Testimony of David Fisher
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Mr. Chairman and Ranking Member, I would like to thank you for your invitation to testify today. It is an honor to be here to speak about the important issue of medical radiation.

I am here today as the Executive Director of the Medical Imaging & Technology Alliance (MITA), the leading association representing the manufacturers, innovators and developers of medical imaging and radiation therapy systems. Our more than 50 member companies comprise more than 90 percent of the market for X-ray imaging, computed tomography (CT), radiation therapy, diagnostic ultrasound, nuclear medicine imaging, magnetic resonance (MR), and medical imaging informatics equipment.

MITA is a division of the National Electrical Manufacturers Association (NEMA), a long-established standards-development organization. NEMA standards include widely accepted guidelines for medical imaging equipment that utilizes radiation, as well as other voluntary guidelines that establish commonly accepted methods of design, production, and testing.

I'd like to begin by stating unequivocally that MITA and its member companies believe that any medical error is one too many and that we want to work with the Committee, relevant agencies, providers and patients to reduce the number of medical errors to as low a number as possible.

Value of Radiation Therapy and Medical Imaging

Radiation therapy and medical imaging such as computer tomography (CT) are two complementary but distinct aspects of patient care involving medical radiation that have revolutionized health care delivery in America.

Not only has the *New England Journal of Medicine* proclaimed medical imaging one of the top "developments that changed the face of clinical medicine" during the last millennium, along with anesthesia and antibiotics, but physicians on the front lines of patient care reinforce that belief each and every day. As one example, in the Dartmouth-Stanford Survey of Medical Innovations, leading general internists ranked MRI and CT technology as the most valuable medical innovations in the last 30 years.

As we continue to innovate, we were heartened to hear President Obama in his State of the Union address specifically reference "treatment that kills cancer cells but leaves healthy ones untouched," as an example of what is possible through innovation. Thanks to the leading-edge research and development of our member companies, the President's vision is not far from reality. To this end, it is critical that health care policies continue to facilitate, not restrict, industry innovation.

With an estimated 1.4 million Americans diagnosed with cancer in 2008 alone, and malignancies claiming over half a million lives, access to radiation therapy is essential for ensuring high quality cancer care. Radiation therapy has become a standard of care for treating many types of cancer. Evolved far beyond the large field, one size fits all therapies of the past, modern radiation therapy

offers highly personalized, tailored, non-invasive and cost-effective care for up to 60 percent of all diagnosed cancer patients in the U.S. That translates to approximately 850,000 Americans each year who are able to attack their cancer.

Both medical imaging and radiation therapy are integral to established medical guidelines. These guidelines reflect clinical recommendations developed by specialty physician groups on how best to diagnose and treat specific medical conditions. They are based upon proven best practices, widely accepted standards and scientific evidence. Some examples include the following:

- Guidelines by the American Heart Association and the American College of Cardiology recommend use of CT and other imaging technologies to diagnose peripheral arterial disease.[i]
- Guidelines developed by the American Cancer Society, the American Medical Association, the American College of Radiology, the National Cancer Institute and the American College of Obstetrics and Gynecology recommend regular mammograms for woman and regular MR imaging for women in specified high-risk categories.
- Guidelines by the National Comprehensive Cancer Network on the most appropriate treatments for various disease sites.
- Guidelines developed by the American Association of Physicists in Medicine that define necessary quality assurance measures for intensity modulated radiation therapy to ensure accurate and safe treatment for cancer patients.[ii]
- Guidelines by the National Cancer Institute define standards of care for screening and testing of specific cancers.[iii]

Our technologies are not only fundamental to standards of care, but they also help patients avoid or limit more invasive procedures, and return to their families, lives, and work more quickly. Indeed, it is because of these advanced technologies that the term "exploratory surgery" is all but obsolete.

For most of us, our own experiences bear this out. We have either benefited personally from or know someone whose life was saved or improved by these technologies. The mother whose MRI of the breast will detect cancer in time to avoid radical surgery. The father who's chest CT tells his doctor that the blockage is worse than anticipated and immediate action is needed. The aunt, uncle, grandparent, and cousin whose Intensity Modulated Radiation Therapy (IMRT) saved their life.

Beyond the anecdotes and what common sense dictates, we also know that the value of medical imaging and radiation therapy is demonstrated empirically.

From receiving a CT scan instead of a cardiac catheterization or detecting a polyp before it is cancerous, or receiving a course of radiotherapy that allows a patient to keep his daily schedule of work and home commitments rather than endure invasive surgery, peer-reviewed research confirms that these medical technologies not only improve health outcomes and save lives, but also reduce health care costs and drive down spending.

Just to give you a brief snapshot into the power of medical imaging and the curative effects of radiation therapy, consider these research findings:

- Increased regular mammography screenings have resulted in a 24 percent decrease in the death rate from breast cancer from 1990 - 2004. If detected early, the five-year survival rate for breast cancer exceeds 95 percent. [iv]

- A recent study in the *Lancet* found that in women who recently underwent mastectomy, the five-year risk of local breast cancer recurrence was only 6 percent for women who also received radiation therapy, compared to 23 percent for those without. Radiation therapy provides a similar advantage in women who undergo breast conserving surgeries or lumpectomies.
- For all cancers, physicians have reported that PET scanning allowed them to avoid additional tests or procedures 77 percent of the time. Moreover, in over 36 percent of cases, PET scanning resulted in a physician's decision to alter their patient's course of treatment.[v]
- Used together, external beam radiation therapy and Brachy therapy (where a radiation source or "seed" is placed inside the area requiring treatment) have demonstrated five-year PSA-based cure rates of 96-100 percent for low risk patients and 69-97 percent for those at high or very high risk.[vi]
- A recent study showed that after treatment with a boosted dose of radiotherapy following a course of external beam radiotherapy, patients with locally advanced nasal carcinoma had excellent outcomes. Five years later, 98 percent of patients were free from local relapse, 83 percent were free from nodal relapse, and overall survival was 69 percent.[vii]
- Coronary Computed Tomographic Angiography (CCTA) rules out coronary artery disease with over 90 percent accuracy, saving patients from unnecessary surgery or un-needed trips to the cath lab. [viii]
- Increased utilization of advanced medical imaging, such as CT and MRI, between 1991 and 2004 improved life expectancy by 0.62 to 0.71 years. This effect was greater than the increases in mortality caused by obesity over the same timeframe.[ix]

Simply put: innovative medical imaging and radiation therapy technologies turn patients into survivors.

Beyond the life-saving impact of medical imaging, researchers have also found that it saves money in the long-run.

For example, every $1 spent on inpatient imaging correlates to approximately $3 in total savings,[x] and according to researchers at Harvard Medical School, every $385 spent on imaging decreases a patient's hospital stay by one day, saving approximately $3,000 per patient. [xi] [xii]

Other, disease specific studies have found that increased imaging could save up to $1.2 billion annually in the treatment of stroke patients,[xiii] and since 1998, CT scans have been found to significantly reduce the negative appendectomy rate and the number of unnecessary hospital admissions, saving $447 per patient.[xiv]

In short, as we look to the future of health care in this country, we cannot see our way to better outcomes and lower costs without the lens that medical imaging and minimally invasive radiotherapy provides. The medical technologies MITA's member companies research, develop and manufacture are the future of delivering better health outcomes at lower costs.

Proactively Ensuring the Safe and Effective Use of Medical Radiation

Each year, millions of treatments and imaging sessions involving the use of medial radiation are completed without error because of the efforts of clinicians, manufacturers, and regulators to adhere to extensive current procedures and standards. Efforts to promote safety over the last several decades have reduced the incidence of errors and misadministration to their lowest levels.

For example, during the design process an extensive analysis is done to evaluate the potential for malfunctions and errors that might affect patient or operator safety and the quality of treatments. For each possible error, remedies are designed, which may include fail-safe interlocks, operator warnings, safe operating procedures, etc. All of these remedies are then tested and documented as part of the verification and validation of the product before it can be released for use.

The utmost care is taken so that imaging devices that use radiation and radiation therapy devices are installed appropriately, calibrated, and ready for clinical use. Additional quality and safety checks are performed frequently, in accordance with guidelines established by the American Association of Physicists in Medicine (AAPM), the Radiological Society of North America (RSNA), and the equipment manufacturer.

When errors or malfunctions that affect patient safety are reported to manufacturers, they inform the Food and Drug Administration (FDA), investigate the cause to determine what actions should be taken to reduce or eliminate the possibility of harm in the future.

Industry Innovations Reduce Radiation Dose and Improve Safety

The imaging industry supports and is committed to the ALARA principle, which stands for "as low as reasonably achievable." This is a universally adhered to principle of radiation dose management and optimization incorporated into all imaging procedures and technologies and is mandated by nearly all regulatory bodies and licensing agencies, including the Nuclear Regulatory Commission.[xv] This foundational industry consensus principle to minimize and optimize radiation exposure demonstrates the commitment of all involved parties to patient dose concerns, both in the short and long term.[xvi]

CT Imaging

In addition to working with medical professionals and federal agencies on efforts to reduce dose during imaging procedures, our members have introduced new products and system innovations during the past 20 years that have reduced radiation dose for many procedures by up to 75 percent, while maintaining, and even improving image quality, enhancing the ability of physicians to diagnose and treat disease.

CT innovations have been especially prevalent with significant advancements that have effectively "built-in" dose reduction into the equipment. For example:

- Weight-based, age-based and other CT scan protocols have been developed by luminary imaging institutions around the world and manufacturers incorporate these protocols into new equipment to help users achieve optimum diagnostic results. These protocols are designed as a starting point for doctors and imaging facilities to provide appropriate diagnostic information while minimizing radiation, and are particularly effective in optimizing dose for children and infants.
- Automatic exposure control (AEC) alters the amount of radiation dose used when scanning different parts of the body. For example, more tube current is needed to maintain image quality during a CT scan in a large or dense area of the body as compared to smaller areas. AEC protocols automatically adjust the current up or down within prescribed bounds as needed, without relying on the imaging technologist. Studies of AEC procedures have shown radiation dose reductions between 20 and 60 percent.[xvii]

- Beam collimation limits dose delivery to coincide with the detector area of interest and scanning field of view, thereby minimizing the photons that do not contribute to the image.
- Beam filtration reduces low energy photons likely to be absorbed by the patient (and not contribute to image formation). They can also shape the beam to optimize it for patient size.
- Adaptive software filtration is governed by noise management software to selectively reduce noise in uniform areas of an image while preserving edges. This enables a lower dose to be utilized while preserving image quality.
- Dose display. CT imaging equipment provides access to dose data, generally by displaying the data on the console, in consistently defined parameters, prior to scanning. This allows the operator to better understand the dose implications of protocol choices and how any change to the protocol will affect dose.
- ECG tube current control for CT cardiac examinations. The advent of cardiac imaging resulted in an additional modulation method based on cardiac cycle as opposed to body location. The primary focus of cardiac dose modulation is to ensure that dose is only delivered during the resting phase of the ECG cycle to reduce the effects of image degrading motion and motion associated artifacts.

It is important however to keep in mind that dose reduction depends not only on equipment, but also on the use of the equipment and the physician determination of the appropriate dose levels for each individual patient. MITA and our members work closely with the physicians and radiologic technologists who use this equipment. We value their feedback and cooperation in developing initial and ongoing training related to these products.

Radiation Therapy: Safe, Targeted, Effective

In the case of diagnostic imaging technologies that use radiation to create images, we are seeking to reduce dose. On the other hand, radiotherapy requires a high amount of narrowly targeted radiation aimed at the cancerous cells to cure and to control the cancer. Radiation therapy provides safe and effective treatment for an increasingly wide range of cancers. By delivering a targeted high dose of radiation directly to cancerous tissue, radiation therapy causes the malignant cells to either stop growing or to die, while simultaneously minimizing radiation exposure to surrounding healthy tissue.

During the past several years, researchers have developed highly targeted and customizable radiation planning and delivery tools. These advances in radiation oncology are translating directly into better clinical outcomes, as well as greater safety and convenience for patients such as fewer treatment-related side effects and complications, and shorter and more convenient courses of therapy. Generally a non-invasive, radiation therapy is often performed in the outpatient setting, which minimizes disruption of daily activities for many of the estimated 643,000 cancer patients who receive radiation treatments each year.

Based on evidence from a large and ever-expanding body of scientific and medical literature, radiation therapy has become integral to medical guidelines and best practices as a standard of care for many types of cancer including breast, prostate, lung, head and neck, rectal, and central nervous system tumors. In some cases, radiation treatments are used instead of surgery. Alternatively, they may be used pre-operatively to shrink a tumor and provide for less invasive, safer and more effective surgery or used post-operatively to prevent disease progression or spread after surgery.

In addition, guidelines for clinical use of radiation therapy have been developed by a number of different national organizations and medical specialty groups, such as the National Comprehensive

Cancer Network and the American Society of Clinical Oncology (a professional organization representing over 25,000 oncologists and others who provide care for cancer patients).

Radiation therapy is prescribed by radiation oncologists to treat cancerous tumors or other diseases that respond to therapeutic radiation. The modern radiotherapy process is a series of steps designed to deliver the radiation oncologist's prescription of radiation dose. This process makes use of a variety of hardware and software equipment to diagnose, prescribe, plan, verify and deliver the patient's treatment.

Systems typically used in the radiotherapy process include:

- Diagnostic systems, which allow the radiation oncologist to locate the disease within the patient and define the shape of the targeted tumor;
- Treatment planning systems, which allow the physician, medical dosimetrist, and medical physicist to calculate the amount of dose that different potential treatments will deliver to the patient's tumor and surrounding tissue and even vary the plan as the patient's treatment needs change;
- Treatment information management systems, which contain the patient's medical chart, including the prescription, schedule of treatments, specific instructions for the treatment machine, a record of treatments completed, patient images, billing data, and other information that is used by clinicians to assure quality and safety;
- Quality assurance systems, with which the medical physicist verifies the calibration of the treatment machine and the accuracy of a patient's specific treatment plan prior to and during the course of the patient's treatment; and
- The treatment machine, which consists of a treatment couch used by the radiation therapist to precisely position the patient prior to treatment using a variety of imaging and positioning sub-systems, and the radiation delivery system itself, which is used by the Radiation Therapist to control, deliver, and monitor the radiation beam(s) in accordance with the approved prescription and the patient's chart.

Hardware and software systems used in the radiotherapy process have multiple safety features designed to assure safe and effective completion of the treatment prescribed by the radiation oncologist. Treatment management systems typically do continuous consistency and integrity checks of the data that controls the radiation dose that will be delivered to the patient. They verify that all pieces of critical data are present before the treatment will be allowed to proceed. The system also checks that the particular patient's treatment plan matches with the requirements and capabilities of the treatment machine and prevents the start of treatment if there is a discrepancy. These systems also include features that allow only authorized users to approve and make changes to treatment plans. The system provides critical data for quality assurance checks performed by the medical physics staff prior to treatment. These are only a few of the numerous safety features contained in the treatment management system.

In addition, treatment delivery systems and the treatment delivery machines themselves have redundant safety features. For example, there are two independent monitoring systems that measure the radiation coming out of the machine during the treatment. The intensity and uniformity of the treatment beam is monitored continuously, and an interlock will stop treatment if the values are abnormal. The system records and retains key data during the actual treatment so that, in the event of a premature shut-down, the radiation oncologist and medical physicist can precisely reconstruct the treatment and proceed to complete it accurately thereafter. Critical aspects

of the treatment are displayed on a treatment console for careful monitoring by radiation therapists during treatments. The systems require the radiation therapists or other trained clinical personnel to be physically present in the treatment room prior to treatment to correctly position the patient so that the dose is delivered accurately to the target. These are just a few of the numerous safety features in treatment delivery software and hardware systems.

It is important to note that radiation therapy devices and systems are subject to requirements, oversight and regulation by numerous government and professional organizations worldwide, including the FDA, international regulatory bodies, and international standards organizations. Radiotherapy device manufacturers adhere to the requirements of these organizations in designing and building their systems and with potential safety implications that come to their attention. Radiotherapy device manufacturers are regularly audited for compliance with regulations and fully cooperate with FDA and other regulatory and standards based inspections.

Efforts to Reduce Radiation Dose

MITA has a long history of working with its members and other stakeholders to track and reduce medical radiation. One essential element in that effort is the Digital Imaging and Communication in Medicine (DICOM) Standards which MITA manages. This is the universal standard for the interoperability of medical images, even when generated by different scanners. Thanks to these standards, imaging is, without a doubt, the most "networked" aspect of health care in the clinical setting. Importantly, the DICOM system already records dose information.

MITA collaborates to proactively tackle issues related to radiation safety. For example, in November 2009 MITA convened a stakeholders meeting in Chicago including physicians, physicists, industry and FDA officials to discuss ways to prevent future medical errors that involve radiation. MITA is also co-sponsoring upcoming CT and Radiation Therapy Radiation Dose Summits to further the education of providers and physicists on the new technologies our member companies have developed and are manufacturing. MITA members have also involved with Image Gently in development of targeted training on pediatric CT.

MITA also believes in ensuring that patients receive the right test at the right time. As part of the Access to Medical Imaging Coalition (AMIC), MITA helped to develop appropriateness criteria for advanced medical imaging included in the Medicare Improvements for Patients and Providers Act (MIPPA). We believe strongly that the integration of these criteria into clinical decision-making by physicians, will help to eliminate unnecessary images. This policy is not only helpful because it can save money, but it also ensures unnecessary scans are eliminated and that patients receive the right test at the right time for their specific symptoms. MITA is committed to working with physicians, CMS and other stakeholders to continue to examine this promising demonstration program and expand it in the future.

More recently, MITA announced its support for the President's proposal in the fiscal year 2011 budget to develop a national dose registry and its support for the FDA *Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging*. MITA intends to participate fully in FDA's efforts to reduce radiation dose.

MITA has also proposed several additional policies designed to reduce medical errors, reduce radiation dose and raise awareness of radiation dose among providers.

New Dose Check Features

Earlier this week, MITA's CT manufactures committed to including a new radiation dose check feature on their new CT products. This new feature will provide an alert when dose levels as determined by hospitals, imaging centers and clinicians are exceeded. This alert is designed to provide a clear indication that the settings for the exam resulted in a dose higher than the pre-determined reference dose for routine use.

In addition, manufacturers are committed to including an additional safeguard which allows hospitals and imaging facilities to set upper radiation dose limits to prevent CT scanning at higher, potentially dangerous radiation levels. This feature is designed to prevent hazardous levels of radiation that could lead to burns, hair loss or other injuries.

Manufactures are also committed to standardizing dose recording by incorporating the DICOM structured dose report.

Our manufactures are already working on or have implemented some of these new features and most will be able to include them on new releases of CT products and to begin deploying to their CT installed base before the end of this year. With this deployment strategy, most new CTs and similarly compatible installed base systems will include these new features during the 2012 calendar year.

MITA and our member companies stand ready to work with professional organizations, regulatory bodies, individual clinicians and other stakeholders on these features.

Reference Values

Another important and specific way that additional understanding of radiation dose can be promoted is through the development of radiation dose reference levels or reference values. The recently announced manufacturer dose check feature could utilize these values and MITA is eager to assist stakeholders in their development. Once determined, the radiation dose reference level serves as a data point at which physicians, physicists and technologists can compare the dose level of the specific procedure they are administering to a wide sample of similar tests. This information gives medical professionals an additional tool to develop and deliver optimized scans commensurate with current clinical practice.

Enhanced Training and Protocols

Training of operators of medical imaging and radiation therapy equipment on the specific machines in their facility is important to the proper use of this complex equipment. To that end, imaging and radiation therapy equipment manufacturers currently provide comprehensive training and education to the users of their equipment.

Training delivery venues include: 1) Onsite training at the customer facility using their own installed equipment, 2) Instructor led classroom training, including lab work as appropriate, delivered at the manufacturer's training center, 3) Remote instructor led training done via the internet and/or 4) Customer self-directed eLearning modules produced by the manufacturer.

Training is especially important when radiation is involved and users of imaging and radiotherapy equipment must have the appropriate clinical competence and professional training in order to leverage the additional education we provide on our specific equipment.

MITA encourages the development of training standards for hospitals and free-standing imaging facilities that purchase imaging equipment that involves the use of radiation and radiation therapy equipment. It's also important to remember that training doesn't end when our equipment is installed. Instead, it is an ongoing effort by the hospital and imaging facilities that includes continuing education, training of new employees and achieving and maintaining certifications and accreditations. We would like to work with all interested parties on these efforts.

MITA members are also eager to work with stakeholders to develop additional operational safety procedures and checklists to reduce medical errors and incorporate those new standards into our training offerings.

Error Reporting

MITA companies are currently mandated by the FDA to report serious injuries that involve their products. This is a mandate that MITA companies take very seriously and work to meticulously comply with.

MITA supports efforts to ensure standardized reporting across stakeholders in a manner that is transparent for patients, their families and physicians. As part of that effort MITA supports mandatory reporting by providers of all medical errors involving medical radiation.

As this committee considers ways to increase the frequency and completeness of error reporting, it must also carefully consider potential disincentives to under-report errors.

Accreditation and Certification

MITA is also committed to policies developed with stakeholders regarding the accreditation of advanced imaging facilities included in MIPPA and the certification of radiologic technologists. The accreditation of imaging facilities has begun this year and will continue with all providers required to be accredited by 2012. MITA supports an examination of whether this policy should be expanded to include additional facilities where radiation therapy medical devices are in use and would like to work with the Committee in this effort.

In addition, MITA supports the establishment of minimum standards for radiologic technologists who perform diagnostic medical imaging exams and deliver radiation therapy treatments.

Conclusion

Thank you for your consideration of this important issue. As the legislative process moves forward, MITA, along with physicians and patient groups, look forward to continuing to work with Congress and the administration to ensure appropriate use of medical radiation and access to life-saving technologies proven to decrease costs, prevent and treat illness, cure illness and improve quality of life for millions of Americans.

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