

The Pitfalls of the Marketplace

Why promising trial results and FDA approval do not guarantee success.

BY MARGUERITE B. McDONALD, MD

There are several reasons why FDA-approved drugs, surgical techniques, and devices with promising clinical trial results bomb when they enter the marketplace. First, however, it is important to establish that true failures are those products that never attain widespread acceptance and use. Extracapsular cataract surgery, for example, was not a failure; it was widely used for many years before being replaced by phacoemulsification. Epikeratophakia and radial keratotomy were also not true failures, because both were popular procedures before being replaced by more advanced technologies. True failures gain so little traction in the marketplace that small companies become insolvent fairly quickly; corporate assets, including the intellectual property, are sold off in an effort to make the creditors whole. When a large company has a product fail, the appropriate division is rapidly closed, the personnel are reassigned or laid off, and the quarterly corporate earnings report suffers a blow. This story is familiar in ophthalmology. Examples include conductive keratoplasty, Intacs (Addition Technology, Inc.), the epikeratomes, laser thermal keratoplasty (Sunrise Technology), the MemoryLens (CIBA Vision Corporation), and several microkeratomes (after receiving 510[k] approvals), including the infamous Innovatome (Innovative Optics, Inc.).

REASONS FOR FAILURE

Poor Corporate Management

Some drugs, surgical techniques, and devices represent advances in the field of ophthalmology but fail due to poor corporate management. For instance, a small company, desperate for an infusion of operating cash, may create a large installed base before the ideal patient candidates are identified, the surgical pearls are worked out, and/or the marketing materials are fully developed. Alternatively, in an attempt to save money, a small company will hire friends and family members to work for cheap or for free in positions in which they have no training or expertise.

Poor Marketing

Timing also plays a role. It took years for ophthalmologists to acquire the sales and marketing techniques required for success in the world of elective procedures such as refractive surgery, onabotulinumtoxinA (Botox; Allergan, Inc.), Restylane injections (Medicis Pharmaceutical Corporation), and premium IOLs. Several excellent products failed in the marketplace largely due to ophthalmologists' not yet knowing how to effectively market them. If these products were instead released today, they would likely be a success.

Considering ophthalmologists' hard-won expertise in sales and marketing and the cuts in reimbursement, it will likely not take long for them to embrace in-office retail sales of items such as heat masks for blepharitis; eyelid cleansing pads; "boutique-brand" artificial tears available only to the trade, like Retaine MGD Ophthalmic Solution (OcuSoft, Inc.); liposome eyelid sprays, anti-aging skin creams and treatments; and even pharmaceuticals, as Mitchell A. Jackson, MD, has proposed.¹

Ophthalmic products are being developed that have only a temporary effect such as eye drops to treat presbyopia for several hours and laser thermal keratoplasty (Opti-K System; NTK Enterprises, Inc.) to treat presbyopia for up to 2 years before retreatment is required. I believe that these products will be successful, if found to be safe and effective, because ophthalmologists have finally learned a lesson that the dermatologists learned long ago: physicians should not apologize to patients because their bodies are aging and in need of serial treatments.

Poor Safety and Effect

Of course, some products fail because they are unsafe or ineffective. The FDA does an amazing job of protecting

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the US populace from bad drugs and devices. Very rarely, however, a suboptimal product makes it to the market. The Innovatome, for instance, was an unsafe mechanical microkeratome with a seriously flawed design. It occasionally and unpredictably cut too deeply into the stroma during LASIK, leading to cases of severe postoperative astigmatism and even open globes. The Innovatome was pulled from the market after numerous disasters occurred nationwide.

Another example of an ineffective product, dapiprazole (Rev-Eyes; Abbott Laboratories, Inc., marketed by Storz Ophthalmics) was advertised as being poised to revolutionize the practice of eye care by reversing pupillary dilation through constriction. The drug worked slowly, often taking hours to return the pupil to its normal state, during which the dilating drops could have worn off naturally. Most patients also experienced stinging upon instillation and significant conjunctival erythema. The product also cost four to five times more than the dilating eye drops. Not surprisingly, dapiprazole is no longer available in the United States.

Sunrise Technology's laser thermal keratoplasty procedure was ineffective as a treatment for hyperopia. It caused early and significant overcorrection, followed by a brief period when the patient usually enjoyed good vision, followed by regression of the effect. Although many ophthalmologists still have one of these lasers in storage (or are using it as an expensive plant stand), this procedure has not been performed in years.

CONCLUSION

Ultimately, FDA approval does not guarantee success in the marketplace. Besides the factors already mentioned, products also fail because the size of the market was overestimated or the product was overpriced. Successful products typically fulfill an unmet need, are managed by a talented team of professionals, and often have a bit of good luck behind them. ■

Marguerite B. McDonald, MD, is a cornea/refractive specialist with the Ophthalmic Consultants of Long Island in New York, a clinical professor of ophthalmology at the NYU School of Medicine in New York, and an adjunct clinical professor of ophthalmology at the Tulane University Health Sciences Center in New Orleans. She acknowledged no financial interest in the products or companies mentioned herein. Dr. McDonald may be reached at (516) 593-7709; margueritemcdmd@aol.com.



1. Jackson MA. Ancillary services in ophthalmic practice: pharmaceutical dispensing. *Cataract & Refractive Surgery Today*. June 2012;12(6):60,62.