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From Hospital to Home: Mastering Home-use Medical Device Warnings

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LAW ELEVATED

Introduction and Roadmap

Medical Devices

What is considered a home-use medical device?

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Home Use Medical Device

FDA defines a ***home use medical device*** as a device intended for users in a non-clinical or transitory environment, which is managed partly or wholly by the user.

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Users and Locations

Users

Professional caregivers [i.e., nurse practitioners, physical and occupational therapists, social workers, and home care aids].

Lay caregivers [i.e., family members or friends]

** **Self-care** [i.e., patients operate a device themselves]

User Locations

- **Nonclinical environments**
  - Homes
  - Workplace
  - Schools
  - Hotels
  - Stores

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Types of Home Use Medical Devices

- **Prescription Home Use Medical Devices**
  - Insulin pumps, hearing aids, contact lenses, cold therapy machines
- **Over-the-Counter Medical Devices**
  - Glucose monitors, bandages, posture-supporting clothing, and TENS muscle therapy
- **General Wellness Devices**
  - Wearables, metabolism trackers, mobile applications

The Range of Home Use Medical Devices

First Aid Equipment

Assistive Technology

Test Kits

**Wearables and Mobile Applications

Pulse Oximeters

Glucose Monitors

Feeding Equipment

Nebulizers

Factors Driving the Growing Market for Home Healthcare Technology

Why Healthcare is Going Home

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Factors Driving the Growing Market

1. Aging Population
2. Rising Healthcare Costs
3. Advanced Technology

Home Use Device Considerations:

Understanding the Benefits and Risks of Home Use Devices

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Benefits of Home Use Devices

Cost and Convenience

Patients can avoid expensive and unnecessary visits to healthcare facilities.

This can be very beneficial for patients with limited mobility or those living in remote areas with limited access to healthcare.

Personal Autonomy

Home-use medical devices assist individuals to be more autonomous in the assessment and management of their health.

Quality of Life

Patients are likely more comfortable in their home compared to hospital-based care.

Patients can remain independent in later life.

Innovation

Technology is revolutionizing the healthcare industry and inspiring others to make meaningful changes.

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Risks of Home Use Devices

Caregiver/Patient Knowledge

Device labeling may include complex or difficult to comprehend warnings and precautions that confuse lay readers.

Disabilities, visual or other sensory impairments.

Device Usability

Older medical devices often come with little to no labeling/IFUs, and the device quality can vary.

Environmental Unpredictability

Unlike the clinical setting, the home is an uncontrolled environment. Risks include space limitations, the presence of children or pets, electromagnetic performance, sanitation issues, temperature, power, and maintenance issues.

Company Liability

Litigation stemming from various product liability theories.

Regulatory Framework for Home Use Medical Devices

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What is Medical Device Patient Labeling?

- Federal Food, Drug, and Cosmetic Act is the basis for FDA jurisdiction over labeling and advertising.
- "Adequate directions for use means directions under which the layman can use a device safely and for the purposes for which it is intended." 21 C.F.R. 801.5
- Labeling includes indication for use, contraindications, risks and benefits, set-up guide, instruction for use, maintenance procedures, and **warnings and precautions**.

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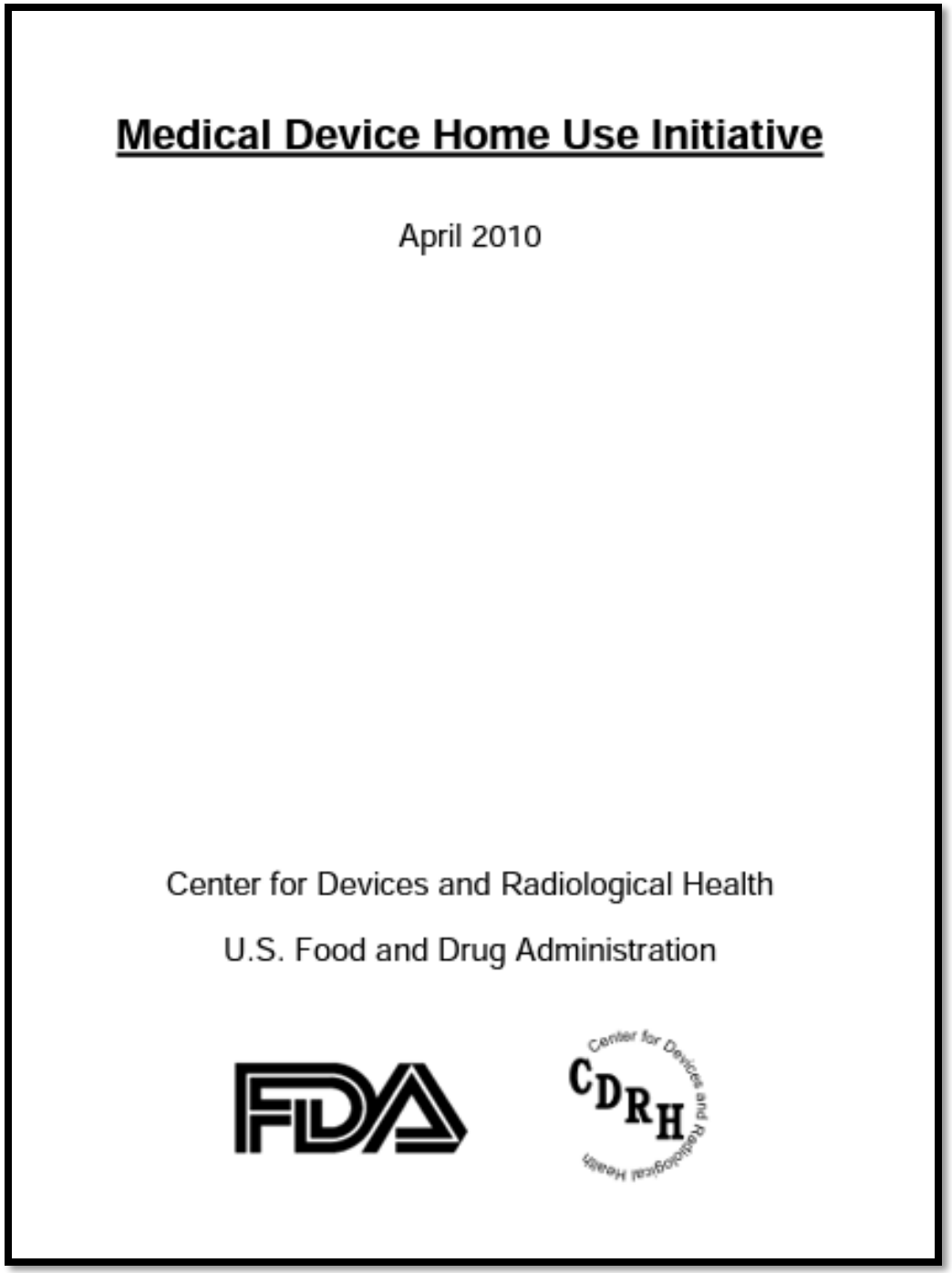
FDA Guidance

To date, FDA has not articulated a clear regulatory pathway for devices intended for home use. We have not described the unique factors manufacturers should take into consideration when designing, testing, and labeling such devices.



Medical Device Home Use Initiative

April 2010

Center for Devices and Radiological Health

U.S. Food and Drug Administration

FDA

CDRH

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Minimum Labeling Requirements 21 CFR 801

General Labeling Provisions

- Name and place of business of the manufacturer
- Street address
- Intended use
- **Adequate directions [directions under which the layman can use a device safely and for the purposes intended."**
- No false or misleading statements

OTC Medical Devices

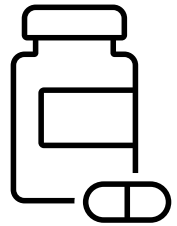
- 801.60-62
- Principal Display Panel
- Statement of Identity
- Net Quantity of Contents Statement

Wellness Devices

Not regulated by the FDA and **not subject to**:

- labeling requirements (21 CFR Part 801 and 21 CFR 809.10)

Guidance suggests that a general wellness product might be considered a "consumer product" under US Consumer Product Safety Commission.



Prescription Devices

- 801.109 - Exemptions
- Information for use including, indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which the device can safely be used.

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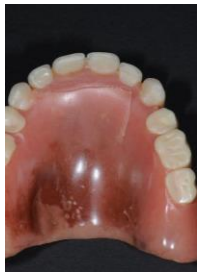
Special Labeling Requirements 21 CFR 801 & 809

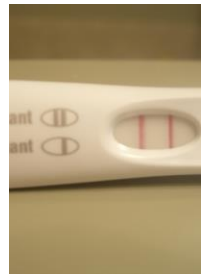


Warning and Caution Statements for Specific Devices

- 801.403
- Denture Repair Kits
- Infrared generators
- Mechanical massagers
- Etc.

Devices Requiring Additional Labeling Requirements

- 801.405 to 801.430
- Certain devices require specific labeling which may include not only package labeling, but informational literature, etc.
- Tampons, and hearing aids



In Vitro Product Labeling

- 21 CFR 809
- Instruments and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent diseases.

FDA's Guidance on Medical Device Patient Labeling

- Regulations are general and broad
- Fail to contain instructions for ***how*** to develop labeling that fits a patient's needs
- No "one size fits all" for labeling as different users have different needs
- According to the FDA, the biggest challenge areas are **warning statements**

Risk Mitigation: The Role of Warnings in a Product Liability Defense

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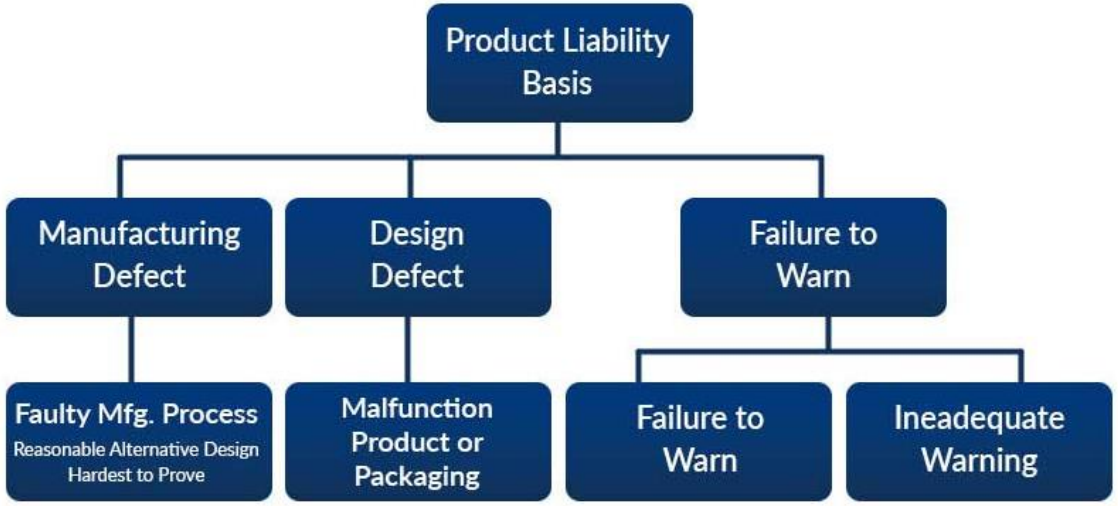
Product Liability Theories



Failure to Warn

The Plaintiff asserts that the defendant placed inadequate warnings of potential hazards on or with the product and the lack of proper warnings was a proximate cause of harm to the plaintiff.

Sufficiency of your device warning may be attacked based on negligence and strict liability in tort.

The Courts Answer: When is a Warning Adequate?

1. Alert the consumer or user to the severity of the hazard [severity being defined as the magnitude of the hazard and the likelihood of it being encountered];
2. Clearly state the nature of the hazard;
3. Clearly state the consequences of the hazard; and
4. Provide instructions on how to avoid the hazard.

Remember…the jury gets to decide the adequacy of warnings.

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Why does an adequate warning matter?

1. An adequate warning mitigates the risk of harm posed by a product because it allows consumers to make informed choices about whether and how to encounter certain risks
2. Warning labels allow companies to prove the negligence was on the part of the consumer.
3. Creates product transparency = patient brand loyalty
4. Warning labels protect innovation

Mitigate your risk

1. **Exceed FDA Requirements**: Maintain strong relationships with the FDA and stay educated about regulatory schemes to lower your risk of being accused of negligence.
2. Write the warnings right…

Risk Mitigation: Know your Audience and Write it Right

When you can't understand the directions, it's hard to be independent.

Prescription Home Use Devices: Challenges

- Complex devices designed for use by trained healthcare professionals
- Device selection by insurance companies. Device may not be optimal for setting
- Training occurs at hospital discharge, which can be suboptimal

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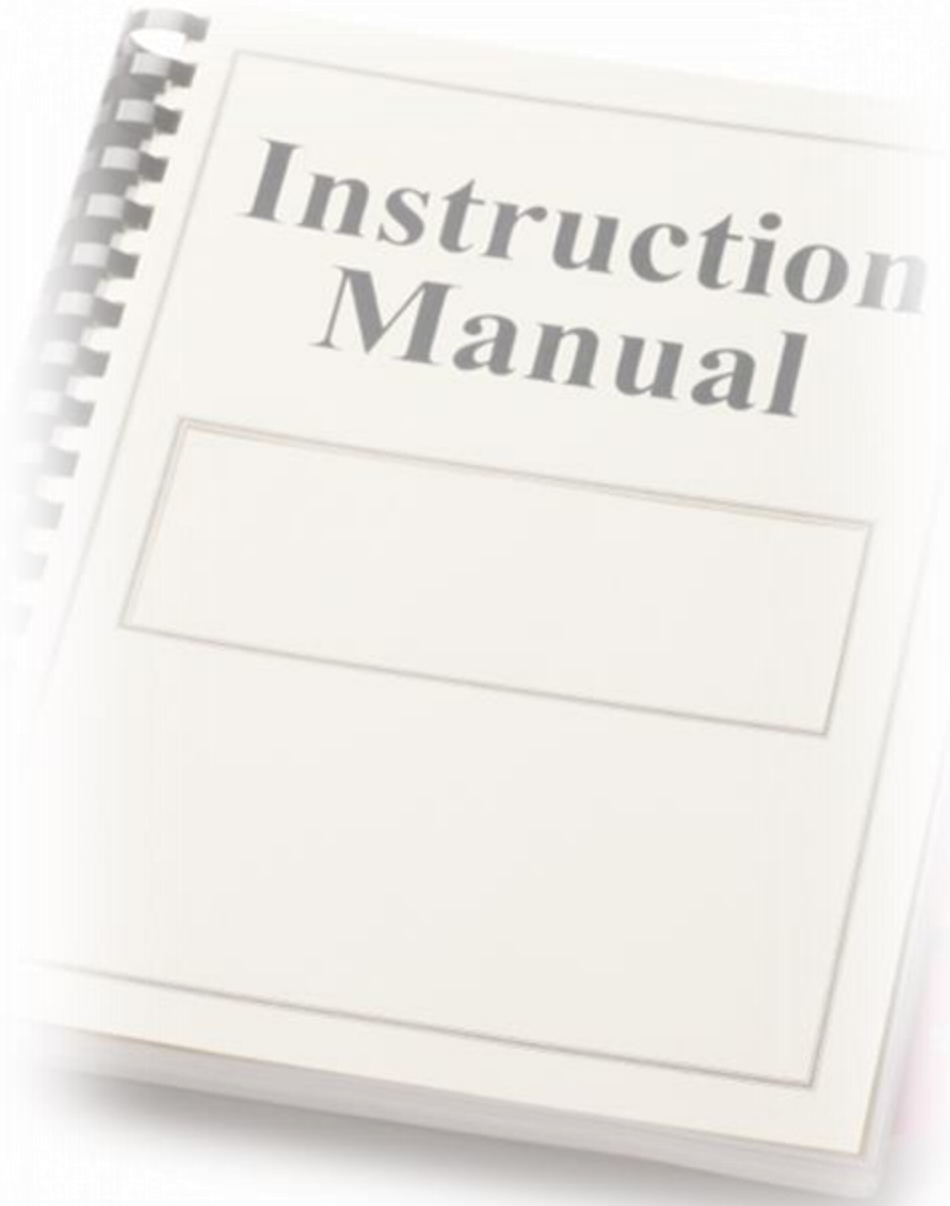
Labeling for the Layperson

- **User research**: *Who is your target audience? Elderly? Physically disabled? Habits & Behaviors?*

- **Task analysis:** *What are the steps necessary for performing the entire process. Should warnings be located within the tasks?*



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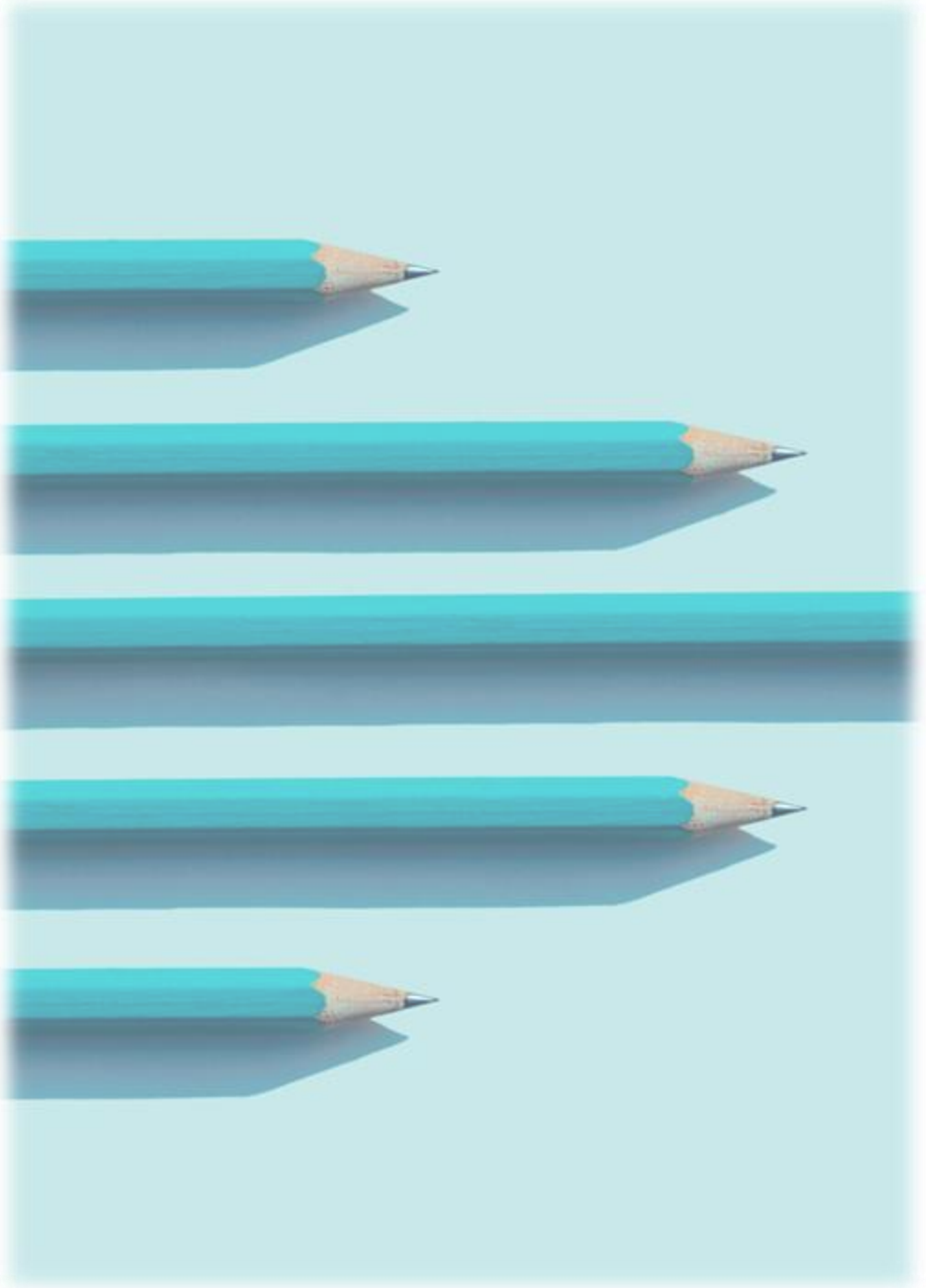
Labeling for the Layperson

- **Formatting**
  - 12 – 13-point font; spacing; white space
  - 4th – 6th grade reading level
  - "Need to know" information first
  - Avoid unnecessary words
  - Bullet points
  - Action words



Labeling for the Layperson: Thoughts

Your goal should be to provide the least competent user with the information necessary to use your device in the most safe and effective manner possible. No recommendations can guarantee that users will not make errors. But, with warnings that are easy to read and understand, the user is more comfortable with the device and is likely to make fewer errors. Good warnings promote the safe and effective use of your device by any user.

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What is appropriate content of an effective warning or precaution?

Signal Words

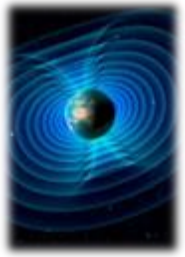
(WARNING, CAUTION) to alert the reader that what follows is important hazard information. A symbol or icon may emphasize the effect of the signal word.

Additional enhancement, such as bolding, larger type, underlining, italics, or color may help the information stand out from the rest of the text. However, studies have demonstrated that a large difference in font size between the signal word and the text may de-emphasize the importance of the text and therefore reduce the likelihood that the text will be read.

Hazard Avoidance Directive

Do Not, Never, Avoid..." (or Do, if more appropriate) followed by the action to avoid (or perform).

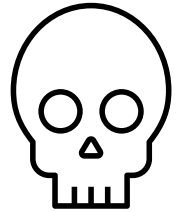
The objective of this directive is to give clear instructions to the user on how to avoid the hazard.



Nature of the Hazard

A clear statement of the nature of the hazard associated with the warning (e.g., allergic reaction to material, strong magnetic field) or precaution

(e.g., environmental effect, damage from resterilization) that characterizes the severity and the likelihood.)



Consequences

The consequences, specifying the serious adverse events, potential safety hazards and limitations in device use that result if users do not follow instructions. The purpose is to give them a clear idea of the risk, which is likely to increase compliance. Hazard alert research has shown that this element has a significant effect on readers. If the consequences are not included, the alert is likely to be less effective.

Other Considerations…Over warning?

1. According to the FDA, "[o]verwarning has the effect of not warning at all. The reader stops paying attention to excess warnings."

2. The inclusion of inappropriate warnings about speculative risks deters medicine use that may improve patients' health or save their lives.

Center for Devices and Radiological Health, FDA, Write it Right: Recommendations for Developing User Instruction Manuals for Medical Devices Used in Home Health Care 7 (1993).

Conclusion: Innovative Solutions for the Future

Issues and Future Solutions

1. Sensory Disabilities → 1. Haptic Feedback Labels
2. Visual Impairments → 2. Voice-Enabled Labels
3. Home Environment Issues → 3. Microfluidic Labels
4. Various Types of Patients → 4. Personalized Digital Apps

References: FDA Draft Guidance

1. Write it Right: Recommendations for Developing User Instructions for Medical Devices Used in Home Health Care, 1993
2. Device Labeling Guidance #G91-1 (blue book memo), 1991: Describes FDA's authority and process for reviewing patient labeling and when it is necessary
3. Guidance on Medical Device Patient Labeling, 2001: Provides significant detail about the construct and format of patient labeling, including formatting, readability, and user testing
4. Medical Device Home Use Initiative, 2010
5. General Wellness: Policy for Low-Risk Devices, 2019

Questions?

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