much longer. However, as we have learned terrible, tragic, heartbreaking events can occur and have occurred when something goes awry with medical radiation therapy primarily in cancer patients.

I was greatly saddened to read the stories in the New York Times which included a tragic story about a breast cancer patients from my district who suffered a radiation overdose in 2006 when a physicist entered incorrect information into the treatment planning computer. Her name who Myra Jean Garman and she was in so much pain from the radiation overdose and resulting side-effects that she

eventually committed suicide. According to the Ohio Department of Health there have been 18 incidence reports with respect to medical radiation over the past 2 years. Obviously, we want to reach a place where there is no need to file any incidence reports because there are no incidents.

Patient safety must always be our primary concern and patient safety in radiation therapy as well as patient safety in diagnostic radiation, are critical. We are here today to learn about the best way to ensure patients are protected to ensure that patients are given the right tests at the right time and that no patient ever suffers through a radiation overdose, to ensure that our medical equipment is safe and that our workers are well-trained, and I look forward to learning about the issues surrounding medical radiation from our witnesses today and I thank the witnesses for being here to deal with this very complex issue.

And I yield back my time.

[The prepared statement of Ms. Sutton follows:]

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Mr. {Pallone.} Thank you.

We are going to have votes and I know there are quite a few and I think they are the last ones of the day. I will find out soon but just so that we probably are not going to get the panel before the votes. We will try to do as many openings as we can and then you will have to wait around probably an hour or so for us to come back, unfortunately.

Next is the gentleman from Illinois, Mr. Shimkus.

Mr. {Shimkus.} Thank you, Mr. Chairman. I want to thank the Parks family for their attendance and being here. We know it is not easy.

I want to concur with the comments of the Chairman. Radiation therapy has been very successful in saving lives. Early diagnosis and early treatment has prolonged the lives of thousands of Americans and this should be in no way an attempt, not an attempt but we don't want to scare people away from doing this and some of these stories are starting to do that and we just have to be careful. You know, cancer survival rates have gone from 50 percent to upwards of 95 percent in many cancer cases and that is because of this technology in this. We have to address, identify the problem, encourage people to move forward so these mistakes don't occur and in this case it would be software

applications and training. In talking with health care professionals and the like, a scalpel in the hands of a trained professional does great good. A scalpel in the hands of someone who is untrained does great harm and that is, I hope, the focus of this hearing and we look forward to the testimony. We do thank the Parks family and those who have suffered loss and your testimony is very, very important because it helps us focus on the truth.

And I yield back, Mr. Chairman.

[The prepared statement of Mr. Shimkus follows:]

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Mr. {Pallone.} Thank you, Mr. Shimkus.

The gentleman from Georgia, Mr. Barrow, and sponsor of the bill that we mentioned before.

Mr. {Barrow.} Thank you, Mr. Chairman and thank you for holding this hearing to call attention to the serious problem of accidents and errors in the delivery of radiological services.

While we can't expect either the people or the technology to be perfect, when you go into a doctor's office or you enter the hospital you have the right to expect a certain level of competence and training from the people taking care of you. I am the lead sponsor of the Care Bill which will set minimum educational and certification requirements for the technical personnel who perform medical imaging and radiologic therapy. Most people are surprised to find that many States don't license or regulate radiologic technologists at all. Common sense tells us that properly educated and certified personnel will produce better medical outcomes, not only that but more efficient delivery and reduction in duplicative testing and waste will also cut costs. I recognize that the problems highlighted by recent media reports are likely to require multifaceted solutions but I am convinced that we must start by ensuring that the

workforce is properly trained and certified.

With that, I yield back. Thank you, Mr. Chairman.

[The prepared statement of Mr. Barrow follows:]

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Mr. {Pallone.} Thank you, Mr. Barrow.

The other gentleman from Georgia, Mr. Gingrey.

Dr. {Gingrey.} Mr. Chairman, thank you.

Whether used in the detection or treatment of patients, medical radiation has become an important part of medical care in this country. From the latter half of the 20th century through today we have seen this technology evolve and add to the quality of health care in our country. As an OB/GYN physician for nearly 30 years, I have seen firsthand the benefits of this technology for the health and welfare of my patients. The chances of survival for a cancer patient, as already mentioned, are increased exponentially the earlier cancer is detected.

During this Congress we have heard from patients and indeed members of Congress alike who credit their health and their welfare to the early detection of cancer. For others radiation treatments like chemotherapy prove the decisive factor in life or death. Ms. Lindley is one such patient who credits Selective Internal Radiation Therapy with saving her life and thank you for coming before this committee and sharing your story with us today, Ms. Lindley.

Unfortunately for all of the benefit that patients see from such technology, there are also troubling stories of

trauma and sorrow. The story of James Parks is one such case and the trauma his son, indeed his whole family endured because of a radiation accident is a sobering tale. His story reminds us how important adherence to proper safety protocols is as well as the review of adverse medical events can be to the overall health of all of our patients.

Earlier this month the Food and Drug Administration announced a new initiative to reduce unnecessary radiation exposure from medical imaging. Therefore, this is a very timely hearing and I would like to thank Chairman Pallone for calling it today, however, I would like to sound one note of caution. Remember the furor that surrounded the United States Preventative Services Task Force recommendations on mammography screenings that had this information, of course, has not faded from the psyche of this country. That incident and the Congressional hearings that followed outline for this committee the importance of protecting the rights of patients and their physicians to decide what medical treatments are appropriate. Medicine is an art form. It can be taught from a book but it must be practiced with medical experience and yes, balanced judgment.

With that thought in mind I want to thank all of you witnesses for coming before the committee today. I look forward to hearing from you and the question period.

I yield back, Mr. Chairman, my time.

[The prepared statement of Dr. Gingrey follows:]

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Mr. {Pallone.} Thank you.

I am going to try to get two more members in so I guess that would be Ms. Eshoo and Mr. Green, and then we are going to have to break but we will continue after if anyone, you know, for those who come back.

The gentlewoman from California.

Ms. {Eshoo.} Thank you, Mr. Chairman, for holding this important hearing.

I think all of us in reading the recent articles on vulnerable patients and what happened to them, we are really stunned by it. That is number one. Number two, I can really track over just the period of time that I have been a member of Congress. This is my 18th year and the co-chair of the medical device caucus, tremendous improvements in this area which holds out so much hope for especially cancer patients in our country. But clearly, something needs to be done in the area of supervision, the area of licensing and that we in my view we need national standards in this area because it is right now it is catch-as-catch can so my, I will submit my full statement for the record.

I look forward to hearing from the witnesses. This is an important hearing. If we need more information, I will certainly participate in all of the hearings so that we come

up with a framework that really fits what the problems are so that no one is subjected to the over-radiation that we have read about.

I also would like to ask for a unanimous consent request that Mr. Waxman's statement for the record be accepted and that he has a--let's see, a statement for the record that are relative to a 52-year-old father who is a constituent of his, you know, and the father of three children in Los Angeles and what happened to him relative to excessive radiation at Cedars Sinai Medical Center in Los Angeles.

[The information follows:]

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Mr. {Pallone.} Without objection, so ordered.

Ms. {Eshoo.} Thank you, Mr. Chairman.

[The prepared statement of Ms. Eshoo follows:]

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Mr. {Pallone.} Thank you.

I think we can get two more in on this so and Ms. Christensen wants to stay. We will start with Mr. Green and then go to Ms. Christensen.

Mr. {Green.} Thank you, Mr. Chairman.

I ask unanimous consent my full statement be placed in the record.

[The prepared statement of Mr. Green follows:]

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Mr. {Pallone.} Without objection, so ordered.

Mr. {Green.} First, I am glad you are having this hearing. A lot of us read the information and our health subcommittee has worked for many years on expanding opportunity for CT scans and treatment because of the new technologies are changing everyday and I will give my own example. I went about 7 years ago in Houston Heart Institute and they had a concern about a problem and I did a scan of my heart, an image of my cardiovascular system and that was great. I went back a few years later but staff and the equipment had already changed because we are seeing better equipment everyday and we don't want to lose that ability to diagnose and to treat in the case of cancers. The problem is that if we don't deal with this, we will scare both practitioners both also patients away from it.

So that is why the hearing is so important today, Mr. Chairman. Thank you for doing it. We need to get it right because the next generation of treatment can be less invasive then what it is now but we surely don't want to stop it because people are scared they are going to be over-radiated, a person is not trained to use the equipment they are using or that it is not the proper dosage.

So, Mr. Chairman, thank you and I look forward to

working with you and see what we need to do to deal with it.

Mr. {Pallone.} Thank you.

The gentlewoman from the Virgin Islands.

Mrs. {Christensen.} Thank you, Mr. Chairman, and thank you for holding this hearing.

I would also like to ask that my full statement be included in the record.

You know, as a physician the practice for if I include my residency maybe 25 years, I have had the opportunity to see the benefits that the diagnostic and therapeutic radiology have and I am sure everyone of us on this committee either ourselves or in our family have seen those benefits firsthand. But we always have to balance the benefits and the risks and in favor of the benefit to the patient and minimizing the risk. So we have seen some instances recently where and this has happened over the years where people have been over-radiated and have had severe repercussions because of it and we have at least one vehicle before us that can rectify this and it is something that we must do.

And I look forward to working with my colleagues to ensure that when individuals go for either diagnostic reasons or therapeutic reasons that they are not harmed by the machinery and the radiation. And so I look forward to hearing the testimony of our witnesses this morning and your

comments on how we can improve the safety of radiation for our patients. Thank you.

Thank you, Mr. Chairman.

[The prepared statement of Mrs. Christensen follows:]

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Mr. {Pallone.} Thank you.

I think we have at least an hour of votes so we will come back after that. If anyone else comes back, we will let them do an opening statement, otherwise we will go right to you but we were talking I am sure no earlier than 11:30. Thank you.

The committee is in recess.

[Recess.]

Mr. {Pallone.} The subcommittee hearing is reconvened and we still have some opening statements starting on our side with our Chairman, Mr. Waxman, from California.

The {Chairman.} Thank you, Chairman Pallone, for holding this important hearing and I know we are anxious to hear from our witnesses and I regret that we had the votes that interrupted our hearing.

But we are looking today at the extraordinary benefits and examining the possible risks associated with the use of radiation in medicine. And let me be clear at the outset, diagnostic technologies like CAT scans that identify tumors and therapeutic procedures such as radioactive seeds that treat prostate cancer are potentially lifesaving. They are important interventions in our medical toolbox and our health care system is unquestionably much better because of them.

But recent reports and studies have raised questions about the relative safety of these technologies. No medical intervention is 100 percent safe and patients' individual tolerance for risks and being exposed to such procedures varies as well. These are dangers that generally cannot be avoided altogether but the purpose of this hearing is to learn more about those risks and hazards from radiation that would appear to be preventable and there have been recent examples as reported in the press. Investigators at the NRC found that a cancer unit at the VA hospital in Philadelphia botched 92 out of 116 procedures using radioactive seeds to treat patients with prostate cancers. Over 200 patients were mistakenly exposed to up to eight times the normal dose of radiation during brain scans at Cedar Sinai Hospital in Los Angeles. Because of a computer error that went undetected, Scott Jerome-Parks, the son of one of today's witnesses was blasted with excess radiation on three consecutive days during his treatment for tongue cancer. Scott died from his radiation exposure at the age of 43. Despite these patients need and consent for the lifesaving technology used, the end result clearly is not what they signed up for.

Alarmingly, as we will hear from a number of today's witnesses, these are not isolated cases. The mistakes made in these instances while perhaps not widespread, we hope not

widespread, appear to be more than just random and rare. They are occurring all across the country and in hospitals and physician offices alike.

The reasons for this poor quality of care would seem to be multifaceted. Whether it is a lack of standardization of equipment or laxity or even nonexistent State licensing requirements for machine operators or outdated Federal oversight authority, experts tell us that more can and should be done to reduce unnecessary radiation exposure and medical errors. Indeed, action has already been called for by the medical imaging manufacturers and some radiation provider groups whom we will hear from today.

As we move forward I would hope that we can all agree on two basic premises. First is the enormous medical value of our various radiologic techniques. As I mentioned earlier we want to underscore the point again both diagnostic and therapeutic radiology interventions save lives and we want them. We need them. Second is the obligation to ensure that these interventions are as safe as they can be and that everything is being done to make that a reality. Patients are entitled to nothing less. With these principles in mind, I believe our job today is simple and straightforward to understand how to lower the risk associated with radiation in medicine to make it as safe as possible without reducing its

many benefits to patients and researchers.

We have an outstanding group of witnesses. It is no longer this morning. It is afternoon. They are here to help us learn more about these issues. I thank each of them in advance for their testimony and I look forward to hearing from them but in my case from reading their testimony because I am compelled to go to a meeting with the Speaker on health care which will require me to miss the testimony but I will have a chance to review and I thank the witnesses for being here.

[The prepared statement of Mr. Waxman follows:]

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Mr. {Pallone.} Thank you, Chairman Waxman.

The gentlewoman from North Carolina, Ms. Myrick.

Mrs. {Myrick.} Thank you, Mr. Chairman, and for the sake of time I am going to submit my statement for the record along with a letter from the Society for Radiation Oncology Administrators.

[The prepared statement of Mrs. Myrick follows:]

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Mr. {Pallone.} Without objection, so ordered.

Mrs. {Myrick.} Thank you.

Mr. {Pallone.} Thank you.

And so I think we have had opening statements from everyone else so we will move to our panel and let me introduce each of the panelists if I could. Beginning on my left is Mr. James and Mrs. Donna Parks from Gulfport, Mississippi. Thank you for being with us today and Suzanne Lindley from Canton, Texas. And then we have Dr. Rebecca Smith-Bindman, who is Professor in Residence, Radiology and Epidemiology and Biostatistics, Obstetrics, Gynecology, and Reproductive Medicine. I didn't realize you have all those at the University of California in San Francisco. And then we have Dr. Eric Klein who is Professor of Radiation Oncology at Washington University in St. Louis. And then we have Dr. Cynthia H. McCollough who is Director of the CT Clinical Innovation Center, Department of Radiology at the Mayo Clinic and Professor of Radiological Physics at the College of Medicine at the Mayo Clinic. That is our panel. We ask you to give us 5-minute opening statements if you can limit it to that please and your statements, your full statements become part of the record. Then we will have questions from the panel. I should mention that beyond this you may get

additional written questions from the panel within the next 10 days or so, as well.

We will start with you, Mr. Parks. Thank you for being here. Let's make sure that your microphone is on. It should be the green light and maybe bring that a little closer to you, Mr. Parks, so that we can.

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^STATEMENTS OF JAMES AND DONNA PARKS, GULFPORT, MISSISSIPPI; SUZANNE LINDLEY, CANTON, TEXAS; REBECCA SMITH-BINDMAN, M.D., PROFESSOR IN RESIDENCE, RADIOLOGY AND EPIDEMIOLOGY AND BIOSTATISTICS, OBSTETRICS, GYNECOLOGY, AND REPRODUCTIVE MEDICINE, UNIVERSITY OF CALIFORNIA, SAN FRANCISCO; ERIC E. KLEIN, PH.D., PROFESSOR OF RADIATION ONCOLOGY, WASHINGTON UNIVERSITY IN ST. LOUIS; AND CYNTHIA H. MCCOLLOUGH, PH.D., DIRECTOR, CT CLINICAL INNOVATION CENTER, DEPARTMENT OF RADIOLOGY, MAYO CLINIC, PROFESSOR OF RADIOLOGICAL PHYSICS, COLLEGE OF MEDICINE, MAYO CLINIC.

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^STATEMENT OF JAMES PARKS

} Mr. {Parks.} Mr. Chairman and committee members, we want to thank you for the opportunity of coming here to talk.

We are here to testify on behalf of our son, Scott, who died from an extreme overdose of radiation by a very inept team of therapists using a linear accelerator. It is a horrible way to die. What was to be a minimally invasive procedure turned out to be a 2-year nightmare for the whole family, especially he and his wife. They were in New York City and that is where most of this occurred. We were with Scott and Carmen when Scott's feeding tube was implanted. At

that time we had been convinced that we were doing the right thing. He had not wanted a surgical procedure which would have been very bad. My hearing aid just went out.

So he chose what he called the laser treatment and we thought it would be very quick. After the implant we thought that was just sort of an inconvenience that would be temporary but it didn't work out that way.

We in Mississippi and our son was in New York so what you get here are snapshots in time as to what we saw him. His wife, Carmen, of course, was with him every moment of every day for 2 years and suffered all of the things he suffered but she can't speak because of a gag order and it is tied to her financial settlement. She is the one who should be here and isn't. She knows everything that has happened.

Each time we would go visit, about every 3 or 4 months we would see him and of course he would change dramatically every time we would go. I am not sure all patients do this but he rapidly became blind and deaf and he had constant pain and vomiting. He became extremely weak and sleepy. We couldn't hardly--he could last for about 15 minutes but he always kept his interests in Carmen. He said he would keep himself alive to make sure that she was all right and he did that. We admired him for suffering so much until the process was ran its course and that she was finally taken care of.

We met him for the last time at Christmas when he called us all together, his brothers and aunts and Donna and I, and we had Christmas with him, and it was very, very touching. One of his friends had sent a big box and in the box was sand and two pails, and on the video that he made he said just lay back and put your feet in the sand and pretend that you are back in Mississippi where you should be, and Scott did that and he wasn't hardly with it at that time. This was at Christmas.

One of his problems was hiccupping. I don't know if that is he would hiccup all the time as you were talking to him, violent hiccups and of course his jaw was calcifying and his teeth were falling out. He couldn't eat. He didn't eat anything from the time he got the stomach implant until he died and he used to like to eat but all he would go to Central Park and this is he would sit on a bench and feed himself with the liquid meals that he would have and that was remarkable for him to do that.

The way it unfolded, he had four successful treatments. On the fifth one it was a terrible onslaught to him. His head swelled up and he suddenly became retching. His wife was there and she got alarmed and asked them to stop the treatment but they ignored her and this went on for a second time and then a third time when the machine was wide open and

he got blasted with unguarded amounts of radiation. The hospital I think made an error in that they told Scott that this has never, ever happened before and that there was be something wrong with him because the machine always works perfectly. Of course, they found out that wasn't true and as for when Scott went into this he knew he was going die. He and his doctor were very close. They were and he went on kind of a mission to make his dying a cause for him to live for as long as he could and he stayed all through all the suffering and until finally there was a financial settlement. And he told me that Carmen was the reason he was staying alive and at the Christmas party I remember hugging him and he whispered to me very weakly that Carmen is going to be all right and he can die now. He says I am ready to go and he, after we left at Christmas, he was very rapidly got much worse and soon died.

It was traumatic for all of us, particularly his wife, Carmen, and she was wanting to testify and, of course, she can't do that and it is a shame that this is a secret that we aren't supposed to talk about and that is why we are here. I told him I would do what I could and what I did is wrote a staving obituary for him which didn't do any good and I wrote a letter to the editor which didn't do any good. And by some miracle, I don't know how it happened but the New York Times

picked up on this whole issue and has gone and it has snowballed. I think it is making an impact and that is exactly what Scott wanted. I am sure he is up looking down and he is very pleased.

I would like to say that we are impressed with the machines. They are not as good as they could be and they must be improved to where they are--we have made a couple of recommendations and I would like to quickly read them. We must develop a strong mandatory database that we don't have and all medical institutions should report to the database and it could become a repository for evaluating trends and identifying medical problems, all medical problems not just radiation. The Veterans Administration has developed a reporting system that reports and responds to medical accidents called NCPS. That is all I know about it but it works in the VA system very well and I think it would be nice if the whole country would adopt such a thing. We are very encouraged that the SBA has taken a regulatory role in radiology and I understand the IMRT systems will be involved in that, too.

We ask the medical equipment manufacturers to develop a failsafe interactive expert system that can interact with human technicians to reduce and eliminate human errors. I think that is what really killed Scott was human errors and

the machines must talk to the technicians and, of course, the technicians should be very trained. Oncologists and supervising physicists must learn to micromanage their radiology departments. That is the only way they will work. If you don't do that you are going to have people dying. It is outrageous to us that untrained and unskilled workers can get anywhere near this dangerous equipment but they do and it happened in Scott's case.

Thank you.

[The prepared statement of Mr. Parks follows:]

********** INSERT 2 **********

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Mr. {Pallone.} Thank you very much, Mr. Parks and also Mrs. Parks, for being here. I mean I know how tough--I shouldn't say I know. It had to be tough for you to be here and give us your testimony but it is really important because this is the very thing that we are trying to prevent in the future so I don't know what to say but to say that it at least your being here in some way, you know, can maybe make up in some way for your loss and at least you are trying to prevent it from happening to others. Thank you.

Mr. {Parks.} Thank you.

Mr. {Pallone.} Ms. Lindley. Ms. Lindley, I think you got to turn that on and move it closer to you. Otherwise we can't hear you. I think it is still not on. Is the green light on? I don't think it is on. I hate to bother you but is the green light on? Do you want to try Mrs. Parks' there maybe.

|

^STATEMENT OF SUZANNE LINDLEY

} Ms. {Lindley.} As a patient, I too want to make sure that I am in safe, qualified hands when I have treatment and it is hard to follow a story like yours, especially when mine has been the complete opposite. Thank you for having me today and as a resident of Canton, Texas I would also like to say a special hello to my fellow Texans on the committee, Congressman Green, Gonzalez, Hall, Barton and Burgess. I am honored to be here to share my experience as not only a cancer survivor but as a patient advocate.

I am here because of cancer research, because of medical imaging technology and because of radiation therapy. I was 31 years old when I was diagnosed with cancer. That was 11 years ago. It was then that I was diagnosed with stage four colon cancer and there are only four stages. Mine was the very most advanced. We found out that I had tumors that had already spread to my liver and I was told that I had about 6 months to live. We were scared. We were sad and we planned our first Thanksgiving as though it would be my last vacation or holiday with family. My daughters were 8 and 11 years old. We focused on the fact that I was going to die and we very much lost sight of the fact that I would live.

I posted a note on an online server asking for guidance from other cancer patients on how to prepare my two young daughters for life without me and instead of answering my question, a gentleman wrote back, Shelly Whiler, and said that he too was going through stage four colon cancer and I should look for some hope and that is what we did. I started with the only chemotherapy that was available, 5-FU. It had been around for 30 years. I was fortunate that colon cancer research was rampant and as my cancer progressed I was able to benefit from each new treatment as it was developed. That worked about 6 years and then the cancer began to spread. There were no more approved options so we went into clinical trials and those bought me a little bit of time, too. Then my liver became just laced with tumors. They were multiplying to the point where it looked like the stars lit up the sky at night. My stomach was swollen. My skin was yellow and I was tired. Every breath, every move was hard and the doctors said that there was nothing else that they could do and that basically I should call in hospice and that my condition was terminal.

We prepared my family again and I sent out an e-mail to friends letting them know that I was at the end of the line. Then after calling hospice, planning a funeral and picking out a casket, I got a phone call from one of the friends that

I had written a letter to and he told me about his doctor in Wisconsin that was using Selective Internal Radiation Therapy. And they are little radioactive beads that are implanted internally and they attack the liver tumors and they leave the healthy tissue healthy. It sounded too good to be true and so at first I was hesitant to call the doctor. And then he kept calling me a dozen times that day and finally I picked up the phone and I called the doctor and we talked for awhile and it turned out that I was a good candidate for the treatment. I went back to my oncologist and I told him about the procedure and thought he would be really, really excited for me and instead he said, you know, I don't think it is going to help you, and then he turned around and said what do you have to lose. No one knew how much I had to gain.

I received the outpatient treatment called radio embolization in January of 2005, and I call them little, magic beads. After a 6-month period we saw a 65 percent of shrinkage and then after awhile we started seeing necrosis of those tumors so they were literally dying from the inside out. My belly started to get back to where there wasn't fluid in it. My color came back and I began to live again. I learned how to scuba dive. I went skydiving. I started telling my private story in very public places. I connected

with other people and I met and shared experiences that I had never seen if it hadn't been for this disease or these treatments. I have continued with systemic therapy and I have also received additional targeted radiation treatments to stay ahead of the curve. I have had external beam radiation for tumors that spread to my spine and that has helped me with the pain control and has given me a better quality of life. I have had Gamma Knife used to treat a brain lesion. I have had radio frequency ablation to treat a returning liver tumor and I have had Cyberknife for lung tumors and they have all given me a little bit more time with my kids.

When you start anything new and especially a new treatment, you hope for the extreme. You pray for the best. You prepare for the worst and you don't really know what is going to happen but all you have is hope. These advance radiation therapy technologies have given me that hope. They have allowed me to watch my daughters grow up, to see them walk across a stage for graduation, to start college and to become adults. They are 19 and 22 now and are both in college. These treatments have allowed me to walk hand-in-hand with my husband and hopefully we will have more of these treatments and we will be able to spend our rocking chair days together.

I still have tumors here, there and everywhere. Systemic therapy after 11 years is just now part of my normal routine. Along with that, I will continue to use the targeted radiological therapies when needed. They allow me to live with colon cancer as a chronic condition and not a terminal one. These existing treatments and medical innovations will be a part of my life until there is a cure for this disease. What they have been able to give me is nothing short of miraculous. The grandest miracle is the realization that I am not dying from cancer. I am living fully in spite of it. I have reaped the benefits of research, of dedicated tumor doctors and increasing options. In my arsenal there has been 5-FU Fluorouracil, with Leuvocorin, Irinotecan, Oxaliplatin, free clinical trials, numerous surgeries, radio frequency ablation, Gamma Knife and vertebroplasty. None of these, other than the 5-FU existed when I was diagnosed. It is important that the momentum continue and that it is not thwarted, not only for me and for my family but for the 1,500 Americans that will lose their lives today and each and every day after today.

Before I close I want to leave you with this one thought. As my personal story makes painfully clear there are barriers out there already and I realize that you are not trying to build those barriers and that you are trying to

make them safe but we also don't want to scare patients or take away their hope at the same time. Thank you.

[The prepared statement of Ms. Lindley follows:]

********** INSERT 3 **********

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Mr. {Pallone.} Thank you very much really for being with us today and sharing that. We appreciate it. Dr. Smith-Bindman. I guess the name is spelled wrong there. I am sorry. It says Binder.

Dr. {Smith-Bindman.} That is how we spell it though.

Mr. {Pallone.} All right, Bindman, thank you.

|

^STATEMENT OF REBECCA SMITH-BINDMAN

} Dr. {Smith-Bindman.} Chairman Pallone, Ranking Member Whitfield and members of the Health Subcommittee, thank you for the opportunity to testify today.

My name is Dr. Rebecca Smith-Bindman, Professor of Radiology, Epidemiology and Biostatistics at the University of California, San Francisco School of Medicine. I am a clinical radiologist and my research focuses on assessing the risks and benefits of medical imaging.

My testimony today focuses on CT because it is one of the most common imaging tests we use and it is the test with the greatest potential for causing harm. CT uses x-rays to obtain extremely detailed images of internal organs and the development of CT is widely considered one of the most important advances in medicine allowing a more timely and accurate diagnosis of disease across every area of medicine. It is simply an extraordinary test and currently one in five individuals in the United States undergoes a CT scan every year.

Although CT scanning is useful, it delivers much higher doses of radiation then do conventional x-rays and exposure to radiation can lead to the development of cancer. To help

put this into context, when you go to the dentist and you are offered dental x-rays some of you may pause to consider any potential harm from those x-rays. The most common type of CT scan that patients undergo in the U.S., an abdominal CT delivers approximately the same amount of radiation as getting 1,500 dental x-rays all at the same time. Additionally, newer applications of CTs such as those used to assess blood vessels in the brain require even higher doses of radiation, as much as 5,000 or more dental x-rays. The increase in the number of CTs and the higher dose for some CTs has resulted in a large increase in the population's exposure to radiation from medical imaging.

The National Council on Radiation Protection, a group dedicated to ensuring that the U.S. population is as safe as possible as it relates to radiation has estimated that the U.S. population's exposure to radiation from imaging has increased dramatically the risks. Exposure to radiation increases a person's risk of getting cancer. The National Academy of Sciences National Research Council reviewed all of the published literature on the health risks of radiation. They found people who received doses in the same range as a single CT would increase risk of developing cancer. Further, many patients in the U.S. receive multiple CT scans over time and their risks are even higher. Thus the doses that we

experience everyday as part of routine CT scanning are potentially dangerous. The cancers may not develop for 5, 10 or 20 years. Even though we can't see the harms immediately, we must take them seriously.

Oversight for CT radiation dosing is very fragmented. The FDA oversees the approval of the CT scanners and medical devices but does not regulate how the test is used in clinical practice. Radiologists determine how the CT tests are performed, however there are few national guidelines on how these studies should be conducted and therefore is great potential for practice variation that could introduce unnecessary harm for excessive radiation dosing. The American College of Radiology has established a voluntary accreditation process to try to standardize practice and collects dose information but only on a very small sample of tests. This approach is promising but at this point in time the data collection is extremely limited making it difficult if not impossible for the college to monitor facilities comply with their guidelines.

The manufacturers of CT equipment have begun work to establish standards of how radiation dose information should be measured and reported. However, the manufacturers have not adopted or implemented these standards.

My research team at UCSF conducted a study to assess the

905 doses associated with typical CT scans. We collected
906 radiation dose on over a thousand patients and found that for
907 nearly every type of CT scan the radiation doses were much
908 higher than commonly reported, that the doses varied
909 substantially between different facilities and even within
910 the same facility the doses varied dramatically between
911 patients. As part of this study, we also quantified the risk
912 of CT. We found that for some patients the risk of a single
913 test could be as high as 1 in 100. That means of 100
914 patients who undergo a CT, one of them could get cancer from
915 the test. This is an extremely high risk for a test that is
916 supposed to find cancer, not cause it.
917 What needs to happen to improve the safety of CT
918 imaging? Given the importance of CT and yes, it's potential
919 for causing cancer it is imperative that we make CT scanning
920 as safe as possible. To do this we need to do two things.
921 First, we need to lower the dose from routine CT scans and
922 second, we need to ensure that we use this technology only
923 when necessary. To lower the dose several steps are
924 important. We need very clear standards for what are
925 acceptable levels of radiation exposure and there should be
926 regulatory oversight for setting of these standards. Doses
927 used in actual patients need to be monitored. Despite the
928 potentially high radiation dose CT can deliver there is no

929 regulation of CT practice in the United States. The dose
930 information should be prominently displayed when CTs are done
931 so that technologists can easily make adjustments if needed
932 if the doses are too high. And lastly, the dose associated
933 with each CT examination should be documented and recorded in
934 each patient's medical record and this information should be
935 tracked over time. Recording and tracking dose information
936 would help educate patients and providers about radiation
937 exposure and would lead to activities to minimize dose.
938 There are currently private businesses that offer full-
939 body CT screening to healthy individuals. The FDA and most
940 professional organizations have voiced concerns that using CT
941 as a screening test could cause more cancers than they find.
942 For diagnostic CT, these are tests that are done in patients
943 who have a clinical problem who have a symptom. It is
944 generally been thought that if the patient is sick enough to
945 get a CT scan that the benefit of that test will outweigh any
946 risk, however we have started to use CT scanning so often and
947 in patients who are really not very sick at all that we need
948 to really think about whether the test is necessary and
949 whether it could cause more harm than benefit. Neither
950 physicians nor patients are aware of the risks associated
951 with CT nor the importance of limiting exposures.
952 In summary, consensus is growing that efforts are needed

to minimize radiation dose from CT and to ensure that patients receive the minimum dose necessary to produce a medical benefit. These efforts must include reducing unnecessary studies, reducing the dose per study and reducing the variation in dose across patients in facilities. Despite the frequency importance of CT imaging, there are no resources available to the research community to study or improve the quality of CT scanning. Creation of an academic consortium to study CT and make it as safe as possible would go a long way towards improving its utilization and safety.

Thank you for allowing me to contribute to this important discussion and I would be happy to answer any questions.

[The prepared statement of Dr. Smith-Bindman follows:]

********** INSERT 4 **********

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Mr. {Pallone.} Thank you, Doctor.

Dr. Klein

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^STATEMENT OF ERIC E. KLEIN

} Mr. {Klein.} Mr. Chairman and members of the committee, thank you very much for the invitation to come and speak here today.

My name is Eric Klein. I am a professor of radiation oncology at Washington University and have been a clinical medical physicist for 28 years. Over this time period, I have seen dramatic changes in terms of our profession's capability to diagnose and treat cancer. Our ability to image patients with modalities such as CT, MRI and PET allow us to visualize tumors and involved lymph nodes with millimeter accuracy. We can now customize how doses are delivered to tumors by performing sophisticated calculations allowing physicians to escalate dose to increase cure rates. Simultaneously we can reduce doses to critical organs, even those close to a tumor.

The delivery technique of intensely modulated radiotherapy, IMRT, which provides superior treatment delivery customization, comes with an increase in complexity in irradiation time compared with conventional radiation therapy thereby increasing risk. Thousands of hospitals and private treatment facilities all over the country have

purchased IMRT machinery, often for competitive purposes and far too often without properly trained staff in place.

Hospitals need to ensure staffing levels are adequate not only in number but in expertise. There should be hands-on testing methods before therapists begin to treat patients with testing on a frequent basis. The training for all staff involved should include the consequence if something is incorrect. There can be as many as 100 steps in each process and each step must be understood by everyone involved especially those steps with greatest volatility. We do a good job teaching people what to do and what to watch out for but not the consequence or the impact if something is wrong. Though the anecdotal reported rate of errors in radiation oncology is quoted as less than one in ten thousand, there are two problems with this quoted rate. First, it may be inaccurate as there is no repository or statewide mandate for reporting such errors. In many States hospitals are not obligated to report errors occurring with a linear accelerator. A national repository for error reporting, anonymous or otherwise should be instituted in order for the community to learn from such errors or even near-misses.

The second problem with this low anecdotal reported rate is that is still too high. Hospitals need to encourage scheduling patterns to allow for timeouts before each

treatment begins to allow for cross-checking of all parameters by therapists. Related to this, the time leading up to a patient's first treatments should allow for careful review by the physicist of all parameters to be used. In addition, the manufacturers testing of radiotherapy delivery and treatment planning equipment should include fault testing and compatibility between systems.

In regards to medical physicists, we are the vital interface between physicians' orders and the eventual treatment. We are responsible for many things including the accuracy of the images used for the treatment plan, the validity of the calculations, the quality of the result and patient treatment plan, the accuracy of the liner accelerators delivery systems and the overall end-to-end validation that each patient will be treated accurately. But having the intuition and wisdom to detect the potential or underlying problem only occurs with rigorous training. Medical physicists are educated in many important areas and after proper training ideally in an accredited residency program may become certified by the American Board of Radiology, ABR.

Starting in 2014, the ABR will only allow physicists who have completed a residency program to sit for the Boards. This will raise the bar for the exam, thereby raising the

1040 competency of all medical physicists in the very near future.
1041 But the ABR has to wait until 2014 to allow the growth for
1042 the number of accredited programs for this to take place.
1043 The growth has been hampered by lack of funding. There are
1044 some funding mechanisms but the most assured and balanced
1045 method would be for the Center for Medicare Services to
1046 provide reimbursement for training physics residents similar
1047 to the method that is in place for training physician
1048 residents.
1049 And finally, there is an ironic situation regarding
1050 oversight of radiation treatment equipment. To operate a
1051 mammography unit and to be reimbursed for the procedure, a
1052 robust quality assurance program must be in place with
1053 oversight by a qualified medical physicist and most
1054 importantly programmatic overview by the FDA and the American
1055 College of Radiology. This model of requiring a quality
1056 program and qualified personnel to be in place with a review
1057 by an agency in order to be reimbursed for providing
1058 radiotherapy treatments should strongly be considered for
1059 radiotherapy as a profession. In closing, approximately a
1060 million patients per year are safely and accurately treated
1061 with radiation therapy, receiving outstanding and vital
1062 treatments but further steps to ensure patients' safety can
1063 and must be made.

Thank you.

[The prepared statement of Mr. Klein follows:]

********** INSERT 5 **********

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Mr. {Pallone.} Thank you, Dr. Klein.

Dr. McCollough.

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^STATEMENT OF CYNTHIA H. MCCOLLOUGH

} Ms. {McCollough.} Thank you. I do have some visual aids for some of the points.

I want to thank you very sincerely for having this meeting today. It is an honor to be here and I want to speak to you about the safety of x-ray computed tomography most commonly referred to as CT scanning. Next slide, please.

[Slide]

I would like to begin by reviewing the difference between the dose levels from radiation therapy and from diagnostic imaging. On the right there at the extreme high doses such as what is required to effectively treat cancer, radiation can cause severe biological effects. In this high dose region the effects are predictable based on the dose that is delivered and can result in cell death, skin injury, skin reddening, hair loss. Next, please.

[Slide]

In contrast, let's look at medical imaging which uses a factor of 1000 times lower radiation doses. At the doses used in medical imaging, there is a chance an effect might occur but there is considerable controversy about the level of risk in developing a cancer from these low doses. Next.

[Slide]

In fact if we look at the risk levels, the blue line here is a relative risk of one meaning no increase in risk, and the vertical lines on the data points are error bars or uncertainties. The National Academy of Sciences report on the Biological Effects of Ionizing Radiation and the Health Physics Society state that these uncertainties, these error bars do not support making any risk estimates below approximately 100 millisievert. A CT dose is about 10 milliSieverts. In this range below 100 milliSieverts, the risk is either so small or zero but it is impossible to definitively measure. Next, please.

[Slide]

So with regards specifically to CT technology, modern systems are equipped with feedback systems that will monitor the amount of radiation passing through a patient and reaching the detectors and then to adjust that radiation output throughout the patient and throughout the scan to adapt the amount of radiation so you get the image quality that is needed at the lowest dose. These systems automatically adapt the dose across within the patient but across the spectrum of patient sizes from children all the way up to morbidly obese patient. So here is an example of an automated setting taking the dose from the adult level

which would be about 165 and it tailored it automatically down to a child level. Next, please.

[Slide]

I would also like to point out that the patient dose for a single CT exam of the abdomen, chest or pelvis is a factor of two or three times lower now then it was two decades ago. The current technical innovations continue to drive doses lower. Next, click.

[Slide]

Even though throughout the years the image quality keeps getting better, these numbers here the section width is the thickness represented by one image and we continue to get thinner which gives higher detail, better image quality. However, CT is a sophisticated medical device and as with any device or procedure human errors or electrical mechanical errors can happen and that is why I am very grateful for the interest of the committee, the FDA and the whole imaging community in ensuring that medical imaging is performed as safely as possible whether or not the exams involve ionizing radiation. Next, please.

[Slide]

I believe that the technology is not our fundamental problem. I believe that the concern is of education for the technologists that operate the equipment, the medical

physicists who test the equipment optimizing it, and the radiologists who prescribe the exam protocols. The education has not been able to keep up with the rapidly growing changes in technology and the single most important factor to make this more safe for our patients is to ensure that all personnel involved in operating medical imaging systems meet nationally prescribed minimum levels of training and competency. The needed accreditation and certification programs already exist but without mandatory requirements for a consistent level of education we are allowing in some cases inappropriately trained personnel to operate some extremely advanced medical equipment. Next slide.

[Slide]

One of the examples of the educational efforts being made by the imaging community is a Dose Summit by the American Association of Physicists in Medicine and we are having this in April of this year. We organized this to teach users how to adapt the scan protocols to make sure that they are appropriate for the diagnostic task and for the specific patient. The faculty and attendees includes physicists, radiologists, technologists and regulators, and the meeting is being contributed to by a large number of professional organizations in the imaging community. Of note, the registration is capped at 200 participants and the

meeting was sold out within 1 week of registration going live. Next slide, please.

[Slide]

So in summary, today's medical imaging as you have heard and you are well aware has some absolutely amazing technology. It can non-invasively diagnose and guide treatment for injuries and diseases that couldn't be accomplished in any other way. Without CT there would be more unnecessary surgeries such as for suspected appendicitis that didn't turn out to be appendicitis, more invasive diagnostic tests and less effective treatments.

Before the advent of CT, exploratory surgery was not uncommon. But clearly, medical tests whether it has ionizing radiation or not should only be performed when they are medically appropriate. When they are, the benefit far outweighs any potential risk. In fact, there is a very real risk to the patient's health if the necessary medical information is not obtained.

Unfortunately, right now the patients are being frightened by the media reports about the dangers of radiation. We are seeing patients come into the clinic with symptoms of potentially severe illness or needing lifesaving surgeries or treatments who have refused their CT exam because they have heard on TV or in the papers about this

cancer causing stuff. They are being harmed because of not getting the needed medical information.

Mr. {Pallone.} I am going to ask you to wrap it up only because I know some of the members aren't going to be able to stay.

Ms. {McCollough.} Okay, I am on my closing right here.

So patients and loved ones, I think, shouldn't be concerned about whether or not the imaging exam is being done properly. We should take care of that with training. They should be concerned about whether they need it.

When my 11-year-old daughter ended up in the emergency room an ultrasound showed a potentially lacerated spleen. They went to CT for the definitive diagnosis. It was normal thankfully and I don't think that was an unnecessary exam. It saved us from having unnecessary surgery.

Thank you.

[The prepared statement of Ms. McCollough follows:]

********** INSERT 6 **********

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Mr. {Pallone.} Thank you, Doctor, and I agree with you.

I am going to pass and have Ms. Eshoo go first because I know she has another commitment.

Ms. {Eshoo.} Thank you, Mr. Chairman. It is called the commute to California, hopefully getting the plane but I didn't want to leave you.

First, I want to thank each of you, the witnesses starting with Mr. and Mrs. Parks. I am a parent and it just should not be the case where parents bury their own child so what you have done in coming forward today is enormously helpful to us, and it is painful for you but I think that what you are doing in the name of your son is an enormous contribution for us to really address and get to the heart of what has happened, and that would be the greatest tribute to him so I want to thank you. And to Ms., is it Lindley? I think that you articulated so well what these technologies bring forward and the hope that they represent, and your own example, and by no means does anyone on this committee want to put a dent in what we have produced in our country and that is in so many cases second to none in terms of the application of the technologies that are lifesaving and life-extending, and I think that what you said really points to that. To the professionals, to the doctors that are here, it

is wonderful to have someone from our region from UCSF, absolutely terrific.

Let me just make a couple of observations. We have, it seems to me in looking at all of this that we have safety procedures and oversight that need to be addressed, that we have obviously 50 States and we have a patchwork quilt of regulations. There isn't any consistency that I can find in terms of what I have read. There is the whole issue of proper supervision. Radiation is lifesaving and it can kill someone so I mean this is something that needs to be supervised and there has to be proper supervision but there also has to be education and training in this, and we don't really have any national standards on that. One of the doctors mentioned the practice variations that exist and there are really no standards across the manufacturing field. Accreditation, I mean I don't think there is any national standard relative to accreditation. What I am stunned by is that there aren't more cases that other than Mr. and Mrs. Parks coming in. Thank God but this has really sent up the red flag.

So what I would like to ask is of the professionals, of the doctors, A, would you recommend national standards in these areas? I can't help but think of the Mammography Quality Standards Act that one of the staffers and it is in

our staff report here that many years ago we were facing with mammography and the Congress stepped up and put that law on the books and it addressed many of the issues that we are talking about here today.

Do any of you disagree about national standards needing to be addressed? So you all agree.

Do you believe that there should be accreditation in this area and licensure of those that administer the radiation?

Ms. {McCollough.} In CT, the American College of Radiology has an accreditation program that is not mandatory by regulators but has become mandatory in a de facto sense because the insurance companies started requiring it in order to get reimbursed, and so the program actually has thousands of units that are accredited. The program does address those. We measure those. We have a database of those and as part of that accreditation program, I have seen it continue to raise the bar of quality in CT since its inception in 2001.

Ms. {Eshoo.} Now, what again from the doctors, what responsibility do you believe the manufacturers have in this? What positive role can they play? Where do you--I mean maybe this is a sticky wicket for you to be telling us but I am not on a hunt against anyone but it seems to me that we have got

to examine each facet of this and if you think that there is an important role for them to play in this and what that would be.

Dr. {Smith-Bindman.} I think in the area of diagnostic medical imaging we have very little data about what is currently going on.

Ms. {Eshoo.} What does that mean, going on?

Dr. {Smith-Bindman.} It means that Dr. McCollough told us that a CT scan has a dose of 10 milliSieverts. When we went and collected dose information, in fact the doses were two to threefold higher then that on average and for one patient the doses ranged for one type of problem ranged from five to 100 milliSieverts for the kind of test that is supposed to have a dose of 10. So in fact we don't know what is currently going on. The doses in general could be much higher then we think and more variable. Part of the problem is there is no organization collecting those, documenting those and part of the difficulty in that is the standards for reporting those vary across the board. So there is no consistent way that dose is reported that a radiologist could easily look at the information on an individual scan and understand. So you asked about the role of the manufacturers. There are several very important committees that over the last several years have agreed upon standards

for reporting dose information, for putting that information in the medical records. These standards have not been adopted by the manufacturers. If these standards were adopted by the manufacturers, we could quickly know what is going on and then determine how closely different facilities abide by those guidelines that we would put out there. So we need guidelines about what is allowable and we need data to decide if places are within those guidelines so I think the manufacturers could enormously move this field forward by adopting these standards immediately and having this data available.

Ms. {Eshoo.} That is very helpful. I know they are going to testify at the on the next panel but I won't be here and we definitely need to work with them.

Dr. Klein, did you want to add to that?

Mr. {Klein.} I would rather have Dr. McCollough respond.

Ms. {Eshoo.} Okay, great and then I will yield back.

Ms. {McCollough.} I do have a slightly different perspective on this. There is an organization called the International Electrotechnical Commission and it is a trade organization that is worldwide that the U.S. participates in through the National Standards Institute and that organization, the IEC, actually sets very well-prescribed

standards about how the radiation output of a scanner is to be measured and the scanners effect in Europe can't even be published with some of these. So in the U.S. we have the same IEC labeling if you will, on all our standards and the value of the dose output of the scanner is actually shown on the console. It is mandatory that it be shown.

Ms. {Eshoo.} Well, who reads that?

Ms. {McCollough.} It is right in front of the technologist.

Ms. {Eshoo.} They do read that before they use it, really?

Ms. {McCollough.} It is in front of them and one of the things is the protocols tend to be prescribed for a given patient and diagnostic task, and the variation that you are hearing about radiation gets stops kind of quickly in tissue so every four centimeters of extra-thick that a patient is, you need to actually double the machine output to get the same image quality. So from a thin, perhaps Asian woman to an obese patient that is a factor of 64.

Ms. {Eshoo.} Yeah, I have to tell you, I mean you are absolutely brilliant. You know this better than anyone. That is why you are one of the expert in terms of testifying but to suggest that the knowledge is somehow transferred through the system because there is a sticker or something on

the equipment doesn't do it for me. I have to say that but thank you very much, Mr. Chairman, and this is going to require some work of our committee but it is what we are here for. And I think that with the people that you have assembled, and we need all of you to be part of the, I am sure legislation that we will draft and pass, and it should be bipartisan. This is something that knows no partisanship because it could be me. It could be you. It could be anyone of us so thank you very, very much.

Mr. {Pallone.} Thank you, Ms. Eshoo.

You can continue, Dr. Klein.

Mr. {Klein.} Well, in regards to radiation oncology equipment and manufacturing responsibility it certainly the machinery goes through quite a bit of testing as when it is in the factory and as it gets delivered. What could be done better is the training for the users, fault training to demonstrate if this message shows up this is exactly what it means and some of the manufacturers are inconsistent on some of the testing that they perform with the users, with the physicists. One company does a very good job, for example, of forcing errors to happen and then watching that the machine will stop and show you what that error is but it is not consistent. And the other problem that is a wide variation is problem reporting. How errors or how machines

that aren't functioning properly, how that information gets to all the users. It varies again how we get that information. Unfortunately, sometimes it is anecdotal or list servers, rather than direct communication to any potential user of this equipment. It might be better to do overkill communication right now which is scant and irregular. Thank you.

Mr. {Pallone.} Thank you.

Mr. Whitfield.

Mr. {Whitfield.} Mr. and Mrs. Parks, I also want to thank you for being here today and sharing your son's ordeals with us. We appreciate that and, Ms. Lindley, thank you for being here, as well.

When we talk about medical imaging, it is rather limited. I mean we talk about CAT scans, MRIs, x-rays and that is primarily it but then when we talk about radiation therapy I am assuming that there, would there be hundreds of radiation therapies or I know that we have linear accelerators. We have Gamma Knives. We have--Dr. Klein, would you help me with that about the different kinds of radiation therapy?

Mr. {Klein.} Sure, the main core of patients are treated with linear accelerators which come in some differences. There are the far majority come in machineries

that can deliver what are called photon, means deep-penetrating and maybe with or without being called electrons which are not so penetrating. And then there are very customized treatment delivery equipment with external beams such as was mentioned by Ms. Lindley as Cyberknife and Gamma Knife which are very specific for specific sites. There is also the use of actual radioactive sources directly placed in the tumor for a technique called Brachytherapy which again was what happened with the VA hospital was a form of Brachytherapy. So there are variations but the core of patients are treated with linear accelerators.

Mr. {Whitfield.} Yeah, okay, and when we talk about beads being placed, what is that?

Mr. {Klein.} Those would, I am sure certain that those must have meant radioactive seeds which are placed in the tumor.

Mr. {Whitfield.} Okay.

Mr. {Klein.} Sometimes they are given over a few days or 5 days or sometimes left in permanently.

Mr. {Whitfield.} Okay, well, let's take a linear accelerator for just a moment. Of course, we have the manufacturer involved because they made it. Typically, how many people would be required to be on the site when the linear accelerator is being used as it was on the Parks' son?

Mr. {Klein.} I would say for the most part two ration therapists are at the console. There can be three, hopefully, not one although I have witnessed that on some occasions.

Mr. {Whitfield.} So two radiation therapists?

Mr. {Klein.} Yes.

Mr. {Whitfield.} Now, are radiation therapists medical doctors?

Mr. {Klein.} No, the word therapist does throw people off. These are radiation technologists who have had the education to become radiation therapists in treating patients but they go by the name therapist.

Mr. {Whitfield.} Well, I know that from reading about Mr. and Mrs. Parks' son, it appears that his injury was sustained because of the filters. The filters were not calibrated or adjusted in the proper way.

Mr. {Klein.} What happens with regulator radiation therapy conventional is that there is an opening beam that treats a patient. With Intensely Modulated Radiation Therapy, there are devices, a little culmination devices that move in and out of the beam which gives it this very customized way of delivering therapy and so if those aren't in place, then the results can be problematic and I am sorry, and that is because of the irradiation time. The time it

takes to deliver IMRT, as I mentioned in my testimony, is longer then conventional therapy because the beam for the most part is being blocked so it creates extra time.

Mr. {Whitfield.} Right, right, well, from the testimony, you all can correct me if I am wrong but it appears that the recording of errors, the doses being used, the sharing of information to the people that should know it, it appears to be really a fragmented system that I am assuming would vary greatly with every institution. Would I be correct in that assumption?

Mr. {Klein.} It certainly would. An institution does from institution to institution is how they handle errors, what type of database they have and how they examine and report back to the entire staff I know will vary considerably.

Mr. {Whitfield.} Yeah.

Mr. {Klein.} And then obviously from State to State and so forth.

Mr. {Whitfield.} Well, you know, I am really glad we are having this hearing because all three of you have indicated that you do feel like there does need to be some national standards to assist in this area, and when we are dealing with equipment like this that can certainly provide healing powers and do miraculous work, it can certainly

destroy a person as well, so your testimony has really been helpful and I do thank you all three of you for being here.

Let me ask Dr. McCollough one question just out of curiosity and now this isn't anything technical but I noticed that either in your testimony or in your resume that it talks about College of Medicine, and I wasn't, I guess I should have been aware but I wasn't even aware there was a College of Medicine and Mayo Clinic. I mean I know you have residency programs.

Ms. {McCollough.} We have a medical school, also.

Mr. {Whitfield.} There is a medical school.

Ms. {McCollough.} Yeah and that is where our academic appointments.

Mr. {Whitfield.} And how many students do you have there?

Ms. {McCollough.} I don't know offhand. It is a relatively small class size, probably 50 to 100.

Mr. {Whitfield.} So this would be interns or residents or undergraduates or all three?

Ms. {McCollough.} Well, the medical school is to train physicians.

Mr. {Whitfield.} Right.

Ms. {McCollough.} The residencies would be physicians in their specialty training, and we have Ph.D. programs, and

we train technologists and allied health.

Mr. {Whitfield.} Okay, so you have the whole gamut then.

Ms. {McCollough.} We try.

Mr. {Whitfield.} Okay, thank you.

Mr. {Pallone.} Thank you, Mr. Whitfield.

I am going to ask some questions now. I wanted to first again I don't know how I could thank the Parks enough for being here and, you know, for relating the story of your son. It is just really a sobering reminder of, you know, why we are here today, frankly, that you are relating to us.

I just wanted to ask Mr. Parks, you mentioned the error reporting, why is that so important, if you would. You mentioned the error reporting, you know, that when they report the errors you mentioned that. Why do you think that is so important, the reporting? Again, I got to ask you to turn that, yeah.

Mr. {Parks.} My understanding is these machines have like a focus and ordinarily it seemed to me they should be shut so that they can over, they can't kill anybody but in this case it was wide open and it was wide open at 3 days in a row where the physicist didn't check the machine. Nobody did and in the little we know about it, there were four unauthorized, untrained people who fiddled with that machine

during those 3 days, and that I can't explain that. I don't know why that happened.

Mr. {Pallone.} Okay, so your view you are basically saying is that if there was more supervision and these things were reported then we might prevent it.

Mr. {Parks.} Yes, the physicist, it is our understanding, was gone. She went somewhere to a meeting or to a seminar or something, and left. There was no one else qualified there. They should not have run the machine if there is nobody can run it but they did, and there needs to be enough staff to where there is somebody all the time watching that machine. Also, we found that the ones that were there were watching the monitor, and apparently it give them some sort of a medication that makes patients vomit sometimes, and his face was covered with a mask and they were watching to make sure he didn't vomit into the mask and aspirate. They weren't watching the monitor that was telling them that something is wrong but they didn't look at it. They didn't look at the monitor and he didn't vomit, of course, but there was just inattentiveness there.

Mr. {Pallone.} Okay, thank you, thank you so much.

Ms. Lindley, you know, I think it is I mean obviously you said and I have said that it is critical that these technologies be available but you also, do you also think

that more needs to be done to make them safer? Maybe let me get the mike again there.

Ms. {Lindley.} I have been in pretty safe hands and I think that especially with Selective Internal Radiation Therapy that I had which was they implanted radiation they did after I had the procedure they actually took me back and did a spec scan to ensure that the radiation was in my liver and that everything was good, and so with it I was very confident. After I read their article, I know that the next time I have a treatment that I will definitely ask more questions and I think that it is good to be proactive.

Mr. {Pallone.} All right, thank you so much.

Let me ask the three doctors, I know time is running out here but I wanted to ask the three doctors a question and this gets a little complicated but if we look at ways to improve the system there are two major models that I know of. One is the Mammography Quality Standards Act which I guess I will call MQSA and then there are changes in the Medicare Improvement for Patients and Provider Act which is MIPPA, I guess. I hate to use these acronyms but I have no choice, and my understanding is that the MQSA is much more detailed and sort of aggressive. That is sort of a general statement on my part. There is no accreditation required for radiation treatment facilities. No licensing requirement for

personnel. So let me start with Dr. Klein, you mentioned the mammography standards in your testimony. I guess that is the MQSA. You know, I believe in the importance of these standards but the question is, you know, radiation therapy too complicated or too diverse for Congress to regulate it the way we are doing with the MQSA? I mean would you think that we could go that route or do you think that we should just leave it up to the practice of medicine?

Mr. {Klein.} I think because of its complication, complexity it is even more necessary to have oversight and to have accreditation for facilities.

Mr. {Pallone.} So you would--would you use the MQSA model?

Mr. {Klein.} Not exactly that model but what it is trying to accomplish, yes, which is uniformity that all mammography centers are giving the lowest doses possible to get the best images, and I think that philosophy should be carried forth that every facility before it turns on a beam has been checked, and the personnel know exactly what they are doing.

Mr. {Pallone.} Okay, now, can I make a distinction between, you know, the mammography standards, the MQSA, and the MIPPA in your mind and, you know, whether you think one is a better model then the other?

Ms. {McCollough.} The MQSA model is very prescriptive in terms of the credentials that each member of the health care team needs in terms of the quality assurance program, how frequently it needs to be performed, and in that sense the sort of consensus of the professionals in the community were able to give a set of best practices. I am not familiar as much with the MIPPA but my understanding is that it has not got as in depth and prescriptive credentialing requirements for the staff, for example certainly not going into the detail with the quality assurance.

Mr. {Pallone.} So you would be more inclined to use the more detailed or aggressive model of the MQSA. I hate to, you know, I am using my own terms here to describe it but you would be inclined that way?

Ms. {McCollough.} I think it has been a very good program. Certainly, there is, you know, a lot of overhead that comes with it so we would just want to be very, you know, cautious as we move forward that we, you know, do the best without adding too many levels of extra steps.

Mr. {Pallone.} Do you want to comment, Dr. Smith-Bindman?

Dr. {Smith-Bindman.} I do. A lot of my research focuses on breast cancer so I know the MQSA rules and regulations in detail, and I know the impact they have had on

the quality of mammography cannot be overstated. Mammography has improved profoundly since the enactment of MQSA regulation and one of the things that is so wonderful about this is they actually follow what happens at the patient level in terms of what they are likely to get when they go for a mammogram to ensure that it is of a high quality. So I think there is probably a role for both of those in oversight but MQSA has improved both the technical quality of mammography, and it has also improved the interpretation of mammography by having agreed upon standards by which these exams are done and interpreted across the country, and so the impact has been really phenomenal on the quality and improving women's access to high-quality mammography.

Mr. {Pallone.} I know I am out of time but let me just ask one more thing since I am on this. Now, CMS is currently implementing the MIPPA standards so I guess one could say, you know, should we see if they are fully implemented before we, you know, use them as an example?

Dr. {Smith-Bindman.} I think it is very important to think about what accreditation is going to do, and I think if accreditation is going to put some general standards out there, that is absolutely a move in the right direction but what you really want to make sure is that every patient at every facility is safe and getting the best quality exam they

can, and I am not sure that an overview of accreditation will give you that. So I think it is certainly a place to start. It makes no sense to have facilities that are not accredited as long as we make sure that accreditation actually gets a quality. But I think in addition to that we also need some safety measure to make sure that we are actually getting the highest possible quality out of these tests as possible.

Mr. {Pallone.} All right, thank you very much.

Mr. Green.

Mr. {Green.} Thank you, Mr. Chairman, and like everyone, I would like to thank all our witnesses and, Ms. Lindley, particularly as I say to my colleagues on the committee, you and I don't have to have an interpreter to talk since we are both from Texas, and but thank you for bringing this up. And I have watched them because some of us have served on the committee for many years and health care is as much as part of my life as it is a physicians, I think, because we, our goal is to expand access and over the last 2 years when we have seen what has happened and, you know, take away that trust that both patients and families have in some of the technology we have, that is what worries me because I look at it, and you all heard in my opening statement that in medical technology we are growing every day in our ability. I know on our next panel is a staff member for M.D. Anderson

and I have been there and watched what both as it was being built but also their laser treatment facility there. It is amazing what can be done today that use to couldn't be done simply because surgery couldn't do it, and that is why I am so concerned about making sure we get it right so we don't take away that growth into technology that makes us healthier people.

Dr. Klein, can you describe the latest advances in radiation therapy? And like I said having been to M.D. Anderson a number of times, I know my local one but I know there are also great facilities all over the country.

Mr. {Klein.} As I mentioned before, there are numerous variations on linear accelerators and what has been the most exciting addition to these linear accelerators as the ability, as the addition of imaging devices actually in the treatment room, and this has had a huge impact because now we can capture exactly how the patient is setting up, and for that matter being maintained in the right position during treatment, and this is very important. So this is what is known as Image Guidance Radiation Therapy. So this has helped us improve our accuracy of setup and also how the patients are being treated throughout the course of a given treatment.

The other new technology that is starting to boom, of

course, is Proton Radiation Therapy. These are large facilities that deliver a very different type of radiation therapy, very customized and idealized for pediatric radiation therapy, for example.

So these are some of the new things that are coming and nothing should ever stop these from happening, again, but the people trained to use them and how they are used, again, needs to be looked at with scrutiny.

Mr. {Green.} Well, I know there is a difference between radiation that maybe we have all been accustomed to for decades but compared to what is happening today whether it be proton or even hyphened usage of radiation, could you just talk about that, the difference between what has happened in the last few years on treating particularly cancer?

Mr. {Klein.} Well, being not a physician, I think almost every tumor sites now, and when I mean site I mean by site of the body, has found a way to be treated with radiation therapy more uniquely and customized. For example, not every patient is a great candidate for Intensely Modulated Radiation Therapy. There are some that still benefit from conventional therapy but certainly for the most cases IMRT has improved our ability because a lot of these tumor sites are in locations that happen to be right next to a critical organ that we don't want to give any dose to and

lately we have been able to give, again, the curative doses we need to those tumors while not giving the dosage that would cause problems to the organs nearby, and that has only been improving over the last 5 or 10 years.

Mr. {Green.} Okay, well, and I know having heard Mr. Parks and, again, what happened to Mr. Parks' son is it just seems like we ought to be able to prevent it but on can we do better on reporting the error although we know there is reporting because otherwise we wouldn't be here today because we see it in lots of different, varying facilities around the country even a VA facility so is it do we need to do better on reporting errors so we can make changes or corrections sooner?

Mr. {Klein.} I always think of error reporting in two flavors. One is anonymous reporting. Reporting that someone sends in an error that it happens with this particular machinery and does an analysis of why it happened but they do it anonymously so that they are more likely to do that because of there wouldn't be any direct liability. Now, the industry learned that that was a great way to go for learning about incidents and near misses too, and not just incidents that happened but ones that almost happened and everyone learns from that. And then, of course, there is the other error reporting for an actual damage to a patient and they

sort of both have to happen but again you can learn something from both. But anonymous reporting is something that we use and need to consider, and a lot of facilities are reticent to do so because they are afraid is they can clearly submit an anonymous report without getting into trouble.

Mr. {Green.} Well, and I know from other members questions on both sides of the aisle that it is not something we may be able to do voluntarily, you know, the industry to regulate itself. It sounds like we actually need legislation to deal with it, is that correct?

Mr. {Klein.} I think that if we go to the step of having error report, every error reported as mandatory then it obviously has to come from an agency. Now, the Nuclear Regulatory Commission does that right now. If you are in a State that is where the isotope used, use of radioactive materials it is still governed by the Nuclear Regulatory Commission. Not every State has that, two-thirds do not but in Missouri if an error were to happen with use of an isotope for radiotherapy such as Gamma Knife, we absolutely have to report that but if an error happened with a linear accelerator in Missouri, we wouldn't have to report it to anyone.

Mr. {Green.} Well, Mr. Chairman, it sounds like we have some ideas on what we need to deal with on the legislative.

Thank you. I know my time has run out.

Mr. {Pallone.} Thank you, Mr. Green.

Ms. Castor.

Ms. {Castor.} Well, thank you very much, Chairman Pallone, for calling this important hearing and thank you each and every one of you for being here today.

There have been such tremendous technological advances in medical treatment but along with these advances come increased hazards when the equipment malfunctions or is improperly setup or used incorrectly, and as the equipment becomes more powerful, I think we would all agree that it is imperative that everything possible be done to minimize the risk of something going wrong. And there was a terrible case in my hometown at the premiere cancer center that has a sterling reputation. It is just outstanding but, unfortunately, and this was a few years ago 77 brain cancer patients were over-radiated because a newer, more advanced machine had not been setup correctly. The problem wasn't discovered until inspectors from the Radiological Physics Center, a Federally financed testing service, came in for an inspection, and the director of the Radiological Physics Center said that if the inspection occurred earlier or if the Center had a regular practice which included inspections earlier they--we really could have avoided these terrible

errors. So I know you all have called for greater training, broader accreditation but on this narrow topic what about the folks that come in and install? The manufacturers' representatives are they--do they bear some responsibility of catching these errors and doing that testing? Should accreditation programs include the manufacturers' technical representatives? Dr. McCollough, do you want to start

Ms. {McCollough.} It is incumbent on the facility to actually have one of their own physicists or a hired physicist or something to test as an independent measure because the equipment manufacturers come and make sure it is operating according to specifications but then there is what I assume happened in this case the secondary test that then that the in-house people measure and calibrate it and set it up for their usage. So I think duplicative systems are always good, checks and balances, and so the manufacturers make sure it is operating. The users then have to make sure they set it up correctly and use it correctly.

Ms. {Castor.} Yeah, because according to their in-house tests, it was operating adequately or acceptably, and it wasn't until the Radiological Physics Center came to again that they noted the errors.

Dr. {Smith-Bindman.} I think that it is very important to know how the machines are used in actual practice, not how

they are used before they leave the factory, and the manufacturers when they come in to setup every CT scan for diagnostic imaging, at least, they work with the local physicians to figure out how to setup those scans. And it turns out it is a complicated topic but you get prettier pictures if you turn the dose up higher, and those default settings are crucial in terms of what most patients receive, and if those default settings are set in such a way that you get the most beautiful pictures then it turns out the patients are getting higher radiation doses then they need to support those pictures. So one of the things that the manufacturers are on the ground doing is setting up those protocols with the physicians and there should be guidelines for how those default settings, the settings that most patients experience are setup. So I would say that is one way the manufacturers could help ensure most patients receive the lowest dose possible.

Second, this awareness of the potential harm for radiation is currently getting a lot of attention and the manufacturers actually have a lot of ways to lower dose so the doses for the most typical scans that patients undergo could be reduced by 50 percent without reducing quality at all, and there are lots of ways to make that happen. Dr. McCollough is an expert on how you make those parameters as

low-dose as possible but the manufacturers have a lot of expertise around that area as well. They have algorithms that you can apply to existing machinery to lower dose, and I would really push for the manufacturers to make those software products available to everyone who currently owns a CT scan and at a reasonable price so that we can get those dose reduction algorithms out there in active practice. I think on the newer machines that will be sold over the next 5 years, this problem may be addressed to a greater degree but I think we really need to ensure the current scans that are out there are done, and there are ways to lower dose dramatically.

Mr. {Klein.} In regards to radiation therapy and in particular maybe to what happened in Florida, that manufacturer did not have any control over the training of the individual who would have been--who was responsible for determining how the machine was designating the dose rate and that is where the problem was lying. The manufacturer did not have control so that the physicist who was responsible would have demanded, and we drive our manufacturers crazy, to do extra tests to validate that everything was going correctly. However, if the manufacturer had said okay, you are buying this very expensive piece of equipment. It is complex and it is potentially dangerous. We are going to

supply and expert physicist to come in from the outside to validate what you are doing. A very simple solution that it would have caught what had happened.

Ms. {Castor.} Thank you very much.

Now, I will yield back so we can get to the next panel.

Mr. {Pallone.} Thank you. We are not going to have a second round because we have to go to the next panel but Mr. Whitfield who has been here by himself on the Republican side would like to ask some questions so I am going to let him do so.

Mr. {Whitfield.} I want to thank you for your sympathy and understanding.

When we talk about Federal guidelines for accreditation and reporting of errors and so forth, I want to ask you three physicians, do we have to be concerned about HIPAA regulations when we get into that area?

Dr. {Smith-Bindman.} I think one of the problems in easily collecting data is that you don't want to release information about the patient and privacy information that would be concerned. As it turns out for the area that we are talking about, you don't need to release any private patient information. To understand those, you need to know a little bit about that patient such as their age and their sex. None of those are covered by HIPAA, and the dose that they

receive, and that is all you need, and none of that data are protected under HIPAA. So I think we use that sometimes as an excuse for not collecting the data but in this particular area for diagnostic imaging, we don't need any of that personal data to understand quality.

Mr. {Whitfield.} And, oh, okay, Dr. Klein.

Mr. {Klein.} There are some databases right now that have a databank of errors that have been reported, the IAEA, and there is also an interesting group, European group called ROSIS, and I can supply that information later. It is all voluntary and everything is anonymous in terms of the patient information and it works very well to learn from that system so I don't think it is an issue really.

Mr. {Whitfield.} Okay, I mentioned to Chairman Pallone that if he is going in for radiation he better have his own checklist to look at and then, you know, when we started thinking about that a little bit more and I think that is one of the problems with our medical system today is frequently patients go in and they just make themselves totally compliant to whatever is going on in there. And should we pursue that in areas like this that have such dire consequences that the providers provide the patient or the patient's family with a checklist that they should be focused on as they go through their treatment?

Mr. {Pallone.} What we are basically asking is, is there anything you can do proactively as a patient to check what is going on? Now, if you go in, can I ask some questions about what is going on here to make sure that I don't get overexposed?

Ms. {McCollough.} One of the things we encourage we have a patient information brochure at the check-in desk after you have agreed with your physician that this is an important exam, is just to make sure your physician aware if you have had any exams recently because perhaps the one you are having today isn't necessary. But also we encourage in general the topic of just making sure that the institution knows that they need to right-size the dose, so to speak. Is this exam being tailored for my particular illness or diagnostic question and for my particular body size, as we all come in different shapes and sizes.

Mr. {Pallone.} Sure, go ahead. That whistling, I think, is the wind. It is not somebody holding a whistle.

Dr. {Smith-Bindman.} It is a win situation although for diagnostic imaging if you went in as an informed patient and said to the technologist or the physician, can you tell me what my dose is on this exam, the answer currently would be I don't know. I have received dozens of e-mails and letters and phone calls from patients who are really very concerned

about this, and one described his experience of asking his physician about the radiation dose and he was told by the hospital that he could hire a private physicist if he wanted that information, and that information is in the CT scan albeit it is a little tricky to get out but I think that information belongs in that patient's medical records. So if you as a patient go to the emergency department and they need to give you a medication there is a big sticker that goes on your chart if you have an allergy to a medicine, and we have tried to put checks and balances in place to make sure that if you have an allergy you don't get that medication. I think around the issue of radiation safety, we need to start thinking about that way so when a doctor sees you and orders your test, they know if you have had 15 others of those tests in the last 2 weeks. They might still get that test but that information would be very important so if information is in the medical record, I think doctors could make more informed choices. Certainly, a patient should keep track of everything they have had done and ask the right questions but we need to have a system in place at the other end that there are answers and information that they can get back.

Ms. {McCollough.} One of--if I could?

Mr. {Pallone.} Yeah, go ahead, sure.

Ms. {McCollough.} One of the difficult things about

seeing the dose is that the equipment and what the manufacturers can do is say what is this machine putting out. The actual dose to the patient then gets much more complex because it is this interaction of the patient, their body size, with what the machine is putting out. And so the data is very clear as to how the machine is set up and then a physicist can go back and make estimates and models of what that patient got, but unless you went to the extent of almost radiation treatment planning on each and every patient, you really can't tell them what your liver dose or your lung dose without actually having a full CT of their body and then modeling what the scanner gives with them.

I don't think I did a great job answering Ms. Eshoo's question about is this information available, and the number that is available is what the scanner is set up to give for a standard patient. Our technologists look at that rigorously, I mean religiously and that tells them have I set up my exam correctly. Are all my parameters typed in and then at that point the scanner adapts to the patient size. Mammography systems do this, fluoroscopy, radiography because the math that is involved to figuring how much is getting through this size patient or that is something you can't kind of do on the side on a calculator. So most radiographic systems actually have that feedback loop and that is where you can't

explicitly say what Mrs. Smith is going to get in her liver because it will take the scan of Mrs. Smith and give the feedback of just how big she is to set the dose.

Mr. {Pallone.} All right, thank you very much. So this is very instructive and I know that, you know, several members have said, you know, are we going to do legislation? Do we need a follow-up? I mean we could easily after we have this hearing today decide that we need additional hearings or get back to you and you may get some additional written questions within the next 10 days or so. So thank you all. We appreciate it and thank you in particular, the Parks and Ms. Lindley, as well. Thank you.

We are going to move to the second panel. All right. It looks like we are very crowded here. I didn't realize that you were going to be rubbing shoulders. So let me start with our second panel and introduce the panelists from my left to right.

First is Dr. Tim Williams who is chair of the board of directors of the American Society for Radiation Oncology. And then we have Dr. Michael Herman who is president of the American Association of Physicists in Medicine. And then we have Sandra Hayden who is vice speaker of the house for the American Society of Radiologic Technologists. And then Dr. Steven Amis who is former chair of the board of chancellors

for the American College of Radiology. And then from New Jersey is Kenneth Mizrach who is director of the VA New Jersey Health Care System within the Department of Veterans Affairs. And then we have David Fisher who is executive director of the Medical Imaging Technology Alliance, and finally, John Donahue who is vice chairman of Medicalis, Inc.

Thank you all for being here and I think you were all here before when I said 5 minutes and your full statements become part of the record and then we will have questions. Now, I have to apologize I mean I know when it is a Friday, of course, if the votes are over we don't have as many people participate but, you know, we had originally scheduled this for a day when it snowed, when we had all the snow so when we tried to reschedule it we didn't have a lot of options so that is why we are here on Friday.

And we will start with Dr. Williams.

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^STATEMENTS OF TIM R. WILLIAMS, M.D., CHAIR, BOARD OF DIRECTORS, AMERICAN SOCIETY FOR RADIATION ONCOLOGY (ASTRO); MICHAEL G. HERMAN, PH.D., PRESIDENT, AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE; SANDRA HAYDEN, B.S., R.T(T), VICE SPEAKER OF THE HOUSE, AMERICAN SOCIETY OF RADIOLOGIC TECHNOLOGISTS; E. STEVEN AMIS, JR., M.D., FACR, FORMER CHAIR, BOARD OF CHANCELLORS, AMERICAN COLLEGE OF RADIOLOGY; KENNETH MIZRACH, MHA, DIRECTOR, VA NEW JERSEY HEALTH CARE SYSTEM, DEPARTMENT OF VETERANS AFFAIRS; DAVID N. FISHER, EXECUTIVE DIRECTOR, MEDICAL IMAGING TECHNOLOGY ALLIANCE; AND JOHN J. DONAHUE, VICE-CHAIRMAN, MEDICALIS, INC. .

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^STATEMENT OF TIM R. WILLIAMS

} Dr. {Williams.} Thank you. Chairman Pallone and Representative Whitfield and members of this distinguished committee, good afternoon and thank you for the opportunity to testify at today's hearing.

I am a practicing, board-certified radiation oncologist and I have been in my location for over 20 years, and I have personally taken care of almost 7,000 cancer patients. I care deeply about the health and safety of my patients.

ASTRO wants patients to have peace of mind when it comes

to safety, quality and efficacy of radiation therapy. We are committed to stronger error reporting, enhanced accreditation, better use of health information technology, patient-centered educational tools and Federal advocacy to help protect patients. I was not involved in any of the tragic situations described by the New York Times but I want to offer my own personal sympathies to those families and particularly the family of Scott Jerome Parks, whose father shared his story with us earlier. His wish was that no one else would go through what he did. We agree. No medical error is acceptable. Cancer patients have enough to worry about.

I have personally witnessed the great benefits of radiation therapy for cancer patients as the medical director of the department of radiation oncology at the Lynn Cancer Institute of Boca Raton Community Hospital. I currently serve as chair of the board of directors of the American Society for Radiation Oncology for whom I am representing here today.

Radiation oncology is an important tool in the fight against cancer, contributing over the past 25 years to steady increases in survival rates for cancer patients. In the mid-1970s, for example, the 5 year survival rate for breast cancer was 75 percent, for prostate cancer it was 69 percent.

Today that survival rate has increased to 98 percent for breast cancer and 99 percent for prostate cancer. These are important gains. More are needed.

ASTRO's highest priority is ensuring that patients receive the safest, most effective treatments. A culture of safety and quality control is woven into the fabric of our field with many checks and balances to assure that safe and effective care is delivered to our patients. While ASTRO is alarmed and concerned by the errors described in recent press reports, we do not believe that there are widespread radiation mistakes leading to patient harm across the country. However, the reports do highlight that there is more work to do. Any error, no matter how small, must be reported, understood and utilized as a tool to reduce the potential for future errors. Failing to report known errors is unacceptable.

This moment is an opportunity to further improve our efforts to strengthen the practice of radiation oncology. We have developed a six-point action plan we call target safely. Number one. Work to strengthen error reporting and to create a national database for the reporting of medical errors.

Number two. Advocate for new and expanded Federal initiatives to help protect patients from radiation errors. This includes supporting passage of the CARE Act that

2081 requires national standards for radiation treatment team
2082 members, supporting increased funding for the Radiological
2083 Physics Center at the M.D. Anderson Cancer Center and the
2084 quality assurance activities of the Advanced Technology
2085 Consortium support a Congressional inquiry into self-
2086 referral. ASTRO is concerned that self-referral of radiation
2087 therapy services may result in short-changing essential
2088 quality control assurance and patient safety protections.
2089 Number three. Work with cancer support organizations to
2090 help patients know what to ask their doctors about radiation
2091 therapy. Empowered patients who actively engage in their
2092 care are important members of our team fighting to beat
2093 cancer.
2094 Number four. Enhance the joint ASTRO ACR Radiation
2095 Oncology Practice Accreditation program. ASTRO recommends
2096 that all radiation oncology practices undergo accreditation.
2097 Number Five. Expand educational training programs to
2098 include an intensive focus on quality assurance and safety.
2099 ASTRO strongly encourages that all radiation oncologists
2100 participate in maintenance of certification.
2101 Number Six. Accelerate our ongoing health information
2102 technology interoperability effort. We want device
2103 manufacturers to implement standards that allow the transfer
2104 of treatment information from one machine to another

2105 seamlessly to reduce the chance of a medical error.

2106 ASTRO has been developing and refining many of these
2107 programs for years. In today's environment, medical
2108 technology and decision-making are increasingly complex. The
2109 above plan holds the promise of ensuring patient safety in
2110 this challenging atmosphere.

2111 Finally, I would like to demonstrate the benefits of
2112 radiation by telling you the story of one of my patients from
2113 South Florida. I treated a 50-year-old woman 15 years ago
2114 who presented with bilateral breast cancer. At that time,
2115 the standard therapy was bilateral mastectomies and the idea
2116 of a lumpectomy and radiation for both sides at the same time
2117 was considered a very advanced form of therapy. She didn't
2118 want both of her breasts removed and we went ahead and
2119 proceeded with the lumpectomy on both sides and simultaneous
2120 radiation to both breasts. She is now alive 15 years late.
2121 I have been following her for the entire time period and she
2122 spends time with her family, enjoys a good quality of life
2123 and is a true success story for today.

2124 This is what keeps me hopeful and looking for advances
2125 in the field. My hope is that patients across the country
2126 will recognize these incidents for what they are, isolated
2127 acts and that these reports will not dissuade patients who
2128 need radiation therapy from receiving needed treatments. We

support the committee's review of these issues and we look forward to working with you to further enhance the quality of care patients receive.

Thank you for the opportunity to testify.

[The prepared statement of Dr. Williams follows:]

********** INSERT 7 **********

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Mr. {Pallone.} Thank you, Dr. Williams.

Dr. Herman.

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^STATEMENT OF MICHAEL G. HERMAN

} Mr. {Herman.} Chairman Pallone and distinguished members, good afternoon. Thank you for the opportunity to testify.

My name is Michael Herman and I am president of the American Association of Physicists and Medicine. Medical physicists are responsible for accuracy, quality and safety of the radiation-producing technology and diagnostic imaging and radiation therapy. Although rare, medical errors can be devastating. We all wish that no one ever made a mistake but errors still can and do occur due to a combination of unlikely events occurring sequentially or simultaneously, many times under unusual circumstances that involve complex systems.

The use of medical radiation occurs in radiation oncology and in radiology practices with millions of people receiving that radiation annually to their benefit. Each patient procedure is a complex, multi-system process which combines technology and human actions. To make the process work requires coordination and participation of a team of humans, physicians, medical physicists, dosimetrists, radiation therapists, radiation technologists. All focus on

the treatment of each patient.

One of AAPM's primary goals is to identify and implement improvements and patient safety for the medical use of radiation. We do this through our association's activities and in cooperation with other societies and regulatory and government bodies. Some of these include the development of procedures and guidelines, producing detailed scientific educational and practical reports, guidance to regulatory and accrediting bodies, oversight of quality assurance and calibration processes, facilitating medical information system communication and providing education on medical errors.

AAPM believes that the position of qualified medical physicists should be recognized nationally for anyone practicing clinical medical physics. A qualified medical physicist is an individual who has completed a unique combination of graduate education, rigorous clinical training and board certification in medical physics. All of these efforts mentioned move us toward more effective patient care and in achieving the absolute minimum error rate, however, some challenges remain.

There is no consistent national recognition of qualified medical physicists. Medical physicists are licensed in only four States in this country and regulated at widely varying

levels in the other States. The reports and guidelines that AAPM and others publish have only the force and effect of professional and scientific guidelines. There are no consensus national staffing guidelines for qualified medical physic services nor are there consistent standards established for accrediting practices that utilize medical physic services.

So what can we do? Well, much effort and progress is being made to improve quality of care and increase patient safety but we can and must do more. Together medical radiation team members, professional associations, manufacturers and government must strive for nationally consistent recognition of the qualified medical physicist and equivalent competency for all medical radiation team members by passing H.R. 3652, the Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy Act of 2009, and specifically requiring that all medical physicists involved in medical imaging and radiation therapy be included in this bill. Provide consistent procedure-specific consensus minimum standards for national practice guidance in radiation oncology and medical imaging that recognize qualified individuals for specific responsibilities. Define communication of the team. Establish minimum staffing levels and receive timely review

and amendment. Establish a rigorous minimum standard for all bodies at accredit clinical medical radiation practices based on the previously mentioned staff list national guidance that includes additional accredit requirements for highly-specialized procedures. Link CMS reimbursement to rigorous practice accreditation for all medical imaging and radiation therapy practices. Create a national data collection system to learn from actual and potential adverse events in the medical use of radiation that allows complete and consistent reporting by medical staff, manufacturers and others. Improve the review effectiveness of product quality in the equipment clearance process.

In summary, we believe that patient safety and the use of medical radiation will be increased through consistent education and certification of medical team members, whose qualifications are recognized nationally, and who follow consensus practice guidelines that meet established national accrediting standards. We have been working together for years on many of these issues. We must do more and we need some help. Together we will continue to make the use of medical radiation safer and more effective for the people that need it.

Thank you for the opportunity to speak to you today.

[The prepared statement of Mr. Herman follows:]

2231 ********** INSERT 8 **********

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Mr. {Pallone.} Thank you, Dr. Herman.

Ms. Hayden.

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^STATEMENT OF SANDRA HAYDEN

} Ms. {Hayden.} Mr. Chairman.

Mr. {Pallone.} It sounds like it is working. Go ahead.

Ms. {Hayden.} Mr. Chairman and members of the committee, my name is Sandra Hayden and I am a radiation therapist at M.D. Anderson Cancer Center in Houston. I also serve on the board of the American Society of Radiologic Technologists and it is in that role that I address you today.

On behalf of the ASRT's 134,000 members, thank you for the opportunity to contribute to this dialogue on the quality of radiation therapy and other medical procedures that use radiation. Radiation therapy is the cornerstone of cancer management programs worldwide. It can contain, control and cure cancer however radiation therapy must be precise to be effective. Accuracy is equally important during medical imagining exams that diagnose cancer. X-ray exams, CT scans and other imaging tests use radiation and radiation comes with some risk. Errors, although rare, can cause devastating side effects.

The ASRT believes the best way to ensure quality and safety of medical radiation procedures is to establish

national educational and certification standards for technical personnel who perform them. CT scanners, gamma cameras and linear accelerators are some of the most complex medical equipment in the world however this technology is ineffective in the wrong hands. That is because the quality of any medical radiation procedure is directly linked to the scale and competence of the person performing it. Individuals must have extensive education and training to perform the exam correctly. Patient safety is in the hands of these individuals yet they remain largely unregulated.

Radiographers are not licensed in eight States. Radiation therapists such as myself are not regulated in 17 States, including the District of Columbia. Medical physicists have no oversight in 31 States and no State regulates medical dosimetrists. Even in States with some type of regulation, the rules are sometimes so weak they offer patients little protection. In some States hairdressers are better regulated than people who perform medical radiation procedures.

Unqualified personnel are a danger to patients. An underexposed x-ray can't reveal a malignant tumor. An inaccurate radiation therapy treatment can't stop its spread. Even worse, when medical radiation is used improperly it can harm the very patients it was meant to help as you have heard

from earlier.

The solution is the Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy bill. The CARE bill introduced by Representative Barrow as H.R. 3652 and pending before Congress since 2000 uses a three-tiered approach to improving quality and safety.

First, individuals who perform medical imaging and radiation therapy would be required to graduate from a specialized educational program. Second, they would be required to pass a national certification exam and third, they would be required to maintain competency by obtaining continuing education.

Only qualified personnel should be allowed to perform medical imaging or radiation therapy. The CARE bill will ensure a minimum level of education, knowledge and skill for those who are responsible for medical radiation procedures. For patient safety, the ASRT encourages Congress to pass the CARE bill.

The ASRT also calls for consistent and mandatory methods of reporting medical radiation errors. Mistakes must be reported and investigated so others may learn from them. By learning how errors occur, we can implement safeguards to prevent them.

Currently, States and Federal oversight of radiation errors is inconsistent. Regulatory bodies do not share information. Even worse, some States do not require that errors be documented at all. The ASRT calls for mandatory reporting of medical radiation errors and also for a consistent system of data collection and tracking.

A model to consider is the FDA's MedWatch program which takes a systemic approach. A reporting system such as MedWatch would build a knowledge based on patient safety and help reduce errors.

Thanks to medical imaging and radiation therapy millions of Americans are cancer survivors. The vast majority of medical radiation procedures are administered safely and successfully however any mistake is unacceptable. ASRT's recommendation will lead to safer care and will help more patients win the battle against cancer.

Thank you again for inviting me to speak on this important issue.

[The prepared statement of Ms. Hayden follows:]

********** INSERT 9 **********

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Mr. {Pallone.} Thank you, Ms. Hayden.

Dr. Amis.

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^STATEMENT OF E. STEVEN AMIS, JR.

} Dr. {Amis.} Chairman Pallone, Congressman Whitfield and distinguished members of the subcommittee, thank you for the opportunity to speak today.

I am Dr. Steven Amis, Professor and Chair of Radiology, The Albert Einstein College of Medicine in Montefiore Medical Center in New York. I am a past president of the American College of Radiology and I am testifying today in my capacity as chair of ACR's blue ribbon panel on radiation dose in medicine.

The ACR which represents more than 36,000 radiologists, radiation oncologists, nuclear medicine physicians and medical physicists is committed to ensuring appropriate use of radiation in medicine. One message I must highlight today is that the proper use of radiation in medicine whether diagnostic or therapeutic saves lives and improves the quality of care for millions of patients each year.

Please consider the following. Advances in medical imaging have rendered exploratory surgery virtually obsolete. Interventional radiologic procedures often replace more invasive surgical options resulting in approved outcomes and reduced hospital stays, and over one million patients each

year are cured or experience relief of pain due to treatment of their tumors with radiation therapy.

Still as has been known for the past 100 years, recent media reports remind us that the medical use of radiation is not without risk. We can and must do a better job of preventing errors.

The ACR has long been involved with numerous radiation-related quality improvement initiatives. These include development of guidelines to ensure that patients get the right exam or treatment performed in the right way. Creation of registries and other tools to help physicians compare their outcomes with those of their peers, and education of radiologists, fellow physicians and the public about the risks and benefits of both diagnostic and therapeutic radiation. Of particular note, ACR strongly supports Image Gently, an educational initiative conceived by pediatric radiologists to promote safe imaging of children.

To help prevent further adverse radiation-related events, ACR asks that Congress seriously consider the following recommendation and we are not pulling any punches. A formal accreditation process must be mandatory for all diagnostic imaging service and radiation therapy practices. In this process hospitals and freestanding facilities should be held to the same standards as patients have a right to

safe and high-quality care regardless of the setting in which they receive it. Such a process should be robust and focus on considerations unique to imaging and radiation therapy such as image quality, dose monitoring, phantom testing, equipment calibration and maintenance, and the qualifications of all involved personnel.

As a corollary, since CT scans are a growing cause of radiation exposure in the United States, a CT dose registry should be required as a component of accreditation for CT practices. This would help ensure ongoing compliance with accreditation baseline.

ACR has been working with industry to develop such a registry but a Congressional mandate would facilitate this process. Congress has already recognized the importance of accreditation. MQSA requires accreditation of mammography practices and has helped save tens of thousands of lives. A similar approach is seen in MIPPA. It has already been described, which requires accreditation of non-hospital-based imaging practices. Both MQSA and MIPPA offer important lessons on how to design an optimal accreditation process.

Further, it is essential that the accrediting bodies have a proven track record in imaging and radiation therapy accreditation. The ACR is the nation's oldest and most recognized medical imaging and radiation therapy accrediting

body and is the only nationwide FDA approved accrediting body for MQSA. ACR accreditation designed to be educational in nature is an efficient process of both self-assessment by the practice being reviewed and independent, external audit by physicians and medical physicists who are recognized experts in the specific type of practice being evaluated.

We recognize there is a desirable middle ground between an accreditation process that is overly burdensome and one that lacks the substance to ensure quality and safety. We stand ready to work with members of this committee to find the right balance.

Thank you again for the opportunity to testify and for holding this hearing on such an important topic.

[The prepared statement of Dr. Amis follows:]

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Mr. {Pallone.} Thank you, Doctor.

Mr. Mizrach.

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^STATEMENT OF KENNETH MIZRACH

} Mr. {Mizrach.} Good afternoon, Mr. Chairman. Thank you for the opportunity to share the radiation oncology experience at the VA New Jersey Health Care System.

I will describe for you our 3-year journey that includes how we identify the problem and the quality of care for radiation oncology patients, how we responded and how we rebuilt our program to make sure that these circumstances would not happen again. Transparency was our constant focus throughout this process and guided our decisions to ensure that we acted in the best interest of our patients, and as soon as we determine that specific patients did not receive the quality of care they deserved, we disclosed this information to 53 patients and their families consistent with the Veterans Health Care Administration policy.

Of the 53 patients, we determined that two patients were harmed. We informed the other 51 patients that they experienced errors that created a risk for them for the future. We are following these patients for any subsequent signs of injury resulting from the identity of any of these errors.

Prior to December of 2006, the East Orange campus of the

VA New Jersey Health Care System radiation oncology program was accredited by a nationally recognized, external, reviewing agency. Our patients were satisfied. Staff members had no complaints and all indications suggested our program was delivering quality care.

In December of 2006, we first heard that two radiation therapy contract technicians unexpectedly were no longer reporting to work at our facility. When we inquired as to why this happened, we learned that they had raised concerns about the quality of care being providing resulting in a conflict with the supervisory staff.

We immediately initiated a review that included a series of increasingly detailed investigations of the quality of care in radiation oncology. The first review by a quality manager validated that the concern raised by the technicians were credible. In response, we made the decision to close the program down until a thorough review was complete and we were certain our program provided safe, quality care for our veterans.

Patients in the need of radiation therapy have received care through fee-basis arrangements with local accredited facilities in their communities. Subsequent reviews by external VHA teams of experts and final comprehensive review by the American College of Radiology confirmed there were

deficits in our programs. These included issues of staff qualifications and communication, implementation of new technology without adequate education and training, gaps in procedures for managing patients and the lack of a robust, quality assurance program.

These findings became the framework for rebuilding our radiation oncology program. We needed to be sure we would deliver the highest standard of care possible and implement corrective actions to rectify all deficits identified by the ACR.

During the course of the investigation, the clinical staff who had been working in our programs resigned. At the same time, the contract for radiation therapy technicians and for contract physicists expired. We then made the decision that it would not be renewed.

We began by improving our program by hiring new staff members including a nationally respected, experience and board-certified chief of radiation oncology. We also hired properly trained and credentialed physicists, a dosimetrist and radiation therapy technicians.

As radiation therapy is complex and rapidly changing, we established a program of continuous education for all staff and a major component of this initial and ongoing training of new technology and equipment. We next established policies

and procedures to guide patients' care and instituted a comprehensive quality management program.

Such a program includes meeting the standards established by the American College of Radiology. This entails identifying quality control for every step of radiation therapy including the dose and technique prescribed, the energy the machine delivers, the dose of radiation the patient receives and how the patient responds to the therapy. We are continuing the routine tests of our machines simulating patient encounters, checking dose calculations, tracking patient outcomes and instituting routine quality reviews of care including peer review.

A culture of openness is fundamental to patient safety. This means an environment where all staff members are considered an equal part of the health care team. To this end, we established multi-disciplinary team meetings prior to, during and after treatment to review all aspects of care. We encourage our staff members at all times to raise questions of concern about that care being provided. The most important lesson we learned through this process was that staff members must be able to communicate openly to feel comfortable about raising issues and to feel confidant that leadership will respond to their concerns.

Thank you again for the opportunity to share my

experience. I am now available for questions at a later time.

[The prepared statement of Mr. Mizrach follows:]

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Mr. {Pallone.} Thank you, Mr. Mizrach. Thank you for being here too, today. I appreciate it.

Mr. Fisher.

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^STATEMENT OF DAVID N. FISHER

} Mr. {Fisher.} Mr. Chairman, Congressman Whitfield, Congresswoman Castor, thank you for the opportunity to be here today.

I serve as the executive director of the Medical Imaging and Technology Alliance, the leading association representing the manufacturers, innovators and developers of medical imaging and radiation therapy systems. We are here today because of a tragic situation and as an industry we are committed to doing our part to prevent such things from occurring in the future.

At the outset, it is important to note that computed tomography, CT, and radiation therapy, RT, are very different modalities used for different purposes. CT is a diagnostic tool that utilizes ionizing radiation to create detailed images of internal tissues. Radiation therapy or RT on the other hand, is a therapeutic tool that utilizes a focused beam of radiation to kill cancer cells. Due to their distinct purposes, the amount of radiation associated with these modalities differs by orders of magnitude.

These two modalities have revolutionized health care delivery. The New England Journal of Medicine recently

called medical imaging one of the top health care innovations ever. Likewise, radiation therapy offers highly personalized, non-invasive and cost effective care for up to 60 percent of all diagnosed cancer patients in the U.S.

MITA has a long history of working with its members, physicians, physicist, technologists, regulatory bodies and other stakeholders to track and reduce medical radiation. Our members continue to introduce new products in system innovations that reduce radiation dose for many procedures while continually improving image quality. New technologies like weight and age-based protocols, automatic exposure control, software improvements and improved interfaces with operators all enable dose reduction.

MITA is also working collaboratively with other stakeholders on issues related to medical radiation and the use of radiation in the equipment. For example, in November of last year, MITA convened a meeting including physicians, physicists, industry and Food and Drug Administration official to discuss ways to prevent future medical errors that involve ionizing radiation. MITA is also cosponsoring an upcoming CT dose summit and is also considering a radiation therapy summit to work with the AAPM on a radiation therapy summit to further the education of providers, physicists and others on the new technologies, dose reduction

technologies in particular our companies manufacture.

As part of the access to medical imaging coalition, MITA helps to develop appropriateness criteria for advanced medical imaging included in the Medicare Improvements for Patients and Providers Act or MIPPA. More recently, MITA announced its support for the President's proposal in the fiscal year 2011 budget to develop a National Dose Registry. We also welcome the FDA's recent actions regarding radiation dose and support many of the policies proposed in their initiative to reduce unnecessary radiation exposure for medical imaging. MITA intends to participate fully with FDA as they work to implement dose reduction policies and MITA has also recently made two announcements in the area of radiation dose that may be of interest to this committee.

Yesterday, MITA announced a new dose check initiative in which CT manufacturers committed to do three things. First, a new radiation dose alert feature which is designed to provide a clear indication that the settings for the CT exam will result in a dose higher than a predetermined reference dose for routine scans. Second, manufacturers are committed to including a dose warning feature to prevent CT scanning at higher, potentially dangerous radiation levels. This feature is designed to prevent hazardous levels of radiation that could lead to injuries. This feature can also be configured

by hospitals or imaging facilities to prevent scans at these higher radiation levels. Third, manufacturers will also standardize dose reporting to help better understand dose levels and facilitate the development of the National Dose Registry proposed by the President.

Several weeks ago MITA also announced a dose reduction plan including the development of radiation dose reference levels to assist clinicians to understand the relative amount of radiation associated with the scan. Expansion of the appropriateness criteria mentioned earlier to ensure that patients receive the right test at the right time, the development of training standards for hospitals and free-standing imaging facilities that purchase imaging equipment that involve the use of radiation and radiation therapy equipment, efforts to develop safety checklists to reduce medical errors and to incorporate those new standards into our training offerings. Efforts to ensure standardize reporting across stakeholders in a manner that is transparent for patients, their families and physicians. An examination of whether the MIPPA accreditation policy should be expanded to include additional facilities where radiation therapy medical devices are in use, and the establishment of minimum standards for radiologic technologists who perform diagnostic medical imaging exams and deliver radiation therapy

treatments.

In each of these cases, MITA and our member companies stand ready to work with professional organizations, regulatory bodies, individual clinicians and other stakeholders on these features. Lastly, MITA continues to work with all of our members whose companies manufacture products that ionizing radiation to develop new ways to reduce dose and reduce medical errors, and I am hopeful we will continue to make strides in this area. As we look to the future of health care in this country, we cannot see our way to better outcomes and lower costs without the lens that medical imaging provides. The medical technologies MITA member companies research, develop and manufacture are the future of delivering better health outcomes at lower costs.

Thank you for this opportunity today. As the legislation process proceeds, MITA looks forward to continuing to work with Congress and the Administration to ensure appropriate use of and access to medical imaging and radiation therapy.

[The prepared statement of Mr. Fisher follows:]

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Mr. {Pallone.} Thank you, Mr. Fisher.

Mr. Donahue.

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^STATEMENT OF JOHN J. DONAHUE

} Mr. {Donahue.} Thank you, Chairman Pallone, Congressman Whitfield.

My name is John Donahue and I am grateful to be here to discuss the issues surrounding ionizing radiation in medicine. I want to begin by expressing my profound admiration for the courage of the Parks Family.

I am here as the vice-chairman of Medicalis. Medicalis is a leading innovator of technology and clinical solutions focused on improving access to high-quality, safe, clinically-appropriate, advanced diagnostic imaging. We are a company founded by the radiologists and information technologists of the Brigham and Women's Hospital in Boston. We provide physicians at the point of ordering with web-based radiation safety and clinical appropriateness decision support.

By way of background, I have been in the health care, the international health care industry for over 25 years in the pharmaceutical vaccine and the radiology industry. In the late 1990s, I co-founded and acted as president and CEO of one of the nation's first and the largest radiology benefit management companies. I have had the opportunity to

interact extensively with CMS, MedPAC, the GAO, Congressional offices and many of the stakeholders in this area on an array of imaging issues.

Diagnostic imaging is rife with many health policy and Federal legislative opportunities. I am hopeful that after today's hearing, we will all agree that radiation safety in imaging is a measurable and very serious issue but there are specific steps that we can take to mitigate the risk.

Radiation safety has been very much in discussion since 1895 when a new kind of light, the x-ray was discovered. In July of 2005, the National Academy of Science has issued a seminal study that examined health risks from exposure to low level ionizing radiation. Today this study is commonly referred to as the BEIR VII report or the Biological Effect of Ionizing Radiation report. The watershed conclusion was that any level of ionizing radiation can induce a carcinogenic effect. The report showed that a single CT of the abdomen emitting 10 milliSieverts of ionizing radiation increases the risk of induced cancer to 1 in 1000 times. Further and importantly, cumulative dosage totaling 100 milliSieverts can ratchet up this carcinogenic risk to 1 in 100 times.

It is also important to note that although radiosensitivity values vary dramatically by body tissue as

well as by gender and by age, studies have shown that there are meaningful dose estimates that can be measured. For example, the Cleveland Clinic submits that an abdominal CT emits roughly 10 milliSieverts of radiation, a Cardiac PET 15, a CT urographic study 44, while a plain chest x-ray emits less than .1 millisieverts.

In 2006, I helped lead a radiation safety dosage initiative and awareness program. The results were startling and they were highlighted extensively in the Wall Street Journal. Firstly, some individuals received radiation exposure more than 1000 percent higher than recommended guidelines. And secondly, one patient received 341 CT scans over an 18-month period bringing the radiation exposure level to almost 1000 milliSieverts.

In 2007, I presented yet another radiation safety initiative focused on the Medicare population. In this particular study over a 12-month period, almost 20 percent of the medical population, of the Medicare population receive radiation exposure that exceeded the BIER VII radiation recommended levels.

Diagnostic imaging is an extraordinary clinical tool. We want to encourage and expand the appropriate and the safe use of diagnostic imaging but the evidence appears to be incontrovertible that patients are all too often exposed to

unnecessary level of ionizing radiation.

I believe the solution is to do four things. Firstly to ensure that every advanced imaging study is clinically proven by evidence and that it is not redundant. Secondly, to measure and report on individual cumulative milliSievert dosage, and present this ionizing history to physicians at the point of ordering. Thirdly, I believe we should require recommendations of viable clinical alternatives to enhanced radiation risk when they exist. For example, could an ultrasound, a lab test or some blood work be sufficient for an initial diagnosis? Finally, the fourth is I believe that once these tests pass these three criteria that they should be performed in facilities by physicians and by RAD techs who are accredited and trained, and that the equipment is assured to be set at the correct specifications.

My company, Medicalis, is able to deliver clinical appropriateness and radiation safety today. We continuously survey and present available patient information to physicians at the point of ordering, including an individual-specific radiation history dosage. We also evaluate the clinical appropriateness of the test and present alternative recommendations if radiation safety sparks a concern.

In 2010, we have no excuse but to leverage available clinical evidence, innovative technology and regulatory

policy to assure that all Americans receive clinically-appropriate and safe advanced diagnostic imaging. I would respectfully suggest that Congress encourage CMS to encourage a web-based or to include a web-based, clinical decision support in radiology safety program in the upcoming radiology pilots.

In addition and finally, I want to commend the Food and Drug Administration's unveiling of its recent radiology initiative, specifically, the two underlying principles of appropriate justification of a radiation procedure and the optimization of the radiation dosage. These two issues address many of the concerns that I have raised in this testimony and we look forward to working with the FDA and other imaging stakeholders as this effort moves forward.

I want to thank the chairman and I want to thank the entire committee for your focus on this issue, and I would be pleased to answer any questions.

[The prepared statement of Mr. Donahue follows:]

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Mr. {Pallone.} Thank you, Mr. Donahue.

Thank all of you. We will take some questions now.

Let me start out by saying that Dr. Michael Hagan, I guess, is here to accompany Mr. Mizrach. That is you? Raise your hand, okay, and that would be if we have any questions about the VA in general, I understand.

And then I also would ask unanimous consent to enter into the record a statement by our Chairman Emeritus John Dingell. Without objection, so ordered.

[The prepared statement of Mr. Dingell follows:]

********** COMMITTEE INSERT **********

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Mr. {Pallone.} I am going to start the questioning and I wanted to start with Ken Mizrach if I could. Again, the reason why your testimony is so valuable in my opinion is because you at the VA hospital in New Jersey went through a situation where there were problems. You closed the facility. You came back and corrected them and so I think that example is sort of a good one, and in part what I am asking is whether these changes that you have made, you know, could be utilized at other facilities? I mean that is really what I am trying to get down to but let me just say, Mr. Mizrach, you mentioned in your testimony that you will require continuous education for all staff specifically with respect to the technology and equipment. Can you elaborate on this in more detail and explain how you think this is going to work in practice and, I guess, also whether it will be useful for other hospitals.

Mr. {Mizrach.} Well, I think there needs to be a constant, continuous education on any new piece of equipment in a medical center, whether it is in radiation oncology or radiology department or audiology and speech. There are programs available nationwide constantly being offered. We need to make sure that our specialists are certified and trained before they have any opportunity to use the

equipment. Recently, as we are getting ready to open our program, we brought in the manufacturers to work with our staff to observe simulations and that was part of the process, and before we get the green light to open, we need to make sure that everyone is equipped. I want to know that my airline pilot is ready to fly that new piece of equipment before I get on that plane and there should be no difference in being treated in a medical center.

Mr. {Pallone.} Now, you mentioned conducting routine tests of the machines to make sure that the therapy you are providing is correct and safe. One of the recent articles in the New York Times highlighted a hospital that has been over-radiating patients for the past 5 years, and their regular system checks did not catch the error. So can you just elaborate a little more on this aspect of the quality assurance plan and how these types of tests work and again, how they would be, you know, help prevent situations in other hospitals?

Mr. {Mizrach.} I would really like to defer that to Dr. Hagan who really has the expertise.

Mr. {Pallone.} Sure, all right, he will have to come up, I guess, and take your place there. I don't know where or use one of the mikes.

Dr. {Hagan.} Mr. Chairman, after East Orange, shortly

2802 after East Orange the VA nationally required ACR
2803 accreditation for all radiation oncology facilities within
2804 the VA. Nationally, fewer than 20 percent of radiation
2805 oncology practices are ACR accredited. This requirement for
2806 accreditation comes with some teeth.
2807 In the last year under signature by the principal deputy
2808 under secretary, any finding by a surveyor at a VA site now
2809 must be corrected. And the authority for that correction
2810 goes up to the network director, and the network director is
2811 required to report through my program office to the under
2812 secretary that each item has been corrected so that puts the
2813 quality control loop.
2814 To answer your specific question though about the
2815 physics oversight for radiation oncology, it is a little bit
2816 different although when ACR evaluates, they evaluate both
2817 with medical physics and the process with the radiation
2818 oncologists. Most of our centers put patients on NCI-
2819 sponsored trials and so they fall under quality assurance
2820 program for the Radiologic Physics Center. You have heard
2821 that mentioned by a couple of panelists today. It is a
2822 federally-funded, undergrad center out of M.D. Anderson.
2823 Prior to initiating treatment again in East Orange, our
2824 PC paid a visit and went through their very extensive
2825 evaluation of the linear accelerator at that facility and so

they have been surveyed with almost 36 hours of continuous operation with a physicist going through each of the planned operations and actually it is a result of that initial evaluation that we are going to hold on treatment of the first patient until all of the issues that were found by the RPC have been resolved.

Mr. {Pallone.} I guess going back to my initial statement, to what extent is what you are doing now something that you would see that we should apply nationwide or to other hospitals not in the VA system?

Dr. {Hagan.} That is an excellent question and RPC is mandated to support with onsite evaluations, all centers place patients on NCI-sponsored trials. To be able to expand that kind of service nationwide would require an order of magnitude increase in the size and facility of like RPC. Actually, it would jeopardize their ability to perform their mandate which is to support clinical trials but to use RPC as a model and then fund a similar organization that can do that level of observation on a routine basis in each center should be mandatory.

Mr. {Pallone.} Okay, thank you very much.

I don't even know what my time is here so I have another 2 minutes. I am not sure that is accurate. I think I may have given myself more time but in any case the, let's see, I

am going to ask this of Dr. Herman, I guess, if I could have shortened this with the time.

In one of the New York Times articles in order to qualify for a clinical trial in radiation therapy, the institution has to submit to enhanced testing to make sure that they were delivering therapy properly. And I guess a lot of the institutions failed those tests according to the New York Times, but in the report by your association, Dr. Herman, you also said this was a sobering statistic, and I agree, and that the tests are quite rigorous but still when our nation's top institutions apply to a clinical trial and often fail we should wonder what is happening. So I wanted to ask you do you think that this is a sign of a larger problem and I don't know, I just wanted someone to respond to that. I guess it could be you, Dr. Herman, sure.

Mr. {Herman.} It is certainly an indication that it is difficult to carry out IMRT treatments. One of the things the sentence that follows the part about the sobering statistic in that same report suggests that there is a larger consideration with the commissioning portion of the systems that comes before the clinical use. So the details of the algorithm and some of the other things that can create additional variations and some of the results, some of the cases that didn't pass in the first, the RPM phantoms, were

also due to not using the entire team to do the treatments. So I think one of the things that would be helpful is to have the phantom go through the entire identical process to what a patient goes through as opposed to sometimes having physicists try to do the whole thing because you are not taking advantage of the entire team component.

Mr. {Pallone.} Okay and, Ms. Hayden, you talked about all these variations in terms of education, standards, accreditation from one State to the next, and you obviously mentioned the CARE bill that you would like to see that promulgated. It seems to me frankly that, you know, what you suggested is probably, you know, it may be one of the most important things to do because the technicians are such an important part of this so I just I don't know if you wanted to comment any more about, you know, the importance of national standards but I have to say that it was really disturbing to me to read that there was so much variation from State to State. And I don't know if you wanted to hit anything more about it but I just thought that that was really sobering more than anything else.

Ms. {Hayden.} Of course, Chairman Pallone, I appreciate this opportunity to speak again on behalf of the ASRT as well as on behalf of the radiologic technologists that administer radiation therapy and do the radiologic technology medical

imaging exams. There is--it is very sobering. The radiation therapists in my case which is what I am, we are the last line of defense for the patients. We are the safety net for the patients. We are the ones that are turning on that machine. We work in collaboration and we follow the prescription from the physician. We work hand-in-hand with physics. I feel like I want to hold hands at the table but certainly the CARE bill itself is just commonsense to have educationally prepared, clinically competent practitioners, radiologic technologists is what we like to be referred as, to actually deliver this care for patients. Patients should be the number one focus of this and I am awfully happy to have the opportunity to comment.

Mr. {Pallone.} Well, let me just ask this and this will be my last question. If we were to implement, let's say we were to pass the CARE bill, I guess you would have to--you couldn't--you would have to make it pro, you know, moving forward. You couldn't make it retroactive presumably. How long would it take before, you know, you would be able to have enough people to perform these tasks that would meet the standards of the CARE bill? I mean are we in position that we would have to say, you know, 2, 3, 4 years from now before we could actually have enough people that would meet the standards?

Ms. {Hayden.} Yes.

Mr. {Pallone.} Sure.

Ms. {Hayden.} We actually have timeframes. There will not be a shortage in regards to the people that will actually be performing examinations with the CARE bill or the passage of the CARE bill. As a total opposite, it also will help save money in regards to not having repeated images and things of that nature. And in addition to that there is effective dates to the CARE bill and so you would, you know, definitely follow that and I have it in my hand here for you but we just want to be sure, the ASRT, that the people providing care to patients that deliver radiation therapy and medical imaging have minimal education requirements and are competent.

Mr. {Pallone.} It makes perfect sense to me.

Mr. Whitfield.

Mr. {Whitfield.} Thank you.

Ms. Hayden, I would just like to expand a little bit on Chairman Pallone's questioning. You indicated you felt like you should be holding hands with Dr. Herman there.

Ms. {Hayden.} We do all the time. I work at night with physics all the time.

Mr. {Whitfield.} But to help me have a little better understanding of this, you are at M.D. Anderson, correct?

Ms. {Hayden.} Yes, sir.

Mr. {Whitfield.} Okay so the team that is involved in the treatment or the diagnostic work would be you, the medical physicist and the radiation oncologist, would that basically be the team for treatment?

Ms. {Hayden.} We also have medical dosimetrists as well and radiation therapists.

Mr. {Whitfield.} Okay and now what is your educational background? What is required to be a radiation therapist? Do you have to have an undergraduate degree and then?

Ms. {Hayden.} Well, you ask--my personal credentials is I have a Baccalaureate in Science degree in radiation therapy technology from Michigan, Wayne State University, and so but there is different qualifications for radiation therapists now as you heard within 17 States. I received registry in my certification exam I passed through the American Registry of Radiologic Technologists which then makes me able to then be a qualified radiation therapy professional.

Mr. {Whitfield.} Now, in some States could you be a radiation therapist with just an undergraduate degree?

Ms. {Hayden.} Yes, you can be radiation therapist with any sort of qualification in the States that don't regulate it. I worked in Michigan and practiced there for over 10 years, sir, and I worked side-by-side by people because

Michigan is an unregulated State for radiation therapy that did not have credentials. And I must say it was very painful and I made sure that our patients were cared for but it is very--it is not a good practice to be able to have practitioners that have all sorts of varying credentials or non-credentials, delivering radiation therapy care.

Mr. {Whitfield.} So, Dr. Williams, are you and Dr. Herman very much concerned about that as well?

Dr. {Williams.} Yes, sir.

Mr. {Whitfield.} Are there 17 States that does not require licensure, is that what you said?

Dr. {Williams.} I am not sure of the exact number, sir, but there are number of States that don't require any licensure whatsoever.

Mr. {Whitfield.} So then the hospital or facility that hires them, they just have the free reign to hire whoever they want to, is that correct?

Dr. {Williams.} Yes, Congressman.

Mr. {Whitfield.} And then, hopefully, they have the training program of some kind and go from there.

Okay we have some work to do.

Dr. Amis, in your testimony you indicated that MIPPA's accreditation mandate should apply to all facilities including hospitals and I was wondering what other settings

besides hospitals are not covered by the MIPPA requirement?

Dr. {Amis.} It is my understanding that basically there is hospital-based and then there are independent centers and that MIPPA only does apply to the free-standing, non-hospital-base centers, and we feel that if there is going to be mandatory accreditation, it should involve all centers so that we all have the same standard of care for patients.

Mr. {Whitfield.} Yeah, okay, so free-standing has to meet the requirements and the hospitals are not required to do so.

Dr. {Amis.} That is correct and my understanding under the MIPPA.

Mr. {Whitfield.} Okay, now, Mr. Fisher, you and Mr. Donahue are involved in a different way in this area we are talking about. You represent some of the medical device manufacturers.

Mr. {Fisher.} Yes.

Mr. {Whitfield.} And you also Dr. Donahue, I mean Mr. Donahue?

Mr. {Donahue.} No, I represent a medical management company that focuses on providing radiation safety to physicians when they order advanced imaging.

Mr. {Whitfield.} So you are a contract manager then for a facility?

Mr. {Donahue.} Yes, we are a health care information technology and a clinical company.

Mr. {Whitfield.} Okay.

Mr. {Donahue.} And we work with large hospitals like the Brigham and Women's system. We work with General Electric and increasingly are working with health insurers throughout the country who are again very focused on clinical appropriateness and radiation safety.

Mr. {Whitfield.} Yeah, I remember in your testimony you talked a little bit, I believe, about individual radiation history.

Mr. {Donahue.} That is correct.

Mr. {Whitfield.} And does your company actually do that now?

Mr. {Donahue.} Yes, sir, we do. It is there are metrics available, readily available that can create a very accurate measure of radiation dosage when it is applied and it is critically important to track this over a long period of time to assure that cumulative dosage doesn't put a patient into carcinogenic risk. So we as a company perform that service. We track dosage. We measure it and embed that information into the electronic medical record of the patient so it is there for the life of the patient irregardless of the insurer or if they move into a Medicare environment.

Mr. {Whitfield.} Isn't the dosage that a patient receives is it required that that be in the medical record, Dr. Williams or Dr. Herman?

Dr. {Williams.} No, sir, not at this time.

Mr. {Whitfield.} It is not. So if a patient comes to a facility that you manage and you don't know anything about what they have been exposed to so you are talking about only while they are a patient at the area you are managing.

Mr. {Donahue.} Yes, sir, but what we do for our health insurers for example, is this is such a concerning issue we do a forensic analysis based on their claims data and based on any available clinical data to try to create a history of ionizing radiation. So for example, we can delve into a multimillion data set of claims data and put together how many CTs, what body part and what the cumulative exposure would be for a patient. So we feel so strongly enough about the safety issue that it is worth the effort to go back and to do this and then on an ongoing basis every new imaging procedure gets measured and tracked. And importantly, if there is a situation where a patient becomes at enhanced risk that that next incremental study could present a carcinogenic risk, the physician is immediately alerted electronically and provided with alternative action to consider.

Mr. {Whitfield.} And how many facilities do you all

manage?

Mr. {Donahue.} We are a relatively young company. Our largest facility is the Brigham and Women's Hospital System in Boston which is we manage inpatient and outpatient very extensively but this approach is gaining a lot of attention and traction throughout the country.

Mr. {Whitfield.} Right.

Ms. Hayden, is it required at M.D. Anderson that on the medical record the dosage of radiation given to a patient be on the medical record?

Ms. {Hayden.} Sir, I respectfully in regard to diagnostic imaging which is not a department that I work in I can get back that answer to you in regards to my own facility. In regards to radiation therapy, yes, the dosage is recorded for radiation therapy.

Mr. {Whitfield.} Oh, okay for radiation.

Ms. {Hayden.} Not for, yeah.

Mr. {Whitfield.} Okay, okay, well, Mr. Chairman, I see I started with 5 minutes and I now have 10 minutes and 50 seconds to go so.

Mr. {Pallone.} Yeah, I think our clocks are a little off.

Mr. {Whitfield.} But I would like to ask unanimous consent however to enter into the record a letter from the

Society of Interventional Radiologists simply on their views on this issue and also from the Radiopharmaceuticals views on this issue.

Mr. {Pallone.} Without objection, so ordered.

[The information follows:]

********** COMMITTEE INSERT **********

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Mr. {Whitfield.} Thank you all very much for your time and your testimony today. We really appreciate it.

Mr. {Pallone.} Thank you, Mr. Whitfield.

Did you want to add something, Mr. Donahue? No.

Let me say this, I mean this has been incredibly useful and thought provoking. As I mentioned to the previous panel we will undoubtedly get back to you with additional written questions, usually about 10 days from now and then we will ask you about it but I got to be honest and this is in no way meant to be offensive. As much as valuable as your responses were in many ways I felt that we ended up with more questions as a result of your responses. In other words, I think it is very likely that we are going to have to have an additional hearing on this subject because so many questions came up today that, you know, that I didn't even think about initially, and if we are going to develop legislation, well, I shouldn't say develop. We already have the CARE legislation. I think before we move on that or, you know, have a legislative hearing or draft something else that we probably will need to have an additional hearing because I just had so many questions that came out of this today, and but really you were extremely helpful in us trying to get to the bottom of some of the problems out there. And not to

suggest that again, we are not suggesting that we don't want people to proceed with CAT scans or other diagnostic tools or other forms of radiation because we know how important that is but there are just a lot of questions I think that need to be answered.

So thank you very much and we will conclude the hearing today but I can't emphasize enough how valuable this was, and without objection, the hearing is concluded.

[Whereupon, at 2:40 p.m., the Subcommittee was adjourned.]