Letters

Off-Label Use of Devices

In response to the January Opinion, "Off-Label Drug Use: Is Regulation Internationally Contagious?" Dr. Arbisser posted this comment online. It is reprinted here with her permission.

I wondered if you knew that the FDA is upping its draconian war on off-label use of devices—and maybe drugs, for all I know. I was reading the Catalys (OptiMedica) literature, which states that this femtosecond laser is "contraindicated" for patients under age 22.

I asked the OptiMedica folks whether there is some evidence that it is in fact harmful to kids (who will ultimately be the big benefactor of perfect reproducible anterior and posterior capsulorrhexes in future). Their regulatory expert talked to me. He said that even though the FDA fully knows that the medical definition of contraindicated is that there is evidence of harm, it has decided to adopt the "language of art" by using "contraindicated" instead of the words "off label."

I then discovered that the FDA has done the same thing with iStent (Glaukos), as well. Their literature says "contraindicated" for narrow-angle glaucoma! Although the device is certainly easier to implant in open-angle cases, there might be some indication for its off-label use in mixed-mechanism glaucoma.

Needless to say, this is an assault on doctors' liability situation for performing off-label procedures. It doesn't take much to imagine how the word "contraindicated" (with its "different" definition) will sound in court!

I wonder if the societies, or anyone for that matter, is aware of this disingenuous and evil (this is my own interpretation, of course) change in policy. Wouldn't patients be better served if the FDA and physicians could work in concert rather than at odds?

Lisa B. Arbisser, MD
Bettendorf, Iowa

***Dr. Arbisser** is a consultant to Bausch + Lomb.*

Pharma: Cost, Quality, and Access

I was struck by the tacit connections in the January *EyeNet* between the Opinion on off-label drug use and Current Perspective on compounding pharmacies. On the one hand, Dr. Mills' Opinion talked about the importance of physicians being able to select the optimum therapy for each patient without restriction of the practice of medicine. On the other hand, Dr. Parke's Current Perspective stated the issues with compounding pharmacies, and the need for ophthalmologists and their patients to be assured that the product they receive is of appropriate quality. I have previously written about these issues of cost, quality, and access in ophthalmology.[1] These were also the topic of an ARVO symposium in 2012.[2]

I am pleased that pharmaceutical firms have invested in ophthalmology to provide quality products approved for ophthalmic indications. For treatment of ocular inflammation, as an alternative to using off-label Kenalog (triamcinolone acetonide injectable suspension) or extemporaneously formulated triamcinolone acetonide, ophthalmologists can use Triesence. For glaucoma filtering surgery, as an alternative to using Mutamycin (mitomycin for injection) prepared off label in the operating room, ophthalmologists can use Mitosol (mitomycin for solution). However, the price of these ophthalmic products is typically more than the off-label products, in part to compensate the innovators for their development. A pharmacoeconomic analysis might evaluate the total cost of each approach (e.g., health care provider time, risk of adverse events for providers and patients, etc.).

It will certainly be interesting to see how these and other ophthalmic products fare in the real-world environment of U.S. ophthalmic practice.

Gary D. Novack, PhD
San Rafael, Calif.

***Dr. Novack** reports no related financial interests.*

1 Novack GD. *Ocul Surf.* 2006; 4(1):58-60.
2 Levy B, Koulen P (moderators). Off label, off the radar, on the hook. Presented at: ARVO; May 8, 2012; Fort Lauderdale, Fla. Workshop 236.

Past issues are online at www.eyenet.org/archives.

WRITE TO US Send your letters of 150 words or fewer to us at *EyeNet Magazine*, American Academy of Ophthalmology, 655 Beach Street, San Francisco, CA 94109; e-mail eyenet@aao.org; or fax 415-561-8575. (*EyeNet Magazine* reserves the right to edit letters.)