



Legal counsel
to product
manufacturers



Product Warnings for Medical Devices

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The content of a warning is only as reliable as the infrastructure supporting the design and manufacturing of the product. This infrastructure already exists when medical device manufacturers design the product, select raw materials, require due diligence from suppliers, write product specifications, perform testing, assure quality, and comply with regulations. The key is to orchestrate this work into a brief safety message that alerts physicians or users about hazards and instructs about use that avoids these hazards. No warning is perfect, but some warnings are more defensible than others. Highly defensible warnings are those that have successfully marshaled the manufacturer's existing work into a safety message that accompanies the medical device.

To Begin. Take four essential steps: (1) determine foreseeable use; (2) identify hazards and rank their adverse consequences, severity, and probability of occurring; (3) comply with federal regulations and federal law; and (4) prepare a safety message that attaches to and accompanies the medical device.

Determine foreseeable use. Hold a foreseeability conference. Its purpose is to identify the product's reasonable intended use and misuse from the corporate disciplines responsible for creating the product, the manufacturer's institutional experience with the product, and other sources including medical device reporting at Manufacturer and User Facility Device Experience (MAUDE). Manufacturers have a duty to account for the

probable results that may arise naturally during normal use or misuse of such a product. (*Henley v. Prince George's County*, 305 Md. 320, 503 A.2d 1333 (1986).) Anticipation of intended use is required by law, but also it frames the product's hazard analysis and defines whether those hazards are reasonable.

Identify product hazards. Identify the device's hazards through an engineering analysis and rank the severity of their consequences. The purpose of the engineering analysis is to capture all hazards unrecognized by a lay person that present danger to a product user. These hazards and their corresponding adverse consequences comprise much of the warning's content. Warnings about general dangers are insufficient. For example, a New Jersey Supreme Court upheld a plaintiffs' verdict that the defendant chemical company's warning was inadequate, adopting the research chemist's testimony that "[i]t's not adequate to say something's an irritant. One has to say how much of an irritant or what kind of organ is affected." *Clark v. Safety-Kleen Corp.*, 179 N.J. 318, 845 A.2d 587 (N.J. 2004).

Comply with federal regulations. In the highly regulated world of medical devices, manufacturers that distribute their products in the U.S. also must comply with the regulatory requirements of the U.S. Food and Drug Administration (FDA). These basic requirements are: Establishment Registration, Medical Device Listing, Premarket Notification (510(k)) or Premarket Approval (PMA), Investigation Device Exemption (IDE) for clinical studies, Quality

System (QS) regulation, Labeling requirements and Medical Device Reporting. Failure to comply with any and all FDA regulations can render the product misbranded or adulterated and subject to FDA action including seizure.

Comply with federal law. First, determine your label audience. Warnings for prescription medical devices are tailored to a prescribing physician as the “user,” the user in this case being a learned intermediary. The learned intermediary doctrine provides an important common law exception to the general rule imposing a duty upon manufacturers to directly warn consumers about the risks of their products (See, *Ralston v. Smith & Nephew Richards, Inc.* 275 F.3d 965, 974 (10th Cir. 2001). This doctrine provides that a drug or medical device manufacturer may be excused from providing a warning directly to each patient who receives the prescription product if the manufacturer properly warns the prescribing physician of the product’s dangers. *Odom v. G.D. Searle & Co.*, 979 F.2d 1001 (4th Cir. 1992). Even where the learned intermediary doctrine applies, the manufacturer still has an obligation to provide adequate information to the prescribing health care provider. Prescription medical devices must also be labeled in conformance with FDA regulations. 21 CFR §801.109.

The learned intermediary or sophisticated user rule does not apply in the context of over-the-counter (OTC) drugs or devices because, in such situations, there is no treating physician intervening between the manufacturer and the consumer. See, *Kirsch v Picker Int’l*, 753 F.2d at 671; *Terhune v. A.H. Robins*, 577 P.2d 975, 977-79 (Wash. 1978)(en banc). For OTC devices, the manufacturer’s duty to warn runs directly to the consumer. OTC devices must also be labeling in conformance with FDA regulations. 21 CFR §§801.61-62.

The FDA mandates more specific labeling requirements for nine (9) specific devices: denture repair kits, impact resistant lenses in

sunglasses and eyeglasses, ozone emission levels, chlorofluorocarbon propellants, hearing aids, tampons, condoms, chlorofluorocarbons or other ozone depleting substances and devices containing natural rubber. 21 CFR §801.63, §§801.405-437.

Second, review labels and warnings in light of Federal Preemption. The U.S. Supreme Court has addressed the contours of federal preemption of state law under the Medical Device Amendments of 1976 (the “MDA”). The Court’s decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), held that the MDA did not pre-empt a plaintiff’s Florida common law tort claims. This case involved a Class III medical device that reached the market under the FDA’s Section 510(k) process for a ‘substantially equivalent’ medical device. The *Lohr* Court concluded that the FDA’s general manufacturing and labeling requirements, which are applicable across the board to almost all medical devices, did not pre-empt the common law claims of negligence and strict liability at issue.

More recently, in *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (February 20, 2008), the court held that the MDA pre-empted plaintiff’s state law negligence, warranty, and strict liability claims for the Class III medical device at issue. There, the device was a catheter which had received premarket approval (PMA).

Prepare the Safety Message. A manufacturer’s warning about its medical device must be “adequate.” (*Anderson v. Owens-Corning Fiberglas Corp.*, 53 Cal.3d 987, 281 Cal.Rptr. 528 (1991) (manufacturers must warn about product hazards not readily recognized by the ordinary consumer).)

Generally, a product warning must communicate the hazards inherent to product use and the likely consequences a user may encounter from those hazards. A warning must also communicate user actions that avoid the hazard, including instructions about when to use or not use the product and how to avoid

specific misuse of the product. Regulatory compliance is essential, of course, but compliance alone seldom creates an adequate warning. A court is more likely to defer to warning content grounded in the product’s engineering and design than a warning based upon cursory, economic, or even regulatory considerations. These warnings are more likely to be found “sufficient” or “adequate” under applicable law. (*Davis v. Avondale Industries, Inc.*, 975 F.2d 169, 172-73 (5th Cir. 1992) (manufacturer has provided an adequate warning of inherent dangers where the purchaser has knowledge of those dangers).)

through studies, communication specialists, or focus groups to determine whether it changes consumer behavior. Evaluate whether the warning complies with industry standards and safety regulations or consult ANSI Z535.1-2006 to determine signal words, font, type size, symbols, and color. Assess consistency of the safety message with marketing materials and with other product lines. Determine whether other hazard communication is required, such as a safety data sheet. Determine placement of the warning on the device and in other locations, such as the user’s manual, packaging, package insert, and website. Assure that the warning label is durable. As a last step, check your warning against competitor’s products.

Next Steps after Completing the Warning Content. Test the effectiveness of the warning

PREPARING THE WARNINGS CONTENT FOR A MEDICAL DEVICE

Determine Foreseeable Use

- What is the institutional knowledge about the medical device?
- What is the experience in the field and by marketing with this device?
- What is the experience from claims, lawsuits and medical device reporting (MAUDE)?
- Who will use the product and what is its original purpose?
- How does this product compare to our other medical device products?

Identify Device Hazards

- What are the product’s Hazards?
- Are they inherent to the product?
- Can they be reduced, eliminated or guarded against?
- Do the Hazards arise from the product’s foreseeable use or misuse?

Prepare the Safety Message

- Which Hazards require a warning?
- What are the natural consequences of these Hazards?
- Is the company compliant with FDA regulations?
- Is the warning and labeling being written for the appropriate audience?
- What content is required by regulations?
- What content should be included from industry standards?
- Is this warning “adequate” under applicable product liability laws?

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