

Comparative Claims: Legally Permissible, But Proceed with Care

Promotional claims comparing one device with another are common and legal. But companies should carefully consider possible pitfalls before making such claims.

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Legally, medical device companies may promote their devices with claims of superiority over competing products—or over previous versions of the company’s own products. However, FDA scrutinizes such claims carefully. The agency views comparisons with suspicion, believing that they are potentially misleading and seldom complete. Over the years, FDA has issued numerous warning letters alleging that comparative claims are false, misleading, or otherwise violative.

Therefore, although manufacturers are free to make superiority claims, it is important to know the legal constraints that FDA imposes. This article reviews the most common legal pitfalls of making comparative claims. It also discusses how to support such claims.

False or Misleading

Under section 502(a) of the Federal Food, Drug, and Cosmetic (FD&C) Act, a medical device is misbranded if its labeling is in any way false or misleading. (For more on labeling, see the sidebar “Labeling”.) Furthermore, a device is misbranded if its labeling contains a false or misleading representation with respect to another device.¹

Under section 502(q) of the FD&C



Act, “restricted devices” are misbranded if their advertising is in any way false or misleading. FDA may classify a device as restricted by regulation or in a premarket approval (PMA) application order.² And, while FDA has no jurisdiction over the advertising of nonrestricted devices (any device cleared under the 510(k) process), the Federal Trade Commission (FTC) does. FTC generally requires substantiation of all claims and prohibits advertising that is false or misleading.³

The bottom line is that comparative claims must be truthful and nonmis-

leading. This legal requirement is easily stated but not so easily applied. FDA has not issued regulations or guidance documents defining what constitutes a false or misleading claim. Without such general guidance, perhaps the best insight comes from analyzing FDA’s warning letters.

Analysis of Warning Letters

FDA has long required adequate data to support specific superiority claims. For example, in a letter to Carrington Laboratories in 1994, FDA wrote that claiming a wound-care product was not cytotoxic implied an unsupported claim of superiority in the absence of data showing other wound-care products to be cytotoxic.

In 2002, Helio Medical Supplies claimed that its silicone-free acupuncture needles were safer than competing needles with silicone. One promotional piece asked: “When there is a better alternative, why take the silicone risk?” FDA’s warning letter said that this comparative claim misbranded the product, because there was no evidence that silicone needles were unsafe.

The requirement for data to support a claim applies even when a manufacturer compares a new product with its own older product. This

point was illustrated in FDA's warning letter to Sunrise Technologies in 1993. The letter said that, without adequate supporting data, it was false or misleading to claim that the firm's "upgrade package" rendered the modified device superior to the original device.

What types of data are adequate to support a superiority claim? It appears that FDA generally requires head-to-head comparative studies. In a warning letter to Pharmacia & Upjohn in 2001, FDA stated: "Comparative claims in general are only appropriate if there are data resulting from head-to-head comparative studies." Likewise, in a warning letter to Sulzer Spine-Tech in 2000, FDA advised that "the agency has determined that before a manufacturer may make a direct comparison of their orthopedic device with that of another manufacturer, randomized, controlled, head-to-head clinical trials would be required." In a warning letter to ELA Medical Inc. in 1992, FDA alleged misbranding in the absence of "adequate and well-controlled studies comparing the [product] to others in studies designed to support comparative statements of superiority."

Even truthful comparisons of product characteristics may be considered misleading without head-to-head data. For example, in the Sulzer Spine-Tech warning letter, FDA objected to the company's promotion of its spinal fusion device with a claim that the Sulzer product had larger holes than a competing product. The company had cited a baboon study suggesting that smaller holes made it easier for fibrous tissue to block or impede fusion. FDA said that this claim implied that the larger holes of the company's fusion device would lead to a more successful clinical outcome. The comparison was misleading, FDA insisted, because there was no evidence that the larger holes in Sulzer's product caused better overall fusion results compared with the competitor's product.

FDA's warning letters also indicate that comparative claims must be based on approved uses for both products in a comparison. The agency may consider it misleading to compare an unapproved use of one product with the

approved use of another product. For instance, in 1998, Bayer Corp.'s prostate specific antigen (PSA) assay had been cleared for monitoring cancer treatment. The company had claimed that the assay had greater specificity than other PSA assays. FDA alleged that Bayer's statements constituted an unfounded claim of superiority, because the other assays were approved for cancer detection rather than cancer monitoring. As another example, in 1999, Thoratec Laboratories Corp. allegedly compared its ventricular assist device with one sold by Abiomed. FDA insisted that the comparison was misleading because Thoratec's device was intended as an intermediate-to-long-term bridge to transplant, while the Abiomed device was approved for a different, short-term use.

Valid head-to-head studies are generally required to support comparative claims. The presentation of the testing results must be fair and balanced. In particular, companies should fully disclose relevant test conditions and the results for all clinically significant points of comparison. Of course, the overall product comparison also must be fair and balanced, not just the presentation of the test results. Finally, if other comparative studies are available that point to a different result, it may be necessary to provide the results of those studies as well.

New Intended Use

FDA also reviews comparative claims to determine whether they indicate that a device requires a new 510(k) clearance or premarket approval (PMA). FDA's position is that both labeling and advertising for any device are relevant to a determination of its intended use.⁴ Therefore, if labeling or advertising promotes a device for an unapproved use, it may misbrand or adulterate the device.⁵ This reasoning applies equally to comparative claims. For example, in the Carrington Laboratories warning letter discussed above, FDA stated that promotional claims of "faster epithelization" and "acceleration of healing" for a wound-care product went beyond the scope of its 510(k) clearance, and thus the device required a new 510(k) clearance or PMA.

LABELING

Section 201(m) of the FD&C Act defines labeling as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." Under long-standing court decisions, the term *accompanying* does not require that the material physically accompany the device to be considered labeling. If it is otherwise part of an integrated sales transaction or offered in conjunction with the product to explain or supplement it, it is considered labeling. Two cases that established this interpretation of Section 201(m) are *Kordel v. United States*, 335 U.S. 345, 346-47 (1948) and *U.S. v. Paddock*, 67 F. Supp. 819 (W.D. Mo. 1946).

Recommendations

Comparative promotional claims should undergo a thorough FDA compliance review. Such a review should consider the following points:

- In general, comparative claims may not be false or misleading, either in terms of a specific representation or the overall impression created by the comparison. Information should be presented in a truthful and balanced manner. All comparisons should be clinically relevant and consistent with the approved indications for use of each of the compared devices.
- All comparative product claims should be supported by reliable, sound scientific data on file at the time the claims are made. This includes any text, photographs, tables, charts, or graphs.
- Comparative claims about clinical outcomes generally require a scientifically valid head-to-head clinical study directly comparing the two products with respect to the claim. The head-to-head comparison should involve products with similar approved or cleared indications for use. Additionally, the study should include only pa-

tients who are within the indications for use of both devices.

- The comparison of clinical study results should disclose all end points for which a relevant difference was observed—not just those end points that favored the company's product.
- It is usually considered scientifically invalid to present a side-by-side comparison of results from two different studies because of likely differences in protocol, end points, or patient populations.
- In general, a comparison of published performance or technical specifications is legally defensible unless for some reason the comparison is known to be false or misleading. For example, the comparison would be misleading if the test or evaluation methods used for the two products were known to be materially different.
- Sometimes, published specifications for the competing products cannot be fairly compared, or specifications are not available for

both products. In those situations, it is probably legally defensible to compare the specifications via testing conducted under the same conditions and methodology for both products. The test methodology should be disclosed with the comparison. However, an unfortunate conundrum may occur—FDA may object if such testing produces results that do not match the specifications in a product's labeling.

- FDA could also object if test results are extrapolated, either explicitly or by implication, to clinical performance. If the context of the comparison implies a clinical superiority based on bench-test results, an appropriate disclaimer may mitigate the risk of FDA objection. For example, a disclaimer could state that information such as bench-test results or technical specifications are “not necessarily indicative of clinical performance.”

There is no absolute legal barrier to comparative claims if they are fair, bal-

anced, and data-supported. On the other hand, this area is fraught with legal risk and has been a fertile field for warning letters. Companies should expect that maligned competitors will complain to FDA. Therefore, it is crucial that manufacturers exercise caution and common sense before proceeding with a promotional campaign that includes comparative claims.

References

1. *Code of Federal Regulations*, 21 CFR 801.6.
2. Federal Food, Drug, and Cosmetic Act (FD&C Act), Sections 515(d)(1)(B)(ii), 520(e).
3. Federal Trade Commission Act, Section 12, “FTC Policy Statement Regarding Advertising Substantiation” (August 2, 1984).
4. *Code of Federal Regulations*, 21 CFR 801.4.
5. FD&C Act, Sections 301(a), 501(f), 502(o). ■