UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
OCALA DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

vs. Case No. 5:10-cv-147-Oc-32TBS

FRANCK'S LAB, INC., et al.,

Defendants.

ORDER

In the seventy-plus years since Congress created the Food and Drug Administration, the FDA has never before sought to enjoin a state-licensed pharmacist from engaging in the traditional practice of bulk compounding of animal drugs. Here, the FDA seeks just such an injunction. This case of first impression implicates matters of statutory construction, federalism, and the proper deference to be afforded to the FDA in interpreting its enabling statute.

I. Facts and Procedural Posture

This statutory injunction proceeding is brought by the United States of America, on behalf of the FDA, against defendants Franck's Lab, Inc. d/b/a Franck's Compounding Lab ("Franck's") and Paul W. Franck, Franck's owner and CEO. Franck's is a pharmacy located in Ocala, Florida which compounds and distributes a wide variety of drugs for both humans and animals to customers across the United States.

The facts of this case are straightforward and largely undisputed. Mr. Franck, a

Florida-licensed pharmacist in good standing since 1981, opened an independent pharmacy practice in Archer, Florida in 1983. Over the next several years, Franck expanded his practice by purchasing or opening additional retail pharmacies, including a location in Ocala in 1985. That same year, Franck began to compound medications at the Ocala location for humans and "non food-producing animals" (such as horses). The Ocala pharmacy was later expanded into two practices which now comprise Franck's: Franck's Lab, which operates as a compounding pharmacy, and Franck's Pharmacy, which is a traditional retail pharmacy. At the time the FDA instituted this action, Franck's employed approximately 65 individuals full-time.

Animal and veterinary drug compounding comprises roughly 40 percent of Franck's Lab's business, while human drug compounding accounts for the remaining 60 percent.[1] Franck's compounds the majority of its animal medications from "bulk" active ingredients,[2] which it receives from suppliers outside the state of Florida. The company also receives prescription orders from customers outside Florida and ships its compounded products to those out-of-state customers. Franck's holds a valid pharmacy license in each of the 47 states in which it is required to do so, and, nationwide, fills approximately 37,000 animal drug

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[1] As will be discussed in greater detail infra, the FDA is not challenging Franck's practice of human drug compounding.

[2] The term "bulk," used in this context, does not refer to size, volume, or quantity; rather, it refers to the raw chemical materials used in the compounding process. See, e.g., 21 C.F.R. § 207.3(a)(4) (defining "bulk drug substance" as "any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug . . . ."). Compounding from bulk ingredients is sometimes referred to as "bulk compounding."

prescriptions per year.

The FDA first inspected Franck's compounding facilities between September 29 and October 4, 2004 and, in January 2005, issued a warning letter expressing concern that Franck's was impermissibly manufacturing drugs. (Doc. 17-1, Declaration of Emma Singleton[3] ("Singleton Dec."), Ex. E.) Among the FDA's concerns were: (i) Franck's practice of compounding veterinary drugs using bulk active pharmaceutical ingredients; (ii) that a number of those drugs "appear[ed] to be compounded outside the context of a valid veterinarian-client-patient relationship;" and (iii) that Franck's was compounding drugs where an approved drug would adequately treat the animal. (Id. at 1-2.)

Franck's responded by letter dated January 27, 2005, asserting its intention to be in full compliance with all FDA requirements. (Id. Ex. F.) However, Franck's also expressed disagreement with the FDA's position that bulk compounding of animal drugs was per se unlawful and noted that "[s]tate law and good compounding practices . . . allow bulk compounding as long as there is a valid patient physician (veterinarian) relationship." (Id. at 1.) Franck's further argued that, because "the FDA allows compounding by bulk chemicals for human use, . . . the same should apply to veterinary compounding." (Id.) Despite the disagreement, Franck's pledged: (1) to dispense compounded veterinary drugs only to licensed veterinarians pursuant to a "valid patient-veterinarian relationship"; (2) to compound from bulk only those drugs that were commercially unavailable; and (3) to place warning labels on its products to make clear that its compounds were "not to be used on food

[3] Director of the Florida District Office, United States Food and Drug Administration.

producing animals."[4] (Id. at 1-2.) In closing, Franck's stated:

> Again, it is Franck's intention to comply immediately and completely with any and all FDA and other legal requirements, and welcomes [sic] the FDA's involvement in these matters. I have tried to the best of my ability to address each item of concern in your letter. If I have fallen short on anything, if you have additional concerns which were not set forth in your letter, or if you have any other questions or concerns, please contact me immediately and I will see to it that we respond immediately, and to your complete satisfaction.

(Id. at 2.) FDA did not respond to Franck's' letter and did not take any further action against the pharmacy at that time.

In April 2009, a veterinarian commissioned Franck's to compound an injectable solution of the prescription drug Biodyl for the Venezuelan national polo team. Due to a mathematical error in the conversion of an ingredient (which went unnoticed by the prescribing veterinarian), the compounded medication was too potent and 21 polo horses died. The incident was thoroughly investigated by the Florida Board of Pharmacy, which imposed fines and reprimanded Franck's for the misfilled prescription.[5] Despite the reprimand, the Board voted to allow Franck's to continue its pharmacy compounding practice without restriction, and Franck's remains in good standing in Florida. The FDA has acknowledged that it was a mathematical error, as opposed to "faulty bulk drugs," which

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[4] On this third point, Franck's noted that it would provide such labeling even though it "does not compound for any food-producing animals." Id. at 2.

[5] James Powers, a member of the Florida Board of Pharmacy's two-person probable cause panel that preliminarily reviewed the polo pony incident, declared that: "After a thorough and careful review of all the facts, the Florida Board deemed the incident a misfill, a mathematical error in converting an ingredient. Nothing in our extensive investigation uncovered any information suggesting that the polo horse incident resulted merely because Franck's compounded the medication using bulk chemical ingredients." Doc. 31, Declaration of James B. Powers ("Powers Dec.") at ¶ 43.

caused the death of the polo ponies. (Doc. 47 at 27.)

Though the Florida Board of Pharmacy had investigated and resolved the matter to its satisfaction, the Venezuelan polo pony incident prompted the FDA to reinspect Franck's facilities three times: May 4–20, 2009; June 18–23, 2009; and December 1–4, 2009. Subsequent to the May inspection, the FDA issued Franck's a Form FDA 483 which contained five specific observations, none of which identified bulk compounding of animal drugs as a concern. (Singleton Dec. Ex. B.)[6]

Franck's responded to the Form 483 by letter dated June 12, 2009. (Id. Ex. C.) The letter stated that the pharmacy had "carefully considered the [FDA's] observations" and used them "to help further strengthen our operations." (Id. at 1.) However, Franck's noted that:

> the observations that FDA has outlined involve pharmacy practices that we must strenuously assert are regulated by the Florida Department of Health and Board of Pharmacy. We are concerned that FDA is attempting to assert authority over Franck's Pharmacy that it reserves for drug manufacturers. Put simply, we are a compounding pharmacy that fills prescriptions to meet the needs of individual patients; we are not a drug manufacturer. . . .
>
> The events that are the subject of the FD-483 observations [i.e., the polo pony incident] represent classic, traditional compounding. Franck's was filling a single prescription from a veterinarian specifically and solely for that veterinarian's patients. This was prototypical compounding . . . .
>
> The Florida Department of Health [conducted] its own inspection and [viewed] the incident as one relating to compounding. Even the FDA investigators orally acknowledged that the activities in question constituted compounding . . . .
>
> Franck's has been compounding human and veterinary drugs for more than 25 years to meet the special needs of doctors, veterinarians, and patients. We take both our obligations to our patients and our regulatory responsibilities very

[6] Rather, the FDA's concerns primarily involved perceived quality assurance and training issues. Id.

seriously.

(Id. at 2-4.) Without further response or discussion, FDA initiated this action in April of 2010, seeking to enjoin Franck's practice of distributing animal drugs compounded from bulk substances.[7]

After Franck's moved to dismiss the complaint (Doc. 13), the FDA sought a preliminary injunction (Doc. 16). The Court heard oral argument on August 18, 2010 (Doc. 43), the record of which is incorporated by reference. The Court subsequently denied both motions (Doc. 44) and, at the parties' request, postured the case for resolution via dispositive motions (Doc. 53). The parties then fully developed the record, each submitting declarations and other materials,[8] as well as a Joint Stipulation of Undisputed Facts (Doc. 55). Thereafter, the parties filed extensive cross-motions for summary judgment and responses thereto (Docs. 54, 56, 59, 60). The Court heard lengthy oral argument on the parties' cross-motions on February 24, 2011 (Doc. 61), the record of which is incorporated by reference.

II. The Record Allows for Disposition on Cross-Motions for Summary Judgment

The FDA acknowledges that this is the first time it has sought to enjoin a state-licensed pharmacist from bulk compounding of animal medications. Further, through its

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[7] More specifically, the FDA's complaint prays that this Court: "Permanently and perpetually restrain and enjoin, under 21 U.S.C. § 332(a), Defendants . . . from compounding, manufacturing, processing, packing, labeling, holding, or distributing articles of drug for use in animals, unless and until Defendants obtain appropriate FDA approvals for their drugs, or meet an appropriate exemption to the approval requirements . . . ." Doc. 1 at 11.

[8] The parties initially filed a number of declarations in connection with the FDA's motion for preliminary injunction. At the parties' request, all such earlier-filed record materials were deemed part of the summary judgment record. Doc. 49 ¶ 7; Doc. 53 ¶ 3.

development of the record and posturing of this case, the FDA has made clear that the legal violation it asserts is not contingent on any fact-specific grounds unique to Franck's. Rather, the FDA has taken the bright-line position that *any* compounding of animal medications from bulk substances violates its enabling statute, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq. ("FDCA"), even when conducted by a state-licensed pharmacist for an individual animal patient pursuant to a valid veterinary prescription. Franck's admits that it routinely engages in this practice, but contends that it does not violate the FDCA.

The FDA's evidentiary support for this action is primarily contained in two declarations that describe: (i) Franck's alleged violative history (as set forth infra, see Singleton Dec.);[9] and (ii) the FDA's rationale and asserted authority for regulating animal drug compounding, (see Doc. 17-2, Declaration of Dr. William Flynn[10] ("Flynn Dec.")). In response, Franck's submitted a number of declarations from veterinarians, pharmacists, and other expert and fact witnesses relating to, inter alia: (i) the FDA's historical acceptance of and shifting

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[9] Shortly before the August 18, 2010 preliminary injunction hearing, the FDA submitted two three-page affidavits purporting to show that Franck's had engaged in additional violative conduct. The first contains allegations that a Franck's pharmacist compounded a medication (Acetyl-D) for a veterinarian after Franck's had voluntarily suspended compounding pending the outcome of this case. See Doc. 24, Declaration of Dr. Robert C. Saunders. The second asserts that the Acetyl-D compound was an unapproved generic formulation of the commercially available drug product Adequan. See Doc. 23, Declaration of Dr. William T. Flynn. The ink was barely dry on Dr. Saunders' declaration when he filed a corrected declaration on behalf of Franck's, providing additional facts which demonstrated that *Franck's had not been the pharmacy that filled the prescription in question* and that the FDA had either (at best) misconstrued or (at worst) mischaracterized his statements. See Doc. 41, Supplemental Declaration of Dr. Robert B. Saunders; see also Doc. 39, Declaration of Kenneth Pettengill (the pharmacist who filled the prescription); Doc. 40, Declaration of Alexis Ells (the client for whom it was filled).

[10] Senior Advisor for Science Policy for FDA's Center for Veterinary Medicine ("CVM").

approach towards "traditional pharmacy compounding"; (ii) their understanding of the FDA's role in regulating the practice; (iii) the necessity of bulk compounding to provide life-saving treatment for non food-producing animal patients; (iv) the ubiquity of the practice of compounding animal drugs from bulk; and (v) the industry standards for quality control in the preparation of such compounded medications. (See Doc. 28, Declaration of Paul W. Franck ("Franck Dec."); Doc. 29, Declaration of Gigi S. Davidson[11] ("Davidson Dec."); Doc. 30, Declaration of Dr. Loyd V. Allen[12] ("Allen Dec."); Powers Dec.; Doc. 32, Declaration of Kevin Stoothoff, D.V.M.[13] ("Stoothoff Dec."); Doc. 33, Declaration of Rick Pelphrey, D.V.M.[14] ("Pelphrey Dec."); Doc. 35, Declaration of Sheldon T. Bradshaw[15] ("Bradshaw Dec.").)

Though the FDA had ample opportunity to dispute these assertions, it chose not to do so, resting instead on its position that compounding animal drugs from bulk—which Franck's admits it does—constitutes a per se violation of the FDCA. As a result, the statements contained in Franck's' declarations are largely uncontroverted in the record, and

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[11] Director of Clinical Pharmacy Services at North Carolina State University College of Veterinary Medicine; Society of Veterinary Hospital Pharmacists' 2003 representative on FDA Ad Hoc Committee on Veterinary Compounding.

[12] Licensed pharmacist; Editor-in-Chief of International Journal of Pharmaceutical Compounding ("IJPC"); former member of FDA's Pharmacy Compounding Advisory Committee.

[13] President, Marion County (Florida) Veterinary Medical Association.

[14] Equine veterinarian and owner of Harthill Company, a veterinary medicine practice located at Gate 5 of Churchill Downs.

[15] Co-Chair, Hunton & Williams LLP Food and Drug Practice Group; former Chief Counsel of the FDA.

where appropriate, the Court treats them as such.[16]

Because no material facts are in dispute, the parties' cross-motions present this Court with a pure question of law. "When the only question a court must decide is a question of law, summary judgment may be granted." Saregama India Ltd. v. Mosley, 635 F.3d 1284, 1290 (11th Cir. 2011) (citing Cook ex rel. Estate of Tessier v. Sheriff of Monroe Cnty., 402 F.3d 1092, 1120 (11th Cir. 2005) ("A summary judgment should not be granted unless the facts are so crystallized that nothing remains but questions of law"). "The principles governing summary judgment do not change when the parties file cross-motions for summary judgment. When faced with cross-motions, the Court must determine whether either of the parties deserves judgment as a matter of law on the undisputed facts." T-Mobile South LLC v. City of Jacksonville, Florida, 564 F.Supp.2d 1337, 1340 (M.D. Fla. 2008).

III. Background

A. Compounding and Compounding from Bulk Substances

Compounding is a process by which a pharmacist combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual human or animal patient. Thompson v. W. States Med. Ctr., 535 U.S. 357, 360-61 (2002); Med. Ctr. Pharm.

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[16] Thus, for example, despite the FDA's unsupported implications to the contrary, the record evidence shows that Franck's has a reputation for *refusing* to compound drugs that are commercially available, see Pelphrey Doc. ¶ 21, and has adequate safeguards against such an occurrence, see Davidson Dec. ¶ 85; Franck Dec. ¶¶ 32-34. The record is also undisputed that Franck's only compounds within the context of a valid pharmacist-prescriber-patient relationship, Franck Dec. ¶¶ 30, 44, 86, and in so doing provides an essential service that is part of the practice of veterinary medicine, Davidson Dec. ¶ 35; Allen Dec. ¶ 18.

v. Mukasey, 536 F.3d 383, 387 (5th Cir. 2008).[17] Compounding is "a traditional component of the practice of pharmacy, and is taught as part of the standard curriculum at most pharmacy schools." W. States, 535 U.S. at 361 (internal citations omitted). Because the practice of pharmacy is state-governed, the States, including Florida, regulate compounding as part of their regulation of pharmacists. Id.[18]

Under Florida law, pharmacists may compound medications when they are prescribed for individual patients by a licensed medical practitioner (i.e., a veterinarian), or in anticipation of prescriptions based on routine, regularly observed prescribing patterns.[19] This

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[17] Though this definition, taken from the Supreme Court's opinion in Western States, captures the overarching principles of compounding, there is no standard definition of the practice. See, e.g., Fla. Admin. Code Ann. 64B16-27.700 ("'Compounding' is the professional act by a pharmacist . . . employing the science or art of any branch of the profession of pharmacy, incorporating ingredients to create a finished product for dispensing to a patient . . . .; and shall specifically include the professional act of preparing a unique finished product containing any ingredient or device"); Allen Dec. ¶ 13 ("Pharmacy compounding is the preparation of a customized medicine that has been prescribed by a doctor in the course of the professional practice of medicine, and which is prepared by a state-licensed pharmacist"); Davidson Dec. ¶ 33 ("Compounding is the preparation of components into a medication either pursuant to a valid prescription based on a valid [practitioner]-client-patient-relationship or for the purpose of dispensing to licensed physicians and veterinarians for office use, where state law permits such use"); Flynn Dec. ¶ 15 ("Drug compounding is a practice in which a pharmacist prepares medications that are not commercially available, for the unique needs of an individual patient").

[18] See Florida Pharmacy Act, Fla. Stat. §§ 465.001 *et seq*. (creating the Florida Board of Pharmacy and conferring upon the Board the duty to regulate the practice of pharmacy within the state); id. § 465.003(13)("'Practice of the profession of pharmacy' *includes compounding*, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug . . . .")(emphasis added).

[19] See Fla. Admin. Code Ann. 64B16-27.700(1)("Compounding includes: (a) The preparation of drugs or devices in anticipation of prescriptions based on routine, regularly observed prescribing patterns[;] (b) The preparation pursuant to a prescription of drugs or devices which are not commercially available . . . .")

"triad" relationship among veterinarian, patient, and pharmacist envisions a compounding pharmacist working collaboratively with a veterinarian to provide a medication tailored to an animal patient's specific and individualized needs. (See Davidson Dec. ¶ 36.) The pharmacist-prescriber-patient relationship forms the basis of what is commonly known as "traditional pharmacy compounding."[20]

"Compounding is typically used to prepare medications that are not commercially available, such as medication for a patient who is allergic to an ingredient in a mass-produced product." W. States, 535 U.S. at 361. When a drug is not commercially available, or the commercially available drug is unsuitable for a particular patient, compounding is often the only way for a human or animal patient to obtain necessary medication for the safe and effective treatment of their condition. See id. at 369. This is especially so for non food-producing animals because limited commercially available products exist and the available products are often inadequate due to the animal patient's

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[20] See, e.g., Prof'ls and Patients for Customized Care v. Shalala, 56 F.3d 592, 593 (5th Cir. 1995)("Pharmacies have long engaged in the practice of traditional compounding, the process whereby a pharmacist combines ingredients pursuant to a physician's prescription to create a medication for an individual patient . . . ."); Bradshaw Dec. ¶ 45 ("Traditional pharmacy compounding. . . is generally understood to mean 'the preparation of Components into a Drug product (1) as the result of a Practitioner's Prescription Drug Order based on the Practitioner/patient/Pharmacist relationship in the course of professional practice . . . .'")(quoting National Association of Boards of Pharmacy, *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy,* Appx. B, subpt. A(a) at 207 (Aug. 2011), *available at* http://www.nabp.net/publications/model-act/ (last visited September 12, 2011); Doc. 54 (FDA's Motion for Summary Judgment) at 4 ("Traditionally, pharmacists have extemporaneously compounded necessary quantities of drugs upon receipt of a valid prescription in response to an individual patient's medical need, or in very limited quantities based on documented records of valid prescriptions generated in an established physician-patient-pharmacy relationship for human drugs and a veterinarian-client-patient-pharmacy relationship for animal drugs").

size, species, and/or intolerance to active ingredients. (Davidson Dec. ¶ 35); cf. U.S. v. 9/1 Kg. Containers, More or Less . . ., 854 F.2d 173, 174 (7th Cir. 1988)("We must take it as given that for significant [animal] diseases there are no effective FDA-approved drugs. . . . For the principal diseases of non-food animals . . . there are few, if any, approved remedies").[21]

A pharmacist can compound a medication requested by the prescribing veterinarian from either a finished drug product or from bulk drug substances. (Flynn Dec. ¶ 15.) Between the two, compounding from bulk substances has become the "widely preferred" method among veterinarians due to "concerns about the quality, safety, and efficacy of animal medications compounded from finished products." (Allen Dec. ¶¶ 17, 24.) Pharmacists also favor compounding from bulk because use of bulk ingredients ensures that the compounded medicine is of the expected purity,[22] potency,[23] and quality; further, it is

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[21] See also Allen Dec. ¶ 18 ("Because each animal patient is different, it has unique and specific needs that make compounded medications a vital part of quality veterinary medicine. In fact, for many animal patients, a customized, compounded medication prescribed by licensed veterinarians and prepared by a trained, licensed compounding pharmacist is the best practice for treating the animal patient. *If compounded medications are not available, there are a large number of animal patients that would not have access to life-saving drugs*")(emphasis added); Pelphrey Dec. ¶¶ 8, 10 ("Compounding is an essential part of my veterinary medicine practice. Without compounding, many of my [equine] patients would not receive the medication that is needed to appropriately treat their unique needs because *many of my patients cannot be treated with commercially available drug products*")(emphasis added); but see Flynn Dec. ¶¶ 5, 26 (asserting that while there is an "*insufficient variety of approved medications*", "the unchecked proliferation" of compounding practices such as Franck's "*may* create disincentives for drug sponsors to develop necessary and useful animal drugs . . . .")(emphasis added).

[22] Bulk ingredients require a certificate of analysis that includes detailed information not available for finished drug products, including the concentration and specification of all ingredients, expiration date, manufacture date, method of analysis, analysis results, and

often not practical[24] or possible[25] to compound a medically necessary animal drug from an FDA-approved finished drug product. (Id. ¶¶ 17, 23-25.) In addition, the standards for potency and purity of compounded medications required by the United States Pharmacopeia ("USP"), which the original FDCA recognized as its "official compendium," Food, Drug and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 ("1938 FDCA") § 201(j), are more readily obtained using bulk ingredients.[26] (Allen Dec. ¶¶ 27-32.) As a result, compounding

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storage conditions. Allen Dec. ¶ 26.

[23] See id. ¶ 21 ("The FDA-approved, commercially available drug products are available only in limited strengths. . . [I]t is unlikely, for instance, that a 5,000 pound elephant can be properly treated with the same strength medication as a 10-pound feline").

[24] Compounding from finished drug products is inefficient because it requires a pharmacist to, in essence, "reverse engineer" the finished product into its unfinished form so as "to identify the finished product's formulation parameters, to distinguish and quantify the ingredients of the finished product (i.e., the active pharmaceutical ingredients, excipients, etc.) and to separate out the distinct ingredients of the finished product. The compounding pharmacist then uses (or removes) the 'separated' ingredients to compound the preparation in the prescribed dosage, formulation, and strength." Franck Dec. ¶ 45.

[25] For example, FDA-approved human drugs are sometimes removed from the market because of safety reasons not associated with the use of the drug in animals. See Davidson Dec. ¶¶ 56-61 (citing Pergolide (used off-label to treat Cushing's syndrome in horses) and Cisapride (used off-label to treat feline megacolon) as examples of discontinued drugs with no current substitutes, and noting that "[i]f compounding pharmacists [we]re not able to compound these medically useful and/or necessary medications from bulk ingredients, animals would needlessly suffer from chronic or catastrophic illnesses").

[26] At the time the FDCA was enacted, the USP contained monographs with instructions on how to compound medications from bulk ingredients; the USP continues to authorize compounding when the monographs are followed. Allen Dec.¶¶ 33-48; see also Bradshaw Dec.¶ 17. The standards of the USP, which the 1938 FDCA recognized as a baseline for the strength, quality, purity, and packaging of pharmaceutical ingredients for compounded drugs, are legally enforceable by the FDA and state boards of pharmacy. Allen Dec. ¶¶ 33-35. Bulk ingredients for a which a monograph is provided in the USP are required to conform to that monograph. Id. ¶ 27. Many FDA-approved finished drugs, on the other hand, do not have USP monographs, making it "difficult for pharmacists to determine

from a finished drug product "is more likely to result in a compounded preparation outside of the [USP's] required potency and purity specifications than compounding from a bulk ingredient." (Id. ¶ 29.)

Under Florida law, traditional compounding from bulk substances is an approved part of the practice of pharmacy.[27] As a result, many, if not all, compounding pharmacies in Florida compound drug products from bulk ingredients. (Powers Dec. ¶ 24.)[28] Florida is not an outlier in this regard; the practice of compounding from bulk ingredients is expressly recognized by many states and is a "widespread practice performed by the majority of licensed compounding pharmacy professionals throughout the country, and has been for

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whether a compounded preparation from finished drug products falls within the desired range of USP purity, potency, and quality compounding standards." Id. ¶ 32.

[27] See Fla. Admin. Code Ann. 64B16-27.700(1)("Compounding includes . . . (c) The preparation of commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient has been made aware that the compounded product will be prepared by the pharmacist. . . ."). Florida regulations also provide standards of practice for compounding from bulk ingredients. See Fla. Admin. Code Ann. 64B16-27.1001(2)(stating that a pharmacist must personally interpret incoming orders for bulk solutions; compound or be physically present for the compounding of bulk solutions; "[p]hysically examine, certify to the accuracy of the final preparation, thereby assuming responsibility for the final preparation"; and "[s]ystemize all records and documentation of processing in such a manner that professional responsibility can easily be traced to a pharmacist").

[28] "Because Florida law explicitly permits bulk compounding, I can say from my experience as a member of the Florida Board [of Pharmacy] that many, if not all, compounding pharmacies in Florida compound drug products from bulk ingredients, and are permitted to do so under Florida law." Powers Dec. ¶ 24; see also Stoothoff Dec. ¶ 14 ("[N]umerous pharmacies in Florida compound medications for veterinary use from bulk ingredients. In fact, there are at least four other local pharmacies in Marion County aside from Franck's that routinely compound medications for use in animals from bulk ingredients").

decades." (Allen Dec. ¶ 23.)[29]

B. The FDA's Regulation of Compounding

1. From 1938 to 1992

The history of the FDA's regulation of pharmacy compounding has been reviewed several times, most notably by the Supreme Court in Western States, 535 U.S. at 360-66, and the Fifth Circuit in Medical Center, 536 F.3d at 387-91. As the Supreme Court recounted (emphasis and footnotes added):

> The Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), 21 U.S.C. §§ 301-397, *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 the Food and Drug Administration] is effective with respect to such drug." 21 U.S.C. § 355(a). "[N]ew drug" is defined by § 201(p)(1) of the FDCA, 52 Stat. 1041, as amended, 76 Stat. 781, as "[a]ny drug . . . not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p).[30] The FDCA invests the Food and

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[29] See also Davidson Dec. ¶¶ 41, 54 (noting that "a large segment of the compounding industry has been built around the practice of compounding animal medications from bulk ingredients"); Pelphrey Dec. ¶¶ 15, 18 ("To my knowledge, compounding medication for use in non-food producing animals from bulk ingredients is an everyday practice for compounding pharmacies. In fact, all the compounding pharmacies I work with regularly compound medications from bulk ingredients. . . . In my opinion, the equine medicine community has a compelling interest in ensuring that compounding pharmacies continue the long-standing practice of compounding medically necessary medications from bulk ingredients when appropriate in response to a prescription made by a licensed veterinarian").

[30] Likewise, and more pertinent to this case, the FDCA defines "new animal drug" as "any drug intended for use for animals other than man . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(v)(1).

Drug Administration (FDA) with the power to enforce its requirements. § 371(a).[31]

For approximately the first 50 years after the enactment of the FDCA, the FDA generally left regulation of compounding to the States. Pharmacists continued to provide patients with compounded drugs without applying for FDA approval of those drugs. The FDA eventually became concerned, however, that some pharmacists were manufacturing and selling drugs under the guise of compounding, thereby avoiding the FDCA's new drug requirements. In 1992, in response to this concern, the FDA issued a Compliance Policy Guide, which announced that *the "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 and . . . results in significant violations of the new drug, adulteration, or misbranding provisions of the Act."* Compliance Policy Guide 7132.16 (hereinafter [1992] Guide).[32] The Guide explained that the "FDA recognizes that pharmacists traditionally have extemporaneously compounded and manipulated reasonable quantities of drugs upon receipt of a valid prescription for an individually identified patient from a licensed practitioner," and that *such activity was not the subject of the Guide*. The Guide said, however, "that while retail pharmacies . . . are exempted from certain requirements of the [FDCA], they are not the subject of any general exemption from the new drug, adulteration, or misbranding provisions" of the FDCA. It stated that the "FDA believes that an increasing number of establishments with

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[31] As is the case with a "new drug," the FDCA empowers the FDA to require approval of any "new animal drug." If it has not been approved by the FDA, a "new animal drug" is "unsafe" under 21 U.S.C. § 360b(a)(1) and thus "adulterated" under 21 U.S.C. § 351(a)(5). An unapproved "new animal drug" lacking "adequate directions for use" is "misbranded" under 21 U.S.C. § 352(f) and FDA regulations. See 21 C.F.R. 201.122. Hence, the FDA asserts that to avoid being deemed "adulterated," "unsafe," or "misbranded," a compounded drug product must either go through the new animal drug approval process or fall outside the definition of "new animal drug."

[32] In reality, FDA had begun to address this concern—in a slightly different but related context—through enforcement actions prior to its issuance of the 1992 Guide. Specifically, the FDA asserted that bulk drugs held by a middleman for compounding by veterinarians were unlawfully misbranded under the FDCA, a position ultimately upheld by the Seventh Circuit in 9/1 Kg. Containers, 854 F.2d at 179. A year later, the Third Circuit upheld the FDA's regulatory authority to limit the sale of new bulk drugs exclusively to holders of "new animal drug applications," a definition that excluded veterinarians. United States v. Algon Chemical, Inc., 879 F.2d 1154, 1155 (3d Cir. 1989).

> retail pharmacy licenses are engaged in manufacturing, distributing, and promoting unapproved new drugs for human use in a manner that is *clearly outside the bounds of traditional pharmacy practice and that constitute violations of the [FDCA]*." The Guide expressed concern that drug products "manufactured and distributed in commercial amounts without [the] FDA's prior approval" could harm the public health.
>
> In light of these considerations, the Guide announced that it was FDA policy to permit pharmacists to compound drugs after receipt of a valid prescription for an individual patient or to compound drugs in "very limited quantities" before receipt of a valid prescription if they could document a history of receiving valid prescriptions "generated solely within an established professional practitioner-patient-pharmacy relationship" and if they maintained the prescription on file as required by state law. Compounding in such circumstances was permitted as long as the pharmacy's activities did not raise "the kinds of concerns normally associated with a manufacturer."

W. States, 535 U.S. at 361-63 (emphasis added and citations omitted).

After acknowledging that the FDA would "generally continue to defer to state and local officials[']regulation of the day-to-day practice of retail pharmacy and related activities," the 1992 Guide listed nine non-inclusive activities that the FDA believed would improperly cross the line between "pharmacist" and "manufacturer" and thus would prompt the FDA to "initiate federal enforcement actions" in the "exercise of its enforcement discretion." 1992 Guide at 4-5.[33] The practice of compounding drugs from bulk substances

[33] The 1992 Guide explained that "[t]he [FDA] has initiated enforcement action when pharmacy practice extends beyond the reasonable and traditional practice of a retail pharmacy," and that "[t]he courts have upheld FDA's interpretation in those cases." Id. at 3 (citing United States v. Sene X Eleemosynary Corp., 479 F. Supp. 970 (S.D. Fla. 1979); Cedars N. Towers Pharm., Inc. v. United States, [1978-79 Transfer Binder] Food Drug Cosm. L. Rep. (CCH) para. 38,200 at 38,826 (S.D. Fla. Aug. 28, 1978)). The Guide also cited Algon, 879 F.2d 1154; 9/1 Kg. Containers, 854 F.2d 173; and United States v. Rutherford, 442 U.S. 544 (1979) for their analysis "*regarding limitations on sale of unapproved and otherwise unlawful products to licensed practitioners*." Id. (emphasis added).

was not among the nine prohibited practices, though the concern that large-scale compounding from bulk might be indicative of manufacturing was mentioned elsewhere in the 1992 Guide.[34]

2. AMDUCA

In 1994, Congress passed the Animal Medicinal Drug Use Clarification Act ("AMDUCA"), which amended the FDCA to permit certain 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).[35] Under AMDUCA, the off-label or extra-label use of an already approved new animal or new human drug prescribed by a licensed veterinarian in the context of a valid pharmacist-prescriber-patient relationship does not require approval under the FDCA's "new animal drug" provisions, and thus does not cause the drug to become "adulterated." Id. AMDUCA authorized the FDA to promulgate regulations which "establish the conditions" for such off-label use. Id. §§ 360b(a)(4)(A), 5(B).

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[34] The "Background" section of the 1992 Guide, in discussing FDA's concern about manufacturing in the guise of compounding, highlighted "establishments with retail pharmacy licenses" which, among other things, "receive and use in large quantity bulk drug substances to manufacture unapproved drug products and to manufacture drug products in large quantity, in advance of receiving a valid prescription for the products." 1992 Guide at 2. Later, the FDA recounted an inspection of a company "operating with a pharmacy license" which "revealed that the firm had hundreds of bulk ingredients on hand to manufacture about 165 different products," a majority of which had been compounded in advance of a valid prescription. Id. at 3.

[35] Prior to AMDUCA, section 360b provided that a "new animal drug" was "unsafe" unless it was subject to an approved application and the drug, its labeling, *and its use* conformed to the application. See Bradshaw Dec. ¶ 37. As a result, the use of a "new animal drug" in a manner different from that set forth in the drug's approved application (i.e., for an off-label or extra-label use) resulted in the drug being classified as "unsafe" and "adulterated" under the FDCA. Id.

Though Congress made no mention of either compounding or bulk drugs in AMDUCA, the FDA regulations promulgated to implement AMDUCA explicitly reference both. Section 530.13, entitled "Extralabel use from compounding of approved new animal and approved human drugs," provides that "[t]his part applies to *compounding of a product* from approved animal or human drugs by a veterinarian or a pharmacist on the order of a veterinarian within the practice of veterinary medicine. *Nothing in this part shall be construed as permitting compounding from bulk drugs*." 21 C.F.R. § 530.13(a) (emphasis added). Despite this language, the regulations do not purport to regulate the practice of compounding, and instead refer parties to FDA's non-binding guidance documents on the subject. See id. § 530.13(c) ("Guidance on the subject of compounding may be found in guidance documents issued by FDA").[36]

3. The 1996 Guide

In 1996, the FDA published notice in the Federal Register inviting public comment on a Compliance Policy Guide outlining the agency's non-binding "policy and regulatory guidelines" with respect to the compounding of animal drugs by veterinarians and

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[36] AMDUCA's implementing regulations also reflect a clear policy distinction between extralabel uses in so-called "food-producing animals" (e.g., cows) and "non food-producing animals" (e.g., horses). Compare 21 C.F.R § 530.21(a) ("FDA may prohibit the extralabel use of an approved new animal or human drug or class of drugs in food-producing animals if FDA determines that: (1) [a]n acceptable analytical method needs to be established and such method has not been established or cannot be established; or (2) [t]he extralabel use of the drug or class of drugs presents a risk to the public health") with § 21 C.F.R. 530.30(a) ("Because extralabel use of animal and human drugs in non food-producing animals *does not ordinarily pose a threat to the public health*, extralabel use of animal and human drugs is permitted in non food-producing animal practice except when the public health is threatened")(emphasis added).

pharmacists. 61 Fed. Reg. 34,849, 34,849 (1996) ("1996 Guide"). The 1996 Guide noted that the FDCA "does not distinguish compounding from manufacturing or other processing of drugs for use in animals," nor does it exempt pharmacists and veterinarians from the FDCA's new drug approval provisions. Id. at 34,850. While the FDA "acknowlege[d] the use of compounding within certain areas of veterinary practice," it also asserted that "compounding allowed under the [FDCA] is limited to the preparation of drug products which do not meet the definition of new animal drugs" and that "[i]n the absence of an approved new animal drug application (NADA), the compounding of a new animal drug from . . . a bulk drug, results in an adulterated new animal drug . . . ." Id.[37]

Despite this broad assertion of the FDA's authority, the 1996 Guide recognized a legitimate place for compounding. Specifically, the Guide provided that "compounding by a licensed pharmacist or veterinary practitioner, when the criteria described in this document are met, [and] within the confines of a legitimate practice" would constitute "compounding ordinarily not subject to regulatory action." Id.[38] With this background, the 1996 Guide's

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[37] As support for this interpretation, the 1996 Guide asserted that "[t]wo Federal Appeals Court decisions, Algon and 9/1 Kg. Containers, affirmed the FDA position that the FDCA does not permit veterinarians to compound unapproved finished drug products from bulk drugs, unless the finished drug is not a new animal drug. The principle established by the court applies equally to compounding by pharmacists." Id. Notably, the FDA similarly asserted that compounding a new animal drug from "an approved . . . human or animal drug" would result in a violation of the FDCA, but acknowledged that this would no longer be the case when AMDUCA became effective. Id.

[38] In turn, a "legitimate practice" was defined as follows:

> (a) *Pharmacist: A person licensed and operating in conformity with state law, and dispensing in response to a valid prescription.*

"Policy" section began with the acknowledgment that "[c]ircumstances exist when it may be necessary for a veterinarian to compound, or direct for a pharmacist to compound, an article that will result in an unapproved animal drug." Id. at 34,851. In such circumstances, the FDA recognized that there was "occasionally a need to utilize . . . bulk drug substances[ ] for compounding into an appropriate dosage form." Id. The FDA would thus condone compounding animal drugs from bulk where: (1) a "legitimate medical need [wa]s identified"; (2) there was an "appropriate dosage regimen" for the patient's species, age, size, or medical condition; and (3) there was "no marketed approved animal drug" that "may treat the condition diagnosed in the available dosage form." Id. Under these conditions, the FDA would ordinarily not exercise its enforcement authority against a compounding pharmacist so long as the medication was dispensed within the confines of a pharmacist-prescriber-patient relationship; the drug was adequately labeled to ensure proper use; and the pharmacist adhered to the National Association of Boards of Pharmacy Good Compounding Practices, or to equivalent state good compounding regulations. Id. The FDA closed its policy pronouncement with the following: "Veterinarians and pharmacists who compound or prescribe compounded medicaments and pharmacists who compound medicaments according to these guidelines criteria set out above would be considered to be engaged in extemporaneous compounding not ordinarily subject to regulatory action."

> (b) Veterinarian: A person licensed and operating in conformity with state law, and prescribing or dispensing in response to a valid Veterinarian-Client-Patient Relationship (VCPR).

Id. (emphasis added); cf. supra n.20, 27.

Id.

The 1996 Guide then listed thirteen situations which would "likely indicate compounding subject to regulatory action." Id. "Compounding from bulk drugs for use in *food* animals," with certain limited exceptions, was among the listed scenarios. Id. (emphasis added).[39] However, "[c]ompounding from bulk drug substances for use in non-food animals" was expressly identified as a "compounding situation [which] would not ordinarily be considered for regulatory action." Id. at 34,852.[40]

4. FDAMA & Western States

In 1997, "in a move the Pharmacies call a reaction to the FDA's 1992 [Guide] and the FDA characterizes as a confirmation of it, Congress amended the FDCA by enacting the Food And Drug Modernization Act of 1997 ("FDAMA"), Pub.L. No. 105-115, 111 Stat. 2296 (codified as amended at 21 U.S.C. § 353a (2000))." Med. Ctr., 536 F.3d at 391.[41] Expressly

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[39] Thus, much like the FDA's regulations implementing AMDUCA, supra n.36, the 1996 Guide draws both a policy and enforcement line between compounding for food and non food-producing animals. See 1996 Guide at 31,851 ("In general, the agency will place its highest regulatory priority on compounding products for use in food animals"). As discussed infra, the FDA later eliminated the food/non-food animal distinction from its guidance without explanation.

[40] The Guide noted that bulk drug substances used to compound medication for non-food animals "would ordinarily be expected to be in small packages that meet or exceed USP standards," and that compounding of any such substance "should be performed in accordance with current standards of pharmaceutical practice (including referral to compendial monographs or established pharmacy textbooks)." Id.

[41] Cf. W. States, 535 U.S. at 364 ("Congress *turned portions of [the 1992 Guide] into law* when it enacted the FDAMA in 1997. The FDAMA, which amends the FDCA, exempts compounded drugs from the FDCA's 'new drug' requirements and other requirements provided the drugs satisfy a number of restrictions")(emphasis added).

addressing "pharmacy compounding," FDAMA, which applies only to human drugs, provides that the FDCA's new drug approval, adulteration, and misbranding provisions "*shall not apply* to a drug product if the drug product is compounded" pursuant to certain guidelines. 21 U.S.C. § 353a(a)(emphasis added).[42] As summarized by the Supreme Court in Western States, those guidelines are as follows:

> First, [compounded drugs] *must be compounded by a licensed pharmacist or physician in response to a valid prescription for an identified individual patient, or, if prepared before the receipt of such a prescription, they must be made only in "limited quantities" and in response to a history of the licensed pharmacist's or physician's receipt of valid prescription orders for that drug product within an established relationship between the pharmacist, the patient, and the prescriber.* 21 U.S.C. § 353a(a). Second, the compounded drug must be made from approved ingredients that meet certain manufacturing and safety standards, §§ 353a(b)(1)(A)-(B),[43] and the compounded drug may not appear on an FDA list of drug products that have been withdrawn or removed from the market because they were found to be unsafe or ineffective, § 353a(b)(1)(C). Third, the pharmacist or physician compounding the drug may not "compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product." § 353a(b)(1)(D). Fourth, the drug product must not be identified by the FDA as a drug product that presents demonstrable difficulties for compounding in terms of safety or effectiveness. § 353a(b)(3)(A). Fifth, in States that have not entered into a "memorandum of understanding" with the FDA addressing the distribution of "inordinate amounts" of compounded drugs in interstate commerce, the pharmacy, pharmacist, or physician compounding the drug may not distribute compounded drugs out of state in quantities exceeding five percent of that

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[42] In enacting FDAMA, Congress also recognized that regulation of compounding was historically the province of the States: "States currently have the authority to license pharmacists and regulate pharmacies, including the scope of pharmacy practice. All states include compounding as a core component of the profession of pharmacy." Food and Drug Modernization and Accountability Act of 1997, S. Rep. No. 105-43 at 67 (1997).

[43] Section 353a(b)(1)(A) authorizes pharmacists to compound drug products "using bulk drug substances" as defined in 21 C.F.R § 207.3 (see supra n.2) so long as the bulk drugs comply with the applicable USP monograph or, if no monograph exists, the bulk drugs are components of drugs approved by the FDA. 21 U.S.C. § 353a(b)(1)(A).

> entity's total prescription orders. § 353a(b)(3)(B). Finally . . . the prescription must be "unsolicited," § 353a(a), and the pharmacy, licensed pharmacist, or licensed physician compounding the drug may "not advertise or promote the compounding of any particular drug, class of drug, or type of drug," § 353a(c).

Western States, 535 U.S. at 364-65 (emphasis and footnote added).

"Shortly after passage of FDAMA, however, trouble arose. In 2002, in Western States, 535 U.S. at 368-77, 122 S.Ct. 1497, the Court invalidated the advertising-related provisions of FDAMA, affirming the Ninth Circuit's holding that those portions were unconstitutional restrictions on commercial speech." Med. Ctr., 536 F.3d at 391.[44] Interestingly, in arguing (unsuccessfully) that FDAMA's advertising provisions advanced a substantial government interest, the Secretary of the U.S. Department of Health and Human Services asserted the importance of

> "preserv[ing] the availability of compounded drugs for those individual patients who, for particularized medical reasons, cannot use commercially available products that have been approved by the FDA. . . . *[B]ecause obtaining FDA approval for a new drug is a costly process, requiring FDA approval of all drug products compounded by pharmacies for the particular needs of an individual patient would, as a practical matter, eliminate the practice of compounding, and thereby eliminate availability of compounded drugs for those patients who have no alternative treatment." The Government argues that eliminating the practice of compounding drugs for individual patients would be undesirable because compounding is sometimes critical to the care of patients with drug allergies, patients who cannot tolerate particular drug delivery systems, and patients requiring special drug dosages*.

W. States, 535 U.S. at 368-69 (emphasis added). The Supreme Court recognized the

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[44] Although the Ninth Circuit deemed FDAMA non-severable, and therefore invalidated the amendment in its entirety, see W. States Med. Ctr. v. Shalala, 238 F.3d 1090, 1096-98 (9th Cir. 2001), the Supreme Court declined to address the validity of the remaining non-advertising portions of FDAMA because the parties had not appealed the severability issue. W. States, 535 U.S. at 366.

importance of these competing concerns; i.e., protecting the new drug approval process while simultaneously permitting traditional compounding's continued existence:

> 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*. *And it 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*. Given this, the Government *needs to be able to draw a line between small-scale compounding and large-scale drug manufacturing*. That line must distinguish compounded drugs produced on *such a small scale* that they could not undergo safety and efficacy testing from drugs produced and sold on a large enough scale that they could undergo such testing and therefore must do so.

Id. at 369-70 (emphasis added). The Court ultimately found that conditioning an exemption from the FDA approval process on refraining from advertising was an inappropriate way to draw the "small-scale" versus "large-scale" distinction. Id. at 370-71. In so holding, however, the Court noted that "[s]everal non-speech-related means of drawing a line between compounding and large-scale manufacturing might be possible here. First, it seems that the Government could use the very factors the FDA relied on to distinguish compounding from manufacturing in its 1992 Guide." Id. at 372.[45] The Court further noted

[45] "For example, [said the Supreme Court,] the Government could ban the use of 'commercial scale manufacturing or testing equipment for compounding drug products.' It could prohibit pharmacists from compounding more drugs in anticipation of receiving prescriptions than in response to prescriptions already received. It could prohibit pharmacists from '[o]ffering compounded drug products at wholesale to other state licensed persons or commercial entities for resale.' Alternately, it could limit the amount of compounded drugs,

that it had been provided no reason why these factors, "alone or in combination, would be insufficient to prevent compounding from occurring *on such a scale as to undermine the new drug approval process*." Id. at 373 (emphasis added).

5. The 2002 and 2003 Guides and Beyond

In the wake of Western States, the FDA issued revised Compliance Policy Guides addressing compounding of human and animal drugs.[46] See Med. Ctr., 536 F.3d at 391. Like the 1992 and 1996 Guides before them, the 2002 and 2003 Guides assert that compounded human and animal drugs are not exempt from the FDCA's new drug approval, adulteration, or misbranding provisions. Id. And the updated Guides continue to assure pharmacists that the FDA will use its enforcement discretion against a compounding pharmacy only where the pharmacy's activities raise the kinds of concerns normally associated with manufacturing. Id. Despite these overarching parallels, however, the new Guides make a number of policy departures from their predecessors.

In the 2002 Guide, which addresses human drugs, the FDA asserts that "all of [FDAMA] is now invalid" in light of the Ninth Circuit's severability holding in Western States. 2002 Guide at 2. Despite this, the 2002 Guide appears to embrace FDAMA's effusive

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either by volume or by numbers of prescriptions, that a given pharmacist or pharmacy sells out of state. Another possibility not suggested by the Guide would be capping the amount of any particular compounded drug, either by drug volume, number of prescriptions, gross revenue, or profit that a pharmacist or pharmacy may make or sell in a given period of time." Id. (quoting the 1992 Guide)(internal citations omitted).

[46] See FDA Compliance Policy Guide Sec. 460.200, Pharmacy Compounding (May 2002) ("2002 Guide") (human drugs); FDA Compliance Policy Guide Sec. 608.400, Compounding of Drugs for Use in Animals (July 2003) ("2003 Guide") (animal drugs).

attitude towards traditional pharmacy compounding.[47] The focus of the guidance is the FDA's desire to eradicate improper manufacturing, which, with regard to bulk drugs, is framed as an issue of scale:

> FDA believes that an increasing number of establishments with retail pharmacy licenses are engaged in manufacturing and distributing unapproved new drugs for human use in a manner that is clearly outside the bounds of traditional pharmacy practice and that violates the Act. Such establishments and their activities are the focus of this guidance. Some "pharmacies" that have sought to find shelter under and expand the scope of the exemptions applicable to traditional retail pharmacies have claimed that their manufacturing and distribution practices are only the regular course of the practice of pharmacy. Yet, the practices of many of these entities seem far more consistent with those of drug manufacturers and wholesalers than with those of retail pharmacies. *For example, some firms receive and use large quantities of bulk drug substances to manufacture large quantities of unapproved drug products in advance of receiving a valid prescription for them.* Moreover, some firms sell to physicians and patients with whom they have only a remote professional relationship. Pharmacies engaged in activities analogous to manufacturing and distributing drugs for human use may be held to the same provisions of the Act as manufacturers.

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[47] The 2002 Guide makes no mention of any public health concerns associated with compounded drugs, nor does it make sweeping assertions of the FDA's authority to regulate the practice. Rather, its "Discussion" section begins with the statement that "FDA recognizes that pharmacists traditionally have extemporaneously compounded and manipulated reasonable quantities of human drugs upon receipt of a valid prescription for an individually identified patient from a licensed practitioner. This traditional activity is not the subject of this guidance." 2002 Guide at 2. Appended to this statement is the following footnote: "With respect to such activities, 21 U.S.C. 360(g)(1) exempts retail pharmacies from the registration requirements of the [FDCA]. The exemption applies to 'Pharmacies' that operate in accordance with state law and dispense drugs 'upon prescriptions of practitioners licensed to administer such drugs to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail.' See also 21 U.S.C. §§ 374(a)(2) (exempting pharmacies that meet the foregoing criteria from certain inspection provisions) and 353(b)(2) (exempting drugs dispensed by filling a valid prescription from certain misbranding provisions)." Id. at 2 n.2.

2002 Guide at 3 (emphasis added). Apart from its use in the sentence "some firms receive and use large quantities of bulk drugs," the word "bulk" appears only one other time in the 2002 Guide. A compounder's use of bulk ingredients that are not "components of FDA approved drugs" is listed as a factor FDA will consider in bringing an enforcement action. Id. at 4.

The 2003 Guide, which addresses animal drug compounding, was, according to the FDA, issued "to ensure the consistency of its policies with regard to compounding of drugs intended for use in humans and in animals." 2003 Guide at 2-3. From the outset, however, the 2003 Guide strikes a decidedly more hostile tone toward compounding than its human drug counterpart (as well as its 1996 predecessor):

> There is a potential for causing harm to public health and to animals when drug products are compounded, distributed, and used in the absence of adequate and well-controlled safety and effectiveness data or adherence to the principles of contemporary pharmaceutical chemistry and current good manufacturing practices. Use of compounded drugs in animals can result in adverse reactions and animal deaths.

Id. at 2. Unlike the 1996 Guide and the AMDUCA regulations, the 2003 Guide makes no distinction between food and non food-producing animals.[48] Further, the 2003 Guide contains no discussion about permitted compounding practices (apart from the use of extra-label drugs under AMDUCA), and instead announces that the FDA intends to target the

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[48] In his declaration, Dr. Flynn (supra n.10) recognized that the 2003 Guide removed the 1996 Guide's exemption for compounding from bulk drugs for non food-producing animals. Flynn Dec. ¶ 28. Dr. Flynn's explanation for this change is that "[t]he 1996 [Guide] was issued before the promulgation of the AMDUCA implementing regulations, which make no distinction between food and nonfood animals. [Thus,] the [2003 Guide] includes no such distinction." Id. But see supra n.36 (comparing 21 C.F.R § 530.21(a) to 21 C.F.R § 530.30(a)).

compounding of animal drugs conducted "in a manner that is clearly outside the bounds of *traditional pharmacy practice . . .* (e.g., compounding that is *intended to circumvent* the drug approval process and provide for the mass marketing of products that have been produced with little or no quality control or manufacturing standards to ensure the purity, potency, and stability of the product)." 2003 Guide at 3 (emphasis added).[49]

However, the most noticeable departure in the 2003 Guide is the FDA's policy regarding the use of bulk drug substances in compounded animal medications. While the 1996 Guide acknowledged the occasional utility of compounding from bulk, the circumstances under which doing so would not subject a pharmacist to potential regulatory action, and the permissibility of the practice for non food-producing animals, such statements are absent—without explanation—from the 2003 Guide. And despite the 2002 Guide's allowance of compounding from bulk for human drugs so long as the bulk ingredients are FDA-approved, the 2003 Guide lists "[c]ompounding finished drugs [for animals] . . . from bulk substances" among the factors which "raise[ ] the kind[ ] of concern normally associated with a manufacturer." Id. at 5.

Attached to the 2003 Guide is an appendix entitled "Appendix A: List of Bulk Drug

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[49] The term "legitimate practice," which was defined in the 1996 Guide, supra n.38, is replaced in the 2003 Guide with the undefined term "traditional pharmacy practice." In addition, the 2003 Guide's list of factors which might prompt FDA to consider an enforcement action do not contain any of the 1996 Guide's language of scale, e.g., "[p]reparation for sale of large quantities of unapproved new animal drugs on an ongoing basis," 1996 Guide at 34,851 (emphasis in original). As a result, the 2003 Guide subjects small-scale practitioners to the same potential enforcement scrutiny as large-scale manufacturers. See 2003 Guide at 4-5.

Substances for Compounding and Subsequent Use in Animals to Which the CVM Would Not Ordinarily Object." Id. at 7. The appendix lists nine such substances, but provides no explication or rationale of the FDA's methodology for the approval of the listed substances to the exclusion of others. Nor does the 2003 Guide draw any distinctions based upon the scale of bulk compounding activity, implying that a pharmacist who compounds one animal medication from bulk for a non food-producing animal has committed a per se violation of the FDCA. Thus, under the 2002 and 2003 Guides, *a pharmacist who compounds medication from bulk for ingestion by a horse is akin to a manufacturer and subject to an FDA enforcement action, while the same pharmacist compounding medication from bulk for ingestion by the human rider of that horse is not*. This is so despite the 2002 Guide's assertion that "all of [FDAMA] is invalid" and the 2003 Guide's stated intent to maintain consistency in the FDA's policies regarding regulation of human and animal drugs.[50]

Because the FDA considered the 2003 Guide's policy changes to be "minor," the

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[50] The FDA's official policy statement on FDAMA, as announced in the 2002 Guide, is that the entire amendment is invalid, see 2002 Guide at 2, and the FDA has never changed this guidance. If FDAMA were invalid, there would be no statutory exemptions for human drug compounding. Under that scenario, the 2002 Guide would reflect *the FDA's* policy decision to endorse traditional bulk compounding of human drugs. The disparate treatment of human and animal compounding in the 2002 and 2003 Guides thus appears at odds with the 2003 Guide's stated goal of ensuring "consistency of [the FDA's] policies with regard to compounding of drugs intended for use in humans and in animals," 2003 Guide at 3. Adding to the confusion, the FDA in this case takes the position–contrary to the 2002 Guide–that FDAMA is in fact valid (perhaps based on the Fifth Circuit's decision in Medical Center?) and that "[t]here is no statutory basis for extending the human drug compounding exemptions of FDAMA to animal drugs because Congress enacted distinct exemption schemes for compounding human and animal drugs." Doc. 54 at 16. This is significant, as FDAMA is even more permissive of bulk compounding of human drugs than the 2002 Guide. See 21 U.S.C. § 353a(b)(1)(A); supra n. 43.

agency did not publish a notice in the Federal Register or invite public comment prior to issuing it. 21 C.F.R. § 10.115 (setting forth "good guidance practices" for FDA to follow in developing, issuing and using guidance documents, which include notice-and-comment procedures for guidance documents which "[s]et forth changes in interpretation or policy that are of more than a minor nature"). Having been deprived the opportunity for public comment, Franck's and a number of other compounding pharmacists, veterinarians, and related associations (including the Small Business Association's Office of Advocacy), wrote letters to Congress and to the FDA's CVM, expressing concern that the policies outlined in the 2003 Guide "would cause many animal patients to suffer needlessly." (Davidson Dec. ¶ 48.) In turn, more than seventy members of Congress wrote separately to the FDA, reiterating the policy concerns of the veterinarians and pharmacists. (Id. at Ex. 6.) The Congressmen called it "disconcerting" that the Guide was "put into effect without the opportunity for public review and comment by stakeholders" and therefore asked "[FDA] to withdraw it and issue a revised [Guide] for public comment." (Id.)

In September 2004, the FDA responded to the various complaints by issuing the following notice:

> 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 veterinary 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.
>
> When it is available, the draft CPG will be posted on FDA's Center for Veterinary Medicine (CVM) Website and a notice of availability will be published in the Federal Register.

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 September 12, 2011)(emphasis added).

Despite its promise to do so, the FDA did not propose or issue any form of revised guidance in the fall of 2004.

In two separate letters to the FDA in June 2005, twenty-six Senators and seventy-two Congressmen voiced their continued displeasure over the agency's failure to revise the 2003 Guide and subject it to notice and comment procedures. (Davidson Dec. Ex. 6.) The Congressmen noted that

> The Agency's failure to follow through on these commitments has serious consequences. While FDA has had more than ample time to act on its assurances to revise the CPGs, their failed promises to reissue these documents represents *a significant threat to vulnerable patient populations*, both humans and animals, served by compounding pharmacies.[51] Patients are continually threatened with not being able to receive crucial, life-giving medications only available from compounding pharmacies. In addition, *pharmacists are being forced to operate under flawed policy, potentially jeopardizing their livelihood and reputation in order to meet patients' essential medication needs*. Further, the FDA has substantially increased inspection and enforcement activities against compounding pharmacies in the last year,

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[51] With regard to human compounding, the Congressmen noted that "the [1992 Guide's presumption that pharmacy compounding was illegal led to the passage of legislation in 1997 [i.e., FDAMA] that underscored the right of patients to have medications compounded to meet their individual needs, performed in the context of a pharmacist-physician-patient relationship." Id.

premised on the very documents that the agency acknowledges as flawed.

(Id.)(Letter from Congressmen Charles Bass and Mike Ross to Dr. Lester M. Crawford, Acting Commissioner, U.S. Food and Drug Administration (June 29, 2005) (emphasis added)).

The lawmakers requested that the FDA "undertake an immediate review of the reasons behind these delays and take the steps necessary to issue proposed CPGs for public review and comment." (Id.) However, almost five years later, when FDA filed this enforcement action, and even to date, FDA has not issued the revised guidance it promised in 2004.[52]

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[52] While finalizing this Order, the Court, on August 1, 2011, asked the parties to advise whether the FDA had issued any revised guidance regarding animal drug compounding. Doc. 65. The FDA replied that it "has not revised [the 2003 Guide] since oral argument in this case, or issued any other guidance regarding animal drug compounding." Doc. 66 at 1. Rather, "[t]he agency has continued to monitor compliance with the [FDCA] consistent with the positions outlined in [the 2003 Guide]." Id. However, as Franck's noted in its response, see Doc. 67, the FDA is currently "requesting comments on approaches for increasing the number of legally-marketed animal drug products, as well as on the use of enforcement discretion for some unapproved animal drug products in certain limited circumstances." 75 Fed. Reg. 79,383 (Dec. 20, 2010); see also 76 Fed. Reg. 9584 (Feb. 1, 2011) (extending comment period to April 11, 2011). Although the Request for Comment does not specifically mention compounding, it seems to address both compounded animal drugs and a number of the concerns raised by the 2005 Congressional letters: "For many years, FDA has been aware that a wide variety of animal drug products are being marketed that meet the definition of 'drug' and 'new animal drug' as defined in the FDCA, but are not approved, conditionally approved, or indexed. *Many of these unapproved animal drugs were, and some continue to be, the standard of care in treating animals, and some are essential to protecting animal health and ensuring an adequate food supply*." 76 Fed. Reg. at 79,383 (providing as examples "injectable vitamins, various topical solutions, shampoos, and liniments, electrolyte and glucose solutions, and antidotes") (emphasis added). Though the extended comment period has expired, see 76 Fed. Reg. 9584, the FDA has taken no further action which would impact the Court's resolution of this case.

6. Medical Center

In 2006, a group of state-licensed compounding pharmacies that specialized in compounding prescription drugs for humans and non-food animals grew weary of waiting for the FDA's promised revisions and brought suit challenging the agency's new assertions of authority as memorialized in the 2002 and 2003 Guides. Med. Ctr. Pharm. v. Gonzales, 451 F.Supp.2d 854 (W.D. Tex. 2006).[53] The pharmacies sought broad-based injunctive relief, including: (i) a declaration that drugs compounded by licensed pharmacists were not "new drugs" or "new animal drugs" per se under the FDCA; (ii) a declaration that the FDA did not have the authority to declare compounding from bulk ingredients for non-food animals illegal; and (iii) an injunction to prevent the FDA from enforcing the 2003 Guide "which unilaterally declares that compounding from bulk ingredients for non-food animals is illegal." Id. at 856-57. After reviewing § 321(p)(1) and § 321(v)(1), the district court noted "the new drug definitions might seem to indicate that compound drugs fall within their provisions." Id. at 859. However, the court ultimately found that Western States, FDAMA,[54] and the legislative history of the FDCA compelled the conclusion that "compound drugs are implicitly exempt from the [FDCA's] new drug definitions." Id. The court then used this implied exemption to conclude, inter alia, that: (i) compounding medications for non food-

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[53] Franck's was a member of a coalition of five pharmacies that filed an amicus brief in support of the plaintiff pharmacies. Franck Dec. ¶ 126.

[54] Because its analysis relied in part on FDAMA, the district court addressed whether the non-advertising provisions were severable from the remainder of the amendment and concluded that they were, rendering the remaining provisions of FDAMA still valid. Id. at 862-63. The Fifth Circuit ultimately upheld this portion of the district court's holding. See Med. Ctr., 536 F.3d at 404-05.

producing animals from bulk drugs was permissible because the resulting medications were not "new drugs," rendering inapplicable the FDCA's unsafe, misbranding and adulteration provisions; and (ii) the FDA could no longer enforce the 2003 Guide to the extent that it conflicted with the court's analysis of the FDCA. Id. at 867-69.

On appeal, the FDA challenged the district court's holdings that compounded drugs were "uniformly exempt" from the FDCA's "new drug" definitions, and that "drugs compounded from bulk ingredients for non-food animals do not violate the FDCA's unsafe, adulteration, or misbranding requirements." Med. Ctr., 536 F.3d at 393. The Fifth Circuit, after reviewing the FDCA in light of its legislative history, initially expressed sympathy for the pharmacies' plight:

> Given the apparent ubiquity of pharmacy compounding at the time Congress passed the FDCA [in 1938], it would have been unprecedented for the FDCA to regulate compounded drugs . . . [I]t seems unlikely that Congress intended to force compounded drugs to undergo the new drug approval process, a requirement that would have made compounding nearly impossible and thus nonexistent. Construing the "new drug" definition in a way that makes compounding effectively unlawful appears inconsistent with the likely expectation that compounding would and should persist and with other provisions of the FDCA that expressly acknowledge the existence of compounding.[55]

Id. at 398 (other footnotes omitted).

Ultimately, however, the Fifth Circuit agreed with the FDA that compounded drugs

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[55] "For example, provisions of the 1962 amendments to the FDCA exempt from registration and inspection requirements licensed 'pharmacies . . . which do not . . . compound . . . drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail.' §§ 360(g)(1), 374(a)(2)(A). As the FDA points out, however, this reference to compounding cuts another way, as it also suggests Congress's awareness of compounding and its ability to create exceptions for compounding when it chooses to do so." Id. at 398, n.33.

are "new drugs" and consequently must satisfy the FDCA's new drug approval requirements. Id. at 394. The Court deflected the argument that this construction would eradicate "the universally-appreciated practice of compounding" because it refused to "infer an absurd result from a maximalist interpretation of the FDA's authority where such authority is tempered by enforcement discretion." Id. at 398-99. However, the Court conceded that such discretion would provide little reassurance to the pharmacies:

> The Pharmacies may quite understandably find cold comfort in the FDA's promised self-restraint. In light, however, of the agency's statutorily-authorized enforcement discretion *and demonstrated willingness to accommodate traditional compounding's continued existence*, there is reason to think pharmacies would continue to compound even if compounded drugs were deemed "new drugs." Construing the FDCA to give the FDA authority over compounding would thus not necessarily "lead to a result so bizarre that Congress could not have intended it."
>
> *Nonetheless, it remains at least questionable that Congress would have intended such a large expansion of the FDA's regulatory authority. And it remains no small burden for compounding pharmacists, as they put it, to "live in sin" – their livelihood having no greater assurance than the FDA's good graces.*

Id. at 399-400 (emphasis added and citation omitted).

Despite these misgivings, the Fifth Circuit found that Congress' enactment of FDAMA made a "difficult case . . . easy" because the amendment provided a "safe harbor" for compounding under certain conditions. Id. at 400, 405. When construing the statute in light of its amendment, the Court concluded that compounded drugs could not be "implicitly exempted" from the FDCA, as the district court had concluded, because "reading the 'new drug' definition implicitly to exclude compounded drugs would make [FDAMA]'s explicit, conditional exceptions superfluous." Id. at 405-06.

At the end of its lengthy opinion, the Court very briefly considered the district court's conclusion that "drug products compounded in bulk by pharmacists and veterinarians are not 'new animal drugs' and therefore are not 'adulterated,' 'unsafe,' or 'misbranded.'" Id. at 406-08. The Fifth Circuit declared AMDUCA a "similar amendment" to FDAMA, and thus concluded that although the amendments contain different provisions,[56] "AMDUCA's effect on construction of the 'new animal drug' definition is much the same as FDAMA's effect on construction of the 'new [human] drug' definition. AMDUCA suggests that the FDCA's use of the term 'new animal drug' includes compounded drugs." Id. at 407-08 (alteration in original). The Court explained this conclusion by finding that:

> paragraph (4) [of AMDUCA] establishes that if a new animal drug is approved for one animal use, it can be used for a different unapproved use (i.e., compounded),[57] and paragraph (5) provides that if a new drug is approved for human use, it can be used for a different unapproved animal use (i.e., compounded).[58] In both cases, the drug must be used pursuant to the order of a licensed veterinarian and is subject to the FDA's discretionary finding that it poses a risk to public health.

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[56] By way of example (though this was not mentioned by the Fifth Circuit), AMDUCA does not mention the words "compounding" or "pharmacy," while FDAMA, i.e. 21 U.S.C. § 353a, is *entitled* "Pharmacy Compounding."

[57] "[I]f an approval of an application filed under subsection (b) [the new animal drug approval provision] is in effect with respect to a particular use or intended use of a new animal drug, the drug shall not be deemed unsafe for the purposes of paragraph (1) and shall be exempt from the requirements of section 352(f) of this title *with respect to a different use or intended use of the drug*, other than a use in or on animal feed . . . ." 21 U.S.C. § 360b(a)(4)(emphasis added).

[58] "If the approval of an application filed under section 355 of this title [the new human drug approval provision] is in effect, the drug under such application shall not be deemed unsafe for purposes of paragraph (1) and shall be exempt from the requirements of section 352(f) of this title *with respect to a use or intended use of the drug in animals* . . ." 21 U.S.C. § 360b(a)(5)(emphasis added).

Id. at 408. As a result, the Court held—citing Algon and 9/1 Kg. Containers as additional support—"that compounded drugs are 'new animal drugs'" under the FDCA, "[a]nd unless the compounded drugs are exempt under the FDCA's AMDUCA provisions, § 360b(a)(4) and (5), compounded animal drugs are subject to FDCA's unsafe, adulteration, and misbranding requirements. As with human drugs, the FDCA *contains no blanket 'implicit exemption'* for animal drugs produced by compounding." Id. at 408 (emphasis added).

Now, for the first time, the FDA has brought an enforcement action under the FDCA seeking to enjoin a pharmacist from compounding veterinarian-prescribed medications from bulk.

IV. The Court's Decision

A. Introduction

The FDA says this is a simple case: the literal, plain language of the original FDCA, enacted in 1938, gives it the enforcement authority to prevent pharmacists from bulk compounding medications for non food-producing animals. Thus, the FDA asserts that it is authorized to enjoin a licensed pharmacist's state-authorized practice of compounding animal drugs from bulk substances, even where a *single* medication is compounded for an individual non food-producing animal pursuant to a valid veterinary prescription. Essentially, the FDA contends that this traditional compounding practice implicates the same concerns under the FDCA as the mass-production, mass-marketing, and mass-distribution of unapproved animal drugs by an unlicensed manufacturer.[59]

[59] The FDA has stated that "[D]efendant's practices of distributing new animal drugs compounded from bulk threatens the approval process that the FDA has instituted and that

Although the FDA's complaint and declarations contain allegations that Franck's has engaged in conduct indicative of a "manufacturer" of drugs, such as compounding commercially available drugs or compounding drugs in advance of a valid prescription, it has provided no factual support for such claims and ultimately does not rely on them to maintain this action. Further, despite the FDA's allusions to Franck's "large" and "interstate" operation, it has not sought to prove a statutory violation based on the size or breadth of Franck's operation. Nor does the FDA contend that Franck's has compounded from bulk substances so as to produce animal drugs which are actually unsafe for animal consumption or are not efficacious. See Doc. 47 at 37-38. Finally, though the FDA references the deaths of the Venezuelan polo horses, that tragic event was unrelated to the bulk compounding that the FDA targets in this suit. Thus, each of these matters proved to be irrelevant. Given the undisputed record in this case and the FDA's broad view of its authority under 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.

Narrowing the inquiry even further, the FDA contends that it needs no more than the plain language of the 1938 FDCA to enjoin Franck's bulk compounding, a position it asserts has been confirmed by three courts of appeal (the Seventh, Third, and Fifth Circuits in 9/1

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the statute has mandated so that consumers of drugs can guarantee that they're drugs and guarantee as close to possible that they're safe and effective." Doc. 62 at 7-8; see also Doc. 47 at 14 (Court: "[I]s it the government's position that any compounding of bulk materials that is then used for animal medication is a violation of the [FDCA]?" FDA counsel: "That is correct. It is.")

Kg. Containers, Algon, and Medical Center, respectively). The FDA expressly disclaims reliance upon any other legal source, including AMDUCA, (see Doc. 54 at 7 ("AMDUCA does not encompass compounding from bulk drugs")); (Doc. 47 at 20 ("AMDUCA doesn't touch what we have here in this case")); FDAMA, (id. at 42 ("neither [FDAMA nor AMDUCA] are the subject of this suit")); any FDA regulation;[60] or the 2003 Guide, which it concedes does not have the force of law, (Doc. 54 at 30 (the 2003 Guide "is nothing more than an expression of a non-binding policy on enforcement discretion")). Thus, reduced to its essence, the parties and the Court are joined on the central issue: whether the FDCA, as originally enacted in 1938, provides the FDA with statutory authority to enjoin Franck's from engaging in traditional compounding of animal drugs from bulk.

Franck's says that Congress, in passing the FDCA, never intended to allow the FDA to prohibit the long-standing and widespread practice of bulk compounding when done by a state-licensed, state-regulated pharmacist, acting on an individual prescription written by a veterinarian for a non food-producing animal. In the alternative, Franck's contends that the FDA has failed to properly exercise this authority by failing to promulgate regulations through notice and comment rule-making before commencing this enforcement action.[61]

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[60] Though the FDA notes that its regulations implementing AMDUCA provide that "Nothing in this part shall be construed as permitting compounding from bulk drugs," 21 C.F.R. § 530.13, it rightly does not rely upon that regulation for its authority to *prohibit* the practice. Rather, it argues that AMDUCA cannot be read to *permit* compounding, because the language of § 530.13 demonstrates that "the AMDUCA exemptions are limited to compounding from approved drugs." Doc. 54 at 7.

[61] Franck's originally alleged in its Answer that the FDA's enforcement action is arbitrary, capricious, and unconstitutional, but elected not to pursue these defenses at summary judgment, focusing instead on its statutory arguments.

The FDA acknowledges that, for over a half-century after enactment of the FDCA, it did not assert authority to regulate traditional pharmacy compounding. Despite this, the agency's position is that the FDCA has always provided the FDA with authority to bring enforcement actions against pharmacists who compound animal drugs, and that its failure to do so in the past was merely the exercise of prosecutorial discretion. The FDA further asserts that it need not undertake rule-making before seeking to regulate in this area because its authority is supported by the plain language of the FDCA. The FDA thus concludes that, once it has shown a violation of the statute (i.e., that a "new animal drug" has been distributed without an approval or exemption in place), it enjoys unfettered enforcement discretion.

B. Discussion

"Because this case involves an administrative agency's construction of a statute it administers, [this Court's] analysis is governed by Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984)." FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 132 (2000). Under Chevron's two-step approach, a reviewing court must first ask "whether Congress has directly spoken to the precise question at issue[, and i]f the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." Chevron, 467 U.S. at 842-43, 843 n.9 ("If a court, employing traditional tools of statutory construction, ascertains that Congress had an intention on the precise question at issue, that intention is the law . . . ."). Second, if the Court finds that "the statute is silent or ambiguous with respect to the specific issue," the Court will defer to the agency's interpretation if it is "based

on a permissible construction of the statute." Chevron, 467 U.S. at 843; see also Gonzales v. Oregon, 546 U.S. 243, 255 (2006) ("An [agency's] interpretation of an ambiguous statute may . . . receive substantial deference")(citing Chevron, 467 U.S. at 842-45).

In applying this two-step analysis, the Supreme Court found in Chevron that "'[t]he power of an administrative agency to administer a congressionally created . . . program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress.'" Chevron, 467 U.S. at 843 (quoting Morton v. Ruiz, 415 U.S. 199, 231 (1974)). Thus, "a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency." Id. at 844. However, the Court also recognized the judiciary's role as "the final authority on issues of statutory construction." Id. at 843 n.9. As a result, "a reviewing court 'must reject administrative constructions . . . that are inconsistent with the statutory mandate or that frustrate the policy that Congress sought to implement.'" Sierra Club v. Johnson, 541 F.3d 1257, 1265 (11th Cir. 2008) (quoting Sec. Indus. Ass'n v. Bd. of Governors of Fed. Reserve Sys., 468 U.S. 137, 143 (1984)). Further, "deference to the agency's interpretation under Chevron is warranted only where 'Congress has left a gap for the agency to fill pursuant to an express or implied delegation of authority to the agency.'" Am. Bar Ass'n v. F.T.C., 430 F.3d 457, 468 (D.C. Cir. 2005) ("ABA I") (quoting Ry. Labor Exec. Ass'n v. Nat'l Mediation Bd., 29 F.3d 655, 671 (D.C. Cir. 1994) (en banc)). Put differently, "the existence of [statutory] ambiguity is not enough per se to warrant deference to the agency's interpretation. The ambiguity must be such as to make it appear that Congress either explicitly or implicitly delegated authority to cure that ambiguity." Id. at 469.

1. The FDCA's Language and the New Animal Drug Approval Process

"We begin, as courts always should in matters involving statutory interpretation, with the statutory language." Durr v. Shineski, 638 F.3d 1342, 1344 (11th Cir. 2011). The FDCA broadly defines "drug" to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." 21 U.S.C. § 321(g)(1)(B). The term "new animal drug" is also broadly defined as

> *any* drug intended for use for animals other than man . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective[62] for use under the conditions prescribed, recommended, or suggested in the labeling thereof.

Id. § 321(v)(1)(emphasis added). This definition provides no general exception for drugs created by compounding, nor a specific exemption for compounding by pharmacists. As the Fifth Circuit noted in Medical Center,

> [T]he language of the FDCA's "new drug"[63] definition is both plain and expansive. A "new drug" is "any drug" the "composition of which" has not

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[62] The Supreme Court has held—in the human drug context—that a drug is not generally recognized among experts as safe and effective without the adequate and well-controlled studies that would be required for its approval under § 355(d) of the FDCA. Weinberger v. Hynson, Westcott & Dunning, 412 U.S. 609, 629-30 (1973); Med. Ctr., 536 F.3d at 394. Franck's raises the argument that, due to the inherent policy differences involved in ensuring the safety and effectiveness of human drugs versus non food-producing animal drugs, veterinarians and pharmacists should be considered "experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs," which would automatically exclude prescription medications compounded within a veterinarian-client-patient relationship from the definition of "new animal drug." However, because § 321(v)(1) does not distinguish between food and non food-producing animals, this argument is a non-starter.

[63] Though this portion of the Fifth Circuit's analysis addressed the FDCA's "new drug" definition, it applies equally to the definition of "new animal drug."

> already been approved for use in accordance with its labeling. Compounded drugs are, after all, drugs. If a compounder changes the composition of an approved drug—by mixing or combining an approved drug with something else to create a different substance or by creating special dosage or delivery forms of an approved drug inconsistent with a drug's labeling—the composition of the individualized concoction created by a compounding pharmacist will not have been previously approved for use. The resulting substance is therefore a "new drug."
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> Belying the Pharmacies' argument that compounded drugs are not "new drugs" by virtue of their creation by licensed pharmacists, *the definition of "new drug" focuses on the drug's composition and use rather than on the process by which it was created.* Under the plain language of § 321(p)(1) [and § 321(v)(1)], it does not matter that the substance has been created through compounding rather than manufacturing—whether it be through rigorous research and development by a pharmaceutical company, through individualized compounding by a pharmacist or through cut-rate production by a rogue manufacturer. Regardless of how and by whom it was created, "any" such substance constitutes a "new drug" within the meaning of § 321(p)(1) [and § 321(v)(1)].

Med. Ctr., 536 F.3d at 395 (emphasis added, footnote omitted).

Before introducing or distributing a "new animal drug," a person must file an application that includes a number of detailed findings. 21 U.S.C. § 360b(b)(1). These include: full reports of investigations demonstrating that the drug is safe and effective for use; a list of the components of the drug; a statement of the drug's composition; a description of the manufacturing, processing, and packaging of the drug; samples of the drug; proposed labeling for the drug; methods for determining its effect on food, if any; and, proposed tolerances or withdrawal periods, if any. Id. A new animal drug is deemed "unsafe" under the FDCA unless the drug, its labeling, and its intended use conform to the FDA-approved application, a conditional approval, or an index listing for use in a minor species. Id. § 360b(a)(1). A drug is deemed "adulterated" if "it is a new animal drug which is unsafe within the meaning of [21 U.S.C. § 360b]." Id. § 351(a)(5). Lastly, the FDCA

requires any new drug to be labeled with adequate information about its contents, intended uses, and effects; drugs that fail to meet this requirement are "misbranded." See id. § 352. The FDCA prohibits the production, sale, and distribution of adulterated or misbranded drugs; see 21 U.S.C. § 331(a) - (c), (k); and authorizes the FDA to enforce its approval provisions utilizing both criminal and civil penalties. See 21 U.S.C. §§ 332 (injunction proceedings), 333 (criminal penalties), 334 (seizure), 335(b) (civil penalties).

Thus, read literally, the type of bulk compounding performed by Franck's (and hundreds of other pharmacists across the country on a daily basis) creates "new animal drugs" within the FDCA's broad definition of that term. According to the FDA, the Court's inquiry ends here. Franck's compounds animal medications from bulk substances (and in so doing implicates the interstate nexus); those medications are "new animal drugs" within the plain language of the FDCA; no statutory exceptions apply which would exempt compounded animal drugs from the FDCA's misbranding or adulteration provisions; the FDA has authority to enforce the new drug approval scheme; and it has chosen to do so here. Thus, FDA urges this Court to "follow the holdings of the Third, Fifth, and Seventh Circuits [in Algon, Medical Center, and 9/1 Kg. Containers] that compounded animal drugs are 'new animal drugs' within the meaning of the FDCA and decline [Franck's'] invitation to re-litigate the issue." Doc. 60 at 7.

2. Algon, 9/1 Kg. Containers, and Medical Center

Algon and 9/1 Kg. Containers each addressed the enforceability of an FDA regulation that exempted bulk drug sales from the FDCA's labeling requirements but limited the exemption to holders of new drug approval applications, thereby excluding veterinarians

from the exemption. See Algon, 879 F.2d at 1156 (quoting 21 C.F.R. § 201.122); 9/1 Kg. Containers, 854 F.2d at 175 (same). In so doing, the Third and Seventh Circuits analyzed the FDCA and noted that "[t]he statutory definition of a 'new drug' . . . does not exempt drugs that are compounded by veterinarians." Algon, 879 F.2d at 1158; see also 9/1 Kg. Containers, 854 F.2d at 175, 179. As a result, the courts concluded that "[t]he effect of § 352(f) [the FDCA's misbranding provision] and § 201.122 [the bulk drug exemption] is that ingredients that can be used to produce 'new' drugs may be sold only to firms that hold approved (or have filed) new animal drug applications." Algon, 879 F.2d at 1157-58 (quoting 9/1 Kg. Containers, 854 F.2d at 178).

There is no doubt that Algon and 9/1 Kg. Containers favor a broad reading of the FDA's authority under the FDCA. See 9/1 Kg. Containers, 854 F.2d at 176 ("Courts defer to the FDA when it construes its governing statutes"). However, though Algon and 9/1 Kg. Containers certainly have implications for this case, they are not on all fours either factually or procedurally. Both cases were enforcement actions against *suppliers* to prohibit them from supplying unapproved bulk ingredients to *veterinarians* for use in compounding.[64] Neither case mentioned pharmacists or the practice of pharmacy.[65] Thus, neither court had

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[64] Accordingly, in the 1992 Guide, the FDA cited to Algon and 9/1 Kg. Containers for their analysis "regarding limitations on sale of unapproved and otherwise unlawful products to licensed practitioners." 1992 Guide at 3. Notably, the FDA has provided no evidence in this case—nor has it alleged—that the bulk ingredients utilized by Franck's are either unlawfully obtained or unapproved.

[65] Despite this, the FDA announced in the 1996 and 2003 Guides that "two Federal Appeals Court decisions, [Algon and 9/1 Kg. Containers], affirmed the FDA position that the [FDCA] *does not permit veterinarians to compound unapproved finished drug products from bulk drugs*, unless the finished drug is not a new animal drug. The principle established by

occasion to consider the FDA's asserted authority to enjoin the practice of traditional pharmacy compounding.[66] This case presents that question, a different (though related) one from that faced in Algon and 9/1 Kg. Containers. Id.[67]

Algon and 9/1 Kg. Containers also predate a number of important legal developments relating to both the FDA's regulation of compounding and the Chevron doctrine. Both were decided before the Supreme Court in Brown & Williamson recognized that in certain circumstances, a literal reading of a broadly drawn public health statute (specifically, the FDCA) should be rejected when it encompasses conduct which exceeds the original congressional intent. See infra, Sec. IV(B)(3)(a). Moreover, two years after deciding Brown & Williamson, the Supreme Court in Western States expressly acknowledged the historical importance of traditional pharmacy compounding, and openly questioned whether Congress

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the court *applies equally to compounding by pharmacists*." 1996 Guide at 34,850; 2003 Guide at 3 (emphasis added). This language is noticeably absent from the 2002 Guide.

[66] The Third Circuit did in fact consider the question of whether the bulk drug exemption impermissibly intruded on the practice of veterinary medicine in violation of the intent of Congress. Algon, 879 F.2d at 1163. Because the record demonstrated that "[t]he only real objection to the government's actions in this case appears to be an economic one," the Third Circuit found that "the FDA's action effecting an increase in cost of drugs to practitioners does not undermine the practice of medicine or treatment decisions of veterinarians." Id. at 1165-66. Interestingly, the court mentioned in a footnote that two veterinarians, in an amicus brief, had suggested "a greater impact on their practices if their access to bulk drugs is restricted than they had previously described in their affidavits of record." Id. at 1165 n.6. However, the court did not consider the statements because it was "confined to considering those facts reflected in the record before the district court." Id.; cf. supra n.21, 29 (describing importance of compounding from bulk in veterinary practice).

[67] See Algon, 879 F.2d at 1164 ("The issue of whether the FDA can control the supply of *bulk* ingredients does not implicate the question of whether it can control the *use* of these ingredients in finished-form products")(emphasis in original).

could have intended to subject compounded drugs to the FDCA's new drug approval process. See W. States, 535 U.S. at 369-70. To answer this question, Franck's urges application of several canons of statutory construction (specifically, the "elephant-in-mouseholes doctrine,"[68] the "plain statement rule,"[69] and the "rule of lenity"[70]), none of which were argued or applied in the cases before the Third and Seventh Circuits (indeed, the elephant-in-mouseholes doctrine did not yet exist).

Medical Center (discussed in detail supra, Sec. III(B)(6)), though more similar to this case, is also different in important ways. First, Medical Center was not an FDA enforcement proceeding aimed at a specific target. Rather, the plaintiff pharmacies in that case sought broad-based prospective declaratory relief, i.e., to be excluded *entirely* from the FDCA's new drug approval regime, a position that the district court vindicated by holding that *all* compounded drugs enjoyed an "implicit exemption" from the FDCA. It was upon this premise that the district court based each of its subsequent findings—including the conclusion that pharmacy compounding of animal drugs from bulk did not fall within the

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[68] The "elephant-in-mouseholes doctrine" recognizes that Congress does not delegate decisions of economic and political significance to an agency in a vague or cryptic fashion; that is, it does not hide elephants in mouseholes. Gonzales, 546 U.S. at 267 (citing Whitman v. American Trucking Assns., Inc., 531 U.S. 457, 468 (2001); Brown & Williamson, 529 U.S. at 160).

[69] The "plain statement rule" requires that Congress speak in clear terms when displacing traditional state regulation of a particular practice. Gregory v. Ashcroft, 501 U.S. 452, 460-61 (1991).

[70] The "rule of lenity" requires that when a statute carries criminal penalties, any ambiguities must be interpreted in the defendant's favor 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).

FDA's enforcement authority.[71] See Med. Ctr., 536 F.3d at 392 n.20 (explaining that the district court "framed the Pharmacies' requested declaratory judgment as a 'declaration that drugs compounded by licensed pharmacists are not 'new drugs' or 'new animal drugs' *per se*'").[72]

The pharmacies' position (and the district court's holding) was simply untenable because, as Franck's concedes, the FDA *does* have the authority to prohibit pharmacists from manufacturing under the guise of compounding. Cf. Med. Ctr., 536 F.3d at 399 ("Construing the FDCA to give the FDA authority *over compounding* would thus not necessarily 'lead to a result so bizarre that Congress could not have intended it.'")(emphasis added and citation omitted); In re Wedgewood Vill. Pharmacy, 270 F. Supp. 2d 525, 549 (D.N.J. 2003)("Congress intended that the FDCA, both in its original form and as amended, allow the FDA broad enforcement powers to fulfill its mandate that it protect the public from unsafe medication"). Thus, the Fifth Circuit was understandably reluctant to issue a blanket declaration that the FDA could not regulate pharmacists who compromised the FDCA's new drug approval scheme, especially in light of the agency's "promised self-restraint" in bringing enforcement proceedings and its "demonstrated willingness to accommodate traditional

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[71] See Med. Ctr., 451 F.Supp.2d at 858, 864 ("[C]ompound drugs are implicitly exempt from the [FDCA's] new drug definitions ... [T]his Court finds that if compounding is a legal activity, then *any drugs created through the compounding process must be exempt from the new drug definitions found in the [FDCA]*")(emphasis added).

[72] Notably, because of the district court's ruling, the Fifth Circuit was faced with the argument that compounded drugs were entirely beyond the scope of the FDCA's new *human* drug provisions, a position that could not be squared with the plain language of the statute as amended by FDAMA.

compounding's continued existence." Med. Ctr., 536 F.3d at 399. The Court therefore declined to *"infer an absurd result from a maximalist interpretation* of the FDA's authority where such authority is tempered by enforcement discretion." Id. (emphasis added).

The Fifth Circuit was able to reject a "maximalist" interpretation of the FDA's authority because the FDA was not advancing such a position. Here, however, the FDA is taking the "maximalist" position that any pharmacy compounding of animal drugs from bulk substances pursuant to a valid veterinary prescription—which, according to the undisputed record evidence, would qualify as "traditional compounding"[73]—is per se unlawful under the FDCA.[74] Thus, the Fifth Circuit's faith that the FDA would not seek to enforce a "maximalist" interpretation of its authority turned out to be misplaced.

There is an additional problem with the Fifth Circuit's disposition when overlaid upon this case. Not only did the Court in Medical Center presume that the FDA would continue to demonstrate its historical willingness to accommodate traditional compounding, but it also presumed that the FDA drew no distinction between human and animal compounding, even though the manifest differences in the 2002 and 2003 Guides belie such a presumption. Here, the FDA is not only asserting its authority to regulate traditional compounding, but is drawing an enforcement line between human and animal drugs. Although Franck's compounds medications for both humans and animals, the FDA is not seeking to enjoin Franck's' human compounding business. Rather, the FDA (despite its statement in the 2002

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[73] Cf. supra n.20, 27, 38.

[74] In Medical Center, the pharmacies had taken the opposite per se position that all pharmacy compounding was legal.

Guide that "all of FDAMA is now invalid") takes the position in this litigation that the FDCA is "more constrictive" with regard to non food-producing animal drugs than it is for human drugs.[75] Though the FDA concedes that this is an unfortunate position to argue from, it contends that interpreting the FDCA—a prophylactic statute designed to protect the public health—in a manner that is less protective of humans than of non food-producing animals "is simply a matter of applying the statutes as written." Doc. 54 at 16. While this statutory inconsistency should theoretically have been before the Court in Medical Center, which passed on the question of both human and animal compounding, the Fifth Circuit did not address it.[76]

And lastly, in analyzing the FDA's interpretation of its authority under the FDCA to regulate compounding, each of the Third, Fifth, and Seventh Circuits afforded Chevron-level deference to the agency. In Algon and 9/1 Kg. Containers, this was appropriate because both cases involved a challenge to an FDA regulation promulgated pursuant to notice-and-comment rule-making. The courts thus showed substantial deference to the FDA's

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[75] See Doc. 47 at 16. Specifically, while FDAMA permits compounding of human drugs from bulk substances under certain circumstances, the practice is entirely prohibited for animals—except for nine listed exceptions—by the 2003 Guide. See supra at 29-31.

[76] This is not altogether surprising, as the Fifth Circuit had no occasion to do so given the posture of the case as framed by the district court. However, it is apparent from a review of the Fifth Circuit's opinion that the Court analyzed the issue of compounding human drugs far more thoroughly than it did compounding animal drugs. Of specific note, the Court did not discuss any of the policy differences between the 2002 and 2003 Guides, and its analysis of AMDUCA as an analog to FDAMA is, with due respect, unpersuasive. The FDA apparently shares this view; while it certainly likes the outcome reached by the Fifth Circuit, nowhere in its briefing or argument does the FDA embrace that court's statutory construction, which relied heavily upon AMDUCA. This may represent a subtle concession that the Fifth Circuit's analysis of the "new animal drug" issue was less than watertight.

construction of the FDCA and its own regulations[77] and placed the burden on the suppliers to show that the "FDA's views about the needs of public health [we]re arbitrary and capricious." 9/1 Kg. Containers, 854 F.2d at 176; Algon, 879 F.2d at 1159. This, as the Seventh Circuit noted, was a "doubly-uphill battle." 9/1 Kg. Containers, 854 F.2d at 176.

Likewise, because the Fifth Circuit concluded on the basis of FDAMA and AMDUCA that the plain language of the FDCA encompassed compounded drugs, it deferred to the FDA's enforcement discretion in regulating pharmacy compounding:

> When it comes to the slippery task of distinguishing true compounding from disguised manufacturing, we should question our own capacity, as a court, to make that distinction in future cases. In exercising its discretion, the FDA relies on numerous factors and considerations to determine whether a pharmacist is engaged in compounding as distinguished from manufacturing. With no guidance from the statutory text, we doubt we could do any better, and we are wary of trading the FDA's discretion for our own.

Med. Ctr., 536 F.3d at 399 (footnote omitted).

For reasons explained more fully infra, Chevron deference is not appropriate in this case, which provides yet another basis for distinguishing Algon, 9/1 Kg. Containers, and Medical Center.

3. Chevron Step One: Whether Congress Intended to Grant the FDA Authority to Regulate Traditional Compounding

The FDA argues that, even if Algon, 9/1 Kg. Containers, and Medical Center are distinguishable, this Court must find that the plain terms of the FDCA encompass compounded drugs because the FDCA grants the FDA "broad authority" to regulate drugs

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[77] An agency's interpretation of its own ambiguous regulation promulgated pursuant to a congressional grant of authority is "controlling unless plainly erroneous or inconsistent with the regulation." Auer v. Robbins, 519 U.S. 452, 461 (1997)(quotation omitted).

"to ensure public health and safety." Nutritional Health Alliance v. FDA, 318 F.3d 92, 97-98 (2d Cir. 2003). As the FDA notes, the primary purpose of the FDCA is to protect and safeguard consumers from dangerous products. United States v. Sullivan, 332 U.S. 689, 696 (1948); see also Brown & Williamson, 529 U.S. at 133 (a "core objective" of the FDCA is to "ensure that any product regulated by the FDA is 'safe' and 'effective' for its intended use"). To effectuate that purpose, the Supreme Court has instructed that "Congress fully intended that the [FDCA]'s coverage be as broad as its literal language indicates . . . [R]emedial legislation such as the [FDCA] is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health." United States v. Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 798 (1969). Thus, the FDA simply asks that this Court enjoin Franck's from distributing animal medications compounded from bulk substances because the FDCA statutorily defines those drugs as unsafe, adulterated, and misbranded.

Franck's concedes that the literal language of the "new animal drug" provision read without any other context is sufficiently capacious to encompass pharmacists and compounding, but argues that further inquiry is necessary to determine whether such an outcome was intended by Congress in 1938. Franck's contends that Congress never meant the FDCA to reach so broadly as to allow the FDA to enjoin the long-standing practice of a state-licensed pharmacist using traditional bulk compounding to fill a veterinarian's prescription for a non food-producing animal. Stated differently, Franck's position is not that Congress left open an implied exception for traditional pharmacy compounding; rather, Franck's argues that Congress never intended to regulate the practice in the first place. See ABA I, 430 F.3d at 469. Franck's therefore urges this Court to consider the FDCA's

structure and legislative history through the lens of several canons of statutory construction so as to place the FDCA's treatment of traditional pharmacy compounding in its proper context.

a. Elephants-in-mouseholes doctrine

Franck's finds support in Brown & Williamson, ABA I, and Gonzales. In Brown & Williamson, the FDA asserted jurisdiction to regulate tobacco products based on its conclusions that nicotine was a "drug" and that cigarettes and smokeless tobacco were "drug delivery devices" under the FDCA. 529 U.S. at 131. While tobacco products appeared at first blush to be encompassed by the FDCA's literal definitions, which might have rendered the statute unambiguous on the question, the Court cautioned that "'[a]mbiguity is a creature not of definitional possibilities but of statutory context.'" Id. at 132-33 (quoting Brown v. Gardner, 513 U.S. 115, 118 (1994)). As such, the Court stated that "[i]n determining whether Congress has specifically addressed the question at issue, a reviewing court should not confine itself to examining a particular statutory provision in isolation. The meaning—or ambiguity—of certain words or phrases may only become evident when placed in context." Id. at 132. After interpreting the FDCA "as a symmetrical and coherent regulatory regime," the Court declared that "Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion." Id. at 133 (citation omitted), 160.[78] As a result, and after consideration of subsequent legislation addressing the issue, the Court found that "the FDA's claim to

[78] This reasoning became the foundation for the Court's invocation of the elephant-in-mouseholes doctrine in American Trucking, 531 U.S. at 468.

jurisdiction contravenes the clear intent of Congress." Id. at 132.

Likewise, in ABA I, the FTC asserted authority to regulate certain attorneys as "financial institution[s]" under the privacy provisions of the Gramm-Leach-Bliley Act ("GLBA"). 430 F.3d at 465–66. The D.C. Circuit noted that neither the statute nor the FTC's regulations described the regulatory scheme as governing the practice of law, and that the word "attorney" did not appear in the GLBA in such a context so as to include attorneys within the definition of "financial institution." Id. at 466. However, because the GLBA defined "financial institution" "quite broadly," under the literal language of the statute, real estate and tax attorneys were potentially implicated through a weave of incorporated statutes and regulations. Id. at 467 (citation omitted).

The Court declared that:

> [t]he statute certainly does not so plainly grant the Commission the authority to regulate attorneys engaged in the practice of law as to entitle the Commission to what is called a "Chevron One" disposition. That is, rather simply we cannot hold that Congress has directly and plainly granted the Commission the authority to regulate practicing attorneys as the Commission attempts. Indeed, such professionals are subject to regulation under the words of the statute only if they are "institutions" and if they are "engaged in the business of financial activity." It is not plain at all to us that Congress has entered such a direct regulatory command by plain language of a statute, a lengthy statute incorporated by reference, and an even more lengthy and detailed regulation incorporated by reference in the second statute, none of which ever mentioned attorneys engaged in the practice of law. Therefore, if the Commission is to prevail, it must do so under a deferential standard of review. That is, to uphold the Commission's regulatory decision, we must conclude first that the words of the statute are ambiguous in such a way as to make the Commission's decision worthy of deference under the second step of Chevron.

Id. at 467-68. The Court reviewed the regulatory scheme in light of the traditional state regulation of attorneys, and noted that the statutory language, while potentially broad or

ambiguous enough to bear FTC's interpretation, made for an "exceptionally poor fit with the FTC's apparent decision that Congress, after centuries of not doing so, has suddenly decided to regulate the practice of law." Id. at 470. Applying the elephant-in-mouseholes doctrine, the Court concluded that Congress did not "intend[ ] to undertake the regulation of the profession of law—a profession never before regulated by 'federal functional regulators'—and never mentioned in the statute." Id. at 469.

And most recently, the Supreme Court in Gonzales considered "whether the Controlled Substances Act allows the United States Attorney General to prohibit doctors from prescribing regulated drugs for use in physician-assisted suicide, notwithstanding a state law permitting the procedure." 546 U.S. at 248-49. After a lengthy review of the Attorney General's delegated authority and the structure of the CSA, the Court declared "[t]he idea that Congress gave the Attorney General such broad and unusual authority through an implicit delegation in the CSA's registration provision is not sustainable." Id. at 267 (citing American Trucking, 531 U.S. at 468; Brown & Williamson, 529 U.S. at 160). Applying the appropriate level of deference due to the Attorney General's position, the Court found the Attorney General's statutory interpretation to be unpersuasive. Id. at 268-69.[79]

The elephant-in-mouseholes doctrine is equally applicable here: it is not at all clear that Congress meant to hide the elephant of the FDA's regulation of traditional pharmacy compounding in the mousehole of the FDCA's new drug approval process. Every court that

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[79] Franck's also finds support in recent Eleventh Circuit case law. See Durr, 638 F.3d at 1349 (describing circumstances where courts may reach results inconsistent with the plain language of a statute by looking to the provisions of the whole law, and to its policy).

has addressed the issue—no matter the context—has recognized that the FDA new drug approval process is an "especially poor fit" for regulating traditional pharmacy compounding, one that would potentially eradicate traditional compounding despite the recognized importance, historical acceptance, and decades-long state regulation of the practice. See, e.g., W. States, 535 U.S. at 369-70 ("[I]t 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"); Med. Ctr., 536 F.3d at 398 ("[I]t seems unlikely that Congress intended to force compounded drugs to undergo the new drug approval process, a requirement that would have made compounding nearly impossible and thus nonexistent"); see also Algon, 879 F.2d at 1161 (noting the argument that "limiting drugs that veterinarians can compound to those lawfully obtainable [at the time, approved animal drugs] means for all practical purposes that veterinarians will be unable to compound"); 9/1 Kg. Containers, 854 F.2d at 177 ("The testing required to obtain a new animal drug approval is costly and extended. . . Testing must isolate the effects of the drug in question from all other environmental influences, then follow the animals for years (even generations of animals) to identify the consequences. This requires data from large populations of animals and the application of powerful statistical techniques. No solitary medical professional can carry out this program of knowledge acquisition for even one drug, let alone for the bevy of drugs a veterinarian may choose to compound."). Likewise, despite the literal language of the

statute, this Court cannot find that Congress has "directly and plainly" said that traditional pharmacy compounding of animal drugs must meet the requirements of the FDCA's new drug approval provisions. See ABA I, 430 F.3d at 467; American Bar Ass'n v. F.T.C., 671 F.Supp.2d 64, 73 (D.D.C. 2009)("ABA II"), *vacated on mootness grounds*, American Bar Ass'n v. F.T.C., 636 F.3d 641, 644 (D.C. Cir. 2011).

Where Congress has not entered a direct regulatory command by the plain language of the statute, further review is warranted to determine whether the statute is "ambiguous in such a way as to make the [agency's] decision worthy of deference under the second step of Chevron." ABA I, 430 F.3d at 468. The question of whether such an ambiguity exists "is for the court, and we owe the agency no deference on the existence of ambiguity. Deference to the agency's interpretation under Chevron is warranted *only where Congress has left a gap for the agency to fill pursuant to an express or implied delegation of authority to the agency*." Id. at 467 (emphasis added and internal quotation omitted). The Court must therefore proceed with a review of the structure and legislative history of the FDCA, using recognized canons of statutory construction, to determine whether deference to the FDA's statutory construction is appropriate here.

b. Statutory structure, legislative history and the FDCA's purpose

Though nothing in the FDCA or its amendments actually *prohibits* compounding by a state-licensed pharmacist, the FDA posits that an explicit prohibition is not required for the agency to enforce against the practice. Rather, the FDA argues that because the statute includes no *exemption* for state-licensed pharmacists or for compounded medications, traditional pharmacy compounding practices are subject to the same regulatory

requirements as new drugs that are manufactured, marketed, and distributed in interstate commerce.[80] The lack of a blanket exemption for pharmacy compounded drugs is at least somewhat instructive because the FDCA does exclude certain "grandfathered" old drugs and investigational drugs from the scope of its "new animal drug" provisions. See 21 U.S.C. § 321(v)(1), § 360b(j).

However, "if we were 'to *presume* a delegation of power' from the absence of 'an express *withholding* of such power, agencies would enjoy virtually limitless hegemony." ABA I, 430 F.3d at 468 (emphases in original) (quoting Ry. Labor, 29 F.3d at 671). And while pharmacists do not enjoy a uniform exemption from the FDCA's new drug approval scheme, the 1962 amendments to the FDCA do exempt from certain FDA registration and inspection requirements "pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy" and dispense drugs "upon prescriptions of practitioners" for their patients, "and which do not manufacture . . . [or] compound . . . drugs . . . for sale *other than in the regular course of their business of dispensing or selling drugs.*" See 21 U.S.C. § 360(g)(1) (requiring drug manufacturers to register annually with the FDA)(emphasis added); id. § 374(a)(2)(A) (granting FDA agents right to inspect manufacturing facilities "[f]or purposes of enforcement of this chapter"). Interestingly, these provisions contain the FDCA's only mention of compounding, and arise

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[80] See Algon, 879 F.2d at 1158 ("The statutory definition of a 'new drug' . . . does not exempt drugs that are compounded by veterinarians"); cf. Prof'ls and Patients, 56 F.3d at 593 n.3 ("Although the [FDCA] does not expressly exempt 'pharmacies' or 'compounded drugs' from the new drug, adulteration, or misbranding provisions, *the FDA as a matter of policy has not historically brought enforcement actions against pharmacies engaged in traditional compounding*")(emphasis added).

in a context which expressly distinguishes drug manufacturers from pharmacists engaged in the practice of traditional compounding. The presence of these exemptions could be interpreted as a congressional policy decision to distinguish compounding from manufacturing. In fact, this very interpretation was recognized by the Third and Seventh Circuits in Algon and 9/1 Kg. Containers in the context of veterinarians. See Algon, 879 F.2d at 1160 ("Congress *intended to authorize compounding with legally acquired drugs . . .* Thus, the medical practitioner exemptions by their terms afford no more than the right to be free from inspection and registration requirements when veterinarians and other practitioners *compound medicine with legally acquired materials*")(emphasis added); 9/1 Kg. Containers, 854 F.2d at 177-78 ("The FDA treats § 360(g)(2) as *allowing veterinarians to* 'prepare, propagate, *compound*, or process drugs *from ingredients they lawfully acquire*', and the added words are no more than those implied in every statute")(first emphasis added); see also U.S. v. Baxter Healthcare Corp., 901 F.2d 1401, 1409 (7th Cir. 1990)("Congress *has decided to treat commercial manufacturers of drugs differently from pharmacies and individual physicians* in [certain] contexts [citing the FDCA's exemption of pharmacists and physicians from the registration and inspection requirements in 21 U.S.C. §§ 360(g)(1), (2), 374(a)(1), (2)]. Therefore, *to the extent Congress has addressed the issue, it has decided to focus governmental resources upon the commercial distributors of drugs rather than upon the trained pharmacists and physicians who must reconstitute drugs for patient use on a smaller scale*. One sound argument for this choice is evident: A drug improperly compounded on a large scale will harm more patients than the same compounding mistake made on a smaller scale.")(emphasis added).

The legislative history of the FDCA also supports the view that manufacturers, not compounding pharmacists, were the intended target of the FDCA's new drug approval scheme.[81] Because Congress appeared to be focused on the fact that manufacturing—unlike the practice of pharmacy—was conducted by unlicensed, unregulated nonprofessionals, it seems unlikely that it would have intended to subject professionally dispensed drugs to the same regulatory scheme. This distinction is even more compelling when one considers the FDCA scheme's poor fit with a traditionally compounded animal medication. The FDCA provides that the introduction or delivery for

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[81] The Fifth Circuit in Medical Center cited these entries from the FDCA's legislative history:

> The President of the American Pharmaceutical Association told a subcommittee of the Senate Committee on Commerce the following:
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> > 'Regulations governing . . . the practice of pharmacy by pharmacists are very strict, but the privileges of unlicensed persons operating outside of pharmacies are so extensive that the public enjoys little protection in the matter of sales of packaged medicines.' Foods, Drugs, and Cosmetics: Hearings Before a Subcomm. of the Comm. on Commerce, 74th Cong. 100, 102 (1935) (statement of Robert P. Fischelis, President, American Pharmaceutical Ass'n) (quoting survey by committee on costs of medical care).
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> In a similar vein, Representative Coffee made remarks to the House, approvingly quoting the Secretary of Agriculture:
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> > 'Pharmacists are licensed to compound and dispense drugs. Electricians, plumbers, and steam engineers pursue their respective trades under license. But there is no such control to prevent incompetent drug manufacturers from marketing any kind of lethal poison.' Extension of Remarks of Rep. John M. Coffee, 83 Cong. Rec. 2279, 2279 (June 1, 1938) (quoting Henry A. Wallace, Secretary of Agriculture).

Med. Ctr., 536 F.3d at 397 (footnotes converted to text).

introduction into interstate commerce of any "new animal drug" without FDA approval is unlawful unless an application is filed that includes, among other things, "a full list of the articles used as components of such drug." 21 U.S.C. §§ 360b(a)(1), (b)(1)(B). And it requires "full reports of investigations" as part of the application, id. § 360b(b)(1)(A), which the FDA has long interpreted to require that new drugs be subject to extensive testing and well-controlled studies to determine their safety and effectiveness. Given that traditionally compounded medications are prepared for individual animal patients in response to a valid veterinary prescription, meaning each compounded medication has unique components and is ill-suited for "adequate and well-controlled studies," it just does not seem plausible that Congress would have intended to subject pharmacy compounded drugs to the lengthy and expensive new animal drug approval process. See Med. Ctr., 536 F.3d at 398; W. States, 535 U.S. at 369-70. The statutory "fit" is especially poor when compounded medications are the best—and sometimes only—way to treat an animal. Cf. supra n.21 and accompanying text.

However, "statutory prohibitions often go beyond the principal evil to cover reasonably comparable evils, and it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed." Oncale v. Sundowner Offshore Servs., Inc., 523 U.S. 75, 79 (1998). While the FDCA might not have been focused on pharmacists behaving badly, it was without question enacted to protect the public from the distribution of unapproved drugs which have been mass-produced without any assurances of safety or quality control. To the extent that a pharmacist's bulk compounding activity moves beyond the bounds of traditional compounding and begins to

approximate the "manufacturing" of unapproved drugs, there seems little question that this activity is squarely within the crosshairs of the FDCA. Cf. W. States, 535 U.S. at 361 ("The Federal Food, Drug, and Cosmetic Act of 1938 . . . regulates drug *manufacturing*, marketing, and distribution")(emphasis added).

Thus, on the one hand, legitimate state-licensed pharmacists have long held the right to bulk compound drugs to fill individual prescriptions, and the desirability and acceptance of that practice has been recognized in various ways by Congress and the FDA. On the other, the FDA needs to be able to enforce against manufacturers masquerading as pharmacy compounders. And the new drug approval process is a poor method for drawing a line between these two interests *precisely* because it fails to allow for the continuance of state-authorized, traditional compounding. This tension was duly noted by the Supreme Court in Western States:

> 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 . . . Given this, the Government needs to be able to draw a line between small-scale compounding and large-scale drug manufacturing.* That line must distinguish compounded drugs produced on such a small scale that they could not undergo safety and efficacy testing from drugs produced and sold on a large enough scale that they could undergo such testing and therefore must do so.

W. States, 535 U.S. at 369-70 (emphasis added).

What the Supreme Court recognized is that Congress delegated to the FDA the authority to *draw a line* distinguishing between compounded drugs that *must* undergo the new drug approval process because they bear the attributes of having been "manufactured"

and "compounded drugs *created to meet the unique needs of individual patients,*" because it "would not make sense" for the latter "to undergo the testing required for the new drug approval process." Id. at 369 (emphasis added); see also Med. Ctr., 536 F.3d at 398. At the time of the Supreme Court's decision in Western States, the government seemed to understand and support this distinction:

> While it praises the FDCA's new drug approval process, the Government also acknowledges that 'because obtaining FDA approval for a new drug is a costly process, requiring FDA approval of all drug products compounded by pharmacies for the particular needs of an individual patient *would, as a practical matter, eliminate the practice of compounding, and thereby eliminate availability of compounded drugs for those patients who have no alternative treatment*.'

W. States, 535 U.S. at 369 (quoting the Government's brief)(emphasis added).

Following this logic, the States, including Florida, expressly distinguish the practice of traditional pharmacy compounding from manufacturing. The Florida Drug and Cosmetic Act, Fla. Stat. §§ 499.001 *et seq.*, which was enacted to "provide uniform legislation *to be administered so far as practicable in conformity with the provisions of, and regulations issued under the authority of, the Federal Food, Drug, and Cosmetic Act*," id. § 499.002(b)(emphasis added), defines "manufacture" as "the preparation, deriving, *compounding*, propagation, producing, or fabrication of any drug, device, or cosmetic," id. § 499.003(30)(emphasis added), and "manufacturer" as, *inter alia*, "[a] person who prepares, derives, *manufactures*, or produces a drug, device or cosmetic," id. § 499.003(31)(emphasis added). However, the term manufacturer "*does not include a pharmacy that is operating in compliance with pharmacy practice standards as defined in [the Florida Pharmacy Act] and rules adopted [there]under*." Id. § 499.003(31)(emphasis

added). And, as mentioned supra, those standards and rules expressly provide for compounding from bulk substances.[82]

The Florida statutory scheme recognizes a critical difference between traditional pharmacy compounding and manufacturing: the existence of a pharmacist-prescriber-patient relationship that controls the preparation of the compounded drug product.[83] Traditionally compounded drugs are not for resale, but rather are responsive to the patient's immediate needs as diagnosed by the patient's licensed healthcare professional, i.e., a veterinarian.[84]

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[82] See Florida Pharmacy Act, Fla. Stat. §§ 465.001 *et seq*. (creating the Florida Board of Pharmacy and conferring upon the Board the duty to regulate the practice of pharmacy within the state); id. § 465.003(13)("'Practice of the profession of pharmacy' *includes compounding*, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug . . . ."))(emphasis added); Fla. Admin. Code Ann. 64B16-27.700(1)("Compounding includes: (a) The preparation of drugs or devices in anticipation of prescriptions based on routine, regularly observed prescribing patterns. (b) The preparation pursuant to a prescription of drugs or devices which are not commercially available. (c) The preparation of commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient has been made aware that the compounded product will be prepared by the pharmacist . . . .").

[83] See Dinah G. Jordan, "Pharmacist compounding vs. veterinarian compounding: Similarities and differences," Journal of the American Veterinary Medical Association (July 15, 1995), at 258 ("There must exist a bona fide prescriber/pharmacist/patient relationship to distinguish compounding from manufacturing. Manufactured products are for resale; compounded products are not . . . . Herein lies the basic difference between compounding and manufacturing").

[84] See Bradshaw Dec. ¶ 44 ("Drug manufacturing generally is understood to consist of the mass commercialization of proprietary or patented drugs in standard formulations and dosages for a large-scale market. Drug manufacturers routinely produce batches consisting of millions of dosage units, such as tablets or capsules, for resale utilizing many personnel and large-scale manufacturing equipment. These drug products are distributed through the normal channels of interstate commerce to individuals unknown to the manufacturing company. Manufacturers are not required to, and do not, provide oversight of individual patients. Federal regulation of large-scale commercial manufacturing is intended to prevent

Moreover, unlike manufacturers, compounding pharmacists are licensed professionals who must operate in conformance with applicable state laws that regulate the practice of pharmacy.

Though it certainly has the statutory authority to do so, the FDA has chosen not to draw the line between manufacturing and traditional compounding with formal regulations. Nor has it sought to distinguish traditional pharmacy compounding from pharmacists who are manufacturing under the guise of compounding.[85] Rather, beginning with the 1992 Guide, it has utilized Compliance Policy Guides to disseminate its policy determinations vis-a-vis the acceptability of compounding animal and human drugs. Along the way those non-binding guidance documents have made clear that "traditional pharmacy compounding"[86] was not the subject of the FDA's guidance. In addition, the agency has continued to recognize that because of an "insufficient variety of approved medications," (see Flynn Dec. ¶ 26), certain compounded medications are medically necessary for the treatment of animals.[87] Accordingly, hundreds of compounding pharmacists like Franck's—who had long

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the production of large quantities of ineffective or dangerous manufactured drugs that then are introduced into interstate commerce").

[85] In Western States, the Supreme Court suggested several means to draw "a line between compounding and large-scale manufacturing" which would be sufficient to "prevent compounding from occurring on such a scale as to undermine the new drug approval process." W. States, 535 U.S. at 372-73; supra n.45.

[86] Or, in the parlance of the 1996 Guide, the "legitimate practice" of pharmacists and veterinarians.

[87] See, e.g., CVM Update, "CVM Working to Address Concerns about Supplies of Pergolide for Horses," May 11, 2007, *available at* http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm048035.htm ("FDA is

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. (See Franck Dec. ¶ 65.)[88] But although the FDA generally deferred to the states with regard to "traditional compounding," and brought no enforcement actions against the numerous pharmacies nationwide engaged in bulk compounding for non food-producing animals, the agency has, since 9/1 Kg. Containers, asserted that it possessed the statutory authority to regulate the practice. As a result, state-licensed veterinarians and pharmacists have, with the FDA's blessing, been "living in sin" (according to the FDA) for over twenty years. Med. Ctr., 538 F.3d at 400.[89]

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working with the sponsors of the approved products and all other interested parties to ensure that pergolide remains available to treat Cushing's Syndrome in horses until a new animal drug application is approved for that use. This includes trying to make the approved product available through veterinary distribution channels and exercising enforcement discretion as appropriate over the pharmacy compounding of pergolide. Bulk substance used for pharmacy compounding should be labeled for 'animal use only.' All pharmacy compounding must be done under a valid veterinary prescription to treat an affected horse").

[88] "In developing my independent compounding pharmacy, I have relied on the fact that pharmacy compounding practices have long and traditionally been regulated by the states." Id.

[89] The FDA claims this cuts another way, namely that pharmacists such as Franck's (which has been compounding since 1983) have been on notice of the agency's asserted authority in this area—and the potential for regulatory enforcement—since the days of Algon and 9/1 Kg. Containers. But cf. Northwest Tissue Center v. Shalala, 1 F.3d 522, 533 (7th Cir. 1993) ("Suppose an agency charged with regulating the nation's highways promulgates regulations requiring 'all vehicles' to conform to certain safety standards. For five years the agency enforces these standards only against automobiles of various types. Then it publishes a notice in the Federal Register announcing that the regulations also apply to bicycles. The dictionary definition of vehicle ('A device, such as a car or sled, for carrying passengers, goods, or equipment; conveyance....') reasonably encompasses bicycle as a

The FDA says that it does adequately account for the continued practice of traditional pharmacy compounding through the judicious exercise of its enforcement discretion.[90] The FDA does not dispute that the practice of pharmacy compounding, including compounding of animal drugs from bulk, was widespread at the time FDCA was enacted (or even that it remains so today). However, it dismisses the notion that this long-standing practice (and the agency's long-standing failure to enforce against it) somehow undermines its current enforcement authority. It notes that the Fifth Circuit rejected the same argument on the basis of FDA's enforcement discretion, which prevented the *reductio ad absurdum* of eradicating the widespread and accepted process of compounding. Thus, the FDA says, "the specter that [D]efendants present of the whole [pharmacy] industry behind bars is farfetched hyperbole. FDA has consistently exercised its enforcement discretion against compounding pharmacies in a manner that clearly demonstrates that it has no intention of shuttering the entire industry." (Doc. 54 at 17.)

Although that argument was appropriately accepted by the Fifth Circuit under the procedural posture of that case, it cannot prevail here. Had the Fifth Circuit upheld the district court's implied exemption of all pharmacists from the FDCA's new drug approval process, it would have handcuffed the FDA's ability to police the line between traditional

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permissible interpretation. Nevertheless, it seems silly to suggest that the nation's bicyclists would have been 'on notice' at the time the regulations were promulgated that the agency's standards applied to their bikes.")

[90] It is the FDA's position that its broad discretionary authority is bridled only by its "responsibility to choose its enforcement actions wisely and under some merit and under some thoughtful consideration." (Doc. 47 at 23.)

compounding and manufacturing because *all* compounded drugs, even those prepared by pharmacists manufacturing in the guise of compounding, would have been exempt from FDA enforcement. Thus, because the Fifth Circuit recognized that the FDA could properly draw a line between compounding and manufacturing, the court relied upon the FDA's enforcement discretion as a counterpoint to the agency's otherwise unfettered authority. Med. Ctr., 536 F.3d at 399 ("Construing the FDCA to give the FDA authority *over compounding* would thus not necessarily 'lead to a result so bizarre that Congress could not have intended it.'")(emphasis added and citation omitted).[91]

Here, the FDA's authority to regulate pharmacy compounding as a disguise for manufacturing is not at issue. Rather, utilizing this first-of-its-kind enforcement action, the FDA seeks to expand its statutory authority by enjoining an individual pharmacy which is engaged in traditional pharmacy compounding of animal drugs in compliance with state law. In so doing, the FDA overreaches. See W. States, 535 U.S. at 369-70 ("[I]t *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 [because] requiring such testing *would force pharmacists to stop providing compounded drugs*")(emphasis added).

Another potential anomaly (not presented to the Fifth Circuit) is in sharp relief here.

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[91] The Fifth Circuit stated: "[E]ven if compounded drugs are effectively made unlawful by the 'new drug' definition and approval requirements, pharmacists still could continue compounding to the extent allowed by the FDA's enforcement discretion. The FDA did not enforce the 'new drug' requirement against traditional compounding for decades, and the agency's Compliance Policy Guide declared only a limited intention to conduct future enforcement in cases in which compounding looks more like disguised manufacturing." Med. Ctr., 536 F.3d at 399.

If the FDA's position is correct, Congress intended to give the agency the authority to require traditionally compounded medications for non food-producing animals to go through the FDA's lengthy and involved new drug approval process but declined to require it for compounded medications prescribed for human beings. This is simply too much for a public health statute like the FDCA to bear.

As a result, though § 321(v)'s "new animal drug" definition affords the FDA license to enforce against pharmacists who manufacture in the guise of compounding, Congress did not, by any remaining contextual ambiguity, give the FDA the authority to enjoin traditional pharmacy compounding of animal drugs, a practice never before regulated by a federal agency and never mentioned in the FDCA. See ABA I, 430 F.3d at 469. The FDA is certainly statutorily authorized to draw clear distinctions between manufacturing and compounding generally. See W. States, 535 U.S. at 372-73. However, what the FDA seeks to do here is reinterpret the FDCA to allow it to *eradicate* the line between manufacturing and traditional compounding of animal medications. Its wholesale assertion of authority over traditional pharmacy compounding in the context of a pharmacist-veterinarian-patient relationship is contrary to congressional intent. See Gonzales, 546 U.S. at 267; Brown & Williamson, 529 U.S. at 160. Thus, the Court concludes that the FDA lacks the statutory authority it seeks to exercise here.

4. Chevron Step Two

However, to the extent that the FDCA could be interpreted as being ambiguous in such a way as to allow deference to the FDA's statutory construction, the agency's interpretation would fail, for many of the same reasons, at Chevron Step Two. That is, even

if FDA's attempt to regulate traditional pharmacy compounding fills a gap in the FDCA, the agency's expansive view of its statutory authority is not sufficiently reasonable to survive Chevron Step Two given the requisite level of deference. See ABA I, 430 F.3d at 471-72.

The FDA asserts that the Court should, in accordance with Chevron, "defer to the agency's interpretation of any ambiguity in its governing statute." (Doc. 60 at 9.) "Chevron deference, however, does not necessarily apply to every interpretation offered by an agency." Sierra Club, 541 F.3d at 1265 n.3; see also United States v. Mead Corp., 533 U.S. 218, 228 (2001) ("The fair measure of deference to an agency administering its own statute has been understood to vary with the circumstances, and courts have looked to the degree of the agency's care, its consistency, formality, and relative expertness, and to the persuasiveness of the agency's position") (citations and footnotes omitted); Gonzales, 546 U.S. at 258 ("Chevron deference . . . is not accorded merely because the statute is ambiguous and an administrative official is involved"). As a result, "[d]eference in accordance with Chevron . . . is warranted 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.'" Gonzales, 546 U.S. at 255-56 (quoting Mead, 533 U.S. at 226–27)(emphasis added). "Otherwise, the interpretation is 'entitled to respect' only to the extent it has the 'power to persuade.'" Id. at 256 (quoting Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944)).

When Congress has generally conferred authority on an agency, Congress expects the agency to speak with the binding authority of law "when it addresses ambiguity in the statute or fills a space in the enacted law," even if there was no congressional intent for a

particular result. Mead, 533 U.S. at 229. In this regard, "[i]t is fair to assume generally that Congress contemplates administrative action with the effect of law when it provides for a relatively formal administrative procedure *tending to foster the fairness and deliberation that should underlie a pronouncement of such force*." Id. at 230 (emphasis added); see also Christensen v. Harris County, 529 U.S. 576, 587 (2000) (suggesting that the "rigors of the Administrative Procedure Act, including public notice and comment" warrant greater deference). Accordingly, most courts have afforded the high level of Chevron deference to agency interpretations which result from notice-and-comment rule-making—namely regulations—or formal adjudications. Mead, 533 U.S. at 229-30; see also Miccosukee Tribe of Indians of Fla. v. United States, 566 F.3d 1257, 1272-73 (11th Cir. 2009) ("Notice-and-comment rulemaking is [ ] 'significant . . . in pointing to Chevron authority'") (citing Mead).

Even if Congress had implicitly delegated authority to the FDA to regulate traditional pharmacy compounding of animal medications, the FDA has never promulgated regulations to this effect through notice-and-comment rule-making. Rather, as discussed supra, the agency has instead utilized non-binding Compliance Policy Guides, such as the 1996 and 2003 Guides, to assert its authority. The Supreme Court in Christiansen stated that "policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law [ ] do not warrant Chevron-style deference." 529 U.S. at 587. Accordingly, the Eleventh Circuit has held that "[i]nterpretations not the product of 'a formal adjudication or notice-and-comment rulemaking . . . which lack the force of law' do not warrant Chevron-style deference, but are still 'entitled to respect . . . to the extent that those interpretations have the power to persuade.'" Sierra Club, 541 F.3d at 1265 n.3 (quoting

Christensen, 529 U.S. at 587); see also Wilderness Watch v. Mainella, 375 F.3d 1085, 1091 n.7 (11th Cir. 2004) ("[W]hen . . . the agency interpretation does not constitute the exercise of its formal rule-making authority, we accord the agency consideration based upon the factors cited in Skidmore[ ]: 'the *thoroughness evident in [the agency's] consideration, the validity of its reasoning, its consistency with earlier and later pronouncements*, and all those factors which give it power to persuade, if lacking power to control'") (emphasis added and other citations omitted). Because the FDA seeks to enforce a prohibition that it has not delineated through notice-and-comment rule-making, Skidmore deference is appropriate here. For the reasons set forth supra, Sec. IV(B)(4), and for the additional reasons below, FDA's statutory interpretation lacks the "power to persuade." Skidmore, 323 U.S. at 140.

The FDA seeks to prohibit Franck's traditional bulk compounding of animal drugs for non food-producing animals because the practice "undercut[s] approved drugs by manufacturing unapproved, compounded bulk drugs that are less expensive alternatives with the same intended use." (Doc. 54 at 5.) However, this unsupported assertion is directly contradicted by the record evidence in this case.[92] Indeed, this only serves to illustrate a significant problem with the FDA's position: the agency has never attempted to

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[92] See, e.g., supra n.21 and accompanying text; supra n.29; Davidson Dec. Ex. 13, "Veterinary Drug Compounding in the US, July 2003," prepared by Brakke Consulting, Inc., at 5-6 ("There are hundreds of approved animal drugs on the market in the US, but the cost of obtaining FDA-CVM approval for a non-food animal drug is estimated at around $15-20 million and 5 years . . . . Because the anticipated sales volume of most veterinary drugs is far below the $100 million per year mark, and research and development budgets are shrinking, the number of new chemical entities approved by the FDA-CVM has been declining for some time . . . . All this means there are limited products at a veterinarian's disposal to treat his or her patients.").

test its views concerning bulk compounding for non food-producing animals by notice and comment review. The agency's failure to allow for public comment on the issue caused consternation to the numerous Congressmen and Senators who protested the agency's issuance of the 2003 Guide. The FDA promised that it would publish new guidance, then didn't. The FDA's behavior on this issue is thus reminiscent of the FTC's recent attempt to regulate identity theft in the attorney-client context:

> The Commission's interpretation is also not dispositive of the issue because it represents an interpretation that evolved after the period for notice and comment closed, and without any fact-finding justification for the decision. To be clear, the Court is not saying that an agency with congressional authority cannot develop, apply, or adapt any reasonable interpretation it deems appropriate. See Rust v. Sullivan, 500 U.S. 173, 186, 111 S.Ct. 1759, 114 L.Ed.2d 233 (1991) (finding that an agency's revised interpretation may still receive deference because "[a]n agency is not required to establish rules of conduct [that once established must] last forever" (citations and internal quotations omitted)); see also Skidmore, 323 U.S. at 140, 65 S.Ct. 161 (indicating that whether an agency's interpretation of a regulation is "consisten[t] with earlier and later pronouncements" may factor into whether an agency's interpretation has the "power to persuade"). Rather, it is the Court's conclusion that the Commission's interpretation is not persuasive *because it does not correspond with any agency factual findings supporting the need to redress identity theft associated with the legal profession and why existing regulations of the profession are inadequate, assuming a problem even exists*. From the record before the Court (or more accurately the lack of a record), *the best that can be gleaned is that identity theft in the attorney-client context is only a theoretical problem, especially given the role of state professional codes of conduct and other ethical codes to which attorneys must abide, and the Court cannot conclude that it is an actual problem given the absolute lack of any legislative, regulatory or other evidentiary findings that have been brought to the Court's attention*.

ABA II, 671 F.Supp.2d at 85-86 (emphasis added, certain citations and footnote omitted).

Similarly, traditional bulk compounding of animal drugs only "theoretically" threatens the FDCA's new drug approval process, because the FDA has not undertaken the

necessary steps to find the facts, explain its rationale and allow for public discourse on the issue. "[W]here an agency has articulated no reasoned basis for its decision—where its action is founded on unsupported assertions or unstated inferences—we will not abdicate the judicial duty carefully to review the record to ascertain that the agency has made a reasoned decision based on reasonable extrapolations from some reliable evidence." Tripoli Rocketry Ass'n v. Bureau of Alcohol, Tobacco, Firearms & Explosives, 437 F.3d 75, 81, 83 (D.C. Cir. 2006)("The fatal shortcoming of [the agency's] position is that it never reveals how it determines that [the standard it employed]. . . reflects reasoned decisionmaking"). "[W]e cannot, under the guise of deference, sanction an agency's use of a standard that the agency has not adequately explained." Federal Exp. Corp. v. Holowecki, 552 U.S. 389, 416 (2008)(Thomas, J., concurring).

Just as it has failed to explain its prohibition of bulk compounding of animal drugs via a "relatively formal administrative procedure," Mead, 533 U.S. at 230, the FDA has chosen not to dispute Franck's showing in this case that the practice is an essential component of veterinary medicine. It is thus undisputed that hundreds of pharmacies currently compound animal medications from bulk under the imprimatur and regulation of state law, and have done so without interference by the FDA for many years. The undisputed evidence in this record also shows that allowing the FDA to enjoin a pharmacist's traditional, state-authorized practice of bulk compounding of animal drugs could destabilize the pharmacy profession and leave many animal patients without necessary medication. See supra at 11-15. Such a result would be especially troublesome because the FDA's longstanding policy has been to permit, and even promote, pharmacists' compounding from bulk ingredients.

The FDA cannot simply upset the expectations it helped to create through decades of inaction without explanation,[93] especially where its asserted expansion of authority impacts the federal-state balance and potentially subjects many individuals and companies to criminal liability. This conclusion is supported by the both the plain statement rule and the rule of lenity.

The essence of the plain statement rule is captured by the D.C. Circuit in ABA I. In rejecting the FTC's assertion of authority to regulate attorneys, the Court stated:

> It is undisputed that the regulation of the practice of law is traditionally the province of the states. Federal law "may not be interpreted to reach into areas of State sovereignty unless the language of the federal law compels the intrusion." City of Abilene v. FCC, 164 F.3d 49, 52 (D.C.Cir.1999). Otherwise put, "if Congress intends to alter the 'usual constitutional balance between the States and the Federal Government,' it must make its intention to do so 'unmistakably clear in the language of the statute.'" Will v. Michigan Dep't of State Police, 491 U.S. 58, 65, 109 S.Ct. 2304, 105 L.Ed.2d 45 (1989) (quoting Atascadero State Hospital v. Scanlon, 473 U.S. 234, 242, 105 S.Ct. 3142, 87 L.Ed.2d 171 (1985)).

ABA I, 430 F.3d at 471-72.

In Gregory v. Ashcroft, 501 U.S. at 461, the Supreme Court held that "[t]his plain statement rule is nothing more than an acknowledgment that the States retain substantial sovereign powers under our constitutional scheme, powers with which Congress does not readily interfere." The same principles are applicable here. The FDA has pointed to no

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[93] Cf., e.g., Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co., 463 U.S. 29, 41-42 (1983) (holding that "[a] settled course of behavior embodies the agency's informed judgment that, by pursuing that course, it will carry out the policies committed to it by Congress")(internal quotation omitted); Thomas Jefferson University v. Shalala, 512 U.S. 504, 524 n.3 (Thomas, J., dissenting)("[A]gency conduct, no less than express statements, can effect a construction of statutes or regulations").

"unmistakably clear" statement that Congress intended the FDA's authority to extend beyond the manufacturer-compounder line identified by the Supreme Court in Western States and into the realm of traditional pharmacy compounding. The FDA is correct in noting that Congress may directly regulate some matters already subject to state regulation, "but it is also true that Congress does not tend to interject itself into an arena where it hasn't generally ventured without explicit explanation hoping that the states will not notice the usurpation of their authority." ABA II, 671 F.Supp.2d at 87(citing ABA I, 430 F.3d at 472).[94] To paraphrase the D.C. Circuit as applied to this case: The states have regulated the traditional practice of pharmacy compounding, which includes compounding of animal drugs from bulk ingredients, throughout the history of the country; the federal government has not. This is not to conclude that the federal government could not do so. The Court simply concludes that it is not reasonable for an agency to decide that Congress has chosen such a course of action in language that is, even charitably viewed, at most ambiguous. See ABA I, 430 F.3d at 472.

There is yet another troubling ramification of FDA's position in this case: because the FDCA provides for both criminal and civil penalties for any act prohibited by 21 U.S.C. §

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[94] The FDA argues that the federal-state distinction is a red herring because "the FDCA explicitly provides the FDA with authority to regulate drugs that travel through interstate commerce[, and f]or that reason alone the Defendants' drugs are subject to federal oversight." Doc. 60 at 14 (internal citation omitted). This misstates the question. The plain statement rule is implicated because the FDA claims that its authority to regulate within a traditionally state-regulated arena *is derived from a seventy-year old statute which is silent on the topic and which has never before been applied to such conduct*. For the same reasons, the FDA's reliance upon Sullivan, 332 U.S. at 692-93, as "long ago reject[ing] the proposition that traditional state authority limits the FDCA," Doc. 60 at 14-15, is misplaced.

331, see id. § 333(a), the compounding of *one* non food-producing animal medication from bulk ingredients subjects a state-licensed pharmacist—whether the pharmacist's practice consists of a "large, interstate operation" or a "Mom-and-Pop" shop—to the criminal penalties of the FDCA. Simply relying on the good graces of the FDA's "enforcement discretion" will not suffice. Such a "standard" openly invites arbitrary enforcement, which is antithetical to our system of criminal justice. It is to protect against such arbitrary enforcement that the rule of lenity requires that when a statute carries criminal penalties, any ambiguities must be interpreted in the defendant's favor to avoid "prohibit[ing] more conduct or punish[ing] more severely than Congress intended." Wright, 607 F.3d at 717 (citing cases).[95] The rule applies in this case because although FDA did not bring this enforcement action under the FDCA's criminal provisions, it could have; the statute must be interpreted consistently in both the criminal and civil contexts. See Leocal v. Ashcroft, 543 U.S. 1, 11-12 n.8 (2004) (explaining that "the rule of lenity applies" to the Court's interpretation of a statute even in noncriminal cases "[b]ecause we must interpret the statute consistently, whether we encounter its application in a criminal or noncriminal context").

V. Conclusion

The Court appreciates the FDA's difficult task in protecting the health of both humans and animals. The Court further understands that the FDCA has given the FDA broad regulatory and enforcement powers to implement this mandate and that the courts must

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[95] The FDA cites to Kordel v. United States, 335 U.S. 345, 348-49 (1948) as "definitively reject[ing]" application of the rule of lenity to the FDCA. This appears to be an overly broad interpretation of Kordel, and the FDA has not otherwise demonstrated that case's applicability here.

afford due deference to the FDA's interpretation and implementation of the FDCA. Nevertheless, the FDA's authority is not unlimited and courts have a role to play in determining whether the agency's actions exceed the statutory powers given to it by Congress.

The FDA has long been on notice that its statutory authority to regulate traditional, state-licensed veterinary pharmacy compounding was questionable. Indeed, in 2004, the FDA acknowledged the concern:

> FDA has received numerous letters from veterinarians, pet owners, compounding pharmacists, and associations expressing concern that the [2003 Guide] 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.

FDA to Revise Its Compliance Policy Guide on Veterinary Compounding, supra p. 32. Rather than follow through with this sensible approach, the FDA apparently abandoned it.[96] Instead, it has decided to proceed with this enforcement action, asserting a "maximalist" interpretation of its authority. However, the FDCA does not support the FDA's action. The Court holds that, in enacting the FDCA in 1938, Congress did not intend to give the FDA per

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[96] Had the FDA done what it said it would do or, even better, gone through formal rule-making, it might have been able to develop criteria for determining whether a large, interstate compounding pharmacy such as Franck's is engaging in impermissible manufacturing or permissible, traditional compounding. See W. States, 535 U.S. at 372-73 (suggesting such criteria); supra n. 45, 83. Though it is not my place to say so, FDA could still choose to follow this alternative course. See supra n.52 (FDA seeking comments in related area). Or, as it did in the case of tobacco, see Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. 111-31 (HR 1256) (2009), it could ask Congress for the explicit authority to regulate this practice.

se authority to enjoin the long-standing, widespread, state-regulated practice of pharmacists filling a veterinarian's prescription for a non food-producing animal by compounding from bulk substances.[97]

Accordingly, it is hereby

ORDERED:

1. The United States' Motion for Summary Judgment (Doc. 54) is **DENIED**.

2. Defendants' Motion for Summary Judgment (Doc. 56) is **GRANTED** to extent described in this Order.

3. The United States is not entitled to the injunction it seeks.

4. Judgment for Franck's and against the United States shall be entered.

5. The Clerk should close the file.

DONE AND ORDERED at Jacksonville, Florida this 12th day of September, 2011.

TIMOTHY J. CORRIGAN
United States District Judge

jmm.
Copies:

counsel of record

[97] Because of this ruling, the Court need not reach other issues raised by the parties, including the standards governing the Court's decision whether to grant the FDA injunctive relief.