No. 11-15350-BB

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

UNITED STATES OF AMERICA,

Plaintiff-Appellant,

v.

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

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF FLORIDA

AMICUS CURIAE BRIEF OF SOCIETY OF VETERINARY HOSPITAL PHARMACISTS IN SUPPORT OF AFFIRMANCE OF THE DISTRICT COURT

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CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

The undersigned counsel of record for Amicus Curiae Society of Veterinary Hospital Pharmacists ("SVHP"), in compliance with Federal Rule of Appellate Procedure 26.1 and Eleventh Circuit Rule 26.1, certifies that the Certificates of INTERESTED PERSONS provided by the United States, the other *amici*, and Franck's Labs with their briefs, identify the interested persons and entities other than the following now added by SVHP:

Black, Dianna – Fellow and Council member of amicus curiae SVHP.

Davidson, Gigi – Officer and Council member of amicus curiae SVHP.

Duran, Sue – Officer and Council member of amicus curiae SVHP.

Gray, Kyle Anne – Counsel for amicus curiae SVHP.

Jehl, Joe – Officer and Council member of amicus curiae SVHP.

Jordan, Dinah – Officer and Council member of amicus curiae SVHP.

Karriker, Margo – Officer and Council member of amicus curiae SVHP.

Kinosian, Laurel – Officer and Council member of amicus curiae SVHP.

Miller, Adrian A. – Counsel for amicus curiae SVHP.

Perry, Maureen – Officer and Council member of amicus curiae SVHP.

Sillers, Karen – Officer and Council member of amicus curiae SVHP.

The Society of Veterinary Hospital Pharmacists ("SVHP").

Respectfully submitted,

Kyle A. Gray
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STATEMENT OF INTEREST

The Society of Veterinary Hospital Pharmacists ("SVHP") is an organization composed of pharmacists working exclusively in the veterinary field, primarily at veterinary teaching hospitals in colleges of veterinary medicine.[1] SVHP's

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

membership is international, with Canada, the Netherlands, Denmark, Australia and New Zealand represented, along with membership from the United States.

The decision maker for SVHP is its Council, which consists of its Officers and one Fellow. The collective veterinary pharmacy practice experience for Officers of the Council amounts to nearly 175 years. The Council has approved the filing of this amicus curiae brief, which is the source of SVHP's authority to file it. SVHP does not file this brief in support of, or against, the particular interests of either party. Instead, as explained in more detail below, SVHP's sole concern in this matter is to protect the ability of its members and other veterinary pharmacists and veterinarians to compound for animal patients using Active Pharmaceutical Ingredients ("APIs," also known as "bulk ingredients") under the traditional pharmacy practice model and within the veterinarian-client-patient relationship.

SVHP believes that the role of the veterinary pharmacist is varied with many clinical and administrative duties including product selection and procurement. Many SVHP fellows hold faculty positions with colleges of veterinary medicine and colleges of pharmacy where they are instrumental in instructing both veterinary and pharmacy students about the medications used in animals. SVHP's associate members include practicing veterinarians, as well as veterinarians with faculty positions.

Among other things, SVHP faculty members teach students how to compound medicines from APIs using formulas set out in the United States Pharmacopeia/ National Formulary ("USP"), a combined set of pharmacopeial standards that Congress has recognized as official compendia. These compounded medicines are used to treat companion animals (and other non-food producing animals) for whom no approved product or route of drug delivery satisfies their medical needs. SVHP's officers and members teach at many of the leading veterinary and pharmacy schools in the United States. The current SVHP officers with university teaching positions are:

President: Maureen Perry, RPh, FSVHP, DICVP
Virginia-Maryland Regional College of Veterinary Medicine.

President-Elect: Margo Karriker, PharmD, FSVHP
University of California Veterinary Medical.

Treasurer: Dinah Jordan, BSPh, RPh, Pharm D, DICVP, FSVHP
College of Veterinary Medicine, Mississippi State University.

Immediate Past-President: Laurel Kinosian, RPh, FSVHP
School of Veterinary Medicine, University of Wisconsin.

Member at Large: Dianna M. Black, RPh, FSVHP
University of Illinois.

Parliamentarian: Joe Jehl, RPh, DICVP, FSVHP
College of Veterinary Medicine, Michigan State University.

Certification Chair: Sue Duran, RPh, MS, PhD, FSVHP, DICVP
Auburn University.

Government Affairs Liaison: Gigi Davidson, BSPh, DICVP
NC State University College of Veterinary Medicine.

Regarding the legality of traditional compounding with bulk chemicals, SVHP has adopted a "Position Statement on Compounding," a complete copy of which is available on SVHP's website. *See* http://svhp.org/position-statements/. That Statement recognizes that in many circumstances traditional compounding with bulk chemicals is essential to providing high quality pharmaceutical care for sick animal patients. SVHP supports the ability of veterinary pharmacists, in consultation with veterinarians caring for animal patients in need, to compound medicines from bulk ingredients as follows: If an FDA approved product is unavailable or not appropriate for treatment, compounding with bulk chemicals (APIs) may become necessary and required for proper treatment. The APIs/bulk ingredients used to compound an appropriate product should be of highest possible chemical grade, and the finished product should be compounded from those bulk ingredients using a formula – preferably a USP formula – with evidence-based documentation of potency and stability.

The legal position taken by the United States in this matter, through the Federal Drug Administration ("FDA"), is that any compounding from bulk materials by pharmacists for animals is illegal under the Federal Food Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, and has been since the statute was first enacted in 1938. SVHP respectfully disagrees, and believes that legal position to be incorrect.

SVHP further believes that if this Court were to overturn the sound legal reasoning of the district court that the health and lives of countless companion animals will be put at risk because veterinarians and veterinary pharmacists will be squarely placed in an impossible ethical dilemma. To wit: Either continue to treat suffering animal patients using the traditional practice of compounding with bulk chemicals when necessary and appropriate and thereby engage in what FDA now says is a federal crime (putting their licenses and livelihoods at risk), or alternatively comply with what FDA now says the law is and let their animal patients needlessly suffer and die despite the availability, through the use of traditional compounding with APIs, of effective and ameliorative treatments. As licensed professionals whose main concern is the health and welfare of the animal patients they care for, but who also respect the law and support the ability of FDA to engage in appropriate regulatory functions, SVHP and its members have a unique and exceedingly important interest in the outcome of this case.

SUMMARY OF ARGUMENT

The history of the traditional practice of compounding animal medicines from bulk ingredients (aka APIs), is well-known and long-standing. When the FDCA was enacted in 1938, Congress was aware that hundreds of licensed pharmacists were regulated in this traditional practice by state boards of pharmacy, not the federal government. In this proper context, FDA's current suggestion that the FDCA

outlaws such traditional practice of compounding with bulk chemicals – a practice that is taught in most pharmacy schools and actually mandated by some state laws – without even a single mention in that statute of the term "compounding," is not plausible and should not be accepted by this Court. Moreover, the undisputed fact that traditional compounding with bulk chemicals is medically necessary to the health and lives of animal patients is itself strong evidence that Congress could not have intended to put veterinarians and veterinary pharmacists in the no-win situation of having to choose between risking their licenses and livelihoods to the whim of prosecutorial discretion, or standing by while countless animal patients needlessly suffer and die. Context is paramount here, and in the face of this undisputed context, the district court's refusal to misconstrue the FDCA as having outlawed traditional compounding with bulk chemicals since 1938, should be affirmed.

Additionally, the exhortations of the *amici* who support the Government's appeal should be given no weight by this Court. Those *amici* are demonstrably wrong on their views regarding the Congress's intent in enacting AMDUCA and FDAMA, and any purported effects from those enactments on traditional compounding with bulk chemicals for animals. As is true for the FDCA itself, AMDUCA does not mention compounding from APIs, and cannot, therefore outlaw it. And FDAMA deals only with compounding of human medications, and specifically does not purport to deal with that practice in the field of animal medicine.

All-in-all, the district court was clearly correct. The Government's brief to this Court fails even to put a dent in the well-reasoned legal fortress assembled in that Order, which belies all the Government's attempts to so ahistorically and acontextually extend the reach of the FDCA. The district court's order and Judgment should be affirmed.

ARGUMENT

I. THE DISTRICT COURT CORRECTLY DECIDED THIS CASE.

The compounding of medications from a variety of active ingredients is a tried and true method used by pharmacists for centuries to assist both physicians and veterinarians in the treatment of their individual human and animal patients, one patient at a time. In fact, the very roots of the pharmacy profession are found in this practice of licensed professionals subject to the authority and discipline of state licensing boards and professional associations.

On the other hand, the manufacturing of large quantities of drugs by pharmaceutical companies in a business setting, and not at the specific request of a specific doctor with a particular patient, is a relatively new practice. The corporate practitioners of this now very large business model are not licensed by state boards, and since 1938 have been regulated by FDA. With respect, where FDA has erred in this matter is by not honoring these long-standing and well-understood differences between traditional compounding and manufacturing. Instead it has painted with

much too broad a brush in seeking to wield a 1938 statute, which Congress enacted to regulate the manufacturing of drugs, to criminalize traditional compounding with bulk chemicals for the treatment of specific animal patients. The district court quite properly recognized this flaw, and SVHP believes that its decision should be affirmed.

A. The History Of Traditional Compounding With Bulk Chemicals For Animals.

The compounding of medicines from bulk ingredients is neither a new nor obscure practice. Instead, it is a common activity that has been engaged in since Colonial times, that continues to occur regularly in all 50 states and the Territories, that is licensed and regulated by state boards, and that produces medically necessary treatments for animal patients that are not otherwise available. As explained by the Supreme Court, pharmacy compounding is "a process by which a pharmacist or a doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360-61, 122 S. Ct. 1497, 1500 (2002). The Court went on to explain that "[c]ompounding 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. *It is a traditional component of the practice of pharmacy.*" *Id.* (emphasis added).

1. The Practice of Traditional Compounding with Bulk Chemicals is Historic and Widespread.

The practice of traditional compounding with bulk chemicals is, and has been, common and widespread. As explained by former Chief Counsel of the FDA, Sheldon T. Bradshaw, in his declaration filed below, the traditional practice of compounding from bulk materials has been part of the practice of medicine in this nation since colonial days. *See* Doc. 35, Bradshaw Decl. ¶7. Indeed, citing *Remington's Practice of Pharmacy* 13 (12th ed. 1961), Mr. Bradshaw explained that John Winthrop, Jr., the son of the first governor of the Massachusetts Colony, engaged in pharmacy drug compounding in the seventeenth century. *Id.*

Before the late 20th century and the advent of Walgreens, CVS and the like, the public image of pharmacists was generally of a trained practitioner who put together (*i.e.*, compounded) medical draughts from the jars of ingredients lining his office. Obvious examples are the affable Mr. Gower, the druggist in Frank Capra's 1946 classic film *It's a Wonderful Life,* and Norman Rockwell's painting "The Pharmacist," complete with mortar and pestle and what appears to be the USP, published on the March 18, 1939 cover of the Saturday Evening Post.[2] Perhaps no more need be said than that the compounding pharmacist's mortar and pestle is the most widely-recognized international symbol of the pharmacy profession.

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[2] A good color copy of the Norman Rockwell cover can be seen at: http://www.art.com/products/p9388042888-sa-i5446600/norman-rockwell-pharmacist-saturday-evening-post-cover-march-18-1939.htm

When the FDCA was enacted in 1938, compounding was an established fact of the pharmacy profession. And it was pharmacists who heavily supported passage of this new federal law to regulate drug manufacturing by newfangled pharmaceutical companies, which before the FDCA was a virtually unregulated business because it was not practiced by licensed professionals subject to state licensing boards. *See* Doc. 35, Bradshaw Decl. ¶¶ 11-16. It is simply not plausible that these pharmacists who compounded drugs as part of their traditional, licensed practices would have fought so diligently for the passage of the FDCA if it was truly intended by Congress – as the Government asserts in this case – to outlaw that practice except through the whim of federal prosecutorial discretion. *Id.*

Even less plausible is the notion that universities would have continued to this day to promote and require that pharmacy students learn traditional compounding methods in the face of a seventy-year old federal statute outlawing the practice. Yet, as the Supreme Court plainly (and correctly) noted in *Western States*, traditional compounding "is taught as part of the standard curriculum at most pharmacy schools." 535 U.S. at 361, 122 S. Ct. at 1500. *See also* Doc. 29, Davidson Decl. ¶¶ 3, 53.

2. The Practice of Traditional Compounding with Bulk Chemicals is Highly Regulated.

There is good reason FDA has never sought clear statutory authority from Congress to regulate the practice of traditional compounding with bulk chemicals,

and until recently, never asserted that the FDCA gave it that authority. Simply put, there was no reason for FDA to do so. In fact, the practice is highly regulated by state pharmacy boards and there has been no need for federal involvement. As shown in the declarations below and in Appellee's brief, compounding has long been specifically provided for by states statutes, and was in the past, and continues today, to be regulated by state boards. *See* Doc. 35, Bradshaw Decl. ¶¶ 9-14; Doc.29, Davidson Decl. ¶¶ 38-42; Doc. 31, Powers Decl. ¶¶ 15-41. *See also W. States*, 535 U.S. at 361-62, 122 S. Ct. at 1500-01 (discussing state regulation of compounding, including some states that "require all licensed pharmacists to offer compounding services").

The day-to-day oversight of pharmacies providing medically necessary compounded medications for individual patients at the request of a veterinarian is precisely the type of traditional, professional practice that local State boards are especially well-equipped to deal with (and have handled for decades). *See, e.g.,* Doc. 31, Powers Decl. ¶¶ 29-41(explaining the safe practice regulations and requirements governing pharmacists in Florida). Although a large federal agency is well-suited to overseeing the business enterprise of mass-producing manufactured drugs, it is ill-equipped to provide the individualized and local response required to regulate the *profession* of pharmacy practice.

Just as FDA today does not regulate physicians, or the FTC regulate lawyers, federal agencies generally have no role to play in regulation of licensed pharmacists and veterinarians. Instead, that is a role traditionally left to the states. *Cf. Am. Bar Ass'n v. Fed. Trade Comm'n*, 430 F.3d 457 (D.C. Cir. 2005) (rejecting FTC regulation of attorneys under a statutory scheme for "financial institutions"). If Congress truly had meant to interfere with this long-established state function, surely it would have said so clearly and unambiguously, and not by the use of statutory language that does not even mention the word compounding. *See, e.g., Gonzales v. Oregon*, 546 U.S. 243, 274-75, 126 S. Ct. 904, 925 (2006) (Congress does not extend its authority into areas traditionally regulated by the states through "muffled hints").

Perhaps most tellingly, if Congress had intended to outlaw traditional compounding with bulk chemicals by the language of the FDCA, why did it incorporate the compounding "bible" – the USP/National Formulary – as part of the FDCA itself? *See* Doc. 35, Bradshaw Decl. ¶ 17. Are we truly to believe that Congress and FDA engaged in a hidden conspiracy to dupe state pharmacy boards to regulate (even require) compounding services by pharmacists, but furtively made that very activity a federal crime, even while using a federally-approved instruction manual? Again, the context of this history cannot be reconciled with the Government's current interpretation of the FDCA. Of course, context is critical for proper interpretation of statutory language. *See, e.g. King v. St. Vincent's Hosp.*, 502

U.S. 215, 221, 112 S. Ct. 570, 574 (1991) ("the meaning of statutory language, plain or not, depends on context").

3. The Practice of Traditional Compounding with Bulk Chemicals is Medically Necessary.

Noticeably absent from the briefs of the Government and its *amici* is any suitable discussion of the critical role that traditional compounding with bulk chemicals plays in the treatment of suffering dogs, cats, horses and other non-food producing animals. The veterinarians and veterinary pharmacists who appeared before the court below by declarations all attested to the medical necessity of traditional compounding with bulk chemicals. For example, Dr. Rick Pelphrey explained that the treatment of equine patients in particular requires compounding with bulk chemicals because horse patients typically weigh around 1200 pounds, they have different bioavailablity and pharmacological needs than humans, and that use of finished drug products approved for humans is frequently inappropriate, if not harmful, in horses. *See* Doc. 33, Pelphrey Decl. ¶ 10. Dr. Pelphrey further testified that his ability to use bulk compounded drugs with his patients "can be the difference between having to put the horse down (death) and the horse being back on the racetrack in a couple of weeks." *Id.* at ¶ 12.

What is true for horses is also true for dogs and cats. We Americans love our companion animals. In fact, the American Veterinary Medicine Association estimates that over 43 million U.S. households have at least one dog, and that over 37

million U.S. households have at least one cat. This means that 37.2% of American households own dogs, and 32.4% of American households own cats, with many of those households having one or more of each.[3] And over the course of their lives, countless numbers of these tens of millions of dogs and cats, living in tens of millions of U.S. households, will need treatment available only through the use of traditional compounding with bulk chemicals. *See* Doc. 29, Davidson Decl. ¶¶ 9, 53-55; Doc. 31, Powers Decl. ¶¶ 23-24; Doc. 33, Pelphry Decl. ¶¶ 8-9, 15-18 (discussing the common occurrence of compounding with bulk chemicals for animals). As but one example, utilization of transdermally delivered therapies is becoming widespread in veterinary medicine, and this skin-penetrating dosage cannot be compounded without use of APIs/bulk ingredients. *See* Doc. 29, Davidson Decl. ¶¶ 69-73.

Imagine just one such (hypothetical) pet-owning household, this one in Florida. It consists of Edna, an eighty-year old retired widow, and her black-and-white Tabby cat named Tux. For Edna, caring for Tux is her reason to get up in the morning and carry on with her independent life, and not move to a long-term care facility. Edna talks to Tux, and Tux purrs and sleeps with Edna; they eat together, garden together and watch television together. The two are inseparable. Unfortunately, six-year old Tux has developed feline idiopathic megacolon disease. This horrible disease affects a cat's bowel functions and left untreated results in

[3] http://www.avma.org/reference/marketstats/ownership.asp

death. Expensive and dangerous surgery that involves complete removal of a cat's colon can be tried, but frequently results in a chronic diarrhea, so euthanasia is often the consequence of a diagnosis of megacolon disease.

Thankfully, Edna's veterinarian, Dr. Smith, knows that megacolon is treatable in many cats with Cisapride, a drug that increases colonic motility. Cisapride is the only pro-motility drug that will work on the colon muscle of cats. Tux responds well to his initial treatments with Cisapride capsules, as compounded by Dr. Smith's veterinary pharmacist pursuant to her prescription. But Edna – like many a feline owner who has tried and failed to pill a cat – finds it almost impossible to give Tux his needed dosage. Dr. Smith's veterinary pharmacist comes to the rescue again, and now compounds Tux's Cisapride as a flavored medicated treat that Tux happily accepts without a struggle, ensuring compliance with Dr. Smith's treatment instructions by Edna, and not stressing the important human-animal bond between Edna and Tux.

So all is well with Edna and Tux, and should continue to be so for many years to come. Except for one thing: Cisapride was originally developed for use in humans, and was associated with serious cardiac arrhythmia when used concomitantly with certain other drugs. As a result, it was discontinued and removed from the market. Since 2000, Cisapride has been available only through traditional compounding with bulk chemicals; the very practice FDA now says is illegal. Edna,

who lives on her Social Security check, cannot afford colon surgery for Tux, and Dr. Smith is uncertain that would help Tux in any event, or if he would survive such major surgery. Because there is no current substitute for the use of Cisapride in cats with megacolon, euthanasia is the remaining option, unless that is, both Dr. Smith and her veterinary pharmacist are willing to continue prescribing and compounding Cisapride for Tux against what the Government now says the law requires.[4]

Should Tux be consigned to death and Edna to depression and guilt, because the Government has chosen to take an illogical and insupportable position about the meaning and reach of the FDCA? Or in order to save Tux's life, should Dr. Smith and her compounding pharmacist be forced each time Tux needs more medicine to violate the law and put their licenses and livelihoods at risk subject to the prosecutorial discretion of the federal government? While somewhat dramatic, these are the realistic types of questions at the very core of this case. Simply put, broad brush litigation choices by governments have real world consequences for their citizens. In this case, those consequences are unacceptable, unnecessary and, indeed, inhumane.

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[4] *See* Doc. 29, Davidson Decl. ¶¶ 53-79, for the medical facts underlying this hypothetical, and for other examples of medically necessary treatments for dogs, cats and horses available only through the use of traditional compounding from bulk chemicals.

B. The History Of Traditional Compounding with Bulk Chemicals Is Inconsistent And Irreconcilable With FDA's Current Position On the Scope Of The FDCA.

Fortunately, Congress has avoided this disaster, not only for the hypothetical Edna, Tux, Dr. Smith and her veterinary pharmacist, but also for FDA. The FDCA does not outlaw traditional state-permitted compounding practices. To the contrary, it applies only when a pharmacy engages under the guise of compounding in new drug manufacturing that *is* subject to regulation by FDA under the FDCA. *W. States*, 535 U.S. at 361-63, 122 S. Ct. at 1500-02.

In *Western States,* the Supreme Court properly recognized the importance of FDA's ability, under the FDCA, to regulate the manufacturing of drugs. *Id.* SVHP agrees that FDA has a critical and crucial role to play in that area. But the Supreme Court also recognized the importance of compounding, and the reality that this traditional practice cannot be held subject to the new drug manufacturing rules and regulations of the FDCA:

> 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, 122 S. Ct. at 1505.

SVHP wholeheartedly agrees. As shown above, when placed in its appropriate historical context, the FDCA has always been properly understood as applying to "large-scale drug manufacturing," and not to traditional compounding *Id.* SVHP supports the ability of FDA to draw an appropriate line between the two, but, *a fortiori,* FDA cannot place **all** animal compounders on the same side of that line as the large-scale animal drug manufacturers. That is, however, precisely what the Government has tried to do in this case. *See* Gov't Br. 47-48 (explaining "FDA's bright-line legal argument" that the FDCA gives FDA "statutory authority over *all* new animal drugs, including those that are produced by traditional compounding pharmacies") (emphasis in original). Because that understanding of the FDCA is clearly wrong, SVHP urges this Court to affirm the district court.

II. THE AMICUS BRIEFS SUPPORTING FDA'S POSITION SHOULD BE ACCORDED NO WEIGHT.

SVHP has reviewed the amicus briefs filed by *amici* Animal Health Institute ("AHI") and Generic Drug Alliance ("GADA"), and believes that this Court should

give no weight to the arguments they make. Their legal arguments are wrong on the law, and their policy arguments are not appropriate for consideration by a court.

A. *Amici* AHI And GADA Are Wrong On The Law.

Amici AHI and GADA base their defense of FDA's atextual reading of the FDCA upon their reliance on the Animal Medicinal Drug Use Clarification Act ("AMDUCA"), Pub. L. No. 103-396, 108 Stat. 4153, which amended the FDCA in 1994; and the Food and Drug Administration Modernization Act ("FDAMA"), Pub. L. No. 105-115, 111 Stat. 2296, which amended the FDCA in 1997. AHI says that AMDUCA "authorizes 'traditional compounding' under very limited circumstances that AHI understands are not present in this case." AHI Br. 7. AHI further asserts that AMDUCA has a "manifest purpose to restrict compounding" that supports FDA's later regulation which AHI contends prohibits "compounding from bulk drugs" for animals. *Id.* at 9. GADA agrees, arguing that FDA's AMDUCA-based regulations limit animal compounding to the use of "existing approved drugs – as distinguished from manufacturing from bulk" chemicals. GADA Br. 10.

In fact, AMDUCA says no such thing. Rather, as the district court points out in several places in its exceptionally well-reasoned Order, "Congress made no mention of either compounding or bulk drugs in AMDUCA." Doc. 68, Op. 19, 37, 51. How a failure to mention something can constitute a "manifest purpose" to ban it, is left unexplained by AHI. FDA has apparently also found no such "manifest

purpose" in AMDUCA. Despite AHI's misstatement to the contrary, FDA's AMDUCA-based regulations do *not* limit compounding from bulk drugs: rather, as the district court properly explained, on that issue the actual, binding regulations "do not purport to regulate the practice of compounding, and instead refer parties to FDA's *non-binding* guidance documents on the subject." Doc. 68, Op. 19 (emphasis added). This is the very non-binding guidance that FDA promised in 2004 to revise through notice-and-comment procedures to address assertions, *inter alia*, that it is "not within FDA's legal authority" to regulate traditional veterinary compounding from bulk chemicals. *Id.* at 32. That long-promised revised guidance has still not been issued, leaving the non-binding language of the current guidance of no use in this matter.

The *amicis'* attempted reliance on FDAMA is equally unavailing. AHI admits FDAMA does "not address compounding for animals." AHI Br. 13. Nevertheless, it argues that by enacting FDAMA – which specifically endorses traditional compounding from bulk chemicals for human patients – Congress meant to put limits on the compounding of medicines for animals that do not exist for humans. AHI Br. 14-15. Again, however, there is nothing in FDAMA itself that suggests this. And, in fact, FDA has not only asserted that it intends "to ensure the consistency of its policies with regard to compounding of drugs intended for use in humans and in animals," but has taken different positions on whether FDAMA is even the law of the

land (an issue on which the Ninth Circuit and the Fifth Circuit disagree). *See* Doc. 68, Op. 28 (quoting FDA's 2003 guidance); *Id.* at 30 (quoting FDA's 2002 guidance that "all of [FDAMA] is invalid"); *Id.* at n. 50 (explaining FDA's position in this case that FDAMA's non-speech limiting provisions are valid). *Compare W. States Med. Ctr. v. Shalala*, 238 F.3d 1090, 1096-98 (9th Cir. 2001) (holding FDAMA's provisions non-severable and the entire act invalid), *with Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 401 (5th Cir. 2008) (holding the non-speech impairing provisions of FDAMA severable and valid).

In sum, neither AMDUCA nor FDAMA provide a valid base on which to rest a defense of FDA's acontextual reading of the FDCA. Despite the shaky and unpersuasive nature of their arguments, it is troubling that AHI and GADA nonetheless advocate positions which, as an unintended consequence, would leave animal patients and their medical care providers with no legal access to medically necessary medicines that are indisputably available only through compounding from bulk chemicals. In other words, but for veterinary pharmacists willing to break what FDA (and AHI and GADA) now say the law is, the hypothetical Tux, and millions of non-hypothetical cats, dogs and horses, would be left to needlessly suffer and die. That simply cannot have been the intent of Congress in passing the FDCA, AMDUCA or FDAMA.

B. The Policy Positions Asserted by *Amici* AHI and GADA Are Proper For Consideration By Congress, Not The Courts.

The members of AHI – often referred to as "Big Pharma" – and the large manufacturers of generic drugs that comprise GADA, ask this Court to uphold FDA's "bright-line," acontextual reading of the FDCA in order to protect them from "unfair competition" from compounding pharmacies. GADA Br. 2-3; AHI Br. 15-18. In other words, although these two interest groups are often foes in other contexts, they come together here with a focus not on the intent of Congress in enacting the FDCA, but on their businesses' bottom lines.

SVHP takes no stance on whether the constituent members of AHI and GADA have a legitimate dispute with Appellee Franck's Labs or other compounding pharmacies. SVHP instead takes the stance that this type of policy fight does not belong in the courts in the context of interpreting the meaning of the FDCA. Rather, this issue of fair or unfair competition is more properly one for litigation under existing fair trade laws, or to be taken before Congress for promulgation of new fair trade laws. But what cannot be allowed to happen is for these business model policy disputes to come between veterinarians, veterinary pharmacists, and the health and welfare of their animal patients.

The very fact that both AHI and GADA see the Government's actions in this case as a means to improve their business interests should speak volumes regarding how far the Government's reading of the FDCA has gone astray. The FDCA is not

about profit, it is about protection of patients, both animal and human. In the world of companion animal medicine, compounding with bulk chemicals is a medically necessary component of animal health that Congress did not intend to outlaw. Whether that simple truth helps or hurts the bottom lines of the members of AHI and GADA cannot possibly have a proper role to play in this matter.

CONCLUSION

For the reasons set forth above, amicus curiae Society of Veterinary Hospital Pharmacists asks this Court to affirm the district court and confirm that the FDCA does not outlaw the long-established, common and medically necessary practice of traditional compounding with bulk chemicals for animals.

Respectfully submitted,

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Dated: April 6, 2012.

CERTIFICATE OF COMPLIANCE

Pursuant to the Federal Rules of Appellate Procedure 29(c)(7) and 32(a)(7)(C), I hereby certify that this brief complies with the type-volume limitation in Rules 29(d) and 32(a)(7)(B). The brief was prepared using Times New Roman proportional font, 14-point, and it contains 5,021 words from its Statement of Interest to its Conclusion as counted by Microsoft Word.

Kyle A. Gray
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CERTIFICATE OF SERVICE

Pursuant to 11th Circuit Rule 31-3, I hereby certify that I have this 6th day of April 2012 sent to the Clerk to the U.S. Court of Appeals for the Eleventh Circuit by first-class mail, postage prepaid, the original and six copies of the foregoing, and by first-class mail, postage prepaid, a copy of the foregoing to the counsel listed below.

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