AMERICAN HEALTH LAW ASSOCIATION

September 19, 2025

Counting Every Dose—How the FDA Tracks Drug Shortages (and What They Might Be Missing)

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Drug shortages were not everyday dinner conversation before the COVID-19 pandemic, but scrambling for vaccines made all of us think about drug availability and who qualifies to be at the top of the priority list. In 2017, semaglutide (Ozempic™) was approved for the treatment of Type 2 diabetes. [1] Millions of diabetics, including my mother, immediately reaped the benefits of Ozempic, including a lower A1C and significant weight loss. Beginning in late 2021, she started expressing frustration with

pharmacies being unable to fill her prescription. She had to drive over an hour to another city to pick up one of her monthly doses. In March 2022, the American Society of Health-System Pharmacists (ASHP) and the Food and Drug Administration (FDA) first placed semaglutide on their drug shortage lists.[2] The media largely attributed the shortage to off-label use for weight loss in non-diabetics.[3] The GLP-1 drama that unfolded highlights several key questions about current tracking methods. How does the FDA track drug shortages? How does off-label use get factored into the calculations? Are cash purchases and compounded drugs included in these calculations? Are there unanalyzed data available to more adequately determine when a shortage starts and ends?

The FDA's Legal and Regulatory Framework for Drug Shortage Determinations

The FDA evaluates drug shortages primarily under the statutory authority granted by the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012, which significantly expanded the FDA's ability to address drug shortages by amending the Federal Food, Drug, and Cosmetic Act (FD&C Act).[4] The FDA's Drug Shortage Staff (DSS) utilizes procedures outlined in its Manual of Policies and Procedures (MAPP) to conduct drug shortage analyses by following these steps:

1. Determining if current product demand is stable or increasing based on historical data using a market research database.
2. Contacting product manufacturer(s) to provide accurate inventory information, manufacturing schedules, and any changes in ordering patterns.
3. Evaluating product distribution at the wholesale level, if needed.
4. Assessing information obtained from market research, manufacturer(s), and wholesaler(s) to determine if an actual drug shortage exists.
5. Requesting a new or updated Medical Necessity Determination Form from the [Office of New Drug] division(s) with the requisite expertise on that drug product, if the existing Medical Necessity Determination Form is more than one year old or if needed.
6. Collecting the same information as in steps 1–4, above, for acceptable therapeutic alternative drug product(s) if acceptable therapeutic alternative drug product(s) exist.
7. Establishing a risk-versus-benefit profile related to an [Office of Compliance] or [Office of Pharmaceutical Quality] action and the potential for a resulting drug shortage, when applicable. This profile should be established with input from the DSS and any other organizational entity mentioned in the Responsibilities section of this MAPP.
8. Monitoring the shortage situation until resolution.[5]

What's Not Included: Gaps in the FDA's Data Model

Per the MAPP, the FDA evaluates the following in its drug shortage analysis: historical data using "a market research database," product manufacturers' inventory information, and wholesale distributors. There is little clarity provided on which market research database(s) the FDA uses explicitly. Still, in a Duke University presentation for a 2018 FDA-led public meeting, the FDA explained that it uses IQVIA National Sales Perspective, a commercial insurance-based claims dataset, to assess the volume of drugs sold during both active shortages and resolved periods.[6] Until the public became aware of the benefits of GLP-1s for weight loss and demand exploded, this dataset seemed to capture the bulk of

drug demand adequately. However, since then, gaps in this data model have become more apparent. Below is a discussion of two hypothetical patients to illustrate where these gaps may exist and their significance in the context of GLP-1s.

Patient A is a school teacher in the lower to middle income bracket who is overweight and is medicated for high blood pressure. Her employer offers health insurance but requires her to pay over $1,000 per month for a GLP-1 prescription. This expense does not fit into her budget. She reached out to a telehealth provider who told her, "Because you have a slight B3 (niacin) deficiency, I can prescribe a compounded version of tirzepatide and niacinamide injections, and it will only cost you $275 per month." Patient A opts for the personalized compounded version and pays the compounding pharmacy directly, thereby circumventing primary care and pharmacy insurance claims. Does the FDA account for that dose in the calculation of drug demand when evaluating whether there is a shortage of tirzepatide?

The short answer is: no. Specifically, the FDA believes that compounded drugs are not FDA-approved and, therefore, are not considered acceptable therapeutic alternatives.[7] As discussed, the FDA's demand calculations are based on data from manufacturers and distributors, sales of FDA-approved products, insurance claims, prescription fulfillment trends, and health system reports. Because Patient A's compounded tirzepatide plus niacinamide is prepared by a compounding pharmacy (not a drug manufacturer) and paid out-of-pocket (not billed through insurance), her dose is effectively invisible in the FDA's demand modeling. That is to say that Patient A's dose is invisible to the FDA under the current methodology for determining whether a shortage exists and when it has ended.

Patient B, a successful actress who struggles with alcohol addiction, reached out for help from a highly sought-after private treatment center that maintains strict confidentiality, where she can pay cash to receive GLP-1s to curb alcohol cravings. She is so impressed with its effectiveness that she decides to stock up on the drug for future use. Does the FDA account for Patient B's dose in the calculation of drug demand when evaluating whether there is a semaglutide shortage?

The short answer is: no. The FDA does not track cash purchases by individual patients, such as those made by Patient B, retail pharmacy sales disaggregated by diagnosis or insurance status, or off-label prescribing trends, unless such use significantly alters manufacturer-supplied demand data. "CDER [Center for Drug Evaluation and Research] does not consider compounded versions, off-label demand, or patient-level purchasing behavior in its formal evaluation unless reported by manufacturers or health systems."[8]

Consequences of Misalignment Between Data and Reality

In the GLP-1 saga, millions of Americans followed the same path as Patients A and B simultaneously. Estimates of the number of compounded doses of tirzepatide and semaglutide filled range from 200,000 per month to 80 million prescriptions for semaglutide in the last 12 months.[9] It is nearly impossible to determine how many private-pay patients were placed ahead of those with insurance or Medicare/Medicaid coverage due to the confidentiality of private contracting and health information privacy laws. Demand for GLP-1 drugs was growing exponentially in areas that were invisible to the FDA's DSS, while insurance companies were scrambling to secure enough doses for diabetic clients.

This conflagration of factors led to the shortage, catching the FDA off guard. Diabetic and non-diabetic patients falling within the approved indications for use were unable to secure their medications before the FDA announced the shortage. Once a shortage was announced, compounding pharmacies were allowed to step in and legally make versions of GLP-1s that were on the drug shortage list.[10] During the evaluation to remove a drug from the shortage list, the same gaps in the data discussed above arguably led the FDA to remove the GLP-1 drugs from the shortage list prematurely. Patients A and B continued to purchase their doses through the same channels that are invisible to the FDA when determining if the shortage has ended. These blind spots in the data cast doubt on the effectiveness of the existing process for evaluating a drug shortage.

Legal Challenge to the FDA's Shortage Decisions

In October 2024, Outsourcing Facilities Association (OFA) and North American Custom Laboratories, LLC, doing business as FarmaKeio Superior Custom Compounding (FarmaKeio), filed suit against the FDA challenging the decision to remove tirzepatide from the drug shortage list. The complaint alleges that "FDA removed tirzepatide from the shortage list without notice, without soliciting input from affected parties and the public, and without meaningful rationale."[11] According to the complaint, industry participants provided evidence of continued high demand and scarcity throughout the drug shortage, and "the agency was in actual or constructive receipt of information demonstrating that supply continued to lag behind demand, even at stark levels.[12] The FDA did not have the usual opportunity for public comment, and thereby "deprived regulated parties and other interested persons of the opportunity to comment on the proposed delisting of tirzepatide and to provide probative information concerning the drug's availability."[13] OFA and FarmaKeio filed a similar challenge in February 2025 after the FDA decided to remove semaglutide from its shortage list.[14] Both cases were dismissed with prejudice. The court gave deference to data from the drug companies (Eli Lilly & Co. in the tirzepatide case; Novo Nordisk in the semaglutide case), as well as to the FDA's decision making regarding supply, demand, inventories, and projected usage. As the data showed, according to the court, the supply was sufficient, and the actions fell within the FDA's authority.[15]

In response to the action involving tirzepatide, CDR Robert Kosko, a consultant on the CDER DSS, issued a memo on December 19, 2024, entitled *Resolution of Tirzepatide Injection Product Shortage and Supply Status*, which described the data justifying the removal of tirzepatide from the drug shortage list.[16] This memo includes approximately ten pages of heavily redacted information about Eli Lilly's internal supply and demand data, including stock reports, cumulative supply and demand reports, and distributor inventory reports. The memo addresses additional information received from various sources, including telehealth companies, pharmacy compounders, associations representing pharmacy compounders, outsourcing facilities, and individual stakeholders. The memo, however, criticizes the data collection and presentation methods of the non-manufacturer sources. The data generation method used by Hims & Hers included an online survey, which the report invalidates because it utilizes an "internet form that anyone can complete" and has inadequate limitations.[17] The report also criticizes data provided by OFA because it is unclear how the data was collected and "does not include details of the reported individual experiences."[18] The question, though, is why doesn't the FDA collect or, at a minimum, facilitate the collection of data from sources other than pharmaceutical manufacturers? As seen with the two hypothetical patients, a drug manufacturer's

internal demand data does not always create a complete picture of actual demand. Reliable data from both manufacturers and non-manufacturers could help ensure that the FDA has the information it needs to accurately determine when a drug is in shortage.

Opportunities for Reform

The GLP-1 crisis has brought to light the potential gaps in the data used to determine if there is an active or complete drug shortage. Below are a few options that might give the FDA a more accurate view of demand and supply for making its determination:

1. Expand the required manufacturer reporting to include off-label demand signals.
2. Collaborate with pharmacy chains, compounding pharmacies, and Pharmacy Benefit Managers on cash sales data.
3. Monitor compounding trends as an indirect shortage signal.
4. Facilitate the collection of demand data from all sources, not just pharmaceutical manufacturers, including online and compounding pharmacies and telehealth providers.
5. Create access to real-time prescription fulfillment data.
6. Integrate prescription drug monitoring programs and health information exchanges.

There are also potential obstacles to these options that require careful consideration, including privacy concerns, taxpayer costs, reporting burdens, and the need for new legislative or administrative action. But ultimately, ensuring a more effective warning system for drug shortages related to changes in demand would benefit patients.

Conclusion

The GLP-1 shortage has been a case study in how a regulatory system built for yesterday's pharmaceutical market struggles to keep pace with today's fragmented, multi-channel reality. What began as a targeted therapy for Type 2 diabetes rapidly transformed into a cultural and commercial phenomenon, fueled by off-label use, viral marketing, and concierge medicine. Yet, the FDA's shortage determination framework, which is rooted in manufacturer reports, wholesale distribution data, and insurance-based claims, remained static. In this model, the millions of doses flowing through compounding pharmacies, telehealth platforms, and cash-only boutique clinics are largely invisible, even as they directly compete with insured patients for limited supplies.

The experiences of hypothetical Patients A and B are not anomalies; they represent entire populations whose purchasing and prescribing patterns were never factored into the official shortage calculus. The consequences were predictable: the FDA was late to recognize the shortage, allowed compounding to fill the gap, and may have prematurely declared the crisis over, despite persistent pharmacy stockouts. The lawsuits filed by the OFA regarding the delisting of semaglutide and tirzepatide underscore the significant legal, economic, and human implications of the FDA's drug shortage determinations. By reengineering its approach to include real-time, multi-source demand data from all points of sale and prescribing, not just those visible to manufacturers and insurers, the FDA could help ensure better, equitable access to critical medicines. Until every dose, whether compounded, cash-purchased, or dispensed off-label, is counted, the nation will remain vulnerable to shortages being "resolved" on paper while patients continue to go without the medications they need.

About the Author

Meredith P. Vanderbilt is a Special Counsel at Barkto Pavia LLP in the Intellectual Property Practice where she draws on a rare combination of legal, regulatory, and engineering expertise to guide clients in the life sciences industry. With a depth of experience spanning engineering, regulatory affairs, and law Meredith brings a perspective that few attorneys can match. She began her career as an engineer in the orthopedic device industry, where she thrived on solving complex problems and helping bring innovative technologies from concept to clinic. Her curiosity about the why behind design and regulatory decisions led her to transition into regulatory affairs, where she advised companies on FDA strategy, submissions, and compliance. Meredith's transition into law was a natural evolution of her career. After years of sitting at the table with legal teams on matters such as FDA warning letters, promotional claims, and internal investigations, she pursued her legal degree to expand the ways she could advocate for clients. Meredith uniquely bridges the worlds of science, regulation, and business, providing not only legal advice, but also practical, strategic guidance informed by decades inside the industry. She combines her technical fluency, regulatory insight, and legal training to help clients navigate enforcement, compliance risks, and competitive challenges in highly regulated markets. She holds a degree in biomedical engineering from Tulane University and has developed educational curricula as well as published several articles related to medical devices.

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[11] Amended Complaint ¶ 2, Outsourcing Facilities Ass'n v. U.S. Food & Drug Admin., No. 4:24-cv-953-P (N.D. Tex. Jan. 28, 2025).

[12] *Id.* at ¶ 32.

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