

Case No. 11-15350 BB

**IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT**

UNITED STATES OF AMERICA,
Plaintiff-Appellant,

v.

FRANCK'S LAB, INC. AND PAUL W. FRANCK,
Defendants-Appellees.

**On Appeal from the United States District Court
for the Middle District of Florida
Case No. 10-CV-147-Oc-32TBS
Hon. Timothy J. Corrigan, District Judge**

**BRIEF OF WASHINGTON LEGAL FOUNDATION
AS AMICUS CURIAE IN SUPPORT OF DEFENDANTS-APPELLEES,
URGING AFFIRMANCE**

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**CIRCUIT RULE 26.1 CERTIFICATE OF INTERESTED PERSONS AND
CORPORATE DISCLOSURE STATEMENT**

Pursuant to Fed. R. App. P. 26.1 and 11th Cir. R. 26.1, the undersigned counsel certifies that Washington Legal Foundation (WLF) is a non-profit corporation organized under Section 501(c)(3) of the Internal Revenue Code; it has no parent corporation, does not issue stock, and no publicly held company enjoys a 10% or greater ownership interest.

The undersigned counsel further certifies that, in addition to the parties and entities identified in the Certificates of Interested Persons filed by Appellant and Appellees, the following persons and entities may have an interest in the outcome of this case:

- a. WLF (*amicus curiae*)
- b. Cory L. Andrews (counsel for *amicus curiae*)
- c. Richard A. Samp (counsel for *amicus curiae*)

/s/ Richard A. Samp
Richard A. Samp

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* Authorities upon which we chiefly rely are marked with asterisks.

**BRIEF OF WASHINGTON LEGAL FOUNDATION
AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS-APPELLEES,
URGING AFFIRMANCE**

INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a non-profit public interest law and policy center with supporters in all 50 states.¹ WLF devotes a substantial portion of its resources to defending free enterprise principles, individual rights, a limited and accountable government, and the proper use of our state and federal administrative systems. To that end, WLF has frequently appeared in this and other federal and state courts to ensure that administrative agencies adhere to the rule of law. *See, e.g., Shinseki v. Sanders*, 556 U.S. 396 (2009).

In particular, WLF focuses much of its work on the activities of the Food and Drug Administration (FDA). WLF has repeatedly criticized FDA for failing to comply with the Administrative Procedure Act (APA) when adopting new rules intended to have broad application. For example, litigation filed by WLF on behalf of patients and doctors forced FDA in 1994 to retract rules regarding the regulation of allograft heart valves, after FDA conceded that it had not complied with the

¹ Pursuant to Federal Rule of Appellate Procedure 29(c), WLF states that no counsel for any party authored this brief in whole or in part, and that no person or entity, other than WLF and its counsel, made a monetary contribution intended to fund the preparation and submission of this brief. All parties to this dispute have consented to the filing of this brief.

APA's notice-and-comment procedures. *Washington Legal Found. v. Shalala*, No. 93-5279 (D.C. Cir. 1994); *see also Prevor v. FDA*, No. 11-1187 (D.D.C., dec. pending). Since 2006, WLF has operated its "OPDP Watch" project, which critiques warning letters and "untitled" letters issued by FDA's Office of Prescription Drug Promotion (formerly known as DDMAC). A recurring theme of WLF's critiques is that OPDP regularly announces new legislative rules by means of its warning letters, yet does so without abiding by the APA's notice-and-comment procedures.

WLF views the enforcement action below as yet another example of FDA's attempting to enforce a new, legislative rule without complying with the APA's notice-and-comment procedures. For more than 50 years after the 1938 adoption of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (FDCA), FDA said nothing to suggest that traditional pharmacy compounding was subject to FDA regulation. FDA now claims, however, that *any* compounding of animal medications from bulk substances is a *per se* violation of the FDCA, even when conducted by a state-licensed pharmacist for an individual animal patient pursuant to a valid veterinary prescription.

WLF is concerned that allowing regulatory agencies to abruptly change their interpretations of statutes, without the formal protections of notice-and-comment

rulemaking, threatens to significantly undercut the predictability that has long been a hallmark of our common law system. WLF fears that if administrative agencies come to believe that formal rulemaking procedures are too cumbersome or inconvenient to follow, and are instead permitted to disrupt settled expectations and impose new substantive requirements under the pretense of merely reinterpreting existing law, an important safeguard for our representative system of government will be lost.

WLF is unfamiliar with the operations of Defendants-Appellees Franck's Lab, Inc., *et al.* ("Franck's") and thus takes no position regarding whether Franck's engages only in traditional pharmacy compounding or whether its operations are more appropriately classified as drug manufacturing. That issue, however, was not litigated below and is not now before the Court. Rather, the issue is whether Congress, when it adopted the FDCA, intended to ban all pharmacy compounding – even the type of compounding in which pharmacies have traditionally engaged for hundreds of years and which FDA concedes “serves important health purposes.” U.S. Br. 3. WLF is highly concerned by the position adopted by FDA: that the thousands of pharmacies that have engaged in compounding over the past 75 years are all criminals, and that they can avoid prosecution only if FDA, in its sole discretion, decides to exercise its enforcement discretion not to prosecute.

Such broad, unreviewable discretion is subject to serious abuse, and is the antithesis of modern administrative law.

WLF also writes to emphasize that FDA's position that all compounding of animal medications from bulk substances is a *per se* violation of the FDCA is not eligible for *Chevron* deference. FDA never put any party on notice that it was planning to enforce such a categorical prohibition, never amended its implementing regulations, and never solicited comments about its new interpretation of the FDCA. Granting *Chevron* deference under such circumstances would be inappropriate.

STATEMENT OF THE CASE

The case is before the Court on appeal from the district court's order denying the United States' motion for summary judgment and granting Franck's motion for summary judgment. *See* Doc. 68.

Franck's is a Florida-based compounding pharmacy licensed to distribute drugs in 47 states. In accordance with Florida law, Franck's compounds medications only in response to a valid prescription from a licensed veterinarian to treat an individual animal, or in limited quantities in anticipation of future need. Franck's veterinary compounding practice is strictly limited to medicines for non-

food-producing animals. Franck's remains a pharmacy in good standing in Florida, which closely regulates pharmacies within the State.

In April 2010, the United States filed a complaint in the Middle District of Florida seeking a permanent injunction against Franck's, alleging that *any* veterinary compounding from bulk ingredients violates the FDCA. *See* Doc. 1. Franck's moved to dismiss; the United States moved for preliminary injunction. *See* Doc. 13, Doc. 16. The district court denied the parties' preliminary motions and directed the parties to confer. Both parties agreed that the lawsuit hinged entirely on a question of statutory interpretation, which could be resolved (without discovery) on cross-motions for summary judgment; the parties filed a joint statement of undisputed facts and cross-moved for summary judgment. *See* Doc. 55.

Following a two-hour hearing, the district court issued a lengthy order granting summary judgment for Franck's and denying summary judgment for the United States. *See* Doc. 68. The court began by noting that although the complaint alleged that Franck's had "engaged in conduct indicative of a manufacturer of drugs in advance of a valid prescription," the United States had "provided no factual support for such claims and ultimately does not rely on them." *Id.* at 39. The court went on to explain that, because the government expressly disclaimed

relying on any factual or legal basis of enforcement besides the text of the FDCA, “this enforcement action could just as easily have been brought against a state-licensed ‘Mom and Pop’ pharmacy for filling, through bulk compounding, one veterinary prescription for one horse.” *Id.*

Reaching the merits, the court held that the FDCA, originally enacted in 1938, does not authorize FDA to enjoin Franck’s from engaging in traditional compounding of animal medications from bulk. Thoroughly examining the FDCA’s text, structure, purpose, and legislative history, the court ultimately concluded that Congress did not “give the FDA the authority to enjoin traditional pharmacy compounding of animal drugs, a practice never before regulated by a federal agency and never before mentioned in the FDCA.” *Id.* at 70. The court noted that “[e]very court that has addressed the issue . . . has recognized that the FDA new drug approval process is an ‘especially poor fit’ for regulating traditional pharmacy compounding, one that would potentially eradicate compounding despite the recognized importance, historical acceptance, and decades-long state regulation of the practice.” *Id.* at 56-57.

Rejecting FDA’s “expansive view of its statutory authority,” the court concluded that “FDA cannot simply upset the expectations it helped to create through decades of inaction without explanation, especially where its asserted

expansion of authority impacts the federal-state balance and potentially subjects many individuals and companies to criminal liability.” *Id.* at 76. Merely relying on FDA’s enforcement discretion, the court held, “openly invites arbitrary enforcement, which is antithetical to our system of criminal justice.” *Id.*

SUMMARY OF ARGUMENT

The question before the Court is, “Did Congress, when it adopted the FDCA, intend to prohibit *all* pharmacy compounding for treatment of animals?” The sole piece of evidence that FDA can point to in support of its affirmative response to that question is the broad definition provided by 21 U.S.C. § 321(v) to the term “new animal drug.” That provision, however, makes no reference to compounding. When one considers the entire statutory text, as well as the purpose and context of the FDCA, it is readily apparent that Congress did not intend to prohibit all compounding. That context includes: (1) the long history of widespread pharmacy compounding (both before and after the FDCA’s adoption) and its extensive regulation by the States; (2) the FDCA’s failure to make any direct references to compounding; (2) the absence of any indication in the legislative history that Congress intended to regulate compounding; (3) FDA’s failure for the first 50 years following adoption of the FDCA to assert any regulatory authority over pharmacy compounding; (4) evidence that adoption of

the FDCA was motivated by concern over the sale of *unregulated* drugs – at a time when products dispensed by pharmacies were closely regulated by the States; and (5) Congress’s decision to provide explicitly in the FDCA that pharmacies were exempt from a number of the regulatory requirements imposed on drug manufacturers.

Indeed, FDA’s repeated endorsements of the public-health value of pharmacy compounding are a tacit admission that even *FDA* does not believe that Congress intended to prohibit all compounding. Rather, in asserting that pharmacy compounding is *per se* illegal but at the same time stating that (in an exercise enforcement discretion) it will refrain from prosecuting pharmacists who engage in “traditional” compounding, its position amounts to an assertion that Congress granted FDA unreviewable authority to decide when pharmacy compounding is and is not in the public interest. That position runs contrary to long-established traditions of modern administrative law. Since passage of the Administrative Procedure Act (APA), the sustained effort of administrative law has been to “continuously narrow the category of actions considered to be so discretionary as to be exempted from review.” Shapiro, *Administrative Discretion: The Next Stage*, 92 *YALE L.J.* 1487, 1489 n.11 (1983). Granting any administrative agency such

broad and unreviewable discretion is an invitation to abuse, and it is highly unlikely Congress intended to do so.

WLF agrees with the district court that FDA possesses “the authority to prohibit pharmacists from manufacturing under the guise of compounding.” Doc. 68 at 49. FDA may yet prevail should it choose to bring an enforcement action against Franck’s based on a theory that Franck’s is not engaged in traditional compounding. In this case, however, FDA foreswore any effort to draw a line between manufacturing and compounding and to demonstrate that Franck’s falls on the manufacturing side of the line. Instead, it has based its action on an untenable interpretation of the FDCA that declares all pharmacists to be criminals.

Moreover, even if FDA’s interpretation were plausible, its failure to adopt that interpretation in compliance with the APA precludes it from asserting that interpretation in this case. FDA adopted its current position (that all pharmacists who engage in compounding are criminals) no earlier than 1992. For the preceding 54 years, it interpreted the FDCA to be inapplicable to traditional pharmacy compounding undertaken under the auspices of state regulators. Under those circumstances, the APA requires FDA to engage in notice-and-comment rulemaking before it can adopt a contrary interpretation. FDA has never engaged in such rulemaking – or even issued its long-promised revised draft Compliance

Policy Guide that would provide stakeholders at least some opportunity to comment on the ramifications of FDA's new interpretation.

FDA also argues that its new interpretation is entitled to *Chevron* deference. That position is without merit. Deference is unwarranted because the new interpretation was not the product of any sort of formal proceedings. FDA did not place parties on notice that it intended to enforce a *per se*, unreviewable prohibition on pharmacy compounding; did not amend any implementing regulations; and did not solicit comments about its new interpretation of the FDCA. At most, FDA's position is entitled to respect to the extent that it is persuasive. For all the reasons stated herein, FDA's position is not persuasive.

ARGUMENT

I. THE FDCA DOES NOT IMPOSE A *PER SE* PROHIBITION AGAINST PHARMACISTS FILLING A VETERINARIAN'S PRESCRIPTION BY COMPOUNDING FROM BULK SUBSTANCES

As the Supreme Court has recognized, compounding – the combining of ingredients to create a medication tailored to the needs of an individual human or animal patient – is “a traditional component of the practice of pharmacy, and is taught as part of the standard curriculum at most pharmacy schools.” *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 361 (2002). Indeed, the mortar and pestle

– tools traditionally used to compound drugs – have long been one of the most pervasive symbols of pharmacology.

FDA has advanced a single legal theory in this lawsuit: that Franck’s is violating the FDCA by compounding animal drugs because *all* compounding of animal drugs from bulk substances violates the FDCA, regardless whether (as Franck’s claims) it is simply engaged in “traditional” compounding practices. That legal theory is untenable.

A. Congress Cannot Plausibly Be Understood To Have Intended, in Adopting the FDCA, To Criminalize Traditional Compounding Practices

The FDCA, adopted in 1938, regulates drug manufacturing, marketing, and distribution. Section 505(a) of the FDCA provides that “[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed [with FDA] is effective with respect to such drug.” 21 U.S.C. § 355(a). The FDA very broadly defines the terms “new drug” and “new animal drug.” 21 U.S.C. §§ 321(p) & 321(v)(1). All agree that pharmacies compounding drugs for individual people and animals cannot realistically obtain “new drug” approval from FDA for their compounded products. Accordingly, if the FDCA is construed so as to encompass traditional

compounding practices, all traditional pharmacy compounding (with a few very limited exceptions) would constitute criminal activity.

For at least the first 54 years following adoption of the FDCA, FDA did not claim that the FDCA provided it with regulatory authority over traditional pharmacy compounding, an activity that was closely regulated by the States. As the district court noted, in the early 1990s FDA began to be concerned “that some pharmacies were manufacturing and selling drugs under the guise of compounding, thereby avoiding the FDCA’s new drug requirements.” Doc. 68 at 16 (quoting *Western States*, 535 U.S. at 362). In response, FDA in 1992 issued Compliance Policy Guide 7132.16, which stated that “FDA may, in the exercise of its enforcement discretion, initiate federal enforcement actions . . . when the scope and nature of a pharmacy’s activities raises the kinds of concerns normally associated with a manufacturer.” In ensuing years, FDA has taken an increasingly aggressive regulatory position with respect to pharmacy compounding; a 2003 guidance document asserted that *all* compounding for animals from bulk substances violates the FDCA. This enforcement action marks FDA’s first effort to establish a *per se* rule prohibiting all pharmacy compounding for animals.

The sole piece of evidence that FDA can point to in support of its *per se* rule is the broad definition provided by 21 U.S.C. § 321(v) to the term “new animal

drug.” That provision, however, makes no reference to compounding. It states that the term “new animal drug” means “any drug intended for use for animals other than man” that meets several additional requirements, but nothing in the provision expressly states that Congress intended the words “any drug” to encompass the products of traditional pharmacy compounding. When one considers the entire statutory context, it becomes evident that Congress had no such intent.

The Supreme Court has repeatedly warned against basing statutory construction on isolated words within the statute. For example, in *Dolan v. U.S. Postal Service*, 546 U.S. 481 (2006), the Court was asked to construe a federal statute that preserved federal sovereign immunity from claims arising out of “negligent transmission” of letters or postal matter. The Court conceded that when considered in isolation, the words “negligent transmission” would most naturally be read broadly to cover “a wide range of negligent acts committed by the Postal Service in the course delivering mail, including creation of slip and fall hazards.” 546 U.S. at 486. The Court cautioned against such statutory construction methods, however:

The definition of words in isolation, however, is not necessarily controlling in statutory construction. A word in a statute may or may not extend to the outer limits of its definitional possibilities. Interpretation of a word or

phrase depends upon reading the whole statutory text, considering the purpose and context of the statute, and consulting any precedents or authorities that inform the analysis.

Id. Taking into account those other factors, the Court concluded that “both context and precedent require a narrower reading” of the term “negligent transmission” than one would have assigned to the term if considered in isolation. *Id.*

When one considers the entire statutory text, as well as the purpose and context of the FDCA, it is readily apparent that Congress did not intend to prohibit all compounding. Perhaps the strongest piece of evidence that cuts against FDA’s interpretation of the statute is the absence of legislative history (or any other sort of contemporary history) suggesting that Congress was intending to outlaw a widespread practice that was regulated and endorsed by governments in all 50 States. As the district court indicated, it is highly unlikely that Congress intends to hide “an elephant in a mousehole” in this fashion. Doc. 68 at 54-58. That is, if Congress intends to undertake a wholesale revision of an existing regulatory regime, it is highly unlikely to hide that intent. *See Whitman v. American Trucking Ass’ns, Inc.*, 531 U.S. 457, 468 (2001) (“Congress . . . does not . . . hide elephants in mouseholes.”).

Another strong indication that Congress did not intend the FDCA to prohibit all pharmacy compounding: for more than 50 years after adoption of the statute, FDA never asserted any regulatory authority over traditional pharmacy compounding; instead, pharmacy compounding continued to be subject to state regulation, just as it had been prior to adoption of the FDCA. If, as directed to do by *Dolan*, one looks to judicial precedent, the Supreme Court's decision in *Western States* provides strong support for the view that the FDCA does not apply to traditional compounding. The Court opined that it would be nonsensical to require compounded products to go through FDA's normal new drug approval process:

[I] would not make sense to require compounded drugs created to meet the unique needs of individual patients to undergo the testing required for the new drug approval process. Pharmacists do not make enough money from small-scale compounding to make safety and efficacy testing of their compounded drugs economically feasible, so requiring such testing would force pharmacists to stop providing compounded drugs.

Western States, 535 U.S. at 369-70. The Court interpreted the FDCA as indicative of a congressional intent to, on the one hand, prevent pharmacists from engaging in drug manufacturer under the guise of compounding and, on the other hand, to preserve the important public health benefits provided by the availability of compounding:

Preserving the effectiveness and integrity of the FDCA's new drug approval process is clearly an important governmental interest, and the Government

has every reason to want as many drugs as possible to be subject to that approval process. The government also has an important interest, however, in permitting the continuation of the practice of compounding so that patients with particular needs may obtain medications suited to those needs.

Id.

FDA also relies on subsequent amendments to the FDCA in support of its interpretation of the statute. That reliance is misplaced. The Animal Medicinal Drug Use Clarification Act of 1994 (“AMDUCA”), Pub. L. No. 103-396, 108 Stat. 4153, makes no mention whatever of compounding or bulk materials. Its largely unrelated purpose: permitting off-label uses of FDA-approved human and animal drugs in the treatment of animals. 21 U.S.C. §§ 360b(a)(4) and (a)(5). The other statute relied on by FDA, the Food and Drug Modernization Act of 1997 (FDAMA), Pub. L. No. 105-115, 111 Stat. 2296, actually cuts against FDA’s position. Its compounding provisions were included because Members of Congress were concerned that FDA was going too far in its efforts to restrict traditional pharmacy compounding. All indications suggest that Congress believed that the FDCA already permitted traditional pharmacy compounding, not that FDAMA authorized a previously forbidden practice. FDAMA included provisions explicitly protecting traditional pharmacy compounding of human drugs. *See* 21 U.S.C. § 353a. There is no plausible inference that Congress intended thereby to

afford a disfavored status to animal compounding, particularly because the health risk inherent in compounding products for non-feed animals are far lower than the health risks inherent in compounding products for human. Rather, the more plausible explanation is that Congress focused on the latter because it was a more pressing concern among the pharmacists who had come to Congress for assistance in fending off FDA.

FDAMA includes a strong indication that Congress wanted to protect traditional compounding while at the same time protecting against large-scale compounding that was more akin to manufacturing: it imposed significant limitations on advertising or promotion of pharmacy compounding as a means of limiting the ability of pharmacies to develop large-scale compounding operations. 21 U.S.C. § 353a(c). That provision (which was struck down by *Western States* on First Amendment grounds) indicates that Congress did not believe that Congress viewed traditional pharmacy compounding as a violation of the FDCA.

B. FDA’s Assertion of Unreviewable Authority to Decide When Pharmacy Compounding Is Permissible Is an Invitation to Abuse

FDA’s repeated endorsements of the public-health value of pharmacy compounding are a tacit admission that even *FDA* does not believe that Congress

intended to prohibit all compounding. *See, e.g.*, U.S. Br. 3 (“FDA has recognized that compounding serves important health purposes by meeting the medical needs of human and animal patients for whom commercially available, approved drugs may be inadequate.”) FDA cannot plausibly claim that it really believes that Congress intended to adopt a *per se* ban on traditional pharmacy compounding if the health benefits of such compounding are so widely recognized.

Rather, in asserting that pharmacy compounding is *per se* illegal but at the same time stating that (in an exercise of enforcement discretion) it will refrain from prosecuting pharmacists who engage in “traditional” compounding, FDA’s position amounts to an assertion that Congress granted it unreviewable authority to decide when pharmacy compounding is and is not in the public interest. That position runs contrary to long-established traditions of modern administrative law. Since passage of the Administrative Procedure Act (APA), the sustained effort of administrative law has been to “continuously narrow the category of actions considered to be so discretionary as to be exempted from review.” Shapiro, *Administrative Discretion: The Next Stage*, 92 YALE L.J. 1487, 1489 n.11 (1983). Granting any administrative agency such broad and unreviewable discretion is an invitation to abuse, and it is highly unlikely Congress intended to do so.

The Supreme Court has held that the FDA's decisions regarding whether to initiate enforcement proceedings are largely left to FDA's discretion and are not reviewable by the courts. *Heckler v. Chaney*, 470 U.S. 821 (1985). In explaining its decision, the court discussed the factors (factors "peculiarly within [an agency's] expertise") that an agency must consider when deciding whether to bring an enforcement action, including "whether the agency is likely to succeed if it acts, whether the particular enforcement action requested best fits the agency's overall policies, and, indeed, whether the agency has enough resources to undertake the action at all." *Id.* at 831. None of those factors are even remotely similar to the discretionary enforcement authority that FDA seeks to exercise with respect to pharmacy compounding: unreviewable authority to decide when pharmacy compounding is not in the public interest and therefore should be prosecuted. Instead, when it delegates enforcement authority to an administrative agency, the normal practice is for Congress to require the agency to establish clear rules regarding what activities are prohibited and then to abide by those rules.

The Supreme Court has repeatedly warned against the dangers of providing unlimited discretion to government officials not only to decide when to bring enforcement actions but also to decide what constitutes a violation of the law, because, *inter alia*, such discretion can lead to discriminatory enforcement. *See*,

e.g., Kolender v. Lawson, 461 U.S. 352 (1983). As Justice Marshall asserted in his concurring opinion in *Heckler*, “Law has reached its finest moments when it has freed men from the unlimited discretion of some rule, some civil or military official, some bureaucrat.” *Heckler*, 470 U.S. at 848 (Marshall, J., concurring in the judgment). It is simply not plausible that Congress, when it adopted the FDCA, overlooked all the dangers of unbridled administrative discretion, declared an entire class of businesspeople to be criminals, and then left it to FDA to decide which criminals were promoting the public good (and should therefore not be prosecuted) and which criminals were undermining public health and deserved to go to jail.

II. FDA SHOULD NOT BE ALLOWED TO CIRCUMVENT THE IMPORTANT NOTICE-AND-COMMENT PROTECTIONS OF THE ADMINISTRATIVE PROCEDURE ACT

Even if Congress had implicitly delegated authority to FDA to regulate traditional pharmacy compounding of animal medications, the agency has never promulgated rules to this effect through notice-and-comment rulemaking. Rather, FDA has relied on non-binding guidance documents to vaguely suggest certain prohibitions that the agency now seeks to enforce for the first time in this litigation. FDA’s desire to use guidance in lieu of rulemaking is understandable; guidance documents involve less effort to promulgate, are subjected to less review, and can

be revised more readily. But ease of use does not excuse FDA from the need to comply with administrative law. Under the Administrative Procedure Act (APA), 5 U.S.C. § 500 *et seq.*, an agency cannot enforce new substantive requirements revealed in guidance documents without first complying with notice-and-comment rulemaking. *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1028 (D.C. Cir. 2000).

Hundreds of pharmacies across the country compound animal medications from bulk under the imprimatur of state law, and have done so without interference by the FDA for over seventy years. *See* Doc. 68 at 75. As Judge Richard Posner has observed, while it may be “possible for an entire industry to be in violation of [federal law] for a long time without the [implementing agency] noticing,” the “more plausible hypothesis is that the . . . industry has been left alone” because it was fully compliant. *Yi v. Sterling Collision Ctrs., Inc.*, 480 F.3d 505, 510-11 (7th Cir. 2007). Here, FDA’s 70-year acquiescence only further confirms that Congress enacted the FDCA to regulate the previously unregulated business of drug manufacturing, not to displace the states from their traditional regulation of pharmacy compounding.

Nevertheless, FDA now seeks to impose a brand new rule of general applicability. According to the Government’s complaint (Doc. 1), Franck’s has

violated the FDCA merely by doing what it has always done, and what hundreds of similarly situated state-licensed pharmacies have done under the watchful eye of FDA for decades: compounding animal medications from bulk ingredients. But Congress, acting through the APA, has sought to guard against arbitrary and capricious regulation by requiring that an agency's modification of its prior interpretations may be accomplished only pursuant to the APA's notice-and-comment procedures. And this Court has long recognized that agencies cannot enforce "rules of general applicability" without satisfying the requirement of formal rulemaking. *Jean v. Nelson*, 711 F.2d 1455, 1476 (11th Cir. 1983).

"[T]he APA requires an agency to provide an opportunity for notice and comment before substantially altering a well-established regulatory interpretation." *Shell Offshore, Inc. v. Babbitt*, 238 F.3d 622, 629 (5th Cir. 2001). FDA's attempt here to reinterpret its authority under the FDCA is unquestionably a "substantive" prohibition because it seeks to impose new obligations on the regulated public. *See, e.g., Paralyzed Veterans of Am. v. D.C. Arena L.P.*, 117 F.3d 579, 588 (D.C. Cir. 1997); *Chamber of Commerce v. OSHA*, 636 F.2d 464, 468 (D.C. Cir. 1980). But a regulatory agency that imposes new substantive duties on the regulated public may do so only pursuant to notice-and-comment rulemaking. *See, e.g., Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 95 (D.C. Cir. 1997); *Cnty. Nutrition*

Inst. v. Young, 818 F.2d 943, 946 (D.C. Cir. 1987). When, as here, an agency relies on a novel statutory interpretation that “produce[s] other significant effects on private interests,” that agency may proceed only by satisfying the formal requirements of notice-and-comment rulemaking. *Nat’l Family Planning & Reprod. Health Ass’n v. Sullivan*, 979 F.2d 227, 238-29 (D.C. Cir. 1992).

WLF is not alone in its view that FDA must comply with notice-and-comment rulemaking before seeking to enforce new substantive requirements. FDA has itself conceded that formal rulemaking is needed. Following the release of its 2003 Compliance Policy Guide, Franck’s and several other compounding pharmacists, veterinarians, and related trade groups wrote letters to both Congress and FDA, complaining that the policies outlined in the non-binding 2003 Guide “would cause many animal patients to suffer needlessly.” Doc. 68 at 31. As a result, more than seventy members of Congress wrote separately to FDA. Many found it “disconcerting” that the 2003 Guide was “put into effect without the opportunity for public review and comment by stakeholders.” *Id.* In response, FDA issued the following notice in September 2004:

FDA is announcing its intention to draft and publish for public comment a revised Compliance Policy Guide (CPG) on veterinary pharmaceutical compounding. FDA anticipates that the draft CPG will be available for comment in the Fall of 2004.

The current CPG, published in July 2003, describes FDA's present thinking on what types of veterinarian compounding might be subject to enforcement action. FDA has received numerous letters from veterinarians, pet owners, compounding pharmacists, and associations expressing concern that the CPG lacks sufficient clarity on the circumstances in which veterinary compounding, particularly from bulk drugs, would be permitted. Many of the letters also disagreed with the current policy, stating that it was not within FDA's legal authority, and complained about the lack of prior public comment. *After meeting with several groups and considering the comments in the letters it has received FDA concluded that issuing a revised CPG is appropriate.*

CVM Updates: *FDA to Revise Its Compliance Policy Guide on Veterinary Compounding*, September 1, 2004, available at <http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm048425.htm> (last visited April 2, 2012) (emphasis added).

Despite promising to do so, FDA neither issued nor even proposed any form of revised guidance on veterinary compounding in the fall of 2004. In June 2005, twenty-six Senators and seventy-two members of Congress wrote to FDA to convey their frustrations over the agency's failure to revise the 2003 Guide and to subject it to proper notice-and-comment procedures. Noting that "pharmacists are being forced to operate under flawed policy, potentially jeopardizing their livelihood and reputation in order to meet patients' essential medication needs," these lawmakers demanded that FDA "undertake an immediate review of the reasons behind these delays and take steps necessary to issue proposed CPG's for

public review and comment.” Doc. 68 at 33. Nevertheless, FDA to date has never issued the revised guidance it promised in 2004, and apparently has no intention of doing so.

WLF is especially concerned about the enormous upheaval that FDA’s new interpretation of the FDCA will have on legitimate reliance interests among the affected stakeholders. Such concern is especially warranted where, as here, an agency’s abrupt, contradictory interpretation of the law creates an unfair surprise for those who had come to rely on that agency’s earlier acquiescence for well over half a century. As the district court aptly noted, “hundreds of compounding pharmacists like Franck’s—who had long been engaged in ‘traditional pharmacy compounding’ under the watchful eyes of state boards of pharmacy—invested in and grew their practices based on their expectations that compounding practices consistent with state law were authorized under federal law.” Doc. 68 at 67.

The case of *Alaska Professional Hunters Ass’n v. FAA*, 177 F.3d 1030 (D.C. Cir. 1999), is especially instructive here. Beginning in 1963, the FAA “consistently advised [Alaskan] guide pilots that they were not governed by regulations dealing with commercial pilots.” 177 F.3d at 1031. Alaskan guide pilots relied on this advice to start and expand their businesses. *Id.* at 1035. They and others within Alaska had opened hunting and fishing “lodges and built up

businesses dependent on aircraft, believing their flights were [not] subject to” certain commercial flight regulations. *Id.* Then, in January 1998, the FAA published a notice announcing that Alaskan guide pilots would have to comply with all regulations governing commercial pilots. *Id.* at 1033. This forced compliance would have driven Alaska's tourism operations out of business. The D.C. Circuit held that FAA’s explicit advice, consistently dispensed for over thirty years, represented more than a mere enforcement policy; it rose to the level of a well-established, definitive, and authoritative interpretation upon which the affected parties relied to their detriment. *Id.* at 1035. Accordingly, the court held that the agency could not change its long-standing interpretation without undertaking proper notice-and-comment proceedings. *Id.* at 1034. That same result should obtain here.

Ultimately, this case presents an issue that is far broader than the fate of one pharmacy and its efforts to prevent FDA from unilaterally overhauling the FDCA and outlawing, overnight, a traditional state-regulated practice. As the size of the administrative state continues to grow, it is vitally important that stakeholders continue to have a meaningful opportunity to participate in the operation of their government. The protections of notice and comment are an important part of that effort. They ensure that administrative agencies will be bound not only by the laws

adopted by Congress but also by the requirements of reasoned decision making, thereby leaving intact citizens' settled expectations until the agencies provide affected citizens appropriate notice of any proposed changes and a meaningful opportunity to comment.

But if administrative agencies come to believe that rulemaking procedures are too cumbersome or inconvenient to follow (as FDA apparently has here), and are instead permitted to disrupt settled expectations under the pretense of merely "reinterpreting" existing law, an important safeguard of our representative system of government will be lost. By affirming the district court, this Court can ensure that agencies produce rules and interpretations of those rules that are sufficiently "clear and definite so that affected parties will have adequate notice concerning the agency's understanding of the law." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 525 (1994) (Thomas, J., dissenting).

III. FDA'S CATEGORICAL PROHIBITION AGAINST PHARMACY COMPOUNDING LACKS THE FORCE OF LAW AND IS THUS UNDESERVING OF *CHEVRON* DEFERENCE

In *Chevron, U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984), the Supreme Court held that "ambiguities in statutes within an agency's jurisdiction to administer are delegations of authority to the agency to fill the statutory gap in reasonable fashion." *Nat'l Cable & Telecomms. Ass'n v.*

Brand X Internet Servs., 545 U.S. 967, 980 (2005) (citing *Chevron*, 467 U.S. at 865-66). All agency interpretations, however, are not entitled to deference. In *United States v. Mead Corp.*, 533 U.S. 218 (2001), the Court held that an agency’s interpretation of a statute qualifies for deference only “when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority.” 533 U.S. at 226-27; *see also Christensen v. Harris Cnty.*, 529 U.S. 576, 587-88 (2000).

Underlying *Mead*’s restriction of the scope of *Chevron* deference are two interrelated concerns. First, a court may defer to an agency’s interpretation of an ambiguous statute only when it is clear that Congress had granted the agency “the authority to promulgate binding legal rules.” *Brand X*, 545 U.S. at 980-81; *see also Mead*, 533 U.S. at 230-31 & n.11. The procedures that Congress instructs an agency to use furnish one indication that such a delegation has occurred. *See Mead*, 533 U.S. at 230 (“It is fair to assume generally that Congress contemplates administrative action with the effect of law when it provides for a relatively formal administrative procedure.”).

Importantly, even an agency exercising its delegated interpretive authority must nevertheless do so through administrative procedures designed to produce rules with the force of law. In *Mead*, for example, the Supreme Court observed that the Customs Service had a “general rulemaking power” by which it could make regulations with the force of law. 533 U.S. at 232. But the interpretations contained in agency rulings promulgated outside that power were *not* entitled to deference. The Court found it “difficult . . . to see in the agency practice itself any indication that [the agency] ever set out with lawmaking pretense in mind” when it made the interpretations. *Id.* at 233. Those interpretations were not themselves subject to the rigors of notice and comment, were of limited precedential value, and were issued with little deliberation. *Id.* at 233-34. In other words, administrative interpretations have the force of law, *i.e.*, are entitled to deference, only when they reflect “the fairness and deliberation that should underlie a pronouncement of such force.” *Id.* at 230.

Although a court may draw some inferences about the fairness and deliberation with which an agency has rendered an interpretation—and, thereby, the interpretation’s authority—from the procedures the agency employed, the Supreme Court has repeatedly emphasized that the inquiry does not end there. Interpretations found in non-binding pronouncements such as “opinion letters,”

“policy statements, agency manuals, and enforcement guidelines” are usually ineligible for Chevron deference. *See Christensen*, 529 U.S. at 587.

While “the presence or absence of notice-and-comment rulemaking” is not “dispositive;” *Barnhart v. Walton*, 535 U.S. 212, 222 (2002), what matters at a bare minimum is “the careful consideration the [a]gency has given the question.” *Id.* To be eligible for deference, then, the agency at least must have engaged in a rigorous analysis of the relevant law and must give precedential effect to those formal determinations. *See, e.g., Pesquera Mares Australes, Ltda. v. United States*, 266 F.3d 1372, 1380 (Fed. Cir. 2001).

In *Wyeth v. Levine*, 555 U.S. 555 (2009), the Supreme Court considered whether to accord deference to FDA’s interpretation of the scope of its own preemption authority. Even though FDA provided a notice of proposed rulemaking, it chose not to seek comment on the scope of permissible preemption. *Wyeth*, 555 U.S. at 1201. When FDA ultimately promulgated a final rule that “articulated a sweeping position on the [FDA’s] preemptive effect in the regulatory preamble,” the Court refused to give those pronouncements deference in light of FDA’s “procedural failure,” which made those pronouncements “inherently suspect.” *Id.* The same result should obtain here.

FDA has obviously failed to adopt its new interpretation of the FDCA

through procedures “reasonably suggesting that Congress ever thought of [such pronouncements] as deserving the deference claimed for them here.” *Mead*, 533 U.S. at 231. FDA never put any party on notice that it was planning to enforce such a categorical prohibition, never amended its implementing regulations, and never solicited comments about its new interpretation of the FDCA. To accord *Chevron* deference under these circumstances, would be to invite agencies to avoid using proper procedures such as notice-and-comment rulemaking simply by imposing new interpretations and substantive requirements on all affected stakeholders through the vehicle of an enforcement action brought against a single entity. Simply put, the scope of *Chevron* deference cannot reach so far.

CONCLUSION

For the foregoing reasons, WLF respectfully requests that the Court affirm the judgment below.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify pursuant to Federal Rule of Appellate Procedure 32(a)(7)(c) that the foregoing brief is in 14-point, proportionately spaced Times New Roman font.

According to the word processing software used to prepare this brief (Word Perfect), the word count of the brief is exactly 6,593 words, excluding the cover, corporate disclosure statement, table of contents, table of authorities, certificate of service, and this certificate of compliance.

/s/ Richard A. Samp
Richard A. Samp

CERTIFICATE OF SERVICE

I certify that on April 6, 2012, I transmitted the original and six copies of the foregoing *amicus curiae* brief to the Clerk of the U.S. Court of Appeals for the Eleventh Circuit by first-class mail and filed the brief through the Court's ECF system. I also electronically served the brief upon the counsel of record listed below through the ECF system and separately by e-mail.

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