

REGULATING THROUGH RULES: SUGGESTED CHANGES IN THE FEDERAL REGULATION OF VETERINARY COMPOUNDING

David Hrnrcir*

TABLE OF CONTENTS

INTRODUCTION..... 129

 DEFINITION OF COMPOUNDING..... 132

 HISTORY OF VETERINARY COMPOUNDING AND ITS
 REGULATION 133

WHY THE FDA SHOULD PREFER NOTICE-AND-COMMENT
RULEMAKING..... 138

 CHEVRON DEFERENCE..... 138

 AUER DEFERENCE 141

 SIMILARITIES IN PROMULGATING CPGs AND RULES..... 142

 THE U.S. SUPREME COURT’S SUGGESTIONS 145

 THE FDA WILL BE DRIVING THE INITIATIVE 145

BENEFITS TO THE COMPOUNDING PROFESSION..... 146

 THE ABILITY TO COMMENT 146

 A MORE CERTAIN REGULATORY ENVIRONMENT 147

THE STATUTORY BASIS FOR A PROPOSED RULE..... 148

POLICY BASES FOR A PROPOSED RULE AND SUGGESTED CONTENT 153

SOME FINAL REBUTTALS TO FDA HESITATION OVER THE ABOVE

* Doctor of Jurisprudence, University of Houston Law Center, 2013

PROPOSALS..... 159
CONCLUSION 160

INTRODUCTION

Since the Food and Drug Administration (FDA) promulgated its first Compliance Policy Guides (CPGs) relating to compounding pharmacy in 1992,¹ and 1993, they have been controversial, and the informal regulatory regime that was created has been frequently litigated.² In general, both the pharmacy profession and the FDA agree that compounding—a small segment of pharmacy that prepares commercially unavailable drugs for specific patients pursuant to physicians' prescriptions—is a necessary component of American healthcare and that states should generally regulate it.³

¹ Ctr. for Drug Evaluation & Research, Food & Drug Admin., Guidance for FDA Staff and Industry: Compliance Policy Guides Manual § 460.200: Pharmacy Compounding (2002) [hereinafter "Human CPG"].

² See, e.g., Ctr. for Veterinary Med., Food & Drug Admin., Guidance for FDA Staff and Industry: Compliance Policy Guides Manual § 608.400: Compounding of Drugs for Use in Animals (2003) [hereinafter "Veterinary CPG"] (outlining the "FDA's current thinking on what types of [veterinary] compounding might be subject to enforcement action"); Human CPG (outlining the FDA's "current thinking" on compounding regulations); Prof'ls & Patients for Customized Care v. Shalala, 56 F.3d 592, 601-02 (5th Cir. 1995) (holding in favor of the government that the CPGs are nonbinding rules that do not need to undergo notice and comment as rules); W. States Med. Ctr. v. Shalala, 238 F.3d 1090, 1097 (9th Cir. 2001) (holding that the advertising sections of FDAMA are not severable and that all of FDAMA is thus unconstitutional); Thompson v. W. States Med. Ctr., 535 U.S. 357, 377 (2002) (holding that the advertising sections of FDAMA are unconstitutional); Med. Ctr. Pharmacy v. Mukasey, 536 F.3d 383, 408 (5th Cir. 2008) (holding that the advertising sections of FDAMA are severable from the rest of the statute and that all compounded drugs are subject to the FDCA's "new drug" and "new animal drug" definitions unless they fall under a FDAMA or AMDUCA exception); United States v. Franck's Lab, Inc., 816 F. Supp. 2d 1209, 1256 (M.D. Fla. Sept. 12, 2011) (holding that the FDCA does not support the FDA's "maximalist" interpretation of enjoining a pharmacy from engaging in state-law-sanctioned veterinary compounding from bulk substances).

³ See, e.g., Veterinary CPG, *supra* note 2, at 3-4; Int'l Acad. of Compounding Pharmacists, *Pharmacy Compounding Subject to FDA Approval?: The Facts Just Don't Fit*, http://www.iacprx.org/site/PageServer?pagename=P2C2_FactsDontFit (last visited Jan. 15, 2012).

However, they have often disagreed concerning the extent to which the FDA should also regulate compounding pursuant to its statutory authority.⁴ Because the FDA's ability to regulate drugs compounded for human use has been the subject of more legislation and litigation, that area of law is more convoluted, and it is much more difficult to provide ready solutions. On the other hand, federal regulation of drugs compounded for animal use has received less attention and provides a regulatory regime ripe for creative remedies. In this paper, I propose solutions for regulating veterinary compounding⁵ with the expectation that solutions for regulating human compounding will thereby more easily present themselves.

Because the veterinary compounding CPG has been frequently contested by compounders and (particularly of late) has not been viewed favorably by courts, I propose that it is in the FDA, the pharmacy profession, and the general public's best interests to replace the CPG with a set of notice-and-comment rules.⁶ With this change, the FDA will enjoy greater deference before courts in promulgating such rules and will be able to solidify its position concerning veterinary compounding without relinquishing much authority. Meanwhile, compounders will be given some needed concessions and have a more certain regulatory environment in which to conduct business.

First, I will describe compounding and the current legal landscape, specifically problems with federal law's treatment of veterinary compounding. Next, I will describe why both the FDA and compounders should prefer notice-and-comment rulemaking over the current CPGs. Finally, I will discuss statutory and policy bases for some proposed rules and their suggested content.

⁴ See, e.g., *Veterinary CPG*, *supra* note 2, at 4.

⁵ Here and throughout I use the term "veterinary compounding" to refer to compounding drugs for use in animals (whether a veterinarian or pharmacist dispenses the drug). I use the term "human compounding" to refer to compounding drugs for use in humans. "Compounder" and "compounding pharmacist" are synonyms.

⁶ See *Franck's Lab*, 816 F. Supp. 2d at 1252 (holding that the veterinary CPG should be given only *Skidmore* deference and suggesting that the FDA could engage in notice-and-comment rulemaking).

Definition of Compounding

In general, courts have defined “drug compounding” as “a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient.”⁷ However, there is no universal definition of the term, despite the federal government’s attempts to devise one, and the above definition has even been treated as mere dicta by some courts.⁸ Each state has its own definition and regulates the compounding segment of the pharmacy profession with its own set of laws.⁹ Some states define the term “compounding” comparatively narrowly.¹⁰ Others define it broadly, even to the extent of including within its denotation mere drug repackaging.¹¹ Still other states do not seem to define compounding at all.¹² In many states, “veterinary compounding” is simply defined as preparing a drug pursuant to a valid prescription for a specific animal patient rather than a specific human one.¹³ Thus, there is no definitional or regulatory difference between human or veterinary compounding except for the type of intended recipient.¹⁴

⁷ *Thompson*, 535 U.S. at 360–61; *see also Shalala*, 238 F.3d at 1092.

⁸ *See United States v. Bader*, No. 07-CR-00338MSK, 2009 WL 2219258, at *10 (D. Colo. July 23, 2009).

⁹ *Id.*

¹⁰ *See, e.g., Ohio Rev. Code Ann. § 4729.01* (LexisNexis 2011) (in which “‘compounding’ means the preparation, mixing, assembling, packaging, and labeling of one or more drugs in any of” a number of circumstances. These circumstances include filling a prescription; filling a modified prescription; “research, teaching activities, or chemical analysis;” in anticipation of an expected prescription; and in office-use administration by a physician. This definition is considered potentially narrow because of the conjunction “and.”); *see also Bader*, 2009 WL 2219258, at *10.

¹¹ *See Bader*, 2009 WL 2219258, at *10; *see also Ky. Rev. Stat. Ann. § 315.010(5)* (LexisNexis 2011) (defining “‘compound’ or ‘compounding’ [as] the preparation or labeling of a drug pursuant to or in anticipation of a valid prescription drug order including, but not limited to, packaging, intravenous admixture or manual combination of drug ingredients. ‘Compounding,’ as used in this chapter, shall not preclude simple reconstitution, mixing, or modification of drug products prior to administration by nonpharmacists.”).

¹² For example, from WestlawNext searches made on January 11, 2012, I could not find any definition of compounding among New York’s statutes.

¹³ *See, e.g., Ala. Code § 34-23-161* (LexisNexis 2010); *Okla. Admin. Code § 535:15-10-13* (2011).

¹⁴ Also, in many states, the Board of Veterinary Medicine, rather than the Board of Pharmacy,

History of Veterinary Compounding and Its Regulation

In order to contextualize the current legal landscape of veterinary compounding, it is helpful to review the history of its regulation. It is also appropriate to summarize select aspects of human compounding history for comparative purposes.

Since antiquity, compounding has epitomized the pharmacy profession, and even up until the 1930s, 75% of prescriptions required compounding rather than simply dispensing manufactured drugs.¹⁵ Up to that time, the federal government had not regulated pharmacy much, but in 1938, a legally marketed toxic elixir (Elixir Sulfanilamide) killed 107 people, and Congress responded by swiftly passing the Federal Food, Drug, and Cosmetic Act (the FDCA), which gave the FDA authority to regulate (among other things) the quality of drugs.¹⁶ For the past seventy years, the FDCA has formed the basis for the FDA's power to regulate enumerated aspects of pharmacy. The FDCA has been amended and changed often since 1938, but the most wide-ranging revisions occurred through the Kefauver-Harris Amendments of 1962, in which Congress required that drugs be proven to be not only safe but also effective based on "substantial evidence" from "well-controlled investigations...by experts."¹⁷ Thus, drugs must undergo testing as to both their nonmaleficence *and* their ability to treat specified conditions or diseases. To this day, the FDCA's definition of "new drug" has not changed from the one quickly passed in 1938 except for the addition of "efficacy" language in 1962.¹⁸

regulates animal drugs. See e-mail from David Miller, Exec. Dir., Int'l Acad. of Compounding Pharmacists (Jan. 17, 2012, 09:12 CST) (on file with the author).

¹⁵ Brief of Amicus Curiae of National Community Pharmacists Association in Support of Respondents at 8, *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002) (No. 01-344), 2002 WL 100339 (citing Kremers and Urdang's *History of Pharmacy* 315 (rev'd by Glenn Sonnedecker, 4th ed. 1976)).

¹⁶ See 1 Am. Health Lawyers Ass'n, *Health L. Prac. Guide* §16:2 at 16-6 to 16-7 (Alice G. Gosfield et al. eds., 2d ed. 2012); *Regulatory Information*, U.S. Dep't of Health & Human Servs., <http://www.fda.gov/RegulatoryInformation/Legislation/default.htm> (last visited Jan. 2, 2012); see generally Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301-399d (2011).

¹⁷ Am. Health Lawyers Ass'n, *supra* note 16, at 16-8; see also *Regulatory Information*, *supra* note 16; 21 U.S.C. § 355(d) (2011) (current law).

¹⁸ James T. O'Reilly & Kellie Ann Moore, *Food and Drug Admin.* § 13:74, at n.5 (3d ed. 2011).

Although the definitions are substantially similar, the FDCA differentiates between “new drug” and “new animal drug,” and most of this comment focuses on the term “new animal drug.”¹⁹ The current definition of that term is “any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed” that experts in the field have not “generally recognized” as safe and effective or that has been so recognized through research but has not been “used to a material extent or for a material time” outside of research.²⁰

In the veterinary context, a pharmacist violates the FDCA if he dispenses a “new animal drug” that is unsafe, ineffective, or misbranded.²¹ The only other relevant statute is the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), which “deem[s] [not] unsafe” a drug that has already been FDA-approved for a particular use and is prescribed and filled within the lawful context of a veterinarian-client-patient relationship.²² A drug also has to comply with FDA regulations, which allow extra-label use of FDA-approved drugs.²³ The statute and regulations together allow a pharmacist to modify an FDA-approved drug for animal use but give no guidance as to compounding from bulk substances, *i.e.*, compounding from raw ingredients, which is the heart of compounding.²⁴

The exceptions through AMDUCA came a couple years after the FDA announced its policy of regulating compounding pharmacy through Compliance Policy Guides, which technically do not bind the FDA or pharmacists but give guidance as to how the FDA

¹⁹ Compare 21 U.S.C. § 321(p) (2011), with § 321(v).

²⁰ 21 U.S.C. § 321(v) (2011).

²¹ See 21 U.S.C. §§ 331(a-b), 351(a)(5), 360b(a), 352 (2011).

²² 21 U.S.C. § 360b(a)(1) (2011).

²³ 21 C.F.R. § 530.13 (2011) (allowing extralabel use in animals of FDA-approved animal and human drugs if 1. there is no other appropriate drug on the market; 2. the compounding is done by an appropriately state-licensed professional; 3. “adequate procedures and processes are followed that ensure the [drug’s] safety and effectiveness”; 4. the scale of the compounding is appropriate; and 5. applicable state law is followed).

²⁴ 21 C.F.R. § 530.13(a) (merely stating that “nothing in this part shall be construed as permitting compounding from bulk drugs” and that guidance on this subject can be found in the Veterinary CPG).

interprets its authority. In 1992, the FDA first promulgated its human compounding CPG, and, in 1996, the veterinary one was published.²⁵ In 1994, a pharmacy trade group²⁶ challenged the human compounding CPG, and both the district court and federal Fifth Circuit Court of Appeals ruled that the CPG was in fact a nonbinding rule that did not need to be subjected to notice-and-comment rulemaking.²⁷

Since that time, most regulatory activity and controversy has arisen in the human compounding, rather than veterinary compounding, context. In 1997, Congress amended the FDCA with the Food and Drug Administration Modernization Act of 1997 (FDAMA), which expressly dealt with human compounding.²⁸ FDAMA exempted compounds from complying with the FDCA's restrictions if they originated from a valid physician-pharmacist-patient relationship and allowed for bulk substance compounding in certain circumstances.²⁹ The law was a marked breakthrough for compounding, but its glory was short-lived. In 2002, the Supreme Court declared unconstitutional a section of FDAMA, and a circuit split that is unresolved as of this writing resulted as to whether the unconstitutional section of FDAMA could be severed from the rest of

²⁵ See *Manufacture, Distribution, and Promotion of Adulterated, Misbranded, or Unapproved New Drugs for Human Use by State-Licensed Pharmacies; Compliance Policy Guide; Availability*, 57 Fed. Reg. 10,906 (March 31, 1992); *Compounding of Drugs for Use in Animals; Compliance Policy Guide; Availability*, 61 Fed. Reg. 34,849 (July 3, 1996).

²⁶ *Patients and Professionals for Customized Care (P2C2): More Than 164,000 Voices Strong and Growing!*, Int'l Acad. of Compounding Pharmacists, <http://www.iacprx.org/displaycommon.cfm?an=1&subarticlenbr=36> (The organization has since changed its name to the International Academy of Compounding Pharmacists, which as of October 2011 had 2,070 member pharmacists and technicians who specialize in pharmacy compounding. It has resurrected the name "P2C2" for its grassroots advocacy organization of patients, doctors, veterinarians, and pet owners); see *Amid Drug Shortages, Compounding Pharmacies Offer Solutions for Growing Problem*, Prof'l Compounding Ctr. of Am. (Sept. 27, 2011), <http://www.pccarx.com/about-pcca/pcca-news/item/95-pcca-compounding-drug-shortage/>.

²⁷ *Prof'ls and Patients for Customized Care v. Shalala*, 56 F.3d 592, 593-602 (5th Cir. 1995).

²⁸ See 21 U.S.C. § 353a, (a)-(b) (West 2011).

²⁹ See 21 U.S.C. §§ 353a(a-b) (West 2011) (including circumstances such as state licensure of the pharmacist and physician involved, using approved ingredients, and not "making [regularly or in ordinate amounts] essentially a copy of commercially available drug product").

the statute.³⁰

Explicitly in response to the Supreme Court's decision, the FDA revised and republished its current versions of both the human and veterinary compounding CPGs.³¹ The CPGs have framed the discussion of compounding regulations since then. In 2007, Senators Kennedy, Burr, and Roberts circulated draft language for the "Safe Drug Compounding Act" (SDCA), which produced a maelstrom of advocacy for and against it, but it did not progress through the legislative process.³² The proposed bill was significant in that it would have clarified (at least in some ways) the FDA's jurisdiction over compounding by explicitly giving the agency wide-ranging authority.³³

The most recent legal activity relating to compounding, which has largely prompted this paper, is a federal district court case in which the FDA sought to enjoin a compounding pharmacist from

³⁰ See *W. States Med. Ctr. v. Shalala*, 238 F.3d 1090, 1098 (9th Cir. 2001); *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 366-77 (2002) (holding that the advertising sections of FDAMA are unconstitutional); *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 400-05, 409 (5th Cir. 2008); see also Jesse M. Boodoo, *Compounding Problems and Compounding Confusion: Federal Regulation of Compounded Drug Products and the FDAMA Circuit Split*, 36 Am. J. L. & Med. 220, 240-47 (2010) (arguing that the Supreme Court would probably agree with the Fifth Circuit's ruling but concluding that a Supreme Court decision or legislation are needed to clarify this area of law).

³¹ See Pharmacy Compounding Compliance Policy Guide; Availability, 67 Fed. Reg. 39,409 (June 7, 2002); Compounding of Drugs for Use in Animals Compliance Policy Guide; Availability, 68 Fed. Reg. 41,591 (July 14, 2003).

³² See Safe Drug Compounding Act Discussion Draft, 110th Congress (2007) (on file with the International Academy of Compounding Pharmacists or available at <http://www.theempowermentcentre.com/uploads/DiscussionDraftCompoundingBill.pdf>); see generally Letter from John Gans, PharmD, Exec. V.P., Am. Pharmacists Ass'n, et al. to the Honorable Edward Kennedy et al., United States Senate, Comm. on Health, Educ., Labor and Pensions (March 7, 2007) (on file with the International Academy of Compounding Pharmacists and the author) (signed by nine state, national, and international pharmacy organizations and representing over 60,000 member pharmacists with the opinion that contrary to the proposed legislation the state Boards of Pharmacy, not the FDA, should in general regulate pharmaceutical compounding); Letter from the Center for Medical Consumers et al. to the United States Senate, Comm. on Health, Educ., Labor, and Pensions (April 9, 2007) (supporting the proposed legislation), available at http://www.consumersunion.org/pub/core_health_care/004384.html.

³³ Ctr. For Med. Consumers, *supra* note 32.

compounding veterinary drugs from bulk substances.³⁴ The case raised suspicions in that shortly before the FDA's motion for an injunction, the pharmacy had received national news coverage by making a compounding mistake that caused the death of twenty-one Venezuelan polo horses.³⁵ Technically, there was no legal connection between the horses' deaths and the FDA's suit, but the FDA argued a "maximalist" definition of "new animal drug" in the FDCA, which would make illegal much veterinary compounding activity across the United States.³⁶ The federal district court ruled against the FDA,³⁷ which has appealed the decision.³⁸

Such is the current legal landscape relating to veterinary compounding. The FDA has sought an injunction through a maximalist reading of its power under the FDCA, and the time is ripe to reconsider the best way to regulate this area of pharmacy. It is difficult to determine exactly how much compounding still occurs in the United States under the current regulatory regime, but at least one estimate is that compounding represents between one and three percent of all prescriptions.³⁹ Thus, compounding in general (much less veterinary compounding) covers a very small segment of the economy. However, millions of patients' lives are affected by compounding each year, and it is vital for treating animals.⁴⁰ These

³⁴ See *United States v. Franck's Lab, Inc.*, 816 F. Supp.2d 1209, 1209-11 (M.D. Fla. 2011).

³⁵ *Id.* at 1213.

³⁶ *Id.* at 1231.

³⁷ *Id.* at 1255-56.

³⁸ See *International Academy of Compounding Pharmacists (IACP) Responds to FDA's Appeal of the U.S. District Court Ruling on Pharmacy Compounding*, PR Newswire (Nov. 11, 2011), <http://www.prnewswire.com/news-releases/international-academy-of-compounding-pharmacists-iacp-responds-to-fdas-appeal-of-the-us-district-court-ruling-on-pharmacy-compounding-133707658.html>.

³⁹ See e-mail from David Miller, Exec. Dir., Int'l Academy of Compounding Pharmacists (Jan. 17, 2012, 09:12 CST) (on file with the author) (citing Loyd Allen, Ed.-in-Chief of the Int'l Journal of Pharm. Compounding and Professor Emeritus of the Univ. of Okla. HSC Coll. of Pharmacy); compare with *Professionals & Patients for Customized Care v. Shalala*, 847 F. Supp. 1359, 1362 (S.D. Tex. 1994) *aff'd*, 56 F.3d 592 (5th Cir. 1995) (citing testimony by Mary Dean Holland, a clinical pharmacy professor at the Univ. of Ill. Pharmacy Sch., that compounds represent less than one half of one percent of all prescriptions).

⁴⁰ See Brief for Nat. Comty. Pharmacists Ass'n as Amicus Curiae Supporting Respondents at 7-8, *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002) (No. 01-344), 2002 WL 100339.

patients deserve a regulatory regime in which their best interests are protected: both availability of their needed compounded drugs and that medication's safety and efficacy. First, I will discuss why the FDA and the profession should prefer to discard the current CPGs and replace them with informal rules,⁴¹ which will provide a better regulatory framework. Then, I will discuss what policies and solutions those proposed rules should contain.

WHY THE FDA SHOULD PREFER NOTICE-AND-COMMENT RULEMAKING

Chevron Deference

One of the most important advantages to the FDA in promulgating veterinary compounding regulations through notice-and-comment rulemaking instead of through CPGs (particularly in distinguishing compounding from manufacturing) is the greater deference that informal rules generally receive before courts in comparison to policy statements.

In general, "interpretations...contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law, do not warrant Chevron-style deference" by a court.⁴² Rather, they warrant only *Skidmore* deference, which involves the court "consider[ing] that the...interpretations..., while not controlling..., do constitute a body of experience and informed judgment to which courts and litigants may properly resort to for guidance."⁴³ Thus, a court is "guided" by an agency's policy statement because of the agency's expertise and out of respect by the judiciary for separation of powers vis-à-vis the executive branch, but it does not give the agency's interpretation of the statute particularly strong deference.

⁴¹ Informal rules are those promulgated by "notice-and-comment" rulemaking per the Administrative Procedure Act, 5 U.S.C. § 553 (West 2011), which is described *infra* Part II.C.

⁴² *Christensen v. Harris County*, 529 U.S. 576, 577 (2000); *U.S. v. Mead Corp.*, 533 U.S. 218, 254 (2001).

⁴³ *See, e.g., Mead Corp.*, 533 U.S. at 234-239 (giving *Skidmore*, rather than *Chevron*, deference to opinion letters that were deemed equivalent to policy statements); *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944).

The veterinary CPG is a policy statement, not a substantive rule, and it should therefore receive *Skidmore* deference from courts as an “advisory opinion.”⁴⁴ An example of the veterinary CPG receiving *Skidmore* deference is *Franck’s Lab*, in which the federal district court judge held that because the 2003 veterinary CPG was “non-binding” and was not promulgated through notice-and-comment rulemaking, it should receive *Skidmore* deference.⁴⁵ Moreover, the judge held that it was not sufficiently “persuasive” under *Skidmore*.⁴⁶ The FDA would likely counter that its CPG has apparently received *Chevron* deference in other cases,⁴⁷ but according to current administrative law as declared by the U.S. Supreme Court, the CPG should receive only *Skidmore* deference, and most recently in *Franck’s Lab* it has received such.

By contrast, a notice-and-comment rule receives *Chevron* deference, by which a court of law asks: (1) whether Congress has spoken directly to the issue; and (2) if Congress has not thus spoken, whether the agency’s interpretation is a “permissible construction of

⁴⁴ See generally *Professionals and Patients for Customized Care v. Shalala*, 56 F.3d 592, 595 (5th Cir. 1995) (holding that the CPG in effect at that time for human-patient compounds was either a policy statement or an interpretive rule but not a substantive one. Rather, the court agreed with the FDA that the CPG was an “advisory opinion” that provided factors by which the agency could be guided in determining whether a pharmacy was acting as a manufacturer or not. The factors were explicitly “not exhaustive” and imprecise, and they merely “‘channeled’ the FDA’s enforcement discretion.”) The FDA’s own regulations concerning whether CPGs have binding effect are ambiguous but favor being non-binding. See 21 C.F.R. § 10.115(f)-(i) (1999) (stating that guidance documents are not legally binding but “represent the agency’s current thinking. On the other hand, the FDA will “ensure” that it “follows” its CPGs, and they “must be followed whenever regulatory expectations are not readily apparent from the statute or regulations are first communicated to a broad public audience.” Nevertheless, ultimately, there are mechanisms for the public to complain if the FDA treats a CPG as “binding.”); see also Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like—Should Federal Agencies Use Them to Bind the Public?*, 41 *Duke Law Journal* 1311, 1335 (1992) (arguing that the FDA’s CPGs in general are rather “binding” in practice on regulated parties).

⁴⁵ *United States v. Franck’s Lab, Inc.*, 816 F.Supp.2d 1209, 1252 (M.D. Fla. Sept. 12, 2011).

⁴⁶ *Id.*

⁴⁷ See, e.g., *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 393 (5th Cir. 2008) (giving *Chevron* deference); *Wedgewood Village Pharmacy, Inc. v. U.S.*, 421 F.3d 263, 272 (3d Cir. 2005) (describing the district court’s use of *Chevron* and explaining why it did not need to reach that question to resolve the case). Neither court in my opinion sufficiently explains why the CPG should receive *Chevron* deference rather than a lower form.

the statute.”⁴⁸ For step one of *Chevron* deference, a court may use traditional canons of statutory interpretation to determine whether a term in the statute is ambiguous or whether Congress has spoken directly to the question.⁴⁹ In general, however, because there are so many canons of construction and many canons contradict each other and overlap, it is often relatively easy to find statutory ambiguity.⁵⁰ Meanwhile, step two of *Chevron* is also often easily satisfied because the interpretation need be only “a permissible construction,” not the only one or even the best.⁵¹ Thus, step two of *Chevron* deference is also generally easy for the agency to satisfy and *Chevron* deference is therefore a powerful aid for an agency interpreting—and enforcing its interpretation of—a statute that it administers. The only exception to this high deference under *Chevron* occurs generally in the D.C. Circuit and occasionally others, in which the court applies “hard look review” in step two of *Chevron*.⁵² Thus, in the D.C. Circuit, the construction by the agency must be not only permissible, but also one that has considered and weighed all factors which Congress wanted the agency to consider and that involves a “hard look” at the issue.⁵³

⁴⁸ *United States v. Mead Corp.*, 533 U.S. 218, 234 (2001); *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984). Supreme Court Justice Antonin Scalia has argued that the amount of authority given by Congress to an agency, rather than the type of rule promulgated, should determine the amount of deference by a court. *See Mead Corp.*, 533 U.S. at 246-47 (Scalia, J., dissenting). However, Scalia’s critique ignores the added weight of a notice-and-comment rule (in that it has also been subjected to public debate) and therefore should also receive greater deference. The rest of the court has not joined his school of thought.

⁴⁹ *See I.N.S. v. Cardoza-Fonseca*, 480 U.S. 421, 427-49 (1987) (using the statutory construction canons of ordinary and plain meaning, *in pari materia*, and legislative history to determine whether a term is ambiguous).

⁵⁰ *See, e.g., id.* at 449.

⁵¹ *See generally* Matthew C. Stephenson & Adrian Vermeule, *Chevron Has Only One Step*, 95 Va. L. Rev. 597 (2009) (emphasis added) (arguing that step two of *Chevron* is in fact just a “special case” of step one).

⁵² *See, e.g., U.S. Telecom. Ass’n v. F.C.C.*, 227 F.3d 450, 459-66 (D.C. Cir. 2000) (applying hard-look review in step two of *Chevron*).

⁵³ *See, e.g., aaiPharma Inc. v. Thompson*, 296 F.3d 227, 242 (4th Cir. 2002); *see also Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50-57 (1983) (holding per hard-look review of a policy question that an agency must consider alternatives to its proposal, particularly those proposed by Congress in a statute, and make a rational decision; also holding that an agency must provide relevant data and articulate a satisfactory rationale for its decision at the time of the decision).

In general, however, a court will agree with an agency's interpretation of a statute under *Chevron* deference.

As long as the FDA relies on its CPG, its interpretation of the FDCA and AMDUCA concerning veterinary compounding will likely receive only *Skidmore* deference, which is far weaker than *Chevron* deference. Moreover, once a court interprets a statute under *Skidmore* deference, the agency cannot change its interpretation later but must follow the court's ruling until that court or a higher one changes it.⁵⁴ By contrast, when a court gives an agency deference under *Chevron*, the court is merely stating that the agency's interpretation is a reasonable one that should be deferred to; the agency is still free to change its interpretation at a later time to another reasonable one.⁵⁵ Unless the FDA wishes to risk more cases like *Franck's Lab*, it is in the FDA's best interest to promulgate regulations through notice-and-comment rulemaking and receive *Chevron*, and as discussed below possibly even *Auer* deference.

Auer Deference

Another reason the FDA should favor notice-and-comment rulemaking is that if it subsequently interprets its own notice-and-comment rule, it will receive in courts not just *Chevron* deference but the even higher form of deference known as *Auer* (or *Seminole Rock*) deference for that interpretation. Under *Auer*, if an agency interprets a validly promulgated notice-and-comment rule (that itself interprets an organic statute of the agency), the agency's interpretation of its own rule will receive "controlling" weight unless it is "plainly erroneous or inconsistent with the regulation."⁵⁶ The U.S. Supreme Court has tempered the potential extremism of *Auer* deference by stating that an interpretation of an exact term in a notice-and-comment rule that is also in the statute should not receive *Auer* deference because the agency is essentially interpreting the statute and not the rule; in other words, a regulation cannot simply "parrot"

⁵⁴ See *Mead Corp.*, 533 U.S. at 247 (Scalia, J., dissenting) (citing *Neal v. United States*, 516 U.S. 284, 295 (1996)).

⁵⁵ *Id.* at 248.

⁵⁶ *Auer v. Robbins*, 519 U.S. 452, 461 (1997) (quoting and *aff'g* *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945)).

the statute and then be interpreted with the advantage of *Auer* deference.⁵⁷ However, even accounting for anti-“parroting,” *Auer* deference is extremely useful for an agency that interprets its own notice-and-comment rule.⁵⁸ By replacing its CPG with a rule, the FDA can likely avail itself of this procedural advantage as well.

Similarities in Promulgating CPGs and Rules

A counterargument by the FDA to the above advantages of notice-and-comment rulemaking may be that although informal rules receive more deference from courts than policy statements, policy statements are easier and more economical for the agency to promulgate. However, in theory, the two processes are extremely similar because the FDA’s own regulations concerning CPG development and enforcement remarkably mirror the Administrative Procedure Act (APA)’s provisions for notice-and-comment rulemaking.⁵⁹ According to the FDA’s own regulations, the agency must announce in the Federal Register that a draft of a guidance document is available, post the draft online, and solicit comments from the public before it publishes the final version of a Level 1 guidance document⁶⁰ (which the veterinary CPG is⁶¹). The FDA also binds itself through its own regulations to review the public’s solicited comments and edit the document at its discretion before

⁵⁷ See *Gonzales v. Oregon*, 546 U.S. 243, 257 (2006).

⁵⁸ See generally Stephen M. Johnson, *Bringing Deference Back (But for How Long?): Justice Alito, Chevron, Auer, and Chenery in the Supreme Court’s 2006 Term*, 57 *Cath. U. L. Rev.* 1, 31-33 (2007).

⁵⁹ Compare 21 C.F.R. § 10.115(f)-(i) (West 2011) (“the FDA’s policies and procedures for developing, issuing, and using guidance documents”) and Administrative Procedure Act, 5 U.S.C. § 553 (West 2011) (the APA’s provisions for rulemaking).

⁶⁰ See 21 C.F.R. § 10.115(g)(1)(ii), (iv) (West 2011). Note that according to the regulation the FDA may also solicit comments from the public, hold meetings and workshops, and hold reviews before it “will” publish the draft in the Federal Register. See 21 C.F.R. § 10.115(g)(1)(i) (West 2011).

⁶¹ See 21 C.F.R. § 10.115(c)(1) (West 2011) (stating that Level 1 guidance documents “set forth initial interpretations of statutory or regulatory requirements, set forth changes in interpretation or policy that are of more than a minor nature, include complex scientific issues, or cover highly controversial issues”); *Compounding of Drugs for Use in Animals Compliance Policy Guide*; Availability, 68 *Fed. Reg.* 134 (July 14, 2003) (describing the CPG as a Level 1 guidance document).

publishing the final version.⁶² The regulation includes an exception if “prior public participation is not feasible or appropriate,” in which case the guidance document may be published without public comment, but the agency is still required to receive public comments after the document’s issuance and change it “when appropriate.”⁶³

The APA meanwhile requires that a “general notice of proposed rulemaking” be published in the Federal Register, and by executive order the public must have at least sixty days during which to comment on the proposed rule.⁶⁴ The agency must give “consideration” to the public’s submissions and then include a “concise general statement of [the rule’s] basis and purpose” in the final rule.⁶⁵ The APA also provides any interested person the right to request amendment or repeal of a rule.⁶⁶ The only way that a rule can be enforced without undergoing the notice-and-comment process is if “the agency for good cause finds. . .that. . .[public comment is] impracticable, unnecessary, or contrary to the public interest.”⁶⁷

Theoretically, these two processes are procedurally nearly identical. The only material differences are that rulemaking has a set time period for notice-and-comment, whereas the FDA regulation does not specify such for CPGs,⁶⁸ and the exception language differs slightly. Thus, the FDA should not object to rulemaking as procedurally more expensive or problematic.

Nevertheless, the FDA will likely also object to the practical differences between the two. The FDA did not submit the CPG to public comment before publication; rather it seemed to utilize the exception provision without explicitly stating so.⁶⁹ In promulgating the CPG, the agency claimed that it did not solicit public comment

⁶² 21 C.F.R. § 10.115(g)(1)(iv)(A).

⁶³ 21 C.F.R. § 10.115(g)(2-3).

⁶⁴ Exec. Order No. 12,866, 58 Fed. Reg. 51,735, Sec. 6(a)(1) (Sept. 30, 1993).

⁶⁵ 5 U.S.C. § 553(c) (West 2011).

⁶⁶ 5 U.S.C. § 553(e).

⁶⁷ 5 U.S.C. § 553(b)(3)(B).

⁶⁸ 21 C.F.R. § 10.115(g)(1)(iv)(A).

⁶⁹ See Compounding of Drugs for Use in Animals Compliance Policy Guide; Availability, 68 Fed. Reg. 134 (July 14, 2003) (in which the FDA “explains” its rushed publication of the CPG without public comment).

before publication because it felt compelled to clarify the legal landscape and its positions after the Supreme Court's 2002 decision in *Thompson v. Western States Medical Center*.⁷⁰ However, as at least one professional trade group has noted, the 2003 CPG was not issued until 15 months after the Court's decision, and during those months, the FDA did not solicit any public input or publish a draft copy.⁷¹ The situation does not appear to meet the "not feasible or appropriate" standard in the FDA's regulations.⁷²

Because the FDA has avoided notice-and-comment in promulgating the original CPGs and has not engaged in rulemaking, it is plausible to hypothesize that the agency has a hidden motive for avoiding public comment and a binding rule. One explanation is that compounding standards are "highly controversial." However, this should not be a sufficient reason, at least to avoid seeking public input, because the FDA's own CPG regulations classify some Level 1 guidance documents (which are explicitly subject to public comment) as ones "cover[ing] highly controversial issues."⁷³ Thus, it is assumed that simply being "highly controversial" should not merit fitting the "not feasible or appropriate" exception.

Also, even if the FDA were validly using its emergency measures to bypass notice-and-comment, it would still need to revise the CPG upon receiving comments after publication.⁷⁴ The FDA has testified in court that it has not revised the 2003 CPG, even though it has solicited comments on animal drugs in general.⁷⁵ Thus, whether or not the original publication of the CPG followed the FDA's own regulations, the CPG is likely due to be revised, and public input is

⁷⁰ *Id.*

⁷¹ Letter from L.D. King, Exec. Director, International Academy of Compounding Pharmacists, to Dockets Management Branch (HFA-305), U.S. Food & Drug Admin., at 3 (Sept. 16, 2003) (on file with the Int'l Acad. of Compounding Pharmacists, the author, and the FDA [re: Docket No. 2003D-0290; Guidance on Compounding of Drugs for Use in Animals]). The letter also notes that the 2003 Veterinary CPG represented a "significant change" from the 1996 version in that the 1996 CPG apparently allowed "in anticipation" compounding in a large number of circumstances. *See* Letter at 11-13.).

⁷² *See supra* note 63 and accompanying text.

⁷³ *See* 21 C.F.R. § 10.115(c)(1)(iv) (West 2011).

⁷⁴ *See id.* § 110.115(g)(3)(ii), (4)(ii), (5).

⁷⁵ *See United States v. Franck's Lab, Inc.*, 816 F. Supp. 2d 1209, 1230 n.52 (M.D. Fla. 2011).

required at some point. Because the FDA cannot avoid public comment, the procedural processes will theoretically and practically be the same, and it would be beneficial for the FDA to take advantage of greater deference through rulemaking.

The U.S. Supreme Court's Suggestions

The U.S. Supreme Court has never ruled specifically on the veterinary compounding aspects of the FDCA or the CPGs, but in the course of declaring the advertising provisions of FDAMA unconstitutional, the Court suggested that the FDA should more clearly define the difference between compounding and manufacturing.⁷⁶ Specifically, the Court endorsed methods of differentiation such as requiring pharmacists to receive a prescription before compounding and restricting either the amount or number of prescriptions that a pharmacy can legally compound.⁷⁷ Some methods are contained in the current CPG, while others are not, suggesting that the Court was thinking beyond mere enforcement of the CPG.⁷⁸ One interpretation of the Court's dicta is that the FDA needs to clarify its position, which is possible through a CPG but can be more definite through a binding rule.

The FDA Will Be Driving the Initiative

Another reason that the FDA may be avoiding notice-and-comment rulemaking is fear of losing control; however, this fear is largely groundless. The FDA would initiate the process and control it as an agency deferred to by the courts, which is a far better alternative than seeking a legislative remedy over which the agency will have far less power.⁷⁹ Although the agency would have to address comments made on the proposed rules, it could exercise discretion in how it addressed them; the APA's guidelines are very liberal towards agencies.⁸⁰ Even in the worst-case scenario, if the

⁷⁶ See *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 372 (2002).

⁷⁷ *Id.*

⁷⁸ Compare *id.*, with *Veterinary CPG*, *supra* note 2, at 4-5.

⁷⁹ See, e.g., *supra* note 32 and accompanying text.

⁸⁰ See *supra* note 65 and accompanying text.

notice-and-comment process proved to be more onerous than expected and an unforeseeably fierce controversy ensued, the FDA could remove its proposed rule or not pursue a final one. It would lose little to nothing in the process, even in terms of resources, because the advantages of having an informal rule outweigh the financial (and any other) risk of failure. Thus, in order to benefit from *Chevron* and perhaps *Auer* deference, as well as follow the Supreme Court's suggestions, the FDA should take the strategic initiative of engaging in notice-and-comment rulemaking regarding veterinary compounding issues. Moreover, as discussed next, rulemaking is likely a better option for the profession that the FDA is regulating.

BENEFITS TO THE COMPOUNDING PROFESSION

The Ability to Comment

Since 1994, compounding pharmacists have repeatedly complained that the FDA has not given the public opportunity to comment on the CPGs before publication.⁸¹ Trade organizations, as well as members of Congress and citizens, have specifically asked the FDA for public comment on the CPGs, and one organization has even described a "desperate need" for it.⁸² In 2004, the FDA announced on its website that in response to public demand, it "inten[ded]" to "draft and publish for public comment a revised [CPG] on veterinary pharmaceutical compounding," but it has failed to do so.⁸³

Compounding pharmacists clearly want to comment on the CPGs and have repeatedly requested such an opportunity for over

⁸¹ See *Prof'ls & Patients for Customized Care v. Shalala*, 847 F. Supp. 1359, 1361 (S.D. Tex. 1994) *aff'd*, 56 F.3d 592 (5th Cir. 1995).

⁸² See, e.g., Letter from L.D. King, Exec. Dir., Int'l Acadd. of Compounding Pharmacists to Dockets Management Branch (HFA-305), U.S. Food & Drug Admin., at 1-5, 15 (Sept. 16, 2003) (on file with the International Academy of Compounding Pharmacists, the author, and the FDA [re: Docket No. 2003D-0290; Guidance on Compounding of Drugs for Use in Animals. Jennifer Goodrum & Patricia Paget, *Veterinary Compounding: What You Should Know*, U.S. Veterinarian 79, 82 (2005).

⁸³ *FDA to Revise Its Compliance Policy Guide on Veterinary Compounding*, U.S. Food & Drug Admin. (Sept. 1, 2004), <http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm048425.htm>.

fifteen years. Because the notice-and-comment rulemaking process is so similar to the FDA's CPG procedures, a notice-and-comment rule would grant the profession its request. Also, the exemption provisions for notice-and-comment rulemaking are more stringent than those for CPG promulgation and require the agency to show "good cause" in order to avoid seeking public comment before final publication.⁸⁴ Courts have narrowly construed this exemption language,⁸⁵ and it is therefore probable that the FDA cannot pass a notice-and-comment rule under the current circumstances without soliciting public comments.

A More Certain Regulatory Environment

In addition to giving pharmacists an almost certain right to comment, the rules will also provide a more certain regulatory environment in which to conduct business. Historically, compounding pharmacists have at least been able to sleep soundly at night knowing that the FDA was not actually enforcing the "maximalist interpretation" of its authority under the FDCA's broad language. As one treatise acknowledges, "[a] pharmacist who compounds a drug may quite understandably find cold comfort in the FDA's promised self-restraint,"⁸⁶ but there was at least that "cold comfort." The Fifth Circuit Court of Appeals has relied on the FDCA's explicit exception allowing the FDA not to enforce against "minor violations"⁸⁷ and the agency's precedent of generally not enforcing a maximalist interpretation too strongly or too often to suggest that it does not matter so much that the FDA could enforce absurd causes of action against compounders. Theoretically for pharmacists, it does not matter what the law says, as long as the enforcement does not actually affect their businesses. However, the

⁸⁴ See *supra* notes 63 and 67 and accompanying text.

⁸⁵ See, e.g., *Tenn. Gas Pipeline Co. v. FERC*, 969 F.2d 1141, 1144-46 (D.C. Cir. 1992) (overruling an agency's use of the exception provision because there was no emergency).

⁸⁶ O'Reilly & Moore, *supra* note 18, at 213.

⁸⁷ *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 399 (5th Cir. 2008); 21 U.S.C. § 336 (West 2011) (giving the Secretary discretion not to enforce the FDCA against "minor violations...whenever he believes that the public interest will be adequately served by a suitable written notice or warning").

mere presence of the law may affect behavioral patterns, as can statements by the government that it has “a substantial interest in preventing widespread compounding.”⁸⁸

However, the *Franck's Lab* case in particular represents an “increased enforcement” against veterinary compounds.⁸⁹ In that case and repeatedly (at least in its briefing), the FDA is promoting a “maximalist interpretation” of its authority through the FDCA over compounding, and in *Franck's Lab*, the agency attempted to enforce that authority with injunctions.⁹⁰ In that case, the court declared in view of the FDA’s suit that “[s]imply relying on the good graces of the FDA’s ‘enforcement discretion’ will not suffice [any more].”⁹¹ The theory that pharmacists can take shelter in lack of enforcement is now moot.

A properly constructed rule has the potential of clarifying which activity is legal and which is not, as well as which is within the FDA’s jurisdiction and which is regulated solely by the states. The CPG itself created a great deal of uncertainty,⁹² which is why pharmacy groups initiated FDAMA legislation to create more certainty at least on the human compounding front.⁹³ The profession is seeking a stable and predictable legal environment in which to assess business risks. Binding rules can potentially create that environment.

THE STATUTORY BASIS FOR A PROPOSED RULE

Although one district court has stated that the FDA “certainly has the statutory authority to . . . draw the line between manufacturing

⁸⁸ *W. States Med. Ctr. v. Shalala*, 238 F.3d 1090, 1094 (9th Cir. 2001) (strongly suggesting that such arguments were made at the district court level).

⁸⁹ James T. O’Reilly, *Food & Drug Admin.* § 16:13 at 3 (3d ed. 2011 & Supp. 2012).

⁹⁰ Memorandum of Law in Support of Plaintiff’s Motion for Preliminary Injunction at 6-10, *United States v. Franck’s Lab, Inc.*, 816 F. Supp. 2d 1209 (M.D. Fla. 2011), (No. 5:10-cv-00147-Oc-32GRJ) 2010 WL 3571632; *see also* O’Reilly, *supra* note 89, at 3.

⁹¹ *United States v. Franck’s Lab, Inc.*, 816 F. Supp. 2d 1209, 1255 (M.D. Fla. 2011).

⁹² *See generally* 21 C.F.R. § 10.115(f)-(i), *supra* note 44.

⁹³ *See* Roger A. Fairfax, “Phederalism”: *The Regulation of Pharmacy Compounding and Two Years in the Regulatory Turf War Between Pharmacy and the Food and Drug Administration*, Leda, Harvard Law School, 17 (1998), available at <http://leda.law.harvard.edu/leda/data/211/rfairfax.html> (last visited Oct. 15, 2012).

and traditional compounding with formal regulations” and the U.S. Supreme Court has, in dicta, advised the FDA to make such a distinction (though it did not specify the procedural mechanism),⁹⁴ how the FDA could accomplish this task through rulemaking requires careful analysis. The most difficult question is where the FDA can find statutory authority for its rulemaking. Without such a statutory basis, the resulting regulations will be difficult to substantiate, enforce, and litigate.

Nowhere in so many words does Congress delegate rulemaking authority to the FDA concerning veterinary compounding.⁹⁵ Congress does not specifically address veterinary compounding anywhere in the FDCA; rather, such compounds technically fit the extremely broad definition of “new animal drug” and therefore arguably fall within the FDA’s jurisdiction.⁹⁶ However, it is quite plausible for the FDA to nevertheless exercise rulemaking authority on the theory that the plain language of the statute is ambiguous.⁹⁷ In this sense, the agency’s treatment of veterinary compounding can be

⁹⁴ See *Franck’s Lab*, 816 F. Supp. 2d at 1230, 1252, n. 52 (holding that the veterinary CPG should be given only *Skidmore* deference and suggesting that the FDA could engage in notice-and-comment rulemaking); see also *Thompson* 535 U.S. at 372.

⁹⁵ See 21 U.S.C. § 360b(a)(4) (West 2011) (giving specific rulemaking authority to the Secretary over certain aspects of “new animal drugs”); see also 21 U.S.C.A. § 371(a) (West 2011) (stating that “the authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary”).

⁹⁶ See 21 U.S.C. § 321(v).

⁹⁷ See *Weinberger v. Bentex Pharm., Inc.*, 412 U.S. 645, 653 (1973) (holding that “it is implicit in the regulatory scheme, not spelled out *in haec verba*, that the FDA has jurisdiction to decide with administrative finality, subject to the types of judicial review provided, the ‘new drug’ status of individual drugs or classes of drugs”); see also *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 396 (5th Cir. 2008) (stating that “[u]pon discovering that a statute’s plain text is in tension with its supposed purpose, one usually concludes that Congress has spoken ambiguously.” The court continues by noting that in order to defeat granting *Chevron* deference to the FDA in that case, the pharmacists would have to prove “congressional intent is in fact not ambiguous—that the statute’s purpose is so clear and compelling, despite tension with the plain text, that it leaves no doubt as to Congress’s intent, [which is] a heavy burden.” If the FDA were to take the pharmacists’ argument that there is a valid distinction between “manufacturing” and “compounding” based upon the legislative history, the FDA would have a nearly invincible legal position because challengers would have to prove an “unambiguously expressed intent” by Congress that the FDA’s interpretation of who qualifies as a “manufacturer” or “compounder” is wrong.).

analogized to that of nicotine products in *Brown & Williamson*.⁹⁸ In that case, the Supreme Court did not give controlling weight to the government's argument that nicotine products technically fit the statute's broad plain meaning definitions of "drug" and "device."⁹⁹ Rather, because the legislative history of the Act, subsequent legislation, and the FDA's own position for the first several decades of the FDCA's enforcement clearly showed that Congressional intent was for nicotine products not to be included within the FDCA's definitions, the FDA was not permitted to include those products within its jurisdiction until it sought express statutory language from Congress.¹⁰⁰

In this case, the legislative history of the FDCA and surrounding circumstances suggest that compounding was not intended to be included within the FDA's scope of authority. In 1938, compounding was still widely practiced, and several courts, including the Supreme Court, have agreed that it is quite unlikely that Congress intended compounded drugs to fall within the FDCA's "new drug" and "new animal drug" definitions because they would then be illegal.¹⁰¹

Likewise, other parts of the FDCA evidence that Congress intends to differentiate between compounding and manufacturing. Two sections of the FDCA particularly stand out: § 374, which deals with inspections, and § 802, which defines "manufacture" for the purpose of regulating controlled substances.¹⁰² The inspection statute exempts pharmacies that comply with "local laws regulating the practice of pharmacy and medicine" from being subject to inspection

⁹⁸ *Food and Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 131-161 (2000) (holding that although nicotine technically fits the definition of "drug" under the FDCA, because of Congress's clear intent that nicotine should not be regulated by the FDA, it should not be included in the definition as a matter of law. Congress's intent was proven by viewing the FDCA as a whole, subsequent legislation by Congress concerning nicotine products, and the FDA's own public stance on nicotine for the first sixty years of the FDCA's history. The Court admitted that "this [was] hardly an ordinary case" because of tobacco's prominence in the U.S. economy.).

⁹⁹ *Id.* at 125-26.

¹⁰⁰ *Id.* at 125-61; *see also* Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (giving the FDA statutory authority to regulate tobacco products).

¹⁰¹ *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 369 (2002); *see also* 21 U.S.C. § 321(v).

¹⁰² *See* 21 U.S.C. § 374(a) (1-2) (West 2011); 21 U.S.C. § 802 (West 2011).

of “all things therein (including records, files, papers, processes, controls and facilities)” which would prove whether a pharmacy was complying with the FDCA’s adulteration and misbranding provisions.¹⁰³ Section 374 thus shows that Congress has a history of recognizing that pharmacies which comply with state law are not breaking federal law by compounding and that Congress does not hold compounding pharmacists to the same standard as manufacturers.¹⁰⁴ In addition to the different standards for compounders in FDA inspections, the definition of “manufacture” in § 802 of the FDCA excepts from the denotation “preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice.”¹⁰⁵ The definition for that portion of the statute thus clearly excepts compounding pharmacists who comply with state law. In § 822, those who “manufacture” controlled substances according to the above definition must specially register with the Attorney General, but those who compound them under state law are exempted.¹⁰⁶ These statutory provisions strongly suggest that Congress does not intend for compounding that complies with state law to be illegal, which would be the effect of the FDA’s maximalist reading of the FDCA’s “new animal drug” definition.

Finally, just as the FDA expressly treated tobacco products as outside the FDCA’s jurisdiction for the first sixty years of its existence,¹⁰⁷ the FDA expressly recognized that compounded drugs

¹⁰³ See § 374(a)(1-2A). Note that the exemption technically requires the pharmacy to not only comply with local laws but also regularly dispense drugs or devices upon valid prescriptions and not “manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business.” See also 21 U.S.C. § 360(g)(1-2), (h) (reiterating the same exemptions).

¹⁰⁴ See *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 398, n.33 (5th Cir. 2008) (noting this argument in part and rejecting it).

¹⁰⁵ 21 U.S.C. § 802(15) (West 2011).

¹⁰⁶ 21 U.S.C. § 822 (West 2011).

¹⁰⁷ *Food And Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 146 (“In the 73 years since the enactment of the original Food and Drug Act, and in the 41 years since the promulgation of the modern Food, Drug, and Cosmetic Act, the FDA has repeatedly informed Congress that cigarettes are beyond the scope of the statute absent health claims

were not “new drugs” for the first fifty years of the FDCA,¹⁰⁸ and in an internal memo from Health and Human Services’ Office of the General Council, the government recognized that there were several practical and policy problems with expansively reading the FDCA to suddenly encompass compounded drugs.¹⁰⁹

Thus, just like nicotine products in *Brown & Williamson*, traditional compounding (however defined) does not appear through the legislative history to be intended by Congress to be regulated through the FDCA, as the FDA recognized for approximately fifty years. Therefore, it seems clear that the broad definition of “new animal drug” is actually ambiguous in light of the legislative history and should be clarified by the FDA through a rule that clearly distinguishes between manufacturing and state-regulated compounding. If the FDA wants a more explicit rack on which to hang its rulemaking hat, it could ask Congress for an explicit one,¹¹⁰ or it may choose to do so because of concern over one federal Circuit Court of Appeal’s hesitation at finding statutory ambiguity through legislative history.¹¹¹ However, the FDA can probably promulgate a

establishing a therapeutic intent on behalf of the manufacturer or vendor”) (citing Brief for Appelle (FDA) in *Action on Smoking and Health v. Harris*, 655 F.2d 236 (CA DC 1980), in 9 Rec. in No. 97-1604 (CA4), Tab No. 4, pp. 14-15).

¹⁰⁸ *Thompson*, 535 U.S. at 363.

¹⁰⁹ Letter from David G. Adams, Dep’t of Health & Human Serv., Office of the Gen. Counsel, Food & Drug Division, to Carl Peck, M.D., Paula Botstein, M.D., and John Palmer, M.D., at 1-4 (Aug. 2, 1989) (on file with the International Academy of Compounding Pharmacists and the author). The memo also notes that the 1938 Act’s legislative history probably does not support including compounding within the Act’s jurisdiction.

¹¹⁰ Suggested language may include, “The Secretary may issue regulations which distinguish with technical definitions between manufactured drugs, which are included in the definition of ‘new drug’ and ‘new animal drug,’ and compounded drugs, which are not.” If the FDA were to seek specific statutory language, *Chevron* deference would likely no longer be granted because the authority would not be based on a statutory ambiguity but an explicit policy question that Congress has given the FDA authority to answer. See *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843-44 (1984) (stating that “if Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute.”). The U.S. Supreme Court has subjected policy questions to hard look review. See *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50-57 (1983).

¹¹¹ See, e.g., *U.S. v. Geiser*, 527 F.3d 288, 292-94 (2008).

valid rule relying simply on the FDCA as is, and if it is properly crafted, it should not even meet much contestation. Next, let us examine the policy bases and suggested content for an FDA rule.

POLICY BASES FOR A PROPOSED RULE AND SUGGESTED CONTENT

The ideal goal for the FDA as a proactive and responsible government agency is to regulate drug making such that all drugs on the market undergo equally intense and comprehensive testing to ensure that they are safe and effective. However, resources are insufficient to meet this goal. First, the FDA does not have the means to regulate so extensively. Currently, the FDA regulates approximately \$1 trillion worth of products each year—approximately 25% of the American economy.¹¹² A Congressional subcommittee has even published its observation that the FDA “suffers from serious scientific deficiencies and is not positioned to meet current or emergency regulatory responsibilities.”¹¹³ For example, FDA investigators have testified in discovery for trials that they have not received training in how to inspect a pharmacy, a duty that the FDA is clearly required to perform by statute.¹¹⁴

Moreover, the ideal image of regulation also fails to account for the market limitations of compounders. It is uneconomical and nonsensical for compounding pharmacists to submit to the new drug approval process with which manufacturers must comply.¹¹⁵ According to a study from 2002, a manufacturer must spend

¹¹² See Fairfax, *supra* note 93, at 32; *Regulatory Information*, U.S. Department of Health & Human Services, available at <http://www.fda.gov/RegulatoryInformation/Legislation/Default.htm> (last visited Jan. 2, 2012); see generally 21 U.S.C. §§ 301–399D (West 2011); compare with Jeffrey N. Gibbs, *FDA’s Regulatory Extensions: An Overburdened Agency Assigns Itself New Responsibilities*, 23 Legal Backgrounder 22, Washington Legal Foundation (June 13, 2008) (estimating that the FDA regulates approximately \$1.5 trillion worth of products each year).

¹¹³ FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology Prepared for FDA Science Board at 2 (Nov. 2007), available at http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf (last visited Jan. 14, 2012).

¹¹⁴ See Gibbs, *supra* note 112, at 4; see generally 21 U.S.C. § 374(a) (1)-(2) (West 2011).

¹¹⁵ See *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 369-79 (2002); *United States v. Franck’s Lab, Inc.*, 816 F. Supp. 2d 1209, 1236 (M.D. Fla. 2011).

approximately \$802 million dollars in research and development costs per new drug before the drug is approved by the FDA.¹¹⁶ Large scale manufacturers can afford this process; compounders cannot.

Not only do compounders have less financial resources but they also work under much more stringent time constraints. Of every five to ten thousand compounds that begin the approval process, only one makes it to the market as a manufactured drug, and the process for approval takes between eight and twelve years.¹¹⁷ In the typical compounding situation, a pharmacist receives a prescription from a physician for a specific patient's compound. A compounder does not have time to undergo the FDA's new drug approval process every time he receives a compounding prescription for a drug that has been pulled off the market for economic reasons or that needs an adjusted dosage, flavoring, combination, etc.; he does not have time to undergo even an abbreviated version of the process. It is simply impractical, and forcing pharmacists to submit to the process would likely cause them to stop providing the compounds that patients need.

A practical goal for FDA regulation is thus to fairly distinguish between manufacturing and compounding, so that the agency can concentrate its limited resources on regulating manufacturers, and leave small-scale compounders to state regulation. The Supreme Court has suggested, in dicta, a series of solutions to make this distinction while reasonably trying to reach the policy goal that all drugs be as safe and effective as possible.¹¹⁸ Its suggestions (which readily apply to veterinary compounding) were the following: 1. "Ban the use of 'commercial scale manufacturing or testing equipment for compounding drug products'" per the CPG in place at

¹¹⁶ Joseph A. DiMasi, Ronald W. Hansen, and Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. Health Econ. 151, 180 (2003) (estimating in year 2000 U.S. dollars).

¹¹⁷ Martin S. Lipsky, MD, & Lisa K. Sharp, PhD, *From Idea to Market: The Drug Approval Process*, 14 JABFP 362, 364 (Sept.-Oct. 2001) (citing E.M. Leonard, *Quality Assurance and the Drug Development Process: An FDA Perspective*, 3 Quality Assurance 178-86 (1994) and J.E. Klees & R. Joines, *Occupational Health Issues in the Pharmaceutical Research and Development Process*, 12 Occupational Med. 5-27 (1997)).

¹¹⁸ *Thompson*, 535 U.S. at 372 (per the CPG in place at the time).

that time;¹¹⁹ 2. Use other permutations of the CPG's guidelines;¹²⁰ 3. Require valid compounds to be compounded only pursuant to a valid prescription and not "in anticipation";¹²¹ 4. Restrict pharmacists' ability to sell compounds at wholesale for resale;¹²² 5. "Limit the amount of compounded drugs, either by volume or by numbers of prescriptions, that a given pharmacist or pharmacy sells out of state";¹²³ and 6. "[Cap] 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."¹²⁴

The proposal concerning manufacturing equipment seems plausible at first blush, but it does not really address the central policy issues, and as the compounding profession has well argued, equipment use is ultimately a poor proxy for measuring manufacturing activity.¹²⁵ Concerning the Court's second proposal, the CPG also suggests that compounding should not occur when an animal's health or life is not at risk;¹²⁶ this generalization is perhaps useful to some extent, but generally a drug would not be administered if the animal's health were not impacted in some way. Moreover, vaccination, vitamins, and preventive medications would be eliminated through this proposal as would possibly other types of

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² *Id.*

¹²³ *Id.*; see also *Wedgewood Village Pharmacy, Inc. v. U.S.*, 421 F.3d 263, 274 (3d Cir. 2005) (noting in dicta that "were we to adopt [the] view that the volume of compounding is irrelevant, much of the FDCA would become a nullity").

¹²⁴ *Thompson*, 535 U.S. at 372.

¹²⁵ Letter from L.D. King, Exec. Director, International Academy of Compounding Pharmacists, to Dockets Management Branch (HFA-305), U.S. Food and Drug Administration, at 13-14 (Sept. 16, 2003) (on file with the International Academy of Compounding Pharmacists, the author, and the FDA [re: Docket No. 2003D-0290; Guidance on Compounding of Drugs for Use in Animals]). Moreover, even producing a large batch of a drug does not necessarily imply "manufacturing" because compounding a large batch can actually be a mechanism to increase quality assurance; generally, the smaller the batch and the more often it has to be separately produced, the more opportunity there is for error.

¹²⁶ See *Veterinary CPG*, *supra* note 2, at 4.

medication that are currently beneficial.¹²⁷ The CPG also suggests that compounding from a human drug should not occur for food-producing animals if an approved animal drug is available and if “illegal residues” would occur from ingestion.¹²⁸ In order to defend manufacturers’ place in the market and to protect human life, both of these proposals (or more specific permutations thereof) seem plausible.

By far the most controversial of the CPG’s factors, however, is the categorical banning of drugs compounded from bulk drug substances (i.e., compounded from raw ingredients and not based on an FDA-approved drug). The compounding profession has repeatedly argued that this ban is too expansive to adequately balance the policies stated above.¹²⁹ Also, not even the FDA’s guidelines for human compounding are so unconditionally against bulk substance compounding, and under FDAMA bulk substance compounding for humans is legal under certain relatively broad circumstances.¹³⁰ The American Veterinary Medical Association

¹²⁷ See generally Jeanie Davis, *Compounding for Creatures: What Works*, 3:3 Int’l J. Pharmaceutical Compounding 182-185 (May/June 1999) (describing a lively assortment of compounding solutions for animals, including the following: peanut butter flavoring for dog medications; placing a tablet in a live mouse for a boa constrictor’s consumption; and extracting “beads from itraconazole capsules” to be dissolved in orange juice and then placed on bread for administration to a bird. Another fascinating compound has been anti-inflammatory gel for horses that have a cut; the gel helps smooth any scar tissue. This smoothing effect is likely more needed to protect an owner’s investment in the horse rather than because of actual medical necessity. Many of these creative solutions would not fit the requirement of a strict necessity that the animal’s life or health be endangered for compounding, yet they clearly meet needs unmet by manufactured products.).

¹²⁸ See Veterinary CPG, *supra* note 2, at 5; but see 21 C.F.R. § 530.13(b)(2) (West 2011) (allowing pharmacists to compound from a human drug for food-producing animals in certain circumstances).

¹²⁹ See, e.g., Letter from L.D. King, Exec. Dir., Int’l Acad. of Compounding Pharmacists to Dockets Management Branch (HFA-305), U.S. Food & Drug Admin., at 5 (June 15, 2004); Letter from Bruce W. Little, DVM, Exec. Vice President, Am. Veterinary Med. Ass’n to Dockets Management Branch (HFA-305), U.S. Food & Drug Admin., at 1 (June 30, 2004), available at <http://www.avma.org/issues/drugs/compounding/CPGdocket.pdf>. Note that the CPG does not technically eliminate bulk substance compounding categorically but includes it as a factor in determining whether to enforce the FDCA’s provisions against a pharmacy or pharmacist. However, the FDA’s position in *Franck’s Lab* appears to be that bulk substance compounding is per se illegal. See *United States v. Franck’s Lab, Inc.*, 816 F. Supp. 2d 1209, 1237 (M.D. Fla. 2011).

¹³⁰ See Center for Drug Evaluation and Research, Food and Drug Administration, Guidance for

acknowledges that “compounding...from unapproved (bulk) substances for use in non-food-producing animals is medically necessary in certain situations” and suggests that rules similar to the ones for extra-label use of FDA-approved drugs be followed.¹³¹ Essentially, illegalizing bulk substance compounds would eliminate most compounding and is therefore a poor proposal.

The Court’s third suggestion, requiring a prescription before compounding, is a possible regulation. The requirement would contradict many states’ laws¹³² and render compounding less efficient, but it would probably not eliminate all market incentives to compound. It is at least a rational attempt to distinguish manufacturing, which envisions a large population of end users, from compounding, which is practiced with a single patient in mind. Limiting the ability to sell at wholesale for resale also begins to draw something of a valid distinction between compounding and mass manufacturing since a legal compound should be customized for a specific patient.

However, the most interesting and perhaps rewarding distinction might be based on drug volume, prescriptions, revenue, and/or sales as suggested by the Court’s fifth and sixth proposals. Some pharmacies would argue that this economics-based distinction is arbitrary. However, it attempts to deal with the policy perspective that compounded drugs would ideally meet the same testing

FDA Staff and Industry: Compliance Policy Guides Manual § 460.200, Pharmacy Compounding at 4 (2002) (casting suspicion on bulk substance compounding only when the ingredients are “not components of FDA approved drugs” and the finished drug has not undergone the new drug approval process); 21 U.S.C. § 353(a) (West 2011).

¹³¹ See *AVMA Policy: Compounding from Unapproved (Bulk Substances)*, American Veterinary Medical Association, available at http://www.avma.org/issues/drugs/compounding/compounding_bulk.asp (last visited Jan. 11, 2012); see also 21 C.F.R. § 530.1-41 (West 2011).

¹³² See, e.g., Ga. Comp. R. & Regs. 480-11-.02(1)(a) (2010) (stating that “based on the existence of a pharmacist/patient/prescriber relationship and...in anticipation of a prescription drug order based on routine, regularly observed prescribing patterns, pharmacists may compound, for an individual patient, drug preparations that are commercially or not commercially available in the marketplace”); 20-4 Vt. Code R. § 20-4-1400:9.22(c) (2011) (stating that “a limited quantity [of prescription drugs] may be compounded in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns”); Ark. Code R. § 070.00.7-07-02-0002(i)(2) (2011) (permitting compounding in anticipation of a prescription as in Vermont, see *supra*, but requiring that “products prepared in anticipation...should not be an inordinate amount”).

standards as those met by manufactured drugs except that compounders cannot afford to meet them (and generally cannot invest the required time).¹³³ Thus, if a compounder is producing a large enough number of compounds or is taking in a large enough revenue from compounding, he begins to approach the economic capacity of a manufacturer and should be subject to the same testing requirements. Theoretically, if a cap is set at an appropriate number, most compounders will be excluded and will not contest the regulation; only large-scale compounders (whose businesses are most suspect for the FDA) will qualify. It is true that under this regime the FDA will “relinquish” the authority to regulate small-scale compounding, but it will be able to concentrate its enforcement against large-scale compounders. Moreover, if large-scale compounders are limited in their ability to compound certain drugs (or certain amounts thereof), their excess business will theoretically fall to small-scale compounders, who are currently far below the threshold cap and thus more likely to remain outside the scope of “manufacturing.” The FDA would need to collect data for establishing the ideal cap(s) for such a regulation, but it has potential as the best solution for all parties. As the Court suggested, the cap(s) may be in the form of limiting (1) the number of different states to which a pharmacy may ship compounds, (2) the number of prescriptions, (3) the amount of compounded drugs or sales, or (4) even revenue.¹³⁴ Based on the economics-based arguments above, limiting revenue and interstate commerce may be the best options.

Because this regulation is the most comprehensive, in order for the FDA to feel most comfortable with enforcing it (particularly since its detractors will be large-scale compounders with relatively deep pockets), the FDA may first seek specific statutory language permitting such a policy-driven rule. However, even in the current statutory framework, it is likely a valid rule and would provide the ideal regulatory environment.¹³⁵ Also, enforcement should be relatively simple, since much can be documented through

¹³³ See *supra* pp. 153-54.

¹³⁴ See *supra* notes 123-24 and accompanying text.

¹³⁵ See *supra* notes 95-109 and accompanying text.

paperwork.¹³⁶

SOME FINAL REBUTTALS TO FDA HESITATION OVER THE ABOVE PROPOSALS

One rebuttal to the above content for proposed rules is that some compounding activity will be outside of the FDA's jurisdiction and there will therefore be deficiencies in safety and effectiveness that the FDA will no longer be able to address. An FDA Commissioner has even stated that if the FDA did not regulate compounding, there would likely be an increase of illegal manufacturing "under the guise of pharmacy compounding."¹³⁷

However, at least in the context of veterinary compounding, a lack of FDA oversight is not critical. First, the states can still regulate veterinary compounding that does not fall under the FDCA. The state boards of pharmacy may still revoke licenses and take other disciplinary action based on a pharmacist's improper or illegal practices,¹³⁸ and animal owners may still bring malpractice tort actions against pharmacists and veterinarians.¹³⁹ Moreover, animals are generally classified legally as personal property in most states, and therefore injury to an animal (unless exempted) can prompt

¹³⁶ Theoretically, documentation could be required for capped categories, and pharmacies could be required to submit reports to the FDA. There is always the possibility that a noncompliant pharmacy will falsify the reports, but there is at least a quantifiable number that can be reported and checked, and falsification can likely subject a pharmacy to fines and penalties.

¹³⁷ Michael F. Conlan, *Compounding Protection Bill Could Lead to Patient Deaths, Kessler Charges*, 140 Drug Topics 22 (May 20, 1996).

¹³⁸ See, e.g., TEX. OCC. CODE §§ 565.001-.003, 565.051 (West 2012); WASH. REV. CODE ANN. §§ 18.130.180, 18.130.190, 18.64.160, 18.64.163 (West 2005 & Supp. 2011). But see Fairfax, *supra* note 93, at 9 (noting that some critics do not believe that the state boards of pharmacy can effectively regulate compounding pharmacists and prevent "unsafe activities," (quoting John H. Perrin, *Unsafe Activities of Compounding Pharmacists*, 52 Am. J. Health-System Pharmacy 2827, 2827 (1995))).

¹³⁹ See *Phillips v. Baus*, DBDCV054003065S, 2007 WL 1976219, at *4 (Conn. Super. Ct. May 24, 2007) (dictum) (stating that although there was little guidance on the subject, plaintiff's claim for veterinary medical malpractice would likely be allowed with damages limited to the value of the animal itself).

trespass to chattel, conversion, or negligence actions.¹⁴⁰ Lastly, if the concern is that compounders are illegally copying manufactured drugs, a patent infringement suit can be brought.¹⁴¹ Thus, there are ample legal remedies for a variety of illegal compounding activities without the FDA exercising jurisdiction over all compounding. Rather, the FDA simply needs to remove some of the current regulatory haze. The FDA may even begin by concentrating on the regulation of drugs for non-food-producing animals, which can still be a considerable market.¹⁴²

CONCLUSION

Therefore, in light of the great benefits to both the FDA and the compounding profession, the FDA should consider replacing its current approach of using CPGs to “regulate” veterinary compounding with a series of rules promulgated through notice-and-comment rulemaking. The FDA will receive greater deference from

¹⁴⁰ See, e.g., *Kennedy v. Byas*, 867 So. 2d 1195, 1197 (Fla. 1st Dist. Ct. App. (2004), *rev. vol. dismiss.*, 879 So. 2d 622 (Fla. 2004) (holding that “while a dog may be considered . . . a member of the family, under Florida law animals are considered to be personal property”) (quoting *Bennett v. Bennett*, 655 So. 2d 109, 110 (Fla. Dist. Ct. App. 1st 1995))). *Contra Corso v. Crawford Dog & Cat Hosp., Inc.*, 415 N.Y.S.2d 182, 183 (N.Y. Civ. Ct. 1979) (stating that “a pet is not just a thing but occupies a special place somewhere in between a person and a piece of personal property”).

¹⁴¹ See, e.g., Edie Lau, *Drug Maker Sues Compounding Pharmacy*, The Veterinary Info. Network, News Serv. Inc., Dec. 17, 2009, available at <http://news.vin.com/VINNews.aspx?articleId=14563>.

¹⁴² See, e.g., *Compounding for Animals: Issue Briefing at 10*, Int'l Acad. of Compounding Pharmacists (on file with the IACP and Hous. J. Health L. & Pol'y) (stating that compounding for non-food-producing animals is a “significant part of most compounding pharmacy practices”); *Defs. Franck's Lab, Inc. & Paul W. Franck's Mot. Dismiss at 5*, *United States v. Franck's Lab, Inc.*, 816 F. Supp. 2d 1209 (2011) (No. 5:10-CV-147-OC-32TBS) (M.D. Fla. 2011), 2010 WL 3571631 (describing Franck's Lab, Inc., which is one of the nation's leading compounding pharmacies and compounds veterinary medications only for non-food-producing animals). See also, *Mem. of Law in Support of Pl's Mot. for Prelim. Inj. at 4*, *United States v. Franck's Lab, Inc.*, 816 F. Supp. 2d 1109 (2011) (No. 5:10-CV-147-OC-32TBS) (M.D. Fla. 2011), 2010 WL 3571632 (describing Franck's Lab as having annual sales of \$8 million, \$3.5 million of which related to 37,600 veterinary prescriptions filled between February 1 and December 4, 2009); *United States v. Franck's Lab, Inc.*, 816 F. Supp. 2d 1209, 1212 (M.D. Fla. 2011) (stating that 40% of Franck's Lab, Inc.'s business consists of veterinary drug compounding).

courts for these types of rules and will be able to revise current policy defects; moreover, the process should not require additional resources or procedures. Meanwhile, pharmacists will be able to participate in the rules' formation and secure a more certain regulatory environment in which to serve their patients. The FDA should be able to assert sufficient statutory bases for the rules and has a long history of regulating the profession that can help show what the rules should regulate and how. Although the FDA will not be able to assert its "maximalist" position through rulemaking, it will be able to focus its resources and expertise where it is most required and where the states are not able to regulate. Hopefully, as the FDA and pharmacy profession establish rules for veterinary compounding, they will also come to more agreement concerning human compounding and, overall, clarify a confusing and controversial area of law.