Blocking Surgical Innovation: Part 1

Most of the subspecialties within ophthalmology have developed sophisticated, modern surgical approaches. Glaucoma remains the glaring holdout for a number of reasons. The need for us to develop a strong bond with our patients and to hold their hands after trabeculectomy is not one of them. Certainly, our not understanding the disease, why it occurs, and what it does is problematic. That we often divide cases into either open- or closed-angle glaucoma based on gonioscopy (rather than use more sophisticated genotypic categories) does not help. The big problem, however, is a lack of surgical options.

Despite what readers may think, the major obstacle in making new technology available for glaucoma is not a lack of novel products. Between the years 2000 and 2004, more than 60 patents in glaucoma were granted versus fewer than five during the period of 1990 to 1994. Nor has the need for a better approach to glaucoma escaped the attention of Big (and Little) Pharma. Seed money from the ophthalmic industry and the venture capital community has helped to fuel research and development (see the interview of Bill Link, PhD, in this issue of *Glaucoma Today*). Currently, at least 14 companies are working in the glaucoma surgical space, and multiple clinical trials are underway or in development.

The regulatory hurdles have also been partially addressed. The FDA recently hired additional staff to deal with the increased number of new glaucoma device applications. These individuals attend the glaucoma meetings and are aware of the pressing need for new technology. They have established new policies for the safety and efficacy data necessary for approval. To date, I have not heard any reports that bureaucracy is delaying the approval of devices in glaucoma (eg, the Trabectome [NeoMedix Corporation, Tustin, CA] or products from iScience Interventional [Menlo Park, CA]). The iStent (Glaukos Corp., Laguna Hills, CA) is currently under review.

I have outlined what the major impediment to glaucoma surgical innovation is not. Next month, I will discuss what *is* keeping devices from the market. ❑

Richard A. Lewis, MD
Chief Medical Editor