

# Stakeholders Debate Proposed Pediatric X-Ray Labeling

Stakeholders said proposed FDA x-ray labeling, which cautions against the device's use in children if there is not data to back up the pediatric use, could force hospitals to use the devices off-label and proposed alternatives, including labeling with the intended use of the device. Stakeholders said x-ray devices already make accommodations for children and worried the FDA-proposed labeling would limit the number of devices available for pediatric uses as companies might not seek the data to make pediatric claims.

Ralph Lieto, a medical physicist at St. Joseph Mercy Health System, said the American Association of Physicists in Medicine "strongly opposes" the FDA proposed labeling. He said the majority of pediatric imaging takes place in community hospital settings where devices are used to image a broad spectrum of patients, with the understanding that the device is acceptable on the entire range of patients. Lieto added that the labeling would only be appropriate for devices that could not be adjusted for patient size. "We feel that these devices can be used on a broad spectrum of patients regardless of age," he said.

The proposed labeling is part of an effort by FDA to encourage x-ray manufacturers to pursue pediatric indications that are not widely sought. The agency is calling for new x-rays to provide data to support pediatric indications or have labeling stating that the device should not be used in pediatric populations.

A draft guidance released in May outlining the proposed labeling -- along with other information that should be provided in premarket notifications for x-ray imaging devices with pediatric indications -- is part of FDA's larger initiative to reduce unnecessary radiation exposure from medical imaging. In its draft guidance, FDA proposed a label that would include a cautionary statement saying the device is not for use on patients under a certain size. The label, along with other aspects of the draft guidance and FDA's approach to pediatric imaging devices, were debated during a public meeting on Monday, July 16.

Lieto said a label cautioning against the use of a device on patients of a certain size would require the end user to operate the machine off-label. Keith Strauss, a clinical imaging physicist at Cincinnati Children's Hospital Medical Center, said pediatric hospitals would likely purchase adult-only equipment and use the devices off-label.

"I don't want to have to be the staff member that explains to Mr. and Mrs. Jones, who are upset because Johnny Jones, who is three, was just imaged on a radiographic machine that's got an FDA label on it that says on it that it is not appropriate for use in children under age five, even though we've done all the right things in the pediatric institution to modify the protocols to appropriately image that child," he said.

Further, Strauss said the pediatric imaging market is small and imaging vendors could decide that it is not worth the extra effort and it would not be cost effective to get a pediatric indication, which could limit the choices for pediatric hospitals who must purchase the equipment. Mahadevappa Mahesh, of the Johns Hopkins University School of Medicine, said labeling confining use of a device to a certain size could underserve populations, especially at smaller hospitals and in certain geographic locations.

Dorothy Bulas, a pediatric radiologist at Children's National Medical Center who spoke at the meeting on behalf of the American Academy of Pediatrics, questioned what impact the labeling changes could have on access to care, including if it could decrease the availability of studies on children if a device is deemed not pediatric-friendly.

The Medical Imaging and Technology Alliance has not taken a formal position on the labeling issue. But Paul Biggins, director of regulatory affairs at Toshiba America Medical Systems, who represented MITA at the meeting, suggested that the labeling could be an intended use statement, rather than a cautionary statement. He added that manufacturers will have to support pediatric scanning but they can't support scanning on a certain segment of the pediatric range. For example, not allowing a device to be used on neonates but allowing it for use on a 5 year old. Biggins also said x-ray devices are used in a broad range of patients in hospitals and can't just be "pediatric systems."

Donald Frush, a pediatric radiologist at Duke Medical Center who was representing the Alliance for Radiation Safety in Pediatric Imaging, said devices on the surface are appropriate for pediatric use but there "are clearly some technical bells and whistles not applicable to children" and there should be a cautionary statement unless they have been well tested. But, he also cautioned against restrictions on use of a device, and advocated for increased testing instead.

Frush proposed that the label could reflect that a device only be used by a person with appropriate training and education, however Biggins said this is already required on the labeling, adding that it is enforced by states but not FDA or CMS. Further, Frush proposed a general label saying a device is approved and designed for use across all patient sizes, much like the indication for use that appears in a device's labeling.

However, Mark Fogel, a cardiologist at the Children's Hospital of Philadelphia, who represented the American College of Cardiology, said there is a need to differentiate if a device can be used on a child. "It would be a disservice to take the pediatric out of it," he said.

FDA officials said the purpose of the labeling is not to drive manufacturers away from making pediatric devices or drive off-label use but to ensure companies consider all populations when making devices. They added that the caution statement being proposed by the agency is not the same as a contraindication, and also stressed that the labeling is only a proposal at this point.