■ A Call to Action to Track Generic Drug Quality Using Real-World Data and the FDA's Sentinel Initiative

The invited perspectives in the May 2020 issue of *JMCP* on the "Safety and Quality of the Generic Drug Supply Chain" should be eye opening to this growing concern for the United States and the global drug supply. While the discussion across the 4 commentators focused on the history and clinical perspectives and outlined some steps moving forward,¹⁻⁴ recent research in generic drug quality funded through ongoing FDA initiatives are worth mentioning, with additional context on the FDA's use of real-world data for their surveillance efforts.

As the number of manufacturing facilities has increased overall, especially internationally, the FDA has relied on a "Site Selection Model (SSM)" to identify high-risk facilities for inspection. The SSM includes site characteristics, compliance and inspection histories, product characteristics, and "hazard signals." Hazard signals are from a myriad of sources that may indicate potential product concerns and include FDA inspection reports, drug recalls, or signals from the FDA Adverse Event Reporting System (FAERS) and the MedWatch program. However, the FDA and manufacturers identify limitations of FAERS data to track generic drug quality, thus, innovations are desperately needed.

Towards this innovation, the FDA recognizes the potential for real-world data in the postmarketing surveillance period. Two recent studies funded by the Office of Generic Drugs exemplify potential approaches to surveil generic drug quality using administrative claims data. One study used the FDA's Sentinel Initiative distributed data network to track patient persistence to therapy, stratified by manufacturer, and revealed clear differences between manufacturers' products.⁵ The other study from my own group also tracked clinical events related to the indications and side effects of a specific drug (metoprolol succinate extended release) and compared the brand with 2 generic versions that were eventually recalled during the initial generic marketing period (2007-2008).⁶ In that study, we were able to capture stronger signals related to specific outcome events (e.g., heart attack and hypotension) compared with utilization metrics (i.e., persistence) and showed that these signals were strongest in the first 90 days of use.

Each of these studies represent opportunities for use of real-world data, specifically claims data, to strengthen generic drug quality research and surveillance with the possibility of near-real time evidence generation. The FDA Sentinel Initiative is the prime resource for postmarketing surveillance, and the onus is now on the relevant groups within the FDA, such as the Office of Generic Drugs and the Office of Pharmaceutical Quality, to use this resource to its fullest potential. In addition, managed care organizations with direct data access for their own members could also answer the call to use their own resources to ensure patient safety. These efforts and the resulting real-world evidence should be communicated to the FDA and be used as another tool to protect the U.S. drug supply and

public health. Physicians, pharmacists, and other providers should likewise take patient concerns, or their own observations, seriously and add these experiences to the regulator's armament of data to combat the generic drug quality issue.

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REFERENCES

1. Lever HM. A physician's perspective on generic drug quality. *J Manag Care Spec Pharm.* 2020;26(5):592-93. Available at: <https://www.jmcp.org/doi/10.18553/jmcp.2020.26.5.592>.
2. Hussar DA. Is the quality of generic drugs cause for concern? *J Manag Care Spec Pharm.* 2020;26(5):597-99. Available at: <https://www.jmcp.org/doi/10.18553/jmcp.2020.26.5.597>.
3. Gaugh D. Global pharmaceutical manufacturing: association for accessible medicines perspective. *J Manag Care Spec Pharm.* 2020;26(5):594-96. Available at: <https://www.jmcp.org/doi/10.18553/jmcp.2020.26.5.594>.
4. Eban K. Can we trust the quality of generic drugs? *J Manag Care Spec Pharm.* 2020;26(5):589-91. Available at: <https://www.jmcp.org/doi/10.18553/jmcp.2020.26.5.589>.
5. Gagne JJ, Popovic JR, Nguyen M, et al. Evaluation of switching patterns in FDA's Sentinel System: a new tool to assess generic drugs. *Drug Saf.* 2018;41(12):1313-23.
6. Brown JD, Henriksen C, Vozmediano V, Schmidt S. Real-world data approaches for early detection of potential safety and effectiveness signals for generic substitution: a metoprolol extended-release case study. *J Clin Pharmacol.* 2019;59(9):1275-84.

■ Flash Continuous Glucose Monitoring in Primary Care Settings: The Need for Measurement of Novel Glycemic Metrics to Adopt Policy and Practice Change

The article "Effect of Pharmacist-Driven Professional Continuous Glucose Monitoring in Adults with Uncontrolled Diabetes" published in the May issue of *JMCP* by Sherrill et al. highlights how pharmacists can collaborate with physicians in primary care settings through use of flash continuous glucose monitoring (CGM).¹ The authors sought to determine the most effective method for lowering hemoglobin A1c (HbA1c) at 6 months among 1 or 2 CGM interpretation encounters with a pharmacist as compared with 1 interpretation encounter with a physician. Clinical interventions were also described based on the encounters. The authors should be commended for undertaking this study, especially in light of only 1 other study published in the literature evaluating outcomes from pharmacist-driven CGM services.² Additionally, the authors included patients with diabetes using oral antidiabetic medications, in