IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WEDGEWOOD VILLAGE PHARMACY, LLC Plaintiff, v. U.S. FOOD AND DRUG ADMNINISTRATION, XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, DR. ROBERT M. CALIFF in his official capacity as Commissioner of Food and Drugs Defendants.	Civil Action No. 22-cv-2649 **NOTICE OF UNOPPOSED MOTION OF ALLIANCE FOR PHARMACY COMPOUNDING FOR LEAVE TO FILE AMICUS CURIAE BRIEF IN SUPPORT OF PLAINTIFF WEDGEWOOD VILLAGE PHARMACY, LLC**

PLEASE TAKE NOTICE that upon the Certification of William R. Hughes, Jr., Esq., in support of the motion for leave to file an amicus curiae brief, Alliance for Pharmacy Compounding respectfully requests the United States District Court for the District of New Jersey to issue an order granting it leave to appear as amicus curiae and to file the amicus curiae brief that accompanies this motion. Counsel for the parties were contacted about the filing of this motion have advised the undersigned that they consent to the Proposed Amicus's request.

PLEASE TAKE FURTHER NOTICE that a proposed form of Order granting the relief requested is submitted herewith.

Dated: May 13, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, William J. Hughes, Jr., hereby certify that I caused the foregoing Motion for Leave to File Brief of Amicus Curiae and supporting documents to be served via the District Court's Electronic Case Files (ECF) System upon counsel for the parties:

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This 13th day of May 2022.

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IN THE UNITED STATES DISTRICT COURT
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WEDGEWOOD VILLAGE PHARMACY, LLC Plaintiff, v. U.S. FOOD AND DRUG ADMNINISTRATION, XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, DR. ROBERT M. CALIFF in his official capacity as Commissioner of Food and Drugs Defendants.	Civil Action No. 22-cv-2649 **MEMORANDUM OF LAW IN SUPPORT OF MOTION OF ALLIANCE FOR PHARMACY COMPOUNDING FOR LEAVE TO FILE BRIEF OF AMICUS CURIAE IN SUPPORT OF PLAINTIFF WEDGEWOOD VILLAGE PHARMACY, LLC**

The Alliance for Pharmacy Compounding ("APC") moves for leave to file the accompanying proposed Brief of Amicus Curiae in support of Plaintiff Wedgewood Village Pharmacy, LLC. Both parties consent to this filing.

The decision whether to grant leave to file an amicus brief is within the sound discretion of the District Court. *United States v. Alkaabi*, 223 F. Supp. 2d, 583, 592 (D.N.J. 2002). In recent years, the District of New Jersey has granted numerous amici leave to file briefs, see, e.g., *Nat'l Union Fire Ins. Co. of Pittsburgh v. K Hovnanian Enters., Inc.*, No. 3:10-cv-6258, 2011 WL 4915899, at *1 (D.N.J. Oct.

17, 2011); *Jama v. U.S. Immigration and Naturalization Serv.*, 334 F. Supp. 2d 662, 673 (D.N.J. 2004); *Alkaabi*, 223 F. Supp. 2d at 592.

Because the issues presented by this case are of substantial interest to APC, and because APC's proposed amicus brief would aid in the Court's consideration of those issues by addressing matters on which APC has particular insight, this Court respectfully should grant leave to file. *See, e.g.*, Fed R. App. P. 29(b); *Harris v. Pernsley*, 820 F.2d 592, 603 (3d Cir. 1987) (concluding *amicus* briefs "may be advisable where third parties can contribute to the court's understanding . . . "). APC's participation as *amicus* satisfies all relevant factors under the Federal Rules of Appellate Procedure for deciding whether to grant leave to file.

I. THE FACTORS SET FORTH IN FEDERAL RULE OF APPELLATE PROCEDURE 29(b) SUPPORT GRANTING ALLIANCE FOR PHARMACY COMPOUNDING LEAVE TO FILE

District courts often consider by analogy the requirements of Federal Rule of Appellate Procedure 29(b) in exercising their discretion whether to grant leave to file *amicus* briefs. *See, e.g., Alkaabi*, 223 F. Supp. 2d at 592*; Foley v. Horizon Blue Cross Blue Shield of N.J., Inc.*, No. 06-6219, 2007 WL 2694069, at *1 (D.N.J. Sept. 11, 2007); *see also Washington Gas & Light Co. v. Prince George's Cnty. Council*, No. 08-0967, 2012 WL 832756, at *3 (D. Md. Mar. 9, 2012) ("District courts . . . have discretion whether to grant or deny such leave and often look for guidance to Rule 29 of the Federal Rules of Appellate Procedure."); *Martinez v. Capital*

Cities/ABC-WPVI, 909 F. Supp. 283, 286 (E.D. Pa. 1995) ("[t]here is no specific statute of rule . . . , and I am therefore guided by Rule 29 of the Federal Rules of Appellate Procedure."). Rule 29 provides that motions for leave to file *amicus* briefs must state "the movant's interest," as well as "the reason why an amicus brief is desirable and why the matters asserted are relevant to the disposition of the case." Fed. R. App. P. 29(b). The Third Circuit has explained that "it is preferable to err on the side of granting leave" so that a court will not "be deprived of a resource that might have been of assistance." *Neonatology Assocs., P.A. v. Comm'r of Internal Revenue*, 293 F.3d 128, 133 (3d Cir. 2002); *see also id.* ("[O]ur court would be well advised to grant motions for leave to file amicus briefs unless it is obvious that the proposed briefs do not meet Rule 29's criteria as broadly interpreted."); *Newark Branch, NAACP v. Town of Harrison*, 940 F.2d 792, 808 (3d Cir. 1991) (amicus briefs help "insur[e] a complete and plenary presentation of difficult issues so that the court may reach a proper decision"). APC and its proposed *amicus* brief satisfy those requirements.

Proposed Amicus APC has a substantial interest in the lawful implementation of Sections 503A (and 503B) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), as proposed Amicus APC represents a diverse array of participants in the compounding industry, including prescribers, educators, patients, and suppliers, including veterinary compounders. Most importantly, APC advocates for those that

prepare and rely on compounded medications services for critical, life-saving treatments that are otherwise unavailable—and unlikely to ever be available—commercially.

Because its membership comprises a majority of the traditional pharmacy compounding industry, APC's members are directly affected by FDA's enforcement actions. The proposed Amicus and its members are uniquely vulnerable to the consequences suffered by compounding pharmacies by the illegal and unconstitutional enforcement of impermissibly vague regulations. Further, APC's interests are distinct from Plaintiff Wedgewood Village Pharmacy, Inc., as the APC encompasses a significant number of industry participants—including certain patient populations and providers—not represented by the single plaintiff pharmacy. APC provides insight on the effects of FDA's selective enforcement, along with the publication of such enforcement actions, on the industry as a whole.

APC's proposed amicus brief discusses issues central to the case. The question of the constitutionality of FDA's interpretation of the term "insanitary conditions" in the adulteration statute of the Federal Food, Drug, and Cosmetic Act is integral to the disposition of the case. A significant consideration in evaluating any agency action is the impact of the imposition of a requirement not only on regulated industry, but also on the general public. FDA's mission is first and foremost to protect the public health by assuring both the safety and efficacy of

drugs, but also to facilitate access. FDA must ensure that the promulgation of mechanisms to enforce provisions of Section 503A occur as through clear standards to avoid arbitrary or discriminatory enforcement. Yet, FDA refuses to use the appropriate administrative pathway, as it has refused to do so over its decades-long history regulating compounding through non-binding guidance documents.

With no discernable standard for enforcement of the "insanitary conditions" clause of the adulteration provision in the FDCA, FDA violates APC members' right to due process set forth in the Fifth Amendment to the Constitution. *See* U.S. Const. amend. 5 ("No person shall . . . be deprived of life, liberty, or property, without due process of law . . . ."). The Brief of Proposed Amicus addresses Fifth Amendment concerns resulting from the vagueness and lack of standards in the compounding industry including FDA's reliance on insanitary conditions guidance for its enforcement determinations.

II. ADDITIONAL FACTORS CONSIDERED BY THIS COURT ALSO SUPPORT GRANTING ALLIANCE FOR PHARMACY COMPOUNDING LEAVE TO FILE

This Court has considered four other factors in determining whether to grant amici leave to file, some of which overlap with the requirements in Rule 29 discussed above. These include whether: (1) "the *amicus* has a 'special interest' in the particular case"; (2) the *amicus's* interest is not "represented competently or at all in

the case"; (3) "the proffered information is timely and useful"; and (4) "the amicus is not partial to a particular outcome in the case." *Alkaabi*, 223 F. Supp. 2d at 592.

As noted, APC has a special interest in the case as a representative of the entire compounding industry, and those interests are not represented by a single company. APC occupies a unique position as its members are not only compounding pharmacists, pharmacy technicians, educators, students, researchers, and suppliers, but APC also represents the interests of physicians, veterinarians, nurse practitioners, and other medical professionals. APC's fundamental interest in safe and accessible medicines.

APC's proposed amicus brief is also timely. It is submitted the same day that the Plaintiff's Reply Memorandum is due.

APC has no direct financial interest in the outcome of this specific proceeding, even if it has an interest in the legal issues presented by the case.

CONCLUSION

In light of APC's significant interest in this case, and the useful information its timely proposed amicus brief would provide the Court on important issues, APC respectfully requests the Court grant this Motion for Leave to File Brief of Amicus Curiae and accept the accompanying proposed amicus brief for filing.

Dated: May 13, 2022

Respectfully submitted,

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Counsel for Proposed Amicus Curiae Alliance for Pharmacy Compounding

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WEDGEWOOD VILLAGE PHARMACY, LLC Plaintiff, v. U.S. FOOD AND DRUG ADMNINISTRATION, XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, DR. ROBERT M. CALIFF in his official capacity as Commissioner of Food and Drugs Defendants.	Civil Action No. 22-cv-2649 **CERTIFICATION OF WILLIAM J. HUGHES, JR., IN SUPPORT OF UNOPPOSED MOTION OF ALLIANCE FOR PHARMACY COMPOUNDING FOR LEAVE TO FILE AMICUS CURIAE BRIEF IN SUPPORT OF PLAINTIFF WEDGEWOOD VILLAGE PHARMACY, LLC**

I, William J. Hughes, Jr., Esq., being of full age, hereby certify as follows:

1. I am an attorney admitted to practice law in the State of New Jersey and the United States District Court for the District Court of New Jersey. I make this certification in support of the motion of Alliance for Pharmacy Compounding ("APC") to appear as amicus curiae in the above-captioned matter.

2. APC is a national trade association advocating on behalf of millions of patients who benefit from compounded medications including compounded veterinary medications. APC's members are not only compounding pharmacists,

pharmacy technicians, educators, students, researchers, and suppliers, but APC also represents the interests of physicians, veterinarians, nurse practitioners, and other medical professionals. APC works to ensure the availability of—and access to—customized medications for patients for whom manufactured drugs are not suited. Its mission is to preserve the rights of physicians to prescribe, of pharmacists to prepare, and of patients to take, personalized medication solutions to meet their unique healthcare needs for a range of issues, including women's health, autism, oncology, dermatology, ophthalmology, pediatrics, veterinary and pet care, and others. APC also always encourages compounders to use compounding practices that fully comply with federal and state laws.

3. District courts have broad discretion to permit the filing of amicus curiae briefs. *See United States v. Alkaabi*, 223 F. Supp. 2d 583, 592 (D.N.J. 2002) ("The extent, if any, to which an amicus curiae should be permitted to participate in a pending action is solely within the broad discretion of the district court."). Although no rule explicitly governs the filing of amicus briefs in this District, District Courts may consider by analogy the requirements of Federal Rule of Appellate Procedure 29 and the Third Circuit's interpretation of the same in exercising their discretion whether to grant leave to file amicus briefs. *See id.; see also Acra Turf Club, LLC v. Zanzuccki*, Civ. No. 12-2775, 2014 WL 5465870, at *5 (D.N.J. Oct. 28, 2014).

4. Under Federal Rule of Appellate Procedure 29(b), a party seeking leave to appear as amicus curiae must state: "(A) the movant's interest; and (B) the reason why an amicus brief is desirable and why the matters asserted are relevant to the disposition of the case." Fed. R. App. P. 29(3). The Third Circuit has explained that "it is preferable to err on the side of granting leave" so that a court will not "be deprived of a resource that might have been of assistance." *Neonatology Assocs., P.A. v. Comm'r of Internal Revenue*, 293 F.3d 128, 133 (3d Cir. 2002); see also *id.* ("[O]ur court would be well advised to grant motions for leave to file amicus briefs unless it is obvious that the proposed briefs do not meet Rule 29's criteria as broadly interpreted."); *Newark Branch, NAACP v. Town of Harrison*, 940 F.2d 792, 808 (3d Cir. 1991) (amicus briefs help "insur[e] a complete and plenary presentation of difficult issues so that the court may reach a proper decision").

5. Proposed Amicus APC has a substantial interest in the lawful implementation of Sections 503A (and 503B) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), as Proposed Amicus represents a diverse array of participants in the compounding industry, including prescribers, educators, patients, and suppliers, including veterinary compounders. Most importantly, APC advocates for those that prepare and rely on compounded medications and services for critical, life-saving treatments that are otherwise unavailable—and unlikely to ever be available—commercially.

6. The matters asserted are relevant to the case because the brief addresses the U.S. Food and Drug Administration's ("FDA" or the "Agency") continued refusal to regulate the compounding industry pursuant to lawfully implemented regulations. Historically, FDA has governed compounding through a series of non-binding guidance and interpretive materials. FDA seeks to continue this practice by unlawfully holding compounding pharmacies including Plaintiff here to a nebulous and undefined standard for "insanitary conditions" set forth only in a guidance document.

7. In maintaining vague standards, the Agency preserves its flexibility to impose criminal sanctions arising from the alleged violation of the adulteration provisions of the FDCA with absolutely no limiting factor. *See* FDA, *Insanitary Conditions at Compounding Facilities* (November 2020) ("Insanitary Conditions Guidance"); 21 U.S.C. § 351(a)(2)(A); 21 U.S.C. § 331(b). The Agency repeatedly applies these vague and indefinite provisions unreasonably to take enforcement action against compounding pharmacies.

8. Indeed, this case is another example of FDA's continued pattern of enforcing the FDCA against compounding pharmacies while providing them as little information as possible. By providing no guiding principles for industry, which makes it extremely difficult to compliantly operate, FDA virtually ensures that

compounding pharmacies will violate the FDCA. Eventually, this approach to regulating compounding could at least jeopardize, if not destroy, the industry.

9. Importantly, though compounding plays a vital role in protecting the public health, as conventional FDA-approved drug products are not appropriate for all patients. APC fully understands and appreciates that ensuring the continued function of the industry is vital. But FDA's repeated attempts to enforce standards set forth only in a vague guidance communication destroys any certainty or principles by which the industry can operate.

10. With no discernable standard, FDA's enforcement of the "insanitary conditions" clause of the FDCA's adulteration provisions violates APC members' right to due process set forth in the Fifth Amendment to the Constitution. *See* U.S. Const. amend. 5 ("No person shall . . . be deprived of life, liberty, or property, without due process of law . . . ."). The Brief of Proposed Amicus addresses Fifth Amendment concerns resulting from the vagueness and lack of standards in the compounding industry including FDA's reliance on insanitary conditions guidance for its enforcement determinations.

11. As a representative of the larger compounding industry—rather than a single compounding pharmacy—APC respectfully urges that it can provide the Court with additional insight into the impact of both the lack of meaningful guidance and lack of defined standards from FDA on the entire compounding industry.

12. Specifically, the Proposed Amicus is concerned about FDA's approach to compounding more generally, which often consists of inspection citations with vague allegations of "adulteration" through "insanitary conditions" coupled with a scathing Press Release published on FDA's website -- all before a compounding pharmacy has the opportunity to respond. The issues in the case are prime examples of that approach, as FDA relies on such allegations to embarrass the particular compounding industry and the compounding pharmacy itself and dissuade patients from relying on compounded formulations that are not, in fact, either adulterated or misbranded based on the applicable standards set forth in the United States Pharmacopeia for non-sterile drug formulations.

13. A significant consideration in evaluating any agency action is the impact of the imposition of a requirement not only on regulated industry, but also on the general public. FDA's mission is first and foremost to protect the public health by assuring both the safety and efficacy of drugs, but also to facilitate access. FDA must ensure that the promulgation of mechanisms to enforce provisions of Section 503A occur as through clear standards to avoid arbitrary or discriminatory enforcement. Yet, FDA refuses to use the appropriate administrative pathway, as it has refused to do so over its decades-long history regulating compounding through non-binding guidance documents. Certainly, eliminating a critical mechanism by which patients obtain medicines is not conducive to facilitating access.

14. APC is dedicated to facilitating and preserving access to compounded medicines. Because its membership comprises a majority of the traditional pharmacy compounding industry, these members are directly affected by FDA's enforcement actions based on impermissibly vague standards. Thus, Proposed Amicus is uniquely vulnerable to the consequences suffered by compounding pharmacies by the illegal and unconstitutional enforcement of impermissibly vague regulations.

15. APC's interests are distinct from Plaintiff Wedgewood Village Pharmacy, Inc., because the Proposed Amicus encompasses a significant number of industry participants—including certain patient populations and providers—not represented by the single plaintiff pharmacy. APC provides insight on the effects of FDA's selective enforcement, along with the publication of such enforcement actions, on the industry as a whole.

16. Because Proposed Amicus APC can provide insight to the Court that is not found in the parties' briefs—specifically the viewpoint of the larger compounding industry—the matters asserted in the Proposed Amicus Curiae brief are relevant to the disposition of the case. *See District of Columbia v. Potomac Elec. Power Co.*, 826 F. Supp. 2d 227, 237 (D.D.C. 2011) (permitting proposed intervenors to participate as amici curiae because "the Court finds that it may benefit

from their input" due to their "relevant expertise and a stated concern for the issues at stake in this case.").

17. On May 13, 2022, undersigned counsel advised counsel for the parties of Proposed Amicus's intent to seek this Court's permission, to submit an amicus brief in support of Plaintiff Wedgewood's Motion for Partial Summary Judgment. Counsel for the parties promptly advised the undersigned that they consented to Proposed Amicus's request.

18. No counsel to the parties authored this brief in whole or in part, nor has any person contributed money that was intended to fund in the preparation or submission of this brief.

19. In accordance with Local Civil Rule 6, a proposed order granting the requested relief is submitted herein.

20. WHEREFORE, the Proposed Amicus APC respectfully asserts that this Court should grant it permission to submit an Amicus Brief in this case. I certify that the foregoing factual statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Dated: May 13, 2022

Respectfully submitted,

By: /s/ *William J. Hughes, Jr.*

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BRIEF OF AMICUS CURIAE ALLIANCE FOR PHARMACY COMPOUNDING IN SUPPORT OF PLAINTIFF WEDGEWOOD VILLAGE PHARMACY, LLC

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GLOSSARY

APC	Alliance for Pharmacy Compounding
CFR	Code of Federal Regulations
DQSA	Drug Quality and Security Act
FDA	U.S. Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*
FDAMA	Food and Drug Administration Modernization Act of 1997

INTERESTS OF AMICUS CURIAE

Amicus Curiae, the Alliance for Pharmacy Compounding ("APC"), is a national trade association advocating on behalf of both pharmacies and the millions of patients who benefit from compounded medications. APC's members are compounding pharmacists, pharmacy technicians, educators, students, researchers, and suppliers. APC also represents the interests of physicians, veterinarians, nurse practitioners, and other medical professionals. APC works to ensure the availability of—and access to—customized medications for patients for whom manufactured drugs are not suited. Its mission is to preserve the rights of physicians to prescribe, of pharmacists to prepare, and of patients to take personalized medication solutions to meet their unique healthcare needs for a range of issues, including women's health, autism, oncology, dermatology, ophthalmology, pediatrics, and others.

STATEMENT OF PARTY COUNSEL'S PARTICIPATION/FUNDING OF AMICUS

Neither Plaintiff's counsel nor Defendant FDA's counsel participated in the funding or drafting of this Brief of Amicus Curiae.

ARGUMENT

For almost thirty years, the U.S. Food and Drug Administration ("FDA" or the "Agency") has been regulating the drug compounding industry through a hodge-podge of informal interpretations set forth in various policies, guidance documents, and statements. Though the FDA Modernization Act of 1997 ("FDAMA"), Pub. L. No. 115-105, § 127(a), 111 Stat. 2296, 2328, and later the Drug Quality and Security Act ("DQSA"), Title I (the Compounding Quality Act), Pub. L. No. 113-54, 127 Stat. 587 (2013), introduced some order into the drug compounding regulatory scheme by enacting Section 503A of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 353a, FDA thus far has failed to promulgate regulations governing compounding, notwithstanding its congressional mandate to do so. *See id.*; *see also* 21 C.F.R. Part 216, Subpart A – General Provisions (Reserved). Instead, FDA continues to try to enforce nebulous laws without providing compounding pharmacies notice of the precise standards with which they need to comply.

Exercising its authority under section 501 of the FDCA, FDA for years has alleged that compounding pharmacies have violated the FDCA when they have "prepared, packed, or held" drug products "under insanitary conditions whereby [they] may have been contaminated with filth, or whereby it may have been rendered injurious to health." 21 U.S.C. § 351(a)(2)(A). FDA appears to have construed that

provision liberally, but the Agency has issued an interpretation of it only in a single guidance document that explains the rubric for "insanitary conditions that could be present in a compounding facility" only by way of examples. FDA, Guidance for Industry: Insanitary Conditions at Compounding Facilities, at 3 (Nov. 2020). Leaving the term open for further interpretation, the Agency provides no clear definition of "insanitary conditions." Instead, the Agency operates through its claimed discretion to "determine[] whether compounding facilities produce drugs under insanitary conditions" and provides no real standard by which it decides to "initiate regulatory action." *Id.*

Rather than provide the "ascertainable certainty" necessary for the enforcement of government regulations under the Fifth Amendment of the U.S. Constitution, the Agency denies compounding pharmacies due process by enforcing and resolving "basic policy matters" on an "ad hoc and subjective basis, with the attendant dangers of arbitrary and discriminatory application," *Grayned v. City of Rockford*, 408 U.S. 104, 108-09 (1972)—the exact conduct that has led to the plaintiff's action in this case. Given the Agency's failure to articulate a standard for "insanitary conditions" in the context of adulterated products, the liability—both civil and criminal—FDA imposes on compounding pharmacies for such conditions violates their Fifth Amendment rights. *See FCC v. Fox TV Stations, Inc.*, 567 U.S. 239, 253 (2012) (the "requirement of clarity in regulation is essential to the

protections provided by the Due Process Clause of the Fifth Amendment"); *see also* U.S. Const. amend. V.

I. FDA's Enforcement of the Nebulous "Insanitary" Standard Violates Compounding Pharmacies' Fifth Amendment Right to Due Process

Notwithstanding the fact that the U.S. Constitution provides the right to due process, FDA continues to try to enforce nebulous laws against compounding pharmacies without providing the requisite notice and explanation so that they can effectively comply with such requirements. Since the enactment of FDAMA in 1997, the Agency has regulated compounding through a series of policy statements and guidance documents. FDA has actively avoided promulgating the statutorily-mandated regulations for compounding pharmacies, making it challenging for them to comply with FDA requirements so that they may continue to provide critical medications to patients. And not only is this disregard for the statutorily-required rulemaking processes unfair to industry, but the Agency's continued discretionary enforcement of wholly imprecise standards without "fair notice of what conduct is required or proscribed" so that regulated parties "may act accordingly" and so that "those enforcing the law do not act in an arbitrary or discriminatory way" violates the Due Process Clause of the Fifth Amendment. *Id.*; *see* U.S. Const. amend. V.

The Due Process Clause of the Fifth Amendment provides that "a conviction fails to comport with due process if the statute under which it is obtained fails to

provide a person of ordinary intelligence fair notice of what is prohibited, or is so standardless that it authorizes or encourages seriously discriminatory enforcement." *United States v. Williams*, 553 U.S. 285, 304 (2008); U.S. Const. amend. V. Similarly, a regulation lacks fair notice when the relevant standard is "so vague as to be no rule or standard at all." *FTC v. Wyndham Worldwide Corp*., 799 F.3d 236, 250 (3d Cir. 2015). This applies "[e]ven in the civil context;" "fair warning requires that government agencies communicate their interpretation of their own regulations with 'ascertainable certainty' before subjecting private parties to punishment under that interpretation." *United States v. Harra*, 985 F.3d 196, 213 (3d Cir. 2021), *citing FTC v. Wyndham Worldwide Corp.*, 799 F.3d 236, 249, 251 (3d Cir. 2015). This principle applies "with equal force"—if not more—when criminal sanctions are involved. *Id.*

Here, the "insanitary conditions" provision of the FDCA's prohibition against adulteration gives compounding pharmacies some idea of the prohibited conduct—where the drug "may have been contaminated with filth" or "rendered injurious to health," 21 U.S.C. § 351(a)(2)(A)—but neither the statute nor FDA's interpretations have provided clear notice as to what *exactly* constitutes violative conduct. Indeed, FDA regulates compounding facilities under vague, ambiguous, and open-ended criteria and fails to provide industry with notice as to the applicable standards for "insanitary condition" allegations. FDA's only attempt to define the activities

prohibited provides little information to actually serve as guideposts for recognizing "insanitary conditions" but instead consists of a non-exhaustive list of examples to provide clarity to compounding pharmacies of insanitary conditions for which they may be prosecuted. Insanitary Conditions Guidance, at 3. The Guidance's emphasis, marked by bolded text, on the fact that "other conditions not described in this guidance may also be considered insanitary" indicates that FDA is applying a flexible and discretionary approach to the term, providing compounding pharmacies with little certainty as to violative conduct. Most problematically, an alleged violation of the Insanitary Conditions Guidance apparently serves as the basis for FDA's enforcement activities as it does here against Wedgewood.

FDA's Guidance—or rather, its list of examples—includes no *principles* from which the compounding industry can extrapolate; unless a specific condition is on the list, there is no way for a compounding pharmacies to guess whether that condition is insanitary. *See id.*. Wedgewood, for example, would have no basis to know under the plain meaning of the term "insanitary conditions" or under the "explanation" set forth in the Insanitary Conditions Guidance that a "observed personnel who 'moved rapidly' in a sterile compounding area" or who "was noted to have their safety glasses down on their nose" would meet the standard for "insanitary conditions." *See* Complaint ¶ 5.

The Government suggests that the term "insanitary conditions," on its face, is sufficient because it "has been broadly interpreted by courts" such that the "common understanding of the term . . . typically describes such things as insect infestation, mold, or filth." Def. Opp. To TRO and PI, at 23. But a court's interpretation is not sufficient where it is the *agency*—and only the agency—that is making the decision as to whether conditions at a given compounding facility rise to the level of "insanitary." This is a significant issue in the context in which FDA, as here, enforces its position only through guidance, warning letters, and policy statements, as it affords no opportunity for public input or for judicial review.

It is also important to note that every violation of the FDCA is criminally sanctionable. That due process right is of particular importance where a violation could result in enormous fines or even imprisonment. *See* 21 U.S.C. § 331. Thus, not only can FDA's subjective and standardless assessment of "insanitary conditions" result in unfettered discretion to effectively shut down a compounding pharmacy, but it could also result in criminal liability. Permitting FDA to arbitrarily enforce the "insanitary conditions" provision of the adulteration prohibition without providing industry "ascertainable certainty" in the definition of "insanitary conditions" fails to comport with the fundamental tenets of fairness, in addition to due process. *See United States v. Williams*, 553 U.S. 285, 304 (2008).

II. FDA's Failure to Provide Concrete Standards Exacerbates Continued Uncertainty in the Compounding Industry.

Undoubtedly, Section 503A of the FDCA provides FDA with the legal authority to regulate human drug compounding—and indeed commands FDA to do so through regulation. *See, e.g.*, 21 U.S.C. § 353a(d)(1) ("The Secretary shall issue regulations to implement this section."). But FDA has categorically failed to do so. Rather, FDA has chosen to repeatedly deprive the compounding industry of its statutory rights and instead address the implementation of Section 503A, and indeed veterinary compounding, only through guidance or policy positions. Industry has been forced to navigate a series of informal guidance documents, some of which expressly contravene a statute that requires rulemaking and regulatory analysis. FDA's dismissal of the regulatory procedures governing rulemaking has jeopardized regulatory certainty, and likely now, the viability of the traditional compounding industry.

Congress enacted Section 503A as part of the DQSA, and, over the course of the next several years issued a series of draft guidance documents addressing Section 503A's substantive provisions and FDA's approach to enforcement.[1] FDA's

[1] *See e.g.* FDA, Final Guidance: Pharmacy Compounding of Human Drug Products Under Section 503A of the FDCA (July 2014); FDA, Final Guidance: Pharmacy Compounding of Human Drug Products Under Section 503A (Rev. 2 June 2016); FDA, Draft Guidance: Hospital and Health System Compounding Under Section 503A of the FDCA (Apr. 2016); FDA, Final Guidance: Prescription Requirement Under Section 503A of the FDCA (Dec. 2016); FDA, Final Guidance: Compounded

approach to regulating under 503A—adopting guidance in lieu of required rulemakings—was so concerning that even Congress opined on FDA's avoidance of the APA:

> The Committee is aware that many provisions of the DQSA and the re-enactment of Section 503A have been implemented through more than 20 agency guidance documents instead of the formal notice and comment rulemaking process as required by the underlying statutes and the Administrative Procedure Act.

H.R. Rep. No. 115-706, at 69 (May 24, 2018). Congress also raised concerns that FDA's attempts to evade the APA to regulate drug compounding stymied Department of Justice ("DOJ") policy intended to limit reliance on enforcement by guidance in place of rulemaking. As the House Appropriations Committee explained in a 2018 Committee Report:

> The Committee is also aware of a January 2018 Memorandum issued by the Associate Attorney General that prohibits the DOJ from using civil enforcement authority to convert agency guidance documents into binding rules. Within 90 days of enactment of this Act, the Committee directs FDA to explain how the agency will implement any applicable changes in its use of guidances to ensure consistency with this policy due to the fact that these guidances serve as the underpinning of enforcement activity for both Section 503A and Section 503B of the FDCA.

Id..

Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the FDCA (Jan. 2018).

Congress's objections make sense: FDA's approach to regulating through guidance ignores the importance of regulatory clarity. Clear regulatory structure is also important to all regulated industries, as it provides a level playing field; each participant is required to conform to the same procedures and processes. Uncertainty creates business risk, "which can discourage investment and innovation." President's Council of Advisors on Science and Technology (PCAST), Report to the President on Propelling Innovation in Drug Discovery, Development, and Evaluation, 41 (Sep. 2012). Reliance on allegedly "non-binding" guidance documents or other types of interpretative documents to govern agency policy and enforcement only increases uncertainty for industry, which leads to less industry investment and reduced public confidence in that industry. Thus, FDA's approach to regulating compounding—obliterating any certainty— discourages innovation and hinders patient access to needed medications that "may be the difference between life and death" for a given patient. H.R. Rep. No. 114-531, at 68 (Apr. 26, 2016).

CONCLUSION

FDA has been relying on guidance and interpretative statements to regulate traditional pharmacy compounding for almost thirty years. Such an approach discourages innovation and hinders patient access to a product that "may be the difference between life and death" for a given patient. H.R. Rep. No. 114-531, at 68. FDA is furthering that approach by enforcing the adulteration provisions based only on an uninformative guidance document detailing examples—rather than definitions or concrete interpretations—of "insanitary conditions." With a lack of fair notice and the unintelligible standard for such insanitary conditions, FDA's enforcement activity violates compound pharmacies' Fifth Amendment right to due process. U.S. Const. amend. V. Accordingly, this Court should grant Wedgewood's Request for a Temporary Restraining Order and Preliminary Injunction to prevent the imposition of sanctions that could destroy the business based on an unconstitutional assertion of authority.

Dated: May 13, 2022

Respectfully submitted,

By: /s/ *William J. Hughes, Jr.*

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CERTIFICATE OF SERVICE

I, William J. Hughes, Jr., hereby certify that I caused the foregoing Motion for Leave to File Brief of Amicus Curiae and supporting documents to be served via the District Court's Electronic Case Files (ECF) System upon counsel for the parties:

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This 13th day of May 2022.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WEDGEWOOD VILLAGE PHARMACY, LLC Plaintiff, v. U.S. FOOD AND DRUG ADMNINISTRATION, XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, DR. ROBERT M. CALIFF in his official capacity as Commissioner of Food and Drugs Defendants.	Civil Action No. 22-cv-2649 **ORDER**

Upon consideration of the Unopposed Motion of the Alliance for Pharmacy Compounding's Leave to File Amicus Curiae Brief in Support of Plaintiff Westwood Village Pharmacy LLC, it is hereby ORDERED that the Motion is GRANTED. It is

FURTHER ORDERED that the proposed amicus curiae brief submitted as Exhibit 1 to the Motion shall be deemed filed as of _____.

SO ORDERED this _____ day of May 2022.

Karen M. Williams
UNITED STATES DISTRICT JUDGE