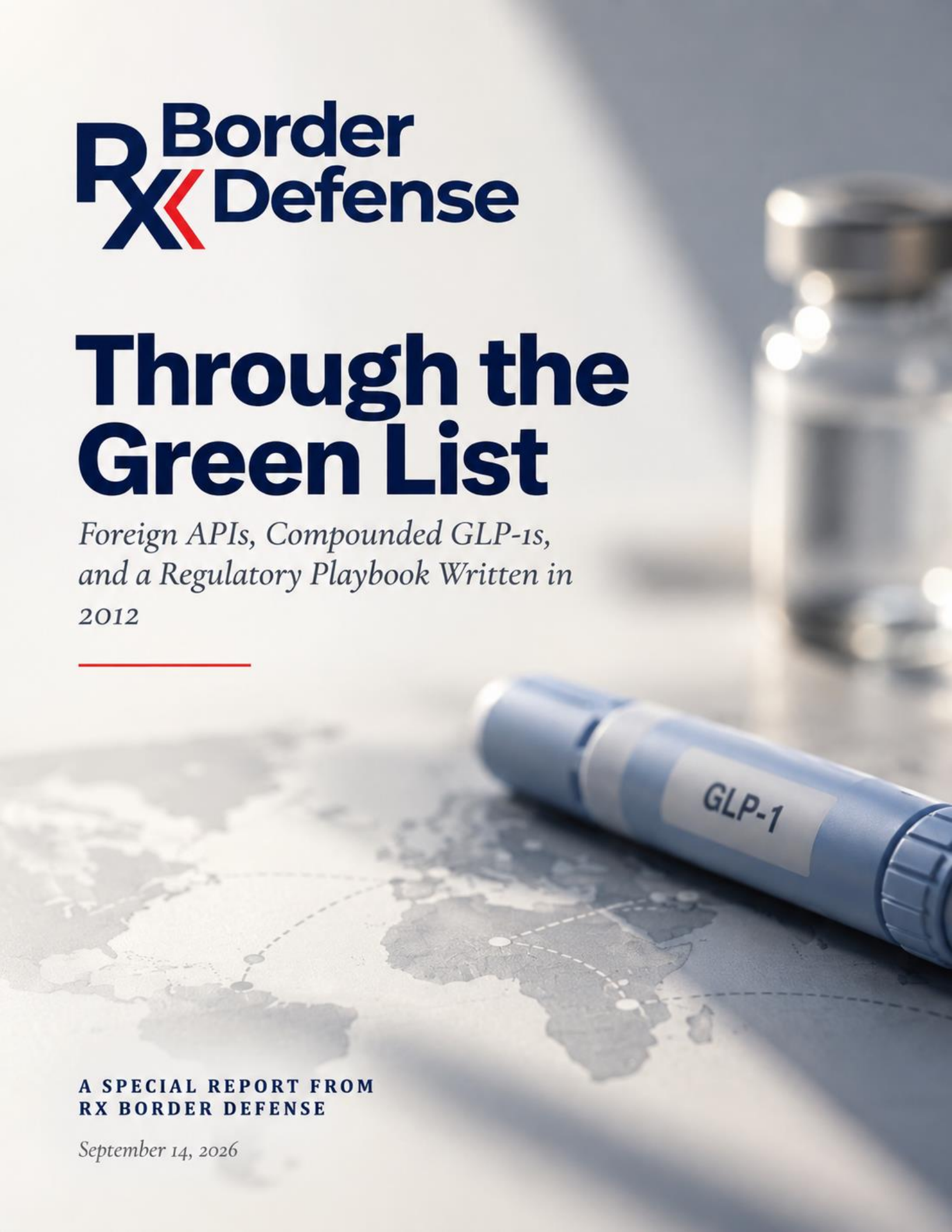
Rx Border Defense

Through the Green List

Foreign APIs, Compounded GLP-1s, and a Regulatory Playbook Written in 2012



A SPECIAL REPORT FROM RX BORDER DEFENSE

September 14, 2026

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Executive Summary

America's GLP-1 boom has created a second, less visible market alongside FDA-approved medicines: unapproved active pharmaceutical ingredients (APIs) and finished products that may be imported from overseas, including from Chinese suppliers, compounded or repackaged in the United States, and marketed to Americans as cheaper or easier alternatives. These products have not gone through the FDA approval process that establishes a medicine's safety, effectiveness, manufacturing controls, and labeling. Independent testing and FDA enforcement records show that parts of this market have included mislabeled ingredients, severe purity failures, bacterial endotoxin, unapproved salt forms, and uncertain manufacturing origin. At the same time, misleading online advertising and look-alike branding can blur the distinction between an FDA-approved medicine and an unapproved compounded or counterfeit product, allowing unverified supply to compete with and undermine the regulated U.S. market for medicines produced under enforceable quality standards.

That concern is not confined to manufacturers or drug companies. On February 19, 2025, a bipartisan coalition of 38 state and territory attorneys general urged FDA to act against counterfeit and illegally sold GLP-1 products. The attorneys general warned that products entering the United States from China, India, Turkey, and other countries could contain contaminants, unknown ingredients, or dangerously high levels of active drug. They also called out online sellers marketing GLP-1 active ingredients directly to consumers from unregulated or undisclosed sources, often using social media promises of easier or cheaper access. Their warning goes to the heart of this report: Americans can be steered by advertising toward products whose identity, provenance, quality, and regulatory status they may not understand.

This report recommends that FDA terminate the Green List mechanism in Import Alert 66-80. The evidence does not support continuing a redacted, firm-based trusted-supplier exception that allows designated foreign manufacturers to be exempt from FDA detention and physical examination. FDA should instead apply the same baseline import-control posture to all non-FDA approved, foreign GLP-1 API shipments, with release based on shipment-specific provenance, records, testing, and other risk-based evidence rather than confidential firm status. This

recommendation is not a claim that every Green List manufacturer is noncompliant. It is a conclusion that the mechanism itself creates avoidable opacity and a reusable trust credential in a supply chain where FDA has already documented provenance manipulation, noncompliance, and rapid changes in registered manufacturing status.

What the public record shows:

- **The Green List should be shut down.** Its core design grants preferential border treatment to unidentified foreign firms importing unapproved API based on firm-level trust, even though FDA has documented that a listed supplier relabeled API from a non-Green-List source and that 21 percent of the 48 GLP-1 API sites the agency evaluated were noncompliant. A safer model would remove the Green List exemption and require shipment-specific proof of manufacturing origin and compliance before release.
- For example, the FDA's own Green List —included Harbin, a Chinese supplier the FDA later determined to have relabeled API sourced from a non-Green-List Chinese facility and shipped it into U.S. commerce. The public Green List also withholds the names of the remaining manufacturers, limiting independent scrutiny of whether the Harbin case was isolated or reflects a repeatable provenance loophole. The only reason we know Harbin held Green List status is a subsequent warning letter, which disclosed the listing. FDA asked Harbin to pull the affected batches at a February 10, 2026 teleconference; the firm began a voluntary recall on February 19 and FDA logged it in a routine enforcement report on March 11. Beyond that listing, the agency issued no consumer-facing alert or direct outreach to providers and patients about the recall or the risks of Harbin's products.
- Consumer confusion is part of the safety problem. A 2025 National Consumers League survey of 1,500 U.S. women ages 18–55 found that 53 percent believed compounded GLP-1 drugs were FDA-approved and 49 percent believed compounded versions contained the same active ingredients as branded drugs. Those findings are consumer-perception evidence rather than clinical evidence, but they reinforce the concern raised by the 38 attorneys general: advertising and online sales practices can obscure the difference between an FDA-approved product and an unapproved,

compounded, or counterfeit alternative, making provenance and regulatory status difficult for ordinary patients to assess before purchase.

- The Green List was issued long after the shortages for GLP-1 medicines ended and now includes products that have never been in shortage. In its August 21, 2026, revision, FDA added orforglipron API — the active ingredient in Lilly's newly approved oral, non-peptide GLP-1 drug Foundayo — to three Green List manufacturers, plus an orforglipron solid-dispersion intermediate at a fourth site. The orforglipron product code is also broader than the separate "for further manufacturing" and "for Rx compounding" subcodes FDA uses for semaglutide and tirzepatide, raising a basic policy question about how broadly the Green List is intended to function.
- This isn't only a paperwork problem. Independent laboratory testing of compounded and gray-market semaglutide has found products with semaglutide purity as low as 7.7%–14.4% against label claims and measurable endotoxin contamination; the study producing those figures sampled unregulated online/research-chemical-style sellers rather than licensed 503A/503B pharmacies specifically. Separately, FDA has documented use of unapproved salt forms (semaglutide sodium, semaglutide acetate) that are chemically different active ingredients with no established human safety data at all.
- Retatrutide, Eli Lilly's next-generation triple agonist, hasn't even been submitted for FDA review yet — and it is already the subject of a social-media-driven black market, six new lawsuits. Before the developer of this product can market it and before providers even have the full safety and efficacy profile of the drug, compounders have begun mass producing the product right in front of the FDA without consequence.
- FDA's own published adverse-event tallies for compounded GLP-1s have climbed in every snapshot the agency has released: roughly 1,424 reports (329 hospitalizations, 23 deaths) as of September 9, 2025; roughly 1,500+ reports (372 hospitalizations, 30 deaths) by mid-March 2026; and, as of May 31, 2026, 990 reports for compounded semaglutide plus more than 730 for compounded tirzepatide — over 1,720 for those two molecules alone. Separate figures compiled for this report, current as of August 2026, put the

cumulative total across all five commonly compounded GLP-1-class molecules at more than 1,700 reports — 1,456 of them serious, 454 requiring hospitalization, and 38 associated with a patient death. That compiled total sits below FDA's two-molecule count from three months earlier, so the two should not be read as a single series; Part VI sets out the discrepancy. However, compounders are not held to the same reporting requirements as manufacturers of FDA-approved drugmakers. Because of this, the FDA and multiple researchers and organizations cited in this report caution that passive reporting likely understates the true number, and none of these counts are adjusted for how many patients are actually using these products — both points this report addresses directly rather than leaving for critics to raise.

Poison-center surveillance independently shows the same growth in acute exposures. A 2026 national analysis of the National Poison Data System identified 10,033 GLP-1 receptor-agonist exposures from 2012 through 2023, including 6,920 after July 1, 2021. Semaglutide exposure calls accelerated by an additional 9.9 percent per quarter after its weight-loss approval, and the share of cases managed in or referred to a health-care facility rose from 23.0 percent to 33.5 percent. The study is not specific to compounded products, so it should be read as independent evidence of rapidly increasing GLP-1 exposure and therapeutic-error burden rather than as a compounding-specific incidence estimate *(Miller et al., Journal of Medical Toxicology, 2026).*

- Behind the aggregate numbers are named patients: a Kentucky woman who went into acute liver failure within four weeks of starting a compounded injection; a North Carolina patient hospitalized for three days after an overdose from a virtual prescribing service; and a Texas woman whose family says a compounded product caused her death.
- None of this is new. Section 503A predates the outbreak; Congress enacted it in 1997. After a 2012 fungal meningitis outbreak killed at least 64 people, Congress created the Section 503B outsourcing-facility category in 2013 and revised and clarified the federal compounding framework. Reporters and regulators alike have noted that several of the safeguards written after that outbreak were softened before they ever took full effect.

The federal-state oversight split remains unresolved. State boards of pharmacy retain primary day-to-day oversight of most 503A pharmacies, while FDA oversees 503B outsourcing facilities and can inspect 503A compounders under federal law. FDA itself emphasizes information sharing with state boards, yet adverse-event reporting, inspection findings, prescribing oversight, and enforcement information can remain fragmented across FDA, state pharmacy boards, state medical boards, and poison centers. A national market operating through 50 state systems needs a more consistent federal-state reporting and escalation framework, particularly for high-volume compounded GLP-1 products moving across state lines. ◀

PART I

Framingham, 2012 — The Disaster That Wrote the Rulebook

Long before Ozempic became a household name, a single Massachusetts compounding pharmacy reshaped American drug law.

In 2012, the New England Compounding Center (NECC), based in Framingham, Massachusetts, shipped contaminated methylprednisolone acetate — a steroid used for epidural pain injections — to 75 medical facilities in 23 states. The fungal contamination triggered a multistate meningitis outbreak that sickened more than 700 people across 20 states and was associated with at least 64 deaths, making it one of the deadliest drug-safety failures in modern U.S. history *(FDA, remarks of Commissioner Robert Califf, 2022)*.

NECC was operating in a regulatory blind spot. Compounding pharmacies were traditionally licensed and overseen at the state level, on the premise that they were making small, patient-specific preparations — not shipping tens of thousands of vials across state lines to hospitals that had never submitted an individual prescription. NECC exploited that gap, and it wasn't alone; it was simply the one that got caught at the worst possible scale.

Congress responded in 2013 with the Drug Quality and Security Act (DQSA), including its Compounding Quality Act provisions. The law created a new category — Section 503B "outsourcing facilities" — that would register with the FDA, follow current Good Manufacturing Practice (cGMP) standards, and submit to federal inspection, distinct from traditional 503A pharmacies that remain primarily state-regulated and are supposed to compound only for individual, prescription-driven patient need *(FDA, "Bulk Drug Substances Used in Compounding Under Section 503A")*.

Here is the part compounding critics keep returning to: reporting on the law's aftermath found that some of the DQSA's own safeguards — particularly limits and controls around interstate shipping of compounded drugs — were **effectively suspended following pushback from the compounding industry** before they were ever fully enforced *(Houston Chronicle, "Key takeaways from a Chronicle examination of Empower Pharmacy")*. A decade after the outbreak, then-FDA Commissioner Robert Califf marked the anniversary by noting the scale of the tragedy that drove the law

and the agency's ongoing work to strengthen oversight; separately, reporting on the anniversary found many of the same regulatory gaps that allowed NECC to happen still existed, even as some compounding pharmacies had grown far larger reach than NECC ever had *(Houston Chronicle, ibid.)*.

That is the throughline of this report: the industry's scale has grown enormously since 2012. The rules meant to contain that scale have grown more slowly, and in places, have been rolled back. ◀

PART II

How a Houston Pharmacy Became a National Supply Line

If NECC was a cautionary tale about a small pharmacy operating past its legal footprint, Empower Pharmacy is the current test of what happens when a compounder operates at genuinely industrial scale under a regulatory framework that the FDA has struggled to apply cleanly at that scale.

A year-long Houston Chronicle investigation, published in 2025–2026, found that Empower — which describes itself as the largest compounding pharmacy in the country and is both a 503A and 503B pharmacy — has been producing tens of thousands of drug units per week under a regulatory framework "designed for small-scale production" *(Houston Chronicle, "Here's how we examined Houston-based Empower Pharmacy's expansion")*. The paper's reporting connected Empower's rapid growth directly to two product categories: compounded testosterone and compounded GLP-1s.

Key findings from that investigation and related coverage:

- **A decade of FDA violations.** The Chronicle documented more than ten years of quality problems across Empower's two Houston-area production facilities, including inadequate quality testing and failures to properly clean equipment *(Houston Chronicle, "Houston's Empower Pharmacy has repeat quality issues, FDA inspections show")*.
- **Insider allegations.** Two former Empower employees have alleged in legal filings that the company used low-quality ingredients to cut costs — allegations Empower has denied, made in the context of the company's own trade-secret lawsuits against those employees *(Houston Chronicle, "Empower Pharmacy's FDA violations muddy its message on quality compounded drugs")*.
- **A live contamination recall.** In January 2026, the Chronicle reported that Empower had issued a voluntary recall after testing found contamination in a sample; Empower said the contamination was isolated to an area outside the primary filling zone and that finished-product testing showed no issue.

- **The Eli Lilly lawsuit.** In April 2025, Eli Lilly sued Empower, alleging the pharmacy was "mass producing" tirzepatide in fixed doses rather than compounding genuinely individualized preparations. Patient-specific prescribing is central to Section 503A. Section 503B outsourcing facilities may compound without patient-specific prescriptions, but they must satisfy a separate set of statutory conditions, including restrictions on drugs that are essentially copies of approved products. Lilly's complaint described the practice as a "mass testing experiment" on patients *(Houston Chronicle, "Big Pharma sues Houston compounding pharmacy over copycat weight loss drugs")*. Empower is fighting the suit, characterizing it as one piece of a broader industry campaign by brand manufacturers to "drive compounders like Empower from the market" *(Houston Chronicle, "Houston-based Empower Pharmacy fights Eli Lilly lawsuit over GLP-1 drugs")*.
- **A structural finding, not just an Empower finding.** The Chronicle's broader conclusion was not that Empower is uniquely bad, but that large-scale compounding *as a category* increases risk to patients and strains regulators' ability to respond — and that the true national prevalence of compounded drug use is currently impossible to quantify because no comprehensive reporting system exists.

A wrongful-death case now moving through the courts adds a human face to that structural finding — see Part V. ◀

PART III

The Green List — Why FDA Should Shut It Down

This is the piece of the story most specific to 2025–2026, and most directly responsive to the "foreign API" question this report set out to examine. It is also where the policy problem becomes larger than a single noncompliant supplier: the FDA has created a category of foreign manufacturers whose products receive different treatment at the border, while the identities of those manufacturers are not publicly disclosed.

What the Green List actually is. On September 5, 2025, the FDA announced an import alert *(Import Alert 66-80, formalized September 19, 2025)* establishing a "Green List" of foreign GLP-1 API manufacturers whose facilities and associated products, based on FDA's evaluation of recent evidence, *appear* to comply with current good manufacturing practice (cGMP) requirements. Shipments of covered GLP-1 APIs from firms *not* on the list can be detained without physical examination; firms and products on the Green List are excluded from that recommendation for detention *(FDA, Import Alert 66-80; Frier Levitt; FDA press release, "FDA Launches Green List to Protect Americans from Illegal Imported GLP-1 Drug Ingredients")*.

The distinction matters because FDA itself describes a significant compliance problem in this supply chain. In the agency's August 21, 2026 revision of Import Alert 66-80, FDA said it had evaluated 48 GLP-1 API sites through inspections or remote regulatory assessments and found 21 percent noncompliant under the Federal Food, Drug, and Cosmetic Act. FDA also described a pattern in which sites registered as GLP-1 API manufacturers, offered APIs for U.S. import, refused FDA records requests, and then deregistered within a short period. Those findings are the government's own rationale for treating foreign GLP-1 APIs as presenting a heightened risk of adulteration.

The accountability paradox: the beneficiaries are unidentified. The public version of Import Alert 66-80 shows countries and covered product codes, but the manufacturer-identifying fields are redacted. The current list contains numerous separate China entries covering semaglutide, tirzepatide, liraglutide and other peptide or anti-diabetic product codes, yet an outside purchaser, patient, researcher, journalist, state regulator, or congressional investigator cannot use the

public list to determine which Chinese firms actually receive Green List treatment. That creates an unusual structure: FDA confers a practical border-screening advantage on specific foreign manufacturers while withholding the identities needed for independent due diligence or outside scrutiny.

The redactions are not merely a transparency complaint. They limit the ability of outsiders to answer basic risk questions: whether a supplier claiming Green List status actually has it; whether nominally separate Green List firms share ownership, facilities, personnel, brokers, or contract manufacturers; whether listed firms have relationships with previously sanctioned or noncompliant entities; and whether a supposedly Green-Listed API can be traced back to the physical site that actually synthesized it. The problem is especially relevant for China because corporate ownership, affiliated trading companies, contract manufacturing relationships, and state or Party ties may matter to economic-security and supply-chain analysis even when they fall outside FDA's traditional cGMP inquiry.

It's worth being precise about what the Green List does and doesn't cover, because this is a point of genuine dispute. The Alliance for Pharmacy Compounding has argued that legitimate compounders should not view the Green List as their problem because pharmacies purchase API through FDA-registered wholesalers that are expected to vet upstream manufacturers and provide certificates of analysis. That position underscores the governance gap rather than eliminating it: if downstream compounders rely on intermediaries and do not independently verify the actual manufacturing site, the integrity of the system depends even more heavily on FDA and wholesalers being able to establish true origin upstream. Harbin showed that a listed firm's identity and the actual manufacturing origin can diverge.

The Green List has expanded beyond the shortage-era compounding problem. FDA's own explanation for Import Alert 66-80 begins with the shortage experience: shortages of approved GLP-1 drugs drove increased compounding using APIs from foreign sources, and FDA says the risk is heightened because 503A compounders are exempt from cGMP requirements that otherwise apply to drug manufacturers. But the agency's August 21, 2026, revision added a very different product to the Green List: orforglipron, the active ingredient in Lilly's Foundayo, an oral, non-peptide GLP-1 receptor agonist approved by FDA on April 1, 2026. FDA added orforglipron API to three Green List manufacturers and an orforglipron solid-dispersion intermediate to

a fourth manufacturer. The public entries identify two China listings for orforglipron API, one Ireland listing, and the solid-dispersion intermediate in Portugal; as elsewhere on the Green List, the manufacturer names are withheld (FDA, Import Alert 66-80, revised Aug. 21, 2026; FDA, Foundayo approval, Apr. 1, 2026). Orforglipron is not the only post-shortage addition. The current alert also carries two China entries whose covered product codes are qualified by the phrase "and the importer description contains the word, Retatrutide" — that is, Green List treatment extends to shipments tied to a molecule FDA has said cannot lawfully be used in compounding at all and that its developer has not yet submitted for approval. Whatever the lawful use behind those entries, the redacted list does not permit an outsider to identify it.

The legal basis for broad shortage-era copying has also narrowed further. In opinions issued on August 27, 2026, with the semaglutide opinion revised on September 1, 2026, the U.S. Court of Appeals for the Fifth Circuit affirmed judgments upholding FDA's decisions to remove both tirzepatide products and semaglutide products from the shortage list, rejecting challenges brought by the Outsourcing Facilities Association. Those decisions reinforce that the principal shortage-based justification for broad 503B production of copies has ended, even as foreign GLP-1 API continues to move through a Green List system created months later.

That matters because the FDA materials reviewed for this report do not identify a shortage of orforglipron as the reason for its inclusion. Unlike semaglutide and tirzepatide, whose product-code families in Import Alert 66-80 expressly distinguish API “for further manufacturing” from API “for Rx compounding,” FDA lists orforglipron under the single code **61P--77, “Orforglipron (Anti-Diabetic)”** without those separate subclasses. The public alert therefore does **not** establish that FDA created a dedicated orforglipron compounding pathway. Nor does Green List status itself authorize compounding. It establishes something narrower but still consequential: shipments of covered orforglipron from the listed manufacturers are excluded from recommendation for detention without physical examination under Import Alert 66-80.

The underlying compounding authorities remain separate. Under section 503B, outsourcing facilities generally may compound from bulk substances only when statutory conditions are met, including shortage status or inclusion on FDA's 503B

bulks list; the current FDA 503B list does not include orforglipron. Under section 503A, a bulk substance may qualify for patient-specific compounding if, among other conditions, it is a component of an FDA-approved drug product when no applicable USP/NF monograph exists; FDA separately restricts compounding of products that are essentially copies of commercially available drugs. Those rules mean that Green List status should not be read as permission for mass copying of Foundayo.

The policy question is therefore not why a shortage tool expanded after a shortage; the Green List itself was launched after the semaglutide and tirzepatide shortages had ended. The sharper question is why FDA created and then expanded a standing trusted-supplier exception for foreign GLP-1 API after the shortage-based compounding rationale had narrowed, including to orforglipron, when the public version of the alert does not disclose the beneficiary firms, their U.S. consignees, or the downstream use supporting each exemption. There may be ordinary and lawful reasons — approved-product manufacturing, contract manufacturing, development, or other supply-chain uses — but the redacted list does not allow outsiders to distinguish those uses from API destined for non-FDA-approved products. That opacity is central to the case for replacing the current Green List with a more transparent, use- and shipment-specific model.

Where the mechanism broke — and why the chronology matters. In September 2025, FDA added Chinese manufacturer Harbin Jixianglong Biotech to the Green List. FDA later found that Harbin had purchased semaglutide API from another Chinese establishment that was not on the Green List, relabeled the material so that Harbin appeared to be the manufacturer, changed manufacturing and retest information, and distributed the relabeled API into U.S. commerce *(FDA warning letter to Harbin Jixianglong Biotech, May 1, 2026)*. FDA said it was concerned that the conduct "may have been an attempt to circumvent" the safeguards of Import Alert 66-80.

The sequence is important. One implicated batch was distributed to the United States on August 23, 2025 — before the Green List formally existed — while a second was distributed on October 3, after Harbin had been added to the list. The August shipment therefore demonstrates that the relabeling behavior predated Green List status; the October shipment is the cleaner example of why status attached to a company name can be exploited when the underlying API originated

elsewhere. The FDA learned all of this in November 2025, but the FDA did not request that Harbin voluntarily recall the product until February 2026. The policy question is therefore not simply whether FDA eventually detected misconduct; it is whether a firm-level trust designation can allow falsely attributed API to move through the supply chain faster than regulators can reconstruct its true provenance.

Dr. Michael Burgess — a physician and former Texas congressman who is affiliated with RX Border Defense, this report's publisher — argued in a June 2026 op-ed that the Harbin episode illustrates a structural flaw rather than a one-off failure: as long as *any* company holds Green List status, brokers and distributors have an incentive to route product through that name regardless of where the underlying ingredient actually came from, turning an intended safety barrier into what he called a "magnet for regulatory gamesmanship" *(Washington Examiner, "Shut down the FDA's failed GLP-1 green list")*.

A national-security question distinct from the drug-safety question. The public record establishes a pharmaceutical-supply-chain integrity problem. It does not, by itself, prove coordinated People's Republic of China (PRC) state direction, deliberate economic coercion, or a national-security operation. Those would require additional evidence. But the current Green List architecture makes the relevant questions appropriate for interagency review: Who ultimately owns the Chinese firms receiving Green List treatment? Do any share beneficial owners, facilities, exporters, brokers, or contract manufacturers? Are any linked to PRC state-owned enterprises, government industrial programs, military-civil fusion entities, sanctioned firms, or networks already known to U.S. law enforcement or the intelligence community? And how concentrated is U.S. dependence on those entities for GLP-1API supply? These are not conventional cGMP questions, and FDA is not institutionally designed to answer all of them alone.

The Harbin case landed alongside a wider pattern flagged separately by federal officials: a February 13, 2026 letter from Senator Tom Cotton to FDA Commissioner Martin Makary cited an FDA and U.S. Customs and Border Protection analysis identifying 195 illegal API shipments that entered the U.S. market between September 2023 and January 2025, roughly 60 of them originating in China or Hong Kong. Members of the House Select Committee on the CCP have sent formal inquiry letters to multiple Chinese biotech firms — including Fujian Genohope Biotech and

Hubei JXBio Biotech — over exports believed to be feeding the compounded weight-loss market. One Senate estimate put the number of Americans potentially using compounded weight-loss products containing unregulated Chinese-sourced ingredients as high as 1.5 million as of January 2026 *(Fox News, "Tom Cotton demands FDA probe into illegal Chinese ingredients in US weight loss drugs")*.

What evidence would justify stronger federal action. The existing record supports an immediate review of the Green List's controls. A substantially stronger intervention — suspension, redesign, or replacement — would be easier to justify if investigators establish one or more of the following: a second Green List firm routing API from a non-listed manufacturing site; inability to reconstruct true manufacturing provenance for a meaningful share of Green List entries; clinical injury traceable from falsely attributed API through a U.S. importer or compounder to a patient; coordinated circumvention among manufacturers, trading companies, or brokers; or evidence that FDA/CBP entry data cannot reliably distinguish API manufactured at a Green List facility from API merely relabeled or repackaged there.

Why the Green List should be terminated, not merely tightened. The Harbin episode is not simply evidence that FDA needs better monitoring of one trusted supplier. It exposes the central weakness of the Green List model: the regulatory benefit attaches to the identity of the listed firm, while the safety question ultimately turns on the origin, handling, testing and chain of custody of each shipment. Once a listed firm's identity can be used to move API produced elsewhere, firm status becomes a credential that can be exploited. Keeping the names confidential compounds the problem by preventing purchasers, state regulators, outside researchers and Congress from independently checking ownership, affiliations, manufacturing relationships or supplier representations.

The case for termination is stronger than the case for incremental reform for four reasons. First, the public cannot audit the beneficiaries because their names are redacted. Second, FDA's own August 2026 alert says 21 percent of the 48 GLP-1 API sites it evaluated were noncompliant, confirming that this is a high-risk supply chain rather than a population where trust should be presumed. Third, Harbin demonstrated that supplier identity and actual manufacturing origin can diverge. Fourth, FDA has expanded the mechanism beyond the shortage-era peptide context

to products such as orforglipron, making the Green List a broader standing trusted-supplier architecture rather than a narrow emergency measure.

What FDA should do now. FDA should suspend and then terminate the Green List provisions of Import Alert 66-80 for unapproved drugs; place all foreign, unapproved GLP-1 API shipments under a common risk-based screening framework; conduct a retrospective provenance audit of shipments admitted under Green List treatment; publicly disclose the identities of firms that received Green List status, subject only to legally required redactions; and refer PRC-based entities and relevant ownership networks for interagency review where national-security, sanctions, procurement, or state-affiliation concerns are present. The objective is not to punish foreign manufacturing as such. It is to replace a trust-based exception with a traceability-based border control.

A second front: the drug that isn't even approved yet. Retatrutide, Eli Lilly's next-generation "triple G" (GLP-1/GIP/glucagon) agonist, has not been submitted to the FDA for approval — Lilly plans to file in early 2027. That hasn't stopped a compounded black market from forming around it. Social media influencers openly tout knockoffs nicknamed "r3ta" or "triple G," some sold for as much as $600 and labeled "research use only" while plainly marketed for human injection. Lilly has filed six new lawsuits against med spas, at least one compounding pharmacy, and other vendors, and is referring thousands of sellers to regulators and law enforcement *(Axios, "Unapproved obesity drug spawns a black market frenzy," Aug. 24, 2026)*. Even the compounding industry's own trade group has acknowledged the enforcement gap isn't really about legal authority — Alliance for Pharmacy Compounding CEO Scott Brunner told Axios the deeper problem is that stronger FDA enforcement would require funding Congress has shown little appetite to provide. Separately, Lilly is fighting the FDA over whether retatrutide should be classified as a biologic rather than a standard drug — a "biologic" designation would hand Lilly 12 years of market exclusivity and block legal compounding entirely, even during a future shortage. Courts have so far split on the question and returned it to FDA for further review. ◀

PART IV

The Science — Why Compounded GLP-1 Peptides Can Fail Differently Than Approved Products

This part addresses the question a skeptical reviewer asks first: *why would compounding a GLP-1 be more dangerous than compounding, say, a topical cream?* The answer is specific to peptide chemistry and to how these particular products are made and administered — and it's the strongest evidence in this report, because it doesn't depend on interpreting an adverse-event report after the fact. It's a direct measurement of what's actually being sold.

Compendial reference materials remain incomplete. Older small-molecule generic drugs are often assessed against established compendial standards. USP launched analytical reference materials for GLP-1 agonists in 2025, including materials for semaglutide, so it is no longer accurate to say the category has no external reference materials. Those materials do not establish an official USP–NF monograph or a complete compendial standard for every GLP-1 molecule or every bulk-API quality attribute. The narrower concern is that official compendial coverage remains incomplete and some manufacturers supplying compounders set their own product specifications *(USP, "USP Launches Resources to Support Product Quality for GLP-1 Agonists," Oct. 23, 2025; Brookings, "The Wild East of Semaglutide," Apr. 21, 2025)*.

Independent lab testing has found real, measurable defects. A 2024 peer-reviewed study *published in the Journal of Medical Internet Research* purchased semaglutide from online sellers and used liquid chromatography–mass spectrometry. The tested products had semaglutide purity ranging from 7.7% to 14.4% against a 99% label claim, and every sample contained detectable bacterial endotoxin despite being marketed and labeled as sterile *(Ashraf et al., J Med Internet Res 2024;26:e65440)*. A separate comparative analysis found new impurities, including high-molecular-weight proteins, trace metals, and residual solvents; lower-than-labeled drug content in some samples; and neoepitopes indicating potential immunogenicity. The authors stated that the clinical effects on safety and efficacy remain unknown and require clinical study. Important disclosure: PubMed lists every Hach et al. author affiliation as a Novo Nordisk unit *(Hach et al., Pharmaceutical Research, Oct.* 2024). The JMIR study sampled unregulated online or research-chemical-style sellers rather than licensed

503A or 503B pharmacies specifically, although that supply channel and the raw APIs it depends on overlap with the import pipeline examined in Part III. A second peer-reviewed study published online in Pharmaceutical Research in July 2026 analyzed follow-on and compounded semaglutide and liraglutide using mass spectrometry, immune-system assays, photostability testing, and related analytical methods. The authors reported impurity profiles that differed from the originator products, including amino-acid additions, deletions, and unidentified impurities; they also found significant changes in some compounded semaglutide samples after light exposure. In vitro testing identified impurity-derived peptides with potential immunogenicity, but the study did not establish clinical immune injury in patients. Important disclosure: the study was conducted by Novo Nordisk-affiliated researchers; the listed authors were employees or shareholders of Novo Nordisk, or were employees at the time of the work *(Kopp et al., Pharmaceutical Research, July 30, 2026, doi:10.1007/s11095-026-04146-9)*.

FDA has separately flagged a distinct, more specific problem: wrong active ingredient entirely. In its own compounding alerts, FDA has stated it received reports that some compounders use salt forms of semaglutide — semaglutide sodium and semaglutide acetate — that are chemically different active ingredients from the base-form molecule used in Ozempic and Wegovy, with no established human safety or effectiveness data for those salts at all *(FDA, "FDA alerts health care providers, compounders and patients of dosing errors associated with compounded injectable semaglutide products")*. The same alert notes some compounders add unapproved combinations — vitamin B12, B6, L-carnitine, NAD — whose safety and effectiveness *in combination with semaglutide* has never been established either. This is not a dosing-error story; it is a formulation-identity story, and it's arguably the single most specific safety signal in the entire compounded-GLP-1 record.

The delivery device itself removes a built-in safety control. FDA-approved semaglutide and tirzepatide products use several presentation types. Wegovy uses prefilled single-dose pens, Ozempic uses prefilled multidose dial-a-dose pens, and approved tirzepatide products are available in single-dose pens and vials. Many compounded injectable versions are dispensed in multidose vials that require patients or providers to measure doses manually with a syringe. FDA has linked that manual step and differences in concentrations and unit conventions to dosing errors. Its alert includes patients who were directed to draw 5 units from a multiple-

dose vial and drew 50 instead, and providers who miscalculated when converting milligrams to units — one prescribed 25 units instead of 5, another 20 units instead of 2. Patients confusing milliliters, milligrams, and syringe units injected 5 to 20 times the intended dose *(FDA, "FDA alerts health care providers, compounders and patients of dosing errors associated with compounded injectable semaglutide products"; CBS News, "People are overdosing on injectable weight-loss drugs, FDA warns")*.

The epidemiology, done rigorously, points the same direction. A retrospective statewide poison-center study (December 2017–December 2023, 1,047 cases) used interrupted time-series analysis — a formal statistical trend test, not a simple before/after comparison — and found a statistically significant increase in both GLP-1 reported exposures (+1.16/month, $p<0.001$) and hospital utilization from those exposures (+0.351/month, $p=0.001$) following Wegovy's 2021 approval and the compounding boom that followed. A 2023 case report in the *Journal of the American Pharmacists Association*, describing calls to the Utah Poison Control Center, documented two patients who self-administered ten times their intended compounded-semaglutide dose. Nationally, America's Poison Centers reported nearly 3,000 semaglutide-related calls in the first eleven months of 2023 alone — more than 15 times the 2019 volume, with the medication the only substance involved in 94% of those calls. **One fairness note the poison-control researchers themselves raised:** not all of this volume is compounding-specific — call centers report rising volume tied to FDA-approved products too, so this trend should be read as "GLP-1 utilization and misuse broadly are rising fast," with compounding format and quality as a documented aggravating factor, not the sole cause.

What this means for the report's headline numbers. Every adverse-event count in Part VI is a floor for a second reason beyond underreporting: none of these figures are adjusted for exposure (how many patients, how many doses were actually administered). A rigorous reading requires holding two things at once — the raw counts are almost certainly an undercount of true harm, *and* they should not be read as a bare incidence rate without a denominator. This report does not have a reliable national denominator for compounded-GLP-1 users; estimates range as high as 1.5–2 million patients (Part III), which would put the reported-hospitalization count at a rate on the order of a few hundredths of a percent of that

population — a figure that itself would be an underestimate for the reasons above, but one intentionally noted here rather than left for a critic to raise first. ◀

PART V

Named Patients, Named Harms

Aggregate adverse-event counts can feel abstract. These are three of the documented cases behind the numbers, compiled from court filings, legislative records, and news coverage:

Kentucky — Jimmie Wilson. Wilson, a Kentucky woman, says she went into acute liver failure within about four weeks of starting a compounded weight-loss injection. Her doctor told her to go to the emergency room after bloodwork came back abnormal; she was placed at the top of a liver-transplant list and underwent an emergency liver transplant. Kentucky state representative Vanessa Grossl filed "Jimmie's Law" (House Bill 729) on February 25, 2026; it would have required Kentucky's Board of Pharmacy to license and inspect businesses that compound injectable drugs, including GLP-1s. Wilson's own account of the episode appeared about five weeks later, as a Washington Post opinion piece on March 31, 2026. The bill's committee chair never scheduled it for a hearing, and it died when the 2026 legislative session adjourned; its backers say they intend to refile it in 2027. Notably, the compounding industry's own trade association described the bill as aimed more at unlicensed operators outside the regulated pharmacy system than at licensed compounding pharmacies *(Alliance for Pharmacy Compounding, state updates, Apr. 17, 2026)* — a useful reminder that "stronger oversight of compounding" and "shut down licensed compounders" are not the same demand, even though they're sometimes conflated in this debate.

North Carolina. A North Carolina patient was reportedly hospitalized for approximately 72 hours with severe vomiting and dehydration after an overdose linked to a compounded GLP-1 obtained through a virtual prescribing service — a case public-health reporting has tied to broader concerns about inconsistent dosing concentrations and inadequate patient instructions across compounded injectable products, and one of several cases cited in a formal submission to the California State Board of Pharmacy urging stricter API
testing standards.

Texas — Shawna Stash. Shawna Stash, a Texas woman, died in April 2024 after using a compounded semaglutide/cyanocobalamin product identified in court

filings as having been supplied by Empower Pharmacy — the same company profiled in Part II. Court filings say she had been on the compounded product since February 2023, was hospitalized for nearly a month before her death, and told providers she had recently increased her dosage. Her family filed a lawsuit against Empower in April 2026 alleging wrongful death, defective formulation, and misrepresentations concerning manufacturing and ingredient quality. Those allegations remain pending and have not been adjudicated. Roughly a year after Stash's death, the FDA issued a warning letter to Empower and its CEO citing failures
to meet federal drug manufacturing requirements.

These are not the only such cases in the public record. The same California Board of Pharmacy submission separately cites an Illinois telehealth patient who required emergency hospitalization after visible particulate contamination and cold-chain failures in a compounded injectable, and two FDA warning letters — one to compounder GenoGenix LLC over a product with excessive bacterial endotoxins that hospitalized three patients, another to MedisourceRx over a hospitalization tied to a compounded injectable the facility failed to report to FDA at all. ◀

PART VI

What the Adverse Event Data Shows

Adverse-event reporting for this category has been a moving target, both because tracking organizations have published incremental updates and because compounded and brand-name reports are not always cleanly separated in FAERS, FDA's passive surveillance system. The table below combines an FDA-published count with FAERS-based figures reported by RX Border Defense, a submission to the California State Board of Pharmacy, and a compilation prepared for this report. These sources do not use a single documented methodology and should not be treated as a standardized time series:

Date	Scope	Total AE Reports	Hospitalizations	Deaths	Source
Dec. 31, 2024	Compounded semaglutide + tirzepatide only	900+	—	17	Sen. Jim Banks letter to FDA
July 31, 2025	Compounded semaglutide (605) + tirzepatide (545)	1,150	—	—	FDA, published count
Sept. 9, 2025	All compounded GLP-1 drugs	1,424	329	23	FDA FAERS, via RX Border Defense
~Mar. 13, 2026	All compounded GLP-1 drugs	1,500+	372	30	FDA FAERS, via CA Board of Pharmacy submission
May 31, 2026	Compounded semaglutide (990) + tirzepatide (730+)	1,720+	—	—	FDA, published count
Aug. 2026	All five commonly compounded GLP-1-class molecules	1,700+ (1,456 serious)	454	38	Report compilation; methodology not documented

Important limitation: FAERS is a passive surveillance system. These figures are counts of reports associated with the products, not findings that a drug caused the reported hospitalization or death, and they are not incidence rates because no reliable exposure denominator is available.

Read across the rows, the direction of travel is consistent: every snapshot shows the total climbing. Hospitalizations rose from 329 to 372 to 454 across roughly eleven

months, and deaths from 23 to 30 to 38 over the same period. The rows are not, however, a like-for-like series, and the two most recent entries cannot be read against each other. FDA's own published count as of May 31, 2026 — 990 reports for compounded semaglutide and more than 730 for compounded tirzepatide — covers only two molecules, yet already exceeds the 1,700+ total that the August 2026 compilation reports across five. Either the compilation applies a narrower inclusion rule than FDA's public tallies, or it undercounts; its methodology is not documented, so this report cannot say which. Readers should treat the FDA rows as the authoritative floor and the compiled row as a separate, differently constructed estimate. As with every number in this table, all of these are counts of *reports*, not a population incidence rate, and not a finding of causation (see Part IV's denominator note and
Part VII below).

Two of the five molecules in that August 2026 figure deserve a specific flag: as of this writing, **neither retatrutide nor cagrilintide is FDA-approved in any form.** Retatrutide remains unsubmitted for FDA review, and cagrilintide (studied in combination with semaglutide as "CagriSema") likewise has not received FDA approval for commercial patient use. Any product marketed as a compounded version of either drug is therefore not a lower-cost copy of an FDA-approved product; it is a product built around an active ingredient that has not been FDA-approved for commercial patient use.

Independent, peer-reviewed pharmacovigilance research points the same direction. A FAERS study focused specifically on compounded formulations (2018–2024) found elevated reporting odds ratios for several outcomes relative to non-compounded versions of the same drugs, including abdominal pain, nausea, diarrhea, cholecystitis, and — notably — a more than six-fold higher signal for suicidality-related reports *(McCall et al., Expert Opinion on Drug Safety, 2025).* A separate FAERS analysis of semaglutide, tirzepatide, and liraglutide in patients with obesity independently identified 1,713 adverse event cases through December 2024 — a different population and methodology than the compounded-only figures above, but a directionally consistent order of magnitude. ◀

PART VII

Why These Numbers Are a Floor, Not a Ceiling

Every organization tracking this issue — the FDA included — has said some version of the same thing: the true scope of harm from compounded GLP-1s is understated in the available data, for reasons that are structural rather than incidental.

- **Reporting to FAERS is incomplete and uneven for this category.** State-licensed 503A pharmacies generally are not subject to a federal adverse-event-reporting requirement. FDA-registered 503B outsourcing facilities do have a reporting obligation, but it is narrower: they must report serious and unexpected adverse events. This asymmetry means FDA does not receive a uniform national stream of safety reports across all compounded-drug channels.

That reporting gap should be closed, and reporting should include market volume. Congress and FDA should establish a uniform federal reporting floor for serious adverse events associated with compounded human drugs and require standardized reporting of compounded GLP-1 prescription or dispensing volume sufficient to create a usable exposure denominator, with rapid information sharing among FDA, state boards of pharmacy, state medical boards, and poison centers. Without both adverse-event data and volume data, policymakers cannot reliably distinguish a growing number of reports caused by higher utilization from a true change in risk.

- **Patients often don't understand the regulatory status of what they're taking.** Telehealth platforms and med-spa-style clinics have sold compounded GLP-1s under branding that, in FDA's assessment, sometimes implies equivalence to the approved product or obscures which compounder actually made it. A 2025 National Consumers League survey of 1,500 U.S. women ages 18–55 found that 53 percent believed compounded GLP-1 drugs were FDA-approved and 49 percent believed compounded versions had the same active ingredients as branded drugs — evidence of substantial consumer confusion even among people aware of the category. The survey was commissioned by an advocacy organization and should be read as consumer-perception evidence, not a clinical study.

- **Counterfeit and diverted product muddies attribution further.** A CNBC investigation into the "Ozempic underworld" documented an international black market in which criminals either alter legitimate product or repackage ingredients shipped in from overseas — meaning a patient experiencing harm may not know whether they took a licensed compounder's product, a counterfeit, or a diverted brand-name pen at all.
- **The immunogenicity issue may not register as a classic** adverse event. The analytical and in vitro studies discussed in Part IV identified potential immunogenicity signals, but they did not establish that patients developed antibodies or clinical immune injury. If such effects occurred, therapeutic failure might be less likely than an acute reaction to generate an adverse-event report.
- **Poison control data tells a consistent story from an independent surveillance system.** Washington state's poison center reported that calls related to GLP-1 diet drugs have doubled since 2024, a trend investigators in multiple states have linked specifically to injectable compounded products.

None of this means the headline totals in this report are inflated. FDA and multiple researchers and organizations cited in this report caution that passive reporting and other surveillance limitations mean the documented cases are likely a **floor**, not a full accounting. ◀

PART VIII

Where This Stands as of September 2026

- Both federal shortage determinations that had permitted mass GLP-1 compounding are now resolved (tirzepatide, December 2024; semaglutide, February 2025), and enforcement deadlines for compounders to wind down copycat production
  have passed.

The Fifth Circuit has now upheld those shortage determinations on appeal. In opinions issued on August 27, 2026, with the semaglutide opinion revised on September 1, 2026, the court affirmed judgments for FDA in separate challenges involving tirzepatide and semaglutide, rejecting arguments that FDA's shortage determinations violated the Administrative Procedure Act. The decisions further weaken any argument that broad copycat production remains justified by the prior shortages.

- FDA has proposed excluding semaglutide, tirzepatide, and liraglutide from the 503B outsourcing-facility bulk drug substances list. If finalized, the proposal would narrow a potential pathway for 503B facilities to compound from bulk substances, subject to the statute's other conditions; the proposal is not yet a final determination.
- Retatrutide is emerging as the next front before that fight is even resolved: unsubmitted for approval, already the subject of a social-media-driven black market.
- FDA's August 21, 2026 revision to the Green List was broadened to include orforglipron, the newly approved oral GLP-1 drug: API from three unidentified manufacturers and a solid-dispersion intermediate from a fourth now receive Green List treatment. The same revision carries China entries keyed to retatrutide, an unapproved molecule that has not been submitted to FDA and cannot lawfully be compounded. FDA's public alert does not identify a shortage rationale for any of these additions, and its orforglipron product code does not distinguish "for further manufacturing" from "for Rx compounding" the way semaglutide and tirzepatide codes do. That does not create a compounding authorization, but it underscores that the Green List

now operates more broadly than the shortage-era peptide compounding problem that originally framed the policy.

- Leadership at the FDA has changed: Commissioner Marty Makary, who launched the Green List, resigned in May 2026; Kyle Diamantas has served as acting commissioner since. The Green List remains publicly redacted at the firm-name level even though the current import alert identifies multiple China entries and the products covered. That leaves FDA able to compare Harbin against the remaining listed firms while outside researchers, purchasers, state regulators and the public cannot independently perform the same network or provenance analysis.
- Litigation on multiple fronts — Lilly v. Empower, the Stash wrongful-death suit, Novo's cease-and-desist campaign, Lilly's new retatrutide suits, and the Outsourcing Facilities Association's suits against FDA — remains unresolved and will likely determine how much of this market survives in its current form.
- State legislative efforts remain uneven. Kentucky's 'Jimmie's Law' died in committee and its backers have discussed refiling; California's AB 1990 advanced through the Assembly but was held under submission in the Senate Appropriations Committee on August 13, 2026. The state activity illustrates the fragmented policy response: different jurisdictions are considering different combinations of advertising, sourcing, testing, licensing, and reporting rules for the same national market.

The parallels to 2012 are not subtle. A disaster exposed a regulatory gap. Congress and the FDA built a framework to close it. Industry scale outran that framework and the FDA continues to fail to use the authorities they were given to prevent another disaster like the one that arose from the New England compounder. The weakness of the Green List allows Big Pharma China to exploit loopholes by relabeling product and disguising the true manufacturer. The remaining beneficiaries of the Green List are publicly unidentified, preventing outsiders from determining whether the same pathway exists elsewhere.

FDA should shut the Green List down. The agency should preserve Import Alert 66-80's heightened scrutiny of foreign GLP-1 APIs but eliminate the standing

exception for Green List firms and non-FDA approved products. Every foreign, unapproved GLP-1 API shipment should be halted. Harbin showed that the identity on the paperwork can be separated from the identity of the true manufacturer. Redaction prevents meaningful external accountability. FDA's own noncompliance findings show the supply chain warrants scrutiny, not presumptive trust. And the expansion to orforglipron shows that the mechanism is becoming institutionalized, despite its documented failings.

The choice is therefore not between the Green List and open borders for foreign, unapproved API. It is between two enforcement models: one that grants opaque, firm-level preferential treatment and tries to remove bad actors after the fact, and one that requires traceable evidence tied to the actual product crossing the border. The record assembled here supports the second model. FDA should terminate the Green List and replace it with shipment-specific, provenance-based screening before another supplier demonstrates the same weakness at larger scale. ◀

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This report was compiled from publicly available FDA communications, court filings, congressional correspondence, state legislative records, investigative journalism, and peer-reviewed pharmacovigilance and analytical chemistry research current as of September 9, 2026. Adverse event figures draw on FDA's Adverse Event Reporting System (FAERS), a passive surveillance system; a report does not establish that a drug caused the reported event, and the underreporting and denominator limitations described in Parts IV and VII apply to every figure cited here.