Medical Devices in the Home: What FDA is Doing

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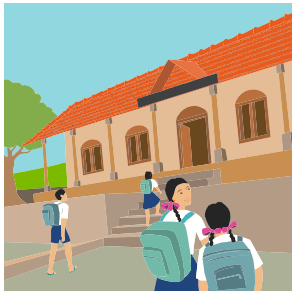
Mary Weick- Brady, MSN,RN
Senior Policy Advisor
Office of the Center Director
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Why Focus on the Home?

- Faster discharges from clinical facilities
- Elderly population
- Individuals with chronic diseases

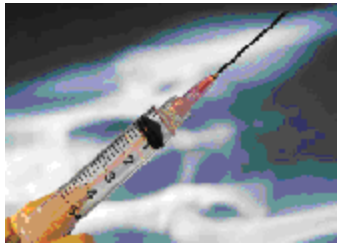
What is considered “Home”?

Any environment other than a professional healthcare facility or clinical laboratory where a device may be used



Home Use Devices Are:

- **Disposables & Accessories**
  - Oxygen therapy related devices
  - Needles, syringes, IV catheters, tubing, foley catheters, gloves
- **Implantables**
  - Defibrillators,
  - Hip/knee implants
- **Computerized Medical Systems**
  - Infusion pumps
  - Dialysis
- **Reagents**
  - Fecal occult blood tests
  - Lyme Disease tests
- **Durable Medical Equipment**
  - Wheelchairs
  - Patient Lifts

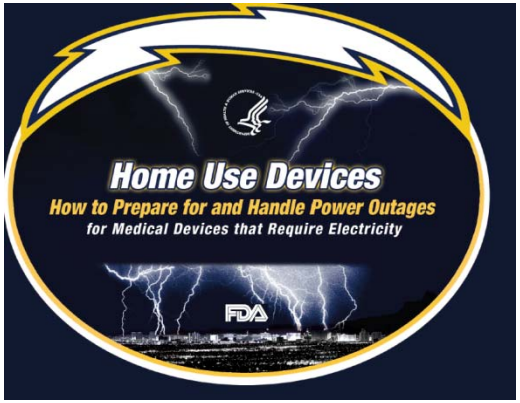


Home Use Medical Device Initiative 2010

1. Establish guidelines for manufacturers of home use devices;
2. Develop a home use device labeling repository;
3. Partner with home health accrediting bodies to support safe use;
4. Enhance postmarket oversight; and
5. Increase public awareness and education

2013: Consumer Information

- CPAP Tips from FDA
- Consumer Update - Making Medical Devices Safer at Home
- How to Prepare for and Handle Power Outages



A. Environmental Considerations

- Location
  - Urban/suburban/rural
  - School/office/retail environments
  - Electromagnetic interference (EMI)
- Physical location
  - Crowded environment
  - Movement from room to room
  - Wireless signal
- Contaminants
  - Non-sterile environment
  - Vermin, pets, tobacco, smoke, household chemicals
- Water Supply
  - Type of water: ex. well water vs. distilled water

Environmental Considerations (cont.)

- Temperature
  - Fluctuations and extremes in temperature
- Dampness and humidity
  - Static
- Atmospheric pressure changes
  - Low pressures on mountains/air travel
  - High pressures below sea level
- Airflow
- Childproofing
  - Minimal detachable parts
- Tampering
  - Intentional or non-intentional use

Environmental Considerations (cont.)

- Travel and International Use
  - Electrical supply/voltage rates
  - Electrical converters
  - Back up batteries
  - Passing through security – pat down, backscatter x-ray
- Fluid Exposure
  - Fluid spills
  - Submersion

B. User Considerations

Physical: size, mobility, coordination, flexibility, strength, stamina

Sensory/Perceptual:

vision/hearing abilities, sensitivities, ambient light conditions, alarm visibility

Cognitive:

literacy level, cognitive impairment

Emotional:

anxiety, fear

Home care recipient

Co-morbidities

19 medications

Can walk 20 feet without assistance

Monthly home visits

Picc line for 7 years

Recuperating from surgery

Full disability

Unable to drive

Self-monitors

Performs infusion therapy

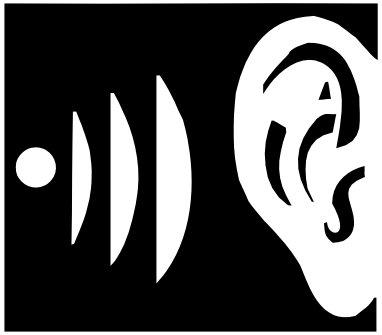
C. Device Considerations

- Lock-out Mechanisms
  - Design solutions vs. lock-out mechanisms
- Calibration
  - No calibration/minimal calibration
  - Step-by-step instructions
- Mechanical Strength
  - Portability
  - Withstand transport conditions on trains, road vehicles, cycles, ships, aircraft

Device Considerations (cont.)

- Electromagnetic Compatibility (EMC)
  - EMC testing

- Wireless Technology
  - Radio frequency (RF) wireless technology
- Alarm Systems
  - Noise inside/outside the home
  - Hearing impairments
  - Visual, auditory, tactile alarm signals



Device Considerations (cont.)
Electrical Issues

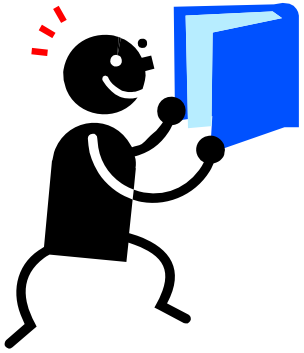
- Supply Mains
  - Interruption of power supply/supply mains
  - Voltage limitations
- Internal electrical power source
  - Typical operation time
  - Recharging
  - Replacing
- Permanently installed devices
  - Protective grounding
- Outlets and Adapters
  - Surge protection
- Power outages
  - Back-up power
  - Emergency contact information
- Battery life

D. Human Factors

- Human factors validation study
- User training and certification
- Outline responsibilities of care partner, caregiver, and care recipient
- Recertification/retraining

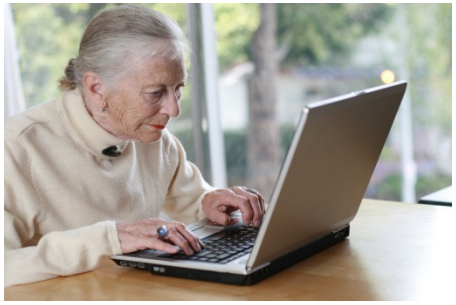
E. Labeling

- Simple, concise, easily understood
- Narrative format and pictures
- Hazardous waste material disposal
- Hygienic maintenance



Post Market Considerations

- Customer service
  - Technical assistance phone numbers, website, email address
- Selling/Purchasing used prescription devices
- Medical Device Reporting
  - MedWatch



MedWatch- Reporting IN

HOW FDA FINDS OUT ABOUT POST MARKETING RISK AND SAFETY ISSUES

- **Reports of serious adverse events**
  - death, life-threatening, required hospitalization, disability or permanent damage, birth defect
- **Reports of medication errors**
  - wrong dose, wrong medication…
- **Reports of product quality issues**
  - contamination, counterfeit, poor packaging or labeling, product mix-ups, device malfunction…

MedWatch
Reporting IN

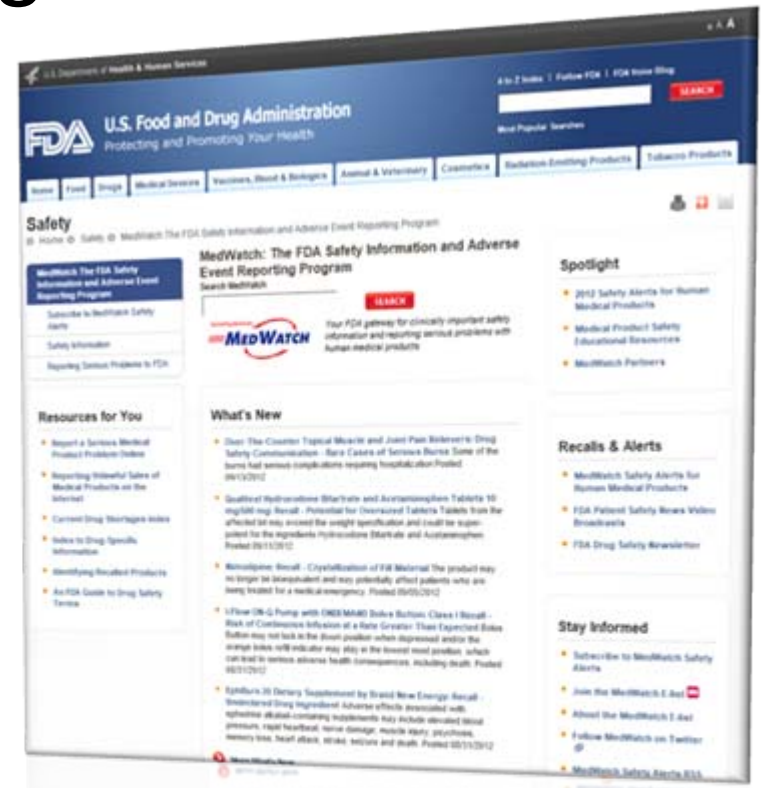
- Anyone can report a serious problem.

Reporters: consumers, healthcare professionals, public

MedWatch
Reporting IN

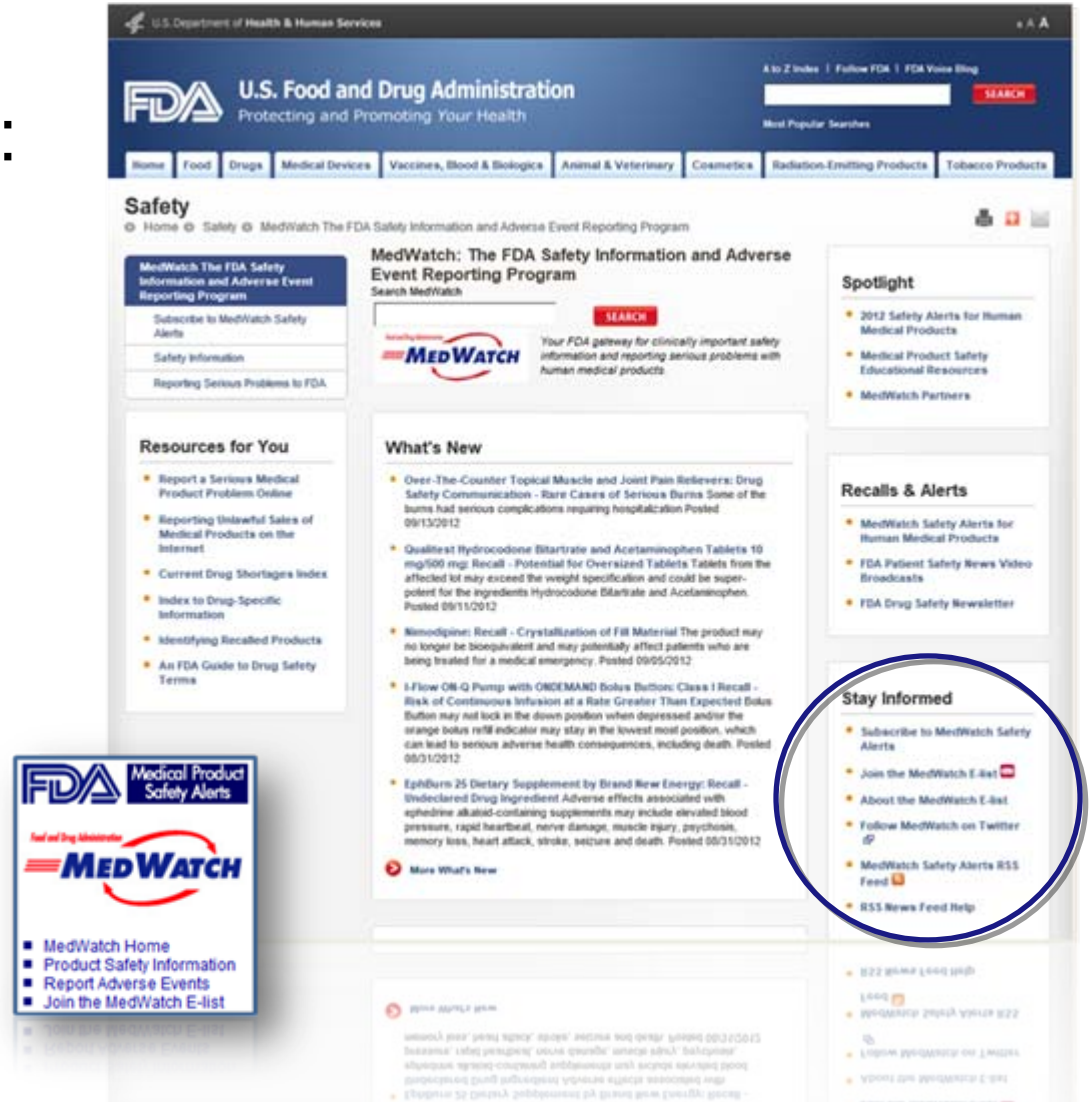
- How to Report:
  - Online (www.fda.gov/MedWatch)
  - Download the form
    - Mail
    - Fax
- For questions about the form:

  1–800–332–1088



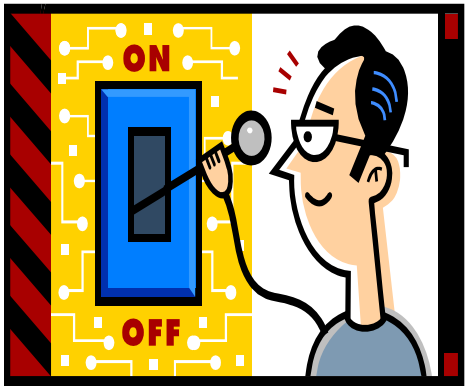
Safety OUT

- Staying Informed: Information Delivered to You
- Subscribe to MedWatch
  - E-list
  - Text alerts
  - Twitter
  - RSS feeds

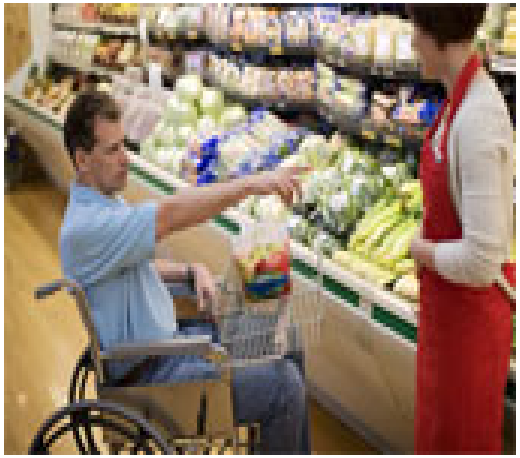


Home Use Devices Should Be:

- Useful
- Usable
- Iterative
- Intentional
- Intuitive
- Integratable
- Informative
- Addressing the risks unique to the home



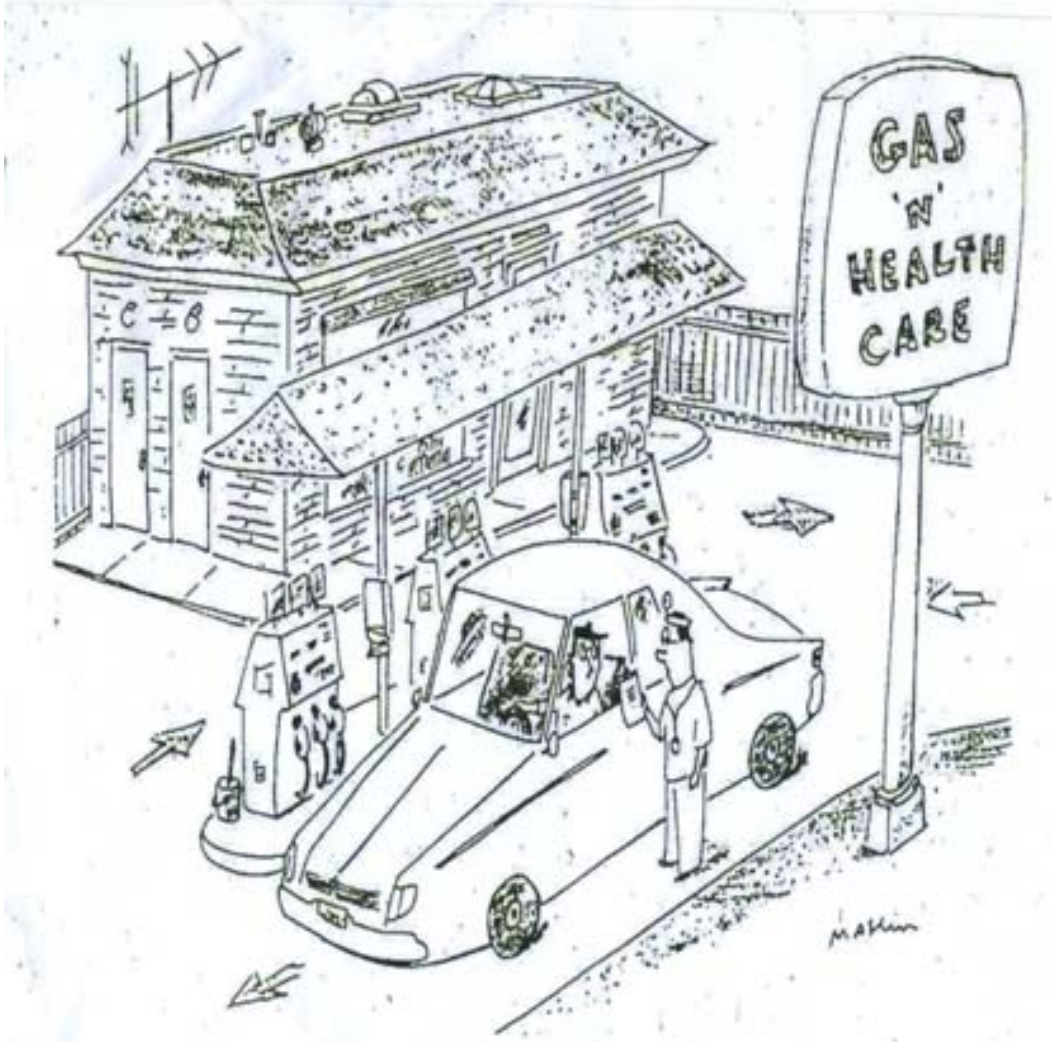
SAFE AND RELIABLE DEVICES LEAD TO LIVING WELL



Resources

- FDA's Home Use Devices website
- Draft Guidance for Industry and FDA Staff - Design Consideration for Devices Intended for Home Use
- Comment on guidance
- Consumer Update - Making Medical Devices Safer at Home
- http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm334501.htm

Questions?



"Your oil's fine, but your blood-sugar level's a little low."