Current Perspective

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Problems With Generic Drugs

Last month, I received a letter from a member asking the Academy to form a nonprofit generic drug company. It nicely articulated the problems many ophthalmologists face with regard to drug shortages and wildly fluctuating prices on long-established medications.

The letter was stimulated in part by a proposal this year from 4 major national hospital chains (Intermountain Healthcare, Ascension, SSM Health, and Trinity Health) to create such a company. Whether they actually implement the proposal remains to be seen. It's a very risky, capital-consuming, regulation-rich, and complex business. Financial analysts have questioned whether these 4 companies, which have combined annual revenues of over $25 billion, can sustain such an operation.

The author posed a reasonable question. Unfortunately, the reasonable answer is that it is way, way beyond the Academy's expertise and financial capability to get into the pharmaceutical business.

The underlying concerns of access to generic medications and costs are well known to both physicians and patients. One issue is that the generic pharmaceuticals business is not an efficient free market. Regulatory issues (U.S. Food and Drug Administration [FDA] and others), reformulations and patent extensions, and some prohibitions against price negotiation all conspire to make the marketplace not transparent.

Added to this are low profit margins and manufacturing and quality issues on some generic medications. According to the FDA, about 70% of generic drug shortages can be attributed to manufacturing issues. Manufacturer consolidation further compounds the problem. The result is periodic shortages of generic drugs, including pilocarpine (where spending rose from $116,092 in 2009 to $2.2 million in 2013), fluorescein strips, timolol, atropine, dorzolamide, and phenylephrine (where the cost has risen up to 1,000% in a short period of time).

Despite those examples, nothing about this is ophthalmology-specific. The rate of newly reported drug shortages increased sixfold between 2008 and 2012. The price of a heart failure generic (captopril) increased more than 2,800% over 1 year. The number of digoxin manufacturers fell from 8 to 3 in a decade, and its price increased more than 600%. Where manufacturing monopolies exist, companies are free to effectively raise prices at will.

From our perspective, the more competition, the better, as it encourages reasonable pricing and more rapid access to generic and biosimilar agents. The U.S. Senate is moving forward with legislation that would preclude brand-name manufacturers from withholding access to the 1,500-5,000 units of drug samples needed by manufacturers to create a generic version of a branded product. It would also smooth the way for generic companies to participate in necessary manufacturing safety protocols. The Academy supports this legislation as does a broad, diverse coalition of organizations including Kaiser Permanente, the AARP, and the Heritage Foundation. Its support in the Senate includes Sens. Dianne Feinstein, D-Calif., and Rand Paul, MD, R-Ky. (How bipartisan can you get?)

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The Academy has also stimulated Senate inquiry into glaucoma drug prices, and we've urged the administration to end the "gag order" practice whereby health plans bar pharmacists from providing drug pricing information to patients. The administration opposes this practice, but the Academy is urging it to go further and actually ban this practice in order to help patients make more informed choices. Prices vary by supplier, by plan, and by pharmacy.

We all understand that the pharmaceutical marketplace is neither efficient nor transparent. Issues such as "value-based pricing," Pharmacy Benefits Managers (PBMs), patent policy, 340B pricing, group purchasing organizations, rebate programs, statutory prohibitions on price negotiation, and gag orders all result in obfuscation and/or inefficiencies. In the generic space, the results can be reflected not only in price but also in availability—and physicians and patients can lose.