

## FDA Launches Home Use Device Initiative

The U.S. Food and Drug Administration (FDA) has stepped up efforts to ensure that devices used in patients' homes are safe and effective.

The new initiative aims to offer guidance to manufacturers who intend to market a device for home use. In addition, the FDA intends to create measures to encourage safe use of these devices and develop educational materials for home use of devices.

An aging U.S. population and the fact that more patients receive at-home care prompted the FDA to take action. According to the FDA, about 7.6 million individuals in the United States currently receive home healthcare from roughly 17,000 paid providers.

Home healthcare, however, creates certain challenges as many medical devices “are still too complex for a lay person to use safely and effectively without proper training,” an FDA white paper notes. “In many cases, home care recipients may use devices that were designed for use by trained healthcare professionals in an acute care facility, not by lay caregivers in a non-clinical setting.”

Environmental factors—such as children, pets, and poor air quality—also present challenges. To address these issues, FDA plans to take the following steps:

- **Establish guidelines for manufacturers of home use devices.** FDA will develop a guidance docu-

ment with actions that manufacturers should take to receive FDA approval or clearance of home use devices, including usability testing with lay users in a non-clinical setting.

- **Develop a home use device labeling repository.** This will provide caregivers information about the proper use of the device. FDA will conduct a pilot program in summer 2010 where manufacturers voluntarily submit their labeling to the agency for this repository.
- **Partner with home health accrediting bodies to support safe use.** The FDA will partner with the Joint Commission and the Community Health Accreditation Program to strengthen accreditation criteria for the safe use of in-home devices.
- **Enhance postmarket oversight.** FDA will strengthen the HomeNet arm of its Medical Product Surveillance Network (MedSun).
- **Increase public awareness and education.** FDA is launching a new website and creating brochures and educational videos.

FDA also held a public workshop recently to solicit feedback from manufacturers and users about the issue. For more information about FDA's home healthcare initiative, visit [www.fda.gov/homeusedevices](http://www.fda.gov/homeusedevices). ■

### Inside the FDA's Home Use Device Initiative

Nurses are often the first to notice problems with medical devices, so it should come as no surprise that a former home healthcare nurse—Mary Weick-Brady, who heads up the FDA's Home Healthcare Committee—played a driving role in the new FDA home use device initiative.

In her six years as a home healthcare nurse, Brady saw firsthand the problems that could be encountered with medical devices in the home. “I was a troubleshooter,” she says, “and found that helping patients use items like infusion pumps was very difficult because there were often no instructions for use or other materials to help you understand the equipment.”

Brady went on to join the FDA's Center for Devices and Radiological Health and, about nine years ago, gathered a group of interested individuals from FDA and other government agencies to discuss issues related to home use devices. This effort led to a public meeting in 2002.

“We held many small meetings over the following

years to work through the issues,” she says. Many of the recommendations developed through that process are being used in the new FDA initiative.

“We are very excited to get this effort started,” says Brady. “We're hoping for feedback from everyone to ensure that we're going down the right track together. Our goal is clarity for all manufacturers across the board.”

Brady also participated in development of the new international home healthcare standard IEC 60601-1-11, *Medical electrical equipment—Part 1-11: General requirements for basic safety and essential performance—Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*. The new AAMI Home Healthcare Committee will be considering American adoption of this standard; for more information on the AAMI committee, contact Jennifer Moyer at [jmoyer@aami.org](mailto:jmoyer@aami.org).



Mary Weick-Brady