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Ophthalmology's Dependence on the Fragile Generic Drug Supply Chain

During the COVID-19 pandemic, online home furnishings store ABC Carpet & Home sent out an email to 204 customers announcing a delay in couch deliveries. When a customer responded using “Reply All,” a digital community emerged. Initially, conversation centered around supply chain complaints, but it evolved into more personal interchanges when one customer announced she was single, living in New York, and looking for a date. The group also created a GoFundMe page to help a family in need.

Supply chain issues affect more than decorating plans, and they don't always have a cheerful ending. For example, the 2022 U.S. baby formula shortage led to responses by federal agencies and the White House. Ophthalmologists feel a similar sense of urgency when our patients are affected by drug shortages. Last year, many of my patients were not able to fill their dorzolamide-timolol drop scripts due to a drug shortage. For some, the co-pay for a branded alternative was more than \$200 and unaffordable. Finding a temporary solution wasn't just frustrating, it was frightening for patients and resulted in a deluge of messages for our staff.

Although the pandemic heightened awareness of supply chain issues, national drug shortages are nothing new. After the number of new drug shortages peaked in 2011, the FDA began requiring drug manufacturers to notify the FDA about impending shortages sooner so that alternative medications and production plans could be developed.¹ Still, ophthalmic drug shortages seem too common.

In the United States, 91% of prescriptions are filled with a generic medication,² and most drug shortages involve generic drugs. Shortages can occur for many reasons, including pandemics, natural disasters, or when a manufacturing plant is closed. When Akorn Pharmaceuticals filed for chapter 7 bankruptcy last year, multiple plants were abruptly closed, resulting in acute shortages of many ophthalmic drugs and diagnostics.

However, most drug shortages are related to the intrinsic fragility of the generic drug supply chain. When patent protections expire and multiple companies begin manufacturing what was previously a brand-name drug, prices for the medication can decrease dramatically—sometimes by as much as 95%.³ The new, slimmer profit margin can reduce a

drugmaker's incentive to produce generic drugs, diminishing the resiliency of the supply chain. A second—and more opaque—factor is the emergence of “buying groups,” which purchase generic drugs from manufacturers and then turn around and sell them to pharmacies and hospitals. This gives the purchasers more control over pricing and suppresses competition. Thirdly, most ophthalmic drugs are manufactured by one or two companies, so any manufacturing problem guarantees a shortage. Finally, when drugs go generic, quality control and manufacturing oversight can decline.

In a December 2023 *New York Times* editorial, Dr. Emily Tucker at Clemson University suggests that markets alone have not been able to solve drug shortages and that legislative action is needed. Emily argues that manufacturing facilities must modernize. Manufacturers should also develop systems to increase adaptability and production between plants. And Dr. Tucker advocates for creating an inventory of generic drugs so that supplies are available when disruptions occur.⁴

The Academy actively works to alleviate drug shortages in ophthalmology and supports additional policy changes. For example, after reaching out to outsourcing facilities during several ophthalmic drug shortages, the Academy recommended that the FDA extend periods for production and distribution of products. And the Academy advocates for more communication about expected length of a shortage and transparency about the causes of a shortage, and for policies that would improve both manufacturing capacity and incentives for pharmaceutical companies to enter the generic market where a single-source drug product exists.

Republicans and Democrats support changes that would promote a more resilient drug supply chain. Our patients need consistent, predictable access to medicines that can save vision and lives. It's more important than sofas and dates.

1 FDA Report to Congress. www.fda.gov/media/169302/download?attachment. Accessed Jan. 17, 2023.

2 FDA. www.fda.gov/drugs/generic-drugs/office-generic-drugs-2022-annual-report. Accessed Jan. 17, 2023.

3 FDA. www.fda.gov/media/133509/download. Accessed Jan. 17, 2023.

4 New York Times. www.nytimes.com/2023/12/06/opinion/drug-shortages-pharmaceuticals.html. Accessed Jan. 17, 2023.