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Ask the Ethicist: FDA Warning Letters

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Q: *I read about the December 2012 FDA Warning Letters sent to five ophthalmology practices stating that their advertising violated sections of the Federal Food, Drug, and Cosmetic Act (the Act) because it provided incorrect or incomplete information about the specific lasers named. The letters noted that failure to correct the violation could result in "seizure, injunction, and civil money penalties." I use very similar information in my advertising and worry that I may receive one of these FDA Warning Letters. What should I do? I don't understand what the issue is with naming specific lasers in my advertising.*

A: In the Warning Letters, the FDA noted that the providers' advertisements did not supply adequate information about risks and potential adverse events associated with refractive surgery. The lasers were considered misbranded because the advertising failed to reveal information that a reasonable person would find significant in influencing their decision-making process (known as material facts). This includes any consequences that may result from use of the device, per the Act.[1,2]

For example, if an advertisement names a specific LASIK device or manufacturer, the advertisement must include "a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications" as found on the laser's FDA-approved labeling. This statement should include the following, especially regarding contraindications for LASIK:

- The risks of dry eye syndrome
- The possible need for glasses or contact lenses after surgery
- Visual symptoms including halos, glares, starbursts, and double vision
- Loss of vision

The Ethics Committee advises you to review additional material (see the Further Reading box, below), meet with your advertising staff, and rewrite your ad copy—either deleting all references to specific lasers or laser companies, or adding the required risk and contraindication information. Then, have a layperson read your draft ad and provide their interpretation of it. Based on what they say, you may have to go back to the drawing board to ensure that there are no potentially false, deceptive, or misleading words or claims in your ad. If uncertainties remain, consider consulting with an experienced health care attorney. You certainly want to avoid the FDA penalties for misbranding or false labeling of a device—up to $15,000 per violation and up to $1 million for all violations resolved in a single proceeding.[3]

You should know that the FDA specifically regulates the advertising and labeling of restricted medical devices (such as lasers used in refractive procedures), and the FTC regulates advertising in general.

To prove a violation of the Act, the FDA requires the labeling or advertising to be false or misleading in any way, while the FTC must show that a misleading statement is materially misleading.

To submit a question, *contact the Ethics Committee staff at ethics@aao.org.*

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1 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §502(q)
2 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §201(n)
3 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §333(f)