



Health Industry Business Communications Council

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FOR IMMEDIATE RELEASE

New York Times Exposé of Medical Device ID Errors that Lead to Patient Deaths Could Spur FDA Action to Require HIBCC Labeling

Phoenix, Arizona (August 20, 2010) – *US Inaction Lets Look-Alike Tubes Kill Patients*, an article written by Gardiner Harris and published in the *New York Times* on Friday, August 20, 2010 describes the death of a 24 year-old expectant mother that was the result of a mix-up of a feeding tube normally inserted through a patient's nose with one used intravenously. Because the tubes are extremely similar in appearance and have the same connection valves, the feeding tube was accidentally inserted into the patient's vein, thereby leading to the death of both the mother and her unborn child.

Medical errors involving incorrect device identification are not uncommon and will be reduced as a consequence of the US Food and Drug Administration (FDA) enforcement of existing and pending regulations that require item identification on package labeling down to the unit-of-use level. These labels will provide nurses and other practitioners the ability to correctly identify items prior to their use by scanning bar code labels on the packages.

The Health Industry Business Communications Council (HIBCC) created the *Supplier Labeling Standard* for precisely this purpose. Already widely deployed and prevalent on medical device packaging, the Standard provides a road-map for unique identification of all medical devices at every packaging level. The HIBCC standard is already accepted by the FDA as appropriate to meet its regulations for pharmaceutical labeling, and is now under active consideration by FDA for its' pending "Unique Device Identification" (UDI) requirements, which are directed at items such as the tubing described in the *Times* article.

"Because the vast majority of device manufacturers are already using and familiar with the HIBCC standard, and because it so well suited to meet FDA objectives – to reduce medical errors and increase patient safety by uniquely identifying every device – implementation of HIBCC labeling standards could dramatically reduce these tragic errors" stated Robert Hankin, PhD, President of HIBCC. "Those manufacturers that are already applying HIBCC labeling, and those hospitals already using the labels at the patient bedside are to be commended. We believe FDA action can make these practices a reality throughout the health care system." Hankin went on to note that "the tubes described in the *Times* article are precisely the type of product for which HIBCC Standards were created."

HIBCC is a non-profit standards development organization that is accredited and recognized by the American National Standards Institute (ANSI), the European Committee for Standardization (CEN) and the International Organization for Standardization (ISO). HIBCC's mission is to reduce medical errors and facilitate electronic commerce by developing appropriate standards for product and location identification among health care trading partners. HIBCC activities are managed globally via various international affiliates.

To read more about ANSI/HIBC 2.3 the HIBC Supplier Labeling Standard, please visit www.hibcc.org.

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