TO THE FDA WITH APPRECIATION

During the past 2 decades, we physicians have observed cycles of innovation within the field of ophthalmology. In the mid-1990s, FDA approvals of topical dorzolamide, brinzolamide, brimonidine, latanoprost, bimatoprost, and travoprost began to transform the medical treatment of glaucoma. The use of pilocarpine, dipivefrin, phospholine iodide, and oral carbonic anhydrase inhibitors dropped precipitously, and the quality of glaucoma care for and the quality of life of glaucoma patients improved dramatically.

The approval of new medications is not without risk; unknown adverse effects may later come to light. One such example is the nonsteroidal anti-inflammatory drug rofecoxib (Vioxx; Merck & Company), which the FDA approved in 1999. This drug quickly became very popular for the treatment of acute and chronic pain. By the end of 2003, the $2.5 billion product had been used by more than 80 million people worldwide. Though efficacious, rofecoxib was soon linked to increased rates of heart attack and stroke, leading to its removal from the marketplace in 2004. Sadly, an investigation revealed that at least some data related to the drug's safety had been falsified, putting the general public at risk. I can only imagine how much pressure FDA leaders must have then felt from governmental peers and the general public. The actions of the investigative physicians and industry members in cases such as that of rofecoxib led to increased regulation of new medical products. Trust is a key component of any positive relationship. Restoring it takes time and effort.

Over the past few years, I have been thoroughly impressed by the FDA's efforts to work with ophthalmologists in a constructive fashion. The agency has set up guidelines that have been very helpful in setting an appropriate bar for new products. It has also worked closely with physicians and industry to determine what safety and efficacy standards are appropriate for new classes of drugs and devices. With the approval of the iStent Trabecular Micro-Bypass Stent (Glaukos), Kahook Dual Blade (New World Medical), CyPass Micro-Stent (Alcon), corneal collagen cross-linking (Avedro), VisuMax Femtosecond Laser ReLEx SMILE procedure (Carl Zeiss Meditec), Tecnis Symfony IOL (Abbott), and the Kamra (AcuFocus) and Raindrop (ReVision Optics) corneal inlays, we appear to be entering an exciting period in the treatment of glaucoma, corneal disease, refractive error, and presbyopia.

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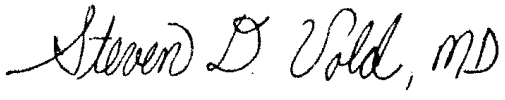
For innovation to flourish during a complete overhaul of the US health care system and despite an extremely challenging political climate speaks to the incredible efforts of the FDA to guard the best interests of our patients. From my perspective, FDA officials deserve our kudos. They have taken great risks and put in long hours to raise the bar in health care. I hope we physicians will all be conscientious and responsible in our use of the promising new technologies in our hands. ■



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