How Private Markets Addressed the GLP-1 Drug Shortage

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In March 2022, the Food and Drug Administration (FDA) added Ozempic and Wegovy to its drug shortage list. Tirzepatide injection followed on December 15, 2022 (Milliman, 2025). Demand for glucagon-like peptide-1 (GLP-1) drugs had outrun what their manufacturers could produce. The two shortages resolved on different timelines: the FDA ended the tirzepatide shortage in December 2024 and the semaglutide shortage in February 2025. It then set wind-down deadlines after which compounded copies could no longer be produced, running to April 22, 2025 for 503A pharmacies and May 22, 2025 for 503B outsourcing facilities (FDA, 2025).

The shortage reached an unusually large share of patients. GLP-1 drugs are among the most widely used pharmaceuticals in recent American history. By October 2025, roughly 12 percent of U.S. adults reported taking one for weight loss, up from 5.8 percent in February 2024 (Noguchi, 2025). Ozempic has also received FDA approval to reduce cardiovascular risk, improve glycemic control, treat kidney disease in adults with type 2 diabetes, and it is regularly prescribed off-label for weight loss (Wang et al., 2024).

The clinical stakes are highest in patients for whom obesity is not an isolated condition. The SELECT trial enrolled more than 17,000 adults with overweight or obesity and established cardiovascular disease but no diabetes. Semaglutide reduced major adverse cardiovascular events by 20 percent, and a prespecified secondary analysis found a 22 percent reduction in a composite kidney endpoint (Colhoun et al., 2024). Among patients with obesity-related heart failure with preserved ejection fraction, a population with few effective pharmacologic options, semaglutide improved symptom scores and six-minute walk distance relative to placebo, with benefits consistent across obesity classes (Butler et al., 2024). For these patients, an interruption in supply is not a cosmetic inconvenience. The benefits are contingent on continued exposure rather than banked. In the STEP 1 extension, participants regained two-thirds of their lost weight within a year of withdrawal, and the accompanying cardiometabolic improvements reverted toward baseline (Wilding et al., 2022). Discontinuation does not pause a course of treatment. It forfeits the gains the trials above document and returns patients with established cardiovascular or renal disease to the risk profile the drug was prescribed to change.

The clinical case also extends to younger patients. Semaglutide is approved for chronic weight management in adolescents aged 12 and older, and meta-analyses of randomized trials find significant reductions in body weight and BMI in children and adolescents with obesity, though long-term pediatric data remain thin (Liu et al., 2024; Chen et al., 2026).

The usual responses to a drug shortage were unavailable. Shortages are ordinarily absorbed by substitution, either to a generic version of the same molecule or to a therapeutically equivalent alternative. Neither route was open here. GLP-1s were too new to have generics, and no other agent reproduced their effects closely enough to substitute clinically for a particular drug, which placed the entire burden of supply on each product's branded manufacturer. Substitutes existed in the broad economic sense; drug-based substitutes for a given GLP-1 did not. Unlike most shortages, which hospitals manage by rationing within supply chains, GLP-1s are patient-administered in community settings and require direct-to-consumer delivery (Whitley et al., 2023). No existing infrastructure could ration them.

The shortage stemmed from demand forecasting rather than regulatory constraints, which matters for how quickly the market would be expected to correct it. Both manufacturers had built capacity against projections for diabetes indications and were overtaken by off-label and subsequently approved weight-loss demand. That is the kind of misestimation entry and expansion ordinarily resolve. Correction was slow here because the binding constraint was physical: sterile injectable fill-finish capacity takes years to build and qualify, and the major capacity acquisitions and plant expansions announced during the shortage did not reach production inside the shortage window. Compounding pharmacies faced no equivalent constraint. Registered 503B facilities held already-qualified sterile capacity and could begin producing within weeks. The asymmetry in adjustment speed, not a difference in willingness to supply, is why the parallel market scaled while branded output did not.

Instead, a parallel distribution system emerged, built by compounding pharmacies and direct-to-consumer telehealth platforms. We examine two questions about it: how much it expanded access, and whether it delivered treatment safely. What follows is in one respect a study of decentralized problem-solving. No central authority designed this system or assigned roles within it. Compounders, telehealth platforms, prescribers, accreditation bodies, insurers, and patients each pursued distinct objectives, and their interaction produced an unplanned allocation. This is the kind of order Vernon Smith (2009) terms ecological rationality: arrangements that work not because anyone reasoned them out in advance, but because they survive the test of use. The question is therefore not whether

this system was well designed. It is whether what emerged performed better or worse than the administered alternative.

Compounding, Telehealth, and the DQSA

Compounding pharmacies prepare medications themselves rather than distributing finished products from a manufacturer. Their legal footing comes from the Drug Quality and Security Act (DQSA) of 2013, passed after contaminated steroid injections from the New England Compounding Center killed 64 people and infected more than 750 across 20 states (Arbour Group, 2014).

The DQSA sorted compounders into two categories. Traditional pharmacies, known as 503A facilities, are regulated primarily by state boards of pharmacy and compound medications for individual patients. Outsourcing facilities, or 503B facilities, may produce medications in bulk without patient-specific prescriptions and sell them to healthcare facilities, telehealth providers, and online pharmacies. One provision mattered above all here: when a drug appears on the FDA shortage list, 503B facilities may produce compounded versions for wide distribution. Those facilities must follow good manufacturing practices, register annually, accept inspections, and report adverse events, but they do not undergo pre-market review (FDA, 2024).

Legal eligibility to produce a drug is not the same as getting it to patients. Telehealth platforms provided the missing layer: a patient completed a brief online consultation with a licensed provider, received a prescription, and had a partner pharmacy ship compounded medication directly home. Platforms handled logistics and patient management that compounding pharmacies could not and reached patients without an accessible local prescriber. At the height of the shortage, more than 100 platforms marketed compounded GLP-1s (Pharmacy Times, 2025). Hims & Hers alone passed 2.5 million subscribers across its product lines in 2025 (KFF Health News, 2026).

This arrangement created the reputational and legal stakes that private governance requires (March, 2017; Leeson, 2014). A 503B facility risked its operating registration if quality failures were documented. A subscription-based telehealth platform risked attrition if patient outcomes suffered. A physician prescribing carelessly risked losing patients and platform relationships. These are the incentives the arrangement created rather than a record of them firing. We are not aware of a documented case in which a 503B facility lost its registration or a platform lost subscribers over compounded GLP-1 quality.

That absence is consistent both with the mechanisms having worked and with their never having been tested.

Because the reporting data are thin, we also reviewed press and trade coverage across the shortage period for severe adverse events. The exercise is informative less for what it found than for what it did not. The harms that drew sustained coverage were dosing errors rather than contamination or counterfeiting. In July 2024, the FDA alerted prescribers that patients had drawn five to twenty times the intended dose from multidose vials, with some requiring hospitalization for severe nausea, vomiting, hypoglycemia, pancreatitis, and gallstones (FDA, 2024). Reporting traced the cause to the delivery format: patients unfamiliar with syringes and confusion between milligrams and milliliters, because the product was supplied in vials rather than the pre-filled pens used by the branded versions. We found no comparable body of reporting on adulterated or counterfeit product reaching patients through registered 503B facilities or established telehealth platforms, which is the harm the contemporaneous commentary had predicted. This is weak evidence, and we present it as such, but it points in the same direction as the reported rates.

Access

The scale of the parallel market was substantial. At its 2024 peak, compounded versions accounted for as much as 30 percent of total U.S. GLP-1 supply (ArentFox Schiff, 2025), and millions of patients were using them by that October (IQVIA, 2025). One study counted 79 separate online distributors still working with compounding pharmacies shortly before the shortage ended (Chetty et al., 2025).

Availability was the first draw and price the second. A shortage is a quantity constraint rather than a high-price equilibrium: patients willing to pay the branded price frequently could not fill a prescription at all. Compounded supply restored the ability to obtain the drug, and did so at lower cost. Compounded doses cost roughly $150 to $300 per month, compared with branded list prices exceeding $1,300, expanding access considerably for uninsured, underinsured, and coverage-denied patients (Pharmacy Times, 2025).

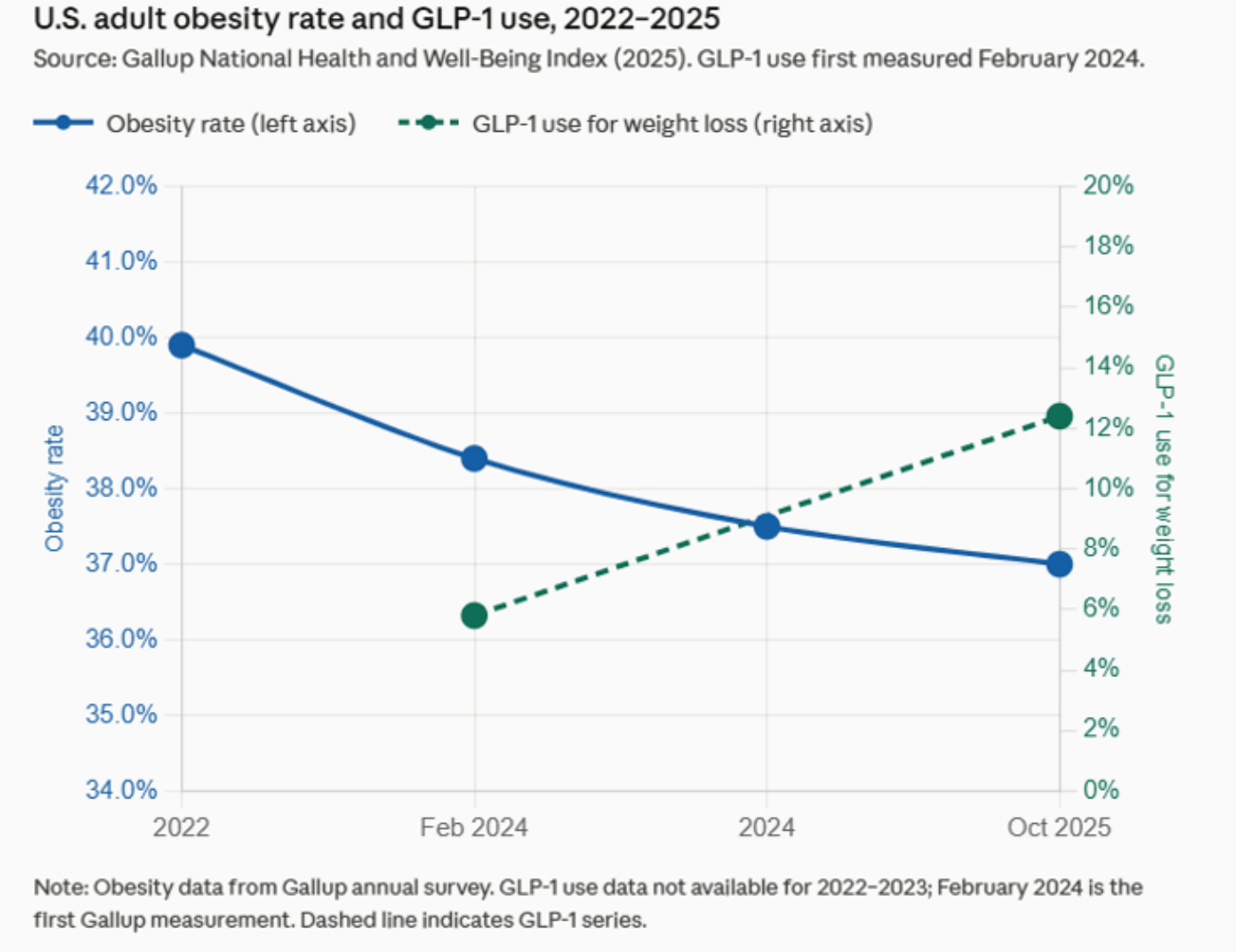
Recent health policy analysis shows why alternative purchase options became essential. Fewer than 1 percent of Affordable Care Act individual marketplace plan formularies covered GLP-1 drugs for obesity as of mid-2024, and state employee health plans in states including North Carolina and West Virginia dropped coverage entirely to manage budgets

(Pearson et al., 2025). With branded options costing more than $1,300 a month and insurers declining to cover them, millions of patients faced a choice between stopping treatment and paying out of pocket. Telehealth platforms and compounding pharmacies filled that gap with cash-pay alternatives for patients who would otherwise have been denied care.

Competitive pressure also reached the branded manufacturers. Facing compounded alternatives priced at $150 to $300 per month, Eli Lilly cut Zepbound's price by roughly half and introduced a single-dose vial to speed production ramp-up (March, 2024). Lilly then launched LillyDirect and partnered with Ro, while Novo Nordisk offered cash-pay options through GoodRx and NovoCare Pharmacy (IQVIA, 2025). Private distribution did not merely substitute for branded supply. It altered the behavior of branded producers.

This is not the only episode in which private actors assembled a parallel channel faster than the administrative one could be adapted. When the FDA relaxed restrictions on COVID-19 testing in 2020, private laboratory capacity rose from fewer than 7,840 tests per day to more than 36,810 within two weeks; private labs performed 85 percent of tests at the pandemic's peak, and only two of 140 authorized tests were later withdrawn for inefficacy (March, 2021). A privately developed and enforced pregnancy prevention program to safely prescribe the popular acne medication Accutane reduced pregnancy rates by roughly half while increasing patient access, performing comparably to the more stringent FDA program that replaced it (March, 2017). In each case, the arrangement emerged without central design and outperformed the predictions made against it.

There is early evidence of effects at the population level. Gallup's National Health and Well-Being Index found the U.S. adult obesity rate fell to 37.0 percent in 2025 from a peak of 39.9 percent three years earlier, an estimated 7.6 million fewer adults with obesity. Declines were most pronounced among adults aged 40 to 64, the cohort with the highest GLP-1 use (Noguchi, 2025). The chart below plots the two series against one another across the shortage period, with the obesity rate falling as reported GLP-1 use for weight loss climbs.



Survey data of this kind cannot establish causation, and we do not claim it. But the period of rising GLP-1 use coincides almost exactly with the period in which compounding pharmacies and telehealth platforms were distributing outside the branded supply chain.

Sustained population benefit is a separate question from initial access, and there the record is weaker. Claims data from Prime Therapeutics covering more than 16 million insured adults show that only 14.3 percent of patients remained on GLP-1 therapy after two years (Gleason et al., 2024). That figure likely overstates true discontinuation, because claims datasets do not capture cash-pay compounded prescriptions from direct-to-consumer platforms, so some patients recorded as having stopped may simply have moved to a cheaper channel. Even so, the drop-off indicates that expanding initial supply is only the first step. Sustained affordability is what determines whether patients capture

the full cardiovascular and economic benefit.

Safety

Much of the commentary published during the shortage warned that counterfeit or substandard products would proliferate as compounders and telehealth platforms took on a larger role (WHO, 2024; Rehman & Nashwan, 2024; Wang et al., 2024). These warnings were reasonable in principle, but they were predictions rather than measurements: the literature emphasizing counterfeit risk generally provides no empirical count of actual incidents.

Several mechanisms operated in place of pre-market review. The 503B facilities producing high-volume compounded GLP-1s were already subject to current good manufacturing practice requirements, annual registration, and inspection under the DQSA. The Pharmacy Compounding Accreditation Board (PCAB) emerged as a voluntary accreditation body supplying an additional quality signal, and some providers sourced exclusively from PCAB-accredited pharmacies (Pharmacy Times, 2025). Competitive dynamics supplied a third layer: subscription revenue depends on retention, so platforms had a commercial reason to maintain quality. More rigorous platforms paired prescriptions with physician review and dosing oversight, which matters because GLP-1s are highly dose-sensitive and patients often escalate doses over time (Whitley et al., 2023).

One quality objection raised during this period was substantive rather than speculative. Some compounders used semaglutide salts — semaglutide sodium and semaglutide acetate — which the FDA identifies as different active ingredients from the base form in the approved drugs and for which the agency has no information establishing equivalent chemical and pharmacologic properties (FDA, 2024). Any defense of the compounded market has to account for this. What matters for the argument here is that compounding with salt forms was never lawful under either pathway. A bulk drug substance qualifies under 503A or 503B only if it has a USP or National Formulary monograph, is a component of an FDA-approved drug, or appears on the applicable bulks list. Semaglutide base satisfies the second condition. The salts satisfy none of the three. Sellers using them were operating outside the shortage exception rather than within it, which makes this a failure of the unregulated margin rather than of the layered oversight described above, and an argument for distinguishing among compounders rather than for foreclosing compounding. What this does not establish is scale. No published estimate separates

lawful compounded supply from the salt-form margin, so an unknown share of the 30 percent figure cited earlier belongs to sellers operating outside the exception rather than within it. The distinction carries the larger argument. The layered oversight described above — cGMP compliance, annual registration, inspection, voluntary accreditation, and reputational exposure — applied to firms that had opted into the 503B framework and could therefore be identified, audited, and sanctioned. Salt-form sellers had opted into nothing and were identifiable to no one. Their conduct is not evidence that private governance failed, because private governance was never operating on them. It is evidence that private governance requires identifiable parties with something to lose. The policy question this raises is not whether oversight is necessary, but which compounders sit inside an accountability structure and which sit outside one, and whether foreclosing the former does anything at all about the latter.

Assessing safety outcomes is complicated by real data limitations, and any strong causal claim would be unwarranted. The FDA's Adverse Event Reporting System (FAERS) is a passive, voluntary surveillance tool. The agency itself cautions against using it to estimate adverse event incidence or comparative risk, because it lacks population-level exposure denominators. Raw report counts rise mechanically as utilization rises, meaning increases in GLP-1 reports beginning in late 2022 may reflect greater use rather than greater risk (Shireman et al., 2026). Underreporting is also likely, since 503A pharmacies are not required to submit to FAERS (UIC Drug Information Group, 2025).

One further limitation applies specifically to the calculation that follows. The reported events cover the period through December 2024, while Novo Nordisk's chief executive offered the most widely circulated estimate of the compounded user population, 1.5 million, in early 2026 (Reuters, 2026). Dividing events from one period by a user base measured a year later understates the rate, and the source of that estimate has a commercial interest in the number being large. We therefore anchor the calculation to independent utilization data contemporaneous with the reports and present a range rather than a point estimate.

With those limits in mind, the available evidence does not describe a system that produced harm at a scale commensurate with the alarm it generated.

Reported Adverse Events for Compounded Semaglutide and Tirzepatide

Measure	Value
U.S. GLP-1 users, all formulations (2024, est.)	6,000,000
Compounded share of GLP-1 users	8.2%–23%
Implied compounded users (2024)	490,000–1,400,000
Manufacturer estimate of compounded users (early 2026)	1,500,000
Reported adverse events (through Dec. 2024)	900
Reported deaths (through Dec. 2024)	17
Implied adverse event rate	0.06%–0.18%
Implied death rate	0.001%–0.003%

Sources: NAM (2025); J.P. Morgan (2026); Hendrix et al. (2025); Reuters (2026). Rates are authors' calculations. FAERS figures are reported events, not confirmed incidence. Rates are computed against 2024 utilization, which is contemporaneous with the reported events; the 2026 manufacturer estimate is shown for comparison only.

By December 2024, FAERS had logged approximately 900 adverse events, including 17 deaths, associated with compounded semaglutide and tirzepatide combined (NAM, 2025). Independent estimates place total U.S. GLP-1 utilization at roughly 6 million patients in 2024 (J.P. Morgan, 2026). Claims-based estimates run considerably higher, which would push the rates reported below downward. We use the smaller figure because it is the more conservative basis for the calculation. The compounded share of those patients is estimated at between 8.2 and 23 percent. The lower bound comes from documented compounded use in a national primary care records cohort of more than 150,000 GLP-1 patients, and the upper bound comes from patient self-report surveys (Hendrix et al., 2025). That brackets the compounded user population between roughly 490,000 and 1.4 million, an upper bound that approaches the manufacturer estimate and corroborates a figure which would otherwise rest on an interested party alone. Across the range, the reported adverse event rate runs from 0.06 to 0.18 percent and the reported death rate from 0.001 to 0.003 percent. These patient shares are not directly comparable to the 30 percent figure cited earlier, which measures volume of supply rather than number of patients.

These figures almost certainly undercount true events. FAERS reporting is voluntary, 503A pharmacies are under no obligation to submit at all, and patients who obtained product through cash-pay telehealth channels had no obvious reporting pathway. True totals are higher than recorded ones, probably by a considerable margin. But the undercounting cuts against claims of failure more cleanly than it supports them, because the gap that would have to be closed is large. Even at the most conservative end of the range, an adverse event rate of 1 percent would require roughly 4,900 true events against the 900 recorded, and a death rate of 0.1 percent would require some 490 deaths against 17. Underreporting on that scale is possible, but it is a far stronger empirical claim than critics have advanced, and none has offered evidence for it. One caveat applies to that reasoning. Compounded users were disproportionately cash-pay and outside coordinated primary care (Hendrix et al., 2025), which means fewer of them had a clinician positioned to file a report. If underreporting is concentrated in the very population being measured rather than distributed evenly, the gap closes faster than the arithmetic above implies.

Rationing Abroad

Comparison with jurisdictions that lacked an equivalent private mechanism reinforces this reading. In the United Kingdom, the National Health Service responded to the same shortage by reserving stocks for existing patients and advising providers against

initiating new prescriptions, including for patients with type 2 diabetes (Diabetes UK, 2025; Iacobucci, 2023). The European Union responded through the Executive Steering Group on Shortages and Safety of Medicinal Products, convened by the European Medicines Agency and the Heads of Medicines Agencies. Its 2024 recommendations directed prescribers to confine these drugs to authorized indications and to avoid prescribing them for cosmetic weight loss (EMA, 2024). Both responses rationed access rather than expanding it, and both came well after the U.S. shortage had begun to ease.

The harms of treatment denial are real: uncontrolled blood glucose, elevated cardiovascular risk, and progression of obesity-related comorbidities. They are also largely invisible in adverse event databases, precisely because patients who never receive treatment generate no drug safety reports. What the evidence permits is a modest but defensible conclusion. The U.S. private distribution system, for all its acknowledged imperfections, expanded access substantially while producing documented harm at a low per-capita rate, and the costs critics emphasize must be weighed against the access harms the system helped to avoid.

The stakes of that weighing are large. Over a ten-year horizon, semaglutide 2.4 mg is projected to prevent nearly 2 million major adverse cardiovascular events and more than 1 million deaths among high-risk adults (Nanna et al., 2025). Those projected gains depend on patients actually receiving the drug. Compounded supply at $150 to $300 per month put treatment within reach of patients for whom branded pricing did not, and the competitive response it provoked brought branded prices down as well. Administrative rationing forgoes those gains rather than capturing them.

Conclusion

From 2022 through 2025, the United States faced prolonged shortages of drugs that had become among the country's most widely used pharmaceuticals. Compounding pharmacies operating under the DQSA's 503A and 503B frameworks, paired with telehealth platforms that provide prescription, logistics, and patient-management infrastructure, filled the gap branded channels could not.

On the provision side, this system reached patients who would otherwise have faced treatment interruption or denial, including uninsured patients for whom branded GLP-1s were financially unreachable and patients with cardiovascular, renal, and metabolic

comorbidities for whom interruption carried clinical consequence. It also generated competitive pressure that changed branded pricing behavior. On the governance side, cGMP requirements for 503B facilities, voluntary PCAB accreditation, and the reputational incentives embedded in subscription telehealth models together provided a layered quality assurance framework that functioned without FDA pre-market approval.

Three implications follow for policymakers.

- Regulatory flexibility during a declared shortage can expand patient access without catastrophic safety failure. This is one data point rather than a general law, but it is a data point on the side of permissiveness.
- The 503A/503B framework functioned as shortage infrastructure, not merely as a compounding rulebook. Whether it generalizes to other drug classes deserves examination before the next shortage rather than during one.
- Layered private oversight substituted for pre-market review reasonably well in this case. Policy design should account for these mechanisms rather than assume that only pre-market approval produces safety.

This episode's relevance is not confined to the shortage that produced it. In July 2026, the FDA's Pharmacy Compounding Advisory Committee voted 8 to 6 to recommend adding BPC-157 to the 503A bulk drug substances list, the first of seven peptides under review, against the written recommendation of the agency's own reviewers (ABC News, 2026). The cases are not identical: the GLP-1s compounded during the shortage were approved drugs that were temporarily unavailable, whereas several of these peptides have never cleared a rigorous human trial. What transfers is the governance question, not a claim that any compound a pharmacy wishes to make is therefore safe.

Important questions remain. The access gains documented here were concentrated among adults aged 40 to 64 with the financial resources to pay cash, while lower-income and older patients remained largely excluded (Noguchi, 2025). The adverse event data deserve more rigorous analysis as exposure denominators become available. And the market is already changing: a pill-form GLP-1 widely covered by insurance would represent a fundamentally different governance environment from the one examined here. Whether the private institutional infrastructure that emerged during the shortage persists, adapts, or dissolves as conditions normalize is an open empirical question with significant implications for how future shortages in this drug class are managed.

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Note

This policy brief is based on a paper titled “Private Solutions Weighing In: How Markets Helped Address the GLP-1 Drug Shortage” by Raymond J. March, Ryan Yonk, and Elisha K. Denkyirah.

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