

House Committee on Energy & Commerce
Subcommittee on Health
Hearing on Medical Radiation: An Overview of the Issues
February 26, 2010

Chairman Pallone, Ranking Member Deal and Members of the Subcommittee, my name is John Donahue and I am honored and grateful to be here to discuss the issues surrounding ionizing radiation in medicine. I am here as the Vice Chairman of Medicalis Inc. Medicalis is a leading innovator of technology and clinical solutions focused on improving access to high quality, safe, clinically appropriate and affordable diagnostic imaging care. We are a company founded by the radiologists and health technologists at the Brigham and Women's hospital system in Boston; we provide on-line, point of order, web-based radiation safety and clinical appropriateness decision support guidance to physicians.

By way of background, I have worked in health care for over 25 years in the international pharmaceutical, vaccine, biotech and clinical laboratory industry. In the late 1990's, I co-founded and was the President and CEO, of one the nation's first and largest radiology benefit management companies. In that capacity, I had the privilege to testify in 2005 before this Committee on imaging policy. Since that time, I have had the opportunity to interact extensively with CMS, MedPAC, GAO, Congressional offices and many of the industry stakeholders on an array of imaging topics. I also lecture at the Harvard School of Public Health on imaging, medical management and health policy matters.

Diagnostic imaging is rife with many health policy and Federal legislative opportunities. I am hopeful that after today's hearing, we will agree that radiation safety in imaging is a measurable and very serious issue, and that there are specific steps that the Federal government and the industry can take now to mitigate risk of over-exposure. Requiring on-line radiation safety guidance and clinical decision support at the point of ordering for all Medicare and Medicaid patients would meaningfully lower the incidence of cancer and improve health outcomes for patients as well as reduce health care spending in the public health programs.

Radiation safety has been in discussion since 1895 when "a new kind of light", the X-Ray, was discovered. In the 1990's, our Food and Drug Administration (FDA) suggested a methodology for recording X-ray absorption. In late 2001, FDA again issued a notice to all health-care professionals emphasizing the need to minimize radiation exposure in pediatric patients. In July 2005, the National Academy of Sciences issued a seminal study that examined health risks from exposure to low levels of ionizing radiation. Today, this is commonly referred to as the BIOLOGICAL EFFECT OF IONIZING RADIATION or the BEIR VII report. The watershed conclusion was that any level of ionizing radiation can induce a carcinogenic effect. The report showed that a single CT of the abdomen emitting 10 milliSieverts (the most common unit of measure, "mSv") of radiation can result in radiation induced cancer 1 in 1000 times. Further, cumulative dosage totaling 100 mSv can ratchet this carcinogenic risk up to 1 in 100 times. Statistically, as exposure to mSv increases so does the likelihood of cancer.

It is important to note that radiosensitivity varies by body tissue as well as by the gender and age of the patient. Studies have shown meaningful dose estimates can be measured. For example, the Cleveland Clinic submits that an abdominal CT emits roughly 10 mSv, a Cardiac PET - 15 mSv, a CT urographic study - 44 mSv, while a plain chest Xray emits less than .1 mSv.

In 2006, I helped lead a radiation dosage safety and awareness program, in conjunction with a leading health insurer. The results were startling. They highlighted widespread radiation safety concerns and were reported extensively in the Wall Street Journal:

1. some individuals received radiation exposure levels more than 1000 percent higher than that recommended by medical guidelines, and
2. one patient, received 341 CT scans over an 18-month period, bringing the radiation exposure level to 993.3 mSv.

In 2007, I presented yet another study on imaging appropriateness and radiation safety to one Medicare Advantage plan. The conclusion was that in one 12-month period, almost 20 percent of this population received radiation exposure exceeding the first BEIR VII threshold of 10 mSv. Additional studies show that there are still widespread misconceptions amongst ordering physicians. One example is that shorter scanning times result in lower dosage. In fact, the opposite can be true because time and CT radiation dose are not proportional.

Diagnostic imaging is an extraordinary clinical tool and the benefit of diagnostic imaging in this context almost always exceeds the risk of induced carcinogenic effects.

However, the studies cited above show incontrovertibly that patients are too often needlessly exposed to dangerously high levels of ionizing radiation that can induce the adverse outcomes of carcinogenesis. I would point out that, in addition, the GAO, MedPAC and CMS have concluded that imaging utilization is growing far ahead of overall health inflation and much of this growth is not clinically warranted and is unsupported by clinical evidence.

I believe the solution is to leverage the clinical evidence, measurement techniques and web technology available to us today to:

1. ensure every advanced imaging exam is clinically supported by evidence and is not redundant
2. measure and report on individual cumulative mSv dosage and present this ionizing history to physicians at the point of ordering
3. require recommendations of viable clinical alternatives to enhanced radiation risks when they exist. For example, is an ultrasound or is a blood or lab test sufficient for an initial diagnosis?
4. ensure that these tests, once deemed clinically supported and safe, are performed by a physician and at a facility that adheres to the highest levels of clinical quality.

My company, Medicalis, is able today to deliver clinical appropriateness and radiation safety guidance to physicians, thereby improving health care outcomes, materially reducing radiation risk, and meaningfully lowering costs by eliminating unnecessary tests. Medicalis has a health data integration tool that links into lab, pharmacy, utilization management, archive systems, electronic medical records and claims data sets. We continuously survey all available patient data, including their personal ionizing radiation history. When physicians use our point of ordering, decision support, web based tool to request an imaging exam, we immediately present clinical evidence to guide that physician to the clinically appropriate test in the form of decision support. We also immediately present an intuitive patient-specific, risk assessment of radiation exposure: by the actual precise absorbed dose for a procedure when available, or by an algorithm considering patient age, gender, and body part based on the estimated mSv dosage for each procedure. If there is further ancillary risk, such as MR gadolinium contrast in certain renal conditions, we immediately present the information to the physician and offer alternative clinical action. Critically, all of this information becomes imbedded into the patient's electronic medical record.

In 2010, we have no excuse but to leverage available clinical evidence, innovative technology and federal legislative and regulatory policy to provide all Americans with clinically appropriate, radiation safe and affordable imaging care. I would respectfully suggest that Congress encourage CMS to include web-based, clinically proven decision guidance with actual radiation safety capabilities into the upcoming radiology pilot initiatives and seriously consider any additional legislation to address these very serious policy concerns.

In addition, the Food and Drug Administration should be commended for the unveiling of its recent, "Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging." This effort will focus on the safe use of medical imaging devices, support informed clinical decision-making and increase patient awareness of their own exposure. Specifically, FDA has highlighted two underlying principles: appropriate justification of the radiation procedure and optimization of the radiation dose. This effort addresses many of the concerns raised in my testimony and Medicalis looks forward to working with the FDA and other industry stakeholders as this effort moves forward.

I want to thank the Chairman and the Subcommittee again for your focus on the medical radiation issues. I would be pleased to answer all questions and to provide any further information.