IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
OCALA DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. FRANCK'S LAB, INC., d/b/a FRANCK'S COMPOUNDING LAB, a corporation, and PAUL W. FRANCK, an individual Defendants.	)	Civil Action No. 5:10-CV-00147-TJC **DEFENDANTS FRANCK'S LAB, INC. AND PAUL W. FRANCK'S RESPONSE TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION**

DEFENDANTS' RESPONSE TO PLAINTIFF'S
MOTION FOR A PRELIMINARY INJUNCTION

This case involves an attempt by the Food and Drug Administration ("FDA") to punish a local Florida pharmacy (Franck's) for compounding medications for animals using bulk ingredients — a traditional, medically necessary pharmacy practice that is expressly permitted under Florida law, engaged in by hundreds of state-licensed pharmacists across the nation, relied on by veterinarians to treat ailing animals when required medications are not commercially available, and considered by experts to be safe, accurate, and appropriate.

The central issue in this case is whether FDA has authority to ban the traditional practice of pharmacy compounding from bulk ingredients. It does not. No federal statute comes close to stating that compounding animal medications from bulk ingredients is unlawful. Instead, FDA's position is that Congress banned compounding from bulk ingredients in 1938 when that practice was common and permitted (and regulated) under state law, as it remains today, and that Congress did so in provisions that did not mention

pharmacy compounding and were supported by the pharmacists whom — according to FDA — it made criminals. FDA's position is every bit as implausible as it sounds.

FDA does have authority to regulate the manufacturing of animal drugs, including manufacturing done in the guise of pharmacy compounding. But the evidence establishes that Franck's does not engage in manufacturing. *See*, *e.g.*, Franck Decl. ¶¶ 82–85; Bradshaw Decl. ¶¶ 53–57. The use of bulk ingredients to compound commercially unavailable preparations is a core part of the traditional practice of pharmacy. In claiming that all compounding from bulk ingredients is banned, FDA is attempting to conjure a prohibition without a statutory basis and without following the administrative procedures that would be required for an agency to create a binding rule even if a statutory basis could be found. Because FDA will fail on the merits of its claim, this Court should deny its motion for preliminary injunction. (*See* Section I, below.)

In addition to lacking legal merit, FDA's claim lacks equity, and its motion should be denied for that additional (and independent) reason. (*See* Section II, below.) FDA has no evidence that Franck's compounding practices pose an imminent threat of harm. To the contrary, FDA's submissions confirm that it has known about Franck's compounding activities for at least five years. That is not surprising: Franck's has not tried to conceal its entirely legitimate business. Nor has FDA demonstrated any material change in circumstances that could justify its request for extraordinary relief. While FDA tries to shut down Franck's animal compounding business, countless other pharmacies across the nation are engaging in the same traditional and state-licensed use of bulk ingredients to compound animal medications. Indeed, FDA has not sought to stop Franck's from engaging in the same

practice to compound medications for *human* use — which speaks volumes about the utter lack of evidence that Franck's activities are unsafe. This action is instead based on the hard-to-fathom position that the use of bulk ingredients to prepare compounded medications poses an imminent threat of irreparable harm when done for non-food-producing animals, but not when done for human use. Against this backdrop, FDA's decision to bring this enforcement action against Franck's is an arbitrary exercise of government power that is anathema to foundational principles of constitutional and administrative law.

FDA suggests that these equitable concerns are irrelevant and that it is automatically entitled to a preliminary injunction if it can show a likelihood of success on the merits. FDA's view is not the law. A preliminary injunction is an extraordinary remedy that is appropriate only when it is equitable. It is not an entitlement, even for the government. FDA has not identified any irreparable harm that will befall anyone if its requested injunction is not entered. On the other side of the equitable balance, Franck's has presented overwhelming evidence that a preliminary injunction would inflict substantial and irreparable harm on Franck's, its employees, and on the veterinarians, animal owners, and animals who depend on Franck's high-quality compounding services. Even if the Court believes that FDA may prevail on the merits, or that the merits involve difficult questions that should not be decided at this stage without fuller consideration, FDA's failure to satisfy the essential equitable prerequisites for preliminary relief that would drastically change the status quo is an independent reason why FDA's motion should be denied.

ARGUMENT

I. The Motion For A Preliminary Injunction Should Be Denied Because FDA Is Not Likely To Succeed On The Merits.

FDA is not likely to succeed on the merits for three independent reasons: Its complaint (1) does not plead legally sufficient claims, (2) exceeds the scope of FDA's delegated authority, and (3) seeks to enforce a prohibition that has not been promulgated through proper rulemaking proceedings.

A. FDA Has Not Pleaded Legally Sufficient Claims.

FDA's motion for a preliminary injunction should be denied for the same reason its complaint should be dismissed — FDA's conclusory allegations do not satisfy the requirements of Rule 8. *See Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007). Because FDA has not pleaded legally sufficient claims, it is not entitled to injunctive relief based on those claims. *See, e.g.*, *Pro Image Installers, Inc. v. Dillon*, No. 3:08cv273, 2009 WL 112953, at *2 (N.D. Fla. Jan. 15, 2009) (motion for preliminary injunction "moot" based on Rule 8 dismissal).

FDA's motion, if anything, reinforces the grounds for dismissal. Instead of citing its complaint, FDA relies on assertions that appear for the first time in declarations. *See, e.g.*, Singleton Decl. ¶ 8 (Franck's improperly "assisted at least one other compounding pharmacy in filling animal drug compound orders"). But FDA is not entitled to injunctive relief for alleged violations not pleaded in its complaint. *See Keh v. Americus & Sumter Cty. Hosp.*, 09-12311, 2010 WL 1718700, at *4 (11th Cir. Apr. 29, 2010) (disputed declarations may not supplement deficient complaint); *Wilchombe v. TeeVee Toons, Inc.*, 555 F.3d 949, 959 (11th Cir. 2009) (review on motion to dismiss is "limited to the four corners of the complaint").

Moreover, the declarations include the same improper "naked assertion[s]" that infect FDA's complaint. *Iqbal*, 129 S. Ct. at 1949. The declarations accuse Franck's in cursory fashion of allegedly compounding commercially available drugs and compounding medications "not intended for a particular patient to meet that patient's unique needs." Flynn Decl. ¶ 32; Singleton Decl. ¶¶ 10–11. But these conclusory accusations are not supported by specific facts. As explained in the attached declarations, they are also incorrect. *See* Bradshaw Decl. ¶¶ 53–56; Franck Decl. ¶¶ 30–35, 37, 44, 82, 86–93; Davidson Decl. ¶¶ 85, 87.

The Supreme Court has made clear that courts should police the requirements of Rule 8 to avoid allowing a person with "a largely groundless claim" to "take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value." *Twombly*, 550 U.S. at 558 (pleading deficiencies should "be exposed at the point of minimum expenditure of time and money by the parties and the court"). That concern applies with particular force where, as here, that person is the United States. If the Court grants preliminary relief, the burden on Franck's — Franck's inability to serve half its customer base while incurring the enormous expense of litigating against the government — will ratchet up pressures to capitulate to FDA without regard to the law.

B. FDA's Attempt To Prohibit Compounding Animal Drugs From Bulk Ingredients Exceeds Its Authority.

FDA's motion also should be denied because its legal theory has no merit. Contrary to FDA's assertions, Congress has not delegated FDA authority to regulate traditional pharmacy compounding of medications used to treat non-food-producing animals. *See* Bradshaw Decl. ¶¶ 7–43, 54. Although FDA has authority to regulate drug manufacturing if it occurs in the guise of compounding, that authority does not permit FDA to override state

law and impose a blanket ban on traditional pharmacy compounding practices. *See* Bradshaw Decl. ¶¶ 9–10, 44–50; Allen Decl. ¶¶ 56–64.

FDA's extreme position is that ***all*** pharmacy compounded animal medications are "new drugs" within the meaning of the Food, Drug and Cosmetic Act ("FDCA") because FDA has not approved them through the new drug application process. FDA Br. 13, 16–17. Because it is financially prohibitive for pharmacy compounded medications to undergo the FDCA's "new drug" approval process, *see* Allen Decl. ¶¶ 65–77, FDA's statutory argument means that, when Congress enacted the FDCA in 1938, it effectively criminalized ***all*** pharmacy compounding practices. *See* 21 U.S.C. § 333(a) (authorizing criminal penalties for FDCA violations); Bradshaw Decl. ¶¶ 9, 11–28. FDA's position means that Congress outlawed compounding human drugs for almost 60 years, until 1997 when it enacted the Food and Drug Administration Modernization Act ("FDAMA"), which expressly contemplates compounding human drugs from bulk ingredients. 21 U.S.C. § 353a. It means that Congress also outlawed compounding animal drugs, and that this traditional pharmacy practice remains a federal crime except in the limited circumstances carved out by FDA's regulations implementing the Animal Medicinal Drug Use Clarification Act ("AMDUCA"), in which FDA deems a compounded medication to be merely a different "use" of an FDA-approved drug. *See* FDA Br. 14. It requires assuming that state laws that expressly permit pharmacy compounding, and numerous State Boards of Pharmacy that closely regulate it, are a nullity. *Cf.* Powers Decl. ¶¶ 15–41; Allen Decl. ¶ 52–55. It suggests that venerable professional organizations (including the National Association of Boards of Pharmacy, American Society of Health-System Pharmacists, and National Formulary, *see* Franck Decl.

¶ 109; Davidson Decl. ¶¶ 22, 25), as well as top pharmacy schools, *see* Davidson Decl. ¶ 3, have encouraged illegal activity. It means that the congressionally authorized, FDCA-recognized United States Pharmacopeia, which provides "recipes" for compounding animal drugs from bulk ingredients, is an official compendium for illegal conduct. *See* Allen Decl. ¶¶ 33–48; Bradshaw Decl. ¶¶ 7, 17. It means that hundreds of pharmacists, acting in collusion with thousands of veterinarians, have been engaged in a decades-long, open and notorious crime spree. And it means that pharmacists who have made the substantial business investments, undergone extensive training, and obtained state certifications to compound animal drugs are a professional class of unprosecuted criminals.

FDA's far-fetched interpretation is implausible on its face and inconsistent with basic principles of statutory construction. *Nixon v. Missouri Mun. League*, 541 U.S. 125, 138 (2004) (courts should not construe statutes in a manner that leads to absurd results). Nothing in the FDCA suggests that pharmacy compounded medications fall within the fold of "new animal drugs" subject to its approval, adulteration, and misbranding requirements. To the contrary, the legislative history shows that Congress enacted the FDCA to address drug ***manufacturing*** because, unlike traditional pharmacy practices, manufacturing was not closely regulated by the states. *Food, Drugs, and Cosmetics: Hearing Before a Subcommittee on Commerce of the United States Senate on S.5*, 83 Cong. 2279, 2279 (1938) (Rep. Coffee) ("pharmacists are licensed to compound and dispense drugs … [b]ut there is no such control to prevent incompetent drug manufacturers from marketing any kind of lethal potion"); *see* Bradshaw Decl. ¶¶ 12–28 (describing legislative history).

Settled principles of statutory construction amplify what the FDCA's text, structure, and legislative history make clear. Significantly, because it authorizes criminal penalties, the FDCA must be narrowly construed to avoid "prohibit[ing] more conduct or punish[ing] more severely than Congress intended." *United States v. Wright*, 607 F.3d 708, 717 (11th Cir. 2010) (Pryor, J., concurring) (citing cases); *Clarity Servs., Inc. v. Barney*, No. 8:08-cv-2278, 2010 WL 1140865, at *6 (M.D. Fla. Feb. 26, 2010) (rejecting "expansive" agency interpretation of criminal statute); *see also Leocal v. Ashcroft*, 543 U.S. 1, 12 n.8 (2004) (rule of lenity applies in civil context because statute with criminal and civil applications must be interpreted consistently). Moreover, although FDA interprets the FDCA as displacing regulation in an area of traditional state concern, it has pointed to no "plain statement" showing that the "clear and manifest purpose of Congress" was to supersede state regulation over traditional pharmacy compounding practices. *See Medtronic v. Lohr*, 518 U.S. 470, 485 (1996); *BFP v. Resolution Trust Corp.*, 511 U.S. 531, 546 (1994) (where Congress's intent to override historical state practice "is doubtful, our federal system demands deference to long-established traditions of state regulation"). As the Supreme Court emphasized in rejecting a similar power grab by FDA, Congress should not be presumed to address an issue of such "economic and political significance" in "so cryptic a fashion." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000); *see* Bradshaw Decl. ¶¶ 41–43.

In fact, there is strong evidence that Congress took care to carve out traditional pharmacy practices from the FDCA's regulation of drug manufacturing. *See* Bradshaw Decl. ¶¶ 12–14; Allen Decl. ¶¶ 56–60. For example, the statute limits FDA's authority to inspect pharmacies and exempts pharmacies from the FDCA's "records inspection" and

"registration" requirements. *See* 21 U.S.C. §§ 374(a)(1), 360(g)(1); *United States v. Baxter Healthcare Corp.*, 901 F.2d 1401, 1411 (7th Cir. 1990) (Congress intended to distinguish between manufacturing and compounding by medical professionals); *see also* Franck Decl. ¶ 65; Davidson Decl. ¶ 39. Moreover, in other contexts, Congress has reinforced the distinction between manufacturing and pharmacy compounding, defining drug "manufacturing" as not including "the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice." 21 U.S.C. § 802(15); *see* Bradshaw Decl. ¶¶ 12–13, 23, 30.

The conclusion that Congress did not intend to outlaw traditional pharmacy compounding in 1938 is borne out by more than a half-century of FDA practice and industry understandings. *See* Bradshaw Decl. ¶¶ 18, 31, 57; *Gutierrez de Martinez v. Lamagno*, 515 U.S. 417, 434 (1995) (statutes should be interpreted consistent with "traditional understandings"); *Davis v. United States*, 495 U.S. 472, 484 (1990) ("contemporaneous construction" is entitled to "considerable weight"). As the Supreme Court has observed, for "approximately the first 50 years after the enactment of the FDCA … [p]harmacists continued to provide patients with compounded drugs without applying for FDA approval of those drugs." *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 363 (2002). To conclude that these traditional understandings were wrong and, in fact, Congress intended to treat compounded drugs as "new drugs" would "not make sense." *Id.* at 369–70. As FDA's former Chief Counsel explains at length, Congress never intended to grant FDA authority to regulate traditional pharmacy compounding. *See* Bradshaw Decl. ¶¶ 12–28.

FDA has no response to these points. It cites certain cases that have previously suggested that the breadth of the term "new drug" in the FDCA covers veterinary compounding practices. *See* FDA Br. 19. But, as explained in Franck's motion to dismiss, those cases are non-binding, do not undertake the required statutory analysis, and are unpersuasive. *See* Mot. to Dismiss 24. FDA also invokes AMDUCA as a supposed source of authority. *See* FDA Br. 14–15. But AMDUCA does not even mention compounding, even though Congress knew how to address compounding in express terms when it wanted to, as it did for human drugs in FDAMA. *See Kimbrough v. United States*, 552 U.S. 85, 103 (2007) ("[d]rawing meaning from silence is particularly inappropriate" when "Congress has shown that it knows how to" address an issue "in express terms"). AMDUCA merely addresses the "extra-label" use of animal drugs — the use by veterinarians of an approved drug for a different indication than the specific indication approved by FDA, 21 C.F.R. § 530.3(a) — and was not intended to "increase or alter overall patterns of drug usage by veterinarians." 139 Cong. Rec. S1447 (1993) (Sen. Heflin). In fact, the statute was motivated by Congress's concern that valuable veterinary treatments necessary to the humane treatment of animals were being criminalized. *See* 140 Cong. Rec. S14071 (1994) (Sen. Heflin) (expressing concern that veterinarians were "forced to repeatedly break the law in order to responsibly carry out their professional duties"). Given this, it would be perverse to interpret AMDUCA as (silently) prohibiting practices at the core of traditional pharmacy compounding and thereby depriving veterinarians of medications needed to treat sick and injured animals. *See* Bradshaw Decl. ¶ 38; Pelphrey Decl. ¶¶ 9–12, 16; Stoothoff Decl. ¶¶ 6–13; Allen Decl. ¶¶ 60–64; Davidson Decl. ¶¶ 44–48.

C. FDA May Not Circumvent Required Rulemaking Procedures.

That Congress did not vest FDA with authority over state-regulated traditional pharmacy compounding does not mean that FDA lacks authority to prevent manufacturing in the guise of compounding. But whatever the scope of FDA's delegated authority, it must identify and exercise that authority by promulgating regulations through proper notice-and-comment rulemaking procedures. *See* Bradshaw Decl. ¶ 10. FDA's attempt to reinterpret the FDCA to impose a blanket rule — *i.e.*, no compounding animal drugs from bulk ingredients — through an enforcement action against a single pharmacy is impermissible. *See Jean v. Nelson*, 711 F.2d 1455, 1476 (11th Cir. 1983) (agency cannot apply "rules of general applicability" without rulemaking); *National Family Planning & Reproductive Health Ass'n, Inc. v. Sullivan*, 979 F.2d 227, 238–39 (D.C. Cir. 1992) (rulemaking required when agency intends to "produce significant effects on private interests"). If it is to be binding and enforceable, FDA's new prohibition on compounding animal drugs from bulk ingredients must be promulgated through proper rulemaking procedures. *Dia Nav. Co. Ltd. v. Pomeroy*, 34 F.3d 1255, 1265 (3d Cir. 1994).

Confirming that its complaint is based on a rule of general applicability, and not case-specific circumstances, FDA contends that its "regulations prohibit compounding animal drugs from bulk substances." FDA Br. 1. But that is not correct. FDA's regulations state only that "[n]othing in this part shall be construed as ***permitting*** compounding from bulk drugs," 21 C.F.R. § 530.13(a) (emphasis added), and refer the public to the agency's ***non-binding*** guidance documents for the agency's policies on animal drug compounding. *Id.* § 530.13(c). Non-binding guidance documents cannot impose legal requirements and cannot

serve as a basis for enforcing a purported prohibition that is not unambiguously created by statute. *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1021 (D.C. Cir. 2000) (agency cannot enforce policies formulated in guidance documents without notice-and-comment rulemaking); Bradshaw Decl. ¶ 51. At best, this "non-permission" merely begs the question whether some other source of law, such as the FDCA, prohibits compounding from bulk ingredients. At worst, it suggests that FDA believes that anything it has not affirmatively permitted is prohibited. That is not how the law works in our free society. Regulatory obligations — especially those that carry a threat of criminal sanctions — must be set forth with sufficient definiteness that ordinary people can understand what conduct is prohibited and in a manner that does not encourage arbitrary and discriminatory enforcement. *See Hill v. Colorado*, 530 U.S. 703, 732 (2000); *New York v. FERC*, 122 S. Ct. 1012, 1023 (2002) ("agency literally has no power to act … unless and until Congress confers power upon it").

Fundamental principles of administrative law thus require that substantive rules be promulgated through proper notice-and-comment rulemaking. 5 U.S.C. § 553; *Jean*, 711 F.2d at 1476. The purpose of these procedures is "(1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review." *International Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005). These "guarantees would not be meaningful if an agency could effectively, constructively amend regulations by means of non-obvious readings without giving the affected parties an opportunity either to affect the content of the regulations at issue or at

least be aware of the scope of their demands." *National Family*, 979 F.2d at 240. If courts mistakenly allow agencies to enforce non-binding guidance documents, "an especially odious frustration is visited upon the affected private parties: they are bound by a proposition they had no opportunity to help shape and will have no meaningful opportunity to challenge when it is applied to them." *Id*. (citation omitted).

Notice-and-comment rulemaking would require FDA to carefully consider its proposed assertions of authority, provide notice to the public about any decision to ban compounding from bulk ingredients, and justify that decision in court. *International Union*, 407 F.3d at 1259. Complying with administrative requirements would test in an appropriate forum FDA's extreme interpretation of the statute and its intrusion on state prerogatives. *See* Exec. Order No. 13,132, 64 Fed. Reg. 43255 (1999) (limiting federal agencies' ability to intrude on state prerogatives). It also would require FDA to consider the costs of its rule and to explain the public health justification (if any) for permitting compounding from bulk ingredients when the medication is prepared for humans but outlawing the practice when the medication is prepared for non-food-producing animals. *See* 5 U.S.C. § 604(a); *see also* Bradshaw Decl. ¶ 52; Pelphrey Decl. ¶ 26; Power Decl. ¶ 48. And, by establishing generally applicable rules, notice-and-comment rulemaking would avoid arbitrary and selective enforcement.

Arbitrary and selective enforcement is a very serious concern in this case. There are hundreds of other pharmacies that compound medications from bulk ingredients. But the purported regulatory prohibition is not being enforced against them. The burden is thus on FDA to come forward with some legitimate reason for singling out Franck's.

FDA has not shown a legitimate reason. And the scant evidence that FDA has submitted suggests the opposite. *See* Stoothoff Decl. ¶¶ 21–22; Pelphrey Decl. ¶¶ 26–27; Allen Decl. ¶¶ 78–87. FDA's moving papers focus on what should be an irrelevant consideration — namely, that Franck's has questioned FDA's authority and "disagreed with FDA's interpretation of the law." FDA Br. 7–10; Singleton Decl. ¶¶ 13, 15; Flinn Decl. ¶ 29. That focus is significant, however, because in other cases discovery has revealed that FDA has arbitrarily exercised its enforcement authority to retaliate against companies that question its authority. *See Utah Medical Prods. Inc. v. FDA*, 404 F. Supp. 2d 1315 (D. Utah 2005) (declining to grant injunctive relief to FDA where no evidence that products were not safe and questioning FDA's reasons for bringing the case); *see also* Franck Decl. ¶ 126; Davidson Decl. ¶¶ 89–90. Indeed, even though Franck's voluntarily suspended compounding animal drugs from bulk ingredients, FDA filed its motion for preliminary injunction one day after Franck's filed its motion to dismiss. *Cf. United States v. Barner*, 441 F.3d 1310, 1315–16 (11th Cir. 2006) (government's attempt to seek heightened charges after defendant's successful appeal presumed to be vindictive). While it is premature to suggest what discovery in this case will show, these factors underscore the wisdom of requiring that an agency follow proper administrative procedures to promulgate generally applicable rules.

II. The Motion For A Preliminary Injunction Should Be Denied Because FDA Has Not Satisfied The Essential Requirements For Seeking Equitable Relief.

FDA's motion should be denied because FDA is not likely to succeed on the merits. If, however, the Court is disinclined to reach the merits at this stage, an independent reason that FDA's motion should be denied is why FDA has not met its burden of satisfying the equitable requirements for preliminary relief. *See Windsor v. United States*, No. 09-13998,

2010 WL 1999138, at *3 (11th Cir. May 20, 2010) (a "failure to establish irreparable injury 'would, standing alone, make preliminary injunctive relief improper'").

A. FDA Is Not Exempt From Making The Showing Required To Justify The Extraordinary Remedy Of A Preliminary Injunction.

A preliminary injunction is "an extraordinary and drastic remedy that should not be granted unless" the moving party "clearly carries [the] burden of persuasion on each of [four] prerequisites." *Comerica Bank v. Hill*, No. 2:10-cv-126, 2010 WL 2854174, at *1 (M.D. Fla. July 21, 2010). The moving party must demonstrate: (1) a substantial likelihood of success on the merits, (2) a likelihood of "irreparable harm," (3) that "the balance of equities tips" in favor of preliminary relief, and (4) that "an injunction is in the public interest." *Winter v. NRDC*, 129 S. Ct. 365, 374 (2008).

FDA has not even attempted to satisfy its burden. Instead, relying on *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953), FDA suggests that to obtain equitable relief it need show nothing more than a statutory violation and a "cognizable danger of recurrent violations." FDA Br. 11. But *W.T. Grant* addressed whether cessation of illegal conduct prevents a court from ordering equitable relief; it did not change the traditional requirements for invoking a court's equitable authority. FDA's position and the cases on which it relies are at odds with recent Supreme Court and Eleventh Circuit precedent.

Rejecting the same sort of arguments that FDA urges this Court to embrace, the Supreme Court has reiterated that a preliminary injunction is an "extraordinary … remedy" that is "***never*** awarded as of right." *Munaf v. Geren*, 128 S. Ct. 2207, 2219 (2008) (emphasis added); *Winter*, 129 S. Ct. at 374–77; *Monsanto Co. v. Geerston Seed Farms*, 130 S. Ct. 2743, 2756–57 (2010). A moving party must carry its burden on all equitable factors in

addition to the threshold demonstration that the defendant's conduct is unlawful, "unless a statute [provides otherwise] in so many words, or by a necessary and inescapable inference." *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 313 (1982); *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006) ("a major departure from the long tradition of equity practice should not be lightly implied"). Contrary to FDA's assertions, the grant of jurisdiction "to ensure compliance with a statute hardly suggests an absolute duty to do so under any and all circumstances, and a federal judge sitting as chancellor is not mechanically obligated to grant an injunction for every violation of law." *Weinberger*, 456 U.S. at 313. This Court is not the handmaiden of FDA. The judiciary must exercise independent judgment to protect citizens against arbitrary government action. *Cf. Madsen v. Women's Health Ctr.*, 512 U.S. 753, 764 (1994) (injunctions carry risk of "discriminatory application").

FDA's attempt to characterize the law as settled in its favor is contrary to a recent Eleventh Circuit decision noting that the standard applicable to a request for injunctive relief under the FDCA remains unresolved. *United States v. Endotec, Inc.*, 563 F.3d 1187, 1196 n.9 (11th Cir. 2009). But the Eleventh Circuit has previously held that, when Congress authorizes injunctive relief, it is presumed to incorporate traditional equitable requirements, unless the statute unequivocally mandates injunctive relief as a remedy for statutory violations. *Klay v. United HealthGroup, Inc.*, 376 F.3d 1092, 1098 (11th Cir. 2004); *CBS Broad., Inc. v. Echostar Commc'ns Corp.*, 450 F.3d 505, 526–27 (11th Cir. 2006); *Hecht Co. v. Bowles*, 321 U.S. 321, 329–30 (1944). These cases should guide the Court here.

The FDCA does not mandate injunctive relief as an automatic remedy for statutory violations. *See* 21 U.S.C. § 332. Moreover, confirming that this case differs from the

Eleventh Circuit precedents cited in FDA's brief, *see Gresham v. Windrush Partners, Ltd.*, 730 F.2d 1417, 1423 (11th Cir. 1984) (listing reasons housing discrimination inevitably results in irreparable injury), FDA has long applied a general policy of not enforcing purported statutory requirements against compounding pharmacies. *See* Bradshaw Decl. ¶¶ 18, 31, 57; Davidson Decl. ¶¶ 42–43, 82; Franck Decl. ¶¶ 65–66, 75. It is therefore FDA's burden to explain why in this case it would be equitable to enjoin activities that FDA has deemed not to impose a general risk to the public.

B. All Traditional Considerations Weigh In Favor Of Denying FDA's Request For Extraordinary Relief.

FDA's motion should be denied because all equitable considerations weigh overwhelmingly in Franck's favor and an injunction would serve only as "an instrument of wrong." *Salazar v. Buono*, 130 S. Ct. 1803, 1816 (2010).

First, FDA cannot show any likelihood of irreparable injury, even though irreparable injury is the "sine qua non of injunctive relief." *Siegel v. LePore*, 234 F.3d 1163, 1176 (11th Cir. 2000). FDA complains that Franck's compounds animal medications from bulk ingredients, but it cannot dispute that countless other pharmacies do so too. *See* Davidson Decl. ¶ 89; Franck Decl. ¶¶ 46, 131; Pelphrey Decl. ¶ 15. Nor can it dispute that compounding from bulk ingredients is expressly permitted under Florida law, *see* Fla. Admin. Code r. 64B16-27.700(3); Allen Decl. ¶ 80; Davidson Decl. ¶¶ 24, 29, 33, 41, 47, 53, 90, taught at pharmacy schools, *see* Davidson Decl. ¶ 3, and widely recognized as an appropriate and traditional part of pharmacy practice. *See* Stoothoff Decl. ¶¶ 14–17; Davidson Decl. ¶¶ 35–39, 43, 53–79. Federal law expressly permits compounding of human drugs from bulk ingredients, *see* 21 U.S.C. § 353a, and FDA offers no reason for treating

compounding medications for non-food-producing animals from bulk ingredients as a public health emergency requiring extraordinary relief. *See* Bradshaw Decl. ¶¶ 10, 44–46; Pelphrey Decl. ¶ 26; Powers Decl. ¶ 48.

Moreover, by FDA's own admission, it has known that Franck's has been compounding animal drugs from bulk ingredients since at least 2004. *See* FDA Br. 7–8. Franck's has not tried to hide that practice; it is perfectly lawful. Even though Franck's told FDA in writing that it intended to continue compounding using bulk ingredients and invited FDA to contact Franck's "immediately" with any concerns, FDA declined that invitation. *See* Franck Decl. ¶ 104. FDA has identified no material change in circumstances that could justify shutting down a business that for the last five years it has apparently not viewed as posing any risk to the public. *See* Franck Decl. ¶¶ 80–93. FDA's request for injunctive relief thus seeks to drastically change, not preserve, the status quo. *All Care Nursing Serv., Inc. v. Bethesda Mem'l Hosp., Inc.*, 887 F.2d 1535, 1537 (11th Cir. 1989) (preliminary injunctions "issued when drastic relief is necessary to preserve the status quo").

Failing to make any showing that Franck's state-approved compounding practices are medically inappropriate, FDA focuses on an unfortunate incident involving polo horses. *See* FDA Br. 9. But that isolated incident a year and a half ago was a mis-fill that resulted from a mathematical error that has nothing to do with the fact that "bulk ingredients" were used to compound the prescription. *See* Powers Decl. ¶ 43; Franck Decl. ¶¶ 106–108; Davidson Decl. ¶ 93. FDA has not alleged facts tying the incident to an alleged statutory violation. Nor can it deny that the incident was investigated by State Boards of Pharmacy, *see* Powers Decl. ¶¶ 42–49; Franck Decl. ¶ 108; Davidson Decl. ¶ 93; that Franck's has paid a fine; and

that Franck's has been found to be in compliance with state requirements for compounding. *See* Powers Decl. ¶¶ 43–45; Franck Decl. ¶¶ 108–110; Davidson Decl. ¶ 93.

Nor has FDA shown an imminent risk that such a mis-fill will happen again or of any other future harm. *Siegel*, 234 F.3d at 1176–77; *see also* Pelphrey Decl. ¶ 22. Although Franck's twice verified the prescription with the veterinarian, a staff member misread the prescription because it was stated at concentration levels that followed foreign (not domestic) standards. *See* Franck Decl. ¶¶ 106–107. This unusual confluence of events is unlikely to recur but, in any event, to avoid any risk of recurrence, Franck's has implemented new standard operating procedures and policies. An independent third-party audited Franck's facilities, policies, and procedures in June 2009, and the audit confirmed that Franck's has adequate and well-controlled compounding practices. *See* Franck Decl. ¶ 110. Nothing in FDA's motion purports to disagree.

Second, an injunction would impose substantial and irreparable harm on Franck's. Franck's has cultivated goodwill and longstanding customer relationships that would be destroyed if Franck's is forced to shut down half its business while this case is litigated. *See* Franck Decl. ¶¶ 128, 130**;** *Ferrero v. Associated Materials Inc.*, 923 F.2d 1441, 1449 (11th Cir. 1991) (irreparable harm due to loss of goodwill and long time customers). If the Court enters a preliminary injunction, Franck's will likely have to sell equipment and lay off more employees. *See* Franck Decl. ¶ 129; *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1381 (Fed. Cir. 2006) (irreparable harm where evidence established potential employee lay-offs); *Quickie Mfg. Corp. v. Libman Co.*, 180 F. Supp. 2d 636, 651 (D.N.J. 2002) (balance of harm favors party where injunction "would likely precipitate layoffs" of 30 employees).

Moreover, the adverse publicity associated with an injunction would likely affect other aspects of Franck's business and its competitive standing. *See* Franck Decl. ¶ 130; *Shell Oil Co. v. Altina Assocs., Inc.*, 866 F. Supp. 536, 541 (M.D. Fla. 1994) (adverse publicity is irreparable harm); *Dominion Video Satellite, Inc. v. Echostar Satellite Corp.*, 356 F.3d 1256, 1263 (10th Cir. 2004) (irreparable harm includes "diminishment of competitive positions").

Third, granting an injunction would be inconsistent with the broader public interest. *Salazar*, 130 S. Ct. at 1816 (court should be "particularly cautious when contemplating relief that implicates public interests"). An injunction would deprive thousands of veterinarians and animal owners of the high quality compounding services that Franck's provides. *See* Stoothoff Decl. ¶¶ 18–20; Pelphrey Decl. ¶¶ 18, 23–26; Allen Decl. ¶ 81–82; Powers Decl. ¶¶ 47–49; Davidson Decl. ¶¶ 88, 92, 95; Franck Decl. ¶ 135. It also would generate substantial uncertainty in the pharmacy profession over the continued validity of state laws expressly permitting pharmacies to compound animal drugs from bulk ingredients. Davidson Decl. ¶¶ 90–91; Stoothoff Decl. ¶ 21; Pelphrey Decl. ¶¶ 24–25. Even more fundamentally, granting an injunction would defy the strong public interest in ensuring that the government does not selectively enforce non-existent or vague prohibitions and that administrative agencies comply with proper notice-and-comment rulemaking when seeking to impose binding rules on the public.

CONCLUSION

For these reasons, and the additional reasons set forth in Franck's motion to dismiss, FDA's request for the extraordinary remedy of a preliminary injunction should be denied.

Respectfully submitted,

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