Legal Challenges to Compounding Drugs for Weight Loss

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The last decade has seen stunning developments in the production of drugs to help with weight loss and the treatment of diabetes. Semaglutide is a glucagon-like peptide-1 receptor agonist ("GLP-1"). Tirzepatide is a combination of a GLP-1 and a gastric inhibitory polypeptide. ("GIP"). The market for GLP-1 drugs is projected to exceed $100B by 2030, with an estimated 30M unique users, about 9% of the population.[1]

Both drugs have shown blockbuster clinical results in weight loss and improvement in complications of diabetes. Over the last three years, a combination of wildly growing demand and near-constant shortages have provided both compounding pharmacies and outsourcing facilities with strong financial incentives to move aggressively into the production and sale of semaglutide and tirzepatide. Although for simplicity's sake, we focus on semaglutide, broadly similar remarks apply to tirzepatide.

This lucrative market has also proved very tempting to physicians working in the weight loss space. The fact that the predominant use of these drugs—to aid weight loss—is not typically covered by insurance, has sweetened the proverbial pot. Because reimbursement is not typically tied to federal health care programs, there is less risk from the attendant federal legal prohibitions on kickbacks and physician self-referral.

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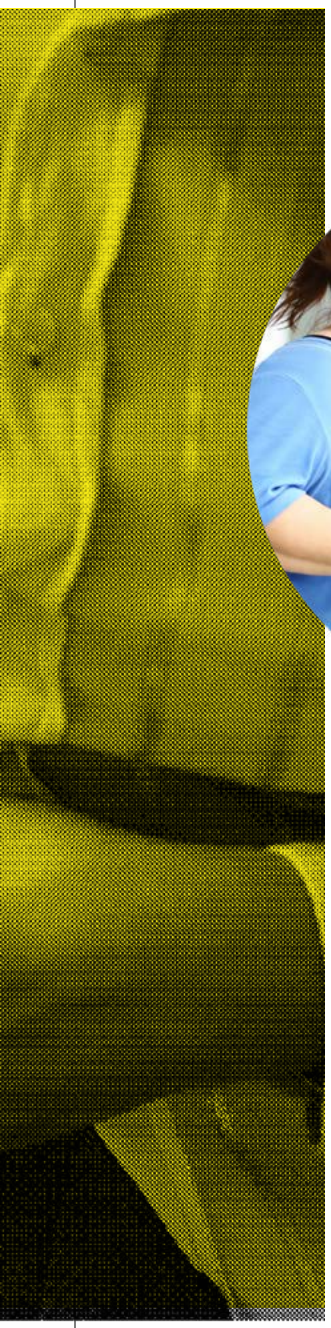

Nevertheless, both compounders and clinical practices currently face significant legal risks from avoiding the branded products in favor of compounding and selling analogous drugs. We review some of the relevant history for semaglutide, including the regulatory framework and an overview of the additional risks of this novel trend in the compounding space. We should note at the outset that the following is only a cursory overview of the risks, which vary significantly and evolve rapidly. If you are considering compounding these drugs, you should seek jurisdiction-specific advice from competent legal counsel.

The Federal Regulatory Framework

Semaglutide is the generic name for a product developed, owned, and patented by the Danish drug manufacturer, Novo Nordisk. Novo Nordisk markets semaglutide under three different brand names. Ozempic (an injectable) and Rybelsus (an oral pill) are marketed to treat diabetes. Wegovy (an injectable) is marketed for weight loss and management. Semaglutide requires a prescription, but is not a controlled substance under federal law.

The production, marketing and sale of semaglutide are subject to multiple intersecting state and federal regulations and distinct regulatory authorities. These activities also give rise to a range of distinct civil liabilities under both state and federal law. Different kinds of litigation may be initiated by federal, state and private actors.

The FDA

All prescription drugs marketed in the U.S. are subject to the primary regulatory authority of the federal Food and Drug Administration ("FDA"), an agency created by the Federal Food, Drug, and Cosmetic Act ("FD&CA").[2] Novo Nordisk filed the first New Drug Application with the FDA for semaglutide on December 5, 2016. Approval followed by unanimous vote a year later.[3]

In addition to regulating branded drugs, the FD&CA contains regulations relating to both compounding pharmacies (or "compounders") and outsourcing facilities (or "outsourcers"). Importantly, the FDA provides compounders and outsourcers limited authority to produce compounded versions of drugs without going through a separate new drug approval process. To ensure product safety, the FDA wields broad regulatory authority over what they may compound and when they may compound it.

Section 503A of the FD&CA clarifies the conditions under which compounders may produce and sell certain drug products.[4] Licensed pharmacists or physicians can compound sterile drugs only if all of the following conditions are met:

- The drug product is compounded from *bulk drug substances* that meet several sub-conditions, including being manufactured by an FDA-registered facility and having a valid certificate of analysis;
- Any other ingredients used comply with the standards of an applicable U.S. Pharmacopoeia or National Formulary monograph, if one exists;
- The drug product does not compound any product on the official list of dangerous drug products not suitable to compounding; and
- The compounder does not regularly compound (or compound in an inordinate amount) drug products that are *essentially copies of commercially available drugs*.

The italicized phrases merit additional attention. Bulk drug substances must:

- Comply with standards of (i) an applicable U.S. Pharmacopoeia or National Formulary monograph (if one exists) and (ii) the U.S. Pharmacopoeia chapter on compounding;
- If a monograph does not exist, be compounded from components of approved drugs; or
- If a monograph does not exist and the components are not of approved drugs, the components must appear on an approved list;

A drug product can be excepted from the "essentially a copy" prohibition if a physician determines that a compounded product produces a significant difference for an identified individual patient that is not available in the commercially available forms of the drug product. In what follows we refer to this as the "Significant Difference Exception," or the "SDE.". Importantly, the scope of the SDE is largely reserved to the medical judgment of the treating prescriber in consultation with the compounding pharmacy.

Section 503A also includes a provision for the development of a list of drugs that produce "demonstrable difficulties for compounding" (the "DDC List"). The inclusion of a drug product on this list effectively bans its production by both compounders and outsourcers.

Somewhat similar conditions for outsourcers are spelled out in Section 503B, which provides that an outsourcing facility may not compound using bulk drug substance unless:

- The bulk drug substance appears on an FDA clinical need list or on the FDA drug shortage list;
- The bulk drug substance is produced comply with an applicable monograph under the U.S. Pharmacopeia, the National Formulary, or other recognized compendium;
- The bulk drug substance is manufactured by an FDA-registered facility; and

- The bulk drug substance has a valid certificate of analysis.

Similarly to 503A, 503B prohibits outsourcers from compounding "essentially a copy" of a commercially available drug.[5] However, 503B provides exceptions both for drugs on the shortage list at the time of compounding and under the SDE. (Note that although the 503B statute uses the phrase "clinical difference," in industry guidance the FDA has treated the type of difference needed between the commercially available product and the compounded product under very similar terms; "SDE" will be used to cover both exceptions.)

Importantly, no form of semaglutide is on the bulks list. In addition, semaglutide has no monograph under the U.S. Pharmacopeia, the National Formulary, or other compendia. In practice, this means that the least risky practical path to compounding semaglutide is for outsourcers to do so when the product is in shortage. However, a narrower path to compliant compounding (and potentially outsourcing) remains under the SDE.

Notably, the FD&CA reserves sole authority to interpret and enforce its provisions to the FDA.[6] The Act provides no right of private action, meaning that private parties are unable to effectively sue others for failure to comply with the Act's rules. With few exceptions,[7] courts have interpreted the FD&CA as broadly preempting private third parties and independent state legislators from regulating the sale of pharmaceuticals.[8] As we shall see, this sole authority has important implications.

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Federal Intellectual Property Protections

The federal government provides a variety of protections for intellectual property. The primary protections derive from the Lanham Act. The Lanham Act provides the legal framework for the registration and protection of trademarks.[9] A trademark can include any word, symbol, phrase, or design that distinguishes one company's goods and services from another's. The Lanham Act provides companies with the right to litigate to prevent other companies from using their registered trademarks or otherwise marketing competing products in a way that is likely to cause consumer confusion. Novo Nordisk has registered trademarks for each of its three branded forms of semaglutide.

Besides the Lanham Act, the Patent Act gives companies the right to litigate to prevent other companies from importing, producing, marketing, and selling their patented products. As of this year, Novo Nordisk owns twenty distinct patents relating to Ozempic, an additional five patents relating to Wegovy, and another ten relating to Rybelsus. Each product shares the same pair of compound patents, known in the industry as the "343 Patent" and the "122 Patent." Another patent (the "462 Patent") relates to the use of the product for diabetic treatment. These patents make it unlikely that a generic form of semaglutide will be available before December 2031. The 462 Patent could extend that date to June 2033. Those patents, together with Novo Nordisk's property rights under state common law, while not affording absolute protection, do broadly protect Novo Nordisk's intellectual property in semaglutide and confer upon it the legal right to challenge any entry into the semaglutide market by would-be copycats and other competitors.[11]

State Regulators

Although the FDA is the primary regulator of outsourcers and a secondary regulator of compounders, both business activities are typically regulated by one or more state agencies. While both businesses are frequently regulated by state boards of pharmacy, some states have opted for alternative agencies to police outsourcing facilities, typically including those rules under the same agencies that regulate drug manufacturers or wholesalers. In Texas, for instance, outsourcing facilities are regulated by the Department of State Health Services.

The overlapping regulations of state and federal agencies give rise to a good deal of regulatory uncertainty in both compounding and outsourcing. As we shall see, additional state bodies, such as state medical boards, may also indirectly impact both compounding pharmacies and outsourcing facilities.

The Semaglutide Shortage

Wegovy was first indicated on the shortage list in March of 2022.[12] Ozempic followed in August. Appearance on the shortage list indicates that the FDA will not consider a drug instance to be "commercially available." While semaglutide remained on the shortage list, the FDA took a very conservative approach to policing supplies from compounders and outsourcers.

On April 27, 2023, the FDA sent a letter to the Executive Director of the National Association of Boards of Pharmacy ("NABP") clarifying that although "compounded drugs can be made and distributed with fewer restrictions when the drug appears on the FDA's drug shortage list," semaglutide sodium and semaglutide acetate—the so-called "salt forms," often marketed as "research grade" API—were not permissible ingredients of compounded semaglutide intended for human use. The "salt forms" were at issue in part because the only FDA-approved form of semaglutide base is property of Novo Nordisk, who clarified that they did not sell their proprietary semaglutide base.[13]

Owing in part to the dramatic rise in third-party compounding, several state boards of pharmacy, including North Carolina,[14] Mississippi,[15] and West Virgina,[16] provided more rigorous guidance. Each Board noted that:

- There was no U.S. Pharmacopoeia or National Formula monograph for semaglutide;
- The Novo Nordisk products contained the proprietary base, not salt forms; and
- No form of semaglutide appears on the FDA's bulks list for compounding.

From this they concluded selling compounds using the salt forms is impermissible, and that the narrow circumstances remaining to commercially compound semaglutide were likely unavailable.[17] Further, attempts to market semaglutide risked manufacturer litigation. Still, a crucial question this guidance left unanswered was whether compounders could procure semaglutide base.[18] Novo Nordisk denied the possibility, citing both sole access to the original peptide production cell banks and proprietary chemical finishing techniques.[19]

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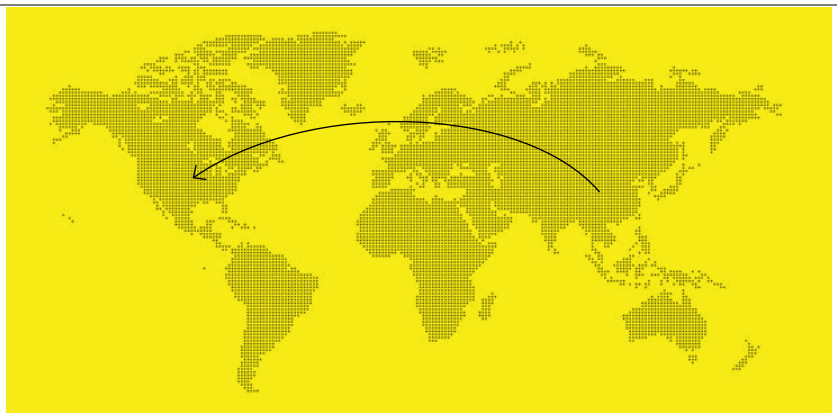
The FDA's relative inaction placed state boards in the unenviable position of trying to protect public health while at the same time making allowances for the high consumer demand for compounded semaglutide. State boards often incorporate federal law into state law, but they are not themselves the FDA and lack broad authority to enforce federal law. This meant that in practice their enforcement actions against what they deemed illicit compounding were limited to failures to comply with explicit FDA guidance and narrower state-level compliance failures.

Compounders were subject to citation for use of the salt forms of semaglutide. Given the skyrocketing demand, some compounders resorted to irresponsible manufacturing practices that outstripped their production capabilities. State infractions may include failures to maintain suitably sterile conditions or to maintain appropriate documentation such as compliant API source documentation, including bills of sale, proof of source licensure, or certificates of chemical analysis.

Some pharmacies have been cited for using commercial drugs against label instructions.[20] For example, Rybelsus, the tablet form of semaglutide, instructs patients not to crush the tablets.

Some compounders attempted to evade the prohibition on salt forms by using crushed Rybelsus as the base and converting the dosage form (generally to sublingual drops) to allow lower therapeutic dosage thresholds. Innovations like this helped compounding to continue to grow to meet the expanding demand but left both businesses and regulators in limbo over complying with different and sometimes conflicting sets of rules.



A Rapidly Evolving Market

Two main adaptations have emerged from these conflicting demands. Domestic fears of litigation and the fall of pharmacy demand for salt forms of the API resulted in a shift away from domestic chemical manufacturers. With the explicit ban on semaglutide salts, compounders and outsourcers frequently turned toward foreign (mainly Chinese) bulk manufacturing sources that claimed—on paper, at any rate—to produce pharmaceutical grade semaglutide while also obtaining the necessary FDA manufacturer registration. Other (primarily Chinese) manufacturers provided the API illicitly.[21]

Second, the combination of (1) the high profitability of supplying off-brand products with (2) the tight connection the Significant Difference Exception draws between a prescriber's judgment and the ability to produce near-copies, together produced contracts and coordination between pharmacies, prescribers, and a variety of clinical locations, ranging from family practices to medical spas to weight loss clinics. Tech companies and telemarketers also aggressively moved into this space, helping to connect clinics and their patients to a multitude of off-brand suppliers.[22]

These connections have been accelerated by the broad avoidance of commercial insurance and federal payer reimbursements. The federal prohibitions on physician self-referral prevent prescribers from having a financial stake in the medication they prescribe if any part of that medication is reimbursed by Medicare or Medicaid. The federal anti-kickback statute has even broader prohibitions, but similarly only applies to federally reimbursed care.

For the blockbuster weight loss drugs, people were often willing to forego insurance coverage entirely. The extra incentives of a cash-rich, regulation-poor environment drove physicians to enter the market, often working directly with compounders and outsourcers to secure product at discounted rates and then frequently either acting as a product-sales intermediary or charging patients for visits and required product administration.

These developments in turn led to expanding sources of regulatory liability. Most states regulate the conditions under which physicians may

hold, administer, and charge patients for prescription medications. While not a controlled substance under federal law, semaglutide is a prescription drug. Some states prohibit physicians from receiving outpatient prescriptions to hold from pharmacies. Others restrict the practice in various ways. Many states, for example, have some prohibition on fee-splitting between physicians and non-physician actors. In addition, many states have so-called mini-Stark and state anti-kickback laws that can prohibit certain arrangements even for cash pay transactions.

However, compounders and outsourcers often perceived the addition of physicians acting as product gatekeepers as an important factor in reducing their risk as suppliers. Laws restricting prescribers from charging for prescription drugs or serving as a waiting station between a pharmacy and an outpatient drug, after all, are regulated primarily by state medical boards rather than boards of pharmacy.

To complicate matters further, prescribers now had powerful financial incentives to deem privately-sourced compounded semaglutide safe, effective, and—because a formulation change was needed to utilize the SDE—to tie changes to the product formulation to ostensibly clinically significant changes for their patients. The combination of high reimbursements, low regulation, persistent shortages, and prescriber buy-in have led to greater collaboration between pharmacists and physicians, and in some cases correspondingly greater risk.

Litigation...And Other Tactics

Beginning in the summer of 2023, Novo Nordisk pursued litigation against several Florida compounding pharmacies. Over the next several years, Novo Nordisk has moved aggressively first against compounding pharmacies and weight loss clinics and grown to include medical spas and telehealth companies. As of April, 2025, Novo Nordisk has initiated at least 111 lawsuits in 32 states.[23]

A pair of early suits are illustrative of what would come. In June 2023, Novo Nordisk sued Effinger Health, the legal entity doing business as Nuvida Rx Weight Loss—Tallahassee Clinic. Here, Novo Nordisk, suing in part under the Lanham Act, was able to show that the clinic had used its proprietary marks—effectively mentioning Rybelsus and Wegovy by name in advertising its compounded products.[24]

The District Court granted a permanent injunction against the clinic's use of any of the relevant marks in the clinic's further business, including injunctions against stating that the clinic's drugs were FDA-tested or approved or had been demonstrated to have any clinical effects. The clinic was prohibited from stating that their compounded products "contain any ingredient (including...semaglutide) that is supplied by Novo Nordisk, is approved by the FDA, or is the same as any ingredient in any Novo Nordisk medicine." Notably, this and other similar injunctions were based, not on the chemical properties or clinical effects of the copycat drugs, but on trademark infringement.

In July 2023, Novo Nordisk sued the Florida compounding pharmacy, Brooksville Pharmaceuticals. Brooksville had adopted a more cautious marketing posture and avoided using any of Novo Nordisk's registered trademarks. The suit proved instructive. Attempting to avoid federal preemption under the FD&CA, Novo Nordisk sued the pharmacy under Florida's Deceptive and Unfair Trade Practices Act, alleging that pharmacy was falsely passing off its product as FDA-approved semaglutide, which both tended to undermine the public health and confuse and mislead its consumers. Novo Nordisk included allegations of violations of Florida's Drug and Cosmetic Act.[25]

The suit was dismissed in early November. While agreeing that Novo Nordisk had legal standing to bring the claim, the Court found that the suit was preempted

by federal law. Although alleging only state law violations, the nature of the allegations essentially involved claims that required interpretations of the federal FD&CA. Those claims could only be litigated by the FDA. The court reasoned that without the underlying alleged violations of the FDA's provisions—e.g., that the drug was not approved, not tested, possibly incorrectly labeled, etc.—none of the state claims about fraudulent marketing and unfair competition could survive. Although Novo Nordisk might in fact be injured by the pharmacy's commercial activities, only the FDA had the authority to establish the essential elements of the underlying complaint.

As a rule, suits alleging deceptive trade practices, without showing any trademark infringement, have proven more vulnerable to dismissal under federal preemption. Suits showing direct comparisons with branded product have been more successful and frequently resulted in injunctions against offending businesses from marketing their products as therapeutically equivalent to the branded products. Notably, despite multiple trademark suits, to date Novo Nordisk has not sued any compounding pharmacy or other business involved in terminal distribution for patent infringement.[26]

In addition to its aggressive litigation strategy, in October of 2024, Novo Nordisk lodged a Citizen Petition ("Petition") with the FDA, requesting that the FDA include semaglutide on the demonstrable difficulties for compounding ("DDC") list.[27] The petition, if successful, would effectively prohibit both 503A compounders and 503B outsourcers from producing, marketing, or selling any form of semaglutide, including not simply injectables and tablets, but also alternative instances such as sublingual drops or buccal forms of delivery.

The heart of the Petition alleges semaglutide has properties that make it unsuitable for compounding. To make the case, the Petition focuses on four factors used by the FDA to evaluate whether a substance should be included on its bulks list, namely:

- Physical and chemical characteristics of the substance;
- Safety issues raised by compounding;
- Evidence of effectiveness of compounded versions of the product; and
- Evidence of use of the substance in compounded products, particularly peer-reviewed literature.

The Petition argues that facts about compounded semaglutide gravitate against its inclusion as a bulk substance.[28]

Novo Nordisk argues that compounders and outsourcers are using chemically synthesized versions of semaglutide, rather than versions produced through recombinant-DNA cell banks. This means the compounded product will have different physical and chemical properties from FDA-approved product. Further:

- The Petition points to serious safety risks raised by compounders and outsourcers, including recalls based on lack of sterility and a growing list of adverse event reports.
- The Petition urges that compounders frequently incorrectly label product potency, pointing to chemical analysis revealing both lower and higher concentrations of semaglutide than indicated on product labels.
- The recent development of semaglutide means that there is effectively little to no historical use of compounded semaglutide.

Recent history has shown the FDA to be resistant to this kind of manufacturer's petition. In particular, Novo Nordisk attempted a similar maneuver with its liraglutide product by a similar petition in 2017. Although that petition was aimed at delaying approval of a pending generic drug version of the liraglutide products, the arguments deployed against effective demonstration of clinical need were strikingly similar. The FDA denied the petition in January 2018.[29] As of this writing, the FDA has taken no action on the semaglutide Petition, but precedent suggests it is unlikely to succeed.

Further, the Petition, like the litigation strategy pursued by Novo Nordisk, represents a serious gamble for the manufacturer. Although taking pains to differentiate compounded from manufactured forms of semaglutide, a focus on different concentrations all but concedes that the API acquired by compounders and outsourcers is, in effect, a generic equivalent of semaglutide. Adverse events also occur with the manufactured product, and concentration errors are generally attributable to identifiable production practices. This risk rises, especially for compounders. While outsourcers are required to meet the more stringent Current Good Manufacturing Practice standards, compounders are held to the recently strengthened, still slightly less stringent, USP <797> standards for sterile compounding.

Resolving the Product Shortage

Facing persistent product shortages in the face of growing demand, Novo Nordisk has invested over $16B dollars to build additional production capacity. This includes a $6B expansion of its Denmark operations. An additional $4.1B project, featuring a 1.4M sq. ft. facility on a 56-acre lot in Clayton, North Carolina, is scheduled for completion between 2027 and 2029.

On February 21, 2025, the FDA announced that it considered the semaglutide shortage resolved and would be removed from the shortage list.[31] The announcement gave compounding pharmacies a 60-day moratorium on enforcement action to cease production of semaglutide. A 90-day moratorium was provided for outsourcing facilities. On February 24, The Outsourcing facilities Association sued for an injunction against the FDA to prevent the removal action.[32] On April 24, 2025, the court denied the injunction, leaving the original notice and timeline in place.[33] The April, 24 ruling ended the FDA moratorium for compounding pharmacies. The moratorium for outsourcing facilities expired, effective May 22.[34]

The FDA's announcement is instructive. Recall that there is no shortage list exception for 503A compounding pharmacies. 503A provides compounding pharmacies may only compound product that is "essentially a copy" of commercially available product under the SDE. Resolution of the commercial shortage would have no effect on whether a compounded form of a therapy was clinically different from a commercially available one. By extending a moratorium on enforcement to compounders, though, the FDA in effect conceded that it was allowing sterile compounding pharmacies to help address the shortages. While this concession makes some practical sense, it also penalizes more cautious market participants.

The resolution of the shortage leaves compounders and outsourcers in a vulnerable position. In effect, the only path to continued compounding of these products will be by way of the SDE. This in effect shifts the risk back toward prescribers, who under the SDE remain the arbiters of whether a change in drug form makes for a clinically significant difference in their patients. This rule is intended to severely restrict the quantities of compounded alternatives produced, on the (generally defensible) presumption that commercially available forms will suffice for the vast majority of the patient population.

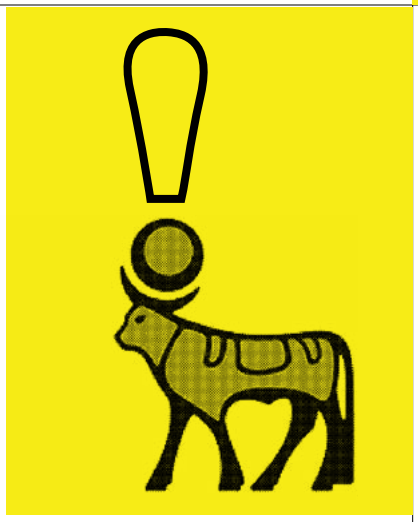
Given the continued financial incentives, less risk averse compounders are likely to proceed down this path, continuing to mass produce semaglutide and other GLP-1s while altering the drug components or dosage form sufficiently to make a *prima facie* case for meeting the SDE threshold.

In effect, the only path to continued compounding of these products will be by way of the Significant Difference Exception (SDE). This in effect shifts the risk back toward prescribers, who under the SDE remain the arbiters of whether a change in drug form makes for a clinically significant difference in their patients. This rule is intended to severely restrict the quantities of compounded alternatives produced, on the (generally defensible) presumption that commercially available forms will suffice for the vast majority of the patient population.

Risk Mitigation

Given the fine line that compounders and outsourcers must walk here, it is important to take action to mitigate risks. Nothing can entirely prevent a manufacturer's lawsuit or adverse agency action. Nevertheless, both compounders and outsourcers would be well advised to proceed with caution. In particular:

- Consult FDA's guidance for both compounders and outsourcers regarding the significant or clinical difference exceptions;
- When relying on the SDE, make sure to document the difference in both the product labels and the prescriptions (where applicable);
- Continue to follow evolving FDA and state board guidance and pay attention to adverse agency actions at the federal and state level;
- Review state regulations on shipment to clinical intermediaries—some states have stricter requirements or outright prohibitions;
- Where state law requires written agreements to deliver products to clinics, make sure your written documents meet all the regulatory requirements;
- Relatedly, make sure that your policies and procedures documentation helps to demonstrate compliance with the applicable rules;



- Make sure that arrangements with prescribers do not run afoul of other state law kickback or self-referral prohibitions;
- Avoid any mention of the branded products, FDA approval, or other words and phrases that might suggest that you are selling branded products;
- Keep up with the evolving litigation strategy of the major manufacturers and any relevant New Drug Applications in the GLP-1 space;
- Periodically have bulk API samples tested to verify the accuracy of the certificate of analysis; and
- Perhaps most importantly, when in doubt, seek legal advice from competent legal counsel with a relevant background in state and federal pharmacy or outsourcing facility law.

The extent to which the FDA and state regulators continue to tolerate compounding these blockbuster drugs or alternatively proceed against them as prohibited by law and public policy, remains to be seen. Outcomes will in part depend on individual facts surrounding the business strategies adopted by outsourcers and compounders. With more cautious industry participants exiting the market while demand for these products shows no sign of abating, it seems likely that the void will be filled by less risk-averse participants, who will face still greater jeopardy of both state and federal enforcement action and aggressive litigation from affected manufacturers. The only safe prediction at this point is that continued market participation by outsourcers and compounders for so long as the shortage is resolved will substantially increase their risk exposure.

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