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FDA's Radiation Exposure Concerns Prompt Development of New Requirements for Certain Medical Imaging Devices

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On February 9, the U.S. Food and Drug Administration (FDA) announced a broad new initiative to reduce unnecessary patient exposure to radiation from medical imaging procedures. The announcement follows the FDA's recent investigation into hundreds of cases of potential radiation overexposure during computed tomography (CT) procedures at facilities in California and Alabama, and a recent series of *New York Times* articles highlighting medical issues associated with excessive or incorrect radiation. The new FDA initiative also coincides with recent congressional scrutiny of medical radiation. For example, the House Energy and Commerce Committee's Subcommittee on Health plans to hold a hearing to examine the potential benefits and risks of the use of radiation in medicine. The FDA initiative targets the three types of medical imaging procedures that account for the largest share of patient radiation exposure in the United States: CT, fluoroscopy, and nuclear medicine.

Of importance to device manufacturers, a key component of the FDA's multifaceted initiative is its plan to develop new requirements and safeguards for CT and fluoroscopy devices to ensure their safe use and reduce unnecessary radiation exposure. The FDA states that it may consider, for example:

- Requiring CT and fluoroscopy devices to display, record, and report radiation settings and doses
- Adding an alarm function to alert users when set doses exceed a diagnostic reference level, a peak skin-dose threshold for injury, or other established value
- Adding the ability to report a patient's radiation dose to his/her electronic health record and national dose registries
- Requiring manufacturers to provide training for healthcare providers on the safe use of CT and fluoroscopy devices

In addition, the FDA is considering requiring that new premarket submissions for CT and fluoroscopy devices include additional data to support specific clinical uses. The FDA is holding a public meeting on March 30-31, 2010 to seek input on what requirements would be appropriate to reduce the risk of unnecessary radiation exposure.

The FDA also is working with the Centers for Medicare and Medicaid Services (CMS) to incorporate quality assurance practices into CMS's accreditation criteria for stand-alone medical imaging facilities and its Medicare participation criteria for imaging facilities and hospitals. Other components of the FDA's new initiative include encouraging further research to establish optimal radiation dosing levels

and developing tools for patients to track their medical imaging and radiation exposure history. Earlier this month, the National Institutes of Health (NIH) also announced its plan to track radiation exposure from CT scans and other procedures in patients treated at NIH.

Device manufacturers, hospitals, and other imaging facilities should consider attending the FDA's public meeting and providing comments on potential new requirements for such devices. Given the recent publicity and regulatory focus on unnecessary and, in some cases, excessive radiation exposure during medical imaging procedures, both manufacturers and imaging facilities should be alert to the potential for additional liability risks related to imaging devices and procedures. At a minimum, key personnel should be sensitized to and properly trained regarding FDA's increased scrutiny in this area. Device manufacturers and hospitals should also consider whether there are other preventative steps that should be taken in connection with their particular products or programs. Additionally, manufacturers, hospitals, and other imaging facilities should consider preparation of a communications strategy to address questions concerning the recent investigations and regulatory actions affecting medical imaging procedures.

Morgan Lewis's FDA/Healthcare Practice regularly represents device manufacturers, hospitals, and other health care providers in FDA and CMS regulatory matters. As congressional and regulatory scrutiny increases for medical imaging devices and procedures, the attorneys in our FDA/Healthcare Practice can assist you in navigating new legislative and regulatory developments related to medical imaging and radiation exposure.

If you would like more information or have questions regarding any of the topics discussed in this LawFlash, please contact either of the following Morgan Lewis attorneys:

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