Alliance for Pharmacy Compounding

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Pharmacy Compounding:

A Blueprint for Eliminating Redundant, Unauthorized, or Ineffective Regulation that Impedes Patient Access to Compounded Drugs

May 2025

Overview

Pharmacy compounding plays a vital and time-honored role in American healthcare, offering customized medication solutions when FDA-approved drugs are in shortage or a prescriber judges a custom formulation is needed for an individual patient's needs. Compounded medications are prepared in licensed pharmacies by trained professionals under rigorous oversight from state pharmacy boards and in general accordance with compounding standards established by the U.S. Pharmacopeia.

Under President Trump's 10:1 Executive Order requiring the elimination of unnecessary federal rules, we believe pharmacy compounding presents a clear opportunity for reform. This document highlights key federal policies or proposals that are redundant, unauthorized by statute, or unproven in their benefit to public health. It offers constructive recommendations to support smarter, more effective regulatory approaches—ones that preserve safety without undermining access or innovation.

A strong regulatory framework for pharmacy compounding is essential. But unnecessary regulation—especially when it fails to deliver a measurable safety benefit—is more than a nuisance; it's a threat to patient access and a burden on the small businesses that serve those patients.

1. Unauthorized or redundant regulation

Obsolete: A 1997 MOU between FDA and States

In 1997, Congress amended the Food, Drug, and Cosmetic Act to require FDA to develop a Memorandum of Understanding with state boards of pharmacy. The MOU was intended to help FDA monitor traditional compounding pharmacies that distributed a substantial portion of their compounded drugs across state lines — specifically those distributed without patient-specific prescriptions for in-clinic or in-hospital use. In pharmacy law, this kind of "distribution" is distinct from "dispensing." Dispensing is what traditional pharmacies do: They provide commercially available or compounded drugs to individual patients based on a prescription from a licensed provider.

This distinction became even more important after Congress passed the Drug Quality and Security Act in 2013. The DQSA created a new category of compounding facility — the 503B outsourcing facility — which is allowed to distribute compounded medications in bulk without a prescription under strict regulatory oversight and compliance with Current Good Manufacturing Practices. With passage of DQSA, FDA has interpreted the prescription requirement in Section 503A to mean that 503A pharmacies are limited to **dispensing** medications pursuant to patient-specific prescriptions and are not permitted to engage in non-patient-specific **distribution** at all.

This shift in regulatory framework rendered the original 1997 MOU requirement effectively obsolete. The 1997 MOU was designed to provide oversight of an activity – distribution – that 503A pharmacies are no longer authorized to perform.

Nevertheless, because the 1997 statutory requirement for an MOU was never formally repealed, FDA finalized one in 2020 — more than two decades after it was first directed to do so. That MOU was quickly challenged in federal court *(Wellness Pharmacy, Inc. et al. v. Xavier Becerra)*, and FDA ultimately acknowledged that it had not followed proper notice-and-comment rulemaking protocols or conducted the required economic impact analysis.

FDA agreed to go back to the drawing board and reinitiate the MOU process. But this raises a fundamental question: **Why should the agency continue pursuing an MOU that, with passage of DQSA, was made obsolete under current law?**

The implications are not theoretical. Multiple states have said they either cannot sign the MOU (due to conflicts with state privacy laws) or will not sign it (due to the administrative and financial burden). For those that do sign, the MOU imposes unfunded mandates, requiring new systems for inspection, reporting, and enforcement. For states that don't sign, the consequences are more severe: Under that 1997 law, pharmacies in those states will be limited to shipping no more than 5% of their compounded preparations across state lines — a restriction that could jeopardize patient access to needed therapies, especially in rural and underserved areas.

The persistence of this outdated MOU requirement creates uncertainty, imposes unjustified burdens, and fails to reflect the modern regulatory framework Congress put in place through the DQSA. We urge the Administration to support the repeal by Congress of the 1997 MOU directive from the FD&C Act, thereby aligning federal law with the current realities of compounding oversight.

Overreach on "Demonstrably Difficult to Compound" Lists

Based on its interpretation of the 2013 Drug Quality and Security Act, FDA has chosen to regulate compounding through two distinct pathways:

- **Section 503A** allows state-licensed pharmacies to compound medications and dispense them to individual patients based on a practitioner's prescription.
- **Section 503B** creates a new category of outsourcing facilities that may compound in bulk and distribute without patient-specific prescriptions — provided they follow CGMP. (503Bs may also dispense patient-specific prescriptions if they choose to do so; however, most do not.)

Both sections 503A and 503B give FDA authority to prohibit compounding of certain medications deemed "demonstrably difficult to compound in a manner that reasonably demonstrates an adverse effect on the safety or effectiveness" of the drug. But Congress drew a sharp distinction in the language it used for each:

- In **503A**, FDA may bar specific *drug products* from compounding — a narrow authority focused on individual formulations.
- In **503B**, FDA is authorized to restrict both *drug products* and *categories of drugs* — a broader power that reflects the scale and manufacturing practices of outsourcing facilities.

There is a big difference between a drug product and a category of drugs. For example, a drug product is a finished drug formulation with a defined strength, dosage form and route of administration, like tacrolimus 0.3% ophthalmic drops. A category of drug products (ophthalmic drug products) would include an entire class of medications intended for use in the eye, regardless of active ingredient or concentration.

Despite this distinction, FDA has proposed regulations that would apply the broader category-based prohibition to 503A pharmacies — an approach not supported by the statute. In its March 2024 proposed rule [Docket No. FDA-2023-N-0061], the agency outlined six vague criteria for evaluating whether a drug is "demonstrably difficult to compound" and may choose to use them to justify banning entire drug classes from 503A compounding.

This is not a permissible interpretation of the statute. Section 503A refers only to "drug products" — not categories — and makes no provision for banning entire classes of medications. By attempting to impose the 503B framework into 503A, FDA is acting beyond its authority.

We urge the Administration to:

- Prevent FDA from finalizing any rule that exceeds its statutory authority under Section 503A; and
- Ensure that only individual drug products — not entire categories — may be added to the 503A DDC list, consistent with congressional intent.

Arbitrary Restriction of Dietary Supplement Monographs

Section 503A of the FD&C Act also permits compounding with active ingredients that comply with applicable monographs in the USP or National Formulary. However, FDA has taken the position — unsupported by statute — that only monographs in the drug section of the USP are "applicable," ignoring those in the dietary supplement section.

This interpretation does not reflect the plain language of the law. It also creates an illogical double standard: Patients can purchase dietary supplements at a supermarket, but their licensed pharmacist cannot compound a precise, prescriber-directed formulation for therapeutic use.

Dietary supplement monographs are developed using the same rigorous scientific standards as drug monographs and define key quality attributes such as identity, strength, purity, and performance — making them equally valid for ensuring safety and consistency in compounding. We ask the Administration to direct FDA to recognize all USP monographs — including dietary supplement monographs — as "applicable" under Section 503A, as the law requires.

2. Proposed restrictions or processes rooted in bias, misinformation, or insufficient evidence

FDA Communications on Compounding Need Evidence and Balance — Not Alarmism

We are increasingly concerned that FDA's public communications about compounded medications too often veer into alarmism — relying on unverified data, disproportionate scrutiny, and selective messaging that can mislead the public, the media, and policymakers.

A recent example underscores the problem. In March 2025, FDA issued a "safety communication" about compounded GLP-1 medications, citing adverse event reports. But as APC outlined in a formal protest letter, the agency provided no specifics, no verification of source data, and no evidence of a causal link between any adverse events and compounded products — much less products prepared by legitimate 503A or 503B facilities. Despite this lack of substantiation, the warning was picked up by major media outlets and widely reported as an official finding of harm.

This is not an isolated case. A permanent page on FDA's website titled "FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss" conflates counterfeit substances with drugs compounded by licensed pharmacies, as if they represent equal risk. They do not. Another example: FDA's publication, "Drug Safety Priorities Fiscal Year 2024," pages 27-28, makes the same conflation; the headline for that section is "Continuing Oversight and Outreach of Compounded Drugs and Fraudulent Products." By lumping them together, the agency misleads the public and discredits lawful, state-regulated therapies that patients rely on.

The language used in these communications is also problematic. FDA has stated that compounded drugs "can be risky for patients" — an imprecise, stigmatizing claim. Yes, compounded medications may carry different risk profiles than FDA-approved drugs, and it is appropriate for the agency to say so. But to broadly label them "risky" — when they are explicitly authorized under the Food, Drug & Cosmetic Act — is misleading and unhelpful.

This imbalance in communication does not reflect the letter or spirit of the FD&C Act, which authorizes the regulation of compounding, not its disparagement. **With recent leadership changes at FDA, we see an opportunity for the agency to take a fresh, more patient-centered approach to how it communicates about compounded therapies — one rooted in evidence, transparency, and public trust.**

We urge the Administration to direct FDA to adopt a more balanced and scientifically grounded tone in its public communications. Alerts and safety messages should be specific, proportionate, and clearly distinguish between legitimate compounded medications and counterfeit or unsafe products. Alarmist messaging without proper context undermines both patient care and FDA's own credibility.

A Case in Point: Compounded Ketamine and FDA's Mixed Messages

Ketamine therapy has emerged as a potentially transformative treatment for patients suffering from PTSD and treatment-resistant depression — conditions that afflict millions of Americans and are often unresponsive to conventional therapies. As clinical interest grows, compounded ketamine has become an essential part of patient care, particularly when customized dosages or alternative delivery forms are required. In these cases, licensed compounding pharmacists, working in concert with prescribers, are helping to bridge critical gaps in access and treatment.

Yet **FDA's messaging around compounded ketamine has been, at best, misleading**. In the past 30 months, the agency has issued two separate warnings about compounded ketamine (February 2022 and October 2023), neither of which was grounded in clinical evidence from human trials. Instead, both relied on animal data and included vague references to adverse event reports, without establishing causality or context. These were not formal guidances or rulemakings — yet they carried the weight of official pronouncements and, as with compounded GLP-1s, were quickly amplified by the media, often with little nuance or balance.

This pattern reflects a broader problem in FDA's communications around compounding: the tendency to issue unverified or premature alerts that disproportionately target compounded medications, even when the evidence is inconclusive. The agency must ensure its public statements support informed perspective — not fear or confusion.

Keep Demonstrably Difficult to Compound Lists Science-Based, Not Profit-Driven

Congress directed FDA to identify drug formulations that are demonstrably difficult to compound — meaning they pose a genuine challenge to compound safely and effectively, based on sound scientific evidence. The goal was clear: protect patients by limiting compounding of formulations where the risks clearly outweigh the benefits.

Unfortunately, some drug manufacturers are now attempting to hijack the process. In its recent proposed rule [Federal Register, March 20, 2024 – Docket No. FDA-2023-N-0061], FDA outlined six criteria it will use to determine whether a drug or category of drugs should be added to the DDC list under Sections 503A or 503B of the FDCA. **But rather than let science lead, companies like Eli Lilly and Novo Nordisk have lobbied aggressively to have GLP-1 active pharmaceutical ingredients added to the DDC lists — not because compounding with the APIs is genuinely difficult, but because drugmakers want to shut down legitimate compounding that they see as a threat to market share.**

APC's formal comments to FDA detail how these GLP-1 APIs fail to meet FDA's own difficulty criteria. These formulations are routinely and safely compounded by both 503A pharmacies and 503B outsourcing facilities. The drugmakers' arguments, by contrast, are often speculative, unsupported by data, and plainly aimed at eliminating lawful competition, not protecting patients.

We recognize the role of innovation and profit in driving pharmaceutical development — but public health decisions must not be swayed by corporate pressure. If FDA allows companies to use the DDC list as a tool for market protectionism, it risks setting a dangerous precedent: one in which science takes a backseat to shareholder value, and patients lose access to therapies their doctors deem necessary.

We urge the Administration to hold the agency to its own standards. FDA should reject any attempt to add substances to the DDC list without clear, evidence-based justification. Under President Trump's Executive Order, FDA is empowered to deprioritize enforcement of regulations not grounded in the best reading of the statute — and the agency should do just that when confronted with rules shaped more by lobbying than by science. In doing so, FDA would reaffirm its role as a guardian of patient access and public health — not a gatekeeper for corporate interests.

Preserve Patient Access to Compounded Hormone Therapy

Millions of Americans — particularly women — depend on compounded hormone therapy (cBHT) to manage the effects of age-related hormonal changes. These are not fringe treatments; they are life-enhancing therapies that physicians prescribe when commercially available options fall short or don't exist — due to limited FDA-approved dosages and delivery methods, patient allergies, or individual patient response.

Yet **FDA may be poised to restrict access to cBHT, not because of legitimate, documented safety concerns or scientific discovery, but based on a flawed and discredited 2020 report** it commissioned from the National Academies of Sciences, Engineering, and Medicine. The agency has stated in public forums and correspondence with Congress that it intends to use the NASEM report to guide future policies on compounded hormones. This is cause for serious concern.

The NASEM report reviewed only four hormones, yet recommended sweeping restrictions on all compounded hormones. No one on the NASEM panel had direct experience prescribing or compounding these therapies. Even more troubling, an independent analysis by Dr. Alyson Wooten of the nonpartisan Berkeley Research Group — "The Panel Put Policy-Making Before Patient Need" — found evidence that FDA improperly influenced the report's direction, resulting in biased and scientifically unsound conclusions. (That report is available at a4pc.org/Berkeley.)

Despite this, FDA has already submitted to the Office of Management and Budget a proposed rule that, based on its summary, may seek to add categories of compounded therapies to the DDC list — a move that could include compounded hormones. If that happens, it would make it unlawful for pharmacies to compound with those ingredients, cutting off access to essential medications for millions of patients.

Under President Trump's Executive Order, agencies like FDA are directed to deprioritize regulations not clearly grounded in statute or sound science. **We ask the Administration to take a clear stand and prohibit FDA from using the flawed NASEM report as the basis for any rulemaking or enforcement related to compounded hormone therapy.**

This is not just regulation rooted in bias — it's a direct threat to patient care. FDA-approved hormone drugs do not meet the needs of all patients. That's why prescribers turn to compounding: to tailor medications to the individual. If FDA is allowed to restrict that clinical freedom based on biased policymaking, patients will pay the price.

Identifying Drug Shortages — FDA Should Rely on Broad Data Sources, Not Just Manufacturer Claims

Drug shortages in the U.S. remain at record highs — and too often, it's compounding pharmacies and facilities that serve as the final safety net, stepping in to prepare medications when manufacturers can't deliver. But current federal law hampers their ability to do so, not because of safety concerns, but because of flawed processes for identifying drug shortages in the first place.

Under current law, FDA can only authorize compounding copies of a drug in shortage if it appears on the agency's official shortage list. But here's the catch: to make that determination, FDA is only required to consider data provided by drug manufacturers — the very companies that often have a financial interest in not acknowledging a shortage.

That means if a drug is technically "available" in a company's inventory system — even if it's functionally inaccessible to hospitals, pharmacies, or patients in quantities or

routes of administration necessary to meet demand — FDA is not required to consider data submitted from prescribers, health systems, and pharmacies. To its credit, the agency has created a webpage where information on drug shortages may be submitted by anyone. Unfortunately, as a means of data collection, such a page is relatively random. Moreover, the agency doesn't specify how it uses and weighs such submissions in its shortage decisions – an important distinction since it is not legally required to consider those submissions.

One fix: Support the reintroduction of Senator Tom Cotton's 2024 End Drug Shortages Act (and the companion proposal by Rep. Adrian Smith in the House). When introduced, the bill would require FDA to consider broader input — from pharmacists, physicians, hospitals, and patients — when assessing whether a drug is in fact in shortage. It brings common sense to the process, ensuring that decisions reflect patient accessibility, not just manufacturer accounting.

The bill also strengthens the system on the front end by requiring drugmakers to notify FDA when demand surges could lead to a shortage — giving the agency a more complete picture and time to respond before care is disrupted.

We urge the Administration to support this bipartisan proposal. In a system meant to serve patients, real-world insight must carry as much weight as manufacturer-supplied data — especially when patient access hangs in the balance.

Restore Patient-Facing Expertise and Balance to Pharmacy Compounding Advisory Committee

Federal advisory committees are meant to provide government agencies with balanced, expert input. But when it comes to FDA's Pharmacy Compounding Advisory Committee, that vision has gone badly off course.

PCAC was established to advise FDA on scientific, medical, and technical issues related to drug compounding under Sections 503A and 503B of the FD&C Act. In practice, however, PCAC functions less as an advisory body and more as a formality — a committee structured to affirm, not challenge, the FDA's internal recommendations. The result is a process that lacks transparency, diversity of viewpoints, and real-world grounding.

The process is broken. Under current procedures, FDA staff receive nearly unlimited time to present their perspective to the committee — often guiding the discussion with prepared questions and backgrounders — *while outside voices, including expert stakeholders, are collectively limited to just 10 minutes of public comment. This lopsided approach silences divergent views and undermines the committee's ability to engage in meaningful deliberation.*

The composition is skewed. By statute, PCAC members are to be drawn from diverse fields, including pharmacy, pharmaceutical compounding, medicine, public health, and patient advocacy. Yet of the six pharmacists currently serving, only two are not FDA employees, academics, or professional advocates — and neither of those two appears to have current patient-facing compounding experience. Incredibly, the FDA has treated actual compounding pharmacists as having a conflict of interest merely because they practice in the field.

That logic is self-defeating. You wouldn't convene a panel on aviation safety and exclude pilots. The same principle should apply here.

We urge the Administration to demand a full review of PCAC's appointment criteria and processes and operating procedures to ensure it meets the standards set forth by law — standards that require balance, transparency, and genuine expert engagement. A properly constituted and functioning PCAC would serve as a vital source of informed, nuanced input — not just for FDA, but for the millions of patients who rely on compounded medications.

Further detail on our concern is available at a4pc.org/PCACreform.

3. Unauthorized, misguided, or misinterpreted regulation

Restore Access and Clinical Flexibility in the Evaluation of Compounded Substances

Under current FDA policy, a substance may not be compounded unless the agency evaluates its suitability for use in compounding and determines that it meets established criteria.

However, **this framework is poorly suited to the context of personalized medicine. In compounding, where pharmacists are prohibited from making clinical claims about a medication's intended use, applying rigid approval standards ignores the unique nature of individualized therapies — and undermines the principle that prescribers and patients should be free to choose the treatment pathway that works best for them.**

The result? Substances with no identified significant safety concerns and potential clinical utility are excluded from the 503A bulks list and from compounding, simply because no drug company has invested the time and resources required to demonstrate effectiveness through traditional pharmaceutical models. That barrier to access is especially troubling given that compounders are legally prohibited from making any claims about effectiveness at all.

In truth, if a substance has an acceptable risk profile, and if pharmacists make no clinical claims about its use, there is no legitimate basis for the government to prohibit its inclusion in compounded therapies. Doing so interferes with the ability of licensed healthcare professionals to deliver patient-specific care — and with patients' ability to access it.

We urge the Administration to direct the FDA to revise its policy so that the assessment of safety risks — not rigid definitions of 'effectiveness' — becomes the appropriate gating standard for compounded substances. A regulatory framework that respects clinical judgment and patient choice is both reasonable and overdue.

FDA's Veterinary Compounding Guidance Lacks Statutory Foundation and Undermines Animal Care

When Congress passed the Animal Medicinal Drug Use Clarification Act (AMDUCA) in 1996, it gave veterinarians the authority to prescribe approved animal and human drugs for "extra-label" use — that is, in ways not specified in approved labeling. Nowhere in the statute did Congress mention compounding or the use of bulk drug substances. **Yet FDA has inserted itself into veterinary compounding through regulation and guidance, despite having no clear congressional mandate to do so.**

FDA's 2023 Guidance for Industry #256 is the latest and most problematic example. While technically nonbinding, GFI 256 imposes broad restrictions on the use of bulk drug substances in veterinary compounding — limitations that second-guess the clinical judgment of veterinarians and create unnecessary barriers to care for animal patients.

Under GFI 256, veterinarians and compounding pharmacies must justify the need for compounded medications and may only use bulk drug substances from an FDA-approved list for compounding office stock medications. Submitting a substance for consideration requires a lengthy, opaque nomination process, and FDA has rejected nearly 93 percent of the roughly 300 substances proposed to date by veterinarians, pharmacists and others — often without clear rationale.

The result is a system that risks failing animal patients. For many species and conditions, FDA-approved products are not available in appropriate strengths, delivery forms, or combinations. Finished drugs may also contain excipients that are harmful to certain animals or lead to poor compliance. Animal drug products do not disclose their excipients in the package insert like human drug products, making it impossible to assess whether an animal drug product can be used in species other than those it was approved for. In these cases, compounding from bulk ingredients is the only viable path to treatment — and one that veterinarians have safely relied on for decades.

FDA's current approach, however, assumes a gatekeeping role Congress never authorized. By constraining the ability of veterinarians and compounding pharmacists to tailor medications to animal patients, the agency is not just overstepping — it is interfering with clinical care.

The guidance should be rescinded in full — and any future effort to regulate veterinary compounding should begin not with a rigid list, but with collaboration among FDA, veterinarians, pharmacists, and other stakeholders. That's the only way to protect both the intent of AMDUCA and the health of millions of animal patients nationwide.

If FDA insists on maintaining GFI 256, it must substantially revise the guidance and align its inspectors' understanding of it to respect the realities of veterinary practice and the essential role of compounded medications in animal health. At minimum, the agency must streamline the bulk substance nomination process, increase transparency in its evaluations, and defer to the expertise of prescribing veterinarians.

FDA's Insanitary Conditions Guidance: Needed, But Not Yet Useful

Compounding pharmacists recognize the importance of FDA's "Guidance for Industry: Insanitary Conditions at Compounding Facilities." Clear expectations around cleanliness and sterility are critical to patient safety—and pharmacists want to meet them. But while the guidance offers useful examples, it stops short of providing the kind of bright-line standards necessary for consistent, reliable compliance.

As it stands, the guidance leaves too much room for interpretation. Without objective criteria, pharmacists are left uncertain about where the lines are drawn—and inspectors are left to make subjective determinations – determinations that routinely differ from inspector to inspector. A facility can adhere fully to USP standards and still be found in violation, simply because an inspector sees something differently.

We urge the Administration to direct FDA to consult with compounding stakeholders and clarify this guidance by defining specific, objective standards for what constitutes an "insanitary condition." The guidance is needed—but in its current form, it does more to confuse than to clarify.

Clarifying Constructive Transfer: Empowering Patients, Not Undermining Prescribers

In certain circumstances, a compounding pharmacist prepares a controlled substance for a specific patient, and that medication—by medical necessity—must be administered by the prescriber in a clinical setting. From the FDA's perspective, Section 503A of the FD&C Act allows the pharmacy to deliver the medication either directly to the patient or to the prescriber for in-office administration.

Unfortunately, the DEA takes a conflicting view. Under its interpretation of the Controlled Substances Act, such a "constructive transfer" of a controlled substance is prohibited—even with explicit patient authorization. The DEA insists that the medication must be handed only to the patient or their agent, even in cases involving medications like intrathecals, where unsupervised administration can pose serious risks.

This interpretation seems to be based on a startling and illogical assumption: that a member of the patient's household is somehow less likely to misuse or divert a controlled substance than a licensed physician or veterinarian is.

We urge the Administration to direct DEA to issue a definition of "dispensing" that would allow pharmacists to deliver a controlled medication to a prescriber's office under two key conditions: (1) the medication is pursuant to a patient-specific prescription; and (2) the practitioner has determined that in-office administration is medically necessary. That reading is not only reasonable—it is the most faithful to the intent of the Controlled Substances Act.

Anticipatory Compounding Is Legal and Necessary—But DEA Thinks Otherwise

Some DEA offices have taken the position that the Controlled Substances Act requires a pharmacy to receive a patient-specific prescription before compounding a controlled medication. However, FDA—under Section 503A of the FD&C Act—explicitly permits anticipatory compounding based on historical prescription trends. The DEA, for its part, allows anticipatory compounding of controlled substances—but only if the pharmacy holds a manufacturer's permit, which isn't feasible (and shouldn't be necessary) for smaller, state-licensed pharmacies.

This narrow interpretation ignores clinical and operational realities. **For sterile injectable controlled substances, anticipatory compounding is essential. It allows pharmacists to complete required sterility, potency, and stability testing before the medication is dispensed—ensuring both safety and timely access to care.**

Despite this, during inspections some DEA field inspectors have warned or disciplined pharmacies for engaging in lawful, FDA- and DEA-recognized anticipatory compounding. Others have not. This patchwork enforcement of unclear rules imposes costly burdens on compliant pharmacies, delays patient treatment, and wastes agency resources.

DEA is notoriously slow to respond to requests for clarity about its rules. We urge the Administration to direct DEA to issue a clear, nationwide interpretation that recognizes the legality and necessity of anticipatory compounding in appropriate contexts. The current uncertainty serves no one—not patients, not providers, and certainly not public health.

4. A directive FDA has (mostly) ignored

Where's the 503B Bulks List?

Nearly a decade after Congress created the 503B Outsourcing Facility pathway, the FDA has yet to complete one of its core responsibilities: finalizing the 503B bulks list, the list of substances FDA allows 503Bs to compound. The agency's review of nominated substances has been unreasonably slow and overly restrictive—so much so that the Outsourcing Facilities Association has taken the unprecedented step of suing the FDA to spur action.

This delay is not just bureaucratic—it has real-world consequences. **Hundreds of APIs remain stuck in regulatory limbo, preventing 503B facilities from producing much-needed compounded medications for hospitals, clinics, and patients nationwide.** In this case, it's the absence of action—not overreach—that is limiting patient access and creating uncertainty for outsourcing facilities. It has now been a dozen years, and FDA still has not done what Congress authorized.

We urge the Administration to direct FDA to accelerate and complete its review of the nominated substances and establish a comprehensive, science-based 503B bulks list. Outsourcing facilities need clarity to serve patients—and patients need timely access to the medications these facilities are equipped to provide.

A Smarter Path Forward

Compounding pharmacists are asking for clarity, consistency, and a regulatory framework grounded in science and statute. Unfortunately, current federal policies often miss that mark, imposing unnecessary burdens, restricting access to care, and stretching the bounds of regulatory authority.

Key Priorities for Removal or Reform:

- **Eliminate** the 1997 MOU requirement in Section 503A of the FD&CA.
- **Correct** overt overreach in FDA's draft DDC rules for 503A pharmacies.
- **Mandate** that both drug and dietary supplement USP monographs are considered "applicable" in law and regulation.
- **Demand** balance and evidence in FDA communication about compounded therapies.
- **Reject** drugmaker petitions to add GLP-1 APIs to the DDC list and ensure that decisions about items added to the DDC list are rooted in science and facts.
- **Reject** any effort to restrict patient access to compounded hormone therapy and disqualify using the 2020 NASEM report in future policy making.
- **Support** legislation to require FDA to rely on a broader range of data in determining drug shortages.
- **Overhaul** the FDA PCAC to include pharmacists with current patient-facing experience and allow for those other than the FDA to have an equal amount of time to present to the PCAC.
- **Repair or rescind** FDA's GFI 256 regarding animal drug compounding.
- **Instruct** DEA to clarify "constructive transfer" policies to allow for the delivery of controlled substance prescriptions to provider offices for administration.
- **Amend** FDA's "Insanitary Conditions" Guidance to include bright-line standards for compliance.
- **Instruct** FDA to finalize a robust 503B bulks list with all deliberate speed.

We urge the Administration to prioritize these reforms. With the right policy leadership, we can protect the integrity of compounding, reduce regulatory confusion, and ensure that patients—human and animal alike—continue to receive personalized treatments their provider says they need.

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About APC:

The Alliance for Pharmacy Compounding is the industry trade association and the voice for pharmacy compounding, representing more than 600 compounding small businesses — including compounding pharmacists and technicians in both 503A and 503B settings — as well as prescribers, educators, researchers, and suppliers.

In traditional compounding, pharmacists create a customized medication, most often from pure ingredients, for an individual patient pursuant to a prescription. Pharmacists' ability to compound medications is authorized in federal law and for good reason: Manufactured drugs don't come in strengths and dosage forms that are right for everyone, and prescribers need to be able to prescribe customized medications when, in their judgment, a manufactured drug is not the best course of therapy for a human or animal patient or the appropriate FDA-approved drug is not commercially available.

Every day, APC members play a critical role in patients' lives, preparing essential, custom medications for a range of health conditions, including autism, oncology, dermatology, ophthalmology, pediatrics, women's health, animal health, and others.

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