CHECKLIST FOR LABELS AND WARNINGS FOR HOME-USE PRODUCTS

Home-use products have been increasingly utilized by patients to improve their quality of life and to allow them greater independence. The increase in demand for home-use devices has been attributed to the United States' aging population and exacerbated by the COVID-19 pandemic. Medical technology and life sciences manufacturers have had to convert products typically used in a clinical setting into products for use by patients at home, without the direct assistance of a healthcare provider. This change in intended user alters the products liability risk profile of these products in several ways, particularly with regard to safety information. It is easier to write safety information for healthcare providers who share a common educational background than for members of the general public. This checklist provides general guidance for manufacturers related to developing labels, warnings, and instructions for home-use products and avoiding common problems that can lead to warning defect claims.

Planning Your Warnings & Labels

Drafting instructions and warnings without adequate information or preparation can generate more work down the road and can create products liability exposures. First, it is important to understand the differences between instructions and warnings. Instructions focus on teaching users how and when to properly operate the product, whereas warnings are intended to alert the user to risks associated with using the product. Both instructions for use and warnings must be drafted with an understanding of certain critical characteristics of the intended user group. For example, what content does the intended user require in order to use the product safely? Is the material written in language that is easily accessible to the average user? Are the warnings drafted in a manner that adequately conveys the severity of associated risks?

A manufacturer should have a good understanding of how patients will use (and misuse) its products before they begin to develop safety information content. This is particularly important as it relates to home-use products because these devices are intended for use by lay persons rather than trained healthcare providers. Before drafting begins, it is helpful for manufacturers to:

☐ **Determine how the labeling is most likely to reach the patient.** Consider whether an intermediary, such as a healthcare provider, should provide instructions for use and warnings to the patient or whether it should be provided directly to the patient without the intervention of the healthcare provider. Examine any potential obstacles to the labeling information reaching the patient and develop solutions to this problem before it arises.

☐ **Identify potential product hazards.** After the product design team has identified as many hazards as possible, attempt to identify remaining risks via risk assessment tools for process analysis (e.g., Failure Mode and Effects Analysis (FMEA), fault tree analysis, event tree analysis, etc.). Consider using multiple risk assessment methods to ensure that you have uncovered and addressed as many potential risks as possible.

Examples of Potential Product Hazards Unique to Home-Use Products

- A patient had been using an infusion pump that delivered medication measured in mL/day. He was given a new pump that administered medication in mL/hour. He programmed it, assuming that it was the same. As a result, the patient's medication was delivered too quickly.

- A seven-month-old patient was at home on a ventilator. The patient's parent found the patient attached to the ventilator, but the ventilator was no longer cycling, and no air was coming out of the circuit. The ventilator alarm did not sound.

- A patient was put on peritoneal dialysis. She had a cat. Although the patient kept the cat out of her bedroom while she was undergoing dialysis, there was cat fur and dander throughout the room. Cat fur got into the patient's dialysis tubing and entered her peritoneum. She contracted peritonitis.

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- **Identify internal personnel who may have valuable insight into the product and its potential hazards.** When identifying the potential hazards of a product, it is helpful to include a variety of persons from multiple disciplines to gain insight into the typical uses of the product as well as any reasonably foreseeable misuses. Such personnel may include any or all of the following:
  - Home healthcare providers,
  - Design engineers,
  - Human factors engineers/psychologists,
  - Packaging engineers,
  - Writers,
  - Marketing,
  - Customer service, and
  - Legal counsel.

- **Identify characteristics of the target audience.** FDA labeling regulations are concerned with instructing on the "intended use of the product," but products liability law requires labels also warn about hazards arising from the "foreseeable misuse" of products. In order to comply with both FDA regulations and state products liability laws, warnings and instructions for home-use products should address potential uses and misuses of the product by lay users in a non-clinical setting. In order to identify typical uses or misuses, begin by identifying likely characteristics of probable product users. This is particularly important for home-use products because the product user is most likely a lay person. Users can be identified by the following characteristics:
  - Age,
  - Gender,
  - Language,
  - Training,
  - Level of literacy (assume a reading comprehension level between grade 6-8),
  - Level of medical literacy,
  - Product familiarity,
  - Personality traits,
  - Hazard perception,
  - Psychological and emotional environment of use, and
  - Cognitive, sensory, or physical impairments.

- **Review external sources for information regarding potential problems.** Research existing problems associated with similar home-use products—or those of a competitor—from a variety of sources (e.g., scholarly journals, FDA website, internet, etc.) in order to anticipate any potential problems that might occur with the product that may require a specific warning.

- **Consider the entire life cycle of the product and the various environments in which product information may be transmitted.** Unlike clinical settings, the home is an uncontrolled environment with the potential for additional hazards. A product may be used in a clean, bright room or in a dark, dusty room; it may be stored with similar products and thus susceptible to mix-ups or be isolated; it may be subject to a great deal of maintenance or very little. Users may give away or resell the product once it is no longer needed, and may or may not have maintained the instructions for use and warnings to pass on to the next user.

Users who are not aware of certain dangers because of these or other contextual factors are vulnerable to injury, so instructions and warnings should be drafted to account for such environmental variables.

- **Plan for post market surveillance to ensure early detection and evaluation of problems.** It is important to continuously review the problems that may emerge with real-life use and to ensure that safety information is adjusted to adequately address these problems.

- **Consider the differences between the clinical setting and the at-home setting.** Some additional factors to consider when planning to draft safety information may include environmental factors like the presence of children; electromagnetic interference (EMI); noise; pets and vermin; power outages and electrical surges; public emergencies; sanitation; space; temperature; and humidity. Other potential risks specific to home-use products include compatibility with the user's lifestyle; the user's educational level; the user's emotional stability; and the user's physical capabilities.

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*Helpful Resources Regarding
Instructions & Warnings*

General Guidance Documents on FDA Website
- Labeling: Regulatory Requirements for Medical Devices (FDA 89-4203)
- "Write it Right" Recommendations for Developing User Instruction Manuals for Medical Devices Used in Home Health Care (drafted by HHS, FDA, and CDRH)
- Device Labeling Guidance #G91-1
- Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers
- Guidance on Labeling for Laboratory Tests; Draft
- Human Factors Principles for Medical Device Labeling
- Medical Device Home Use Initiative (April 2010)

International Standards Organization
- 3864—2: Design Principles for Product Safety Instructions
- IEC 60601-1-11

American National Standards Institute (ANSI)
- Z535.1—Safety Color Code
- Z535.2—Environmental and Facility Safety Signs
- Z535.3—Criteria for Safety Symbols
- Z535.4—Product Safety Signs and Instructions
- Z535.5—Safety Tags and Barricade Tapes
- Z535.6—Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials

Consumer Product Safety Commission
- Manufacturers' Guide to Developing Consumer Product Instructions (2003 Oct)

□ **Consult appropriate regulations and standards.** In products liability, the sufficiency of a product's label will be determined by comparing its label to that of similar products as well as to requirements set forth in regulations and standards. For this reason, manufacturers should be aware of any laws or FDA regulations regarding instructions and warnings that may be applicable to their products and should monitor any changes to applicable regulations. Voluntary standards that apply to the product and provide guidance regarding instructions and warnings must also be considered. Other applicable standards include AAMI TIR 49, ANSI, GHTF (SG1 N009R6), FDA's home-use device labeling repository, and 21 CFR 801.5.

Content—Narrative Messaging

The content, including the language used, is the most important part of a warning or instruction. When writing the text of the warning or instruction, consider the following:

□ **Make sure warnings sufficiently inform of the product's potential dangers and how to avoid them.** Warnings should identify the foreseeable hazards of a product, explain how to avoid them, and describe the consequences for failing to comply.

□ **Use everyday language**. Warnings and instructions should be written so that they can be understood by the target audience—those who use and/or service the product. Avoid jargon, acronyms and hyper-technical words, and choose words that accurately describe the specific hazard and how to avoid it in terms a lay person will understand.

□ **Be clear and complete in your ideas and writing**. Have definite assertions and be precise and explicit in any directions given. Avoid potentially vague and ambiguous language (e.g., "Use with adequate ventilation"), inconsistency in terms (e.g., "install a spacer"), and idioms (e.g., "Cut the power to the engine").

□ **Avoid long, drawn-out sentences**. Use short sentences that express only one idea. Lengthy messages may decrease the likelihood a message will be read in full and comprehended by the reader.

□ **Focus on serious hazards**. Focus on the greatest danger first and use selective repetition to emphasize it. Focus on the need-to-know information, however, be careful not to overwrite or overuse signal words (such as "DANGER"), as the overuse of a signal word dilutes its impact.

□ **Use active voice.** Using the active voice in warnings makes them more straightforward, direct, and comprehensible. (E.g., "Keep hands away from rotating blade," is better than, "Your hands must be kept away from rotating blade;" or, "Lock out power before servicing equipment," is better than, "Power must be locked out before servicing equipment.")

□ **Delete extra words.** Unnecessary words can lessen the impact of the message (e.g., "Disconnect power to service equipment," as opposed to, "Disconnect power in order to service equipment.")

□ **Sequencing and Organization of the information.** The way the information in the warnings or instructions is sequenced and organized can have a significant impact on its effectiveness. Consider the following tips when organizing information:
- Present the most important information first;
- Ensure that labeling flows logically;
- Use highlighting to guide the user;
- Be mindful of space limitations;
- Use "white space" effectively;
- Use lists appropriately;
- Use headings to help the user navigate the text;
- Avoid justified and centered text;
- Set messages with capitals and lower-case type, since upper-case type can be harder to read.

□ **Use the appropriate language.** If the product will be distributed in foreign countries, consider the countries' labeling regulations and whether translating the warnings and instructions into multiple languages will be required. However, do not add other languages unnecessarily as doing so could diminish the effectiveness of the original message.

Content—Symbols and Pictorials

Symbols and pictorials are graphic representations that convey messages without the use of words. Visuals may be substituted for some instructions for use or used in conjunction with text for clarification. The effective use of symbols and pictorials on warnings and instructions can inform users quickly and efficiently of important product characteristics and hazards. They can also be used to identify parts, components, and locations that have nomenclature that may be misunderstood. When using symbols and pictorials, consider the following:

□ **Convey the specific danger.** A symbol or pictorial used on a warning should clearly convey the specific hazards of the product. As with a word message, symbols and pictorials may also convey how to avoid the hazards and the consequences for failing to do so. ANSI Z535 is an excellent resource for standardized hazard symbols.

□ **Have a distinctive background.** A warning or instruction should have a distinctive background that is different from the surrounding area upon which it will be affixed in order to ensure that it is seen.

□ **Make pictorials simple, accurate, and size-appropriate.** Pictorials should be clear enough to convey quickly any foreseeable hazards to the potential user.

□ **Make sure any colors used convey the appropriate message.** Be mindful that colors used on symbols and in pictograms can send a message (e.g., red is often used in conjunction with a fire hazard).

□ **Do not include operating symbols in safety instructions.** Operating symbols should be kept separate from safety instructions in order to avoid any confusion as to the message being conveyed.

Note: Foreign language problems are ameliorated somewhat by the use of symbols/pictorials on the instructions. If it is reasonably foreseeable that a large number of the product's users may not be able to read English warnings and instructions, companies may want to include pictorials to aid the user's understanding.

Delivery Methods

The means by which a warning or instruction is conveyed can have a significant impact on its effectiveness. There are a number of factors that can help determine the most appropriate delivery method for a warning or instruction, such as the amount of information required to use the product safely and the conditions under which the product will be used. When deciding the method best to convey an instruction or warning, consider the following:

□ **Utilize appropriate media.** There are a variety of methods by which a warning or instruction can be conveyed, such as:
  • On-product instructions/markings,
  • Signs,
  • Hangtags,
  • Instruction manuals/booklets/CDs/DVDs,
  • Training programs and materials,
  • Packaging/packaging inserts,
  • Point-of-purchase materials,
  • Videos and websites, and
  • Ads and promotional materials.

□ **On-product instructions and warnings should remain legible and affixed to the product.** On-product instructions should remain legible and affixed to the product for the life of the product and throughout the customary conditions of the product's processing, storage, handling, distribution, and use. Warnings and instructions that are affixed directly to the product should stay with the product after transfer to subsequent users, assuring that subsequent users are adequately warned about the safe use of the product.

□ **Make sure the label is appropriately prominent.** Instructions and warnings that are hidden or buried cannot adequately inform a user of important product characteristics or warn a user of potential hazards. They should be located in places that set them apart from the product itself, ensuring that they will be seen by the end user.

□ **Ensure that access to support is readily accessible.** Customer support phone numbers and online support center information should be easily identifiable. This includes general operational troubleshooting, instructions regarding how to obtain replacement parts if necessary, and general care and maintenance information. If the product is likely to be passed to a subsequent user, consider whether support contact information should be permanently affixed to the device in case other warnings and instructions are misplaced.

Evaluation and Follow-Up

The warning and instruction development process extends beyond the actual creation of the warning or instruction. After a warning or set of instructions has been developed, there are a number of steps a manufacturer can take to help ensure that this information remains as effective as possible and does not expose the company to unintended liability. Consider the following:

□ **Inspect for accuracy.** Prior to storage or use, an internal, designated individual should examine the labeling for accuracy.

□ **Have instructions and warnings reviewed by external persons unfamiliar with the product.** Using focus groups to test the warnings and instructions can help identify potential errors that were overlooked in the development process. These tests should include an examination of human factors and usability concerns. Ensure that labeling is being tested through the iterative design process.

□ **Keep documentation used in the process of developing the warning or instruction.** Maintain on file any documentation used throughout the development process to demonstrate that reasonable care was taken to identify and understand product hazards as well as to develop warnings that adequately communicate the hazards to potential product users.

□ **Keep track of important regulatory changes.** Implement a monitoring program to keep track of changes in regulations and standards, changes in competitor's warning information, new scientific findings regarding warning information, warranty returns, customer service complaints, and litigation claims. Tracking these changes and revisiting your warnings as necessary demonstrates a good faith effort to provide post-sales warnings. Exceptional companies should strive to meet and exceed the current laws, standards, and industry practices.

□ **Review with legal counsel.** Review the drafts of instructions and warnings with legal counsel to ensure that the final versions are compliant with the applicable laws and regulations. An attorney experienced in products liability law should review labels and warnings to assess whether they meet the "standard of care" — the legal threshold by which they will be assessed in a products liability lawsuit.

□ **Create Standard Operating Procedures (SOPs) for label creation.** Make the label and warning process part of the larger context of company-wide product safety/liability prevention efforts by instituting SOPs that incorporate these and other best practices into the product development processes. Manufacturers that do this have a substantially greater chance of prevailing during a subsequent challenge to the adequacy of its warnings and/or instructions.