

tJun17 Life Sciences Advisors

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When evaluating what should be considered when evaluating whether FDA labeling and warnings are adequate in a medical-device product-liability case attorneys and their regulatory experts should evaluate warning adequacy as a time-specific, device-specific question. They should not merely ask whether FDA cleared or approved the labeling.

The central inquiry is:

Given what the manufacturer knew or reasonably should have known at the relevant time, did the labeling communicate the material risk clearly enough, and did it provide usable instructions for avoiding or responding to it to the legally relevant audience?

Steps in the Process

1. Identify the regulatory status of the device

Determine whether the device was:

- Exempt from premarket review
- 510(k)-cleared
- *de Novo* authorized
- PMA-approved
- Approved under a Humanitarian Device Exemption
- Investigational or used under an IDE
- A device-led combination product

This distinction matters both substantively and for preemption. PMA approval produces device-specific federal requirements and may preempt state-law claims that would impose requirements “different from, or in addition to” those requirements. A 510(k) clearance ordinarily presents a different analysis because it is principally a substantial-equivalence determination. [Riegel v. Medtronic](#); [21 U.S.C. §360k](#).

2. Obtain the exact labeling in effect at the relevant time

Do not rely on the current instructions for use. Establish:

- The device model, lot, version and manufacture date
- The date of implantation, prescription, purchase or use
- The exact IFU and patient materials distributed with that unit
- Every prior and subsequent labeling revision

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- When the manufacturer first became aware of the alleged risk
- When a warning was drafted, approved, submitted to FDA and implemented

A later warning is not automatically an admission, but its timing and evidentiary treatment should be evaluated under the applicable rules.

3. Define the complete universe of “labeling”

FDA “labeling” is broader than the physical package label. Review:

- Professional instructions for use
- Patient labeling and medication-style guides
- Surgical technique manuals
- Implant cards
- Training materials and videos
- Websites, brochures and sales presentations
- Field safety notices and “Dear Healthcare Provider” letters
- Technical-support scripts and troubleshooting instructions
- Promotional representations regarding safety or comparative performance

Conflicting promotional claims can dilute an otherwise accurate warning.

4. Identify the relevant audience

For prescription devices, 21 CFR §801.109 requires labeling directed to licensed practitioners to include relevant hazards, contraindications, side effects and precautions needed for safe use.

[21 CFR §801.109](#).

Attorneys should determine whether the warning needed to reach:

- The prescribing physician
- The implanting surgeon
- Nurses or technicians
- The patient or caregiver
- A hospital reprocessing department
- More than one of these audiences

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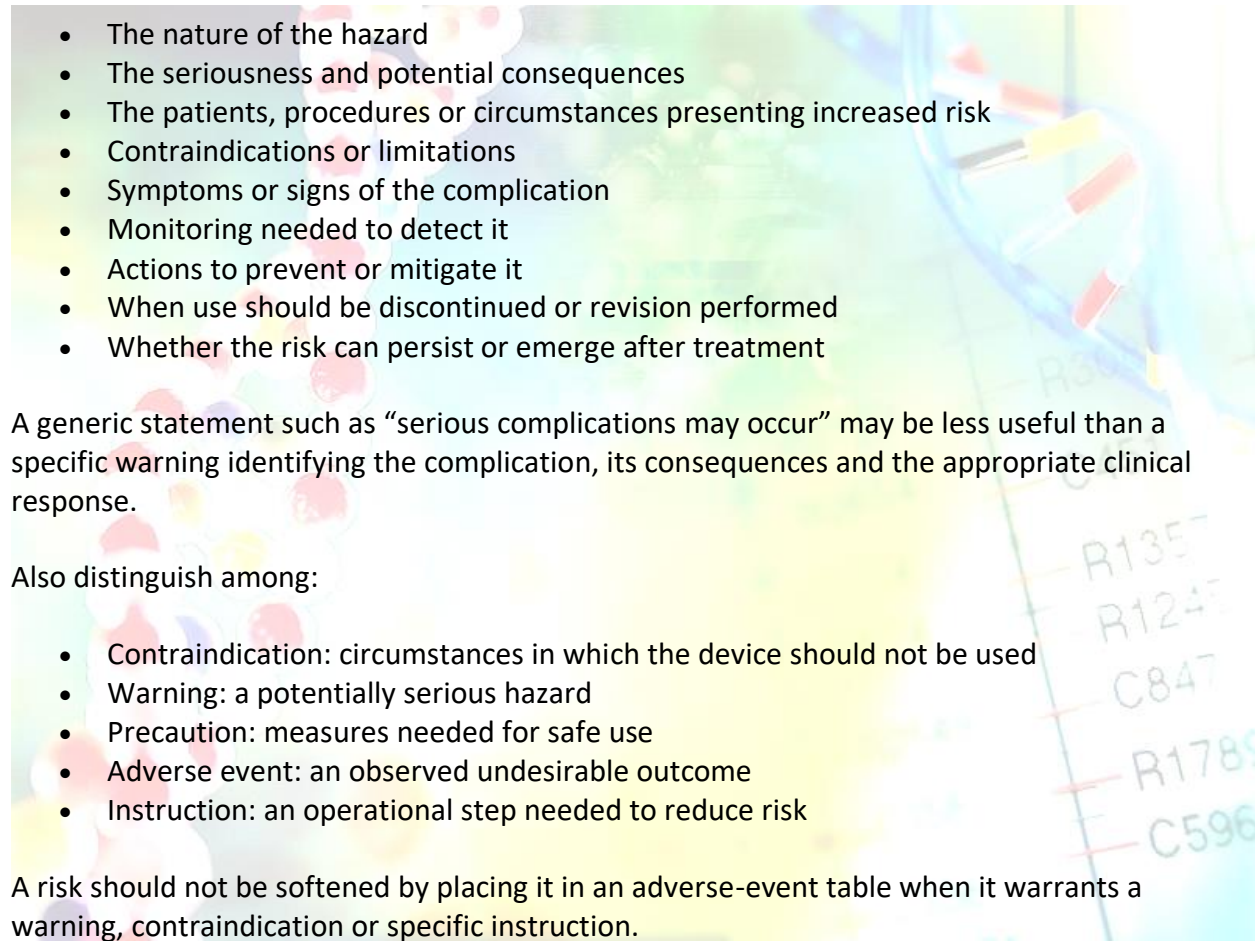
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The learned-intermediary doctrine and any exceptions are matters of state law. Even when the physician is the legally relevant intermediary, patient labeling may still be significant—particularly for home-use, implantable and patient-operated devices.

5. Evaluate the substance of the warning

An adequate warning should ordinarily address:

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- The nature of the hazard
 - The seriousness and potential consequences
 - The patients, procedures or circumstances presenting increased risk
 - Contraindications or limitations
 - Symptoms or signs of the complication
 - Monitoring needed to detect it
 - Actions to prevent or mitigate it
 - When use should be discontinued or revision performed
 - Whether the risk can persist or emerge after treatment

A generic statement such as “serious complications may occur” may be less useful than a specific warning identifying the complication, its consequences and the appropriate clinical response.

Also distinguish among:

- Contraindication: circumstances in which the device should not be used
- Warning: a potentially serious hazard
- Precaution: measures needed for safe use
- Adverse event: an observed undesirable outcome
- Instruction: an operational step needed to reduce risk

A risk should not be softened by placing it in an adverse-event table when it warrants a warning, contraindication or specific instruction.

6. Examine prominence and usability

Accuracy alone is not sufficient if users are unlikely to notice, understand or act on the information. Consider:

- Placement and heading

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- Font, contrast and visual hierarchy
- Whether the warning is buried among numerous minor risks
- Consistency of terminology
- Literacy and technical level of the intended user
- Whether the instructions state concrete actions
- Whether the warning appears at the point in the procedure when it is needed
- Whether reasonable users misunderstood it during testing or actual use

FDA's human-factors framework focuses on intended users, uses and use environments and on minimizing harmful use errors. [FDA Human Factors and Usability Guidance](#). FDA also recommends that patient labeling be understandable, usable, balanced and consistent with professional labeling. [FDA Medical Device Patient Labeling Guidance](#).

7. Determine what the manufacturer knew and when

Potential evidence includes:

- Clinical-study results
- Published literature
- Complaint files
- Medical Device Reports
- Returned-product investigations
- CAPA records
- Risk-management files
- Failure-mode analyses
- Post-approval studies
- Registry data
- Foreign adverse-event reports
- Distributor and sales-representative communications
- Internal medical, regulatory and safety-committee minutes
- Competitor warnings, recalls and safety communications
- FDA correspondence, inspection observations and warning letters

MAUDE is useful for signal detection and chronology, but FDA cautions that MDR data have limitations. The reports alone generally cannot establish incidence rates or causation. [FDA MAUDE Database and Limitations](#).

8. Analyze postmarket regulatory conduct

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Investigate whether the manufacturer:

- Properly evaluated complaints
- Submitted required MDRs
- Escalated emerging signals into CAPA or risk management
- Considered a labeling change
- Conducted trend analysis
- Issued a correction, removal or field communication
- Reported corrective actions to FDA when required

Manufacturers generally must report qualifying deaths, serious injuries and malfunctions under 21 CFR Part 803. Corrections or removals initiated to reduce a risk to health may trigger reporting under Part 806. [21 CFR Part 803](#); [21 CFR §806.10](#).

Apply the quality-system regulations that were in effect during the relevant period; FDA's QMSR amendments became effective on February 2, 2026.

9. Determine whether the manufacturer could lawfully strengthen the warning

For a PMA device, labeling changes affecting safety or effectiveness generally require a PMA supplement. However, FDA regulations permit certain “changes being effected” to add or strengthen contraindications, warnings, precautions, adverse-reaction information or safe-use instructions based on newly acquired information. [21 CFR §814.39](#).

For a 510(k) device, determine whether the change could significantly affect safety or effectiveness or constitute a major change in intended use, potentially requiring a new 510(k). [21 CFR §807.81](#).

This analysis is critical to both negligence and impossibility/preemption arguments.

10. Do not treat FDA compliance as the end of the inquiry

FDA authorization is important evidence, but its legal effect depends on:

- The type of authorization
- The particular claim pleaded
- Whether FDA imposed a device-specific requirement
- Whether the plaintiff seeks a warning different from the FDA-approved warning
- Whether the claim is genuinely based on traditional state tort law

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- Whether it parallels an identifiable federal requirement
- The law of the governing jurisdiction

Claims existing solely because of an alleged FDCA violation may be impliedly preempted because private parties generally cannot enforce the FDCA directly. Conversely, a properly pleaded state-law claim paralleling a federal requirement may sometimes survive. This “parallel-claim” analysis is highly circuit- and state-specific.

11. Test warning causation separately

Even a demonstrably inadequate warning does not establish liability without causation. Determine:

- Whether the physician or patient received and read the warning
- Whether the physician already knew the risk
- Whether a stronger warning would have changed prescribing, implantation, monitoring or consent
- Whether the injury was the same risk allegedly omitted or understated
- Whether compliance with the existing instructions would have prevented the event
- Whether the treating physician would testify differently under a properly framed hypothetical warning

For prescription devices, the prescriber’s deposition is often pivotal.

Most important discovery categories

At minimum, counsel and their regulatory experts should seek the regulatory submission and authorization history; all labeling versions and redlines; risk-management and human-factors files; complaint, MDR and CAPA records; labeling-change assessments; FDA correspondence; postmarket-study data; field actions; training and promotional materials; and documents showing when the manufacturer first recognized the particular risk.

Ultimately, the strongest analysis connects four elements in chronological order: **1) The evolving safety evidence; 2) The manufacturer’s knowledge; 3) The labeling response and the prescribing or 4) Use decision that allegedly caused the injury**