FDA Final Rule on Intended Uses



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FDA's Final Intended Use Rule

CRN's Regulatory Affairs Committee Meeting
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History

2015

- Proposed rule to amend FDA's "intended use" regulations for drugs and devices
- Intended to better align regs with FDA's practices for evaluating intended use

2017

- Final rule
- FDA would consider the "totality of the circumstances" to determine intended use
- Controversial; FDA reopened docket for public comment and delayed effective date
- CRN submitted comments

2020

- New proposed rule

2021

- Proposal finalized, largely identical to 2020 proposal
- Effective September 1, 2021

CRN's 2017 Comments

- Concerns focused on proposed "totality of evidence" standard
- Also expressed particular concerns about
  - Clinical trial endpoints as evidence of intended use, even if intended to support s/f claims
  - Lack of certainty among industry with "totality" standard
  - Inhibition of research and innovation
  - First Amendments concerns – chilling truthful and non-misleading speech

Final Rule (Drug Provision)

The words *intended uses* or words of similar import in [FDA's drug regulations] refer to the **objective intent** of the persons legally responsible for the labeling of an article (or their representatives). The intent **may be shown by such persons' expressions**, the **design or composition of the article**, or by the **circumstances surrounding the distribution of the article**. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. Objective intent may be shown, for example, by circumstances in which the article is, with the knowledge of such persons or their representatives, offered or used for a purpose for which it is neither labeled nor advertised; provided, however, that a firm would not be regarded as intending an unapproved new use for an approved drug based solely on that firm's knowledge that such drug was being prescribed or used by health care providers for such use. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he or she received the article, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses.

Evidence of Intended Use is Not Limited to Promotional Claims

- FDA disagreed with commenters that its statutory authority was so narrow, and said that courts have upheld a broader approach
- Such a limitation would allow companies to circumvent FDA regulation by masking their true intent, either by omitting claims or making false statements about use
- FDA cited examples of persons distributing imitation drugs or products with APIs but labeled as dietary supplements
- In these situations, evidence of intended use has included:
  - general knowledge of actual use by consumers
  - known effects of a product or substance
  - implied claims from using names that sound similar to controlled substances
  - statements made in training sessions

"Design or Composition of the Article" as Evidence of Intended Use

- FDA could deem spiked supplements to be drugs regardless of marketing claims
- Should obviate the need for FDA's desired legislative change to more clearly have jurisdiction over supplements containing drugs?
  - "simply being outside the dietary supplement or food definition does not make a product unlawful and subject to enforcement action. To establish jurisdiction over a product as a drug and remove it from the marketplace . . . FDA must be able to establish that the product is a drug based on evidence of its intended use."

Additional Evidence of Intended Use

- FDA will also consider "circumstantial evidence," including the circumstances of sale or distribution
  - Sales to/through HCPs?
    - FDA referred to existing guidance (directed to medical products)
    - Declined to formally establish "safe harbors," *i.e.*, for scientific exchange
- FDA does appear to retain an overarching approach to the totality of the circumstances, on a case-by-case basis
- But ultimately, as a practical matter, no likely change in FDA approach

Questions?

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