ASTRO

TARGETING CANCER CARE

Statement of
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On Behalf of the American Society for Radiation Oncology (ASTRO)
Before the Health Subcommittee of the
House Energy and Commerce Committee
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Chairman Pallone, Ranking Member Deal, and members of this distinguished committee, good morning and thank you for the opportunity to testify at today's hearing, "Medical Radiation: An Overview of the Issues." 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 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. All patients deserve to feel reassured about their treatment's safety; cancer patients have enough to worry about.

While, I am not personally involved in any of the tragic situations described by the *New York Times* I do want to offer my sympathies to those families and especially to the parents of the courageous Scott Jerome-Parks, who are here today and shared his story. According to the *New York Times* article of January 24th it was his wish that this tragedy be used to make sure no one else goes through what he did. We agree. No medical error is acceptable. 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.

I am the Medical Director of the Department of Radiation Oncology at the Eugene M. and Christine E. Lynn Cancer Institute at Boca Raton Community Hospital, where I've practiced as a board certified radiation oncologist since 1989. We treat about 1,300 patients per year and I have treated more than 6,500 patients in the past 20 years. My medical education was at the Medical College of Georgia, and my residency was at Shands Hospital at the University of Florida. Before moving to the Lynn Cancer Institute, I was an Assistant Professor at the Bowman Gray School of Medicine of Wake Forest University. I serve as the Chairman of the Board of Directors of the American Society for Radiation Oncology (ASTRO), which I am representing today. I have also served as President of the American Registry of Radiologic Technology, President of the Florida Radiological Society, and Councilor to the American College of Radiology from Florida. Additionally, I am the Medical Director of the radiation therapy technology training program for Broward Community College, and a member of the Advisory Committee for Radiation Protection for the State of Florida Department of Health.

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. Advances in radiation oncology have contributed to saving lives. 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

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has increased to 98% 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, and pancreatic cancer where the five-year survival rate remains below 50%.

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. We have been a leader in efforts to improve patient safety within our specialty, and protecting our patients from radiation mistakes requires constant vigilance. While ASTRO is alarmed and concerned by the errors described in recent press reports, we do not believe nor is there evidence to support that there are widespread radiation errors leading to patient harm across the country. However, recent reports do highlight to us that there is more work to do to protect our patients. Any error, no matter how small, must be reported, understood and utilized as a tool to further reduce the potential for future errors. Failing to report known errors is unacceptable.

ASTRO's Board of Directors has committed to redouble our efforts with respect to quality and safety so that patients can be reassured about their care. A systemic, 360-degree review of our ongoing patient safety and quality assurance projects was conducted and an action plan emerged, consolidating all of our efforts into a unified six point plan to:

1) Work closely with relevant regulatory authorities to create a national database for the reporting of linear accelerator medical errors.
2) Significantly enhance the radiation oncology practice accreditation program, and develop additional accreditation modules specifically addressing new technologies, such as Intensity Modulated Radiation Therapy (IMRT), Stereotactic Body Radiation Therapy (SBRT), as well as other radiation treatments.
3) Expand our educational training programs to include an intensive focus on quality assurance and safety.
4) Work with cancer support organizations to develop tools for cancer patients and their families for use in their discussions with their physicians to help them understand the quality and safety programs at the sites where they are being treated.
5) Accelerate an ASTRO-led effort, called Integrating the Healthcare Enterprise – Radiation Oncology (IHE-RO). IHE-RO works to ensure that radiation therapy technologies from different device manufacturers can transfer treatment information seamlessly to reduce the chance of a medical error.
6) Advocate for new and expanded federal initiatives to help protect patients from radiation errors, including support for immediate passage of the Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy ("CARE") Act to require national standards for radiation therapy treatment team members; additional resources for the National Institutes of Health's investments in this area; and federal examination of the impact of physician self-referral arrangements on the quality of radiation therapy treatments in those clinics.

ASTRO has been developing and refining many of these programs for years, and they have been making a huge difference in the quality of cancer treatment. Now, we are redoubling our

efforts to ensure that patients receive the safest possible care. We welcome the opportunity to work with this Committee and other stakeholders to gather data and learn about where additional improvements can be made. For instance, we are working with patient support organizations to develop a toolkit for cancer patients and caregivers for use in their discussions with their radiation oncologist to help them understand their quality and safety protocols. This toolkit will include a series of questions to ask their treatment team, such as, "Do you have daily safety checks?" and "What kinds of safeguards do you have to make sure I'm given the right treatment?" It is important to have empowered patients who actively engage in their care.

My hope is that patients across the country will recognize these incidents for what they are – isolated acts– and that these reports will not dissuade patients who need radiation therapy from receiving needed treatments. It's hard enough to face a cancer diagnosis, and we are concerned that patients may be frightened into not receiving life saving treatments.

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. Radiation oncologists, radiation oncology nurses, medical physicists, radiation technologists, dosimetrists and biologists comprise ASTRO's more than 10,000 members, making it the largest radiation oncology organization in the world. These medical professionals, found at hospitals and cancer treatment centers around the globe, make up the radiation therapy treatment teams that are critical in the fight against cancer.

Radiation therapy is a treatment to safely and effectively treat cancer and other diseases. Doctors use radiation therapy to eradicate cancer, to control the growth of the cancer 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.

Radiation therapy works by damaging the DNA in cancer cells so that they cannot repair or reproduce. New technology and improved techniques allow radiation oncologists to better target radiation to eliminate cancer cells while 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, including caring treatment teams of clinical nurses, physicists and technologists, use sophisticated equipment to provide patients with safe, effective care. Radiation oncologists discuss and agree upon treatment options with their patients and their families and plan and deliver that care in conjunction with the patient's other physicians, as well as 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.

Training Requirements
Radiation oncologists complete four years of medical school followed by five years of post-graduate training 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. As you know, 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 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 23 SAMs on a wide range of topics including radiation cancer and biology, thoracic malignancies, gynecologic malignancies, central nervous system tumors, and genitourinary cancers.

ASTRO recently launched a new quality and safety focused self-assessment module on best practices to improve clinical care in radiation oncology. This online education tool provides best practice guidelines for dosimetrists, physicists, therapists, physicians, and nurses. The new module emphasizes the use of peer review, including an analysis of treatment steps that may be prone to human error, documentation of "near misses," development of departmental checklists to catch errors, and engaging the entire radiation oncology treatment team to openly discuss 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 strongly encourages that all radiation oncologists participate in maintenance of certification and ongoing quality improvement activities.**

In March, ASTRO's journal, which is the leading radiation oncology professional journal, will have a supplement dedicated to practical guidance about recommended radiation dose for 16 organs/disease sites. These articles represent a comprehensive review of the literature and are product of more than 60 physicians and physicists from ASTRO and the AAPM working together. This effort was prompted by a desire to consolidate information about how different radiation doses affect healthy tissue and to identify future research that would help radiation oncologists reduce side effects for patients.

ASTRO also has led the field in educating radiation oncology team members in advanced technologies and techniques. Specifically, ASTRO began sponsoring a hands-on meeting for radiation oncologists, radiation therapists, physicists and dosimetrists focusing on the treatment team's approach to safe use of IMRT in 2002. We launched another meeting in 2006 focused on the safe use of image-guided radiation therapy (IGRT). Through these programs, ASTRO has educated thousands of professionals about the clinical applications and safe use of these technologies. This year, we have combined the IMRT and IGRT meetings to also include SBRT into a single symposium. These courses provide entire treatment teams with hands on training on the latest technologies. In addition, ASTRO's Annual Scientific Meeting attracts 12,000 medical professionals from around the world who discuss the latest breakthroughs in cancer treatments.

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 to best target them for radiation therapy. 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 world 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.

High quality radiation therapy requires not only highly skilled and well trained physicians, but also medical physicists, dosimetrists, and technologists. **We applaud the leadership of Rep. Barrow, along with seven Members of the Energy and Commerce Committee, for supporting the CARE Act (HR 3652) to require credentialing of these radiation oncology team members. ASTRO supports passage of this important legislation. ASTRO also supports requiring board certification for medical physicists.**

Quality Assurance

Over the last two decades, the sophistication of and technologies available to improve clinical cancer patient care delivered with radiation therapy have advanced dramatically. Modern radiotherapy techniques including 3-D treatment planning, IMRT, stereotactic radiosurgery (SRS), SBRT, IGRT, high-dose-rate (HDR) brachytherapy, and other such sophisticated systems are in wide clinical use. These technologies provide significant new capabilities that can improve our ability to treat and control the patient's cancer while minimizing potential toxicity and side effects. Technology, however, cannot substitute for appropriate medical training and clinical judgment.

The safe use of these new technologies requires the concerted efforts of the entire team involved in the delivery of patient care. This multi-faceted team must continually work together to assure quality throughout all aspects of the treatment planning and delivery processes. A primary focus of this team is to effectively identify risks, develop improved methods for avoidance of errors, and to identify and investigate possible sources of errors.

Error reduction and quality assurance, in particular, has been the subject of major efforts by ASTRO and collaborating organizations including the American Association of Physicists of Medicine (AAPM), American College of Radiology (ACR), and other groups. Collaboration

between the National Cancer Institute (NCI), ASTRO, ACR, AAPM, and the Food and Drug Administration (FDA) and other organizations, led to a September 2005 roundtable meeting to identify proposals to address improvements in our ability to avoid errors. One of the important outgrowths of this meeting was the creation of the ASTRO quality assurance symposium, "Quality Assurance of Radiation Therapy and the Challenges of Advanced Technologies" held in February 2007.

This symposium directly focused on error prevention, and the quality assurance needs of modern high technology radiotherapy treatment. The symposium participants proposed that our field adopt modern process-oriented and risk-aware failure analysis methods, and systems engineering approaches that have proven successful in other fields. ASTRO and AAPM have launched new initiatives based on this workshop, including presentations and panel discussions, as well as the publication of a special supplement to our professional journal dedicated to papers given at this symposium. Both organizations have groups working to provide quality assurance guidance to the radiation oncology community for IMRT and other high tech procedures. ASTRO currently is working to develop a "Best Practices" paper and on-line course from the results of this symposium to make sure this information is easily accessible and understood by the entire field.

Improving our processes to reduce the risk of error is an ongoing effort. We must continually balance quality assurance checks of equipment and processes that are aimed at avoiding errors with the need for efficient delivery of high quality treatment. New technologies and evolving methods for using existing technologies should be analyzed in detail to develop processes that minimize potential failure, both technological and human. Such analyses require the cooperation of radiation oncologists, medical physicists, dosimetrists, therapists, and other radiation oncology professionals, and related organizations, including the vendor community. Through cooperation and collaboration, these groups must work together to identify possible limitations and failure modes in radiation oncology equipment (hardware and software), in the clinical process for treatment planning and delivery, and in the medical decisions that guide therapy. Systematic quality assurance checks, including peer-review methods, are an important component part of this process. We must continue and accelerate our efforts to improve both technical and medical quality improvement methods.

Reporting Requirements

There is a patchwork of federal and state regulations that applies to the provision of radiation therapy services. While the FDA has authority over the safety of medical devices, the Nuclear Regulatory Commission (NRC) has authority to protect against radiation exposure associated with radioactive materials. States have jurisdiction over patient protection of radiation-producing equipment.

The FDA requires manufacturers of electronic products to report all accidental radiation occurrences arising from the manufacturing, testing, or use of any product introduced or intended to be introduced into commerce. "Accidental radiation occurrence" is defined as a single event or series of events that resulted in injurious or potentially injurious exposure of any person to electronic product radiation (21 CFR 1000.3). In addition, the FDA encourages health professionals and consumers to voluntarily report problems with medical products including

serious reactions, product quality problems and product use errors. The data collected through voluntary reporting is used to maintain the FDA's safety surveillance of all the products it regulates, and a voluntary report can result in a modification in use or design of the product.

ASTRO sees opportunities for advancing necessary data collection by working with the FDA to reach the goals of the Center for Devices and Radiological Health's FY2010 Strategic Priorities. These goals include putting in place systems and procedures to more efficiently and effectively capture, analyze, and share high-quality information about adverse events (Goal 1.1.3.1), implementing strategies to increase real-time adverse event reporting and establishing pathways for interactive information exchange with healthcare providers (Goal 1.1.3.2), and developing collaborative relationships to promote the establishment of and gain access to registries that provide important information for medical device surveillance (Goal 1.1.3.3). **ASTRO welcomes the opportunity to participate in initiatives underway at the FDA.**

The NRC, which regulates the medical use of radiological materials, requires licensees to report medical events, defined in detail at 10 CFR 35.3045. Medical events include an administration of a wrong radioactive drug, administration by the wrong route, to the wrong individual or delivered by the wrong mode of treatment, or a total dose delivered that differs from the prescribed dose by 20 percent or more or the fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

Reporting of medical events or misadministrations involving radiation-producing machines is regulated by each individual state. There is some variability from state-to-state in how a misadministration or a medical event is defined and in the reporting requirements. New York is seen as a leader in its misadministration reporting requirements and data collection. New York regulations [10 NYCRR 16 (Part 16)] define "misadministrations" as a radiopharmaceutical or radiation from a source other than the one ordered, or by route of administration or to a part of the body other than that intended by the ordering physician. Not all events that are defined as misadministrations result in harm to a patient, but all occurrences involve an error or errors in a patient's treatment, and are required to be reported in New York.

To help create a standardized national reporting framework, ASTRO will be working with state regulators through the Conference of Radiation Control Program Directors (CRCPD), a national professional organization of state regulators dedicated to radiation protection. Once standards are developed, we will collaborate on a pilot tracking system for machine-based radiation medical events. Although the overall clinical benefit and safety record for radiation therapy and other radiation procedures is high, ASTRO believes that errors in administration should be tracked for causes and trends to help facilitate the establishment of effective prevention strategies. The pilot would include the development of a definition of reportable events to include radiation therapy using linear accelerators and electronic-brachytherapy technology.

ASTRO supports this Committee's efforts to promote quality measurement and improvement, particularly through the adoption and effective use of health information technology (HIT). ASTRO has devoted significant time and resources to developing clinical guidelines and quality measures for radiation oncology. ASTRO is proud of the high rates of HIT adoption among radiation oncology practices. In addition, ASTRO is leading IHE-RO to develop interoperability

standards to allow vital clinical information to be passed seamlessly from one manufacturer's radiation oncology system to another system, within and across practices, and made readily available at the point of care. This effort reduces the chances that a medical error can occur. **ASTRO encourages device manufacturers to rapidly implement these interoperability standards as we partner to protect patients.**

Practice Accreditation

In late 2008, ASTRO and ACR entered into an agreement to offer radiation oncology practice accreditation. The accreditation process is designed to promote quality. It includes an on-site survey performed by board certified radiation oncologists and board certified medical physicists. Over the past year, we have been working with our colleagues at ACR to review and strengthen the accreditation program.

In its current format, surveyors review 10 charts of recently treated patients, including de-identified patient records with simulation information and CT planning documentation. The surveyors also collect medical and dosimetry/physics data from the cases selected for review. Each chart is assessed by answering questions on the data collection forms developed by the joint ACR/ASTRO Radiation Oncology Practice Accreditation Committee. The data are used to evaluate information contained in the patient chart, including such items as consent forms, pathology reports, history and physical, physician management during treatment and follow-up, completeness of prescription, simulation, treatment planning and simulation and dosimetry activities. The radiation oncology physicist surveyor is responsible for the design and implementation of the physics quality management program.

Because of the thoroughness of the review, this practice accreditation process is resource intensive. We are exploring creative new ways to increase the pool of volunteer surveyors, such as requiring accredited facilities to provide a volunteer surveyor to review another facility. ASTRO is working with ACR to significantly enhance this practice accreditation program, and to begin the development of additional accreditation modules specifically addressing technologies such as IMRT, SBRT and brachytherapy. **ASTRO is recommending that all radiation oncology practices undergo practice accreditation.**

NCI Investments

ASTRO has long advocated for increased funding for the National Cancer Institute (NCI), and we appreciate the efforts of this Committee to strengthen the NCI in its battle to defeat this dreaded disease. It is hard to find a family in this nation that has not been touched by cancer and we need all the resources possible to alleviate the suffering it causes. Indeed, one of the many reasons that ASTRO supports increased funding for NCI is the important work done by the one-of-a-kind Radiological Physics Center at the M.D. Anderson Cancer Center in Houston. ASTRO strongly supports the important work of the RPC to ensure that institutions participating in clinical trials deliver prescribed radiation doses that are clinically comparable and consistent. We believe that RPC's auditing and monitoring tools have led to improved radiation dosimetry. RPC is an NCI grantee with a budget of approximately $3.5 million per year, $2.5 million of which comes from NCI and the rest from fees levied on participating institutions. Unfortunately, RPC's funding has decreased over the past decade.

ASTRO is aware of and troubled by 2008 RPC data showing that approximately 30 percent of participants failed to accurately irradiate head and neck phantoms, which simulate human patients. While RPC uses more stringent standards for determining accuracy than regulatory agencies, quibbling over the data misses the point: there is room for improvement. Prior to and since the release of RPC's data, numerous institutions have worked with the RPC to identify and resolve problems. RPC also has called problems to the attention of manufacturers, who have used the information to upgrade their equipment and software. We greatly appreciate the efforts of the RPC to shed light on shortcomings, develop quality assurance protocols, and help educate the radiation oncology community to resolve quality problems. We are confident that participating institutions will continue to improve their performance in future RPC analysis. ASTRO also has incorporated information and tools from the RPC to develop enhanced quality assurance programs to educate its membership.

ASTRO also supports the mission of the Advanced Technology Consortium (ATC) at Washington University's School of Medicine in St. Louis. The ATC capitalizes on the existing infrastructure of national quality assurance programs. It facilitates and supports NCI sponsored advanced technology clinical trials, particularly those requiring digital data submission. This effort includes radiation therapy quality assurance, image and radiation therapy digital data management, and clinical research and developmental efforts.

ASTRO asks Congress to support increased funding to expand the capabilities of the RPC and ATC to deal with increasingly complex treatment technologies and processes as well as to further analyze already existing data to ascertain their clinical significance.

Physician Self-Referral

ASTRO has expressed concern to Congress and the Administration that financial incentives and the self-referral of radiation therapy services in the Medicare program may be leading to patients not being fully informed on the full range of treatment options and potentially to the overutilization of health care services. ASTRO also is concerned about anecdotal information indicating that when self-referral is in place, those business arrangements often can cut corners on important quality assurance and patient safety essentials like having robust staffing and qualified medical physicists on-site. We believe Congress should request a study to examine the quality of radiation therapy delivered to patients when self-referral is involved.

Conclusion

Finally, I would like to illustrate the benefits of radiation therapy by telling you the story of one of my patients. I treated a 50 year old woman in 1995 for bilateral breast cancer. A breast cancer diagnosis is always scary, and in the mid-1990s, we were in the process of making the discoveries that have led to the current overall 98 percent five year survival rate for breast cancer patients. At that time, her surgeon recommended bilateral mastectomies, but she opted for bilateral wide excisions followed by radiation. Both breasts were treated at the same time, and we used what was then considered a new, advanced technology called 3D conformal radiation. She is now 15 years out from treatment, lives a full life, spends time with family and friends, and still has both her breasts. Together with the treatment team, we successfully treated her tumors while preserving her quality of life. This is what keeps me hopeful and looking forward to advances in the field.

In sum, ASTRO wants patients to have peace of mind when it comes to safety, quality and efficacy of radiation therapy. We are committed to stronger error reporting, more training, enhanced accreditation, better use of health information technology, patient-centered educational tools and federal advocacy to help protect patients. ASTRO shares the Committee's concerns about the health and safety of all patients and recognizes the importance of maintaining access to high quality cancer treatment. **We support the Committee's review of these issues. We look forward to working with you on policies that could be implemented to further enhance the quality of care patients receive.**

Thank you again for the opportunity to testify.