



Insight

Illegal Drug Compounding May Increase Under Tightening Customs Policy

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Executive Summary

- Since April 2025, the Trump Administration has worked to end the de minimis exemption for low-cost imports of goods; on January 20, 2027, the next policy limiting these importations takes effect.
- Though personal pharmaceutical importation is generally unlawful, patients have long purchased drugs from foreign pharmacies to lower out-of-pocket costs and maintain access to certain medicines.
- This customs change may incentivize patients to explore alternative routes to access medications; the Food and Drug Administration should be prepared to enforce existing compounding laws and prevent this change in trade policy from creating new risks in the drug supply chain.

Introduction

Beginning [January 20, 2027](#), new customs [requirements](#) could significantly disrupt Americans' ability to receive prescription drugs from foreign pharmacies. International mail containing Food and Drug Administration- (FDA) regulated products will now face greater reporting and regulatory scrutiny by Customs and Border Protection (CBP), and several Canadian and international pharmacies have already warned that the new requirements may disrupt or effectively end their existing U.S. shipping models. Personal pharmaceutical importation is generally unlawful, but it is nonetheless widely practiced and has long persisted under FDA's exercise of enforcement discretion.

The immediate effects of the policy will occur at the border, as packages are admitted, delayed, or refused. The consequences, however, may extend beyond the border and into the retail prescription drug market. Patients that lose access to one source of medicine may seek alternatives, creating new demand elsewhere. For the FDA, one such market deserves particular attention: pharmaceutical compounding.

Traditional compounding serves a legitimate but narrow purpose, allowing pharmacists to meet individualized clinical needs or respond to drug shortages. Yet portions of the industry have repeatedly stretched those exceptions toward commercial-scale production of non-FDA-approved drugs. If the January 2027 CBP changes steer even some patients toward compounded alternatives, they could create another opportunity for compounders already willing to test the limits of the regulatory system. FDA should be prepared to enforce existing compounding laws and prevent this change in trade policy from creating new risks in the drug supply chain.

A Brief Regulatory History of the Suspension of the De Minimis Exemption

The changes taking effect on January 20, 2027, are the latest in a broader effort to unwind duty-free de minimis treatment for low-value imports and replace it with a more formal customs process. The current policy developed in stages. On April 2, 2025, President Trump [ordered](#) the suspension of duty-free de minimis treatment for low-value imports from China and Hong Kong, with the change taking effect May 2 that year. Congress [eliminated](#) the commercial de minimis exemption altogether in the One Big Beautiful Bill Act, signed into law on July 5, 2025, although the statutory repeal does not take effect until July 2027. To enforce this law before the statutory deadline, the administration [expanded](#) the de minimis suspension to all countries beginning August 29, 2025, and [extended](#) the suspension in February 2026. CBP followed in June 2026 with [regulations](#) implementing an indefinite suspension and [establishing](#) new entry procedures for shipments that previously qualified for de minimis treatment. Originally [slated](#) for implementation on October 22, 2026, these rules will finally take effect on January 20, 2027, with the end of the delayed-compliance period and the use of the new Entry Type 13 process.

Personal Importation's Unusual Legal Status

Understanding the significance of the January 2027 deadline first requires some context on the unusual position that personal drug importation occupies under federal law. Americans routinely order prescription drugs from pharmacies in Canada and other countries and receive them via international mail. The Canadian International Pharmacy Association (CIPA), for example, reported that its member pharmacies have served more than [10 million patients](#) since its founding. Yet personal prescription importation is not, as a general matter,

legal. Drugs purchased abroad are typically [illegal](#) to import if the particular product has not been approved for sale in the United States, even when another country's regulator has approved it.

That prohibition has never meant that the FDA intercepts every package, though. [Federal law](#) directs the Department of Health and Human Services to focus enforcement against individuals whose imports pose a significant public health threat and to exercise discretion when a drug is clearly for personal use and does not appear to pose an unreasonable risk. The FDA accordingly maintains a personal importation policy under which agency personnel may permit certain shipments, generally involving no more than a three-month supply, based on factors including the patient's medical need, the product's risk, and whether the drug is being commercially promoted in the United States.

The result is an unusual but long-standing equilibrium. Personal importation is widely practiced and often tolerated, but it is not an authorized alternative pathway for obtaining prescription drugs. Patients have instead relied on FDA's enforcement discretion and a postal system in which officials historically had limited information about many individual packages.

A Technical Change to Consumers' Traditional Customs Processes

This personal importation pathway will be directly affected with the final termination of the de minimis exemption and the [introduction](#) of a new entry pathway. The new electronic informal-entry process - Entry Type 13 - permits qualifying international mail shipments valued at \$2,500 or less to enter without undergoing the full formal-entry process. But Type 13 also requires an importer of record to electronically provide information including the product description, country of origin, tariff classification, value, duty owed, carrier, tracking number, and arrival port. Shipments regulated by another federal agency (called a Partner Government Agency in the rule) must also provide the information necessary to satisfy that agency's requirements.

For prescription drugs, the consequential change is therefore not a new prohibition. Personal importation was already generally unlawful. Instead, products that previously moved through a postal environment heavily dependent on case-by-case enforcement discretion will enter a more structured electronic system in which CBP, the FDA, and an accountable importer of record have substantially more information about each shipment. A more structured, electronic entry gives the FDA greater visibility into products that previously moved through the international postal system with comparatively little parcel-level information.

International pharmacies expect that difference to matter. CIPA [says](#) the arrangements used to deliver many personal prescription orders will no longer be workable after January 20, 2027. This assessment is supported by some pharmacies attempting to develop alternative arrangements. The disruption is already visible due to the original October 22 implementation date. Marks Marine Pharmacy set October 14 as its last day for Canadian shipments. Canadian Prescription Drugstore stopped taking new orders after October 7 and had already halted products sourced from Canada, New Zealand, and Australia while evaluating its shipping options. Other pharmacies are warning customers about delays, refusals, or interruptions.

How Many Patients Could Be Affected?

There is no current federal census of Americans who personally import prescription drugs, making the potential impact difficult to quantify precisely. The best nationally representative estimate comes from a 2020 *JAMA Network Open* [analysis](#) of National Health Interview Survey data collected between 2015 and 2017. Among U.S. adults taking prescription medicines, 1.5 percent reported purchasing medicines from outside the United States to save money during the previous year. Applied nationally, that represented approximately 2.3 million people. The estimate from nearly a decade ago should not be treated as a current head count, but it establishes that personal importation has long been more than a fringe practice. Self-reported industry figures point in the same direction. CIPA says its member pharmacies have served more than [10 million](#) patients since its founding.

More relevant to the potential downstream effects is what the *JAMA* analysis indicates about the consumers involved. People who purchased medicines outside the United States had 2.3 times the adjusted odds of using an online pharmacy and were substantially more likely to report cost-related medication nonadherence. Personal importation therefore already attracts a population accustomed to looking outside conventional pharmaceutical distribution channels when existing arrangements do not meet their needs.

If Difficulties Arise, Where Does the Demand Go?

Patients affected by the CBP change will respond differently. Some may continue to attempt to import drugs under the new system. Many will likely obtain the same or alternative FDA-approved drugs through the domestic market, or change therapies. Others may delay treatment. But in several consumer-facing pharmaceutical markets, patients searching online for another option may turn to compounded medicines.

The extent of the overlap should not be exaggerated. Commonly imported cardiovascular, respiratory, and diabetes medicines do not necessarily have mass-market compounded

substitutes. But the compounding market may be substantial in some highly consumer-facing categories, including GLP-1 medicines, ED treatments, hair loss products, and hormone therapies. These are also markets in which telehealth has made obtaining a compounded prescription exceptionally easy.

A 2025 [survey](#) from the Alliance for Safe Online Pharmacies Foundation provides important perspective. Among consumers who reported buying GLP-1 products online, 32 percent had used an international online pharmacy, and 27 percent had used an online compounding pharmacy. These consumers were not tied to a single distribution channel: Thirty-nine percent reported experience with two or three types of online sources, while another 34 percent had used four or more. The survey comes from an organization focused on unsafe online drug sales and should be read with that context in mind, but the findings indicate that international pharmacies and compounders already operate within overlapping consumer markets.

The survey also illustrates why potential substitution of compounded products merits regulatory attention. Eighty-six percent of online GLP-1 purchasers incorrectly believed compounded medicines were evaluated by FDA for safety and efficacy, while 57 percent incorrectly believed compounded medicines were the same as generic drugs.

This misconception is concerning. Compounded drugs are not FDA-approved. The FDA does not review them for safety, effectiveness, or quality before they are marketed. Drugs produced by traditional Section 503A compounders are also exempt from current good manufacturing practice requirements if the statutory conditions are satisfied. The FDA says compounded medicines should only be used when a patient's medical needs cannot be met by an FDA-approved product.

Compounding law was designed to accommodate individualized medical needs, not to create an alternative pharmaceutical industry whenever an approved medicine becomes expensive, scarce, or inconvenient to obtain. Yet portions of the industry have repeatedly sought to turn those exceptions into scalable business models.

Previously Identified Compounding Issues

Past shortages of semaglutide and tirzepatide (GLP-1 medications) temporarily created broad opportunities for lawful compounding. Companies responded with large-scale production, telehealth prescribing, and direct-to-consumer advertising. When the shortages ended, however, some businesses did not simply exit the market.

In March 2026, the FDA [sent](#) warning letters to 30 telehealth companies over allegedly false or misleading marketing of compounded GLP-1 products. Among the agency's concerns

were claims implying that compounded drugs were the same as FDA-approved medicines and branding that obscured who had actually compounded the drug. FDA explicitly warned that compounding should not be used to circumvent the drug-approval process. A September 2026 [warning letter](#) to Empower Pharmacy went further. The FDA said evidence collected during an inspection indicated that the pharmacy regularly produced compounded semaglutide and tirzepatide products that appeared to be essentially copies of commercially available drugs. Investigators found repeated, nearly standardized assertions of patient-specific differences and concluded that the volume of production suggested those differences may have been pretextual.

Quality concerns have accompanied those enforcement issues. The FDA [reports](#) that, as of May 31, 2026, it had received 990 adverse-event reports associated with compounded semaglutide and more than 730 involving compounded tirzepatide (those figures do not establish that the compounded product directly caused every event). The agency also cautions that the totals are likely incomplete because traditional state-licensed compounding pharmacies generally are not required to report adverse events to the FDA.

The concerns extend upstream. In August, the FDA [warned](#) an Indian producer about the production of sildenafil and tadalafil (ED medications) active pharmaceutical ingredients (APIs) that were imported into the United States and used by compounding pharmacies. FDA investigators observed unidentified residues, inadequately gowned employees, and corroded equipment near production operations and concluded that the APIs were produced under insanitary conditions. A patient who previously obtained a manufactured ED drug through an international pharmacy may encounter domestically marketed compounded alternatives with little difficulty. Moving the final preparation inside the United States, however, neither eliminates international supply chain risks nor makes the compounded product FDA approved.

Enforcement Vigilance

The actual impact of the customs changes will only become clear after implementation. But the FDA does not need to know the precise magnitude of the shift to recognize and prepare for the perverse incentives it could create. Disruptions in access to an established source of medicine for consumers may cause some patients to migrate toward compounded alternatives. Even more concerning may be what additional demand does to the compounding industry, including incentivizing its improper expansion. More demand creates greater incentives for high-volume production, standardized formulations, aggressive direct-to-consumer marketing, greater purchases of bulk APIs, and increasingly creative efforts to characterize commercially scalable products as individualized preparations.

The constituent pieces are already visible. A sizeable population has historically obtained medicines abroad. International pharmacies are changing their operations in advance of the new customs requirements. Those consumers are comparatively accustomed to obtaining medicines online. And in at least some therapeutic markets, international pharmacies and compounders already serve overlapping groups of consumers who frequently misunderstand the regulatory differences between their products.

The recent compounding experience outlined earlier demonstrates how rapidly a large source of new demand can encourage commercial behavior far removed from traditional patient-specific pharmacy practice. To combat this potential shift and ensure safety and efficacy of medicines for U.S. patients, the FDA does not need new regulatory authority. Its chief task is enforcement.

The law allowing pharmaceutical compounding is relatively [narrow](#). Section 503A of the Federal Food, Drug, and Cosmetic Act generally allows pharmacies to compound drugs for individual patients on an as-needed basis and restricts improper production of medicines that are copies of patented, commercially available drugs. Section 503B of the same law allows for outsourcing facilities to operate under a different, looser framework but likewise limits the compounding of products that are copies of approved medicines.

As the new customs system takes effect, the FDA should monitor therapeutic categories in which personal importation and commercialized compounding overlap. The agency should also watch for compounders or telehealth firms explicitly targeting patients whose international prescriptions have been interrupted. It should scrutinize sudden increases in high-volume Section 503A production, formulaic assertions of individualized clinical differences, growth in bulk API imports, and products altered only enough to create the appearance of “individualized compounding.”

The agency should also continue toughening the enforcement posture it has adopted during 2026. Recent warning letters demonstrate that the FDA understands previous experiences and the danger of allowing statutory exemptions intended for genuine compounding to become a means of avoiding the approval and manufacturing standards applicable to conventional drug companies.

Conclusion

The January 2027 deadline is unlikely to produce a one-for-one migration from foreign pharmacies to compounders. But the second- and third-order risks are difficult to ignore. Compounding has an appropriate place in medicine. If disrupted personal importation channels create new customers for commercial-scale compounders, FDA should not wait for

a new market to form around it. The compounding industry has shown remarkable comfort with exploiting exemptions to manufacture and market non-FDA-approved substitutes at scale. The agency already has the authorities necessary to police these channels, and as the new customs regime takes effect, FDA should ensure that this change in trade policy does not become the compounding industry's next business opportunity.