

An Interview with the FDA's Mary Brady

Patricia Patterson recently interviewed Mary Brady of the Food and Drug Administration's (FDA) Center for Devices and Radiological Health. Brady was one of the driving forces behind the FDA's new home use device initiative (see related article in this publication).



Brady shared these thoughts to share about home use devices and labeling:

On the importance of technology in home healthcare:

More people are living at home with chronic conditions, from premature infants with lung defects to people with congestive heart failure. Patients may be relying on technology for monitoring and treating conditions on a continuous basis, or have been sent home from the hospital still needing equipment to help them recuperate. As the population is becoming more independent with personal care, they are demanding technology that is useful and usable, and that will fit into their daily lives

and schedules. Technology has to adapt to the lay user and this uncontrolled environment.

On the importance of labeling:

Right now, labeling for home healthcare users is extremely varied. This is especially true if the device has been rented from a medical device supplier or if it is being purchased second-hand. Often, if healthcare professionals are setting up the equipment, they develop their own set of instructions or reinterpret existing labeling for the end user to make it easier to understand. Without a healthcare professional in the mix, the caregiver or care recipient is at risk of misunderstanding the instructions.

The labeling needs to be standardized, easily read, in large print, step by step, and short. There should be minimal contraindications, warnings and precautions—the user should not be afraid to use the device. If the device is not easily used or is not compatible with the care recipient's lifestyle, he or she will not use it.

See *Human Factors in Labeling and Training for Homecare Technology*, by Patricia A. Patterson, p. 33, in **Home Healthcare Horizons**, 2010.