

compliance," he said. "But if the agency decides to seize these devices, it would not look very good if US Marshalls burst into the doctor's office and decided to seize the product in front of all his patients. I am not saying that is what we are going to do, but that is one option the agency has."

So far the FDA has not seen fit to shut down any of the excimer laser centers or confiscate any of the homemade devices, in part because the agency has received no reports of any patient injuries. However, within portions of the ophthalmic community, increasing questions are being raised about quality control, proper technique, development of appropriate algorithms, and other technical, legal, and ethical issues. However, none of the physicians, employees, or others familiar with the lasers' operations have apparently been willing to go on record with the FDA with any specific charges.

"We told [Sullivan] unequivocally that if we hear of any injuries" caused by the use of his lasers, said the FDA official, "that would put us in a different mode and we would be out there immediately to seize them. Right now we do not have that information and it does not appear it exists."

## REFERENCE

1. Kearns LA. 'Homemade' excimer lasers are operating today in the US--the rest of the country watches and waits. *J Refract Surg.* 1995;11:230-235.

## SEE ALSO

- [Letter to the Editor](#) regarding prior news article.
- News article in same issue, [Custom Excimer Users Threaten PRK Success](#).
- Subsequent news article, [FDA Investigates Injury Reported From "Homemade" Laser](#).

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Lisa A. Kearns investigates and reports industry news for *The Journal of Refractive Surgery*.

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