HANSZEN LAPORTE
ATTORNEYS AT LAW

Matthew R. Ludowig
Partner
mludowig@hanszenlaporte.com

8 August 2024
*****FOR RELEASE*****

Mr. Scott Brunner, *Chief Executive Officer*
Alliance for Pharmacy Compounding ("APC")
100 Daingerfield Rd, Suite 100
Alexandria Virginia 22314

RE: EXAMINING THE DEMISE OF CHEVRON THROUGH THE LENS OF COMPOUNDING

I. BACKGROUND

On June 28, 2024, the U.S. Supreme Court overruled *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*[1] That decision established the "Chevron framework", wherein federal agencies were entitled to a deferential level of judicial review (also known as "Chevron deference"), in instances where a federal statute was considered ambiguous or silent[2]. Under that framework, a court first determined "whether congress [had] directly spoken to the precise question at issue."[3] If not, the court focused on whether "whether the agency's answer [was] based on a permissible construction of the statute."[4] The second prong of this test, which accepted "permissible construction", ultimately allowed an agency to use its technical and practical expertise to interpret or enforce a statute it was authorized to administer.[5]

The Court in *Loper Bright Enterprises, Inc. v. Raimondo*, however, disagreed, by overruling the extensive deference granted to federal agencies outlined in *Chevron*.[6] Specifically, the Court held that future courts "may not defer to an agency's interpretation of law simply because a statute is ambiguous" because courts, rather than agencies, have sole competency to resolve statutory ambiguities.[7] Furthermore, the Court reasoned that *Chevron*'s presumption was "misguided because agencies have no special competence in resolving statutory ambiguities."[8] As such, "an agency's interpretation of a statute cannot bind a court" even though it may prove "informative."

On the surface, *Loper* appears to be a significant deviation from the status quo, with the potential to fundamentally change administrative oversight and enforcement. That position isn't necessarily unreasonable considering that over the past forty years federal agencies have relied heavily on *Chevron* to increase and expand their power and influence. The Food and Drug Administration ("FDA") was no different. FDA was originally created to enforce the Pure Food and Drug Act of 1906[9], and later the Federal

---

[1] *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 104 S. Ct. 2778, 81 L. Ed. 2d 694 (1984).
[2] *Id.*
[3] *Id*. at 842.
[4] *Id.* at 838.
[5] *Id.*
[6] *Loper Bright Enterprises v. Raimondo*, No. 22-1219, 2024 WL 3208360 (U.S. June 28, 2024).
[7] *Id.*
[8] *Id.* at 2247.
[9] 21 U.S.C.A. §§ 1 to 5. Repealed. June 25, 1938, c. 675, § 1002(a), formerly § 902(a), 52 Stat. 1059; renumbered § 1002(a), Pub.L. 111-31, Div. A, Title I, § 101(b)(2), June 22, 2009, 123 Stat. 1784

Food, Drug and Cosmetic Act of 1938 (the "FDCA").[10] For nearly a half-century FDA's oversight responsibilities did not include the practice of compounding drug products, which was instead left to the individual state boards of pharmacy. Yet, in 1992 – a mere 8 years after *Chevron* – FDA issued Compliance Policy Guide 460.200 which expressed the fear that "some firms receive and use large quantities of bulk drug substances to manufacture large quantities of unapproved drug products in advance of receiving a prescription for them."[11] In response, FDA proposed to treat these pharmacies as drug manufacturers, exposing them to potential violations of the FDCA. Thus, kicked off a thirty plus year campaign to regulate and restrict the practice of compounding through administrative interpretation and enforcement.

Today, compounders are faced with vigorous regulatory scrutiny, on the state and federal levels respectively, stemming largely from arbitrary and opaque statutory interpretation and enforcement. Regulators have created a complex structure of guidance documents, opinion pieces and policy papers, governed or enforced by individuals and committees. Though rooted in legislation, many of these documents were drafted because FDCA is either silent, or ambiguous, on issues the agency has deemed significant. In one extreme scenario, *Loper* renders these documents (and most of the administrative scheme upon which it was built) obsolete, recognizing these "non-binding" documents have taken on a life of their own in supplementing, or occasionally supplanting, federal law, based in part on agency deference granted in *Chevron*. Nevertheless, *Loper* becomes largely symbolic. While explicit deference is no longer afforded, courts continue to place such a significant value on an agency's expertise that the status quo remains largely unchanged. The reality likely lands somewhere in between.

Yet, *Loper* may be more limited than landscape altering. For instance, *Loper* affirmed the premise that judicial intervention applies to *questions of law* rather than *findings of fact*. The Court cited *Stock Yards Co. v. United States*, a Supreme Court Case from 1936, which stated in part "Congress could…appoint an agent to act within that sphere of legislative authority and endow the agent with power to make findings of fact which are conclusive, provided the requirements of due process, which are specifically applicable to such an agency are met."[12] For example, the industry could, in theory, challenge the FDA's interpretation of "essentially a copy" using *Loper* as its basis. However, it would probably be unsuccessful in challenging a finding by FDA that a specific drug is essentially a copy.

Furthermore, *Loper* applies solely to federal statutes. There is no evidence to suggest the holding extends to guidance, or other types of policy pieces. Recently, the industry grappled with the term "shortage" as applied to the FDA's Drug Shortage List. Whether a drug listed as "Available" or "Limited Availability" could be recognized on "shortage", remained an open question. However, even if *Loper* had been published at that time, it probably would not have been applicable. The term "shortage" is not referenced Section 503A of the FDCA, rather, it appears in an FDA guidance, outside the purview of this opinion.[13]

Finally, *Loper* distinguishes an agency's "binding" authority from its "persuasive" authority. The Court reinforced the notion that "although an agency's interpretation of a statute cannot bind a court, it

---

[10] 21 U.S.C.A. § 301

[11] FDA Compliance Policy Guide § 460.200, *Pharmacy Compounding* (Issued March 16, 1992).
[12] *Loper Bright Enterprises v. Raimondo*, No. 22-1219, 2024 WL 3208360 (U.S. June 28, 2024); *St. Joseph Stock Yards Co. v. United States,* 298 U.S. 38, 51, 56 S.Ct. 720, 80 L.Ed. 1033 (1936).
[13] FDA Guidance for Industry, *Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act* (Issued January 2018).

may be especially informative" recognizing "such expertise has always been one of the factors which may give an Executive Branch interpretation particular power to persuade, if lacking power to control." While an agency's interpretation or position is just one factor, it is unrealistic to assume that it will not remain a powerful factor. Stated plainly, where is the line between influence and deference?

With this context in mind, there are a few important areas in which *Loper* may impact the practice of compounding.

II. FDA's Memorandum of Understanding

Section 503A of the FDCA prescribes that "A drug product may be compounded…only if such drug is compounded in a State that has entered into a Memorandum of Understanding ("MOU") with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate".[14] Notably, the terms "dispense" and "distribute" have different meanings in the Code of Federal Regulations ("CFR"). The term "dispense" includes "the act of delivering a prescription drug product to a patient or an agent of the patient…by an authorized dispenser or an agent of an authorized dispenser under a lawful prescription of a licensed practitioner."[15] The term "distribute" means "the act of delivering, other than by dispensing, a drug product to any person."[16] However, as highlighted in a lawsuit styled *Wellness Pharmacy, Inc. et al v. Azar et al*, FDA's most recent version of the "Final Standard MOU" defines the term "distribution" as follows: "that a pharmacy or physician has sent (or caused to be sent) a compounded drug product out of the state in which the drug was compounded."[17] Assuming the FDA's definition remains unchanged in an updated MOU, an ambiguity will persist.

With the *Wellness Pharmacy* case still pending, it is reasonable to presume *Loper* may influence its outcome because the case deals with a statutory ambiguity that is rooted in law. The terms "dispense" and "distribution" are statutorily defined in a manner that cannot be reconciled. Yet, the FDA's definition essentially makes these terms interchangeable in an effort to bypass the matter altogether. *Loper's* holding is clear that this is not what agencies are designed to do, stating explicitly "agencies have no special competence in resolving statutory ambiguities. Courts do."[18] And although the court will be charged with reconciling how, why, and if the term "distribute" can be reconciled with Section 503A, it is less likely to simply disregard the ambiguity in its entirety. As such, *Loper's* holding may prove significant in determining the outcome of this issue.

III. Drug Products that Present Demonstrable Difficulties for Compounding

In accordance with Section 503A, one of the conditions for compounding exists when "such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product."[19] Since its inception, the Demonstrably Difficult to Compound List (or "DDC list") has been mired in ambiguity and FDA's process for making such determinations have historically been undefined and unclear. In March 2024, FDA published a proposed rule for establishing

---

[14] 21 U.S.C.A. § 353a
[15] 21 C.F.R. § 208.3(b)
[16] 21 C.F.R. § 208.3(c)
[17] *Wellness Pharmacy, Inc. et al v. Azar et al,* No. 1:20-cv-03082-CRC (D.D.C. July 20, 2024).
[18] *Loper Bright*, 2024 WL 3208360.
[19] 21 U.S.C.A. § 353a

criteria to evaluate whether drug products or categories of drug products are difficult to compound. The proposed rule establishes six criteria for making these determinations, including, (1) complex formulation; (2) complex drug delivery mechanism; (3) complex dosage form; (4) bioavailability achievement complexity; (5) compounding process complexity; and (6) physicochemical or analytical testing complexity.[20] The proposed rule then highlights three categories of drug products, including, those produced using hot melt extrusion, liposome products, and oral solid modified release products that employ coated systems.[21] Yet, arguably, the plain language of Section 503A doesn't mandate FDA to establish a process for making determinations. Instead, it simply directs FDA to identify drug products.

Unlike FDA's MOU, this issue is less tangible and more abstract. The MOU has two statutory terms which are fundamentally at odds. The ambiguity is clear because the terms "dispense" and "distribute" are separately defined in the FDCA. This type of clear discrepancy seems tailormade for *Loper,* given its holding. However, in this case the issue does not involve two fundamentally competing terms. Instead, it poses questions about the action(s) an agency can take to effectuate legislative intent. It is clear the legislature prescribed FDA to draft and publish a DDC list, however, Section 503A is otherwise silent on the matter. As such the FDA would argue that's why they engage in rulemaking, pursuant to certain conditions. Their rules are designed, in part, to detail the manner in which the FDA will effectuate its statutory obligations. The industry has an opportunity to submit comments in which it asserts substantive objections through a comment period. The industry also has an opportunity to challenge the rulemaking process, and whether FDA has properly followed it. However, there's little argument to be made about whether the FDA has the authority to engage in rulemaking generally. And to the extent any legal challenge refers just as much to the substance than the process, it is reasonable to assume a court may be persuaded by the fact that this is more an issue of fact than a question of law. For now, the issue is not yet ripe for a legal challenge.

IV. Examining Guidance Documents – Including GFI 256

Finally, there are guidance documents like GFI 256, which claim to be "non-binding" in nature, and yet, have the practical effect of supplementing federal law.[22] Frustrating as this may be, there is no evidence to suggest that *Loper's* holding extends beyond resolving statutory ambiguity. The more attenuated the issue is from a legitimate ambiguity, the less willing a court may be to intervene. In the case of GFI 256 for example, compounders may have a valid claim that FDA, in the absence of explicit statutory authority, is enforcing the compounding of veterinary drug products strictly through guidance. However, it would be an uphill battle to convince a court that FDA does not possess the designated authority to regulate veterinary products. The impact of such a ruling would be so significant that it would threaten to undermine the very fabric of the agency's enforcement power. Instead, a court may take a more measured approach, given FDA's stated position it has authority to regulate compounded veterinary drug products under sections 512, 517 and 572 of the FDCA, respectively. The Court in *Loper* erased *Chevron* because its mechanical application was ineffective and impractical. It replaced *Chevron* by allowing future courts to ask a fundamental question: "Does the statute authorize the challenged agency

---

[20] FDA Draft Rule, *Drug Products or Categories of Drug Products That Present Demonstrable Difficulties for Compounding Under Sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act*, No. FDA-2023-N-0061 (Published March 20, 2024).
[21] *Id.*
[22] FDA Guidance for Industry #256, *Compounding Animal Drugs from Bulk Drug Substances*, No. FDA-2018-D-4533, (Published April 2022).

action?"[23] Regulators may argue the agency issues guidance to compounders at its discretion in order to formally publish its thoughts on areas of significance, for the benefit of both the agency and the industry. However, their underlying authority to regulate is derived from the FDCA. Since a statute can only contain so much information, guidance is published to assist with compliance and enforcement. Yet, even when viewed through this lens, it is appropriate to ask again, where does government influence end and deference begin?

Ultimately, *Loper's* holding certainly diminishes an agency's unilateral power to interpret federal law in a manner consistent with its enforcement interests. However, the practical effect of this decision remains to be seen. Compounders may, in fact, reap the benefit of an impartial judiciary on matters of administrative significance, without any guaranty of a change in the underlying outcome.

[23] *Loper Bright*, 2024 WL 3208360.