MEDICAL DEVICES IN THE HOME

FDA BASICS WEBINAR
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Why Care About the Home?

- Patient demographics
- Economic forces
- Technological advances in devices
- Devices not intended for the home are going home
- The home is an uncontrolled environment
- Patients are smarter about their health
- Quality of life better when living at home
Home Care Facts

- 17,000 home care organizations (9284 Medicare certified)
- 7.6 million individuals in home care
- 44 million are caregivers of someone >18
- 1/5 US adults report a disability (47.5 million)
- $57.6 billion per year
- Growing 20% per year
- 75% receive skilled nursing
- 69% > 65 years old
- 2/3 are women
- By 2030, 71.5 million over 65

(National Association for Homecare 2008 and BCC Research 2010)
“A home use medical device is:

intended for users in any environment, apart from the professional healthcare facility or emergency medical services, and may require training for the user by a qualified healthcare professional to assure safe and effective use.”
Regulated Devices in the Home

- **Capital Equipment**
  - Beds, wheelchairs, lifts

- **Therapeutics**
  - Hemodialysis, infusion therapy, wound therapy

- **Instruments**
  - Pulse oximeters, AEDs

- **Telemonitoring**
  - Telemedicine, cardiac monitors

- **Disposables and Accessories**
  - Filters, canisters, needles, tubing

- **Implantables**
  - Pacemakers, aneurysm clips

- **Computer Systems**
  - Hardware, software, mobile applications

- **Reagents**
  - Fecal occult blood

- **Over the counter**
  - Band aids, toothbrushes
Technology for the Home

- Sensors
- Smart Homes or Medical Homes
- Health Informatics
- RFID for orthopedic implants
More Technology for the Home

- Wireless and Broadband
- Mobile Apps
- Telehealth
- Remote Monitoring
Unique Challenges in the Home

- Unpredictable environment
  - Children
  - EMI
  - Location
  - Noise
  - Pets and vermin
  - Power outages and sources
  - Public emergencies
  - Safety
  - Sanitation
  - Space
  - Temperature, air quality, humidity
  - Water
Unique Challenges in the Home

Device Usability

- Compatibility with lifestyle
- Instructions for use are poor or nonexistent for lay users
- Interface and ease of use
- Off label use
- Ruggedness of the device for many conditions
- Selling Rx devices on the Internet
- User’s
  - educational level
  - emotional stability
  - physical capabilities
Newer Technology? New Problems

- Assurance that messages are transmitted
- Failure in one part of a system
- Hacking into systems
- New versions of software or apps
- Privacy of information
- Security
- Support of the “old” apps or software
#1: Guidelines

- Develop a total product life cycle guidance for manufacturers
  - Covers
    - design and human factors
    - labeling and instructions for use
    - design for use in an uncontrolled environment
    - the user
    - post market oversight
  - Public Workshop held May 2010
  - Out for public comment this year
  - Incorporates an international electrical standard for home use medical equipment
#2: Home Use Labeling Repository

- Receive labeling for home use labeled products
- Electronic transfer of information
- Pilot test ongoing until August 2011
- 6 volunteer manufacturers
- System is new to devices
- Make the labeling searchable and readable by anyone, includes pictures and graphs
- Have all device labeling on a website?
#3: Partner With Home Health Accrediting Agencies

- 4 main accrediting bodies in
- Review their standards
- Incorporate medical devices
- Incorporate Unique Device Identifiers when this is ready
#4: Enhance Post Market Oversight

- Monitor device performance in use
- Identify problems and safety issues
- Detect and evaluate problems early
- Address problems that occur with use
- Require post market studies as needed
#5: Increase Public Awareness and Education

- Work with non-profit organizations to educate their customers about devices
- Developing You Tube videos
- Brochures and booklets
- Website (www.fda.gov/homeusedevices)
- Numerous presentations, webinars, and articles
MedWatch

• US adverse event reporting system
• Passive
• Voluntary reporting of product problems
• Mandatory reporting by manufacturers and user facilities
  – Manufacturers report deaths, serious injuries, and malfunctions to FDA
  – User facilities report deaths to FDA and the manufacturer, and serious injuries to the manufacturer
How Do I Report?

• Voluntary reports can be submitted by calling the FDA at 1-800-FDA-1088 or by mailing in the MedWatch 3500 form, available online at:

Home Use Devices Must Be…

- Useful
- Usable
- Iterative
- Intentional
- Intuitive
- Integratable
- Informative
- Address the risks unique to the home
- Address human factors design requirements