



November 9, 2006

Andrew C. Von Eschenbach, M.D.
Acting FDA Commissioner
Division of Dockets Management (HFA-305)
Food and Drug Administration (FDA)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. 2006N-0292 – Unique Device Identification; Request for Comments

Dear Dr. Von Eschenbach:

The American Society for Therapeutic Radiology and Oncology (ASTRO) greatly appreciates this opportunity to respond to the FDA's request for comments about the possible development of unique device identification (UDI) systems as noticed on August 11, 2006 at 71 Federal Register 46233. ASTRO is the largest radiation oncology society in the world, with more than 8,500 members who specialize in treating patients with radiation therapies. As a leading organization in radiation oncology, biology and physics, the Society is dedicated to the advancement of 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 a rapidly changing healthcare environment.

ASTRO supports measures aimed at increasing quality of care and reducing the likelihood medical errors. While there has been more study of the benefits of bar coding for pharmaceuticals, it stands to reason that for some devices, the development of UDI could also have a meaningful impact in increasing patient safety and reducing medical errors. We also can appreciate the efficiency that could be provided by UDI in improving delivery and supply chain functions in hospitals. For these reasons, ASTRO looks forward to working with the FDA as it contemplates promulgating regulations in this area.

As the FDA evaluates comments received in response to this request and determines if a new UDI system is in fact needed, ASTRO would recommend that a workgroup of stakeholders be formed. This workgroup could be particularly helpful in bringing practical knowledge about the types of devices that might be suited to UDI implementation, in reviewing the advantages and disadvantages of existing UDI technologies, in sharing information to help facilitate global harmonization, and in reducing redundancy with other regulations.

In general, we agree that if FDA proceeds in this direction, identification should be placed on the packaging of devices at the unit of use level. We think it is important to have a balanced approach and would support a reasonableness test with regard to patient safety in determining the unit of use for devices. For instance, items such as gloves, cotton balls, tongue depressors, and many Class I devices sold over the counter, should not require identification of every single item.

Should FDA decide to develop regulations for a UDI system, ASTRO recommends grandfathering devices, particularly capital equipment, from such a system. ASTRO also believes a process should be developed for regular, ongoing monitoring and evaluation of the UDI system to assess whether the system is in fact reducing medical errors and enhancing patient safety by improving device tracking, adverse event reporting, and product recall processes.

ASTRO believes that bar coding or some other UDI system for some devices could be beneficial to both doctors and patients. Potential benefits in the field of radiation oncology might be associated with a UDI system for catheters and some brachytherapy applicators. Hospital supply chain management might also be improved with UDI for items such as the component parts used to make individually-tailored patient immobilization devices for radiation therapy.

We have questions, however, about the reasonable applicability of UDI to all devices used in the practice of radiation oncology. For example, we do not see how the application of such a UDI system would be beneficial or practical for the capital equipment used in the provision of radiation therapy such as linear accelerators.

The Nuclear Regulatory Commission (NRC) has jurisdiction over the use of medical isotopes and hence regulates much of the practice of radiation oncology. The NRC's mission is to ensure health and safety and its regulations provide for the radiation safety of workers, the general public, and patients. NRC's regulations govern both the quality assurance practices in the manufacturing of devices with radioactive materials as well as the training and experience requirements of those individuals who are authorized to handle this equipment. We are concerned that a new UDI requirement for capital equipment used in radiation oncology could be duplicative or in conflict with these regulations and request that the FDA carefully review the safety standards that are currently in place to determine if there is a need for additional standards.

In addition to the NRC's regulations, the private sector has driven other efforts to enhance patient safety and reduce medical errors. For example, to help secure patient safety, many radiation oncologists use patient verification systems that include barcodes on patient charts or on patient identity cards to verify that the each patient is receiving the treatment that was tailored to his or her needs. In other words, a voluntary UDI system has been implemented for patients. This voluntary safety system is practical, efficient, and reasonable given the risk factors involved in the radiation oncology setting.

In conclusion, ASTRO supports the concept of UDI but urges the agency to create a workgroup to assess the need and practicability of a UDI system across various types of devices. We would look forward to participating in such a workgroup.

Sincerely,

Laura Thevenot
Chief Executive Officer