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EXAMINING THE APPROPRIATENESS OF STANDARDS FOR MEDICAL IMAGING AND RADIATION THERAPY TECHNOLOGISTS

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED TWELFTH CONGRESS

SECOND SESSION

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EXAMINING THE APPROPRIATENESS OF STANDARDS FOR MEDICAL IMAGING AND RADIATION THERAPY TECHNOLOGISTS

FRIDAY, JUNE 8, 2012

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10 a.m., in room 2322, Rayburn House Office Building, Hon. Joseph R. Pitts (chairman of the subcommittee) presiding.

Members present: Representatives Pitts, Burgess, Whitfield, Blackburn, Latta, Lance, Guthrie, Pallone, Engel, and Waxman (ex officio).

Also present: Representative Barrow.

Staff present: Andy Duberstein, Deputy Press Secretary; Ryan Long, Chief Counsel, Health; Katie Novaria, Legislative Clerk; John O'Shea, Senior Health Policy Advisor; Chris Sarley, Policy Coordinator, Environment and Economy; Heidi Stirrup, Health Policy Coordinator; Alli Corr, Democratic Policy Analyst; Amy Hall, Democratic Senior Professional Staff Member; and Anne Morris Reid, Democratic Professional Staff Member.

Mr. PITTS. The subcommittee will come to order. The Chair recognizes himself for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Today we are addressing the quality of medical imaging and radiation therapy services and their impact on patient safety and cost. I am sure that many people would be surprised to learn that there are no uniform licensure standards for the technologists who perform tests such as MRIs and CT scans every day in our country. Currently radiologic technicians are regulated at the State level and those standards can vary widely between States, from those with stringent standards to those that do not regulate the education or competency of these medical professionals at all. Patient safety can be impacted by improper positioning or poor technique by the technician, which can lead to misreading of scans and a need for duplicate tests. These tests cost Medicare billions of dollars every year, and we cannot afford to pay for multiple tests that should have been done right the first time.

I am a firm supporter of a bill by our colleague Ed Whitfield, H.R. 2104, the Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy Act, or the CARE Act. This commonsense bill enjoys bipartisan support and has been the subject of three hearings in this subcommittee over the last few years.

It would direct the Secretary of HHS to, one, establish minimum standards for personnel who perform, plan, evaluate, or verify patient dose for medical imaging examinations or radiation therapy procedures; two, establish a program for designating certification organizations after consideration of specified criteria; three, provide a process for the certification of individuals whose training or experience are determined to be equal to or in excess of those of a graduate of an accredited educational program; and fourthly, publish a list of approved accrediting bodies for such certification organizations. Medicare reimbursement will be contingent on meeting the minimum training standards.

I know that we have witnesses representing imaging and radiologic technicians here with us today. And I look forward to their insight and expertise in this area and their thoughts on the CARE Act. I would like to thank all of our witnesses for being here, and I look forward to your testimony. And at this time I yield to the gentleman Mr. Whitfield.

[The prepared statement of Mr. Pitts follows:]

Opening Statement of the Honorable Joseph R. Pitts
Subcommittee on Health
Hearing on "Examining the Appropriateness of Standards for Medical Imaging and Radiation Therapy Technologists"
June 8, 2012
(As prepared for delivery)

Today we are addressing the quality of medical imaging and radiation therapy services and their impact on patient safety and cost.

I'm sure that many people would be surprised to learn that there are no uniform licensure standards for the technologists who perform tests such as MRIs and CT scans every day in our country.

Currently, radiologic technicians are regulated at the state level, and those standards can vary widely between states – from those with stringent standards to those that do not regulate the education or competency of these medical professionals at all.

Patient safety can be impacted by improper positioning or poor technique by the technician, which can lead to misreading of scans and a need for duplicate tests.

These tests cost Medicare billions of dollars every year, and we cannot afford to pay for multiple tests that should have been done right the first time.

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Medicare reimbursement will be contingent on meeting the minimum training standards.

I know that we have witnesses representing imaging and radiologic technicians here with us today. And I look forward to their insight and expertise in this area and their thoughts on the CARE Act.

I would like to thank our witnesses for being here, and I look forward to your testimony.

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OPENING STATEMENT OF HON. ED WHITFIELD, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF KENTUCKY

Mr. WHITFIELD. Thank you very much, Mr. Chairman. I genuinely appreciate you and Ranking Member Pallone working with us on this important legislation. I certainly want to thank Mr. Barrow who is a cosponsor of this legislation, a lead cosponsor of this legislation.

All of this started—at least for me—a couple of years ago, I guess in 2010, when we had a hearing and we had some people here involved in linear accelerators, and there was a case up in New York where the patient was severely burned. And as a result of that hearing, it came to our attention—although I am sure people like Dr. Gunderson and Dr. Martino knew this already—but it was quite obvious that all States do not require licensing for these technologists. And those States that do, frequently the standards are quite different.

So the purpose of this legislation is simply to ensure that patients undergoing imaging or radiation therapy can feel comfortable that the personnel performing those procedures are qualified to do so. We have approximately 130 cosponsors of this legislation, and I think it is an important piece of legislation. And, hopefully, I look forward to working with all of the members of this subcommittee and the full committee to try to get this legislation to the floor as soon as we possibly can. Thank you.

Mr. PITTS. I will yield the remainder of the time to the vice chairman, Dr. Burgess.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. I thank the chairman for yielding. Both radiation therapy and medical imaging are important. Critical medical advancements, when used properly, save lives and should be used only when necessary and utilized properly to employ the safe use of radiation.

That is kind of where the similarities end. Radiation therapy is just that. It is a treatment. Imaging is a screening tool. It is the difference between taking a picture and doing an operation. With medical imaging our goal, the goal should be to employ the lowest radiation while achieving the clearest picture. The therapy is to employ the most concentrated dose and achieve the goal of killing the tumor.

With imaging radiation as a secondary thought, well, with therapy it is actually the tool that is used. In developing this—looking at our file cabinet under "R" and pull up the first two things that contain radiation and trying to lump them together may not be in the best interest, but there is no question that they both need to be properly utilized.

Once again our approach is to two very different areas to address different issues. Certainly we should do everything in our power to make certain that providers, whether that be hospitals or doctors, reduce redundancy and only take an image one time if indeed only one image is indeed necessary. The creation of radiation benefit

managers is something that concerns me and it is a clear way to achieve denial of service rather than enhancement of service.

On the therapy side, we need to look at the improved technological safeguards, increase medical education, specialty society accreditation, as was mentioned by the chairman, and coordination of medical professionals.

Mr. Chairman, I thank you for the consideration. And I will yield back the balance of my time.

Mr. PITTS. The Chair thanks the gentleman.

I now yield to the ranking member, Mr. Pallone, for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you Chairman Pitts. Today the subcommittee is meeting to discuss the appropriateness of standards for medical imaging and radiation therapy technologists. I am glad that we are having this hearing because it is an important patient safety issue.

When I was the chairman, we held a hearing on the overview of medical radiation, and Mr. Whitfield talked about it. And that was in response to a series of alarming reports in The New York Times on medical radiation errors. Those stories raised red flags, and I felt it was important that members have an opportunity to better understand the landscape. What we learned at that hearing was critically important in that there were gaps in the oversight of certification and licensing of allied health professionals. We also determined, however, that radiation undoubtedly saves lives because it has reshaped the world of diagnostics and has offered patients less invasive alternatives for treating complex and life-threatening conditions.

In addition, a direct result of the examination of this subcommittee has led to a number of efforts underway within the imaging field. In 2010 the FDA launched the initiative to reduce unnecessary radiation exposure for medical imaging, and working with manufacturers to improve the safety of imaging equipment through its regulation authority.

In addition, in 2010, through the Medical Imaging & Technology Alliance, or MITA, manufacturers developed the CT dose check standard which includes features that assist an imaging team in providing better care. In addition, MITA is currently finalizing the CT access control standard which will produce an extra safeguard that will ensure only an authorized operator can alter the controls of a CT scanner. These efforts are commendable and should continue and be expanded.

But there is clearly still work to be done to better ensure that the driving factors of why things go wrong are rectified. One issue that still remains is licensure and certification. While advancements in the industry become more complex and complicated to operate, 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 licens-

ing requirements, the requirements are weak and not enforced. And I just don't think that is acceptable.

So that is why Representatives Whitfield and Barrow have introduced the CARE Act, a bill that would establish standards for the personnel who perform medical imaging examinations or radiation therapy procedures. This seems like commonsense policy and a legitimate first step in addressing radiation safety. And I hope that the subcommittee will consider that bill in the near future, Mr. Chairman.

What we also know is that we have no idea how often errors occur and have no good data on where the weaknesses in the system truly are. So I do think there is a need to find ways to ensure that patients do not receive radiation doses in excess of recommended levels. I look forward, Mr. Chairman, to hearing from all our witnesses. We appreciate your taking the time to speak to the subcommittee on this very important issue.

And I would like to yield the remainder of my time to the gentleman from Georgia who is the Democratic sponsor of the legislation, the CARE Act.

OPENING STATEMENT OF HON. JOHN BARROW, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Mr. BARROW. I thank the chairman and I thank Chairman Pitts and especially Chairman Whitfield for his leadership on this issue. I am glad we are having this hearing to shine a light on the fact that not all the folks performing radiation diagnostics and treatment are properly trained. Many people I represent are shocked to hear that. They know that it is a direct threat to public health when radiation technology is misapplied, and it is also an economic problem because of the direct and indirect costs of poor image quality.

Along with Chairman Whitfield, I am the lead cosponsor of the CARE Act which will address this issue by requiring a standardized certification process for radiologic technologists. I think that is common sense, and I hope and expect it would be the consensus and position of this committee. I look forward to hearing from the witnesses and hopefully to moving this bill forward. With that, Mr. Chairman, I yield back the balance of my time.

Mr. PITTS. The Chair recognizes the ranking member of the full committee, Mr. Waxman, for 5 minutes.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you very much, Mr. Chairman. The focus of today's hearing, the accreditation of medical imaging and radiation therapy technologists, suggests that the certification process is key to maximizing patient safety when radiation delivery is involved. Accreditation of personnel may be an important component of patient safety, but as we learned at this subcommittee's hearing on medical radiation in the last Congress it is not the silver bullet.

Let me be clear at the outset: Diagnostic and therapeutic radiology interventions save lives and improve health outcomes. They are important procedures in our medical toolbox that unquestion-

ably have made our health-care system better. CT scans minimize the need for exploratory surgery. Radiation therapy aids in the treatment of other breast and other forms of cancer. Even the basic X-ray plays a critical role in modern medicine. But with this technology comes an important obligation: making these interventions as safe as possible. Of course that includes qualified technologists, but it also means the delivery of the right procedure at the right time and with an appropriate dose of radiation. Patients are entitled to nothing less.

Since we last met on this topic, there have been some notable advances in the public and private sectors alike. Consider the following: CMS has developed an accreditation process for physicians and other nonhospital providers who bill Medicare for advanced imaging services. The FDA has launched an initiative to reduce unnecessary radiation exposure in medical imaging. And several professional societies are working to communicate best practices to health professionals and patients and to begin to capture data on the amount of radiation patients are receiving.

These efforts should be commended and continue to move forward, yet deficiencies still exist. We find only a patchwork of State regulation for the technologists who position patients and deliver radiation doses. And far too many patients continue to receive radiation doses in excess of recommended levels.

Today's hearing will examine all of this, hopefully with an eye on the ultimate prize: ensuring that all medical radiation services are designed, delivered, and monitored with the highest quality of care. I look forward to hearing from our witnesses this morning and I thank each of you in advance for your testimony. Thank you, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman.

That concludes opening statements for the members. The Chair requests unanimous consent the following statements be introduced into the record: a statement of the Society of Nuclear Medicine Technologists section; a statement of the American College of Radiology; a statement by the American Society of Nuclear Cardiology; a statement of the American Academy of Ophthalmology; a statement of the American Association of Physicists in Medicine; a statement of the Medical Imaging & Technology Alliance; and a statement of the Society of Diagnostic Medical Sonography. Without objection, so ordered.

[The information follows:]

Statement of Lynne Roy

Director of Medical Imaging, Cedars Sinai Hospital, Los Angeles, California

Chair, Scope of Practice Task Force for the Society of Nuclear Medicine Technologist Section

In Support of H.R.2104, the "Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy (CARE) Act of 2011

June 8, 2012

My name is Lynne Roy, and I serve as the Director of Medical Imaging at Cedars Sinai Hospital in Los Angeles, California. I am submitting this statement in my capacity as the Chair of the Scope of Practice Task Force for the Society of Nuclear Medicine Technologist Section, and I am a certified Nuclear Medicine technologist. Thank you for allowing me the opportunity to convey our views regarding "the Appropriateness of Standards for Medical Imaging Technologists," and to give our enthusiastic support for H.R.2104, the "Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy Act of 2011," known simply as the "CARE Act."

The Medical Imaging Department at Cedars Sinai where I work treats and diagnoses over 330,000 patients per year. Physicians refer their patients to our department to determine a myriad of diagnoses, from what is causing a persistent cough to identifying heart disease and cancer. Advances in imaging have been very exciting in recent years, including the enhanced ability to determine if a particular chemotherapy agent is working after just one day. This can save a patient months of needless suffering, not to mention savings to the healthcare system.

The patients who come to our department rely on our 180 imaging technologists to take the right picture at the right time so our imaging physicians can deliver vital diagnostic information or treatment. All of our X-Ray and Nuclear Medicine technologists are licensed by the state. All ultrasound and MRI technologists, unless in training, are certified by the American Registry of Radiologic Technologists (ARRT) or the American Registry of Diagnostic Medical Sonographers (ARDMS). Therefore, patients who come to Cedars Sinai Medical Center for their imaging procedures will be treated by technologists that have met the minimal educational and credentialing requirements for medical imaging set by the state of California.

However, that is not the case in all areas of the country. For the past decade, the Society of Nuclear Medicine Technologist Section (SNMTS) and the Alliance for Quality Care and Radiation Safety have worked hard to raise awareness of the need for quality education and standards for the technologists performing diagnostic imaging tests.

In the case of nuclear medicine, 20 states do not regulate the nuclear medicine technologists that are delivering radiation to patients. Additionally, there are 11 states that do not regulate X-Ray technologists and no state regulates MRI or ultrasound technologists. That means imaging providers in hospitals and freestanding centers are able to hire someone off the street to deliver radiation to patients. The CARE Act, which currently has 122 cosponsors in the House, would require all those who perform medical imaging and radiation therapy procedures to meet minimum education and credentialing standards in order to receive Medicare reimbursement.

We believe that the CARE Act is vital to ensure the best treatment possible. Most Americans know very little about the technical aspects of medical imaging and radiation therapy treatment and assume the individuals performing these tests are qualified and competent. However, this is not always the case as inadequately trained personnel perform medical imaging and therapeutic procedures in many areas of the United States every day.

Under current law, minimum education and credentialing standards are voluntary in some states, allowing individuals to perform imaging procedures without any formal education. Poor quality images can lead to misdiagnosis and/or additional testing often times with additional radiation, delays in treatment, and increased cost.

The CARE bill will regulate all imaging technologists and radiation therapists. Since I began my career in nuclear medicine, and have spent the last 20 years directing the imaging department of a very large medical center, I would like to explain the responsibilities of imaging technologists and why it is so important that individuals performing these tests have received the education that is needed to be competent and to provide the patient a safe environment.

X-Ray and CT use X-Rays to produce anatomical pictures. This records a snap shot in time of what the body part looked like. However, just as in photography, if the settings, in this case dose, are not correct, any abnormalities in the organ may be hidden because it is too bright or too light. If the technologist does not interview the patient, or review the history, the incorrect angle or "pose" may be chosen, which could also obscure an abnormality. The resulting image could be non-diagnostic, a false negative, or a false positive. The patient may have to return for additional imaging which is costly, delays treatment and delivers the patient an additional radiation dose.

Nuclear medicine uses radioactive materials, known as "radiopharmaceuticals" that can image how an organ works. Rather than a snap shot in time, nuclear medicine uses "time lapsed photography" to trace what happens to an organ over time, or to see how it responds to a certain stimulus. Nuclear Medicine studies provide physicians with molecular level—not only anatomical or structural level—data that can help personalize treatment.

Nuclear medicine and molecular imaging technologists are responsible for performing a wide variety of highly specialized procedures. Because nuclear medicine looks at bodily functions, it is critically important for the technologist to understand how the radioactive medicine works and how a patient's own medications or diet could interfere with the study. For example, many medications and food contain caffeine. Caffeine interferes with the way heart vessels expand and contract. If some nuclear heart scans were to be performed on a patient who unknowingly did not discontinue caffeine, the picture could appear normal, even though the patient has coronary artery disease.

Like CT and X-Ray, MRI records a snap shot in time. Rather than using X-Rays to produce the image, magnetic radiation, combined with radiofrequency, can create a very detailed display of what an organ looks like. Based on the history of the patient, the technologist must select the correct settings, called sequences, to image. If the technologist does not fully understand anatomy, they can fail to capture the correct area or cut off part of the organ, making an accurate diagnosis impossible. In addition, if the technologist fails to conduct a thorough safety interview

with the patient or does not provide adequate security against metal objects entering the magnet, the patient can be seriously harmed.

Ultrasound technologists use ultrasound waves to create images. Some of these images can be like a video that records the movement of blood through the veins and arteries. Other images record pictures of abnormalities in an organ. Unlike X-Ray that captures the entire organ in one picture, the ultrasound technologist scans the entire organ until an abnormality (or not) is found. The technologist selects the images to be recorded. If they did not program the scanner correctly, they won't see the differences between normal and abnormal tissue. If they do not have an excellent understanding of anatomy and pathology they will not be able to identify abnormalities and record them for the imaging physician to interpret.

As you can see, these are not simple tasks that can be performed by unqualified individuals. When performed properly, an imaging study can provide unique information that allows doctors to better diagnose, guide management of, and treat diseases. If a scan is performed incorrectly, a poor-quality image may be produced. This can result in the misdiagnosis of disease, delays in treatment, and needless anxiety for the patient. If additional testing is required, patients are exposed to an increased amount of radiation. While imaging can be an invaluable tool, the procedures do carry a potential health risk, and radiation can be harmful if administered improperly. Without proper safety precautions and careful patient screening a patient can be harmed in a MRI scanner.

It is clear that mandatory, stringent education and certification standards must be enacted for technologists performing imaging scans to ensure excellent patient care, safety, and effectiveness.

In 2006, there were roughly 395 million imaging procedures performed in hospitals and medical settings across the United States [1]. This is because imaging is a valuable tool that allows physicians to obtain unique insights into a patient's body that allow for a more personalized approach to the evaluation and management of all diseases. With early detection, heart disease, cancer, and other diseases can be successfully diagnosed, treated, and even cured. Yet despite

the important implications these procedures can have for patients' health, in many states technologists are not required to have certification or a license to perform these tests.

Certification and ongoing registration in radiation imaging is managed by the American Registry of Radiologic Technologists (ARRT). In addition to the ARRT, Nuclear Medicine Technologists can also be certified by the Nuclear Medicine Technology Certification Board (NMTCB). MRI Technologist certification is through the ARRT. Ultrasound certification is managed by the American Registry of Diagnostic Medical Sonography (ARDMS) or the ARRT.
All of these certifying agencies require technologists to have successfully completed an educational program that is accredited by an acceptable mechanism.

Beauticians, cosmetologists, and insurance agents are a few examples of professions that are regulated in every state. However, medical imaging technologists and radiation therapists are not. To improve the quality of medical imaging, the CARE Act must be passed. If enacted, this bill would require those who perform medical imaging and radiation therapy procedures to meet minimum education and credentialing standards in order to receive Medicare reimbursement. As a result, institutions that provide medical imaging or radiation therapy to Medicare patients would need to employ personnel who meet or exceed these standards. Currently across the country, individuals with possibly little or no training are performing sophisticated medical imaging procedures that, if performed improperly, could harm patients and cost the health care system millions of dollars. It is time to take a stand and fight for the safety of these patients. It is time for Congress finally to pass the CARE Act.

Reference

1. Mettler, F.A., Jr. Radiologic and Nuclear Medicine Studies in the United States and Worldwide: Frequency, Radiation Dose, and Comparison with other Radiation Sources, 1950-2007. *Radiology* 2009. 253: 520-531.

Statement of the American College of Radiology To the House Energy and Commerce Health Subcommittee's Hearing "Examining the Appropriateness of Standards for Medical Imaging and Radiation Therapy Technologists"

Friday, June 8, 2012

Chairman Pitts and Distinguished Members of the Subcommittee:

Introduction:

The American College of Radiology (ACR), a professional organization representing approximately 36,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists, appreciates the opportunity to present our views to the House Energy and Commerce Health Subcommittee on the importance of minimum education and certification standards for medical imaging and radiation therapy technologists. As an organization with a long commitment to quality and safety in medical imaging, and as vigorous advocates of continued timely access to imaging services, the subject of this hearing is of utmost importance to us.

As members of this subcommittee recognize, an accurate diagnosis through quality medical imaging plays a key role in patient care. Advances in medical imaging have improved disease screening and diagnosis while lowering radiation dose for a range of acute and chronic conditions. These advances have allowed many diseases to be identified early when they can more readily be treated. Image-guided medical procedures have essentially replaced more invasive surgical options for many patients while improving outcomes and reducing hospitalization and recovery times.

CARE Act and H.R. 3269, the Diagnostic Imaging Services Access Protection Act:

Ensuring that all medical imaging and radiation therapy technologists maintain basic educational and certification standards will undoubtedly help protect patients from unnecessary exposure to radiation while simultaneously lowering health care costs by eliminating the need for repeat testing due to poor technique or improper positioning. Today, numerous witnesses will testify that, in order to achieve these commendable goals, the Health Subcommittee must consider and enact H.R. 2104, the Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy (CARE) Act of 2011. The CARE Act would require personnel

performing or planning the technical components of medical imaging and radiation therapy to meet federal education and credentialing standards in order to participate in Medicare. If medical imaging and radiation therapy services were performed by unqualified personnel, Medicare would be permitted to deny technical component payments to imaging and radiation therapy facilities. ACR agrees that appropriately trained personnel are a critical component of quality imaging and we, therefore, support the CARE Act.

In addition to enacting the CARE Act, ACR believes Congress should expand the current federally mandated accreditation requirements for advanced imaging to include radiation therapy. More specifically, the accreditation mandates enacted under the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 should apply to all facilities, including hospital settings. Furthermore, the accrediting of these imaging and radiation therapy procedures should only be conducted by organizations with experience and expertise in the area for which they are accrediting. In addition, accepted accrediting bodies should employ uniform accreditation standards and apply them to all facilities and settings. Currently, there is wide variation regarding crucial aspects of the facility review process amongst existing accrediting bodies. A required dose index registry would also be a critical new component that could measure ongoing performance of the accreditation baseline.

Yet, the CARE Act isn't the only widely supported and vital imaging legislation before the House Energy and Commerce Health Subcommittee. While maintaining quality is essential to the delivery of imaging services, preserving access to these services is equally as important. Although ACR applauds Congress for recognizing and analyzing the role of medical imaging technologists, radiologists, as the physicians who interpret these images, also play an extremely important role in the delivery of medical imaging technology to the patient. Unfortunately, patient access to life-saving advanced diagnostic imaging services, specifically CT, MRI, and PET scans, has been reduced due to repeated cuts in radiology reimbursement over the last 6 years. In light of this alarming reality, the Health Subcommittee must also immediately consider and enact H.R. 3269, the Diagnostic Imaging Services Access Protection Act. This bipartisan piece of legislation would block the latest round of unfounded and arbitrary imaging cuts, specifically a 25 percent multiple procedure payment reduction (MPPR) to the professional component of advanced diagnostic imaging services. The professional component represents Medicare reimbursement for radiologists interpreting images for the presence of disease or patient trauma. H.R. 3269 currently has more than 250 cosponsors, including 12 of the 15 Republican and 8 of the 10 Democratic Health Subcommittee members. Failure to immediately consider and then enact this bill will cause many independent radiology practices to close their doors resulting in the loss of countless high-tech, health care jobs at a time when our country can least afford it.

Finally, below are some initiatives the College would like to share with the Health Subcommittee detailing its efforts to improve medical imaging and radiation therapy services through our quality and safety programs, education and public awareness campaigns, and related projects:

Accreditation

The ACR is the nation's oldest and most recognized medical imaging and radiation oncology accrediting body with a long history of developing and administering accreditation programs that assess the quality of imaging facilities. Designed to be educational in nature, ACR accreditation is an efficient process of both self-assessment and independent external expert audit, based on the ACR practice guidelines and technical standards, which assesses the qualifications of personnel, policies, and procedures, equipment specifications, quality assurance (QA) activities, patient safety, and ultimately the quality of patient care. Clinical and phantom image quality reviews, as well as radiation dose assessments, are critical elements of imaging accreditation.

ACR accreditation began in 1987, within the then-voluntary mammography and radiation oncology accreditation programs. Due to ACR's success with the voluntary mammography program, Congress passed the Mammography Quality Standards Act (MQSA) in 1992 to mandate accreditation of all mammography facilities. In 1994, the ACR became the only national accrediting body for mammography to be approved by the Food and Drug Administration (FDA) under MQSA.

Mandatory mammography accreditation has been credited with saving tens of thousands of women's lives and vastly improving patient care. Much of the success of MQSA can be attributed to the fact that the FDA relied on existing medical specialty society expertise when establishing standards it would adopt. In fact, it built upon standards and processes that were already being successfully implemented on a voluntary basis within the profession by the ACR's voluntary accreditation program. Rather than relegating the quality review to federal employees who may not have practical experience in the field, MQSA relies upon accrediting bodies, named and reviewed by FDA, to serve these functions.

In addition to the mammography and radiation oncology programs, the ACR developed accreditation programs for ultrasound (1995), stereotactic breast biopsy (1996), magnetic resonance imaging (1996), breast ultrasound (1998), nuclear medicine (1999), computed tomography (2002), positron emission tomography (2002) radiography/fluoroscopy (2002) and breast magnetic resonance imaging (2010). Like the radiation oncology program, these other accreditation programs were not mandatory. However, Congress adopted accreditation requirements as a requisite to receiving payment from Medicare for advanced diagnostic imaging services as part of MIPPA in 2008. The MIPPA requirements represented a paradigm shift in which Congress made the decision to tie payment to quality and safety in medical imaging.

During implementation of the MIPPA provisions, CMS recognized the ACR, the Intersocietal Accreditation Commission (IAC), and The Joint Commission in January 2010 as deemed accrediting organizations. However, not all accreditation programs are robust enough to sufficiently improve quality and safety. Accreditation can only be successful if the accrediting bodies can clearly demonstrate their experience, expertise, and track record in evaluating actual image quality and phantom review in the overseen modalities. These elements are the

foundation of any valid imaging accreditation program and were specifically included in the medical imaging provisions contained in MIPPA.

While previously voluntary accreditation programs for certain medical imaging modalities became mandatory in ambulatory settings in 2012 due to MIPPA, radiation oncology accreditation remains voluntary and participation is not as extensive as is clearly needed. This is made evident by the fact that the radiation oncology accreditation program is utilized by less than 20 percent of radiation therapy practices in the country. Congress must step in and mandate accreditation for radiation therapy per the lessons learned by MQSA and MIPPA.

ACR Appropriateness Criteria

In addition to its respected accreditation programs, the College offers other important quality and safety resources to radiologists and referring physicians, most notably the ACR Appropriateness Criteria (AC). The ACR AC is designed to reduce unnecessary exams by guiding ordering physicians and patients to the appropriate procedure. The ACR Task Force on Appropriateness Criteria was created in 1993 to develop nationally accepted, scientifically-based guidelines to assist ordering physicians in making appropriate imaging decisions for specific clinical conditions. Currently, the ACR AC are the most comprehensive, evidence based guidelines for diagnostic imaging selection, radiation therapy protocols, and image-guided interventional procedures. There are 175 topics with over 850 variants as of December 2011. Much of the ACR AC has been included in CMS's Medical Imaging Demonstration project, which is examining the impact of decision support using national medical specialty society guidance regarding the use of advanced imaging on prevalent, high cost clinical conditions. By using the AC in making decisions regarding radiologic imaging and treatment, physicians enhance quality of care and, therefore, provide the most efficacious use of radiology services.

First offered in hard copy form, the ACR AC are now incorporated in many of the computerized order entry systems (CPOE) with clinical decision support (CDS) systems that allow ordering physicians to determine which imaging exam is best and safest for the patient. With the ACR-AC available as an integrated component to CPOE systems, access to evidence based clinical guidelines may be attainable for all ordering clinicians and their facilities. This enhanced accessibility through CPOE and CDS streamlines the use of ACR AC during the normal course of patient interaction and the exam ordering process, therefore, improving clinical decisions.

With regard to radiation dose, the ACR AC is guided by the principle that the overall risk of cancer induction from a diagnostic imaging procedure involving ionizing radiation is small, but not zero. Therefore, ACR AC recognizes the importance of minimizing patient radiation exposure and avoiding the ordering of unnecessary examinations, especially when it involves ionizing radiation. ACR AC advises referring physicians who are planning to order an imaging exam for their patient to consider the patient's previous imaging examinations. Above all, any risk that may be attributed to radiation exposure from an imaging procedure should be justified based on the benefits to the patient.

In 2008, Congress recognized the potential for better patient care and reducing imaging utilization by including a demonstration project in MIPPA for using national medical society guidelines in decision support. In addition, the Center for Medicare and Medicaid Innovation (CMMI), created through the Patient Protection and Affordable Care Act (PPACA), is expected to review the effectiveness of appropriateness criteria in curbing medical imaging utilization and spending in the coming years. These demonstration projects are expected to prove the value of expanding the use of ACR AC in decision support to improve medical imaging and may indicate the benefit of expanding to all physicians throughout the country, which the ACR strongly supports. Due to the lack of market penetration in many locations and the lack of widespread acceptance and utilization of electronic medical records, the benefits of CPOE under the current voluntary utilization of AC by physicians who order medical imaging studies is relatively low.

"Image Gently ®" and "Image Wisely ®" Awareness Campaign

ACR helped launch the Image Gently campaign in January 2008 as a founding member of The Alliance for Radiation Safety in Pediatric Imaging- a coalition of more than 70 organizations dedicated to raising awareness and promoting education about radiation protection for children undergoing medical imaging examinations. The goal of the campaign is to change practice: to raise awareness of the opportunities to lower radiation dose in the imaging of children. The initiative has reached out through social media and advertising campaigns to educate radiologic technologists, medical physicists, radiologists, pediatricians and parents about radiation dose used during the more than 4 million pediatric computed tomography (CT) examinations performed on children in the U.S. each year. One of Image Gently's ongoing efforts is ensuring the medical protocols for the imaging of children keep pace with advancing technology. The program has been expanded to include digital radiography, fluoroscopy, interventional procedures, nuclear medicine, ultrasound, and dental imaging.

The Image Gently website includes guidance for developing protocols to optimize pediatric techniques used during CT imaging of children based on size. The campaign emphasizes the need to differentiate these methods for children compared to adults. To date, 15,798 medical professionals have taken the pledge to "image gently" when performing pediatric imaging exams.

The overall success of the Image Gently campaign is especially important in light of the recent publication of a study in the *Lancet* on radiation exposure from CT scans in children and the small increased risk of developing leukemia or brain tumors. This retrospective study, which focused on close to 180,000 children under the age of 15 that underwent a CT scan between 1985 and 2002 in the United Kingdom, found that radiation exposure received from 2 to 3 CT scans of the head can triple the risk of later developing brain cancer, while around 5 to 10 such scans could triple the risk of developing leukemia. However, the authors stressed the absolute lifetime cancer risks found in the study are very small compared with the lifetime risk of developing cancer in the general population, and are likely small compared with the benefits of a clinically justified scan. It is important to note, however, that the CT scanners from the period studied used radiation doses much higher than those of today. In addition, current protocols, such as

those outlined in the Image Gently campaign, allow for the use of lower dose than what was employed during the period studied. Finally, Image Gently encourages parents and physicians to closely monitor the total number of imaging studies given to a child.

In 2010 ACR, in conjunction with the Radiological Society of North America (RSNA), American Society of Radiologic Technologists (ASRT), and American Association of Physicists in Medicine (AAPM), established the Image Wisely campaign for the broader population with the objective of lowering the amount of radiation used in medically necessary imaging studies and eliminating unnecessary procedures through a program of education and awareness initiatives. Image Wisely offers resources and information to radiologists, medical physicists, other imaging practitioners and patients. To date, 13,891 imaging professionals and several hundred facilities have pledged to "image wisely."

Both Image Wisely and Image Gently have gained traction throughout the medical community nationally and internationally and have been instrumental in raising both provider and patient awareness about the importance of tailoring radiation treatments to different patients.

ACR National Radiology Data Registry: Dose Index Registry

Another pertinent ACR program is the Dose Index Registry (DIR), which collects and provides feedback to facilities on radiation dose levels. Launched in 2011, DIR allows facilities to compare their dose indices for each of their imaging protocols to corresponding values for other facilities like them. The registry currently collects data on CTs only, but will be expanded to include other modalities, such as radiography and fluoroscopy. Data are collected in imaging industry-standard format (DICOM), and are collected automatically, anonymized, and transmitted to the ACR, with minimal intervention from staff at the facility. In less than a year since launch, the registry has accrued over 400 facility participants, and has collected radiation dose information from over a million scans.

DIR is part of the ACR's larger National Radiology Data Registry (NRDR) program, which is a data warehouse for the DIR, General Radiology Improvement Database (GRID), National Mammography Database (NMD), CT Colonography (CTC), National Oncologic Positron Emission Tomography (NOPR), and IV Contrast Extravasation (ICE) data registries. The primary purpose of NRDR is to aid facilities with their quality improvement programs and efforts to improve patient care by comparing facility data to that of their region and nation. Participating facilities may choose to share data with any or all registries as appropriate for their practice, and ultimately use NRDR to compare their own performance to that of other participants.

Conclusion

Although the use of radiation in medicine saves lives and improves patient care, there are inherent risks with these procedures. ACR, like many other stakeholders, recognizes that requiring medical imaging and radiation therapy technologists to achieve and maintain basic

education and certification standards, as is required by the CARE Act, will improve overall patient safety.

As always, the College is ready to assist the Health Subcommittee in its efforts to improve the treatment, safety, and overall quality of care delivered to our patients.

Contact Information

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June 7, 2012

The Honorable Joe Pitts
House Energy and Commerce Committee
Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

Re: Support for H.R. 2104, The Consistency, Accuracy, Responsibility, and Excellence in Imaging and Radiation Therapy Act of 2011 (CARE Act)

Mr. Chairman and Members of the Committee:

On behalf of the American Society of Nuclear Cardiology (ASNC), I am writing to provide comments on and urge passage of the *Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy Act of 2011* (CARE Act).

ASNC is a 4,700 member professional medical society that represents physicians, scientists, technologists, and others in the profession of nuclear cardiology. ASNC has a rich history of developing clinical guidelines and standards related to safety, patient-centered imaging, and quality control for the profession. As a leader in the development of evidence based guidelines and professional standards to ensure high quality care, ASNC understands the importance of establishing clear standards to promote ongoing professional development as the field of nuclear cardiology evolves.

ASNC supports the important objectives of the CARE Act to ensure that medical imaging examinations and radiation therapy treatments are safer and more accurate, which will help to reduce duplicative services and lower costs. Poor quality images can lead to misdiagnosis, additional follow up testing, delays in treatment and anxiety in patients, costing the U.S. Healthcare System millions of dollars every year . The CARE legislation would require technologists to be certified by an accreditation entity determined by the Secretary of HHS in order to be reimbursed by Medicare – and – must comply with any state licensing requirement.

We also support the inclusion of representatives of all medical specialties that perform medical imaging and radiation therapy procedures as recognized experts to assist in the development of the minimum standards for qualification and, as a major stakeholder, we expect and stand ready to participate in this process.

Our technologists are the front lines of the nuclear cardiology laboratory, continuously working to ensure the safety of their patients and colleagues. We look forward to participating in the development of the qualification standards once the CARE Act becomes law, and I hope that the Energy and Commerce Subcommittee on Health will view ASNC as a resource and partner in developing safe and accurate medical imaging standards.

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We greatly appreciate you taking this into consideration, and please feel free to contact Andy McKinley, Associate Health Policy Director, for any further assistance that ASNC may provide.

Thank you very much for your time.

Sincerely,

John J. Mahmarian, MD, FASNC
President

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Federal Affairs Department

June 23, 2009

Dear Senate Finance Committee Member:

On behalf of the American Academy of Ophthalmology, I am writing to express our concern that an effort may be made during consideration of health reform legislation in the Senate to extend certification requirements to the physician supervised personnel that plan and carryout the technical portion of office-based ultrasound. The Academy is the world's largest association of eye physicians and surgeons—Eye M.D.s—with more than 18,000 members in the U.S. If costly and burdensome new certification for ultrasound scans or other minimally or non-invasive ophthalmic imaging is mandated, it could jeopardize patient access to timely care and Medicare beneficiaries would suffer and could in fact incur more costs than savings for the Medicare program. Many of these staff have a broad ophthalmic tech certification that includes but is not specific to ultrasound imaging.

In ophthalmology, we use very specially trained personnel that provide many of the key support functions in an ophthalmology practice and they are essential in order to meet the growing demand for medical eye care. These Ophthalmic Medical Technicians (OMTs) perform the technical portion of testing and other patient services as requested by and supervised by the ophthalmologist.

There is a growing shortage of these specially trained individuals, with the demand expected to outpace the supply by more than 30% in the next year. In fact because of the need to grow this area of trained individuals the US Department of Labor has recently created a special category just for OMTs. These individuals are certified by the Joint Commission of Allied Health Personnel in Ophthalmology (JCAHPO). The testing is comprehensive over all areas of their training far beyond just the special testing/ultrasound aspects. We are very concerned though that they would not meet the very limited definitions of certification and there exists no entity that currently certifies solely on ophthalmic ultrasound.

Ophthalmologists use ultrasound to obtain both one-dimensional images (A-scan) to characterize eye tissue and two-dimensional images (B-scan) for architectural information. Ophthalmologists are the most qualified to interpret the necessary imaging studies that provide further diagnosis of a wide variety of ophthalmic diseases and conditions including glaucoma progression, intraocular tumors, vitreoretinal, choroidal, and posterior segment issues. Ophthalmologists also use imaging to determine the axial length of the intraocular lens prior to cataract surgery.

Neither radiologists, nor their techs are trained in these techniques and this is reflected in the world's largest claims data: Medicare. The following is 2007 Medicare claims data.

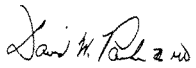
- 76519-ophthalmic ultrasound, A scan biometry, with intraocular lens calculation. Volume of .9 million. Performed 98% by ophthalmologists and less than 0.01% by radiologists.
-
- 76510-ophthalmic ultrasound, diagnostic A and B scan. Volume 13,000 with 95% performed by ophthalmologists and 0% by radiology

- 76513-ophthalmic ultrasound, immersion B scan, Volume 17,000. 98% ophthalmology and 0% radiology
- 76514-ophthalmic ultrasound, diagnostic, cornea. Volume 476,000. 80% ophthalmology and O% radiology

This data clearly demonstrates that it would make no sense to have the technical component of ophthalmic ultrasound performed by anyone but ophthalmic medical technicians or ophthalmologists for whom these services are currently within the scope of their ophthalmic training.

The specialty specific imaging utilized by ophthalmology has produced significant improvements in patient care. Many factors have influenced imaging services for ophthalmology, including improved technology; changes in the standard of care for many illnesses, and most importantly shifts in the site of service from hospitals to other less expensive health care settings. The improvement in quality has meant that many specialties, including ophthalmology are now using imaging for therapeutic purposes rather than simply a diagnosis tool. This is especially true for the advances that have come about for the treatment of age-related macular degeneration (AMD) and diabetic retinopathy. Data obtained by ultrasound-based imaging is critical in making treatment decisions is diseases such as age-related macular degeneration (AMD), glaucoma, and diabetic retinopathy. This imaging technology has permitted us to arrest the progression of vision loss in about 90% of eyes with the most severe form of AMD.

Sincerely,



David W. Parke II, M.D., Executive Vice President
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June 8, 2012

American Association of Physicists in Medicine Statement on
***The Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy Bill* (H.R. 2104)**

Chairman Upton, Ranking Member Waxman, Subcommittee Chairman Pitts, Subcommittee Ranking Member Pallone and members of this distinguished committee the American Association of Physicists in Medicine[1] (AAPM) commends you for this hearing to examine why we must establish standards for medical imaging and radiation therapy technologists.

AAPM is grateful for the bipartisan leadership of Reps. Whitfield and Barrow -- along with 20 Members of the full committee and 10 from the health subcommittee -- for supporting the *Consistency, Accuracy, Responsibility and Excellence (CARE) in Medical Imaging and Radiation Therapy Act* (H.R. 2104). **AAPM strongly supports immediate passage of the CARE Act (H.R. 2104).**

Passage of the CARE legislation is critical to ensuring that essential standards for medical imaging and radiation therapy professionals are established.

The use of medical radiation occurs in radiology and radiation oncology practices with millions of people receiving that radiation to their benefit annually. Patients and the public may see the results of medical radiation, but few understand the details of the process and most assume that everyone who performs an imaging or radiation therapy procedure is competent and appropriately educated and trained. However, that is not always the case.

Each patient procedure is a complex multi-system process, in which each system involves a combination of technology and human actions. This process requires the coordination and participation of teams of clinical staff: physicians, medical physicists, dosimetrists, radiation therapists, radiologic technologists, information system engineers, linear accelerator and other vendor related engineers, nursing and support staff – all of these individuals and all of their effort must be focused on the diagnosis or treatment of each patient.

Qualifications of Personnel

Qualifications required for radiation team members are state regulated (by some but not all states) and widely variable. In many states, most of the team members including the Medical Physicist, Radiation Therapist and Medical Dosimetrist, have no specific qualifications required.[2] The CARE legislation - H.R. 2104 will require that minimum standards for personnel who perform, plan, evaluate, or verify patient dose for medical imaging examinations or radiation therapy procedures be established. **The intent**

[1] The American Association of Physicists in Medicine's (AAPM) is the premier organization in medical physics; a broadly-based
[2] There are specific requirements for individuals to use radioactive materials defined by the NRC and Agreement States. These address the use of radioactive materials only (not x-ray producing equipment) and do not specify the credentials to practice.

of the bill is to cover all subspecialties of clinical medical physics. We believe that passage of this bill will enhance patient safety in the use of medical radiation. Thus, we urge that ALL individuals involved in these procedures be included in this legislation. The Federal Government pays for a substantial portion of these radiation-related medical services in the United States, and thus has a strong interest to assure that the procedures are properly administered by qualified staff.

The Medical Physicist

Medical physicists are uniquely positioned across medical specialties due to our responsibility to connect the physician to the patient through the use of radiation producing technology in both diagnosing and treating people. The responsibility of the medical physicist is to assure that the radiation prescribed for imaging and radiation therapy is delivered accurately and safely.

AAPM has devoted a substantial part of its energy to the creation and recognition of the Qualified Medical Physicist, or QMP. These physicists have a unique combination of education in the principles of physics, radiobiology, human anatomy, physiology and oncology through a graduate degree, as well as clinical training in the applications of radiation physics to medicine, such as the technologies of medical imaging and treatment delivery, radiation dose planning and measurement, as well as safety analysis and quality control methods. Following this, an individual demonstrates competence in his/her discipline by obtaining board certification (currently offered for ionizing radiation imaging and radiation therapy through the American Board of Radiology). Certification is a rigorous, multi-year process that requires considerable supervised clinical experience as well as passage of written and oral examinations. The AAPM recognizes a Qualified Medical Physicist for the purpose of providing clinical medical physics services, as an individual who is board-certified in the appropriate medical subfield and has documented continuing education.

Current Challenges

All of the efforts mentioned are aimed at providing safer, more accurate and more effective patient procedures using medical radiation and we will continue to work toward achieving the absolute minimum error rate. However, there are some challenges we face in trying to meet these goals:

- While the AAPM has a clear definition of a Qualified Medical Physicist, **there is no consistent national recognition of this credential.**
- **Medical physicists are licensed in only 4 states (TX, NY, FL, HI)** and regulated at widely varying levels in the other 46 states.

As we stated in our letter dated April 7, 2010 to then Chairman Pallone as follow up to the February 26, 2010 Hearing on *Radiation Use in Medicine: An Overview of the Issues*, accreditation is very important and perhaps is the mechanism that could ensure that qualified individuals are staffed in appropriate numbers, and perform procedures based on national consensus guidelines. Accreditation must be tied to reimbursement in a hybrid of the *Mammography Quality Standards Act of 1992*[3] (MQSA) (P.L. 102-539) and *Medicare Improvements for Patients and Providers Act of 2008* (MIPPA) (P. L. 110-275), MIPPA models.

The difference between MQSA and MIPPA is in the prescriptiveness of the regulations. MQSA is much more prescriptive and MIPPA, much less so. We believe that the required qualifications for individuals to deliver radiation should be mandatory by federal legislation. This is consistent with the CARE legislation – H.R. 2104.

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[3]By MQSA we mean as amended by the Mammography Quality Standards Reauthorization Acts of 1998 and 2004 (MQSRA).

It is clear that MIPPA as currently in place does NOT require consistent qualifications for individuals who are involved in the delivery of medical radiation, especially in the case of medical physicists. **Thus immediate passage of CARE legislation - H.R. 2104 is necessary**. Legislation should specify that the medical community develop minimum staffing levels by qualified individuals and specific practice guidelines to be followed. This means that it would be expected that the medical community adopt consensus standards of practice by which uniform national accrediting would be accomplished. Subsequently, a robust combination of mandatory qualifications and consistent accreditation, required for payment by the Centers for Medicare & Medicaid Services (CMS), would improve patient safety and care.

Future Directions

Although rare, medical errors can be devastating. We all wish that no one ever made a mistake, even more so, no event that could injure another person. 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 the complex systems in the delivery of this type of medical care.

AAPM stated in our testimony in 2010 before this subcommittee that significant effort has been placed and progress is being made in the following areas, but that we can and must do more to improve the quality of care and increase patient safety. This is still true today. We continue to believe that together we all (medical radiation team members, professional associations, manufacturers and government) must:

1. Provide robust, consistent, and financially stable education, training and clinical experience for the Qualified Medical Physicist in clinical practice. To achieve this, we must:
   - continue strong support for the AAPM 2014 initiative, which will meet the goal of requiring every candidate who applies to take the American Board of Radiology medical physics exams to receive structured didactic medical physics education and complete an accredited clinical residency prior to completing the certification exam beginning in 2014 and
   - obtain recognition for medical physics residency programs for Centers for Medicare & Medicaid (CMS) reimbursement equivalent to that of physician residencies.

2. Strive for nationally consistent recognition of the Qualified Medical Physicist and equivalent competency for all medical radiation team members;
   - pass H.R. 2104, *Consistency, Accuracy, Responsibility and Excellence (CARE) in Medical Imaging and Radiation Therapy Act* and specifically require that all medical physicists involved in medical imaging and radiation therapy be included in the bill and
   - facilitate consistent implementation of CARE nationally.

3. Provide national practice guidance in radiation oncology and medical imaging based on consensus and consistent minimum quality standards. Standards must:
   - recognize qualified individuals; specifically the Qualified Medical Physicist,
   - establish minimum staffing levels,
   - require that Qualified Medical Physicists be involved in the supervision of the processes that determine image quality and patient dose/exposure,
   - define procedure-specific guidance, including explicit process communication within and beyond the medical team, and
   - undergo periodic review with timely amendment or replacement when necessary.

4. Establish a rigorous minimum standard for accrediting clinical practices that specifically includes the oversight of dose and quality assurance for medical imaging and radiation therapy technology. This standard should require that:

- sites have work performed per national practice guidance by qualified individuals with appropriate staffing levels,
- additional accreditation requirements are established for highly specialized procedures, and
- practice reviews are performed by qualified individuals.

5. Link Centers for Medicare & Medicaid (CMS) reimbursement to rigorous practice accreditation for all medical imaging and radiation therapy practices to insure steps one through four above are followed.

6. Create a national data collection system to learn from actual and potential adverse events in the medical use of radiation. The system must:
   - allow reporting by medical staff and manufacturers and others in a complete and consistent manner,
   - be searchable to identify patterns, risks and corrective actions and to provide education, and
   - require a partnership between all involved (federal and state government, manufacturers, users, patient advocates).

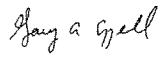
7. Improve the effectiveness of product clinical quality, application and integration review in the regulatory equipment clearance process by partnering with the U.S. Food and Drug Administration (FDA), the International Electrotechnical Commission, (IEC) and manufacturers.

Conclusion

In summary, the AAPM believes that patient safety in 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. That is why we urge you to move *The Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy Bill* (H.R. 2104) forward for quick passage in this session and look forward to working with you on other legislation to further secure quality patient care.

If you have questions or would like to discuss further, please contact me or Lynne Fairobent, Manager of Legislative and Regulatory Affairs at 301-209-3364 or via email: lynne@aapm.org.

Sincerely,



Gary A. Ezzell, Ph.D., FAAPM

TESTIMONY – JUNE 8, 2012

Medical imaging manufacturers have made tremendous strides in advancing and safeguarding patient access to safe and effective medical technologies. Of critical importance is the assurance that lifesaving medical technologies are being used appropriately.

The Medical Imaging & Technology Alliance (MITA) supports the Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy (CARE) Act. The tenets of the CARE Act build upon efforts of the medical imaging industry to ensure safe and effective patient care, promoting access to high-quality medical imaging and radiation therapy (RT) services.

Manufacturers have invested extensive resources to design and implement improvements in medical radiation imaging and radiation therapy equipment to lower the dose required to provide a patient and their physician with the information needed to inform medical decisions. This equipment is complex, and it is best operated by radiologic personnel fully educated in anatomy, positioning, exposure techniques, and radiation safety. The CARE Act, H.R. 2104, will help ensure that all imaging technologies are used properly to so that continued effectiveness, safety, and high-quality patient care is provided.

Our members have a long-standing commitment to ensuring safe and appropriate usage of medical imaging services. MITA and a coalition of individuals and organizations such as Image Gently have recently received the U.S. Food and Drug Administration (FDA) "Leveraging/Collaboration Award" for its dedication to excellence in accomplishing the mission of the Agency's Center for Devices and Radiological Health (CDRH). The team organizations developed collaborative network aimed at reducing unnecessary radiation exposure from imaging exams to pediatric patients.

MITA and its members believe that central to reducing exposure to unnecessary medical radiation is working jointly with the imaging community – including physicians, medical physicists, nurses, and technologists – to improve patient care.

That's why, in addition to our collaboration with FDA, MITA collaborates with the larger imaging community on initiatives like the 'Image Wisely', 'Image Gently' and 'Choosing Wisely' campaigns, which focus on reducing unnecessary radiation exposure for adults and children, as well as educating patients and caregivers about benefits and risks of diagnostics and therapies.

This week, MITA unveiled a series of new dose-reduction initiatives. Among the new dose-reduction efforts, the CT Access Control Standard will provide an extra safeguard by standardizing the tools that ensure only an authorized operator can alter the controls of a CT scanner. This industry-wide standard will require the establishment of administrative privileges, access and authorization levels and the recording of clinical protocols to help ensure safe and appropriate usage.

Our members are also incorporating new breakthrough products and system innovations that reduce radiation dose while continually improve the ability of these technologies to aid physicians in diagnosing disease and staging treating options:

- Automatic Exposure Controls (AEC) which automatically adjust the amount of x-rays within prescribed bounds as needed to achieve the desired image quality. Studies of AEC procedures have demonstrated significant dose reductions when used properly.

- New advances in Adaptive Software Filtration and Iterative Reconstruction allow manufacturers to selectively reduce dose noise in uniform areas of an image while preserving edges, thereby enabling a lower dose while preserving image quality.

- Innovations in Beam Filtration and Collimation help to minimize exposure to photons that do not contribute to the quality of an image.

- In nuclear medicine, Advanced Detector Materials and Electronics as well as Image Reconstruction Algorithms allow clinicians to administer less radiopharmaceutical while still achieving the same diagnostic quality.

- Radiation Therapy (RT) manufacturers have developed Advanced Camera and Detector Technologies which allow decreased dose and state-of-the-art Positioning Technologies that respond to real-time patient and organ positions—accounting for even the smallest patient movements during therapy—to ensure radiation does not affect healthy tissue surrounding a tumor.

- Advance Digital Radiography detector materials such as cesium needle phosphor improve image quality and reduce dose for digital radiography. Studies have shown equivalent image quality is possible by employing advanced digital detectors instead of conventional digital detector technology.

- Additional Quality Control, Dose Management, and Information tools and instructions are being developed to aid facilities in dose management, participation in dose index registries such as ACR's, and management of equipment settings. Currently, the MITA Interventional Group is working with FDA and AAPM to create a User Quality Control Mode and the MITA CT Group is working with stakeholders to finalize uniform User Information dose management documentation.

- Focused efforts on Pediatric Dose Optimization and Management continue to be a priority for MITA. MITA has been working with the healthcare community including Image Gently, AAPM, and FDA, combining resources on dedicated training modules, proposed dose metrics tailored for pediatrics, and support for FDA's draft guidance on "Pediatric Information for X-ray Imaging Device Premarket Notifications". MITA is also extremely honored to have been a part of the Pediatric Dose Reduction Group that recently received the *FDA Leveraging/Collaboration Award* for developing a collaborative network aimed at reducing unnecessary radiation exposure to pediatric patients from imaging exams.

These new dose-reduction efforts build on existing industry-wide initiatives to develop and implement additional patient protection features for CT and radiation therapy (RT) equipment, guaranteeing scans are safe and effective:

- In 2010, CT manufacturers also released the CT Dose Check Initiative, a commitment to add new features to CT scanners, such as dose notification and alert features as well as a new dose recording feature to track dose and develop reference dose levels to help providers understand how their facility compares to local and national standards.

- Together with the Advanced Medical Technology Association (AdvaMed), MITA also launched the Radiation Therapy Readiness Check Initiative to further enhance the safety of radiation therapy equipment through the development and implementation of additional patient protection features that confirm that patient treatment plans are delivered as intended, and that radiation therapy equipment, accessories, and patients are properly positioned prior to delivery of therapy.

- Additionally, MITA supports the American College of Radiology (ACR)'s Dose Index Registry (DIR), which allows imaging facilities to compare their CT dose indices to regional and national values. Data from the DIR are being used to establish national benchmarks for CT dose to help ensure that patients receive safe, quality imaging care.

MITA advocates for the development and use of physician-developed appropriateness criteria to guide treatment decisions and training of hospital and imaging facility personnel who perform medical imaging exams and deliver RT treatments. In order to provide optimal care and prevent medical errors, physicians and technicians must account for the patient's individual needs, including adjusting dose levels based on these needs and characteristics. By providing proper training and adhering to these standards and initiatives, we can limit unnecessary radiation exposure and ensure patients receive the life-saving benefits of medical imaging and radiation therapy technologies.

Above all else, the medical imaging industry works to safeguard and advance high-quality patient care. The CARE bill promises to build on our commitment to improve the diagnosis and treatment of countless patients. Ensuring that operators are appropriately qualified is a significant – albeit, singular – step the medical industry has taken to secure patient access and safety.

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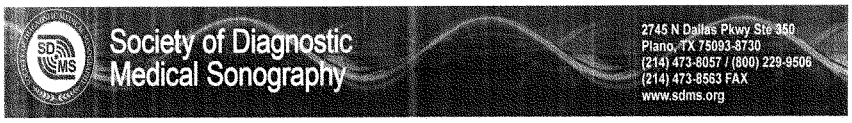

Testimony of Donald Haydon
Submitted to the House Energy & Commerce Committee
Passage of the CARE Bill: Good Public and Fiscal Policy
June 8, 2012

My name is Donald Haydon. I am the Chief Executive Officer for the Society of Diagnostic Medical Sonography (SDMS), the largest non-profit association of sonographers in the world, with a current membership of over 25,500 sonographers who practice in all of the ultrasound specialties including OB/GYN, cardiac (adult/pediatric/fetal), vascular, abdomen, musculoskeletal, and neurosonography. My testimony here today is provided in support of the CARE bill (H.R. 2104).

The members of SDMS, sonographers, are the health care professionals who perform the overwhelming number of ultrasound examinations on patients. Sonographers provide physicians with detailed information for diagnostic and treatment decisions. This requires not just the knowledge and the skill necessary to capture useful images but the ability to make real-time adjustments to ultrasound equipment and patient scanning techniques to ensure accurate images.

There are too many medical horror stories and too many bad patient outcomes that could have been avoided if the medical imaging personnel actually performing these examinations had proper training and certification.

Ultrasound equipment is rapidly evolving and becoming even more sophisticated. However, as we have seen not only in the practice of medicine but in many other areas, more sophisticated technology, better computer graphics, and the digital read-outs can easily lull us into a false sense of security. Better color imaging and smaller devices cannot take the place of human judgment, and that is particularly true for sonographers performing ultrasound examinations. Without skilled and well-trained sonographers, and other imaging personnel, inaccurate diagnoses, improper treatments, and bad patient outcomes will continue to increase.

A skilled and well-trained sonographer must have a detailed knowledge of anatomy and pathology, as well as the clinical skills necessary to apply that knowledge. Unfortunately, under current federal law, there are no standards in place to ensure that the person performing an ultrasound examination has the appropriate education and training to perform this critical task. Current federal law does not require sonographers or other imaging personnel to obtain certification attesting to their competence.

In most states, the person who cuts your hair must obtain a certificate or license attesting to their training and competence. However, in almost all states the person who performs your diagnostic medical sonography examination that is used to make potentially life-saving medical diagnostic and treatment decisions does not need to possess certification or even attest to their education and training.

The CARE bill would address this glaring deficiency in public policy. It would establish certification standards for non-physician providers of medical imaging services, including sonographers, through the nationally recognized medical imaging credentialing organizations.

States, and not the federal government, have traditionally regulated the practice of medicine. The CARE bill would not change this relationship. The CARE bill would not require states to offer medical imaging licensure or change existing state regulation.

The CARE bill would require the federal Medicare program to become a prudent purchaser of services and only pay for imaging services when they are performed by an individual educated, trained, and certified to perform this service. This is the standard the Medicare program uses for nearly every other medical profession from physical therapists, to nurse practitioners, and physicians.

One might reasonably ask, "What public need would the CARE bill serve?" This very issue was the subject of a congressional hearing held by this committee on February 26, 2010. There were a series of articles, published in *The New York Times* (one having appeared on the front page), documenting the horrendous outcomes on patients when medical imaging was applied by improperly trained personnel or malfunctioning equipment was not properly identified by

inadequately prepared providers. Some of these cases resulted in excruciating death suffered by unsuspecting patients. All of these cases created suffering for patients and their families alike and need not, nor should not, have happened.

Patients believe that the people in the medical imaging examination room wearing the white lab coat are appropriately educated, clinically trained, and certified. Unfortunately, this is often not true. The CARE bill is the first step in addressing this problem.

It is worth noting that MedPAC, the non-partisan advisory body to Congress on matters pertaining to Medicare policy has, on multiple occasions, supported the very approach reflected in the CARE bill and has urged both CMS and Congress to adopt certification standards for technical component personnel involved in medical imaging.

There has been some suggestion that the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) may be an appropriate vehicle for addressing this problem. We believe that MIPPA may not be the best option for accomplishing the CARE bill's objectives. Congress limited the scope of MIPPA to "advanced medical imaging" modalities including CT, PET, MRI, and Nuclear Medicine, and required the Secretary to regulate "advanced medical imaging" modalities through lab/facility accreditation, and specifically excluded ultrasound and x-ray. The CARE bill focuses on the education, training, and certification of medical imaging personnel for all imaging modalities.

Additionally, it is possible to comply with the MIPPA lab/facility accreditation requirements and still have non-certified personnel performing ultrasound examinations across a broad range of ultrasound specialties. We believe that this outcome is not consistent with the public interest.

The CARE bill may not be perfect, but it is a very, very good bill. In most instances, when this Committee addresses a health or medical issue, there is opposition from one or more groups. In this instance, there is no organized opposition to the CARE bill. Indeed, there is widespread support for the CARE bill within the healthcare professional community and within public policy advocacy organizations. The literature on this issue is clear: quality medical imaging studies,

performed by appropriately certified personnel, are most cost-effective, cause fewer repeat studies, provide better patient care, and increase patient safety.

I also understand that some Members of Congress would like to add new provisions and requirements to the CARE bill. The CARE bill as drafted can pass both houses of Congress and become law. The need for the CARE bill is acknowledged and well established, and it represents good public policy. If you pardon my use of the vernacular, it would be a shame to kill a very, very good bill because it does not solve every problem.

Our organization, representing sonographers practicing in every state in the country, the nation's hospitals, medical imaging centers, physician offices, and other healthcare facilities strongly urge members of the this committee to support the CARE bill and move its passage without delay.

Mr. PITTS. I will introduce the panel at this time.

Today's witnesses are Mr. John Spiegel, who is the director of the Medicare Program Integrity Group at the Centers for Medicare and Medicaid Services, United States Department of Health and Human Services; Dr. Leonard Gunderson, chairman of the board of directors for the American Society for Radiation Oncology, and emeritus professor and consultant in radiation oncology at the Mayo Clinic; Dr. Rebecca Smith-Bindman is a professor in the departments of radiology and biomedical imaging, epidemiology and biostatistics and obstetrics, gynecology, and reproductive sciences at the University of California San Francisco; and Dr. Salvatore Martino is a registered radiologic technologist and is the chief executive officer for the American Society of Radiologic Technologists.

We are happy to have all of you with us today. Your written statements will be made part of the record. And at this time you are recognized for 5 minutes each to summarize your testimony.

STATEMENTS OF JOHN SPIEGEL, DIRECTOR, MEDICARE PROGRAM INTEGRITY GROUP, CENTER ON PROGRAM INTEGRITY, CENTERS FOR MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES; LEONARD GUNDERSON, CHAIRMAN, BOARD OF DIRECTORS, AMERICAN SOCIETY FOR RADIATION ONCOLOGY; REBECCA SMITH–BINDMAN, PROFESSOR OF RADIOLOGY, EPIDEMIOLOGY/BIOSTATISTICS, OBSTETRICS, GYNECOLOGY, AND REPRODUCTIVE SCIENCES, UNIVERSITY OF CALIFORNIA, SAN FRANCISCO SCHOOL OF MEDICINE; AND SAL MARTINO, CHIEF EXECUTIVE OFFICER, AMERICAN SOCIETY OF RADIOLOGIC TECHNOLOGISTS

Mr. PITTS. Mr. Spiegel, you are recognized for 5 minutes.

STATEMENT OF JOHN SPIEGEL

Mr. SPIEGEL. Thank you. Chairman Pitts, Ranking Member Pallone and members of the subcommittee, I am pleased to be here today to discuss the role of the Centers for Medicare and Medicaid Services and accrediting suppliers of advanced diagnostic imaging services. CMS is working to ensure that Medicare beneficiaries receive advanced diagnostic imaging services from suppliers that meet quality and safety standards. Section 135 of the Medicare Improvements for Patients and Providers Act of 2008, or MIPPA, requires that beginning January 1, 2012, Medicare can only make payments to the supplier of the technical component of advanced diagnostic imaging services if the supplier is accredited, including personnel standards, by an accrediting organization approved and designated by the Secretary of the Department of Health and Human Services.

CMS has implemented these statutory provisions. This advanced diagnostic imaging accreditation requirement applies to MRI, CT, nuclear medicine, including PET. The law also gives the Secretary flexibility to expand the scope of the diagnostic imaging to which the imaging accreditation could apply, but the statute specifically excludes X-ray, ultrasound, and fluoroscopy procedures.

MIPPA requires the Secretary to approve organizations that then accredit advanced diagnostic imaging suppliers. By law, the accred-

iting organizations must establish standards in specified areas, including qualifications of personnel performing advanced imaging services, qualifications of medical directors in supervising positions, procedures to ensure that the equipment used meets performance specifications, standards to ensure the safety of both beneficiaries and staff performing the imaging test, and quality assurance and control program to ensure the reliability of the diagnostic images.

CMS selected three national accrediting organizations that meet all the standards and requirements prescribed in MIPPA: the American College of Radiology; the Intersocietal Accreditation Commission; and the Joint Commission. MIPPA provided that suppliers previously accredited by one of these approved accreditation organizations did not need to seek new accreditation to comply with the MIPPA requirements but must continue to maintain their accreditation.

As of May 25 of this year, there are 15,821 accredited suppliers and a total of 61,434 locations, two-thirds of which are accredited by the American College of Radiology. The accrediting organizations designated by the Secretary have developed detailed standards that address the qualifications of individuals performing the technical component of advanced diagnostic imaging. Each accrediting organization has developed specific guidelines for staff performing different advanced diagnostic imaging modalities. For example, the ACR requires that radiologic technologists performing a CT be certified by the ARRT or have a State license, have documented training in CT, and complete various continuing education requirements. The other accrediting organizations have similar requirements or assurances.

In States where there is a licensure or certification requirement, the accrediting organization standards include those State requirements. However, the accrediting organization's personnel standards go beyond these minimum State requirements to include a range of standards that address different aspects of advanced diagnostic imaging. This assures that only technicians and technologists that meet the experience and education requirements established by the accrediting organizations are considered qualified personnel.

CMS believes that the MIPPA accreditation provision strikes a careful balance by focusing oversight and attention on areas of imaging that pose the greatest risk to patients in a manner that minimizes the burden imposed on physicians and others who furnish imaging services. The exclusion of X-rays, fluoroscopy, and ultrasound from accreditation requirement limits burdens on individual physician practices, especially primary care physicians who may perform these tests in their offices.

The use of accrediting organizations is required in MIPPA and enhances patient safety. This approach enhances patient safety without the need for additional direct Federal Government oversight of every supplier of advanced diagnostic imaging that serves Medicare beneficiaries.

As physicians increasingly rely on advanced imaging services to diagnose complex medical conditions, the MIPPA accreditation requirement provides Medicare beneficiaries with assurances of imaging facilities with well-trained staff, using safe machines and procedures to conduct diagnostic imaging tests.

We will continue to work to fulfill our statutory requirements to oversee the accreditation process and ensure that accrediting organizations, suppliers, and beneficiaries continue to have the information they need on these requirements. Thank you and I would be happy to answer any questions.

Mr. PITTS. The Chair thanks the gentleman.

[The prepared statement of Mr. Spiegel follows:]

STATEMENT OF

JOHN SPIEGEL

DIRECTOR
MEDICARE PROGRAM INTEGRITY GROUP
CENTER ON PROGRAM INTEGRITY
CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

ADVANCED DIAGNOSTIC IMAGING ACCREDITATION

BEFORE THE

U.S. HOUSE COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH

JUNE 8, 2012

U.S. House of Representatives Committee on Energy and Commerce
Subcommittee on Health
June 8, 2012

Chairman Pitts, Ranking Member Pallone and Members of the Subcommittee, I am pleased to be here today to discuss the role of the Centers for Medicare & Medicaid Services (CMS) in accrediting suppliers of advanced imaging services. The Department of Health and Human Services takes very seriously our role in ensuring the health and well-being of all Medicare beneficiaries and CMS in particular is working to ensure that Medicare beneficiaries receive advanced diagnostic imaging services from suppliers that meet quality and safety standards.

Medicare Improvements for Patients and Providers Act Requirements

Congress, in section 135 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (P.L. 110-275), amended the Social Security Act to include a new section 1834(e) in response to concerns about the quality and safety of imaging services provided under Medicare. This new imaging accreditation provision specifies that beginning January 1, 2012 Medicare can only make payments to the supplier of the technical component of advanced diagnostic imaging services if the supplier is accredited by an accreditation organization designated by the Department of Health and Human Services (HHS). The technical component is the taking of the images (as contrasted with the professional component comprised of a physician's interpretation of the images).

Per the statute, this requirement applies to all physicians, non-physician practitioners, as well as other entities that are paid under the Medicare Physician Fee Schedule for furnishing the technical component of advanced diagnostic imaging services. The accreditation requirement applies only to the physician, practitioner, facility, or entity that furnishes the technical component of advanced diagnostic imaging services, not to the professional component of the service.

The statute requires that the imaging accreditation requirement apply to the following advanced diagnostic imaging procedures: Magnetic Resonance Imaging (MRI), Computed Tomography (CT), and nuclear medicine imaging, including positron emission

tomography (PET). The law also gives the Secretary flexibility to expand the scope of diagnostic imaging services to which the imaging accreditation could apply, but the statute specifically excludes X-ray, ultrasound and fluoroscopy procedures. Diagnostic and screening mammography, which is subject to quality oversight by the Food and Drug Administration (FDA) under the Mammography Quality Standards Act, is not covered under the MIPPA provision. The imaging accreditation requirement has been in place since January 2012, and the Secretary has not expanded the requirement to other diagnostic imaging services.

MIPPA requires the Secretary to approve organizations that then accredit advanced diagnostic imaging suppliers. The law requires that the accrediting organizations establish standards in six specified areas covering:

- Qualifications of non-physician personnel furnishing the technical component of advanced imaging services;
- Qualifications and responsibilities of medical directors and supervising physicians;
- Procedures to ensure that the equipment used in furnishing the technical component of imaging service meets performance specifications;
- Standards that require the supplier to have procedures in place to ensure the safety of both persons who furnish the technical component of the test and beneficiaries who receive the test;
- Establishment and maintenance of a quality assurance and quality control program to ensure the reliability, clarity, and accuracy of the technical quality of the diagnostic images produced by the supplier; and
- Other factors as the Secretary determines appropriate.

While this statute does not explicitly require it, the personnel standards that were established by the accrediting organizations include State licensure or State certification requirements where they exist. In addition, where there is no State licensure or certification requirement, only technicians/technologists that meet the education and experience requirements established by the accrediting organizations are considered qualified personnel.

CMS believes that the MIPPA accreditation provisions strike a careful balance by focusing new oversight and attention on areas of imaging that pose the greatest risk to patients in a manner that minimizes the burden imposed on physicians and others who furnish imaging services. The exclusion of X-rays and ultrasound from the accreditation requirement limits burdens on individual physician practices, especially primary care physicians who may perform some X-rays or other imaging services in their offices, yet do not provide more advanced diagnostic imaging services.

In MIPPA, Congress adopted a private sector approach to imaging accreditation. Instead of prescribing requirements for imaging facilities or tasking the Secretary of HHS with developing specific standards of care, the statute called for CMS to evaluate and approve accrediting organizations that establish specific health and safety standards and that ensure these standards are met by imaging suppliers. This approach enhances patient safety without the need for additional direct Federal government oversight of every supplier of advanced diagnostic imaging that serves Medicare beneficiaries.

Implementation of Medicare Improvements for Patients and Providers Act Provisions

To implement these provisions, CMS issued a Notice of Proposed Rulemaking (NPRM) on July 13, 2009.[1] Several stakeholders submitted comments in response to the NPRM, with most affirming their support for the requirement. The rule was finalized on November 25, 2009, as a part of the Medicare Physician Fee Schedule final rule with comment period for calendar year 2010 (74 FR 62189) and provided a more detailed description of the application requirements that CMS would consider in selecting accreditation organizations.

CMS also issued a Request for Proposals (RFP) on November 25, 2009, requesting applications for organizations interested in applying to be an accrediting body. CMS received three applications from this solicitation, which were reviewed by an internal professional panel. MIPPA established a number of criteria for consideration in the selection of accreditation organizations including:

- The ability of the organization to conduct timely reviews of accreditation applications;

[1] http://www.gpo.gov/fdsys/pkg/FR-2009-07-13/pdf/E9-15835.pdf

- Whether the organization has established a process for the timely integration of new advanced imaging services into the organization's accreditation program;
- Whether the organization uses random site visits, site audits or other strategies for ensuring accredited suppliers maintain adherence to the accreditation standards;
- The ability of the organization to take into account the capacities of suppliers' location in rural areas; and
- Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.

Based on these criteria for selecting accrediting organizations, and an assessment of how well the specific accreditation requirements met the statutory criteria, on January 26, 2010, CMS announced the selection of three national accreditation organizations that met all MIPPA standards and requirements: the American College of Radiology (ACR), the Intersocietal Accreditation Commission (IAC), and The Joint Commission (TJC). Imaging suppliers work directly with one of the three accrediting organizations to demonstrate that they meet quality standards and receive accreditation. The accreditation process may include several different components, including: an unannounced site visit; review of staff credentialing and records of equipment maintenance; review of quality data, patient health records, and beneficiary complaints; and ongoing data monitoring. CMS launched a variety of outreach initiatives to help educate suppliers about the accreditation requirements. Efforts included national provider calls, Medicare Learning Network articles, outreach messages on CMS' provider listservs, and online resources with additional information on the requirements.[2]

The accreditation requirements became effective on January 1, 2012. CMS is not aware of any disruptions in beneficiary access to diagnostic imaging services that resulted from the implementation of the MIPPA requirements. MIPPA also grandfathered facilities that were previously accredited by one of the selected accreditation organizations; as a result, previously-accredited suppliers did not need to seek new accreditation to comply with MIPPA. However, these suppliers must continue to maintain their accreditation. As of May 25, 2012, there are

[2] http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/AdvancedDiagnosticImagingAccreditation.html

15,821 accredited suppliers, with a total of 61,434 locations, with a majority of locations (41,019) accredited by the ACR.

As part of our commitment to safeguarding Medicare beneficiaries and ensuring they maintain access to quality care, CMS routinely verifies that only accredited suppliers are eligible to receive Medicare payments for advanced diagnostic imaging services. By verifying accreditation status before paying claims, CMS can quickly identify any supplier that may have had their accreditation revoked for any violation and take appropriate action to stop Medicare payment.

Conclusion

Since the beginning of this year, the advanced diagnostic imaging accreditation requirements included in MIPPA have helped CMS ensure that all Medicare beneficiaries are receiving high quality, safe diagnostic advanced imaging services. As physicians increasingly rely on advanced imaging services to diagnose complex medical conditions, this requirement provides beneficiaries with assurance that imaging facilities have well-trained staff using safe machines and procedures to conduct diagnostic imaging tests. CMS will continue to work to fulfill our statutory requirements to oversee this accreditation process and ensure that accreditation organizations, suppliers and beneficiaries continue to have the information they need on these requirements.

Thank you for the opportunity to testify today; I would be pleased to answer any questions you may have.

Mr. PITTS. Dr. Gunderson, you are recognized for 5 minutes for your summary.

STATEMENT OF LEONARD GUNDERSON

Mr. GUNDERSON. Chairman Pitts, Representative Pallone, and members of this distinguished committee, good morning and thank you for the opportunity to testify at today's hearing.

ASTRO and its over 10,000 members applaud the leadership of Representatives Whitfield and Barrow for sponsoring the CARE Act which has broad bipartisan support in this committee. ASTRO strongly supports immediate passage of the CARE Act which is a key component of our patient safety initiative.

I am an emeritus professor and consultant in radiation oncology at Mayo Clinic where I have practiced for 28–1/2 years, 21 years in leadership positions. I am the chair of the ASTRO board of directors who I am representing today. I care deeply about my profession and the health and safety of our patients.

It is important to note the marked difference in the use of radiation for treatment of cancer patients versus for diagnostic purposes. In diagnostic radiology, low doses of radiation are used for imaging studies to determine if problems exist. With radiation oncology, we use high-dose radiation to kill cancer cells, and we often find better results with higher doses.

When a patient is diagnosed with cancer, a radiation oncologist discusses and agrees upon treatment options with the patient and their family. We plan and deliver that care with support from nonphysician members of the radiation oncology treatment team. This treatment team consists of a medical physicist responsible for quality assurance programs and making sure the equipment is working properly; a dosimetrist carefully develops a computerized plan in conjunction with the radiation oncologist to make sure the cancer gets the prescribed dose while nearby healthy tissues are spared; and a radiation therapist or technologist who administers daily radiation treatments under the physician's supervision.

ASTRO has long advocated for Congress to improve the safety of radiation therapy by establishing minimum education and credentialing standards. As you are aware, in some States, basic training standards are voluntary, allowing individuals to perform some radiation oncology procedures without any formal education. Without a minimum level of standards, patients are at risk.

The CARE Act would set needed education and certification standards for radiation therapists, medical physicists, and medical dosimetrists who participate in the delivery of radiation therapy for Medicare patients. These minimum standards will help ensure that patients are treated accurately and safely, leading to reduced complications and potentially higher patient survival rates.

We are concerned about proposals to expand MIPPA in lieu of proceeding with the CARE Act. As you know, MIPPA applies only to advanced diagnostic imaging services provided in freestanding centers, not radiation therapy services. If MIPPA were simply expanded to include radiation therapy services, we are concerned that the vast majority of radiation oncology patients won't benefit because they are treated in hospital outpatient departments, not in freestanding centers.

While a critical step, we do not believe that the CARE Act alone can prevent medical errors that are possible in a complex treatment such as radiation therapy. That is why ASTRO is committed to working with Congress and this committee on additional efforts to ensure patient safety, particularly in the area of practice accreditation, which is different than credentialing the nonphysician members of the radiation oncology treatment team. The CARE Act is one of the many pathways toward increased patient safety. ASTRO has been a leader in efforts to improve the quality of care and patient safety and these initiatives are detailed in our written testimony.

Finally, I want to conclude with a story of one of my patients that immediately came to mind when I was asked to testify. It involves a man diagnosed with metastatic terminal cancer that was not responding to chemotherapy. His dying wish was to walk his daughter down the aisle at her wedding. He needed, of course, radiation therapy to treat his metastatic cancer, relieve his pain, and hopefully prolong his life. Just before his first radiation treatment, one of our well-trained radiation therapists caught a computer error that if left unchecked would have resulted in a less-than-favorable outcome. We corrected his treatment plan and delivered a high-quality course of treatment. Although his cancer ultimately killed him, it was not before he achieved his wish of walking his daughter down the aisle.

This story illustrates the importance of ensuring that every cancer patient is treated by a team that includes top-notch, highly trained and qualified individuals, which is why we need to pass the CARE Act. ASTRO wants patients to have peace of mind when it comes to safety, quality, and efficacy of radiation therapy. We urge the committee to immediately pass the CARE Act and we look forward to working with you on additional policies to further enhance the quality of care patients receive. Thank you again for the opportunity to testify, and I would be happy to answer any questions.

Mr. PITTS. The Chair thanks the gentleman.

[The prepared statement of Mr. Gunderson follows:]

Statement of
Leonard L. Gunderson, M.D., M.S.
Chairman of the Board of Directors
on Behalf of the American Society for Radiation Oncology (ASTRO)
Before the House Committee on Energy and Commerce Subcommittee on Health
June 8, 2012

Chairman Upton, Ranking Member Waxman, Subcommittee Chairman Pitts, Subcommittee Ranking Member Pallone and members of this distinguished committee, good morning and thank you for the opportunity to testify at today's hearing on the standards for radiation therapy technologists. High quality radiation therapy requires not only highly skilled and well trained radiation oncology physicians (radiation oncologists), but also an entire team of medical physicists, dosimetrists, and radiation therapists (technologists). ASTRO and its over 10,000 members applaud the bipartisan leadership of Reps. Whitfield and Barrow -- along with 20 Members of the full committee and 10 from the health subcommittee -- for supporting the Consistency, Accuracy, Responsibility and Excellence (CARE) in Medical Imaging and Radiation Therapy Act (HR 2104). **ASTRO strongly supports immediate passage of the CARE Act, a key component of our *Target Safely* patient safety initiative, to help ensure the safety of radiation therapy.**

I am an Emeritus Professor and Consultant in Radiation Oncology at the Mayo Clinic, where I served in leadership positions for over 21years. I've practiced as a board certified radiation oncologist for more than 35 years, and had 10-30 patients per day under treatment during that time. My medical education was at the University of Kentucky, and my residency/fellowship was at the Latter-Day Saints (LDS) Hospital/Intermountain Health Care Inc. (IHC) in Salt Lake City, Utah, including a rotation at the MD Anderson Cancer Center in Houston, Texas and other institutions. After completing my training, I was on staff at LDS Hospital/IHC for 2 years, followed by Massachusetts General Hospital/Harvard Medical School for nearly 5 years and subsequently at the Mayo Clinic for 28.5 years.

My clinical research has focused on external beam radiation therapy as a component of multimodality treatment for patients with gastrointestinal (GI) cancers (colorectal, gastric, pancreas, biliary, anus, esophagus) and soft tissue sarcomas. I have worked closely with colleagues in surgery, medical oncology and other specialties to develop consensus on both diagnostic and treatment pathways in the care of patients.

Leadership positions I have held include Chair of Radiation Oncology and subsequently Chair of the Department of Oncology at the Mayo Clinic in Rochester, Minnesota (I was the only radiation oncologist to serve as chair of the Department of Oncology). At Mayo Clinic in Arizona, I was Chair of Radiation Oncology and Deputy Director for Clinical Affairs at Mayo Clinic Cancer Center Arizona. I also have been a leader in the Radiation Therapy Oncology Group (RTOG) clinical cooperative group for 14 years, including Chair of the RTOG Gastrointestinal (GI) Cancer Committee/GI Steering Committee and Vice-Chair for Disease

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Sites. I am proud of my more than 30 years of service to ASTRO, which includes a leadership position as a member of the Board of Directors for 8 years. I currently serve as Chairman of the Board of Directors of ASTRO, which I am representing today.

I have personally witnessed the great benefits of radiation therapy for cancer patients. I care deeply about my profession and care even more deeply about the health and safety of my patients. I look forward to telling you why we support the CARE Act, how radiation therapy works, ASTRO's longstanding efforts to improve quality and patient safety, as well as ASTRO's plans to further enhance patient protections.

I believe my testimony is critical to help Congress and the public understand that radiation therapy is a very safe treatment with a long track record of effectively curing cancer with minimal side effects (alone or in conjunction with surgery and chemotherapy or other systemic therapy). We believe passage of the CARE Act – in concert with ASTRO's many patient safety initiatives and the important projects being undertaken by our close partners in physics, radiation oncology technology and device manufacturing – will contribute to our efforts to improve patient care and prevent errors.

As you know, radiation oncology is an important tool in the fight against cancer. Over the last 25 years, the five-year survival rate for cancer patients has increased steadily. For example, in the mid-1970s, the five-year survival rate for breast cancer was 75%, for prostate cancer it was 69%. Today, the five-year survival rate has increased to 90% for breast cancer and 99% for prostate cancer. While these are important gains for some of the most common cancers, progress lags for other cancers such as lung, ovarian, brain and pancreatic cancer where the five-year survival rate remains below 50%. While progress has been made in some areas, more scientific research funding is still needed to continue to improve cancer survival.

ASTRO and Radiation Oncology

Founded in 1958, ASTRO's mission is to advance the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research and disseminating research results and representing radiation oncology in the rapidly evolving healthcare environment. ASTRO's physicians and medical professionals are found at hospitals and cancer treatment centers around the globe and make up the radiation therapy treatment teams that are critical in the fight against cancer.

Radiation therapy safely and effectively treats cancer and some benign conditions. Doctors use radiation therapy to eradicate cancer, to control its growth or to relieve symptoms, such as pain. It can be used to treat cancer in almost any part of the body, although breast cancer, lung cancer and prostate cancer typically make up more than half of all patients receiving radiation therapy.

New technology and improved techniques allow radiation oncologists to better target radiation in an attempt to eliminate cancer cells while at the same time protecting healthy cells. As highly trained specialists, radiation oncologists know the various forms of radiation therapy – brachytherapy or external beam radiation – their efficacy in specific cases, and the potential side effects and risks.

Radiation oncology practices use sophisticated equipment to provide patients with safe and effective care. Radiation oncologists discuss and agree upon treatment options with patients and their families and plan and deliver that care in conjunction with the patient's other physicians, as well as with the non-physician members of the patient's care team. This team approach assures that the radiation therapy component of a patient's clinical care fits appropriately in the overall patient treatment plan.

Though their uses are very different, radiation therapy is often confused with diagnostic radiology or imaging. Diagnostic radiology is used in preferably low doses to view inside the body in order to diagnose conditions or monitor the spread of cancer. Radiation therapy delivers a targeted high dose of radiation in an attempt to eradicate the cancer/tumor while sparing normal organs and structures. Higher dose often leads to better local tumor control, which has the possibility of translating into higher cure rates. While total dose is important in radiation oncology, other factors are equally important such as the dose of irradiation per treatment and the number of days over which the treatment occurs.

Radiation Oncologist Training and Board Certification
Radiation oncologists complete four years of medical school followed by five years of post-graduate training, including 4 or more years in a radiation oncology residency program. To earn board certification after residency, they must pass three components of a written examination (clinical, radiobiology, and physics) as well as an oral examination. Ninety-eight percent of all practicing radiation oncologists in the United States are board certified. Radiation therapy should only be delivered by physicians who have been specifically trained to deliver this type of treatment.

There are approximately 4,500 board-certified radiation oncologists in the United States, and about half of them must participate in maintenance of certification (MOC) programs to maintain their board-certified status. MOC programs are designed to evaluate six essential competencies on a continuous basis: medical knowledge; patient care; interpersonal and communication skills; professionalism; practice-based learning and improvement; and system-based practice.

In addition to passing an oral exam every 10 years, the MOC process requires radiation oncologists to attain 200 hours of continuing medical education (CME) credits (80 percent of which must be related to radiation therapy or oncology), to take eight self assessment modules (SAMs), and to complete three Practice Quality Improvement (PQI) projects. ASTRO currently offers 37 online SAMs on a wide range of topics. In February 2012, ASTRO launched an American Boards of Medical Specialties Patient Safety Foundation module. This course has been adapted to fit the needs of the radiation oncology team and focuses on communication and the various aspects of patient safety.

In today's environment, medical technology and decision-making are increasingly complex, and rapid changes in diagnosis and care delivery compound the situation. Initial certification and maintenance of certification offer a strong defense against loss of skills and provide continuous and rigorous quality assurance throughout one's medical career. ASTRO's Performance Assessment for the Advancement of Radiation Oncology Treatment (PAAROT) program is an example of our commitment to continuous quality improvement at the physician level. For

PAAROT, physicians select a baseline sample of 10 consecutive medical records and enter data on a series of measures for every medical record in the sample. Performance is computed per measure across the sample of medical records and is compared to aggregate peer data and pre-established performance goals. Next, pursuant to the review of the scores for each measure, physicians select a measure for performance improvement. An improvement plan is developed and implemented over the course of three months. Finally, re-measurement is completed by selecting another sample of 10 consecutive records and re-entering all measures in every record in the sample to assess the impact of the quality improvement plan. All data collected in PAAROT are HIPAA compliant and de-identified. PAAROT meets the American Board of Radiology (ABR) criteria for Practice Quality Improvement as part of the requirements of the ABR Maintenance of Certification Program.

Because of the speed of innovation in the field of radiation oncology, ASTRO actively supports physician participation in MOC activities and other continuing medical education to assure that physicians are up-to-date in the approaches for delivering radiation therapy to cancer patients. For example, each spring we offer a "State of the Art" meeting that includes workshops so that our members can be well informed about new advances and to help them anticipate workforce and training needs that will be needed to safely use new, advanced technology.

Additionally, ASTRO provides "eContouring" courses, both online and in person. Contouring is the term used to describe how a radiation oncologist outlines the contours of a tumor, plus nodal areas at risk, to best target them for radiation therapy, while excluding normal organs and structures as much as feasible. These sessions are designed to provide crucial clinical education for physicians and provide an opportunity to practice and discuss core treatment issues. Participants have the opportunity to practice contouring and compare their contours to those of renowned experts in a particular disease site. In addition, participants can take sample cases home with them to continue to practice and further improve their skill.

Radiation Oncology Treatment Team

While the radiation oncologist is ultimately responsible for the patients' care and safety, a team of highly trained medical professionals is needed to plan and deliver radiation therapy services. These treatment team members perform hands on services to both the complex planning software and machinery that delivers the radiation, and the patients that receive treatment. The team's training and certification can directly affect safety and treatment outcomes. In addition to the radiation oncologist, the treatment team includes:

- *Medical physicists*: Qualified medical physicists work directly with the radiation oncologist during treatment planning and delivery. They oversee the work of the dosimetrist and help ensure that complex treatments are properly tailored for each patient. Medical physicists are responsible for equipment software and systems acceptance testing, maintenance and commissioning, and for developing and directing quality control programs for equipment and procedures. Medical physicists follow college with additional graduate training in medical physics to receive a master's or doctoral degree. In some cases, a medical physicist will complete an additional one- or two-year training program at a hospital. Medical physicists preferably are certified by the American Board of Radiology or the American Board of Medical Physics.

- *Dosimetrists*: Dosimetrists carefully calculate the dose of radiation prescribed by the radiation oncologist to make sure the tumor gets the prescribed dosage. Using computers, they develop treatment plans that can best encompass the tumor while sparing normal tissue from radiation. Since treatment plans are often very complex, dosimetrists work with the radiation oncologist and medical physicist to develop a plan that is appropriate for each individual patient. Many dosimetrists start as radiation therapists and then, with on-site training, become dosimetrists. Others are graduates of one- to two-year dosimetry training programs. Dosimetrists may become certified by the Medical Dosimetrist Certification Board.
- *Radiation therapists (technologists):* Radiation therapists work with radiation oncologists to administer daily radiation treatments under the doctor's prescription and supervision. They are trained in how to properly position a patient to ensure that the radiation is delivered to its intended target. They maintain daily treatment records and, in conjunction with the medical physicist, check the treatment machines to make sure they are working properly. Certified radiation therapists go through a two- to four-year educational program following high school or college. By passing a special examination, radiation therapists may be certified by the American Registry of Radiologic Technologists. Some states require radiation therapists to be licensed but some do not.

Patient Safety in Radiation Oncology – The CARE Act
ASTRO has long advocated for Congress to help us further improve the safety of radiation therapy by establishing minimum education and credentialing standards for radiation therapy personnel through passage of the CARE Act. More than 1 million patients are treated with radiation therapy each year. Having highly skilled radiation therapy professionals on the treatment team is crucial for patient safety.

In some states basic training standards are voluntary, allowing individuals to perform some radiation oncology procedures without any formal education. Without a minimum level of standards, patients are at risk. The CARE bill sets education and certification standards for the radiation therapists, medical physicists and medical dosimetrists who treat Medicare and Medicaid patients. These minimum education and certification standards will help ensure that patients are treated accurately, leading to higher patient survival rates and reduced complications.

The CARE bill would advance safety and quality by requiring individuals who perform radiation therapy to graduate from a specialized educational program and pass a national certification exam. Personnel would also be required to maintain competency by obtaining continuing education, much like their physician counterparts, which will help ensure that personnel have the skills to perform their duties without error.

The need for federal minimum education and certification standards for radiation therapists, medical physicists and medical dosimetrists is clear. ASTRO is proud to be a member of the Alliance for Quality Medical Imaging and Radiation Therapy, as we agree that consistent and uniform national standards for technical personnel will improve the quality and safety of care,

and reassure patients that their treatments are being assessed, planned, and delivered by highly qualified personnel.

While a critical step, we do not believe that the CARE Act alone can prevent the medical errors that are possible in a complex treatment such as radiation therapy. That is why ASTRO is committed to working with Congress and this Committee on additional efforts to ensure cancer patient safety, particularly in the area of practice accreditation, which is different than credentialing various members of the radiation oncology care team.

However, ASTRO is concerned about proposals to expand the Medicare Improvements for Patients and Providers Act (MIPPA) in lieu of proceeding with the CARE Act. As you know, MIPPA applies *only* to advanced diagnostic imaging services – not radiation therapy services – provided in free-standing centers paid under the Medicare Physician Fee Schedule (MPFS). If MIPPA were simply expanded to include radiation therapy services, we anticipate two problems. First, while MIPPA may have been an effective way to regulate the vast majority of advanced imaging providers, only about one-third of radiation therapy providers operate as free-standing centers paid under the MPFS, so the remaining two-thirds of the radiation oncology providers who are hospital-based would not be covered by newly revised MIPPA requirements. Secondly, only about 10-15% of the radiation therapy centers in the country (both free-standing and hospital-based) are currently accredited. Accreditation done right is resource intensive, involving a full-day onsite inspection by an independent, peer radiation oncologist and medical physicist. A grace period would be needed to allow facilities to come into compliance with the accreditation requirements.

For these reasons, ASTRO believes the more straightforward approach to addressing necessary standards for radiation therapists, dosimetrists and medical physicists is via immediate passage of the CARE Act, which already enjoys vast bipartisan and bicameral support. Following passage of the CARE Act, ASTRO is open to working with the Committee to mandate radiation oncology practice accreditation using the ASTRO/American College of Radiology (ACR) Radiation Oncology Practice Accreditation (ROPA) program that thoroughly assesses the complexity of care processes and safety standards in both hospital and freestanding radiation oncology clinics.

Should the Committee be interested in incorporating this accreditation program into the Medicare program, we would like to work closely with you to ensure that such a program is successful. For instance, we would strongly recommend that such a program be phased-in over sufficient time to ensure that there are an adequate number of radiation oncology physician and medical physicists certified to conduct on-site accreditation reviews to meet the demand of centers seeking accreditation. Because accreditation is labor intensive, our practice accreditation program has struggled with training adequate numbers of reviewers. Medicare would need to account for this workforce challenge with a phased-in approach.

***Target Safely* Radiation Safety Initiative**

ASTRO's highest priority has always been ensuring patients receive the safest, most effective treatments by providing education and professional guidance to our members. A culture of safety and quality control is woven into the very fabric of our field, and there are many checks

and balances, at many levels, to assure that the safest and most effective care is delivered to our patients. Because of the technological advances in our field, radiation therapy treatments are increasingly complex. We have been a leader in efforts to improve patient safety within our specialty, and protecting our patients from potential errors requires constant vigilance.

In 2010, ASTRO's Board of Directors committed to redouble our efforts with respect to quality and safety. We undertook a systemic, 360-degree review of our ongoing patient safety and quality assurance projects and developed an action plan, called *Target Safely,* to improve the safety and quality of radiation therapy and reduce the chance of medical error. Since the plan was established, ASTRO has made great strides in meeting its goals, including:

- Worked with patient support groups, cancer survivors and other medical organizations to create a list of questions patients should ask their physicians and cancer centers when considering radiation therapy as a treatment for their disease. These are designed to help patients better understand the safety checks and balances that are put into place to guard against errors. Those questions are available for download on our patient website rtanswers.org and to view as videos posted on YouTube.
- Continued to serve as the chief financial supporter and lead organization in the IHE-RO (Integrating the Healthcare Enterprise -- Radiation Oncology) program. This program brings together radiation oncologists, physicists, other cancer care professionals and the medical device industry to prevent errors by creating an environment of interconnectivity and interoperability where vital clinical information is passed seamlessly from system to system, within and across practices, and made readily available at the point of care. ASTRO is asking all radiation oncologists and hospitals to consider only IHE-RO compliant technologies when selecting new radiation therapy equipment.
- Strengthened the ASTRO/ACR ROPA program with more robust and meaningful measures. ROPA aims to ensure that radiation therapy clinics are fully competent to perform the services they provide. ROPA provides impartial third-party peer review through assessment of daily practices that demonstrate an impact on professional competence according to recognized standards of the scientific community. More than 300 practices have been accredited since 2008. ASTRO strongly supports practice accreditation and encourages its members to participate in the program.
- Developed several white papers on safety considerations in the clinic, including safe use of Intensity-Modulated Radiation Therapy (IMRT) and Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy (SRS/SBRT). Three more white papers on Image-Guided Radiation Therapy (IGRT), High-dose-rate (HDR) brachytherapy and peer review in the clinic are nearing completion.
- Committed to incorporating quality and safety educational content in all ASTRO meetings to ensure attendees have the resources necessary to provide safe and effective patient care.

A centerpiece of *Target Safely* that is becoming a reality is the creation of a national medical error reporting system and patient safety database for radiation oncology. We are proud to report that ASTRO is building on Congress' bipartisan Patient Safety Act of 2005 by beginning work with a federally-certified Patient Safety Organization (PSO) to create an unprecedented

national medical error reporting system for radiation oncology to detect potential problems and identify national error trends. ASTRO greatly appreciates the foresight of Congress, particularly the leadership of this Committee, in passing this legislation that will allow us to efficiently leverage a PSO's experience, expertise, resources, and confidentiality protections to create a radiation oncology-specific error reporting system. We believe that contracting with a PSO will allow us to meet our goal of collecting radiation oncology patient safety data and analyzing it to improve the safety of radiation oncology. In our 2011 ASTRO membership survey, 85% of radiation oncologists and 94% of medical physicists responding said they would use an ASTRO-sponsored confidential reporting system for medical errors and near misses.

While radiation oncology is focused on targeting and delivering maximum doses of radiation directly to the cancer, we remain vigilant of the importance of reducing complications and protecting patients by sparing normal organs and structures as much as feasible from the harmful effects of radiation.

Quality Improvement

Quality assurance and error reporting is only one piece of the puzzle, and ASTRO appreciates this Committee's efforts to promote quality measurement and improvement. ASTRO has devoted significant time and resources to developing clinical guidelines and quality measures for radiation oncology. Over the past four years ASTRO has developed five clinical practice guidelines to improve patient care and reduce treatment variation. These topics include:

- Accelerated partial breast irradiation (APBI),
- Fractionation for whole breast irradiation,
- Palliative radiotherapy for bone metastases,
- Palliative thoracic radiotherapy for lung cancer, and
- Radiotherapeutic and surgical management of newly diagnosed brain metastases.

These five guidelines have all been accepted for inclusion in the National Guideline Clearinghouse sponsored by the Agency for Healthcare Research and Quality. ASTRO also is developing an evidence-based clinical practice guideline on the role of post-operative radiation therapy for endometrial cancer as well as post-operative radiotherapy after radical prostatectomy (joint ASTRO/American Urological Association guideline). Finally, ASTRO is exploring a guideline on radiation therapy in the treatment of lung cancer. In developing clinical practice statements, we have refined our process based on the Institute of Medicine's recommendations in the report *Clinical Practice Guidelines that We Can Trust*.

Since radiation oncology is a specialty that relies on, and has made dramatic advances in effective cancer care through the use of, complex breakthrough technologies, ASTRO has recognized the need for clinical practice statements on the appropriate use of new technologies in the delivery of radiation therapy. Therefore, ASTRO recently launched an initiative to develop and promulgate "Best Practices Statements." These statements will use the Rand Appropriateness Methodology and a modified Delphi approach to address important clinical questions. Experts in the field will engage in consensus deliberations on evidence to determine the appropriateness of different technologies in the treatment of cancer. ASTRO's first such statement is underway, and it will address the appropriate use of different technologies in the treatment of post-operative endometrial cancer.

While developing these collaborative guidelines and "Best Practice Statements" is an exhaustive and resource-intensive endeavor, ASTRO is committed to continuing to invest significant time, money and energy into the development of these statements. They also serve as the impetus for the development of quality measures. A newly developed measure, External Beam Radiotherapy for Bone Metastases, is being considered for endorsement by the National Quality Forum (NQF). Given the interdisciplinary team approach to cancer treatment, ASTRO also has partnered with other medical societies to develop multidisciplinary measures. An oncology measure group that was jointly developed with the American Society for Clinical Oncology (ASCO) is being reviewed by the Quality Measurement and Health Assessment Group at CMS. ASTRO has worked closely with the AMA Physician Consortium for Performance Improvement (PCPI) to develop NQF-endorsed quality measures included in the Medicare Physicians Quality Reporting System (PQRS).

ASTRO, in partnership with our foundation -- the Radiation Oncology Institute (ROI) - is developing the National Radiation Oncology Registry (NROR), the first of its kind for radiation oncology. The intent of the registry is to improve the care of cancer patients by capturing real-time reliable information on radiation treatment delivery and health outcomes through a prospective electronic registry infrastructure. The pilot project for this nascent registry is scheduled to begin in the fall of 2012 and will be focused on radiation oncology treatments for patients with localized prostate cancer. The registry will collect numerous data points, including total dose, dose per treatment, and the number of treatments and days required to deliver the total dose. Additionally, other important factors in better understanding cancer patients care will be collected, such as whether radiation therapy is delivered post-operative, pre-operative, or used as the sole therapy. The objectives for NROR are to:

- Collect patient-specific radiotherapy data electronically;
- Determine national patterns of care and gaps in quality of treatment;
- Provide benchmark data and tools to individual practitioners for quality improvement;
- Generate hypotheses linking processes of care and outcomes and identifying subpopulations for which a particular form of radiation therapy is most effective.

This spring, ROI hosted a high-level forum for thought leaders and visionary registry stakeholders to raise awareness of the NROR, gather recommendations from the group, and build longer-term involvement from the community. Forum attendees included radiation oncologists and physicists, representatives from NIH, FDA, and CMS, foundation and professional society participants, private payers, patient advocates, and industry leaders.

While the promise of the data collected by registries, such as NROR, to inform quality improvement efforts and to demonstrate the value (or lack thereof) of particular health care services is great, considerable resources are needed to launch and sustain these efforts. ASTRO strongly supports NCI's funding for clinical trials conducted through the cooperative groups, as we believe these trials are needed to help us answer key questions. We note, however, that observational data obtained in registries will give us a more complete view of how particular subpopulations (e.g., particular genetic markers, particular comorbidities) respond to treatment outside of a controlled clinical trial environment. We anticipate that the insights gained from this knowledge will have a significant impact on the cost and quality of cancer care. As federal

programs like Medicare will benefit tremendously from this information, we urge Congress to provide federal funding to support registry efforts and to create a regulatory environment that supports these efforts.

Conclusion
In summary, dealing with a cancer diagnosis is hard enough for patients without having the additional burden of worrying about the accuracy and safety of their treatments. With every cancer patient, the goal is to treat and/or cure their disease in the safest and most effective way possible. That is why we're focused completely on ensuring patient safety. We believe that any error is one error too many. ASTRO remains devoted to our patient safety goals and passing the CARE Act is a critical step toward achieving these goals.

ASTRO is also committed to supporting national error reporting, more training, enhanced accreditation, better use of health information technology, patient-centered educational tools and federal advocacy to help protect patients. We share the Committee's concerns about the health and safety of all patients and recognize the importance of maintaining access to high quality cancer treatment. **We urge the Committee to immediately pass the CARE Act, and we look forward to working with you on additional policies that could be implemented to further enhance the quality of care patients receive.**

Thank you again for the opportunity to testify.

Mr. PITTS. I now recognize Dr. Smith-Bindman for 5 minutes for an opening statement.

STATEMENT OF REBECCA SMITH–BINDMAN

Ms. SMITH-BINDMAN. Mr. Chairman, ranking member, and members of the subcommittee, thank you for this opportunity to testify today. I am Dr. Rebecca Smith-Bindman, a professor at the University of California, San Francisco School of Medicine. I am a clinical radiologist and I conduct research focused on assessing the risk and benefits of medical imaging.

My testimony today focuses on CT because it is one of the most common imaging tests that we will use for medical diagnosis, and is also the test for the greatest potential for causing harm because of the amount of radiation it uses. CT uses X-rays to obtain extremely detailed images of internal organs, and the development of CT is widely considered among the most important advances of medicine.

In part because it is so useful, the use of CT has increased dramatically over the last 15 years. Last year approximately 75 million CT scans were obtained and approximately 1 person in the U.S. per 10 obtained a CT. Although CT is useful it delivers much higher doses of radiation than do conventional X-rays, and exposure to radiation can cause cancer.

To help put this into context, when you go to the dentist and you are offered dental X-rays, you may pause to consider the benefits as well as potential harms associated with getting X-rays. The most common type of CT scan that patients undergo in the U.S. delivers the same amount of radiation as approximately 1,500 or more dental X-rays.

In other contexts, people have been concerned about the X-rays that are used at airports to screen passengers. One CT delivers the same amount of radiation as approximately 200,000 airport screenings.

My research team at UCSF has conducted several research studies to assess the radiation dose patients receive when they undergo CT and we have found that for every type of CT scan patients undergo, the radiation doses are higher than most physicians are aware, and we have found tremendous variation in the doses between patients in the same facility. For example, one patient may receive a dose of radiation 20 times another, even at the same hospital and for exactly the same clinical problem. Put another way, if a patient goes to a facility to get a CT scan of her abdomen, she has no idea if she will receive a low dose or a high dose. And yet the patient who receives the higher dose study may be at risk 20 times-fold of getting cancer for that examination while receiving no extra benefit from the radiation dose to which she was exposed.

These differences in how much radiation are used for diagnostic CT is not accidental and yet these are not considered errors, but instead, I believe incorrectly, these are considered and labeled the "art of medicine." This sadly is more akin to Russian roulette than personalized health care.

There are clear-cut cases of errors in the use of CT when the technologist delivers a dose vastly higher than intended. And when these kinds of errors are made, patients from diagnostic CT can be

exposed to doses that cause skin burns, hair loss, and severe damage to the tissue. Thousands of such cases have been reported and many of these errors have happened because of errors in how the technologist programmed the scanner. However, even when CT scanning is done correctly, patients who undergo CT—even a single CT—have an increased risk of cancer; and the higher dose of radiation to which they are exposed, the greater their risk. Since many patients who undergo CT undergo multiple scans, their risks are even higher.

An important research paper was published yesterday in the Medical Journal of Atlanta, and that study directly showed that healthy children who were exposed to even a single CT were more likely to develop brain cancer and leukemia. Thus, doses we experience every day as part of routine CT are potentially dangerous.

My research team has studied millions of individuals enrolled in large integrative health-care systems and we have found a large number of patients receive unnecessarily high doses of radiation because of repeated scanning with CT and because some CTs deliver higher doses than needed. Several people are involved when a CT scan is done. Radiologists order the scan and they select the protocol or set of instructions that should be used, but it is the technologist who does the study.

The console of a modern CT scanner looks a lot like the control panel of a fighter plane, and it is not possible for the technologist to simply press a "low dose" button and generate the desired image. Instead, the technologist must make a large number of independent decisions and follow complex instructions on how to program each patient. Yet despite the complexity of the machines and the profound importance of what the technologist does, the technologist who conducts CT examinations receives little education on what doses are excessive, receive no consistent education on how to lower doses they deliver, and there are no consistent standards. In some States technologists receive only minimal on-the-job training.

Further, because there are no uniform design standards, technologists have to scan patients on different machines that all work differently. As part of the research project I am leading to standardize dose, we have organized a large meeting that will be available to all, to be held in February of next year. While the meeting will target physicians, physicists, administrators, referring physicians, the primary focus is to educate and certify radiology technologists on how to understand and monitor and lower the doses to which they are exposed.

There is a second and equally important problem that must be addressed, however, to improve the safety of CT. Radiologists determine how the test should be performed but there are few guidelines on what target doses are desirable. Each radiologist starts from scratch in creating these protocols at their institution. And while the general principle is that doses should be kept as low as reasonably achievable, there are few guidelines about what doses are reasonable or achievable.

In order to improve the safety of CT, we need clear standards for what are acceptable levels of radiation for diagnostic CT. The doses used in clinical practice must be monitored. The National Quality

Forum, a leading organization that develops and endorses measures of health-care quality, has endorsed the measure to focus on CT. And if facilities follow this measure, they will quickly learn what they are doing and where they need to improve.

Lastly, the dose should be reported in every patient's medical record. California recently enacted a law that goes into effect in several months that requires this and provides a template for national legislation. There are a growing number of data monitoring software products that help facilities conduct the kind of dose assessment and monitoring that I have suggested, and ideally these dose-monitoring software products can be used and can be integrated with manufacturers and radiology information systems to help us work together to enable the electronic capture of patient dose information and inclusion of the information in the medical record.

Lastly, oversight of CT is highly fragmented. The FDA oversees the approval of the CT scans but does not have regulatory oversight for how these machines are used in practice. Through MIPPA, CMS has an accreditation process in place that we heard about. Separately CMS' other authorities to encourage the adoption of quality standards, such as those adopted by the National Quality Forum that could facilitate facility assessment, reporting, standardization of the radiation dose used for CT, and CMS should be incorporated to incorporate such quality measures in their systems.

Mr. PITTS. Could you wrap up?

Dr. SMITH-BINDMAN. Given the importance of CT and yet its potential for causing cancer, it is imperative we make CT scanning as safe as possible. These efforts must include education, certification of technologists, the creation of benchmarks, the requirement of recording and monitoring data, as well as a reduction in the necessary exams.

Thank you for allowing me to participate in this discussion.

Mr. PITTS. Thank you.

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

Improving the Safety of Medical Imaging

Testimony of Rebecca Smith-Bindman, MD

Professor of Radiology, Epidemiology and Biostatistics,

Obstetrics, Gynecology and Reproductive Sciences, at the

University of California, San Francisco School of Medicine

Before

The Subcommittee on Health

Committee on Energy and Commerce

United States House of Representatives

Examining The Appropriateness Of Standards For Medical Imaging Technologists

June 8, 2012

Chairman, Ranking Member, and members of the Health Subcommittee, thank you for this opportunity to testify today. I am Dr. Rebecca Smith-Bindman, Professor of Radiology, Epidemiology and Biostatistics, Obstetrics, Gynecology and Reproductive Sciences, at the University of California, San Francisco School of Medicine. I am a clinical radiologist and I conduct research focused on assessing the risks and benefits of medical imaging.

My testimony today focuses on computed tomography (CT) because it is one of the most common imaging tests that we use in medical diagnosis, and it is the test with the greatest potential for causing harm because it uses high doses of radiation to create its images. It is a test where I believe we need more consistent education and certification of the radiology technologists who conduct these studies, and where we need closer oversight in how these examinations are conducted to ensure that when patients undergo these examinations, they receive the lowest dose of radiation possible for diagnosis.

CT uses x-rays to obtain extremely detailed images of internal organs, and the development of CT is widely considered among the most important advances in medicine. It is truly an extraordinary test, allowing the accurate diagnosis of disease, and treatment planning for children and adults. In part because it is so useful, the use of CT has risen dramatically. The number of CTs performed annually has increased by 3 times during the last 15 years. Last year approximately 75 million CT examinations were performed in the United States, approximately 1 in 10 individuals underwent a CT, and among those individuals, they underwent an average of 2 CT examinations.

Although CT is useful, it delivers much higher doses of radiation than 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, you may pause, to consider the benefits and the potential harm associate with getting x-rays. The most common type of CT scan patients undergo in the U.S. is a CT scan of the abdomen, and this delivers approximately the same amount radiation as getting 1,500 dental x-rays. Additionally, newer applications

of CT, such as those used to assess the heart, or to assess blood vessels in the brain, require even higher doses of radiation, as much as 5,000 dental x-ray. In other contexts, some people have worried about the x-rays at our airports to screen passengers. One CT scan is equal to approximately 200,000 airport screens

The Variation in Radiation Dose for Each CT Scan Across Patients and Facilities

My research team at UCSF has conducted several studies to assess the radiation doses patients receive when they undergo CT. We have collected radiation dose information on over 7,000 patients who have undergone CT scanning across a large number of institutions and hospitals across the country. We found that for every type of CT, the radiation doses were far higher than most physicians or physicists are aware. Further we found that the radiation doses vary substantially between different facilities, and that *even within the same facility*, these doses vary dramatically between patients evaluated for the same clinical problem. For example, we found that one patient had 20-times the radiation dose of another patient for a routine head CT or routine abdominal CT when both studies were done at the same institution. This means that two patients at the same hospital, who have the same need, for the same test, are getting very different amounts of radiation, and will have very different risks for subsequent cancer, without any benefit to the person who got more radiation. Put another way, if a patient goes to a facility to get a CT scan of her abdomen, she has no idea if she will receive a low dose or a very high dose, and yet the patient who receives the higher dose scan may be ten times more likely to develop a cancer from that examination, while receiving no extra benefit from the extra radiation to which she was exposed. These differences in how much radiation is used to create the CT image picture are not accidental and currently are not recognized as errors but are labeled, I believe incorrectly, as the *art* of medicine. This sadly is more like Russian roulette than personalized care.

Risks

There are clear-cut cases of errors in the use of CT when the technologist delivers a dose much higher than was intended. *When errors are made* in how CT scans are performed, patients can be exposed to much higher doses of radiation than necessary and these doses can lead to skin burns, hair loss and even more severe damage to the tissue in the area scanned, for example confusion and memory loss if the brain is over radiated. Hundreds to thousands of cases have been reported where patients who underwent CT scans of their brains were exposed to radiation doses that were 100 times higher than intended or needed. Many of these errors happened because of errors in how the technologist programed the scanner.

However, *even when CT scanning is done correctly*, CT scanning is associated with an increased risk of cancer and the higher the dose of radiation that is delivered the greater the risk of cancer. There have been a large number of research studies that have found that people who receive radiation doses in the same range as a *single* CT scan are at increased risk of cancer, and many patients receive multiple CT scans over time- so their risks are even higher. We know from a very large number of research studies that the doses that are used for CT can be harmful. An important research study was published yesterday in the medical journal *the Lancet* that directly showed that healthy children who underwent CT scans of their brains were more likely to develop brain cancer and leukemia following these scans. Thus the doses that we experience every day as part of routine CT scanning are potentially dangerous. The cancers may not develop for 5, 10 or 20 years. But the use of CT today can result in a patient developing a cancer that they would otherwise not have had. This is in direct conflict with the notion that a physician should do no harm. Thus even though we can't see the harms from CT immediately we must take them seriously.

My research team has studied millions of individuals who were enrolled in large integrated health care systems across the United States and we found large number of patients – children and adults alike- received

unnecessarily high doses of radiation because some CT examinations delivered doses that were higher then necessary.

Why The Doses Patients Receive When They Undergo CT Are So Variable: Technologist Training

CT scanners are highly sophisticated machines, and the complexity of these machines has increased over time. While Radiologists order scans and provide the overall direction on what protocol, or set of instructions, should be used, a technologist actually performs the examination. The console of a CT scanner looks very much like the control panel of a fighter plane. It is not possible for a technologist to simply press a button on a CT scanner to generate the desired image, or to generate an image that uses as little dose of radiation as possible. Instead the technologist must make a large number of independent decisions and follow a complex set of instructions on how to program each individual CT scan. Yet despite the complexity of the machines and the profound importance of the decisions they must make –if the technical parameters are not adjusted correctly for the size of the patient or the clinical question that is being asked, the dose the patient receives can be much higher than needed- the technologists who conduct CT examinations receive little education on what doses are excessive, receive no consistent education on how to lower the doses they deliver to their patients, and there are no consistent standards for certification of these technologists. In some states, there is virtually no required training for technologists to learn how to use a CT scan, and they may receive only minimal on-the-job training on how to use these sophisticated, powerful and potentially dangerous machines.

Further, because there are no uniform design standards or naming standards within the machinery itself across the different manufacturers, technologists may have to scan patients on different machines that all work differently. For example, GE has defined a measure known as the noise index, and the *higher the* values in the noise index, the *lower* the dose. Siemens has defined reference mAs –and the *higher* values in the effective mAs, the *higher the* dose. Thus, if a technologist who has a small patient and would like to

reduce the dose the patient receives, they need to turn the noise index *up* on a GE machine, whereas they need to turn the effective mAs *down* on a Siemens machine - seemingly opposite directions to achieve the lower dose. A technologist who is working on a GE machine all morning, but who covers for a colleague on a Siemens machine over lunch, may have no knowledge of how to use the machine on which they now are working. There is surprisingly little education of the technologists in how to obtain the lowest dose images across the different machines.

As part of a research project I am leading to standardize the radiation doses across the University of California Medical Centers - the UC DOSE Project (The University of California Dose Optimization and Standardization Endeavor) - we have organized a large virtual meeting available to all to be held in February of 2013. The meeting is targeted to physicians, technologists, physicists, radiology administrators, referring physicians and trainees, although its primary focus is to educate and certify radiology technologists on how to understand, monitor and lower the doses to which they expose their patients, and how to do so across different manufacturer's platforms. The meeting will include a competency and certification program for technologists as my collaborators and I believe it will help technologists improve their knowledge, their performance, their comfort and satisfaction in conducting CT examinations. We will make this meeting widely available to anyone who is interested in participating, as we believe there is a dire need for this type of education. I believe this type of education and certification should be available and required of every technologist who conducts CT in the US. As part of the same meeting participants can upload samples of their CT examination data to our web site and will receive instant audit feedback on how their doses compare with national benchmarks we create. This is the type of direct assessment and feedback that should be widely adopted to help facilitate understanding how the doses they use compare with benchmarks.

Every patient who undergoes CT should know that the technologist who conducts their examination is knowledgeable and qualified to ensure that their CT examination is not only diagnostic, but that it also minimizes the dose to which they will be exposed. If technologists do not understand the doses they use and

how to minimize them, they can't possibly be expected to provide the safest examination possible. I strongly believe the US Congress should pass the CARE Bill (H.R. 2104, The Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy) as a way to improve the training of those who order and conduct imaging examinations. The training and certification of technologists is an essential first step in ensuring the safety of CT.

Why Are The Doses Patients Receive So Variable: Absence of Standards

While technologist training is extremely important, there is a second and equally important problem that must be addressed to improve the safety of CT, and to ensure patients receive the lowest doses possible when they undergo CT.

Radiologists together with technologists determine how the CT tests are performed. However, there are few national guidelines on how these studies should be conducted or what target doses should be used for most imaging examinations. Thus each radiologist starts from scratch in creating the protocols for scanning at their institution. The general principle is that doses should be as low as reasonably achievable (ALARA), but there are few guidelines regarding what doses are reasonable or achievable, and in the absence of explicit guidelines, dramatic practice variation introduces unnecessary harm from excessive radiation exposure. We have found this variation in even our recent research studies – and this problem of variation is getting worse not better over time, as machines now have greater capacity to perform specialized and often higher dose studies, but are also more difficult to use. Not only is there variation, but many physicians who conduct CT are ill informed of the doses they are delivering to their patient. If a patient asks their physician about the dose they are likely to receive, or have received as part of a prior CT examination, or even asks about the dose that most patients who go to that institution receive when they undergo a chest or abdominal CT, their physician and institution would most likely not be able to provide an answer.

To Improve the Safety of CT We Need To Generate and Adopt Standards

In order to improve the safety of CT we need very clear standards for what are acceptable levels of radiation exposure associated with CT and there should be regulatory oversight for the setting of these standards. These standards would lead to consistency and optimization of CT examination protocols and techniques. There is evidence that for many types of CTs the radiation dose can be reduced 50% or more without reducing quality. Further the dose used in actual patients needs to be collected and monitored.

The National Quality Forum, a leading national organization that develops and endorses measures of quality across all areas of health care, has endorsed a measure focused on the radiation delivered for CT. If facilities began to follow this quality measure, they would quickly learn how they are doing and this would facilitate activities to lower doses where necessary. Facilities should be encouraged to adopt this measure, through quality efforts of the Centers for Medicare and Medicaid Activities.

Lastly, the dose associated with each CT examination should be documented and recorded in each patient's medical record and this information should be tracked over time. Recording and tracking this information would help educate patients and providers about radiation exposure and would lead to activities to minimize dose. It will also lead allow us to ensure the safety of these doses over time through epidemiologic analysis. Further, monitoring patient doses will protect them against unnecessary or repeated scans, or doses that are higher than they need to be. It is only by measuring the doses that they deliver to their patients that clinicians can begin to do everything in their power to keep those doses as low as possible. California has recently enacted legislation that goes into effect on July 2012 (Senate Bill 1237) requiring the dose used for CT exams be recorded in every patient's medical record, and further requires inadvertent CT radiation over-doses to be immediately reported to the State. This will inform patients and referring providers about dose,

and will further encourage facilities to begin assessing and reducing the doses they are delivering to their patients. The California legislation provides a good template for consideration of national legislation.

Oversight

Oversight for CT radiation dosing is currently fragmented. The FDA oversees the approval of the CT scanners, as medical devices, but does not regulate how the tests are used in clinical practice. The FDA recently asked for public comment on a proposal encouraging manufacturers to provide education for radiologists and technologists when using their scanners on children, but have no legislative oversight to demand compliance with guidelines.

Through a provision in MIPPA (The Medicare Improvements for Patients and Providers Act) of 2008 that went into effect on January 1, 2012, the Center for Medicare and Medicaid Services has an accreditation process in place for suppliers that bill Medicare for the technical component of CT and other advanced imaging services. Under this requirement, the Secretary of the Department of Health and Human Services designates accrediting organizations that establish standards for these services. Five areas are covered in the standards the accrediting organizations must have: non-physician medical personnel, medical directors and supervising physicians, safety of equipment, patient and personnel safety, and quality assurance and control. The role of CMS through the implementation of MIPPA includes oversight of organizations that ensure the certification of technologists and physicians who conduct CT. Separately, CMS has other authorities to encourage the adoption of quality standards, such as those adopted by the National Quality Forum, to facilitate facility assessment, reporting and ultimately standardization of the radiation dose used for CT. As of yet, CMS has not incorporated such quality measures into their payment systems, but should be encouraged to do so in the near future. It is time for the adoption of more consistent national oversight to ensure the safety of this important examination.

Manufacturers' Efforts

Manufacturers are developing and marketing devices that can create diagnostic images using considerably lower doses of radiation, although it may take decades for these devices to replace those currently in operation. The manufacturers also have developed innumerable software upgrades that can allow existing machines to generate diagnostic images using much lower doses of radiation. The manufacturers should be encouraged to work closely will all facilities who use their equipment to provide these software upgrades to immediately reduce the doses to which patients are exposed.

Additionally, a large number of dose-monitoring software companies have been created over the last several years. In California, a large number of these companies are marketing their products because of the impending legislation that requires the radiation dose information for each examination be included in the medical record. Ideally, the manufacturers, dose monitoring-software vendors, and radiology decision support and information system providers will begin working together using a shared set of standards that will enable the electronic capture of patient information and dose and transmission of that information to electronic medical systems.

Reduce The Number of CT Scans Performed

Although not the primary focus on my testimony today, an important approach to minimize medical radiation exposure should focus on reducing the number of CT examinations. There is growing awareness that advanced diagnostic imaging, and in particular CT, is over-utilized. The European Commission Office of Radiation Protection and the Canadian Association of Radiologists developed guidelines highlighting where CT imaging should be curtailed including repeating investigations that have already been done; investigations unlikely to affect patient management because a positive finding is irrelevant, such as

assessment and surveillance of incidental findings; investigating too often—before the disease could have progressed or before the results could influence treatment; performing the wrong investigation; and over-investigating. Many CT examinations in the United States almost certainly fall into these categories. Much more explicit discussion and guidelines are needed on how to reduce these unnecessary CT studies. While there are many reasons CT scanning is over utilized, in part this stems from a lack of research and evidence regarding when imaging tests should be used to improve patient health outcomes. It is imperative that we support the creation of evidenced-based guidelines for imaging and this will need to be supported through research funding at organizations such as the National Institutes of Health, the Agency for Health Research and Quality and the Centers for Disease Control and Prevention.

Summary

It has generally been thought that if a patient is sick enough to get a diagnostic CT scan, the benefit of the test out weighs any risk. However, we have started to use CT so often, and in patients who may actually be not very sick, that we need to think about whether the test is really necessary and whether it could cause more harm than benefit. Many physicians and patients are not aware of the risks associated with CT, nor the importance of limiting exposures. Patients need to be educated that CT scanning comes with both risks and benefits, and unnecessary exposure to radiation should be limited. Further, alternative tests need to be used, such as ultrasound, wherever possible, as this test does not use radiation. Given the importance of CT and its potential for causing cancer, it's imperative that we make CT scanning as safe as possible. We need to lower the radiation dose of routine CT and ensure patients receive the minimum dose necessary to produce a medical benefit. These efforts must include education of technologists and creation of clear benchmarks in order to reduce the dose per study, and the variation in dose across patients and facilities; but it must also include efforts to reduce unnecessary studies.

Thank you for allowing me the privilege of contributing to this discussion.

References

Board of Radiation Effects Research Division on Earth and Life Sciences. Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII Phase 2 Washington, D.C. The National Academies Press, 2006.

Caoili EM, Cohan RH, Ellis JH, Dillman J, Schipper MJ, Francis IR. Medical decision making regarding computed tomographic radiation dose and associated risk: the patient's perspective. *Arch Intern Med.* Jun 8 2009;169(11):1069-1071.

Choosing Wisely, a multi year effort by the American Board of Internal Medicine Foundation, to help physicians be better stewards of finite health care resources. Choosing Wisely partners include a large number of medical specialty organizations. http://www.abimfoundation.org/Initiatives/Choosing-Wisely.aspx.

Keegan J, Mehta P, MacGregor K, Smith-Bindman R. The National Quality Forum Patient Safety Measure: Radiation Dose of Computed CT. Abstract submitted for the Radiological Society of North American 2012 Annual meeting.

McCollough C, Branham T, Herlihy V et al, Diagnostic Reference levels from the ACR CT Accreditation Program. Journal of the American College of Radiology. 2011; 8:11

Food and Drug Administration. FDA Makes Interim Recommendations to Address Concern of Excess Radiation Exposure during CT Perfusion Imaging. 2009 http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm193190.htm.

Food and Drug Administration. Draft Guidance for Industry and Food and Drug Administration Staff - Pediatric Information for X-ray Imaging Device Premarket Notifications, May 10, 2012, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm300850.htm

Greess H, Wolf H, Baum U, et al. Dose reduction in computed tomography by attenuation-based on-line modulation of tube current: evaluation of six anatomical regions. *Eur Radiol.* 2000;10(2):391-394.

Griffey RT, Sodickson A. Cumulative radiation exposure and cancer risk estimates in emergency department patients undergoing repeat or multiple CT. *AJR Am J Roentgenol.* Apr 2009;192(4):887-892.

McBride J, Paxton BE, Wandrop RM. CT Scans: Most Doctors Lack Knowledge of Radiation Exposure Risks 2009 American Roentgen Ray Society, Annual Meeting in Boston, MA, April 26-30.

Medicare Payment Advisory Commission. A Data Book: Healthcare Spending and the Medicare Program, June 2007, http://www.medpac.gov/documents/Jun07DataBook_Entire_report.pdf (accessed 15 November 2008).

Mehta P, Smith-Bindman R. Airport full-body screening: What is the risk? Archives of Internal Medicine 2011 ;171:1112-5.

Mettler FA, Jr., Thomadsen BR, Bhargavan M, et al. Medical radiation exposure in the U.S. in 2006: preliminary results. *Health Phys.* Nov 2008;95(5):502-507.

Pearce MS, Salotti JA, Little MP, et al. Radiation Exposure from CT scans in Childhood and Subsequent Risk of Leukaemia and Brain Tumors: A Retrospective Cohort Study. The Lancet early on-line publication, June 7, 2012, http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(12)60815-0/abstract

Semelka RC, Armao DM, Elias J, Picano E. The information imperetive: is it time for an informed consent process explaining the risks of medical radiation? Radiology 262:1: 15-

Smith-Bindman R, Johnson E, Feigelson H, al. e. Utilization of Diagnostic Imaging in the HMO Research Network: Modality and Organ System Trends 1994-2008. *Abstract to be presented at the The 16th Annual HMO Research Network Conference "Emerging Frontiers in Healthcare Research and Delivery" March 21–24, 2010, Austin, Texas.* Vol 2010.

Smith-Bindman R, Miglioretti DL, Larson EB. Rising use of diagnostic medical imaging in a large integrated health system. *Health Aff (Millwood).* Nov-Dec 2008;27(6):1491-1502.

Smith-Bindman R, Lipson J, Marcus R, et al. Radiation dose associated with common computed tomography examinations and the associated lifetime attributable risk of cancer. *Arch Intern Med.* Dec 14 2009;169(22):2078-2086.

Smith-Bindman R, Miglioretti D, Johnson E, et al. Use of Diagnostic Imaging Studies and Associated Radiation Exposure for Patients Enrolled in Large Integrated Health Care Systems, 1996-2010. Journal

of the American Medical System (JAMA) In press, will be published June 13, 2012 Vol 302, 22, p2400-2409

Sodickson A, Baeyens PF, Andriole KP, et al. Recurrent CT, cumulative radiation exposure, and associated radiation-induced cancer risks from CT of adults. *Radiology.* Apr 2009; 251(1):175-184.

Symposium on Radiation Safety and Computed Tomography, February 26-28, 2013, organized by the Radiology Outcomes Research Laboratory (RORL) of The University of California San Francisco, and the University of California CT DOSE Project. http://rorl.ucsf.edu/Symposium.html

Twombly R. Full-body CT screening: preventing or producing cancer? *J Natl Cancer Inst.* Nov 17 2004;96(22):1650-1651.

Mr. PITTS. Dr. Martino, you are recognized for 5 minutes for your summary.

STATEMENT OF SAL MARTINO

Mr. MARTINO. Chairman Pitts and members of the subcommittee, my name is Sal Martino and I am the chief executive officer of the American Society of Radiologic Technologists. I am also a registered radiologic technologist myself. On behalf of ASRT's 146,000 members, thank you for calling this hearing to examine why we must establish standards for medical imaging and radiation therapy technologists.

These individuals perform procedures that are critical to accurately diagnosing and treating millions of Americans each year, from the X-ray that monitors the lungs of a premature infant to the radiation therapy that extends the life of a grandmother fighting cancer. Because these procedures expose patients to powerful doses of radiation, most of us assume that everyone who performs them is competent and educated. But the truth is, unqualified personnel examine and treat thousands of patients every day. That is because Washington, DC, and 11 States do not regulate radiographers, 15 States do not regulate radiation therapists, and 20 States do not regulate nuclear medicine technologists.

In States without regulations, people are allowed to expose patients to potentially dangerous levels of radiation after just a few weeks of on-the-job training. And even in States where personnel are regulated, laws vary widely.

Unqualified personnel represent a serious health risk to the American public. Fortunately, a solution is within reach. The Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy bill, known as the CARE bill, asks the Federal Government to establish standards for technical personnel in the radiologic sciences.

Under the CARE bill, anyone who performs medical imaging or delivers radiation therapy would be required to graduate from a formal educational program in the field. They also would have to pass a national certification exam that tests their understanding of radiation protection and patient care techniques. And finally, they would be required to obtain continuing education throughout their careers, ensuring that they remain proficient.

Many of you are familiar with the CARE bill. It was first introduced in the 106th session of Congress in 2000 and it has been introduced in every session since then. In 2006, the Senate passed the bill by unanimous consent, but the session ended before the House could take action.

The current version of the CARE bill, H.R. 2104, has more than 120 bipartisan cosponsors in the House of Representatives. It also has the support of dozens of health-care and patient advocacy organizations that represent millions of Americans.

Together we support the CARE bill for three important reasons: First, the CARE bill will improve quality. The accuracy of any radiologic procedure depends on the skill of the person performing it. An X-ray won't reveal a broken bone and a CT won't find a growing tumor if the person using the equipment doesn't know the basics of anatomy, exposure, and technique. Accurate exams lead

to diagnosis, treatment, and cure. Poor-quality exams lead to additional testing, delays in treatment, and unnecessary anxiety for patients. Even worse, they may cause a misdiagnosis that has tragic consequences. Radiologic technologists must be properly educated to perform their work accurately.

Second, the CARE bill will improve safety. Medical radiation comes with risks. Overexposure can cause skin burns, lead to the development of cancer, and cause birth defects in future generations. CT scanners, gamma cameras, and linear accelerators are some of the most complex technology in the medical field, and patients could be injured or even killed if this equipment is not used properly. Educated technologists know how to properly administer radiation, position patients, and shield organs to deliver the lowest possible dose.

And third, the CARE bill will reduce health-care costs. More than 300 million medical imaging procedures are performed in the United States every year. Unfortunately, thousands of these exams have to be repeated every day because unqualified personnel made positioning or exposure errors. The Federal Government pays for many of those mistakes. Medicare spent approximately $11.8 billion on medical imaging in 2009. If we can reduce the number of repeated exams by just 1 percent, Medicare would save more than $100 million a year.

In an era when difficult budget decisions must be made, the CARE bill makes good fiscal sense. The best way to ensure the quality, improve the safety, and reduce the cost of radiologic procedures is to establish standards for personnel who perform them. For the past 12 years, that has been the straightforward goal of the CARE bill. It is time to pass this important piece of legislation. Your support for the CARE bill shows your support for America's patients. Thank you.

[The prepared statement of Mr. Martino follows:]

Examining the Appropriateness of Standards For Medical Imaging and Radiation Therapy Technologists

Testimony in Support of the Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy Bill (H.R. 2104)

Submitted to the House Energy and Commerce Committee, Subcommittee on Health
June 8, 2012

SUMMARY OF REMARKS BY SAL MARTINO, CHIEF EXECUTIVE OFFICER, AMERICAN SOCIETY OF RADIOLOGIC TECHNOLOGISTS

The Consistency, Accuracy, Responsibility and Excellence (CARE) in Medical Imaging and Radiation Therapy bill asks the federal government to establish standards for technical personnel in the radiologic sciences. Under the CARE bill, individuals who perform medical imaging exams or plan or deliver radiation therapy treatments would be required to graduate from a formal educational program in the field, pass a national certification exam, and obtain continuing education throughout their careers.

- The CARE bill will **improve quality** by ensuring that individuals are properly educated to perform their work accurately.The accuracy of any radiologic procedure depends on the skill of the person performing it.
- The CARE bill will **improve safety** by ensuring that radiologic procedures are performed by personnel who know how to properly administer radiation, position patients and shield organs to deliver the lowest dose radiation possible.
- The CARE bill will **reduce health care costs** by lowering the number of procedures that must be repeated because unqualified personnel made positioning or exposure errors. Reducing the number of repeated exams by just 1 percent will result in Medicare savings of more than $100 million a year.

The best way to ensure the quality, improve the safety and reduce the costs of radiologic procedures is to establish standards for personnel who perform them. That is the goal of the CARE bill, H.R. 2104.

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The best way to ensure the quality, improve the safety and reduce the costs of radiologic procedures is to establish standards for personnel who perform them. For the past 12 years, that has been the straightforward goal of the CARE bill. It is time to pass this important piece of legislation.

Your support for the CARE bill shows your support for America's patients.

Thank you.

Mr. PITTS. The Chair thanks the gentleman and thanks all the panel for your testimony. We will now begin questioning. The Chair recognizes himself for 5 minutes for that purpose.

Mr. Spiegel, we will begin with you. Can you tell us why MIPPA does not include imaging services that are done in the hospital setting? It seems to me that patients in the hospital would be at the same risk of harm as any other patient if these services are performed by personnel that are not adequately trained.

Mr. SPIEGEL. I wasn't employed at CMS at the time the bill was enacted, but the provisions of the statute don't address advanced diagnostic imaging in a hospital setting. We implemented the provisions that were enacted in the MIPPA statute.

Mr. PITTS. Would it be appropriate to address this issue by an expansion of MIPPA?

Mr. SPIEGEL. I am really not in a position to say whether or not hospital radiology needs to be addressed apart from MIPPA or some other way. I know CMS has in place hospital conditions or participation that address requirements for imaging in a hospital setting and we enforce them.

Mr. PITTS. Dr. Smith-Bindman, an individual patient in discussion with their doctor may be willing to be exposed to increased risk for radiation exposure in order to diagnose or treat their cancer. Do you think that if we err on the side of overregulation by, for example, instituting rigid guidelines that we run the risk of inhibiting patients' care and possibly exposing providers of these services to liability?

Ms. SMITH-BINDMAN. I think that you mentioned two things. I think, first, we need to have those discussions between patients and providers that acknowledge there are risks and benefits of medical imaging. So first those discussions have to happen.

Second, if we can encourage facilities to start to look at the doses that they use, they can lower those doses, literally overnight. And so part of what I am encouraging is both looking at doses and then not imposing rigid standards on how to lower, them but just requiring facilities look at how they are doing. And just looking at how they are doing, I have had experience at a large number of facilities, has led to an overnight reduction in doses for patients who get very high doses.

Mr. PITTS. Dr. Martino, or any of you, what question should patients ask the technologist or the radiologist before getting an imaging exam? And what questions should they ask the referring physician before going forward with an exam?

Mr. MARTINO. Well, the first question they would ask—and if I took my granddaughter in for an X-ray, the first question I would ask is, are you a certified radiologic technologist? And if they were not, I would not let them take my X-ray or that of my granddaughter. So that is the number one fundamental question for me.

Ms. SMITH-BINDMAN. I think going back a step, anytime advanced imaging is ordered, a patient should ask their physician if it is absolutely necessary. Do I need this test? Do I need this test now? Or can I wait to have this test? Can I have another test that may help? Or if I do need this test, is it possible to have a test that does not use ionizing radiation?

And now we are so enamored with testing that often patients begin that discussion wanting the test, without appreciating that there are choices to be made and that there are both risks and benefits.

So first I decide, do I actually need to go forward? And then if they go forward, I think the more patients that ask their physicians and their technologist, can you tell me what kind of radiation dose I am going to be getting from this test will really encourage the technologists and providers to look at their own data so they can provide really informed information.

Mr. PITTS. Thank you. Dr. Gunderson, could you tell us why this is an issue that needs legislation rather than something that could come from within the medical societies or State level boards?

Dr. GUNDERSON. Radiation oncology societies can certainly make recommendations to individuals as far as whether certification should exist. And we certainly do do this. But that does not require our members to listen to what we say and to carry it out.

So I think there is an absolute need to have the CARE Act passed so that it does put in place minimum standards. I think of this as a foundation for building further with regard to safety issues as putting in place the minimum standards that are required by the CARE Act which societies can encourage but certainly cannot enforce in any way.

Mr. PITTS. I just have 10 seconds. Dr. Martino, is there any benefit to State flexibility with regard to technician licensing? I assume that the availability of accredited schools varies. Might States with many health professional shortage areas lose out if unlicensed technicians can no longer practice?

Mr. MARTINO. No. There are more than adequate radiologic technology programs throughout the country. Even in rural areas. And the CARE bill also does have provisions to phase in and allow those individuals to get the additional education that they would need to become certified.

Mr. PITTS. My time has expired. The Chair recognizes the ranking member for 5 minutes for questions.

Mr. PALLONE. Thank you, Mr. Chairman. I was going to start with Dr. Gunderson.

In your testimony you describe differences between diagnostic imaging and radiation therapy. And I wondered if you would elaborate on those differences and tell us more about the varying safety considerations and how might the education and training of radiation therapists differ.

Dr. GUNDERSON. With regard to the marked differences between diagnostic radiology and radiation oncology, as I mentioned, diagnostic radiology uses much lower doses of radiation, primarily for imaging purposes to determine if problems exist, and they are exceedingly helpful to a radiation oncologist with CT imaging or an MRI to say, here is where the cancer is and here is where we need to focus upon.

In radiation oncology we use much higher dose levels of the radiation, but dose alone is not the thing that one needs to think about. We use much higher doses, where if we are treating with radiation alone, we are going to be delivering often a series of 30 to 40 treatments over a time period of 7 to 8 weeks, treating 5 days a week.

And dose alone is—total dose becomes important, what the dose per fraction is, and whether we are using it with curative intent or intent to try to totally kill the cancer versus with palliative intent.

What are we doing with regard to patient safety issues? We are very delighted with the provisions that were put into the Patient Safety Act in the mid-2000s with regard to the ability to collect information on medical errors or near misses without there being legal ramifications. We have, in fact, begun a process of contracting with an existing patient safety organization to launch the first radiation oncology error reporting system.

As I noted, we believe the confidentiality provisions provided by the Patient Safety Act are going to ensure that accurate data is submitted and will also mean better participation from radiation oncologists throughout the United States. We think that contracting with a PSO will allow us to meet our goal of collecting radiation oncology patient safety data, analyzing it to improve the safety of radiation oncology, being able to do root-cause analyses, and pass that information along to our membership in appropriate ways so that they can learn from it and apply those things in their own practices. And we expect the patient safety organization to be functioning by the end of 2012.

Also in our written testimony we talked about things that we have done starting—and expanding on in 2010. Patient safety has always been an important issue in radiation oncology. But with the 2010 incidents, we did a 360 look. We put forward the "Target Safely" plan which is discussed in some detail in pages 6 to 8 of the written testimony with regard to working with industry to have standardization of talking across different systems from different providers. We call it the IHE–RO program where if we buy one thing from one provider of equipment versus another, that they will talk to one another and that there won't be errors in that. We are interested in practice accreditation. We have written a series of white papers.

So there are a number of things that we are doing that are outlined in there. And we feel strongly and we will continue to discuss these with our members and to work carefully with this committee and Congress in trying to improve patient safety.

Mr. PALLONE. Well, thank you, Doctor. I appreciate that.

I wanted to ask Dr. Smith-Bindman, you testified that credentialing of the personnel who position patients and administer radiation consistent with the goals of the CARE Act is an essential first step in improving the safety and quality of CARE. That is correct?

Ms. SMITH-BINDMAN. Yes.

Mr. PALLONE. OK. You also mentioned the importance of other strategies to improve safety and quality, such as the development and adoption of additional clinical guidelines, capture of info on the doses that patients receive, and documentation of dose information in the patient's medical records.

I want to focus on the tracking and documenting of the radiation dose a patient receives and the quality measure you mentioned. Can you explain why you believe that the adoption of the National Quality Forum-endorsed CT quality measures in clinical practice or

one with similar goals would improve the safety and quality of CARE?

Ms. SMITH-BINDMAN. I think radiologists really want to do the best job that they can. And most radiologists understand that that means lowering the doses, keep them within a very narrow range. But unfortunately, most radiologists currently have no idea of the doses to which their patients are exposed. So if a patient goes to a facility and says, Doctor, can you tell me how much radiation I got on that exam or how much am I likely to get, or what kind of doses do you usually give your patients who undergo abdominal—an abdominal CT, most physicians and most facilities would have no way to answer that question.

So by adopting the quality measure, facilities are asked to summarize the doses they are using. What is the average dose for an abdominal CT? And that would quickly allow facilities to see how they are doing.

And as I mentioned, I have worked with a large number of facilities. And for each of those, the first step of us showing them their data has been surprise that the doses have been so high. And the second step has been to figure out how to lower them. And it is not so difficult to lower them once you figure out the problem. So if patients in general are being imaged for a larger area, well, then you image a smaller area. If patients undergo four scans of their chest and that leads to higher doses, well maybe you want to reduce that to one. So I think it is a way to just allow facilities to see how they are doing, to start having standard metrics so all facilities start using the same words to describe dose and use the same standards against which they are assessing their quality and performance.

Mr. PALLONE. Thanks a lot. Thank you, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman.

We are in a series of votes that are going to last past the noon hour. We will take one more line of questioning from the vice chairman, Dr. Burgess, for 5 minutes before we break.

Mr. BURGESS. My question is: Why do we have so many votes that are going to take us past the noon hour, Mr. Chairman? Who thought that was a good idea?

Well, Dr. Spiegel, I just have to tell you, you struck a chord with me with your discussion, perhaps not entirely in the confines of what we are considering on the committee today. But I practiced OB/GYN for 25 years back in Texas and I recognize that, just like you, you recommend the test or a procedure to a patient, and the next question is generally not is it safe, is it necessary? We wouldn't even get down to the detail of how much radiation to which I would be exposed. But it is, Does my insurance cover it? And if my insurance covers it, suddenly the curiosity drops right off.

And perhaps one of the failings of the third-party payment system that we have developed and why I believe so much in a consumer-directed health care and health savings account is that you have to get the patient back into this equation. And the money is one way to do it. And as a consequence of the patient being in charge of the money, perhaps even the questions about the radiation safety or the dosage might be something that is introduced back into the conversation.

So I appreciate very much your observation on that. And I will just tell you, I am sure it is happening hundreds of times this very morning, where a radiological procedure is being recommended. And the patient is anesthetized and the doctor also may be anesthetized as well, except in our specialty, in OB/GYN, when a pregnant woman inadvertently gets an IVP, then suddenly everybody is concerned about what the dose of radiation was that was involved in that study. And then we go into great detail to try to figure it out.

Do you have any other observations on that? Because that was a particularly powerful statement that you made.

Ms. SMITH-BINDMAN. I mean, in addition to being an academic, I am a parent who has three children. And I have been in many circumstances where imaging with radiation is advised to my children. And in those circumstances, I want to know the risks and benefits to my child of that exam. And I try very hard to go in not as a radiologist but to go in as a mom. When my youngest fell out of a tree and had a CT scan, that seemed like the right thing to do. He did a head-dive out of a cherry tree.

Mr. BURGESS. That was your son, correct? Not your daughter?

Ms. SMITH-BINDMAN. That was my son. Only the CTs of the head are my son's.

But last year, he had a very small fall, skiing; and I couldn't get ahold of my husband and I took him to the emergency department. And the emergency department physician told me later that from across the room he could see that my son had a concussion, but knew for sure he didn't have a bleed. And I went in very open. If he needs a CT, he needs it. If not, I am not going to influence his decision. And the ED doctor said, if you want a CT, I am happy to do it, but I don't think he needs it. So I was very happy with that decision.

And partly what I do when I educate technologists and radiologists is to think of every patient as if it is your own family member and use all the information to decide whether it is necessary: the value of the test, the effectiveness, the risks. And then I agree with you, I think the payment piece has disappeared from our consideration, but it is a very important issue.

DMr. BURGESS. Thank you.

Dr. Martino, I need to ask you—again, this is a bit off topic, too. But the dosage of radiation that we get when we walk through that TSA scanner at the airport, is that a significant source of radiation for people?

Mr. MARTINO. All radiation is not good, but we have it in the environment and wherever. I believe that those are low enough that I don't worry about that.

Mr. BURGESS. Bear in mind that you are talking to a panel of frequent flyers here. Anyone who lives west of the Mississippi is probably higher on the dosage chart.

Mr. MARTINO. Myself also. But it is so low down compared to what medical radiation is in terms of the individuals that are giving those doses to patients.

Mr. BURGESS. Well, I will tell you why I was concerned about this. Several years ago in the transportation bill, I tried to get language in addressing the radiation exposure to flight crews. You

know, the solar activity varies from time to time. And this is information that is available but not generally dispensed to the airlines, such that they might select a different flight route or altitude because of solar activity and solar radiation that might be emanating that day.

So you are right. We have got it in our environment all the time. And as a consequence, any is possibly dangerous, so why wouldn't we do the things necessary to minimize that? I was a little taken aback when we developed these back-scatter imaging devices, you know, to catch the bad folks. But at the same time you are putting a lot of innocents through this device. And for those of us up on the dais here, that is twice a week, 35 weeks a year.

Mr. MARTINO. Myself included. I would add though, I think anyone who has anything to do with any kind of equipment that dispenses radiation, even the low doses, say, in an airport scanner, should have some kind of minimum knowledge and understanding about what it is they are operating. And if there was an error—I mean, it could be a simple hour course for the TSA scanners, that they understand.

Mr. BURGESS. Are they certified in any way as far as radiation understanding?

Mr. MARTINO. No, not that I am aware of.

Mr. BURGESS. Did the FDA get involved in this? Because they can be pretty tough on medical devices.

Mr. MARTINO. I deal with the certification of those individuals that are dispensing radiation for medical purposes.

Mr. BURGESS. Thank you, Chairman. I will yield back. Thank you.

Mr. PITTS. The Chair thanks the gentleman. We are in the middle of a series of votes. There are about 5 minutes left on the first vote. We will recess until about 5 minutes after the last vote, which will be around 12:15, I am told. So we ask for your patience. At this time, the subcommittee stands in recess.

[Recess.]

Mr. PITTS. The time for recess having expired, we will reconvene, and we have finished the first round of questioning. We will go to follow-up with Dr. Burgess for 5 minutes for questions.

Mr. BURGESS. Thank you, Mr. Chairman. Dr. Gunderson and Dr. Martino, if I could ask you, do you think if we put in place a Federal minimum standard for accreditation for technologists that it will restrict entry into that field and we are going to end up with difficulty filling those positions?

Dr. Gunderson, if you will go first, and Dr. Martino.

Mr. GUNDERSON. At the present time, the main issue I think with certification programs and training programs for radiation therapy technologists is the fact that we may not currently have enough training programs that exist out in the real world, and part of that is because some of the programs have contracted instead of expanded.

And when I moved from Mayo Clinic in Rochester, Minnesota, down to Mayo Clinic in Arizona, we were surprised to find that there were no training programs for radiation therapists in Arizona, and so we actually worked together with the radiation oncology practices in Arizona and with the community college and actu-

ally set up a program which actually required the institutions putting in some financial support because the community college wasn't willing to take that on themselves upfront. And so we felt strongly enough about the need for a training program with radiation oncology technologists that we convinced our colleagues in what ended up being competing institutions to say the need exists, let's work together and make sure this happens. And that program has stayed as a continuous program ever since that time, so that will be one of the issues, just making sure there are——

Mr. BURGESS. Just to be sure, did those programs result in certification of those students who completed the requirements?

Mr. GUNDERSON. They did. They would have progressed through the training and gone to certification. But it is an issue, and that is why once the CARE Act is passed, we will have to be careful to phase in some of these things so that if there aren't programs that exist in certain States, that one has time to put those programs into place and allow them to function. In my mind it will not prevent people from going into the field, because it is a very attractive field, and we have not had any problem at all filling the positions in the school that we created in Arizona, for example.

Mr. BURGESS. Very well. Dr. Martino, you may have actually answered that before we went to break, but your thoughts on that?

Mr. MARTINO. ASRT has a significant research department, and we do a lot of research and publish research. Every year we do an enrollment survey to see what the enrollment in the educational programs are throughout the country, both in medical imaging and radiation therapy. Right now, in fact, there is a bit of an oversupply of medical imaging technologists, and students have waiting lists in most community colleges and are——

Mr. BURGESS. If I could interrupt you for just a minute. What about the geographic distribution, though; are there areas in the country where it would be more of a challenge to fill those positions?

Mr. MARTINO. Not right now. Yes, of course, you have, you know, more programs in some of the urban areas, but even in the rural and suburban areas, community colleges are very interested in these kinds of programs because they lead to employment when students get out of school. They have also now raised the requirements; starting in 2016, you are going to need an associate's degree to enter the field. So many community college programs are now opening. So we don't really expect there to be that much of a shortage in radiography.

Radiation therapy, right now there is only a 4–1/2 percent vacancy rate in radiation therapist positions. Dr. Gunderson is right, it is somewhat regional. There are a couple of States that don't have radiation therapy programs, but there are a couple of radiation therapy programs coming online. But our—both our workplace surveys and our enrollment surveys show that there is more than enough of supply right now to meet demand and that many of the programs, like nursing programs, have waiting lists to get in because students are realizing that they want to go to college and get a job when they get out, and health care is a really expanding area. And in any places where there might be a problem, there

is a phase-in period for the CARE bill, so there should be enough time for supply to meet demand.

Mr. BURGESS. Very well. You know, remembering the passage of MIPPA in the summer of 2008, it was July of 2008, and we have had another hearing in this committee on this issue back in 2010, and I think Chairman Pallone led that hearing, and we are very grateful to him for doing that, but I am hard pressed to recall a hearing on this subject prior to the passage of MIPPA.

I have only been on the committee since 2004, so staff may correct me that there have in fact been other hearings, but it is a fairly significant and fairly complex issue, and when MIPPA passed, for those of you familiar with the Doc Fix, this was the passage of the Doc Fix. It came up on suspension rather rapidly one summer morning, and nobody ever wants to vote against the Doc Fix, myself included, because the docs always get mad if you do.

But there were all these other ancillary policies that were then cobbled together and thrown on this so-called MIPPA bill, and I think it is just a cautionary tale for us here on this side of the hearing room that we must be careful when we take these things on, because they do have far-reaching, real-world consequences that affect people in very profound ways, both positively and negatively. And I wish we had taken the time to study this issue a little bit more before the leadership at that time put it onto that bill that came up rather hastily on the House floor in order to make a political statement and cause a stir in the then-Presidential campaign in 2008.

Mr. Chairman, thank you for the indulgence, and I will yield back.

Mr. PITTS. The Chair thanks the gentleman. For follow-up for 5 minutes, the ranking member, Mr. Pallone.

Mr. PALLONE. Thank you. I just have a brief question because I didn't get to ask it before of Dr. Gunderson. It was clear from your testimony that you believe credentialing for technologists will do a great deal to improve patient safety. But can you elaborate on why ASTRO believes that additional patient quality and safety activities are an important complement to the goals of the CARE Act?

Mr. GUNDERSON. Rephrase your question?

Mr. PALLONE. Sure. You said that you believe—or at least I thought from your testimony—you believe that credentialing for technologists would do a lot to improve patient safety. So I just wanted you to tell me why you believe that, you know, that that is true, why additional quality and safety activities are important to the goal of, you know, the CARE Act, which is the bill that——

Mr. GUNDERSON. We believe it is important for the three components of the treatment team beyond the physician—the medical physicist, the medical dosimetrist, as well as the therapist/technologist. And if you think of a machine with gears that mesh together, if we have two members of that treatment team that have education and training but the third person doesn't, then things can fall out of phase and things won't work as smoothly as they need to work.

So while the plans that we put in place for radiation therapy are a combination of interactions between the radiation oncologist and the dosimetrist where the radiation oncologist uses a CAT scan or

MRA to see here is where the cancer is, here is where the lymph node areas are that are at risk, and we contour that, and we also help contour the normal tissues and the healthy tissues that we want to spare. That information then is put into place by hopefully a trained dosimetrist who can integrate that and say, "OK, I am going to put my radiation beams in through all of these angles and put them in place so we can encompass the tumor and protect the normal tissues."

That information is then passed on to the therapist on the treatment machine, and as Representative Burgess I think talked about previously, if you have somebody that doesn't have the training to make sure that the machine is turned on properly, to make sure the patient is positioned properly, then all of the work done by the radiation oncologist and dosimetrist comes to naught. So this is why we feel there needs to be minimum standards for all components.

The physicist is the one that supervises the whole—if you want to call it—the safety team beyond the M.D. To make sure everything is running properly, and so he is at the top of that safety chain from the treatment team perspective along with the radiation oncologist. But if the dosimetrist and therapist don't understand what they are doing, then what we envision happening with our—with the safety and care of our patients isn't going to come to pass. And that is why we support the CARE Act for all three components, the physicist, the dosimetrist, and the therapist having adequate training and adequate certification, and why we strongly support the CARE Act.

Mr. PALLONE. All right, thanks a lot, and thank you, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman. I will remind all members of the subcommittee who were unable to attend or return to the hearing that they may submit their questions in writing. They have 10 business days to submit questions for the record.

I ask the witnesses to respond to their questions promptly, and I would like to thank the excellent panel we had today for the information they have shared with us. Members should, by the way, submit their questions by the close of business on Friday, June 22nd. Without objection, the subcommittee is adjourned.

[Whereupon, at 12:30 p.m., the subcommittee was adjourned.]

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