FDA NEWS OF SAFETY

Facts from the U.S. Food and Drug Administration

"Home Use" Medical Devices: Benefits And Challenges

(NAPSA)—The rapid growth in sales of medical devices used at home represents one of the "hottest" emerging areas in health care. Well-known trends are converging to increase the role of home use devices. They are:

• a changing population, in which there are decreasing numbers of nurses and an increasing geriatric patient population.

• insurance company practices, which encourages patients to leave hospitals earlier and to continue medical care at home.

• sophisticated new products being designed into smaller and less expensive packages.

Examples of advanced medical technology used at home include medical delivery devices, implanted pacemakers and defibrillators and "telemedicine" devices that transmit information about patients—such as weight, blood pressure, body temperature, blood oxygenation, blood glucose and lung function—from their homes to the doctor's office.

Some of the devices that patients will be taking home in the near future would have looked like science fiction a few years ago.

• "Smart bandages" will be able to detect signs of infection and "recommend" treatment.

• Exoskeleton systems and functional electrical stimulation (FES) systems will restore use to the paralyzed limbs of quadriplegic patients.

• A biosensing toothbrush will check patient's blood sugar and levels of bacteria during toothbrushing.

As these complicated and more capable devices are being introduced, they challenge the ability of home users who often lack familiarity with high-technology devices and medical care. Manufacturers usually include manuals and may give training, but this is no guarantee that patients will be able to avoid problems. This is because some devices require the user to understand complex processes and terminology.

These are called "human factors" problems and they are well-known and problems in hospitals, despite the fact that medical devices are being operated by well-trained health practitioners, with on-site service, and the support of other doctors and nurses.

The FDA's Human Factors Program helps ensure that manufacturers are making human factors part of the design and testing of their new medical devices. When a dangerous problem ("adverse event") with a medical device—a serious injury, death, or near miss—is reported to the FDA, members of the Human Factors Group help investigators find out if the event was caused by human factors or shortcomings in the design of the device.

The FDA is working hard to keep up with the rapid changes in the design and sale of home use medical devices. To learn more, visit www.fda.gov.