Health Care and Product Liability Alert

July 2010

Authors:
Charles F. Rysavy
charles.rysavy@klgates.com
+1.973.848.4053

Medical Imaging Devices and Radiation Exposure: To Scan, or Not to Scan?

There is little doubt that modern medical imaging devices utilizing ionizing radiation, such as x-ray machines, CT scanners, fluoroscopes and other diagnostic nuclear medicine equipment, have revolutionized the process of diagnostic medicine and, in so doing, have saved countless lives. The technology has become extraordinarily sophisticated. As the technology improves, so too does the range of practical applications and the raw number of imaging procedures administered to patients worldwide.

The undeniable benefits of advanced medical imaging devices do not come without risk, however, as is virtually always the case with any medical procedure or test. The primary risk from CT scanners, fluoroscopes and diagnostic nuclear medicine procedures arises from the fact that every such procedure provides a non-trivial dose of ionizing radiation to the patient—and with it, the potential for radiation-related health effects. The issue has received a great deal of recent attention from the United States Food and Drug Administration (FDA), the scientific community and the press. While no one has seriously questioned whether the overall benefits of diagnostic nuclear medicine procedures outweigh this risk, many have advocated that equipment manufacturers, and healthcare providers—each in their own sphere of control—take all reasonable steps to limit the risks.

Recent Government, Scientific and Media Attention

In December 2009, the FDA provided interim recommendations for imaging facilities and practitioners to reduce or eliminate cases of excess radiation exposure. Among the FDA’s recommendations are that facilities: (1) assess all patients who undergo CT perfusion scans to determine whether they received excess radiation doses; (2) review their radiation dosing protocols to ensure correct dosing is planned for each study; and (3) implement quality control procedures to ensure dosing protocols are followed every time and the planned amount of radiation is administered.

In February 2010, the FDA announced its Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging (“Initiative”), which focuses on CT scans, fluoroscopy, and nuclear medicine. The overall goal of the Initiative is to “support the benefits associated with medical imaging while minimizing the risks.”

Also that month, the Congressional Subcommittee on Health held hearings on medical diagnostic and therapeutic radiation. The media widely reported that the members of the Subcommittee seemed surprised and pleased that all testifying organizations recommended changes to promote best practice radiology and radiation oncology guidelines. For example, at least one healthcare professional advocated mandating uniformity in the ways that CT scanners of different manufacturers report radiation dose, since the current lack of uniformity makes it difficult for radiologists to standardize their practices.
The first step in the FDA’s Initiative took place in March at an FDA meeting on device improvements for the three main types of scanners. The meeting, conducted by the FDA’s Center for Devices and Radiological Health (CDRH), which has regulatory authority over such devices, focused on equipment features that manufacturers should incorporate into CT scanners and fluoroscopy systems to increase patient safety. Among the mandatory equipment features being considered by the FDA are that CT and fluoroscopic devices display, record, and report radiation dose uniformly and alert users when the dose exceeds a diagnostic reference level, a peak skin-dose threshold for injury, or some other established value. This has been prompted in part by recognition that individual scanning doses are currently known only within a large range of uncertainty, and that doses to patients receiving CT scans can vary widely for the same procedure, even within the same healthcare facility using the same manufacturer’s device pursuant to the same protocol. The FDA is also considering requiring manufacturers to provide additional data in their pre-market submissions to support specific clinical uses, and incorporate that information into product labeling and training to enhance safe use of these devices.

The public meeting drew substantial media attention, due in large part to claims made at the meeting by a former FDA scientist that his job was eliminated after he raised concerns about the risks of radiation exposure from high-grade medical scanning.

Recent media reports of adverse health affects have focused primarily on extreme cases involving acute radiation-related health effects. In one recent incident, operator error reportedly resulted in a child receiving 151 CT scans of his head and neck over the course of an hour, resulting in a whole body radiation dose comparable to 700 chest x-rays. The only immediately apparent acute adverse health effect, however, was erythema (reddening of the skin) on the head and neck, although the child is likely to develop cataracts within three to eight years. In another well-publicized series of incidents, technicians at Cedars-Sinai Medical Center in Los Angeles and three other facilities performed manual manipulation of CT scanners to produce better pictures, causing hundreds of patients to receive higher than intended radiation exposures from brain perfusion CT scans for diagnosis and treatment of strokes. One patient, testifying before Congress, reportedly received a dose equivalent to 50,000 chest x-rays.

Although popular media interest has focused on the rare acute overexposure, the scientific community has been directing its attention increasingly to the potential for latent health effects from repeated low-level exposures to radiation. Latent health effects are more likely to become an issue with medical imaging equipment than are acute effects—simply because accumulated radiation doses from repeated, properly-administered scans are far more common than overexposures caused by operator error or equipment/software malfunction. Cancer is the potential latent health effect of primary concern, although it is much less of an issue for projection radiographs (x-rays, mammograms) than it is for CT, interventional fluoroscopy and nuclear medicine studies, due to the size of the doses administered with each procedure. Even a single CT scan typically delivers an effective dose greater than the dose the average nuclear plant worker in the United States receives in an entire year. The National Council on Radiation Protection announced in 2009 that average “background” radiation doses to the general U.S. population have nearly doubled since publication of its last report in 1987. Virtually the entire increase in background dose is attributable to diagnostic and therapeutic medical radiography, and approximately half of that dose is from CT scans alone.

When considered over the life span of an individual patient, and across the population of patients in the United States receiving these procedures, the statistical long-term risk of cancer from medical imaging procedures becomes substantial. Estimates of this risk include 29,000 future cancers related to CT scans performed in 2007 alone. Another estimate is that one in 270 women and one in 600 men who undergo CT coronary angiography at age 40 will develop cancer as they age. Children are particularly vulnerable to the health risks from imaging scans employing ionizing radiation because they are more sensitive to radiation and have a longer life expectancy than adults. As a result, accumulated exposures over a child’s lifetime elevate his/her cancer risk over that of an adult receiving the same procedures.
With this increased governmental and media attention, equipment manufacturers and operators should anticipate an upsurge in liability suits around these issues.

**Potential Claims**

Liability suits alleging radiation-related injuries against healthcare providers are likely to remain negligence-based malpractice claims and, less frequently, civil battery. Likely factual allegations include equipment or software malfunction, operator error, intentional overriding of safety systems, failure to train the operator adequately, utilizing equipment outside of the manufacturer’s design parameters, and that the scans were not medically necessary.

Recent media coverage suggests that imaging equipment manufacturers may be more frequent targets of lawsuits. In the vast majority of instances, these suits will also include the equipment operator, prescribing doctor and healthcare institution, and be based on a claim of combined operator error, design defect and failure to warn.

**Design Defect**

Design defect claims against manufacturers are likely to allege that the scanner(s) could have been designed so as to produce the same or comparable quality images while delivering a lower dose of radiation to the patient, that the scanner(s) allowed the operators too much leeway in setting radiation doses, and that the scanner(s) lacked fail-safe functions to protect against operator error.

Actions proposed by the FDA may reduce the potency of design defect claims by introducing a greater level of uniformity in scanner designs. The FDA has announced that it will issue targeted requirements for manufacturers of CT and fluoroscopic devices to incorporate important additional safeguards into the design of these machines and develop safer technologies.\(^i\) In an effort to reduce radiation doses, CDRH partners with the international CT community by actively participating in the International Electrotechnical Commission (IEC) standards development committees to ensure that equipment is designed and built to maximize the diagnostic information while allowing the control and reduction of unnecessary radiation dose.\(^i\)Irrespective of whether a court concludes that the IEC standards are legally binding on manufacturers, they will help define the minimum standards against which experts and juries will assess the adequacy or inadequacy of the imaging equipment at issue in a lawsuit.

Some manufacturers have recently introduced new model CT scanners designed specifically to reduce patient dose. The reduced radiation doses delivered by these manufacturers’ scanners likewise will be used to define the minimal standard against which other manufacturers’ scanners will be compared by plaintiff experts and juries. This does not mean that industry safety leaders are immune from design defect claims, however. Plaintiffs’ experts may opine that even the best models in the industry are inadequately designed to reduce patient radiation exposures. Industry safety leaders may also face design defect claims related to older equipment still in service or from scanners purchased in secondary markets.

**Failure to Warn/Inadequate Instructions**

Failure to warn is also likely to be a favorite legal theory of plaintiffs claiming medical radiation-related injuries. Again, these claims will target both healthcare providers and manufacturers.

Planned FDA action in this area also may reduce the risk of claims. FDA-targeted requirements for manufacturers of CT and fluoroscopic devices will include providing clinicians with more information to guide their decision making. The FDA may require, for example, that CT and fluoroscopic devices be capable of specific functions, such as capturing the radiation dose value from each exam and linking it with the study image to facilitate the storage of dose information in a patient’s paper or electronic medical record. The FDA may also require that devices be capable of automatically recording radiation dose information in a standardized report, and transmitting this information to a patient’s electronic medical record or a dose registry. The FDA is collaborating with other organizations to develop and disseminate a patient medical imaging history card.\(^i\) The FDA may require manufacturers to provide additional data in their pre-market submissions to support specific clinical uses, and incorporate that information into product labeling and training to
Health Care and Product Liability Alert

enhance safe use of these devices. Such steps will give healthcare providers more comprehensive information about a patient’s imaging and radiation dose history and support their decisions about the most appropriate clinical course of action for each patient.\textsuperscript{x}

**Potential Defenses**

The most compelling defense against claims of latent injuries, particularly when radiography is utilized in emergency room and oncology applications, is likely to be one of risk/benefit. That is, the equipment was not defective because the risk of injury could not be further diminished without reducing the utility of the equipment, and that the benefit conveyed by using the equipment substantially outweighed the risk of injury. Logically, the immediate medical risk of not undergoing a scan will virtually always trump the possibility of cancer years or decades in the future. It will be difficult for a plaintiff to argue convincingly that, had she been provided with sufficient information on the small risk of future cancer, she would have chosen instead the immediate, perhaps life-threatening, risk arising from refusing the scan.

Arguing that the balance between risk and utility weighs heavily in favor of utilizing imaging equipment is much more difficult where the clinical need for the scans is questionable, especially when they involve self-referrals and screening scans given to asymptomatic people. “[A]t this time the [FDA] knows of no scientific evidence demonstrating that whole-body scanning of individuals without symptoms provides more benefit than harm to people being screened. The FDA is responsible for assuring the safety and effectiveness of such medical devices, and it prohibits manufacturers of CT systems to promote their use for whole-body screening of asymptomatic people. The FDA, however, does not regulate practitioners and they may choose to use a device for any use they deem appropriate.”\textsuperscript{x}

**Claims Avoidance**

Although claims for latent radiation-related injuries from medical imaging procedures should be defendable on several levels, there nonetheless are claims avoidance actions that prudent manufacturers and healthcare providers might consider in advance of any FDA action. These include reviewing existing warnings for new and older scanners and revising them if/as necessary, assuring that prescribing physicians and radiologists are thoroughly educated on the radiation risks from CT scanners (since these medical professionals receive very little training in medical school on radiation risk), providing devices to measure patient dose, requiring radiologists to record this information in patient charts, evaluating insurance coverage for potential liabilities, and reviewing the in-house paper trail for vulnerabilities.

Above all, technical and medical issues must be carefully coordinated with the legal and regulatory side to establish a comprehensive approach for the protection of the patient.
Radiation-related adverse health effects may be either acute or latent. Acute health effects, caused by an excessive dose of ionizing radiation over a short period of time, include skin burns, hair loss, cataracts, tissue necrosis and, in extreme cases, death. Acute health effects are extremely rare from diagnostic equipment, but they do occur.


