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Generic Drug User Fee Reauthorization Amidst Alleged Concerns of Safety and Efficacy

On September 17, the U.S. Food and Drug Administration (FDA) held a public meeting on recommendations for Generic Drug User Fee Amendments (GDUFA) reauthorization. After discussing the reauthorization process, Abbreviated New Drug Application (ANDA) assessment enhancements, both the industry and the public provided feedback. There were only three industry representatives from the Association for Accessible Medicines, Pharma & Biopharma Outsourcing Association, and Bulk Pharmaceuticals Task Force. In general, these industry speakers supported reauthorizing GDUFA but also wanted FDA to provide more transparency for reference listed drugs and their ingredients / drug master files to the extent FDA could do so.

When it came to the public testimony, one theme seemed to emerge – mistrust not just in FDA's oversight of generic drugs and their manufacture via inspections and approvals, but also with alleged differences in generic products and compared to their referenced listed drug products. Such allegations are not new and emerged even in the beginning of the generic drug approval process established in Hatch-Waxman. In addition, comments were raised about concerns with drug shortages caused by manufacturing procedures with tight margins due in part to the lower prices of generic drugs.

In March/April 2026, several doctors from Stanford University and Emory University published a paper in the *New England Journal of Medicine* perhaps relevant to this allegation, Substandard Generic Drugs – Threats to Patient Safety and National Security. The authors noted that, according to FDA, more than 60% of generic drug shortages are due to quality. And fear of drug shortages, in turn, may lead to the FDA prioritizing minimizing drug shortages over ensuring safety – at times bringing in

drugs that had been previously banned from export to handle a shortage situation while not informing the public of such decisions. The authors cited issues with nitrosamines (carcinogens) in drugs made by generics as well as cases of low-quality drugs that impact patients, e.g., poor quality immunosuppressive drugs that led to cases of organ failure.

The authors noted that Europe has a more proactive approach to ensure the safety of generic drugs including the European Medicines Agency's risk-based surveillance and systematic post-approval testing of commercial products in addition to facility inspections. The authors recommend five actions to ensure drug safety in the U.S.:

- FDA needs to acknowledge that it cannot verify its claim that generic drugs are equally safe and effective without additional product testing.
- FDA could encourage independent generic drug testing by International Organization for Standardization-accredited laboratories and use test results to prioritize factory inspections and strengthen oversight.
- FDA, including the Centers for Medicare and Medicaid Services (CMS), could purchase drugs on the basis of best value versus lowest cost. CMS's use of only high-quality generic medications could reduce costs by preventing complications and improving outcomes.
- Quality scores could be made transparent to consumers. Once drug-quality information was more widely available, then patients, health systems, and pharmacies would reward high-quality suppliers with contracts and greater market share. The authors speculated that such drug-quality information would drive the market to higher-quality drugs faster and more effectively than periodic FDA inspections.
- The U.S. government could oversee an effort to rebuild U.S. capacity to manufacture generic drugs with investment for purchasing through CMS programs. The authors noted that the U.S. Department of Health and Human Services found 87% of sites that make active pharmaceutical ingredients and 63% that make finished dosage forms were outside the U.S., making the supply chain vulnerable to an embargo of essential drugs or the materials to make them.

Overall, the authors noted that while there is only a minority of generic drugs with safety or efficacy issues, they advocated that the U.S. take a more proactive

approach for testing and reporting the test results more publicly.

Key Takeaways

User fee discussions are often viewed as an opportunity to not only recommit to certain application review metrics but to improve FDA's regulatory oversight. The current GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2028-2032 discusses some improvement in communications regarding inspections but perhaps some enhancements to improve FDA oversight over generics would help the industry and consumers as suggested by the above authors? The docket for comments on the next round of GDUFA ends October 17, 2026, at FDA-2025-N-0873 and as of publishing, there are only three filed public comments.

This blog was drafted by Brian Malkin, co-lead of the Spencer Fane FDA Pharmaceutical and Biologics Market Team. For more information, visit spencerfane.com.

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