A Presumption of Guilt

At the last few major meetings I have attended, I have been a bit uncomfortable while speaking. The current setup for many main sessions involves three screens, a large one directly behind the speaker and a smaller screen off to each side. I start my talk by displaying and reading aloud my financial disclosures, characterizing my relationships with industry, and stating whether or not I am involved in any off-label practices. The large screen behind me displays my relationships with industry for the duration of my talk. The smaller side screens present the science. What does this setup imply? I understand and agree with the need for full disclosure of any financial relationships, but is that the most important thing I have to say? Is my experience tainted?

I do not believe that a relationship with industry will make me dishonest with my patients or colleagues. Can you imagine the practice of cataract and refractive surgery today without the innovations created through the partnership between the private sector and industry? Many of the developments in our field involved collaboration with a forward-thinking industry. Yes, companies are profit driven, but they invest a substantial proportion of their revenue in research and development.

Is the disclaimer of any off-label use of a drug or device a law? I do not mind making this disclosure, but am I not simply stating the obvious? What physician does not routinely engage in off-label practices? Do you use antibiotics or steroids after cataract surgery? Do you perform wavefront-guided PRK or any refractive enhancements after LASIK or PRK? These are all off label. All over the world, the off-label use of drugs and devices is commonplace, with an occurrence as high as 90% in the pediatric population and 40% in adults.[1] In a recently conducted US survey, the off-label use of 160 commonly prescribed medications was 21% overall and higher than 80% for some drugs.[2]

The FDA approves drugs and devices, and the documented approval details the way in which the drug or device was used in the trial (ie, the labeling). The agency states on its Web site, "Good medical practice and the best interest of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment."[3] As Robert Maloney, MD, has stated, physicians may be confusing "unproved with off label."[4] The term *off label* simply means that that usage was not studied and therefore was not included in the labeling proposed to the FDA. The practice of medicine, however, generates extremely valuable information about off-label uses that benefit patients. Allergan, Inc. (Irvine, CA), is working to persuade the FDA to allow companies to provide scientific information about off-label uses of their products.[5]

Certainly, we should feel free to disclose off-label practices to our patients, but should this disclosure be a standard for informed consent? According to Dr. Maloney, "A robust consent process is appropriate for unproven therapies, but rarely is indicated simply because of the labeling of a device or drug in a particular jurisdiction."[4]

Why do we "disclose" what is routine? Why make disclosures the main theme of a scientific talk? In doing so, we disrespect ourselves and ask others to presume us guilty of wrongdoing. ■

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