# THE POSTAPPROVAL WILDERNESS

During this summer's American-European Congress of Ophthalmic Surgery (AECOS) meeting in Deer Valley, Utah, three separate FDA product approvals in ophthalmology were announced—a welcome development in an increasingly difficult regulatory environment. With the additional approvals of corneal collagen cross-linking and small-incision lenticule extraction or SMILE, 2016 has already been a very good year for ophthalmology. Despite meaningful improvements in the FDA process, for better or for worse, the US approval path remains the toughest in the world. The latest round of new products and procedures initiated a phenomenon that I have not observed before: casual photographs on social media documenting several surgeons' first cases. Announcements of pioneering firsts in medicine are common, but they have historically been formal press releases or news stories. Initially, this social media barrage struck me as odd, but of course, it makes perfect sense.

Even when I have been fortunate enough to be an FDA investigator for a product, I have never really felt that I had a complete understanding of the technology until it became commercially available. Only then could I fully evaluate when the product performed optimally and when it did not. The highly controlled environment of an FDA trial may not test a product at the extremes of its indicated usage, but the commercial market certainly will. FDA trials typically employ carefully selected subjects and tight controls of as many variables as possible. These studies simply cannot contemplate every potential clinical situation in the wilderness of widespread postapproval usage.

Presbyopia-correcting technologies are a prime example. As I have written in this space in the past, presbyopia is so objectionable that some people will put up with almost anything to escape it. When a new surgical technology seems to instantly solve this problem, patients sometimes enter into a state of euphoria over their newly recovered ability to see at near. Months later, a small subset of these individuals may begin to notice and complain about imperfections in the quality of their vision. The novelty of their near vision is gone, and they may become unhappy with their surgical choice.

The early euphoria can extend to surgeons, as we become excited about each new product release and hope that this generation of technology will truly solve all of our problems. The presbyopia-correcting IOLs available to us today are substantial improvements over older lenses, but all forms of surgical presbyopic correction involve some degree of optical compromise, which we do not fully appreciate until we have several months of experience with a technology. Our ongoing goal is to make that optical compromise smaller and smaller.

In the United States, our experience with the two corneal inlays now available is limited. In the trials of both devices, the investigators achieved very good results, thus satisfying the FDA's requirements. Inlays offer the prospect of presbyopic correction to a completely new set of patients, but disciplined patient selection and careful surgical technique will be necessary to achieve the same very good results postapproval. This matter is not trivial, because the general population might incorrectly perceive a poor result in an inlay patient as an indictment of not only that technology but of LASIK as well.

Perhaps more than any other specialty, ophthalmology has introduced entirely new categories of products several times in the past 2 decades. Whether it is corneal collagen cross-linking, extended-depth-of-focus IOLs, or corneal inlays, we have an opportunity and a responsibility to properly shepherd these new technologies along. In the past, we have sometimes done a better job than others, but in an environment where even a few unhappy patients can make their voices widely heard, our duty is more important than ever. ■

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