How Far Can Medical Device Firms Deviate from FDA’s Cleared Indications for Use?

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Presented by Philip J. Phillips
Becker & Associates Consulting, Inc.
Washington, D.C.
Outline

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Scope of the Topic

• “Cleared” means class I/II, SE under section 510(k)
  – Includes class I/II [510(k) exempt] devices
  – Excludes class III devices subject to PMA

• “Deviate” involves any activities that suggest an objective intent to promote outside the authorized indications for use
  – Labeling claims
  – Advertising matter
  – Oral or written statements

• “Indications for use” is a narrow domain within the concept of “intended use”
Terms and Definitions

Intended Use

- A *regulatory concept* that affords FDA considerable discretion to get involved in labeling, promotion, advertising, and device design
- FDA’s definition (21 CFR 801.4):
  - Defined as “…the objective intent of the persons legally responsible for the labeling of devices…”
  - Encompasses all aspects of how and for what purposes and under what circumstances the device is intended to be used
  - Not always readily apparent or well documented
Terms and Definitions

Indications for Use

- FDA’s definition [21 CFR 814.20(b)(3)(i)]:
  - A general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate
  - Includes description of the patient population for which the device is intended

- A statement in attachments to SE letters that reflects FDA’s view on an aspect of intended use

- Indications for Use do not depict a device’s *entire* intended use
Terms and Definitions

Claims

• The term “claim” is not defined by FDA
• Often used synonymously with “intended use” and “indications for use”
• Today’s ground rules
  – Consider claims to be separate from the indications for use statement
  – Claims can only affect a device’s intended use, not design or performance
  – Claims may include statements regarding consequences of use, device performance, or the use environment
Rules v. Expectations

FDA’s rules

- Making false or misleading statements in labeling constitutes misbranding prohibited under the act [21 CFR 801.6]
- A new 510(k) is required to make claims that represents a major change or modification in intended use [21 CFR 807.81(a)(3)]
- Introduction of claims that create an intended use that differs from legally marketed predicate devices exceeds the limitations of 510(k) exemptions [21 CFR 862-892.9]
Rules v. Expectations

FDA’s expectations; some generalizations

• Changes in indications for use require clearance
  – Exception – changes in words that do not affect meaning

• Claims alter intended use
  – The need to differentiate devices via claims is not appreciated – “substantiate” or “delete them”
  – Claims appearing in 510(k) require substantiation and FDA review
  – The addition of post-clearance claims require 510(k) clearance
Navigating Unchartered Waters

Guiding principles

• Do not change the indications for use in any substantive way without filing a 510(k)

• Establish claims substantiation and authorization procedures
  – In general, file a 510(k) before making claims that:
    • Expand the patient population beyond the population eligible for diagnosis or treatment
    • Target a specific diagnostic or treatment use not identified in Indications for Use
    • Contradict any restrictions on intended use
Navigating Unchartered Waters

• Establish claims substantiation and authorization procedures
  – In general, 510(k) not required for claims that do not affect safety or effectiveness and are consistent with FDA’s indications, including:
    • Performance/design/mode of action claims
    • Environmental compatibility
    • Cost effectiveness
  – Establish similar SOPs for class I and class II 510(k) exempt devices
Complicating Factors

Good Reprint Practices

• Draft guidance (February 2008) on Good Reprint Practices
  – FDA recognized public health value of distributing truthful information regarding off-label device use
  – Provides guidelines for distributing scientific and medical information to physicians for a new use

• Manufacturers can disseminate credible scientific and medical information on off-label uses of devices to physicians
  – However, important to understand difference between:
    • Making promotional claims for off-label uses
    • Disseminating truthful medical and scientific information to physicians about off-label uses
Complicating Factors

The Practice of Medicine

- Reality: FDA prohibited from interfering in the practice of medicine, but regulates an industry capable of influencing it

- The “chicken or the egg” phenomenon!
  - Does the practice of medicine shape industry activities, or do industry activities create demand from the medical community?
  - Example: Biliary stents for peripheral vascular applications

- Regulations require manufacturers to take action if aware of off-label use of their device
  - “provide adequate labeling” [21 CFR 801.4]
  - FDA expectations and permissible actions are unclear
The Bottom Line

• Clinical, regulatory and marketing departments require guidance to navigate the muddied regulatory waters that surround activities that affect a device’s intended use
  – Exercise extreme caution in changing “indications for use”
  – Substantiate all claims
  – Develop criteria for filing 510(k)s and document the basis for all decisions