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Abstract

Pharmacy compounding of drugs for companion animals and humans is as old as time. For hundreds of years, pharmacists created these drugs using active pharmaceutical ingredients, otherwise known as bulk drug substances, to address the medical needs of these patients. Congress recognized this longstanding practice when it enacted the Food, Drug, and Cosmetic Act ("FDCA"), with lawmakers then noting that while pharmacists, physicians, and veterinarians were already highly regulated by the states, mass-producing drug manufacturers were not regulated. The FDCA would regulate such manufacturers.

Thereafter, pharmacy compounding from bulk drug substances continued for decades after the FDCA's enactment and without any attempted interference by the Food and Drug Administration ("FDA"). But, approximately fifty years after Congress enacted the FDCA, the FDA began to change its tune. The FDA's policy guides first proclaimed such compounding to

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be illegal under the FDCA in relation to human drugs. Congress pushed back and, in 1997, created the Food and Drug Administration Modernization Act ("FDAMA"), which expressly permits pharmacy compounding from bulk drug substances for human use. Despite this congressional statement, the FDA persisted in its position that using bulk drug substances to compound drugs for companion animals is illegal per se. Its latest 2022 policy guide adheres to this position, stating that the FDA, "in its discretion," will permit such compounding only in limited, delineated circumstances. But in that same year, the Supreme Court officially recognized the "major questions doctrine," which attempts to rein in overzealous agency assertions of power beyond that which Congress likely granted. In West Virginia v. EPA*, the Court announced that, when faced with dramatic claims of agency authority that have political or economic significance, are novel or unprecedented, or impact traditionally state-regulated areas, the Court will look for a "clear statement" from Congress that it delegated such authority to the agency.*

This Note analyzes the legality of the FDA's 2022 policy guide for pharmacy compounding from bulk drug substances for companion, nonfood animals. For several reasons, the "major questions doctrine" should apply to curtail the FDA's claimed authority. The FDA's position ignores centuries of history, several FDCA textual provisions, the FDA's own inconsistent policy positions, and traditional state regulation over pharmacy and medical practices. And, at bottom, the FDA's policy jeopardizes companion animals' medical needs and runs counter to the FDCA's mission. If the FDA's 2022 policy guide is allowed to stand, it will have a substantial and unnecessary negative impact on the health and wellbeing of nonfood companion animals—who, for many of us, are beloved members of our families.

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INTRODUCTION

My cat, Patch, suffered from hyperthyroidism. Before his treatment, he lost half of his body weight, his hair fell out in chunks, he became lethargic, and his eyesight deteriorated. Three years ago, my veterinarian prescribed the only FDA-approved medication for feline hyperthyroidism,

Felimazole, a coated oral tablet made from the active pharmaceutical ingredient methimazole.[1] But, despite attempts to force Patch to swallow the tablets or hide them in his food, he refused to take them, and Felimazole's directions for use specifically warned against crushing the tablets.[2] I returned to the veterinarian with Patch a year later and could see the concern on the doctor's face. But she did have some good news. A local pharmacy had started compounding the same active pharmaceutical ingredient, methimazole, into a transdermal cream that I could simply rub inside Patch's ear twice a day. Patch improved swiftly and dramatically. Within months, he gained four pounds, returned to his normal, silky self, and stopped missing the sofa when he jumped toward it. Six months into Patch's treatment, my veterinarian confessed that, upon seeing Patch months prior, she had not believed that he would live much longer.

Methimazole, like many drugs used in pharmacy compounding, is an active pharmaceutical ingredient[3] ("API"), otherwise known as a bulk drug substance.[4] The Food and Drug Administration ("FDA") acknowledges that FDA-approved drugs do not exist for many medical conditions that afflict nonfood animals,[5] such as pets, and that "no medicine will work if you can't get it into the patient,"[6] as I experienced with Patch.

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1. *See Hyperthyroidism in Cats—There's an FDA-Approved Drug to Treat It*, U.S. FOOD & DRUG ADMIN. (Dec. 3, 2019), https://perma.cc/6NRL-NLGM (noting the creation of Felimazole from methimazole when, previously, veterinarians had to rely on human medications, even though they had "not been proven to be safe and effective in cats").

2. *See* DECHRA VETERINARY PRODS., HYPERTHYROIDISM CAN TAKE AWAY THEIR HEALTH. HELP RESTORE IT 10 (2020), https://perma.cc/SA3R-MDXC (PDF) (describing the "Do's" and "Don'ts" of caring for a cat on Felimazole).

3. *See* 21 C.F.R. § 207.1 (2024) (defining an active pharmaceutical ingredient as "any substance that is intended for incorporation into a finished drug product . . . to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease").

4. *See id.* (stating "bulk drug substance" means the same thing as API).

5. *See Medicines for Your Pet: What's the Difference Between FDA-Approved & Pharmacy-Compounded Drugs?*, U.S. FOOD & DRUG ADMIN. (Apr. 13, 2022), https://perma.cc/8H6G-3S45 (noting that while, "an FDA-approved drug is the gold standard," such drugs do not always exist or work for many animals, such as "stubborn cat[s]").

6. *Id.*; *see id.* ("If you've ever had to give your cat a dose of medicine, you know that it can go sideways quickly.").

Thus, pharmacy compounding of drugs for nonfood animals forms a necessary part of veterinary medicine and, often, those compounded medications are best prepared using bulk drug substances.[7]

Nonetheless, in August 2022, the FDA issued a policy guide[8] declaring that compounding drugs for nonfood animals using bulk drug substances is illegal under the Food, Drug, and Cosmetic Act ("FDCA").[9] This is true, says the FDA, even though compounding drugs for humans using bulk drug substances is legal under the Act.[10] The question thus becomes: does the FDA have statutory authority to assert this prohibition, specifically for nonfood animals?[11] Federal courts have reached conflicting decisions.[12] But, in 2022, the United States Supreme Court

7. *See* Corrected Amicus Curiae Brief of Former FDA Officials in Support of Franck's Lab, Inc. for Affirmance at 20, United States v. Franck's Lab, Inc., No. 11-15350 (11th Cir. Oct. 18, 2012) [hereinafter Amicus Curiae Brief of Former FDA Officials] ("The need to use bulk substances in animal drug compounding is particularly acute . . . due to the relative lack of animal drug products manufactured and on the market and the abundance of animal species. In many cases, compounding is a necessity for the treatment of ailing animals.").

8. *See* U.S. FOOD & DRUG ADMIN., COMPOUNDING ANIMAL DRUGS FROM BULK DRUG SUBSTANCES 1–2 (Aug. 10, 2022) [hereinafter 2022 GFI], https://perma.cc/D8EC-VVKB (PDF) (detailing the FDA's policy #256 and noting that, in specific circumstances, the FDA may exercise its "discretion" and not take enforcement action).

9. Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–1013); *see* 2022 GFI, *supra* note 8, at 4 ("The law permits compounding of an animal drug when the source(s) of the active ingredient(s) for compounding is a finished FDA-approved drug(s) and *not a bulk drug substance*." (emphasis added)).

10. *See infra* Part III.B.1.

11. *See Animal Compounding and GFI #256*, ALL. FOR PHARMACY COMPOUNDING, https://perma.cc/Z8U4-9Z59 (last visited Mar. 10, 2024) ("FDA bases its authority for GFI #256 on a misreading of language in a section on extra-label use of compounded drugs . . . . On that mistaken authority, FDA would needlessly interfere with veterinarians' ability to provide the best care for their animal patients.").

12. *Compare* Med. Ctr. Pharmacy v. Mukasey, 536 F.3d 383, 406–08 (5th Cir. 2008) (straining to find an FDCA provision addressing compounding for nonfood animals and relying on an "extralabel" drug use statute that nowhere mentions "compounding"), *with* United States v. Franck's Lab, Inc., 816 F. Supp. 2d 1209, 1240 n.76, 1250 (M.D. Fla. 2011) (finding the Fifth Circuit's analysis "unpersuasive" and rejecting the FDA's claim of authority), *vacated as moot on voluntary dismissal of appeal*, No. 11-15350 (11th Cir. Oct. 18, 2012).

signaled, in *West Virginia v. EPA*,[13] that it will look closely at an agency's claim of authority[14] that appears "economical[ly] and political[ly] significan[t];" "novel" or "unprecedented;" or impacts "areas traditionally regulated by the states."[15] In such cases, separation of powers is at issue, and the Court looks for more than a "merely plausible" basis for the agency's claimed authority.[16] Deemed the "major questions doctrine,"[17] the Court analyzes the statutory scheme, the Act's history and purpose, and the agency's past interpretations, in search of a clear statement from Congress that it granted to the agency the power that the agency claims.[18]

This Note investigates whether the major questions doctrine and the Supreme Court's guiding principles in *West Virginia* open an avenue for challenging the FDA's claim of authority to ban, or limit, the use of bulk drug substances in compounding for nonfood animals. Part I provides an overview of the Supreme Court's major questions doctrine. Part II explains the history and significance of pharmacy compounding, as well as its traditional and continued state regulation, both of which provide triggers for the doctrine. Part III analyzes the evolution of relevant FDCA statutes and the agency's contradictory past policies to show that neither congressional statutes, nor administrative history, support the FDA's current position. Part IV argues that application of the major questions doctrine, as well as extant policy concerns, should prompt the FDA to change its stance. Finally, absent FDA capitulation, this

13. 142 S. Ct. 2587 (2022).

14. *See id.* at 2609 ("Agencies have only those powers given to them by Congress . . . .").

15. *See id.* at 2608, 2615 (citations omitted) (explaining these indicia); *id.* at 2621 (Gorsuch, J., concurring) (citation omitted) (highlighting areas of traditional state control).

16. *Id.* at 2609; *see id.* ("We presume that 'Congress intends to make major policy decisions itself, not leave those decisions to agencies.'" (citation omitted)).

17. *Id.* at 2605; *see also* Justine E. Lenehan & T. Daniel Logan, *West Virginia v. Environmental Protection Agency*, FOOD & DRUG L. INST. (June 22, 2023), https://perma.cc/8T2H-NH2T (noting that while the Court has previously applied the major questions doctrine, it did not refer to it by that name until *West Virginia v. EPA*).

18. *See West Virginia*, 142 S. Ct. at 2607–09; *id.* at 2609 (noting the "recurring problem" of agencies pushing the limits of their congressionally delegated authority).

Note recommends that Congress either amend the FDCA or enact a new statute that permits pharmacies to use bulk drug substances in compounding drugs for nonfood animals, just as pharmacies may do when compounding drugs for humans. Otherwise, the FDA's current policy will have a substantial and unnecessary negative impact on the health and wellbeing of nonfood animals, such as my pet cat, Patch.

I. OVERVIEW OF THE MAJOR QUESTIONS DOCTRINE

The major questions doctrine casts doubt on the FDA's assertion of authority over bulk drug compounding for nonfood animals given the FDCA's text, the FDA's past policy positions, and its current policy's impact on animal medical treatment. In *West Virginia*, the Court relied on prior cases and reaffirmed that, under the right circumstances, it will closely analyze "whether Congress in fact meant to confer the power the agency has asserted,"[19] by reviewing the statute in "context and with a view to [its] place in the overall statutory scheme."[20] Indicia that may trigger the doctrine include: (1) the "economic and political significance" of the agency's assertion of authority, (2) the "novel[ty]" of such assertion of authority,[21] and (3) the impact of such assertion of authority on "areas traditionally regulated by the states."[22] Thus, the Court cited *FDA v. Brown & Williamson Tobacco Corp.*,[23] where it rejected the FDA's "expansive construction" of the terms "'drugs' and 'devices,'" because such a construction would have allowed the FDA "to regulate, and even ban, tobacco products," when the FDCA's context, other congressional statutes, and "common sense" showed that was not Congress's intent.[24] Congress does not delegate "such a

19. *Id.* at 2608.

20. *Id.* at 2607 (citation omitted).

21. *Id.* at 2608, 2615 (citation omitted).

22. *Id.* at 2621 (Gorsuch, J., concurring) (citation omitted); *see also id.* (noting that "this list of triggers" for applying the major questions doctrine "may not be exclusive").

23. 529 U.S. 120 (2000).

24. West Virginia v. EPA, 142 S. Ct. 2587, 2608–09 (2022) (citing *Brown & Williamson*, 529 U.S. at 126–27, 133, 160); *see also id.* at 2612 (rejecting the EPA's "generation shifting" because, although it technically fit the definition of a "system," the claimed authority "effected a 'fundamental revision of the

sweeping and consequential authority 'in so cryptic a fashion.'"[25] The Court also noted *Gonzales v. Oregon*,[26] where the Attorney General claimed that the Controlled Substances Act[27] ("CSA") gave him the authority to rescind a practitioner's license for prescribing drugs for assisted suicide, despite a state law allowing this practice.[28] It found "such broad and unusual authority through an implicit delegation . . . not sustainable."[29] Instead, "the structure and limitations of federalism . . . allow the States 'great latitude under their police powers'" to regulate the medical practices, regulation which "the [CSA] presume[s] and rel[ies] upon."[30] Finally, the Court relied on *National Federation of Independent Business v. OSHA*,[31] a case in which the agency sought to require Americans to either get a COVID-19 shot or undergo weekly testing at their own expense.[32] The Court found that OSHA's requirement lacked historical precedent because, "in its half century of existence,"

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statute, changing it from [one sort of] scheme of . . . regulation' into an entirely different kind" (citation omitted)).

25. *Id.* at 2608 (citing *Brown & Williamson*, 529 U.S. at 160); *see id.* at 2610 (stating that an agency may not simply "discover," within "a long-extant statute," that it has the power to fundamentally change a regulatory scheme (citation omitted)).

26. 546 U.S. 243 (2006).

27. Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801–904 (commonly known as the Controlled Substances Act).

28. *See West Virginia*, 142 S. Ct. at 2608 (citing *Gonzales*, 546 U.S. at 267).

29. *Id.* (citing *Gonzales*, 546 U.S. at 267); *see id.* at 2618 (Gorsuch, J., concurring) (complaining that, absent court intervention, "little would remain to stop agencies from moving into areas where state authority has traditionally predominated").

30. *Gonzales*, 546 U.S. at 270 (citation omitted); *see West Virginia*, 142 S. Ct. at 2622 (Gorsuch, J., concurring) (finding the EPA's rule "unquestionably ha[d] an impact on federalism, as 'the regulation of utilities is one of the most important of the functions traditionally associated with the police power of the States'" (citation omitted)); *see also* Ala. Ass'n of Realtors v. Dep't of Health and Hum. Servs., 141 S. Ct. 2485, 2488–90 (2021) (rejecting the CDC's eviction moratorium because Congress must "enact exceedingly clear language if it wishes to significantly alter the balance between federal and state power" (citation omitted)).

31. 142 S. Ct. 661 (2022).

32. *See West Virginia*, 142 S. Ct. at 2608 (citing *Nat'l Fed'n of Indep. Bus.*, 142 S. Ct. at 665–66).

OSHA had never before asserted such "remarkable" authority.[33] It also noted that the Agency's rule "significant[ly] encroach[ed] into the lives—and health—of a vast number of employees."[34]

In all of these cases, the Court rejected claims of agency authority, despite "a colorable textual basis," because statutory "context" and "common sense" did not support congressional delegation of such authority.[35] This version of the major questions doctrine operates as a clear statement rule, disavowing any deference that might have been given to an agency's interpretation of a statute under *Chevron U.S.A., Inc. v. National Resources Defense Council, Inc.*[36] Instead, in major question cases, "[t]he agency . . . must point to 'clear congressional authorization' for the power that it claims."[37]

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33. *Id.* at 2608–09 (citing *Nat'l Fed'n of Indep. Bus.*, 142 S. Ct. at 666); *see also* FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 159 (2000) (noting that the FDA's claim of authority was "[c]ontrary to its representations to Congress since 1914").

34. *Nat'l Fed'n of Indep. Bus.*, 142 S. Ct. at 665; *see Ala. Ass'n of Realtors*, 141 S. Ct. at 2489 (noting that the agency's action would have severely "burden[ed] . . . landlords").

35. West Virginia v. EPA, 142 S. Ct. 2587, 2607, 2609 (2022) (citation omitted).

36. 467 U.S. 837 (1984). Under *Chevron*, a court first determines whether Congress's statute spoke "directly . . . to the precise question at issue." *Id.* at 842. If so, then Congress's intent is clear, and the analysis stops there. *Id.* at 842–43. If the court finds Congress's statute silent or ambiguous—i.e., Congress has "not directly addressed the precise question at issue"—then the court defers to the agency's interpretation if it is "permissible" or "reasonable," but rejects that interpretation if it is "arbitrary, capricious, or manifestly contrary to the statute." *Id.* at 842–44; s*ee* Daniel T. Deacon & Leah M. Litman, *The New Major Questions Doctrine*, 109 VA. L. REV. 1009, 1011–13 (2023) (recounting the evolution away from *Chevron* deference and toward this "new" "clear statement" rule, which changes the major question inquiry from one among many interpretative tools to the dispositive interpretative tool); *see also* Petition for Writ of Certiorari at i–ii, Loper Bright Enter., Inc. v. Raimondo, Sec'y. of Com., No. 22-451 (Nov. 10, 2022) (asking the Court to overrule *Chevron* or, at the least, "clarify that statutory silence concerning controversial powers expressly but narrowly granted elsewhere in the statute does not constitute an ambiguity requiring deference to the agency"); Petition for Writ of Certiorari at i–ii, Relentless, Inc. v. Dep't of Com., No. 22-1219 (June 14, 2023) (presenting the same issue as in *Loper*).

37. *West Virginia*, 142 S. Ct. at 2609 (citation omitted); *id.* (relying on an "identifiable body of law" addressing a "recurring problem: agencies asserting highly consequential power beyond what Congress could reasonably be understood to have granted"); *id.* at 2617–18 (Gorsuch, J., concurring) (stating the clear statement rule protects constitutional guarantees by ensuring that

II. HISTORY AND SIGNIFICANCE OF COMPOUNDING USING BULK DRUG SUBSTANCES

The history and significance of bulk drug pharmacy compounding, as well as its traditional and continued state regulation, both support application of the major questions doctrine to the FDA's claim of authority to ban, or limit, that practice for nonfood animals. This Part describes pharmacy compounding, its longstanding history, and its traditional state regulation.[38] It also compares the FDCA's legislative history and the continuation of pharmacy compounding from bulk drugs, for decades, following the FDCA's enactment.[39] Finally, this Part underscores the necessity for bulk drug compounding for nonfood animals, as it plays a critical role in animal patient care.[40]

A. *The Longstanding Pharmacy Practice of Compounding Bulk Drug Substances*

For thousands of years, pharmacists have compounded medications using bulk drug substances.[41] The word "bulk" is a misnomer; it has nothing to do with size, quantity, or volume, but with the raw pharmaceutical ingredient that a pharmacist uses to create a finished drug product.[42] This finished drug

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Congress, which represents the people, is not divested of power by an executive agency subject to the whims of changing leaders).

38. *See id.* at 2621 (Gorsuch, J., concurring) (stating that when an agency intrudes on "areas traditionally regulated by the States," federalism requires a clear congressional statement (citation omitted)).

39. *See id.* at 2608–09 ("We found it 'telling that [the agency], in its half century of existence,' had never relied on [this] authority . . . ." (quoting *Nat'l Fed'n of Indep. Bus.*, 142 S. Ct. at 666)).

40. *See id.* at 2608–09 (stating that the Court has rejected the FDA's claim of authority "to regulate, and even ban," certain products because the FDCA's text and common sense "made it very unlikely that Congress" had granted the Agency that authority (citing *Brown & Williamson*, 529 U.S. at 126–27, 133, 160)).

41. *See* CHARLES H. LAWALL, CURIOUS LORE OF DRUGS AND MEDICINES (FOUR THOUSAND YEARS OF PHARMACY) 3–4, 12 (1927) (dating back to 1552 B.C., the Eber Papyrus, found tucked between the knees of a mummy in the Theban Necropolis, provided "an unofficial formulary or private recipe book" for making medicines).

42. *See* United States v. Franck's Lab, Inc., 816 F. Supp. 2d 1209, 1212 n.2, 1250 (M.D. Fla. 2011) (citing now-amended 21 C.F.R. § 207.3, which

product[43] results from compounding, which is the "process by which a pharmacist . . . combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient."[44] In the United States, pharmacists have compounded drugs for centuries—long before the FDCA's enactment in 1938.[45]

"The pharmacist-prescriber-patient relationship forms the basis of what is commonly known as 'traditional pharmacy compounding.'"[46] Unlike drug manufacturing, traditional pharmacy compounding envisions this triad relationship whereby "a compounding pharmacist work[s] collaboratively with a veterinarian to provide a medication tailored to an animal patient's specific and individualized needs."[47] Since 1820, the *United States Pharmacopeia* ("USP")—a compendium that includes instructions for compounding and monograph standards[48] for both bulk drug substances and finished drug

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defined "bulk drug substance" as "any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form"), *vacated as moot on voluntary dismissal of appeal*, No. 11-15350 (11th Cir. Oct. 18, 2012); *Animal Drug Compounding*, U.S. FOOD & DRUG ADMIN. (Sept. 12, 2022), https://perma.cc/7DS3-LXGX (defining "bulk drug substance" as "a substance used to make a drug that becomes an active ingredient in the finished dosage form of the drug").

43. "Finished drug product" means "a finished dosage form . . . that contains at least one [API], generally, but not necessarily, in association with other ingredients in finished package form suitable for" dispensing "to patients or consumers." 21 C.F.R. § 207.1.

44. Thompson v. W. States Med. Ctr., 535 U.S. 357, 360–61 (2002).

45. *See* Norman Gevitz, *"Pray Let the Medicines Be Good": The New England Apothecary in the Seventeenth and Early Eighteenth Centuries*, 41 PHARMACY IN HISTORY 87, 90–91 (1999) (noting that compounding in the United States can be traced as far back as the seventeenth century).

46. *Franck's Lab*, 816 F. Supp. 2d at 1216 (citations omitted).

47. *Id.* By contrast, drug manufacturers mass produce drugs of the same formulation and dosage for interstate marketing and resale, and they do not have a relationship with the patients. *See* Amicus Curiae Brief of Former FDA Officials, *supra* note 7, at 13–14 (citing Human and Veterinary Drugs: Current Good Manufacturing Practice in Manufacture, Processing, Packing, or Holding, 43 Fed. Reg. 45014 (Sept. 29, 1978)).

48. A USP monograph details the identity, strength, purity, and performance requirements for a drug and the tests used to validate that it meets these quality criteria. *See An Overview of USP Monographs*, USP (Sept. 2019), https://perma.cc/R66E-2956 (noting that USP monographs are continuously updated).

products—has guided pharmacists in their compounding practice.[49] The Pure Food and Drugs Act of 1906[50] followed the USP's monographs for drug purity, quality, and strength[51] and, in 1938, the FDCA incorporated the USP and similar standards of the National Formulary ("NF").[52]

Prior to the 1938 FDCA, pharmacy compounding was widespread and widely accepted.[53] With few pharmaceutical drug companies mass manufacturing drugs, pharmacy compounding served as the primary source for obtaining medications, even for a decade after the FDCA's enactment.[54] The practice of pharmacy was then, is now, and traditionally has been, state-regulated as part of the healing arts.[55] At the time of the FDCA's enactment, every state's pharmacy laws permitted drug compounding, including using bulk drug ingredients.[56] The same was true for the District of Columbia which, at that time,

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49. *See* LAWALL, *supra* note 41, at 485 (noting that "the [USP] is the peer of all the pharmacopoeias of the world" (citation omitted)).

50. Pub. L. No. 59-384, 24 Stat. 768 (1906).

51. *See id.* at 769 (defining "drug" to include all USP medicines and preparations).

52. *See* Pub. L. No. 75-717, 52 Stat. 1040, 1050 (1938) (codified as amended at 21 U.S.C. § 321(j)) (naming the USP and NF as "official compendium[s]" of the FDCA). The NF, like the USP, is "a book of [drug] recipes." LAWALL, *supra* note 41, at 515; *see id.* (noting the NF's "coequal" authority with the USP).

53. *See* Med. Ctr. Pharmacy v. Mukasey, 536 F.3d 383, 398 n.31 (5th Cir. 2008) (noting that, "By one estimate, pharmacists annually compounded more than 250 million prescriptions around the time of the FDCA's enactment").

54. *See* W. Thomas Smith et al., *There Is No Such Thing as a Compounding Manufacturer! (Or Is There?)*, 27 HEALTH LAW. 1, 1 (2015) (stating that, through the 1940s, most prescriptions were pharmacy compounded, with "mass drug manufacturing" arriving in the 1950s); Paul W. Shaw et al., *The NECC Fungal Meningitis Outbreak Revives the Controversy over the Regulation of Drug Compounding*, 7 J. HEALTH & LIFE SCI. L. 42, 46 (2013) (noting that compounds accounted for "80 percent of prescriptions" through the 1940s).

55. *See* Thompson v. W. States Med. Ctr., 535 U.S. 357, 361 (2002) (finding that, even after the FDCA, the FDA left regulation of pharmacy, including compounding, to the states).

56. *See* Amicus Curiae Brief of Former FDA Officials, *supra* note 7, at 6–7 (citing *Joint Session of the Am. Pharm. Ass'n, the Am. Ass'n of Colls. of Pharmacy, and the Nat'l Ass'n of Bds. of Pharmacy*, 17 J. AM. PHARM. ASS'N 1000, 1010–13 (1938)); *Med. Ctr. Pharmacy*, 536 F.3d at 398 n.31 (noting that, at the time of the FDCA, state pharmacy laws "defined the practice of pharmacy to include compounding").

was under the direct regulation of the United States Congress.[57] Thus, pharmacy compounding of bulk drug substances has long been a "traditional component of the practice of pharmacy,"[58] a standard part of pharmacy school curricula, and regulated by the states.[59] This longstanding history and traditional state regulation provide triggers for the major questions doctrine.[60]

B. *The FDCA's Legislative History and the Continuation of Bulk Drug Compounding*

The Act's legislative history and the post-Act continuation of compounding also support application of the major questions doctrine.[61] In the years leading up to the 1938 FDCA, Congressional members and interested stakeholders noted that the Act would focus on drug manufacturers, contrasting them with licensed pharmacists and their longstanding state regulation.[62] Thus, in 1935, a Senate Subcommittee reviewed S. 5, a "bill to prevent the manufacture, shipment, and sale of adulterated or misbranded" drugs.[63] During discussions, the Council on Pharmacy and Chemistry proposed several measures, including that parties "engaged in interstate commerce in drugs" be required to register with and obtain a license from the government, and that, for drugs not listed in

57. *See* D.C. CODE ANN. § 191 (1929) (mandating that only licensed pharmacists could "compound, dispense, or sell, at retail, any drug . . . or pharmaceutical preparation," provided, however, a veterinarian could "compound[] his own prescriptions" or "supply[] to his patients such medicines as he may deem proper").

58. *See W. States*, 535 U.S. at 361 (citing J. THOMPSON, A PRACTICAL GUIDE TO CONTEMPORARY PHARMACY PRACTICE 11.3 (1998)).

59. *See id.* (citing AM. COUNCIL ON PHARM. EDUC., ACCREDITATION STANDARDS AND GUIDELINES FOR THE PROFESSIONAL PROGRAM IN PHARMACY LEADING TO THE DOCTOR OF PHARMACY DEGREE, Standard 10(a) (1997)). *See generally* PEW CHARITABLE TRS. & NAT'L ASS'N BD. PHARMACY, STATE OVERSIGHT OF DRUG COMPOUNDING (2018), https://perma.cc/LZ3U-NXN6 (PDF) (graphing each state's regulations for the practice of pharmacy compounding).

60. *See supra* Part I.

61. *See supra* Part I.

62. *See infra* notes 63–72 and accompanying text.

63. *Food, Drugs, and Cosmetics: Hearings Before a Subcommittee of the Committee on Commerce of the United States Senate on S. 5*, 74th Cong. 1, 1 (1935).

the USP or NF compendiums, their drug labels list the active ingredients used in their drug products.[64]

The American Pharmaceutical Association ("APhA"), a professional association of pharmacists, and the American Association of Colleges of Pharmacy ("AACP"), both favored the passage of the FDCA, citing insufficient regulation of manufactured proprietary and patented medications.[65] The APhA drew material contrasts between the professional medical practices, which were already heavily state regulated, and drug manufacturers and retailers, who were not, and it found the differences "incongruous."[66] Supporting a drug labeling requirement, it noted that manufacturers sell "patent medicines," "the composition of which [they keep] secret and the action of which [the lay person] does not fully understand."[67] Supporting a licensure requirement, it explained that regulations governing licensed pharmacists "are very strict, but the privileges of unlicensed persons operating outside of pharmacies are so extensive that the public enjoys little protection."[68] APhA, therefore, advocated for drug manufacturers being "compelled to obtain licenses to operate" conditioned on "competency of personnel, equipment, and sanitary surroundings, and standardization of finished products."[69] These remarks were echoed during a session of the Seventy-Fifth Congress, just months prior to the FDCA's passage.[70] John M. Coffee stressed, "[I]n the interest of safety, society has required that physicians be licensed to practice the healing art. Pharmacists are licensed to compound and dispense drugs. . . . But there is no such control to prevent incompetent drug manufacturers from marketing any kind of lethal

64. *See id.* at 167 (suggesting a prohibition for drugs not fitting compendium standards).

65. *See id.* at 64, 102 (showing support of the AACP and APhA, respectively).

66. *Id.* at 102–03 (statement of Robert P. Fischelis, President, APhA); *accord* at 62–63 (statement of C.B. Jordan, Chairman, AACP).

67. *Id.* at 102 (statement of Robert P. Fischelis, President, APhA).

68. *Id.* (noting that, "[l]egally, anybody can manufacture medicines, regardless of ability, skill, training, equipment, or knowledge").

69. *Id.* (citing a need "for better public control of the medicine industry," to promote "the public welfare as well as the public's pocket book").

70. *See* 83 CONG. REC. app. 1199, 2279 (1938) (statement of John M. Coffee, Rep., Cong.).

poison."[71] These repeated contrasts between licensed and trained pharmacists and unregulated drug manufacturers underscore that the FDCA aimed to regulate drug manufacturers, not to impact the medical practices, which were already heavily regulated.[72]

After the passage of the FDCA, the federal and state governments continued to approve of pharmacy compounding, including with bulk drug substances. For example, the Department of Defense stated in its policy guide that military pharmacies "may bulk compound pharmaceutical preparations using formulas from official compendiums, other references, or a locally developed formula."[73] Similarly, the United States Navy's medical department manual provided for pharmacy compounded drugs in accordance with USP standards.[74] The federal government also provided Medicare and Medicaid insurance coverage for a pharmacy compounded drug that used multiple different ingredients.[75] And, as mentioned, Congress made the District of Columbia laws before the FDCA's enactment, and it continued to do so through the 1970s.[76] Over the course of those years, it issued six editions of the D.C. Code and, in each one, it left intact the ability of licensed pharmacists to "compound, dispense, or sell, at retail, any drug[] . . . or pharmaceutical preparation" as well as the ability of licensed

71. *Id.* (quoting Henry A. Wallace, Sec'y, Dep't of Agric.); *see id.* at 2281 (arguing, also, for "[a] licensing system for proprietary preparations" to protect against "manufacturers of harmful preparations").

72. *See* United States v. Baxter Healthcare Corp., 901 F.2d 1401, 1409 (7th Cir. 1990) ("Congress . . . decided to treat commercial manufacturers of drugs differently from pharmacies and individual physicians . . . ."); *id.* ("Therefore, to the extent Congress has addressed the issue, it has decided to focus governmental resources upon the commercial distributers of drugs rather than upon . . . trained pharmacists and physicians . . . .").

73. Memorandum from Stephen C. Joseph, Assistant Sec'y of Def., to the Assistant Sec'ys of the Army, Navy, and Air Force 5 (July 26, 1995), https://perma.cc/6WAF-5ZZS (PDF).

74. *See* U.S. NAVY, MANUAL OF THE MEDICAL DEPARTMENT art. 21-4 (2018), https://perma.cc/SHW9-5B3Q (PDF) (permitting Navy pharmacists to compound drugs).

75. *See* U.S. DEP'T HEALTH & HUM. SERVS., UPDATED INSTRUCTIONS: REQUIREMENTS FOR SUBMITTING PRESCRIPTION DRUG EVENT DATA 13 (2006), https://perma.cc/SAR2-V7ZJ (PDF) (providing that coverage will be at the cost of "the most expensive drug" component).

76. *See supra* note 57 and accompanying text.

veterinarians to "compound[] . . . prescriptions" and "supply[] to . . . patients such medicines" as they "deem[ed] proper."[77] Finally, "the practice of compounding from bulk [drug] ingredients is expressly recognized by many states and is a 'widespread practice performed by the majority of licensed compounding pharmacy professionals throughout the country, and has been for decades.'"[78]

C. *The Need for Bulk Drug Compounding for Nonfood Animals*

Each year, approximately seventy-five thousand pharmacies fill more than six million compounded drug prescriptions for nonfood animals.[79] As several FDA officials have recognized, "The need to use bulk substances in animal drug compounding is particularly acute (more acute than for human compounding)."[80] Several circumstances make compounding for nonfood animals unique. First, compounding typically is used when no FDA-approved drug exists for the illness, or when the patient cannot use the mass manufactured approved drug for reasons such as allergies or requiring a

77. D.C. CODE ANN. § 2-601 (West 1940); *accord* D.C. CODE ANN. § 2-601 (West 1951); D.C. CODE ANN. § 2-601 (West 1961); D.C. CODE ANN. § 2-601 (West 1967); D.C. CODE ANN. § 2-601 (West 1973).

78. United States v. Franck's Lab, Inc., 816 F. Supp. 2d 1209, 1219 (M.D. Fla. 2011) (citing experts), *vacated as moot on voluntary dismissal of appeal*, No. 11-15350 (11th Cir. Oct. 18, 2012); *see also* Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350–51 (2001) (stating the FDA does not have legal authority to regulate the medical practices and may not limit the way practitioners prescribe drugs); Planned Parenthood of Cin. Region v. Strickland, 531 F.3d 406, 408 (6th Cir. 2008) (finding the FDA does not regulate the practice of medicine, "which is the exclusive realm of individual states"); United States v. Evers, 643 F.2d 1043, 1048 (5th Cir. 1981) (noting the repeated congressional statements when the FDCA was created that the Act did not intend to interfere with or regulate the medical practices).

79. *See* Compounding Animal Drugs from Bulk Drug Substances: Draft Guidance for Industry, 80 Fed. Reg. 28,624, 28,627 (May 19, 2015) (calculating prescription figure after subtracting treatment for food animals); *see also* Compounding Animal Drugs from Bulk Drug Substances: Guidance for Industry, 87 Fed. Reg. 22,212, 22,214 (Apr. 14, 2022) (calculating more than eleven million prescriptions, per year, but not differentiating between nonfood and food producing animals).

80. Amicus Curiae Brief of Former FDA Officials, *supra* note 7, at 20.

different dosage level or delivery method.[81] The FDA acknowledges, and federal courts have found, that limited FDA-approved drugs exist for nonfood animals, thus making compounded drug treatments a necessity.[82] Similarly, even when approved products do exist, they often are "inadequate due to the animal patient's size, species, and/or intolerance to active ingredients."[83] Thus, bulk drug compounding for these nonfood animals is not only "desirable," but "critical" to their wellbeing.[84] While "[t]he spectrum of therapeutic need in veterinary medicine is large," "the availability of approved drug products for all veterinary species is relatively small."[85]

Finally, veterinarians and pet owners cite economic reasons for relying on bulk drug substance compounding.[86] Owners do not usually have medical insurance for their pets, thus requiring them to pay for pet medications "out of pocket."[87] Because FDA-approved drugs (if available) often are more costly than compounded preparations, owners can face the unenviable, sometimes insurmountable, choice of placing their pocketbooks over their pets' health.[88] The impact on consumers' pocketbooks served as one consideration when Congress created the FDCA,[89]

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81. *See* Thompson v. W. States Med. Ctr., 535 U.S. 357, 369 (2002) (highlighting the governmental interest in the continuation of pharmacy compounding, for these reasons).

82. *See* Amicus Curiae Brief of Former FDA Officials, *supra* note 7, at 20 (noting "the relative lack of animal drug products manufactured and on the market"); *Franck's Lab*, 816 F. Supp. 2d at 1217 (stating that "limited commercially available products exist"); *Medicines for Your Pet*, *supra* note 5 (recognizing a lack of approved drugs for many conditions).

83. *Franck's Lab*, 816 F. Supp. 2d at 1217.

84. *W. States*, 535 U.S. at 369; *see* Amicus Curiae Brief of Former FDA Officials, *supra* note 7, at 20 (stating that compounding for animals is a "necessity").

85. Gigi Davidson, *Veterinary Compounding: Regulation, Challenges, and Resources*, 9 PHARMACEUTICS 1, 1 (2017).

86. *See id.* at 3 (citing chronic or systemic conditions as costly regimes for which compounded therapies are much cheaper).

87. *Id.*

88. *See id.* (noting that owners may be unable "to pay for expensive approved therapies").

89. *See* David. F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 LAW & CONTEMP. PROBS. 2, 3 (1939) (noting that the FDCA was to be a measure "of consequence to the health and pocketbook of every citizen").

and economic significance serves as one triggering factor under the major questions doctrine.[90]

III. STATUTORY LANDSCAPE AND FDA POLICIES

In applying the major questions doctrine to a challenged agency policy or rule, the Court reviews the relevant statutory provision, the "overall statutory scheme," the "age and focus of the statute," "the agency's past interpretations," and the fit between the agency's "action" and its "mission."[91] This Part explicates the pertinent FDCA statutes, their amendments over time, and the overall focus of the FDCA's scheme. It also investigates the FDA's earlier, contradictory policies, Congress's and stakeholders' reactions to them, and the FDA's irrational 2022 policy, which unnecessarily limits bulk drug compounding for nonfood animals when such compounding is not prohibited for humans. All of these factors bear relevance to whether Congress granted the FDA the authority that it now claims.

A. *A Text that Carves Out the Medical Practices*

"[W]e begin, as we must, with a careful examination of the statutory text."[92] Nowhere in the FDCA's original text did the Act mention the terms "pharmacy" or "compounding," or any derivation of those terms.[93] However, the Act broadly defined the term "new drug"[94] and imposed a "new drug" application requirement,[95] without which the introduction of a new drug into interstate commerce constituted an FDCA violation,[96] if not

90. *See supra* note 19–21 and accompanying text.

91. West Virginia v. EPA, 142 S. Ct. 2587, 2622–24 (2022) (Gorsuch, J., concurring) (citations omitted); *see id.* at 2607–09 (reviewing cases that establish the types of analysis and evidence the Court reviews in major questions cases).

92. Henson v. Santander Consumer USA Inc., 137 S. Ct. 1718, 1721 (2017).

93. *See generally* Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–1013).

94. *See id.* at 1041–42 (codified as amended at 21 U.S.C. § 331(p)).

95. *See id.* at 1052–53 (codified as amended at 21 U.S.C. § 355).

96. *See id.* at 1042 (codified as amended at 21 U.S.C. § 331(d)); *id.* at 1052 (codified as amended at 21 U.S.C. § 355(a)).

a crime.[97] A "new drug" is any drug "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling."[98] The "new drug" application process is quite extensive, time consuming, and costly.[99] And, for fifty years after the 1938 Act, the FDA never claimed that the "new drug" application process applied to pharmacy compounds created to meet the needs of individual patients.[100] Instead, it left regulation of compounding to the states, which allowed pharmacists "to provide patients with compounded drugs without applying for FDA approval of those drugs."[101]

This regulatory framework continued even after revised FDCA provisions first mentioned "pharmacy" and "compounding." In the Drug Amendments of 1962,[102] Congress strengthened the FDCA in several ways, but, at the same time, prevented interference with state regulation of the medical practices.[103] First, it amended the "new drug" definition and "new drug" application process to require that, in addition to being "safe," "new drugs" also be "effective" for their intended

97. *See id.* at 1043–44 (codified as amended at 21 U.S.C. §§ 332–334) (granting the power to seek civil penalties, product seizure, injunctions, criminal fines, and imprisonment). *But see id.* at 1045 (codified as amended at 21 U.S.C. § 336) (stating the Secretary may refrain from prosecution when "he believes that the public interest will be adequately served by a suitable written notice or warning").

98. *Id.* at 1041–42 (codified as amended at 21 U.S.C. § 321(p)(1)).

99. *See* Med. Ctr. Pharmacy v. Mukasey, 536 F.3d 383, 388–89 (5th Cir. 2008) (noting that, for human drugs, "the 'test is rigorous,' requiring expensive and time-consuming clinical trials estimated by some to cost more than $800 million per drug" (citation omitted)).

100. *See* Thompson v. W. States Med. Ctr., 535 U.S. 357, 362 (2002).

101. *W. States*, 535 U.S. at 362; *see* United States v. Franck's Lab, Inc., 816 F. Supp. 2d 1209, 1219 (M.D. Fla. 2011) (noting the continued, "widespread practice" of bulk drug compounding for animal patients), *vacated as moot on voluntary dismissal of appeal*, No. 11-15350 (11th Cir. Oct. 18, 2012).

102. Pub. L. No. 87-781, 76 Stat. 780 (codified as amended at 21 U.S.C. §§ 360(g)(1), 374(a)(2)(A)).

103. *See id.* at 793 ("Nothing in the amendments made by this Act . . . shall be construed as invalidating any provision of State law . . . unless there is a direct and positive conflict between such amendments and such provision of State law.").

uses.[104] Next, it required drug producers to register with the FDA and enhanced the FDA factory inspection of such registrants.[105] Both provisions applied broadly to anyone who "engag[es] in the manufacture, preparation, propagation, compounding, or processing" of drugs.[106] But, in recognition of state regulation of the medical practices, Congress expressly provided that the registration and enhanced inspection provisions do not apply to pharmacists who (1) practice in accordance with local pharmacy laws, (2) regularly dispense drugs pursuant to prescriptions, and (3) "do not . . . manufacture, prepare, propagate, compound, or process drugs for sale other than in the regular course of their business of dispensing or selling drugs . . . at retail."[107]

Congress showed similar respect to the state-regulated medical practices just eight years later when it enacted the CSA in 1970.[108] The CSA defines the term "manufacture" to exclude "preparation, compounding, packaging, or labeling of a drug . . . in conformity with applicable State or local law by a practitioner" incidental to administering or dispensing the drug "in the course of his professional practice."[109] Correspondingly, Congress defined "practitioner" to include state-licensed pharmacies.[110] Thus, Congress, in these post-1938 enactments, continuously clarified that state-law compliant pharmacy compounders are not subject to these rigorous federal provisions designed to regulate drug manufacturers.

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104. *Id.* at 781 (amending 21 U.S.C. § 321(p)(1) and § 355).

105. *See id.* at 793 ("[I]n order to make regulation of interstate commerce in drugs effective, it is necessary to provide for registration and inspection.").

106. *Id.* at 794; *see also id.* at 792 (allowing general inspection of "all pertinent equipment, finished and unfinished materials; containers, and labeling therein" under § 374(a) in sentence one); *id.* (providing enhanced inspection of "all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs" are adulterated, misbranded, or otherwise violate the Act under § 374(a) in sentence three).

107. *Id.* at 793 (codified as amended at 21 U.S.C. §§ 360(g)(1), 374(a)(2)(A)); *see also id.* (providing the same for state-licensed medical practitioners) (codified as amended at 21 U.S.C. §§ 360(g)(2), 374(a)(2)(B)).

108. Pub. L. No. 91-513, 84 Stat. 1236 (1970) (codified as amended at 21 U.S.C. §§ 801–904).

109. 21 U.S.C. § 802(15).

110. *See id.* § 802(21) (including, also, veterinarians, physicians, and dentists).

B. *FDA Policies and Congress's Responses*

Despite its respect for state pharmacy regulation for fifty years, the FDA embarked on a sea-change in focus around 1989. In a memorandum written by David G. Adams, Associate General Counsel for the FDA, the Agency considered the practical and jurisdictional obstacles it would face if it adopted the novel approach of treating pharmacy compounds as "new drugs" subject to the FDCA "new drug" application process.[111] By that time, a "new animal drug" definition and a "new animal drug" application process substantially similar to the definition and process for human drugs had been created.[112] As with new human drugs, new animal drugs had to undergo a rigorous and costly application process, including, for animals, years of testing across large populations, even generations.[113] Counsel Adams' 1989 memorandum equally implicated both human and animal compounded drugs.[114] It flagged that treating them as "new drugs" would be a "departure" from the Agency's "traditional approach," which was to regulate "the materials and machinery that are *used in* compounding by the pharmacists, rather than the final dosage forms that *result from* compounding."[115]

Counsel Adams admitted that, based on the FDCA's legislative history, the 1962 Drug Amendments, and past Agency statements, "one could reasonably argue that Congress did not intend this degree of regulation over the practice of

111. *See* Memorandum from David G. Adams, Assoc. Gen. Couns., Food and Drug Admin., on Regulating PET Products as New Drugs: Legal Issues 1 (Aug. 2, 1989) [hereinafter 1989 Memorandum], https://perma.cc/82PF-KWXF (PDF) (expressing "general reservations" about this approach).

112. *See* Med. Ctr. Pharmacy v. Mukasey, 536 F.3d 383, 407 (5th Cir. 2008) (noting the "substantially identical" new animal drug provisions). *Compare* 21 U.S.C. §§ 321(p)(1), 355(b) (defining new human drug and the application process), *with* 21 U.S.C. §§ 321(v)(1), 360b(b) (defining new animal drug and the application process).

113. *See* United States v. Franck's Lab, Inc., 816 F. Supp. 2d 1209, 1243, 1252 n.92 (M.D. Fla. 2011) (describing the process and stating, then, that it takes "$15-20 million and five years"), *vacated as moot on voluntary dismissal of appeal*, No. 11-15350 (11th Cir. Oct. 18, 2012).

114. *See* 1989 Memorandum, *supra* note 111, at 3 (discussing cases where the FDA brought enforcement actions against suppliers of unapproved or otherwise unlawful bulk drug substances to veterinarians).

115. *Id.* at 1.

pharmacy."[116] He candidly stated that the FDA would "have to establish new legal precedents":[117]

> [O]ur position will be that, in light of state regulation of the practices of pharmacy and medicine, the agency will continue to exercise its discretion not to regulate . . . compounding . . . under the new drug provisions of the act. *Although this leaves pharmacists in the objectionable position of "living in sin," . . . we cannot, as a responsible federal regulatory agency, concede a lack of jurisdiction*.[118]

1. The Progression to Permitted Bulk Drug Compounding for Humans

Perhaps to begin establishing its new precedents, the FDA created a compliance policy guide for pharmacy compounding of human drugs in 1992 (the "1992 CPG").[119] Akin to the 1989 Memorandum, the 1992 CPG asserted that all pharmacy compounded drugs are "new drugs" and illegal unless FDA approved.[120] It also adopted the Memorandum's "enforcement discretion" approach, i.e., the FDA would only take regulatory action against those pharmacies acting as drug manufacturers by producing large quantities of drugs "under the guise of

116. *Id.* at 4; *see id.* at 2 (citing legislative history, statutes, and agency inaction showing that the FDCA "was not intended as a medical practices act and would not interfere with the practice of the healing arts"); *id.* at 4 (noting the Agency's changed position would "give pause to any jurist," especially given the prevalence of compounding when Congress enacted "the relevant statutory provisions").

117. *Id.* at 2.

118. *Id.* at 4 (emphasis added); *see id.* at 4–6 (noting separate jurisdictional issue regarding the ability to regulate *intrastate* sales when the FDCA extends only to *interstate* sales).

119. *See* Manufacture, Distribution, and Promotion of Adulterated, Misbranded, or Unapproved New Drugs for Human Use by State-Licensed Pharmacies: Compliance Policy Guide, 57 Fed. Reg. 10,906 (March 16, 1992) (announcing CPG 7132.16 addressing "unapproved new drugs for human use by State-licensed pharmacies in a manner that is clearly outside the bounds of traditional pharmacy practice").

120. *Compare* Thompson v. W. States Med. Ctr., 535 U.S. 357, 362 (2002) (quoting the 1992 CPG), *with* 1989 Memorandum, *supra* note 111, at 4 ("[W]e must assert, if asked, that our jurisdiction extends to all such products . . . .").

compounding."[121] The CPG listed nine activities that raised concerns normally associated with manufacturing, some of which supported drawing a pharmacy compounder versus drug manufacturer line.[122] Notably, however, the 1992 CPG also prohibited pharmacy compounding of bulk drug substances to create drugs for human use.[123]

Uproar following this FDA CPG "led to the passage of legislation in 1997 that underscored the right of patients to have medications compounded."[124] Congress enacted § 127 of the Food and Drug Administration Modernization Act ("FDAMA"),[125] which prevents the FDA from regulating all pharmacy compounds as unapproved "new drugs" and overrides its prohibition against compounding using bulk drug substances.[126] The congressional record shows that, in passing FDAMA, Congress solidified state regulation of pharmacy compounding, while ensuring that federal law governs drug manufacturing.[127] It also ensured "the continuation of pharmacy compounding, without unnecessary FDA regulation," by

121. *Compare W. States*, 535 U.S. at 362, *with* 1989 Memorandum, *supra* note 111, at 4 (outlining use of "discretion" because "we cannot, as a responsible federal regulatory agency, concede a lack of jurisdiction").

122. *See W. States*, 535 U.S. at 363 (citing compounding large quantities of FDA-approved drugs, using commercial scale equipment, and selling compounded drugs at wholesale).

123. *See* Prof. & Patients for Customized Care v. Shalala, 56 F.3d 592, 593–94 (5th Cir. 1995) (citing the 1992 CPG, and noting that such nonbinding policy guides are permissible under the law).

124. Letter from Charles Bass et al., Congressman, Cong., to Dr. Lester M. Crawford, Acting Comm'r, Food and Drug Admin. 1 (June 29, 2005) [hereinafter 2005 Bass Letter], https://perma.cc/H3FX-YMU9 (PDF).

125. Pub. L. No. 105-115, 111 Stat. 2296, 2328 (1997) (codified as amended at 21 U.S.C. § 353a).

126. *See* FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997: REPORT OF THE COMMITTEE ON LABOR AND HUMAN RESOURCES OF THE U.S. SENATE ON S. 830, S. REP. NO. 105-43, at 167 (1997) (stating that FDAMA was "intended to clarify the law," because "[a]ll states include compounding as a core component of the profession of pharmacy").

127. 143 CONG. REC. S9839 (1997) (daily ed. Sept. 24, 1997) (providing that "State boards of pharmacy, which regulate pharmacy compounding," should determine when "activities are outside proper parameters" and "refer [that] pharmacist to the FDA for review" (statement of Sen. Hutchinson)).

providing that pharmacy compounds "are not subjected to the new drug provisions of the Act."[128]

Notably, FDAMA specifically permits compounding using bulk drug substances when creating drugs for humans.[129] A pharmacist may compound using any bulk drug substance that (1) complies with a USP or NF monograph, (2) is a "component" of an FDA-approved drug, *or* (3) "appear[s] on a list developed by the [FDA] through regulations."[130] While litigation caused questions about FDAMA's validity for several years,[131] Congress reaffirmed the statute in 2013.[132]

2. The Inconsistent Policies for Bulk Drug Compounding for Nonfood Animals

Regrettably, when Congress overrode the FDA's 1992 CPG for human drug compounding by enacting FDAMA, it did not create a similar statute for animal drug compounding.[133] In

128. *Id.*; *see id.* (closing only the "loophole for unregulated drug manufacturers").

129. *See* 21 U.S.C. § 353a(a) (requiring compounding based on prescriptions for individualized patients and in accordance with other requirements of the section).

130. *Id.* § 353a(b)(1)(A)); *see id.* (adding that the bulk drug substance must come from an FDA-registered manufacturer, contain a certificate of analysis, and not appear on any list of drugs withdrawn or removed from the market as being unsafe, ineffective, or difficult to compound).

131. A First Amendment challenge to FDAMA resulted in it being declared invalid, in its entirety, by the Ninth Circuit. *See* W. States Med. Ctr. v. Shalala, 238 F.3d 1090, 1094–96 (9th Cir. 2001) (finding the statute, as a whole, struck a balance between "compounding and manufacturing"). Thereafter, the FDA asserted that FDAMA was dead, although, in 2008, the Fifth Circuit severed the speech provisions and found the rest of FDAMA valid. *See* Med. Ctr. Pharmacy v. Mukasey, 536 F.3d 383, 400–05 (5th Cir. 2008) (finding the remaining provisions accomplished Congress's goals). This circuit split and legal uncertainty existed until 2013, when Congress reaffirmed FDAMA and created a second statute to allow compounding of human drugs for office use. *See* 21 U.S.C. § 353a (allowing pharmacy compounding by prescription); *id.* § 363b (allowing "outsourcing facilities" to compound for "office use"). While beyond the scope of this Note, "office use" compounds are nonpatient specific, prepared in advance, and later given to patients. *Id.*

132. *See* Pub. L. No. 113-54, 127 Stat. 587, 589 (2013) (amending 21 U.S.C. § 353a to delete provisions offending the First Amendment). In the interim years, the FDA's CPGs continued to guide the use of bulk drug substances in pharmacy compounding. *See infra* Part III.B.2.

133. *See* United States v. Franck's Lab, Inc., 816 F. Supp. 2d 1209, 1223–24 (M.D. Fla. 2011) (noting that FDAMA only applies to compounding

1994, Congress did pass the Animal Medicinal Drug Use Clarification Act ("AMDUCA"),[134] but that Act does not address compounding.[135] It only clarifies that "extralabel use"[136] of FDA-approved drugs is acceptable to treat animals, provided, *inter alia*, the different use is ordered by a veterinarian.[137] Nonetheless, in 1996, ostensibly in furtherance of administering AMDUCA, the FDA created 21 C.F.R. § 530.13.[138] Section 530.13 addresses compounding from FDA-approved drugs and adds that "[n]othing in this part shall be construed as permitting compounding from bulk drugs."[139] "Despite this language, [however,] the regulations do not purport to regulate the *practice* of compounding, and instead refer parties to FDA's non-binding guidance documents on the subject."[140]

The FDA has disclaimed reliance on AMDUCA or § 530.13 as authority for prohibiting bulk drug compounding for nonfood animals.[141] And, following AMDUCA, the FDA's subsequent

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drugs for humans), *vacated as moot on voluntary dismissal of appeal*, No. 11-15350 (11th Cir. Oct. 18, 2012).

134. Pub. L. No. 103-396, 108 Stat. 4153 (1994) (codified as ammended at 21 U.S.C. § 360b(a)(4)–(5)).

135. *See* 21 U.S.C. § 360b(a)(4)–(5).

136. "Extralabel" means "using a drug in a manner not indicated on the FDA-approved manufacturer's label; this can include the use of a drug for a condition, in a dosage, or in any animal species for which the drug has not received FDA approval." Takhar v. Kessler, 76 F.3d 995, 997 (9th Cir. 1996).

137. *See* 21 U.S.C. § 360b(a)(4) (providing that "extralabel" use of FDA-approved animal drugs does not require approval under the "new animal drug" provision); *id.* § 360b(a)(5) (providing the same for "extralabel" use of FDA-approved human drugs for animal treatment).

138. *See* 21 C.F.R. § 530.13 (titled, "Extralabel use from compounding of approved new animal and approved human drugs").

139. *Id.* § 530.13(a).

140. *Franck's Lab*, 816 F. Supp. 2d at 1221 (citing 21 C.F.R. 530.13(c)) (emphasis added).

141. *See, e.g.*, *Franck's Lab*, 816 F. Supp. 2d at 1234 ("[T]he FDA contends it needs no more than the plain language of the 1938 FDCA to enjoin Franck's bulk compounding . . . . The FDA expressly disclaims reliance upon any other legal source, including AMDUCA . . . ."); Defendant's Memorandum in Opposition to Plaintiffs' Motion for Summary Judgment at 15, Med. Ctr. Pharmacy v. Gonzales, 451 F. Supp. 2d 854 (W.D. Tex. 2006) (No. 04-cv-130) ("FDA does not . . . rely on [AMDUCA] . . . to prohibit compounding from bulk APIs."); *id.* at 17 n.12 (stating AMDUCA is not relevant to the use of bulk and § 530.13 "is not authority for a prohibition on compounding from bulk ingredients;" AMDUCA and its regulation are "silent on the subject of bulk APIs"). As discussed *infra* Part IV.B.1, however, at least one court has cited

guide (the "1996 CPG") did not prohibit such compounding for *nonfood* animals.[142] Instead, the 1996 CPG noted concern about pharmacies circumventing the "new animal drug" approval process by mass producing compounded products, and it articulated factors it would consider,[143] with special focus on drugs for *food* producing animals.[144] The 1996 CPG clearly stated, that while "[c]ompounding from bulk drugs for use in food animals" *would* trigger FDA enforcement action, doing the same for nonfood animals *would not* trigger such action.[145]

This 1996 CPG governed bulk drug compounding for nonfood animals until the early 2000s. At that time, the FDA issued two contradictory policies, one in 2002 for human drug compounding (the "2002 CPG")[146] and one in 2003 for animal drug compounding (the "2003 CPG").[147] Whereas the 2002 CPG allowed compounding from bulk drug substances for human drugs, the 2003 CPG "str[uck] a decidedly more hostile tone."[148] It conflicted with the human drug CPG,[149] drew no distinction between food and nonfood animals, and, for the very first time, stated that compounding for nonfood animals using bulk drug

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AMDUCA to prohibit compounding from bulk drug substances for nonfood animals.

142. *See* Compounding of Drugs for Use in Animals: Compliance Policy Guide, 61 Fed. Reg. 34,849 (July 3, 1996) (announcing CPG 608.400, which provided differing rules for food and nonfood animals).

143. *See id.* at 34,851 (listing, e.g., preparation of "large quantities," compounding drugs "essentially similar" to approved drugs, "offering compounded medicaments at wholesale").

144. *See id.* at 34,851–52 (placing "highest regulatory priority" on compounding for food producing animals). Compounding for food producing animals will not be addressed in this Note.

145. *Id.*; *see id.* (articulating expectation that bulk drug compounding for *nonfood* animals would adhere to USP standards and monographs).

146. *See* Pharmacy Compounding: Compliance Policy Guide, 67 Fed. Reg. 39,409, 39,409 (June 7, 2002) (announcing revised CPG 460.200 and stating that, after the Ninth Circuit's 2001 decision, all of FDAMA "is now invalid").

147. *See* Compounding of Drugs for Use in Animals: Compliance Policy Guide, 68 Fed. Reg. 41,591 (July 14, 2004) (announcing revised CPG 608.400).

148. United States v. Franck's Lab, Inc., 816 F. Supp. 2d 1209, 1228 (M.D. Fla. 2011), *vacated as moot on voluntary dismissal of appeal*, No. 11-15350 (11th Cir. Oct. 18, 2012).

149. *Compare id.* (noting the 2002 CPG allowed compounding from bulk for human drugs, but the 2003 CPG prohibited it for animal drugs), *with* Compounding of Drugs for Use in Animals, 68 Fed. Reg. at 41591 (stating that the FDA aimed for consistency between the two policies).

substances raised illegal manufacturing concerns.[150] The incongruity between the 2002 CPG and the 2003 CPG could not have been more obvious: Under the 2002 and 2003 CPGs, "a pharmacist who compound[ed] medication from bulk for ingestion by a horse [was] akin to a manufacturer and subject to an FDA enforcement action, while the same pharmacist compounding medication from bulk for ingestion by the human rider of that horse [was] not."[151]

Twenty-six senators and seventy-two congressmen pushed back, complaining to the FDA that its policy would force pharmacists "to operate under flawed policy, potentially jeopardizing their livelihood and reputation in order to meet patient's essential medication needs."[152] They reminded the FDA that a similarly hostile policy for human drug compounding had led to FDAMA[153] and expressed concern that the 2003 CPG would cause animals "needless suffering and harm, if not addressed."[154]

In response to these congressional concerns, the FDA promised to withdraw the 2003 policy and issue a new one, but, for many years, it failed to do so.[155] Not until 2015 did it finally act,[156] issuing a new draft policy (the "2015 draft GFI").[157] This

150. *See Franck's Lab*, 816 F. Supp. 2d at 1228 (highlighting that the 1996 CPG *had* properly distinguished between food and nonfood animals and allowed bulk drug compounding for nonfood animals).

151. *Franck's Lab*, 816 F. Supp. 2d at 1228.

152. 2005 Bass Letter, *supra* note 124, at 2; *see also* Letter from U.S. Senate to Dr. Lester M. Crawford, Acting Comm'r, Food and Drug Admin. 1 (June 24, 2005) [hereinafter 2005 Senate Letter], https://perma.cc/8LR6-KWD4 (PDF).

153. *See* 2005 Bass Letter, *supra* note 124, at 1 ("In the realm of human compounding, the CPG's presumption that pharmacy compounding was illegal led to passage of [the FDAMA] legislation in 1997.").

154. *Id.*; *see id.* at 1–2 (adding that, just one year prior, seventy members of Congress had written to the FDA expressing the same strong concern that the FDA's policy posed "a significant threat to vulnerable patient populations").

155. *See* 2005 Senate Letter, *supra* note 152, at 1 (reminding the FDA of its unfulfilled promise to Congress).

156. *See* Compounding Animal Drugs from Bulk Drug Substances: Draft Guidance for Industry, 80 Fed. Reg. 28,624, 28,625 (May 19, 2015) (withdrawing the 2003 CPG as "no longer consistent with FDA's current thinking on the issues").

157. *See* U.S. FOOD & DRUG ADMIN., COMPOUNDING ANIMAL DRUGS FROM BULK DRUG SUBSTANCES: DRAFT GUIDANCE FOR INDUSTRY (2015),

draft continued FDA's stance that compounding using bulk drug substances for nonfood animals creates illegal "new drugs," but declared that it would allow such compounding, in limited circumstances.[158] After receiving more than 150 comments, the FDA withdrew this draft and issued a new draft in 2019 (the "2019 draft GFI").[159] This draft, again, stated that compounding using bulk for nonfood animals is illegal, but said that the FDA would exercise enforcement discretion if no other "medically appropriate treatment option exist[ed]."[160] Again, the policy received complaints from interested stakeholders.[161]

The FDA's 2022 final policy (the "2022 GFI") maintains that nonfood animal drugs compounded from bulk drug substances are illegal "new drugs."[162] But, the FDA says, it will exercise

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https://perma.cc/H3HW-8XPD (PDF) (announcing GFI #230). Prior to this 2015 guide, the FDA changed its terminology from "compliance policy guide" ("CPG") to "guidance for industry" ("GFI"). *See id.* at 1–2 (noting terminology change).

158. *See id.* at 3–4 (requiring the pharmacist to first determine that he or she could not obtain the API from an FDA-approved drug); *cf.* 21 C.F.R. § 530.13 (allowing compounding for nonfood animals using an API extracted out of an FDA-approved finished drug).

159. *See* Compounding Animal Drugs from Bulk Drug Substances: Draft Guidance for Industry, 84 Fed. Reg. 64,085, 64,085 (Nov. 20, 2019) (noting the significant number of comments).

160. U.S. FOOD & DRUG ADMIN., COMPOUNDING ANIMAL DRUGS FROM BULK DRUG SUBSTANCES 3–4 (2019), https://perma.cc/Z5ZN-FHQA (PDF); *see id.* at 9–10 (describing ways to determine whether an FDA-approved drug, or an API extracted from an FDA-approved, can be used instead of bulk—pharmacists should only compound from bulk if they cannot use API extracted from an approved drug).

161. *See, e.g.*, Letter from Shawn Hodges, President, All. for Pharmacy Compounding, to Dockets Mgmt. Staff, Food & Drug Admin. (Oct. 14, 2020), https://perma.cc/6USX-ZG2R (PDF) (arguing the FDCA does not provide the FDA with authority over compounded drugs, its guidance interferes with the practice of veterinary medicine, and its position limits animal access to needed medications and increases the cost of animal medicine); Christy Corp-Minamiji, *FDA Tries Again to Address Veterinary Drug Compounding*, VIN NEWS SERV. (Jan. 23, 2020), https://perma.cc/L7R4-MYPE (arguing that "using bulk drugs isn't a 'sometimes affair,'" that it "ensures a safer, more consistent product;" and that starting with an approved drug causes dangerous unknowns, as their potency can vary by "plus or minus 15%," which matters when preparing a precise drug based on an animal's weight and size).

162. *See* 2022 GFI, *supra* note 8, at 2 (claiming that, unlike FDA-approved drugs, pharmacy compounds do not have the same assurance of safety, efficacy, and quality and are not routinely monitored for adverse events by the FDA).

enforcement discretion if the compounding is by a licensed pharmacist based on a prescription, the pharmacist complies with state law and USP or NF standards, and no FDA-approved drug can be used to extract the API source.[163] Even then, if the compound has the same active ingredient and can be used via the same route of administration as an approved drug, the veterinarian must document a "clinical difference" for prescribing the bulk drug compound.[164] Again, both Congress and interested stakeholders pushed back.[165] They expressed dismay that the FDA had ignored Congress's directive to "preserve treatment options available to veterinarians" and "recognize the need for compounded medications by pet owners, animal shelters, zoos and other stakeholders."[166] In response, the FDA temporarily delayed implementation of its 2022

163. *See id.* at 8–9 (prioritizing extraction of the ingredient from approved finished drugs over the use of the pure bulk drug substance). *But see* United States v. Franck's Lab, Inc., 816 F. Supp. 2d 1209, 1218 n.24 (M.D. Fla. 2011) (explaining that, as opposed to compounding from bulk, compounding from a finished drug product requires breaking the drug apart and isolating the API before compounding it, which is more likely to result in a drug that falls outside of required purity, potency, and quality standards), *vacated as moot on voluntary dismissal of appeal*, No. 11-15350 (11th Cir. Oct. 18, 2012).

164. *See* 2022 GFI, *supra* note 8, at 9–12 (defining "clinical difference" as excluding harmful ingredients or changing strength, dosage form, or flavoring, *but not* "drug preference" or "pricing differences").

165. *See* Letter from John Carter et al., Congressman, Cong., to Steven M. Solomon D.V.M., M.P.H., Ctr. for Veterinary Med., Food & Drug Admin. 1 (Oct. 4, 2022) [hereinafter 2022 Congress Letter], https://perma.cc/TQE5-C3Z7 (PDF) (requesting a briefing within sixty days on "how the agency will implement and enforce GFI #256 in a manner that will not disrupt veterinarian's practices and be detrimental to their patients' health"); Letter from Scott Brunner, All. for Pharmacy Compounding and Nat'l Cmty. Pharmacists Ass'n to William Flynn, D.V.M., Ctr. for Veterinary Med., Food & Drug Admin. (July 26, 2022), https://perma.cc/GE6K-ZS9T (PDF) (raising five pages of concerns); *Animal Compounding and GFI #256*, *supra* note 11 (challenging the FDA's jurisdiction to prohibit bulk drug compounding and noting its needless, negative impact on animal health); *accord* Luke Eilers, *Preparing for the Implementation of the FDA's Ground Shaking New Requirements for Compounded Pet Medications*, NW. COMPOUNDERS (May 24, 2022), https://perma.cc/M3FB-KQ3A (stating that using approved drugs is "less easy than it sounds and in many instances is entirely impossible" because "inactive ingredients" and "severe formulation issues . . . decrease the quality of the compounded product and are likely to have a negative effect on desired results").

166. 2022 Congress Letter, *supra* note 165, at 1.

policy,[167] but then it began "phasing in inspectional activity" in April 2023.[168]

IV. THE MAJOR QUESTIONS DOCTRINE'S APPLICATION TO THE FDA'S CLAIM OF AUTHORITY

Ongoing political debate, continued state regulation, contradictory and confusing FDA policies, tenuous connections to statutory provisions, and Congress's consistently negative reactions to the FDA's bulk drug use prohibitions,[169] all counsel in favor of applying the major questions doctrine to the 2022 GFI. As this Part shows, Congress has not granted the FDA clear authority to declare bulk drug substance compounding for nonfood animals illegal, and it is untenable to expect these compounding pharmacists to simply "live in sin" and subject to the FDA's whim. FDA's current policy also hinders nonfood, companion animal health and works counter to the FDCA's goals. Thus, this Part concludes by urging Congress either to amend the FDCA or to enact a new statutory provision to make clear to the FDA that pharmacy bulk drug compounding for nonfood animals is not only *not prohibited*, but it is *expressly permitted*.

A. *Significance, Novelty, and Impact on State-Regulated Medical Practices*

The lynchpin of the FDA's position that it may ban or limit use of bulk drug ingredients to compound for nonfood animals emanates from its novel stance that all pharmacy compounded drugs are unapproved "new drugs" and, therefore, illegal.[170] The

167. *See* Letter from Steven M. Solomon, D.V.M., M.P.H., Director, Ctr. for Veterinary Med., Food & Drug Admin., to Scott Brunner, C.E.O., All. for Pharmacy Compounding, Am. Coll. of Veterinary Pharmacists, Am. Pharmacists Ass'n, Nat'l Cmty. Pharmacists Ass'n, and Soc'y for Veterinary Hosp. Pharmacists (Sept. 9, 2022), https://perma.cc/3LEN-55AX (PDF) (stating the FDA will not "shift [its] resources toward routine inspectional activities until April 2023").

168. *Letter to Industry: Phase-In of Inspectional Activities Related to Compounding Animal Drugs from Bulk Drug Substances*, U.S. FOOD & DRUG ADMIN. (Mar. 10, 2023), https://perma.cc/5QJT-VDMU.

169. *See supra* Parts II–III.

170. *Compare* 1989 Memorandum, *supra* note 111 (stating that treating pharmacy compounded drugs as "new drugs" would be a "departure" from the

FDA cites the broad definition of a "new animal drug," and it states that pharmacy compounds satisfy that definition; thus, absent approval under the "new animal drug" application process, they are "unsafe," and, by extension, "adulterated," and "misbranded."[171]

This "new animal drug" application process, however, is quite extensive, time consuming, and costly. Even two decades ago, the process for obtaining a new animal drug application approval ran about "$15–20 million and 5 years" of time, and more recent figures approximate "6.5 years and $22.5 million."[172] As the Supreme Court has found, "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" completely, a result which is "undesirable."[173]

While the FDA has a valid interest in drawing a line between pharmacies that are "manufacturing . . . under the guise of compounding" and traditional pharmacy compounders operating pursuant to state law,[174] neither application of the "new animal drug" provisions,[175] nor prohibiting the use of bulk

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FDA's "traditional approach," which was to regulate "the materials and machinery . . . *used in* compounding," rather than the final dosage forms that *result from* compounding"), *with* West Virginia v. EPA, 142 S. Ct. 2587, 2609 (2022) (noting the EPA had never before "devised a cap by looking to a 'system," rather than "set[ting] emissions limits," as it historically had done).

171. 2022 GFI, *supra* note 8, at 2; *see id.* (echoing statements made regarding human drug compounding in its 1992 CPG (which Congress overruled with FDAMA), and professing that the Agency will exercise enforcement discretion in delineated circumstances).

172. *Franck's Lab*, 816 F. Supp. 2d at 1252 n.92; *Approval and Regulation and Animal Medicines*, ANIMAL HEALTH INST., https://perma.cc/7D9T-MM45.

173. Thompson v. W. States Med. Ctr., 535 U.S. 357, 369, 369–70 (2002).

174. *Id.* at 362; *see id.* at 362–63, 370 (permitting the FDA to draw a line between, on the one hand, pharmacies acting as manufacturers and trying to "avoid[] the FDCA's new drug requirements" and, on the other hand, traditional pharmacy compounders acting under governing state law for the practice of pharmacy); *see also* Gonzales v. Oregon, 546 U.S. 243, 246 (2006) ("Congress regulates medical practice insofar as it bars doctors from . . . engag[ing] in illicit drug dealing . . . . Beyond this, the Act manifests no intent to regulate . . . medicine, which is understandable given federalism's structure and limitations.").

175. *See* United States v. Franck's Lab, Inc., 816 F. Supp. 2d 1209, 1246 (M.D. Fla. 2011) ("[T]he new drug approval process is a poor method for

drug compounding for nonfood animals, promotes that goal.[176] If they did promote that goal, the FDA's line-drawing policy in its 1996 CPG would have prohibited the use of bulk drug substances to compound prescription drugs for nonfood animals; it did not.[177] Instead, it expressly permitted it.[178] And, just a year later, in 1997, Congress created FDAMA to permit compounding from bulk for human drugs.[179] FDAMA expressly provides that the "new drug" approval process does not apply to such compounds.[180]

In passing FDAMA, Congress noted that the "States currently have the authority to license pharmacists and regulate pharmacies, including the scope of pharmacy practice," and that "[a]ll States include compounding as a core component of the profession of pharmacy."[181] Such compounding has long included compounding from bulk drug substances.[182] Thus, the FDA's 2022 GFI impacts an area "where state authority has traditionally predominated"[183]—an established reason, under

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drawing a line between these two interests *precisely* because it fails to allow for the continuance of state-authorized, traditional compounding."), *vacated as moot on voluntary dismissal of appeal*, No. 11-15350 (11th Cir. Oct. 18, 2012); Amicus Curiae Brief of Former FDA Officials, *supra* note 7, at 16–17 (stating that compounding using bulk drug substances is "an imperfect proxy for ascertaining whether a pharmacist is engaged in compounding that falls within the bounds of traditional pharmacy practice").

176. *See W. States*, 535 U.S. at 363, 372 (suggesting indicia to distinguish manufacturers from compounders, *but not* including the use of bulk drug substances in compounding).

177. *See* Compounding of Drugs for Use in Animals: Compliance Policy Guide, 61 Fed. Reg. 34,849, 34,852 (July 3, 1996) (distinguishing between nonfood and food animals).

178. *See id.* (providing, however, that using bulk for *food* animals would trigger concern).

179. *See* 21 U.S.C. § 353a(b)(1)(A) (permitting use of "bulk drug substances").

180. *See* 143 CONG. REC. S9839 (1997) (daily ed. Sept. 24, 1997) (providing that the states continue to regulate compounding, but that they should refer to the FDA any pharmacy that crosses the line into manufacturing).

181. FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997: REPORT OF THE COMMITTEE ON LABOR AND HUMAN RESOURCES OF THE U.S. SENATE ON S. 830, S. REP. NO. 105-43, 167 (1997).

182. *See Franck's Lab*, 816 F. Supp. 2d at 1219 (citing numerous experts).

183. *See* West Virginia v. EPA, 142 S. Ct. 2587, 2619 (2022) (Gorsuch, J., concurring) (noting the "particularly ironic outcome," where states already have robust regulations, for which they are accountable to their constituents);

the major questions doctrine, to require a clear statement from Congress before sanctioning the FDA's current policy.[184]

The FDA's willingness to exercise "enforcement discretion" does not cure its reach for authority or the confounding nature of its position.[185] An agency cannot support an unsupported expansion of authority by voluntarily adopting a more limited approach.[186] And, not until 2003 did the FDA, inexplicably, reverse its stance and state that compounding drugs for nonfood animals from bulk drug substances is a factor that will "raise manufacturing concerns."[187] In other words, such compounds would violate the FDCA and subject the pharmacists to numerous penalties, including potential prison time—yet another reason to demand evidence that Congress clearly granted this authority to the Agency.[188]

Then FDA Chief Counsel, Daniel E. Troy, later admitted he "was embarrassed" by the 2003 policy, noting its stark contrast

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Gonzales, 546 U.S. at 272 ("[W]hen Congress wants to regulate medical practice in the given scheme, it does so by explicit language in the statute.").

184. *See West Virginia*, 142 S. Ct. at 2621 (Gorsuch, J., concurring) ("To preserve the 'proper balance between the States and the Federal government' . . . , courts must 'be certain of Congress's intent' before finding that it 'legislate[d] in areas traditionally regulated by the States.'" (citation omitted)); JANE PERKINS & ERICA TURRET, NAT'L HEALTH L. PROGRAM, DELEGATION OF RULEMAKING AUTHORITY IN LIGHT OF THE "MAJOR QUESTION DOCTRINE" 5 (2023), https://perma.cc/2BNK-WL9K (PDF) (highlighting the "close relationship between the major questions doctrine and the federalism canon," and stating that "[t]he interplay of these doctrines may be a particular concern for health care statutes because of the traditional role of the states in this area").

185. *See* 2022 GFI, *supra* note 8, at 5–12 (proclaiming that compounding from bulk for nonfood animals is illegal, but that the FDA will exercise discretion, in limited situations).

186. *See* Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 472 (2001) ("We have never suggested that an agency can cure an unlawful delegation of legislative power by adopting in its discretion a limiting construction of the statute."); *see also West Virginia*,142 S. Ct. at 2612 ("[T]his argument does not so much *limit* the breadth of the Government's claimed authority as *reveal* it.").

187. *See* United States v. Franck's Lab, Inc., 816 F. Supp. 2d 1209, 1228–30 (M.D. Fla. 2011) (recounting FDA's shift in position), *vacated as moot on voluntary dismissal of appeal*, No. 11-15350 (11th Cir. Oct. 18, 2012).

188. *See id.* at 1255 (noting that compounding even "*one*" nonfood animal compound from bulk ingredients subjects even a "Mom-and-Pop" state-licensed pharmacist to criminal penalties—an "invit[ation] to arbitrary enforcement").

with the 2002 policy for human drugs, which allowed compounding from bulk, and its irrationality under the 1938 FDCA.[189] Discussing the FDA's unreasonable, even "religious fervor," in litigation, he said:

> The FDA has taken the position . . . that it is unlawful per se to compound animal drugs from bulk ingredients. . . . [I]t is simply not credible for the Agency to maintain that, in 1938, Congress made every corner pharmacist into a criminal, which is the position [the FDA] has been taking in these compounding cases.[190]

Other FDA officials have concurred. Former FDA Chief Counsel Shelton Bradshaw and former FDA Deputy Commissioner Scott Gottlieb have stated, "[T]he FD&C Act was enacted to regulate drug manufacturing, which is categorically distinct from traditional pharmacy compounding. Additionally, none of the amendments to the FD&C Act reflect Congress's intent to criminalize traditional pharmacy compounding, including compounding animal drugs from bulk substances."[191] In sum, the FDA's 2022 GFI not only is "novel" and intrudes upon an area within "the particular domain of state law," [192] but it also proves to be a poor fit when considered within the FDCA's overall scheme and the FDA's goal to ferret out disguised manufacturers.

In addition to these considerations, the absurdity of the FDA's current policy should give any court pause.[193] The FDA offers no reason for distinguishing between bulk drug compounding for humans and bulk drug compounding for nonfood animals. It relies on lack of FDA approval, alleged

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189. *See* Shelton T. Bradshaw et al., *Former FDA Chief Counsels Roundtable at the 55th Annual Conference of the Food and Drug Law Institute*, 67 FOOD & DRUG L.J. 293, 298 (2012).

190. *Id.*; *see* Gonzales v. Oregon, 546 U.S. 243, 272 (2006) ("In the face of the CSA's silence on the practice of the medicine generally and its recognition of state regulation of the medical profession it is difficult to defend the Attorney General's declaration that the statute impliedly criminalizes physician-assisted suicide.").

191. Amicus Curiae Brief of Former FDA Officials, *supra* note 7, at 3–4.

192. *West Virginia*, 142 S. Ct. at 2620 (Gorsuch, J., concurring).

193. *See* West Virginia v. EPA, 142 S. Ct. 2587, 2610 (2022) (citing reliance on a "long-extant" statute for authority in an area that Congress "declined to enact itself" as a reason "'to hesitate before concluding that Congress' meant to confer" that authority (citations omitted)).

safety, efficacy, and quality issues, and that nonfood animal compounds are not monitored for adverse events by the FDA.[194] But, the same concerns hold true for pharmacy compounds permitted by Congress for humans. FDAMA permits bulk drug compounding for humans, and these compounds, similarly, lack FDA approval, subscribe to the same safety, efficacy, and quality issues, and are monitored by the states.[195] Congress, nonetheless, passed a statute approving them.[196]

As noted, members of Congress and stakeholders have consistently protested the irrationality and impracticality of the FDA's position, thus demonstrating that the FDA's policy remains the subject of significant political debate.[197] The Supreme Court has also stated that requiring FDA approval "would, as a practical matter, eliminate the practice of compounding, and thereby eliminate availability of compounded drugs for patients who have no alternative treatment."[198] The Court found that eliminating compounded drugs would "undesirabl[y]" impact "critical" patient care, contrary to the public interest and the FDA's mission.[199] Yet, the FDA's 2022 GFI rationale, at bottom, adheres to a new animal drug approval requirement.[200] Congress undoubtedly knew when it enacted

194. *See* 2022 GFI, *supra* note 8, at 3–4.

195. *See* 21 U.S.C. § 353a(b)(1)(A) (permitting human bulk drug compounding, within generous parameters); *id.* § 353a(b)(3)(b)(i) (envisioning that the states will investigate complaints about pharmacy compounds prepared for humans).

196. *See id.* § 353a.

197. See *supra* notes 152–154, 159, 161, 165–167 for citations showing that bulk drug compounding is a necessity for nonfood animal treatment and eliminating it would disrupt veterinary and pharmacy practices and cause many animal to needlessly suffer, even die. *See also West Virginia*, 142 S. Ct. at 2617 (Gorsuch, J., concurring) (noting the constitutional design that elected representatives make our laws to ensure that those laws reflect the people they represent).

198. Thompson v. W. States Med. Ctr., 535 U.S. 357, 369 (2002) (quoting the government's attorney); *see also West Virginia*, 142 S. Ct. at 2621–22 (Gorsuch, J., concurring) (rejecting claimed agency authority that would force an industry to stop operating, impact jobs and the economy, and intrude on an area traditionally falling within state police powers).

199. *W. States*, 535 U.S. at 369 (quoting the government's attorney and noting the tension between the FDA's position and the need to permit pharmacy compounding to continue).

200. *See* 2022 GFI, *supra* note 8, at 2 ("[D]rugs compounded from bulk drug substances violate the FD&C Act because they are not approved . . . .").

the FDCA—a time when pharmacy compounding was prolific[201]—that "it would not make sense" to require compounded drugs to undergo the new drug approval process.[202] Thus, for the FDA's position to be cognizable, one must believe that in the 1938 FDCA, and its amendments thereafter, Congress intended to illegalize pharmacy compounding for nonfood animals using bulk drug substances.[203] The FDCA's history, and its amendments, do not support that position.[204]

Finally, the FDA's policy on bulk drug compounding for nonfood animals not only suffers from inconsistency and arbitrariness, but also hinders pet health, increases their medication costs, and harmfully impacts the medical community.[205] In 2021, Americans spent $123.6 billion on their pets, more than one-fourth of which was for veterinarian care and drug products ($34.3 billion).[206] According to the 2021–2022 National Pet Owners Survey, 70 percent of all United States households owned a pet in 2021, which equates to 90.5 million

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201. *See supra* Parts II.A–B.

202. *W. States*, 535 U.S. at 369; *see* Med. Ctr. Pharmacy v. Mukasey, 536 F.3d 383, 398 (5th Cir. 2008) ("[I]t seems unlikely that Congress intended to force compounded drugs to undergo the new drug approval process, a requirement that would have made compounding nearly impossible and thus nonexistent."); United States v. Franck's Lab, Inc., 816 F. Supp. 2d 1209, 1244 (M.D. Fla. 2011) ("[D]espite the literal language of the statute, this Court cannot find that Congress has 'directly and plainly' said that traditional pharmacy compounding of animal drugs must meet the requirements of the FDCA's new drug approval provisions."), *vacated as moot on voluntary dismissal of appeal*, No. 11-15350 (11th Cir. Oct. 18, 2012).

203. *See* Amicus Curiae Brief of Former FDA Officials, *supra* note 7, at 11 ("Under FDA's theory in this case, traditional pharmacy compounding is illegal. The FDA may permit aspects of the practice as a matter of its enforcement discretion, but the practice itself unquestionably is illegal according to the FDA.").

204. *See supra* Parts II–III.

205. *See* West Virginia v. EPA, 142 S. Ct. 2587, 2622 (2022) (Gorsuch, J., concurring) (noting that the agency's proposed rule would "aggressive[ly] transform[]" the industry, force many to stop operating, and cause job losses and consumer costs to escalate).

206. *See Pet Industry Market Size, Trends & Ownership Statistics*, AM. PET PROD. ASS'N, https://perma.cc/HG83-VBFL (last visited Feb. 3, 2024) (documenting that pet expenditures have continued to increase each year, moving from $90.5 billion in 2018, to $97.1 billion in 2019, to $103.6 billion in 2020, and to $123.6 billion in 2021).

homes.[207] The United States equine industry involves 7.25 million horses owned by 1.6 million households, and it supports approximately 1.7 million jobs, resulting in $38 billion in wages, salaries, and benefits and an annual $122 billion impact on the economy.[208] Meanwhile, compounding pharmacy accounted for market revenue of approximately $10.32 million in 2022, and it is anticipated to reach $23.43 million by 2033.[209] The FDA estimates that pharmacists fill approximately 11.34 million prescriptions for compounded animal drugs in the United States each year.[210] Of this number, at least half, or 6.35 million prescriptions, treat nonfood animals.[211] Thus, the FDA's position will have a significant economic impact on both compounding pharmacies and veterinarians who prescribe compounded drugs for nonfood animals. As one court has noted, because "hundreds of pharmacies currently compound animal medications from bulk under the imprimatur and regulation of state law," accepting the FDA's position would "destabilize the pharmacy profession and leave many animal patients without necessary medication."[212]

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207. *See id.* (chronicling that, since 1988, household pet ownership has increased 14 percent, up from 56 percent of households, at that time).

208. *See Horse Industry Statistics in 2021 (U.S. Data)*, HORSES ONLY (Jan. 2, 2023), https://perma.cc/957U-5AHN (citing the American Horse Council's 2020 Economic Impact of the United States Horse Industry report and the United States Bureau of Labor Statistics).

209. *See USA Compounding Pharmacies Market Outlook from 2023 to 2033*, FUTURE MKT. INSIGHTS, https://perma.cc/C546-H3MQ (last visited Feb. 4, 2024) (citing reports). Notably, the United States lags behind global pharmacy compounding. *See Compounding Pharmacies Market Research, 2031*, ALLIED MKT. RSCH., https://perma.cc/NE4B-5SX6 (last visited Feb. 3, 2024) (reporting a market revenue of $8.12 *billion* in 2021, which is anticipated to reach $14.84 *billion* by 2031).

210. *See* Compounding Animal Drugs from Bulk Drug Substances: Guidance for Industry, 87 Fed. Reg. 22,212, 22,214 (Apr. 14, 2022) (citing the APhA).

211. *See* Compounding Animal Drugs from Bulk Drug Substances: Draft Guidance for Industry, 80 Fed. Reg. 28,624, 28,627 (May 19, 2015) (subtracting out treatment for food producing animals). This $6.35 million figure could be higher in 2022, but the FDA failed to differentiate between food and nonfood animals in that calculation. *See* Compounding Animal Drugs from Bulk Drug Substances, 87 Fed. Reg. at 22,214 (referring only to compounding for "animals," generally).

212. United States v. Franck's Lab, Inc., 816 F. Supp. 2d 1209, 1253 (M.D. Fla. 2011) (citing experts), *vacated as moot on voluntary dismissal of appeal*, No. 11-15350 (11th Cir. Oct. 18, 2012); *see* Thompson v. W. States Med. Ctr.,

Moreover, the 2022 GFI requires pharmacists, if at all possible, to work from a finished approved drug by breaking it apart and isolating the API, and then compounding it.[213] This method is more likely to result in a medication that falls outside of the purity, potency, and quality standards required for the animal.[214] "Commercially available products are filled with inactive ingredients that when used for compounding can cause severe formulation issues, such as 'caking,' 'crashing,' discoloration, separation and more."[215] And, accompanying these safety concerns, there is the significantly increased cost of having to purchase and break down an approved drug to extract the API before compounding the drug. For example, for six commonly compounded animal drugs, evidence shows that compounding from the finished product, rather than starting with the bulk ingredient, can raise the cost anywhere from 62 percent to 928 percent.[216] The 2022 GFI states that "price" is not a sufficient reason to compound using bulk, but many approved drugs are "prohibitively expensive," and "some animal owners are unable or unwilling to buy" them.[217] In sum, the 2022 GFI's impact is not only economically significant and hotly debated, but irrationally dangerous and limiting upon the ability of veterinarians and pharmacists to treat their nonfood animal patients. Given the role that companion animals play in people's lives, the major questions doctrine should apply to test whether

535 U.S. 357, 369 (2002) (noting the FDA's concession that eliminating compounding would critically impact patient care); INT'L ACAD. COMPOUNDING PHARMACISTS, COMPOUNDING FOR ANIMALS 9 (2004), https://perma.cc/ZK4Z-5T72 (PDF) (stating that compounding using bulk drug ingredients is "essential to a veterinarian's ability to properly treat his or her patients").

213. *See* 2022 GFI, *supra* note 8, at 8–9 (mandating that pharmacists only compound from bulk if they cannot use API extracted from an approved drug).

214. *See Franck's Lab*, 816 F. Supp. 2d at 1217–18 (citing experts); Corp-Minamiji, *supra* note 161 (bulk drug compounding "ensures a safe, more consistent product" because the potency of approved drugs can vary by "plus or minus 15%," which adds danger, particularly when compounding for small animals).

215. Eilers, *supra* note 165.

216. *See id.* (citing doxycycline (350% more expensive), prednisolone (359% more expensive), and prazosin (928% more expensive)).

217. *See* Davidson, *supra* note 85, at 3 (citing chemotherapy drugs and drugs for chronic or systemic conditions as costly regimes for which compounded therapies are much cheaper).

Congress clearly gave the FDA the authority to adopt this prohibitive and dangerous policy.[218]

B. *Lack of a Clear Congressional Statement*

In determining whether Congress has clearly authorized the FDA's 2022 GFI, courts will look at the FDCA's "overall statutory scheme," the "age and focus" of the statute, "the agency's past interpretations," and the fit between the agency's "action" and its "mission."[219] Here, the 1938 FDCA aimed to regulate drug "manufacturing, marketing, and distribution,"[220] and that is how the FDA observed it for more than half a century.[221] Indeed, provisions within the FDCA's statutory scheme bely the FDA's novel and contradictory position—not promulgated until 2003—that pharmacy compounding using bulk drug substances for nonfood animals is illegal.[222] For example, Congress designated the USP and NF as "official compendiums" of the FDCA.[223] Pharmacy compounds prepared

218. *See* West Virginia v. EPA, 142 S. Ct. 2587, 2608–09 (2022) (citing numerous cases where health related policies and rules formed important issues of profound political debate, triggering major questions doctrine analysis by the Court).

219. *West Virginia*, 142 S. Ct. at 2622–24 (Gorsuch, J., concurring) (citations omitted).

220. *W. States*, 535 U.S. at 369. Notably, a traditional compounding pharmacist is neither a manufacturer, nor a distributor. *See supra* notes 46–47 (explaining that a traditional compounder worked within the triad relationship and dispensed pursuant to prescriptions). *Compare* 21 C.F.R. § 802(10) (defining "dispense," under the CSA, to mean delivery to the "ultimate user" pursuant to a practitioner's order), *with id.* § 802(11) (defining "distribute," under the CSA, to mean "to deliver" other than by "dispensing").

221. *See W. States*, 535 U.S. at 362 (denoting the FDA's longstanding position); *see also West Virginia*, 142 S. Ct. at 2610 (quoting Justice Frankfurter stating, "[J]ust as established practice may shed light on the extent of power conveyed by general statutory language, so the want of assertion of power by those who presumably would be alert to exercise it, is equally significant in determining whether such power was actually conferred" (citation omitted)); Nat'l Fed'n of Indep. Bus. v. OSHA, 142 S. Ct. 661, 666 (2022) (finding the agency's action lacked "historical precedent" because, "in its half century of existence," it had never before asserted such authority).

222. *See supra* notes 187–192 and accompanying text.

223. 21 U.S.C. § 321(g)(1); *see supra* note 48–52 and accompanying text; *see also* United States v. Franck's Lab, Inc., 816 F. Supp. 2d 1209, 1218 n.26 (M.D. Fla. 2011) (noting that the USP contains "instructions on how to compound medications from bulk ingredients" and it "continues to authorize

using bulk drug substances pursuant to USP or NF standards would seem to remove them from the "new drug" realm, both because they prepared using "official" FDCA drug standards,[224] and because they reflect criteria established by USP or NF scientific experts regarding drug identity, strength, purity, and performance.[225] Yet, pursuant to its 2022 GFI, the FDA claims that even compounding using USP or NF monographed ingredients for nonfood animals is illegal and permitted only in the FDA's discretion.[226] This FDA position appears to conflict with the FDCA's original text.

Later amendments to the FDCA's statutory scheme also bely the FDA's 2022 policy. As noted above, the FDCA did not even mention pharmacies or compounding until the 1962 amendments,[227] and, then, it did so only to ensure they were not swept into the Act's new provisions.[228] Traditional pharmacies that compound in compliance with state law, pursuant to a

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compounding when the monographs are followed"), *vacated as moot on voluntary dismissal of appeal*, No. 11-15350 (11th Cir. Oct. 18, 2012).

224. *See* Cavers, *supra* note 89, at 33 (describing drugs created in compliance with compendium standards as "official drugs" that were not adulterated, differentiating them from manufactured drugs that substituted different ingredients); *id.* at 37 (noting that, for labeling and misbranding purposes, only "non-official" drugs were required to list their active ingredients); *see also id.* at 33 ("To assure the advantage of standardization, it was thought necessary to compel drug manufacturers to choose either to comply with the official formulae as well as standards or to cease offering their deviating products as official drugs.").

225. *See supra* note 48 and accompanying text; *USP 200th Anniversary: Building Trust for over 200 Years: A Timeline of USP*, USP, https://perma.cc/P982-3JSL (last visited Feb. 3, 2024) (stating that the USP is an "independent, scientific, non-profit organization dedicated to" establishing a "national, uniform set of guidelines for the best understood medicinal substances and preparations"); *id.* (noting that both the 1906 Act and the FDCA required drugs to meet USP standards). *But see* Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 617–19, 629–312 (1973) (recounting the strict standards and clinical investigations required to establish "substantial evidence" that a drug is safe and effective).

226. *See* 2022 GFI, *supra* note 8, at 5–12. But see *supra* notes 185–186 and accompanying text for an explanation of how an agency cannot have "enforcement discretion" over an area for which Congress did not grant it any authority.

227. *See generally* Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–1013); *see also supra* notes 63–72 and accompanying text.

228. *See supra* notes 102–107 and accompanying text.

prescription, and in the course of their professional practice need not register with the FDA or undergo the enhanced FDA factory inspection designed to uncover adulteration, misbranding, and other Act violations.[229] The FDA's position that, absent enforcement discretion, these compounds must satisfy the costly and time consuming "new animal drug" approval process, does not make sense when Congress does not even require these pharmacies to register with the FDA and withholds this inspection authority.[230] What does make sense is that Congress enacted the 1962 provisions, using broad terms, to cover manufacturers, while ensuring they did not capture state-law compliant pharmacists and practitioners, because it did not intend to regulate the medical arts.[231] Congress did the same thing when it enacted the CSA in 1970, explaining that the term "manufacture" excludes a pharmacist who compounds drugs in compliance with state law in the course of his professional practice.[232] Thus, in its enactments after the FDCA, Congress continuously said that state-law compliant pharmacy compounders who dispense drugs pursuant to a prescription in the ordinary course of their practice are not subject to more rigorous drug provisions regulating manufacturers. To find otherwise, would be to sanction the FDA's position that the FDCA empowers it to ban and, thereby, eradicate this

229. *See* 21 U.S.C. § 360(g)(1) (absolving of registration); *id.* § 374(a)(2)(A) (precluding inspection of "all things therein . . . bearing on whether . . . drugs" are "adulterated or misbranded" or "otherwise bearing on violation of this chapter"); *see also* West Virginia v. EPA, 142 S. Ct. 2587, 2610 (2002) (refuting alleged agency authority "to adopt a regulatory program that Congress had conspicuously and repeatedly declined to enact"); FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 160 (2000) (declining the FDA's claimed authority when Congress consistently had denied it the power it sought).

230. *But see* Med. Ctr. Pharmacy v. Mukasey, 536 F.3d 383, 398 n.33 (2008) (conducting a *Chevron* analysis and concluding that the 1962 provisions cut both ways because Congress did not modify the "new drug" provisions). Of course, this finding assumes that Congress intended pharmacy compounds to undergo the "new drug" approval process in the first place.

231. *See* cases cited *supra* note 78; *see also* Amicus Curiae Brief of Former FDA Officials, *supra* note 7, at 5 ("If FDA is correct, then Congress in 1938 *criminalized* a widespread and longstanding practice, and did so without the knowledge of either pharmacies or the States, which have continued to closely regulate the practice of pharmacy compounding (just as they have done for centuries).").

232. 21 U.S.C. § 802(15); *see id.* § 802(21) (defining "practitioner" to include pharmacists, veterinarians, physicians, and dentists).

centuries-old pharmacy practice[233]—a practice which Congress, itself, affirmatively sanctioned in crafting the District of Columbia's laws through the 1970s, long after passage of the FDCA, and again sanctioned when it created FDAMA for human drugs in 1997.[234]

1. AMDUCA Does Not Provide a Clear Statement

AMDUCA does not provide clear congressional authorization for the FDA's 2022 nonfood animal bulk drug compounding policy. Congress enacted AMDUCA only to clarify that "extralabel" use of already approved animal and human drugs may be used to treat animals.[235] AMDUCA did not purport to address compounding.[236] The FDA's creation of 21 C.F.R. § 530.13, ostensibly in furtherance of administering AMDUCA, addresses only compounding using *approved* drugs as the API source.[237] Despite its last sentence stating that "[n]othing in this part shall be construed as permitting compounding from bulk drugs,"[238] the regulation does not address bulk drug compounding by pharmacies within the scope of their state-regulated practices.[239] Even after Congress passed AMDUCA in 1994, the FDA's 1996 CPG continued to permit pharmacy compounders to use bulk drug substances for nonfood animal drugs.[240]

233. *See Brown & Williamson*, 529 U.S. at 159–60 (rejecting the FDA's claimed authority to regulate a product that technically fit within the Act's broad "drug" or "device" definitions, but that was not contemplated by the FDCA's scheme and had been rejected by later congressional enactments).

234. *See supra* notes 57, 77, 124–130 and accompanying text; *West Virginia*, 142 S. Ct. at 2614 (refusing an agency "regulatory writ" that Congress had "'considered and rejected' multiple times" (citation omitted)).

235. *See* 21 U.S.C. § 360b(a)(4)–(5).

236. *See generally id.*

237. *See* 21 C.F.R. § 530.13 (dealing with "compounding of a product from approved" drugs only).

238. *Id.* § 530.13(a).

239. *See* United States v. Franck's Lab, Inc., 816 F. Supp. 2d 1209, 1221 (stating the same), *vacated as moot on voluntary dismissal of appeal*, No. 11-15350 (11th Cir. Oct. 18, 2012).

240. *See* Compounding of Drugs for Use in Animals: Compliance Policy Guide, 61 Fed. Reg. 34,852 (July 3, 1996) (outlining this FDA policy in the 1996 CPG).

More than a decade prior to the Court's "clear statement" rule announcement in *West Virginia*, one federal court incorrectly found refuge in AMDUCA, erroneously believing that it allowed the same compounding for animals that FDAMA allows for humans.[241] As a second federal court later held, however, the prior court erroneously "presumed" that the FDA, in its discretion, would not treat compounding for humans and nonfood animals differently,[242] wrongly believed that AMDUCA was the equivalent of FDAMA, and, as a result of these errors, insufficiently analyzed the issue of bulk drug compounding for animals.[243]

Indeed, because AMDUCA only addresses extra-label use of drugs, the FDA regulation, which gratuitously adds an "approved drug" compounding provision, is both unsupported by the enabling statute[244] and unsafely requires pharmacists to break apart a finished approved drug to compound the ingredient.[245] Even more telling for purposes of the "clear statement" rule, the FDA has expressly disclaimed reliance on AMDUCA or its regulation for bulk drug compounding,[246] yet

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241. *See* Med. Ctr. Pharmacy v. Mukasey, 536 F.3d 383, 406–08 (5th Cir. 2008) (finding that Congress passed FDAMA to address compounding of human drugs and passed a similar amendment, AMDUCA, to provide the same for nonfood animal drugs).

242. The court, in *Medical Center Pharmacy*, believed that the FDA's position that pharmacy compounds are illegal was tempered by its longstanding exercise of "enforcement discretion." *Id.* at 399. But, in so holding, the court wrongly relied on one indicium of *lack of a clear statement*, namely, that after the 1938 Act, the FDA *had not* enforced the "new drug" provisions against bulk drug compounding pharmacies, for decades. *Id.*

243. *See Franck's Lab*, 816 F. Supp. 2d at 1239–40, 1240 n.76, 1249–50 (finding the court's reliance on AMDUCA "as an analogue to FDAMA" was "unpersuasive"); Amicus Curiae Brief of Former FDA Officials, *supra* note 7, at 8 (confirming that AMDUCA "did not grant FDA authority to regulate pharmacy compounding of animal drugs from bulk ingredients").

244. *See* West Virginia v. EPA, 142 S. Ct. 2587, 2609 (2002) ("'[E]nabling legislation' is generally not an 'open book to which the agency [may] add pages and change the plot.'" (citation omitted)).

245. *See supra* notes 161, 163, 165, 214–215 and accompanying text.

246. *See Franck's Lab*, 816 F. Supp. 2d at 1234 (quoting the FDA stating "AMDUCA does not encompass compounding from bulk drugs"); *id.* ("The FDA expressly disclaims reliance upon . . . AMDUCA . . ."); Defendant's Memorandum in Opposition to Plaintiffs' Motion for Summary Judgment at 15, 17 n.12, Med. Ctr. Pharmacy v. Gonzales, 451 F. Supp. 2d 854 (W.D. Tex. 2006) (No. 04-cv-130) (stating AMDUCA is not relevant, § 530.13 "is not

another indication that AMDUCA does not provide a clear statement that the FDA may prohibit, or limit, the use of bulk drug substances in compounding for nonfood animals.[247]

2. Significant "Elephant-in-a-Mousehole" Problems

The FDCA's history and focus likewise show that Congress did not intend to sweep state-law compliant pharmacy compounds within the "new animal drug" definition or require that they satisfy the "new animal drug" approval process.[248] Although Congress sometimes "passes broadly worded statutes seeking to resolve important policy questions in a field while leaving an agency to work out the details of implementation," an agency may not "exploit some gap, ambiguity, or doubtful expression . . . to assume responsibilities far beyond its initial assignment."[249] In short, Congress does not "hide elephants in mouseholes."[250]

Numerous courts have noted the elephant-in-a-mousehole problems with the FDA's current position. In *Thompson v. Western States Medical Center*,[251] the Supreme Court, while noting the dual government interests in protecting the new drug provisions and permitting the continuation of compounding, nonetheless found that "it would not make sense to require compounded drugs created to meet the unique needs of individual patients to undergo the testing required for" FDA

authority for a prohibition on compounding from bulk ingredients," and AMDUCA and its regulation are "silent on the subject of bulk APIs").

247. *See West Virginia*, 142 S. Ct. at 2611 (noting that the agency previously had capitulated to the statutory focus that the Court ultimately found to be the proper one).

248. *See id.* at 2608 ("Despite its textual plausibility, we noted that the Agency's interpretation would have given it permitting authority over millions of small sources . . . that had never before been subject to such requirements.").

249. Nat'l Fed'n of Indep. Bus. v. OSHA, 142 S. Ct. 661, 669 (2022) (Gorsuch, J., concurring).

250. *West Virginia*, 142 S. Ct. at 2623 (Gorsuch, J., concurring); *id.* at 2622–23 (citing "elephant-in-a-mousehole" cases where the Court found that Congress does not implicitly delegate "broad and unusual authority" in an "oblique" fashion (citations omitted)).

251. 535 U.S. 357 (2002).

approval.[252] And, before erroneously finding that AMDUCA cured the issue, the court, in *Medical Center Pharmacy v. Mukasey*, concurred. *First,* it recognized the "unlikel[ihood] that Congress intended to force compounded drugs to undergo the new drug approval process," a requirement that would make compounding "nearly impossible and thus nonexistent."[253] *Second*, it acknowledged that applying the "new drug" provision, to "effectively" render these compounds" unlawful, "appears inconsistent with the likely expectation that compounding could and should persist, and with other provisions of the FDCA that expressly acknowledge the existence of compounding."[254] The court found it "questionable" that, in 1938, Congress "intended such a large expansion" of the FDA's authority and saw "no small burden" for the pharmacists "'liv[ing] in sin'—their livelihood having no greater assurance than the FDA's good graces."[255] Presumably, but for the court's erroneous reliance on AMDUCA, its decision would have turned out quite differently.

United States v. Franck's Lab, Inc.[256] took the step that the prior court failed to take. Articulating the elephant-in-a-mousehole problem, the court held that "in enacting the FDCA in 1938, Congress did not intend to give the FDA *per se* authority to enjoin the long-standing, widespread, state-regulated practice of pharmacists filling a veterinarian's prescription for a nonfood-producing animal by compounding from bulk substances."[257] In *Franck's Lab*, the FDA sought to enjoin Franck's Lab from ever again compounding using bulk drug substances for nonfood animals,[258] based on its now

252. *Id.* at 369; *see id.* at 369–70 (stating that the FDA may "draw a line between small-scale compounding and large-scale manufacturing" to distinguish the former, which cannot undergo the new drug process, from the latter, that should be required to do so).

253. Med. Ctr. Pharmacy v. Mukasey, 536 F.3d 383, 398 (5th Cir. 2008).

254. *Id.* at 398; *see id.* at 398 n.33 (citing the 1962 laws that negated any need for state-law compliant pharmacy compounders to register with the FDA or undergo enhanced FDA inspections for violations of the Act).

255. *Id.* at 396 n.26 (citing Am. Bar Ass'n v. FTC, 430 F.3d 457 (D.C. Cir. 2005)).

256. 816 F. Supp. 2d 1209 (M.D. Fla. 2011), *vacated as moot on voluntary dismissal of appeal*, No. 11-15350 (11th Cir. Oct. 18, 2012).

257. *Id.* at 1256.

258. *See id.* at 1214 n.7 (seeking a "permanent[] and perpetual[]" injunction).

admittedly irrational 2003 CPG,[259] and arguing that such compounding is illegal under the FDCA.[260] In contrast to *Medical Center Pharmacy*, where the court trusted that the FDA would responsibly exercise enforcement discretion,[261] in *Franck's Lab*, the court confronted head on the FDA's "'maximalist' position" of illegality, and it determined that the FDA's claim of discretion could no longer be countenanced.[262] Conducting far more in-depth analysis than did the court in *Medical Center Pharmacy*, this court held that, while the "new animal drug" definition might be sufficiently broad to encompass pharmacy compounds,[263] no FDCA language shows that Congress intended to subject them to the "new drug" approval process.[264] The court expressly found it "not at all clear that Congress meant to hide the elephant of the FDA's regulation of traditional pharmacy compounding in the mousehole of the FDCA's new drug approval process,"[265] emphasizing:

> Every court that has addressed the issue—no matter the context—has recognized that the FDA new drug approval

259. *See supra* notes 189–190 (quoting Daniel E. Troy, FDA Chief Counsel in 2003, who said, "[I]t is simply not credible for the Agency to maintain that, in 1938, Congress made every corner pharmacist into a criminal.").

260. *See Franck's Lab*, 816 F. Supp. 2d at 1214 (noting that the FDA took "the bright-line position that any compounding of animal medications from bulk substances violates . . . the FDCA, even when conducted by a state-licensed pharmacist for an individual animal patient pursuant to a valid veterinary prescription"); *id.* at 1233 (highlighting that the FDA was arguing that "traditional compounding practice implicates the same concerns under the FDCA as the mass-production, mass-marketing, and mass-distribution of unapproved animal drugs by an unlicensed manufacturer").

261. *See Med. Ctr. Pharmacy*, 536 F.3d at 399 (declining to "infer" what the court called "an absurd result from a maximalist interpretation," based on the fifty years of FDA inaction following the FDCA's enactment).

262. *Franck's Lab*, 816 F. Supp. 2d at 1239; *see id.* at 1239–40 (noting that *Medical Center Pharmacy* wrongly "presumed that the FDA drew no distinction between human and animal compounding").

263. *See id.* at 1241 ("[T]he literal language of the 'new animal drug' provision without any context is sufficiently capacious to encompass pharmacists and compounding . . . .").

264. *See id.* at 1244–46 (finding that, given the longstanding practice of compounding animal drugs, "it just does not seem plausible" that Congress intended them to go through "the lengthy and expensive new animal drug approval process").

265. *Id.* at 1243.

> process is an 'especially poor fit' for regulating traditional pharmacy compounding, one that would potentially eradicate traditional compounding despite the recognized importance, historical acceptance, and decades-long state regulation of the practice.[266]

This court also found that the FDCA's legislative history demonstrated that Congress designed the "new drug" provisions for drug manufacturers,[267] and that later FDCA enactments, such as the 1962 amendments, signaled "a congressional policy decision to distinguish compounding from manufacturing."[268] Finally, the court highlighted the FDA's half century of respect for state regulation of pharmacy practice, and noted that, when Congress intends to displace traditional state regulation, it must do so plainly and clearly.[269] Thus, while the FDA may, by regulation, draw a line between traditional pharmacy compounding and drug manufacturing under the guise of compounding, it cannot "reinterpret the FDCA to allow it to eradicate the line" for animal medications.[270] In sum, *albeit* under *Chevron* analysis, the court in *Franck's Lab* presciently held what the Supreme Court likely would hold today, post-*West Virginia*: absent a clear statement from Congress that the FDA has the authority to prohibit pharmacy compounding using bulk drug substances for nonfood animals, the FDA *does not* have

266. United States v. Franck's Lab, Inc., 816 F. Supp. 2d 1209, 1243–44 (M.D. Fla. 2011), *vacated as moot on voluntary dismissal of appeal*, No. 11-15350 (11th Cir. Oct. 18, 2012).

267. *See id.* at 1245–46 (noting that, in 1938, Congress focused on unregulated drug manufacturers in contrast to already regulated pharmacies).

268. *Id.* at 1245; *see id.* at 1246 (finding "the new drug approval process is a poor method for drawing a line" between compounders and manufacturers because it does not allow state-authorized compounding to continue).

269. *See id.* at 1220, 1254 (explaining that, to alter the federal-state balance in an area of traditional state regulation, Congress must speak in "unmistakably clear" terms); *see also id.* at 1253 (noting that the FDA's position would "destabilize" the pharmacy profession and leave many animals without necessary care).

270. *Id.* at 1250; *see also id.* (stating that the FDA cannot expand its jurisdiction using "enforcement discretion," especially for a statute that has criminal penalties); *id.* (stating that requiring "citizens to rely[] upon the good graces of the FDA's enforcement discretion" would "openly invite arbitrary enforcement, which is antithetical to our system of criminal justice").

that authority and may not limit pet owners' ability to obtain these much needed medications for their pets.[271]

3. Extant Policy Concerns

Critics of this proposed application of the clear statement rule might argue that it hinders the FDA's mission and impacts institutional concerns.[272] To coin the dissent's argument in *West Virginia*:

> A key reason Congress makes broad delegations . . . is so an agency can respond, appropriately and commensurately, to new and big problems. Congress knows what it doesn't and can't know when it drafts a statute; and Congress therefore gives an expert agency the power to address issues—even significant ones—as and when they arise.[273]

Thus, the argument proceeds, the major questions doctrine's requirement of a clear congressional statement nullifies the purpose of *Chevron*, which directs courts to follow Congress's mandate when faced with an unambiguous statute or, if faced with a silent or an ambiguous statute, to defer to any

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271. *See* West Virginia v. EPA, 142 S. Ct. 2587, 2612 (2002) (rejecting agency's claim of implicit authority over an industry, and finding its promised restraint less "limiting" and more "revealing" of the breadth of power it sought over decisions important to Americans); *see also Franck's Lab*, 816 F. Supp. 2d at 1241–50 (holding that the FDA "lacks the statutory authority it seeks").

Notably, the Court in *Franck's Lab* alternatively held that the FDA's position would also fail *Chevron* step two. *See Franck's Lab*, 816 F. Supp. 2d at 1250. But rather than applying *Chevron* deference, the Court found *Skidmore* persuasiveness more appropriate. *Id.* at 1251 (citing Christensen v. Harris County, 529 U.S. 576, 587 (2000)). Under *Skidmore*, an agency's interpretation is only "entitled to respect" if it has the "power to persuade" the Court that the agency's position is correct. Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944). In conducting such analysis, the Court considers the thoroughness of the agency's investigation, validity of its reasoning, and consistency (or inconsistency) with its earlier positions. *Id.*

272. *See* Deacon & Litman, *supra* note 36, at 1014 (arguing that, when assessing the major questions doctrine in light of "previously understood institutional and political pathologies," the doctrine fairs "quite poorly"); *West Virginia*, 142 S. Ct. at 2641 (Kagan, J., dissenting) (arguing that the doctrine "[p]revent[s] agencies from doing important work").

273. *West Virginia*, 142 S. Ct. at 2628. *But see id.* at 2609 (majority opinion) (stating, per the majority, that "enabling legislation" does not grant an agency carte blanche authority to expand its jurisdiction into new areas).

reasonable agency interpretation.[274] Critics argue that the major questions doctrine, instead, places that interpretative power in the hands of federal judges,[275] thereby creating legal uncertainty,[276] and negating Congress's ability to rely on its agency delegations by constraining agency effectiveness.[277] In so doing, the doctrine allegedly also impacts separation of powers[278] and infuses politization into the legislative process.[279]

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274. Chevron U.S.A., Inc. v. Nat'l Res. Def. Council, Inc., 467 U.S. 837, 842–44 (1984); *cf.* Deacon & Litman, *supra* note 36, at 1017–23, 1036–39 (arguing that, "[r]ather than being one factor" in *Chevron* analysis, "the new major questions doctrine flips the entire analysis" to "courts, rather than agencies").

275. *See* Deacon & Litman, *supra* note 36, at 1050–56 (explicating cases showing how policies—usually the fodder of congressional or agency rulemaking—are instead being decided by courts using the doctrine). *But see* Nat'l Fed'n of Indep. Bus. v. OSHA, 142 S. Ct. 661, 668 (2022) (Gorsuch, J., concurring) (arguing that the doctrine ensures that lawmaking stays with Congress—"the people's representatives"—rather than being ceded to agencies filled with unelected officials appointed by the executive branch).

276. *See* Deacon & Litman, *supra* note 36, at 1014 (describing the doctrine as "radically indeterminant"); *id.* at n.23 (citing sources saying it is "unclear, unpredictable, and arbitrary").

277. *See id.* at 1078 (asserting that, by "limiting" agency authority "to familiar contexts, the Court undermines the reasons why Congress [] delegate[s] in the first place," namely, to benefit from generous agency staffing, developed expertise, and adaptive flexibility).

278. *See supra* note 275 and accompanying text. Elsewhere, Litman has argued that an agency's ability to exercise enforcement discretion makes that agency—through its Chief Executive—"accountable to the people." Leah M. Litman, *Taking Care of Federal Law*, 101 VA. L. REV. 1289, 1306 (2015) (quoting *Chevron*, 46 U.S. at 865–66). However, the *Franck's Lab* case demonstrates that agencies cannot always be trusted to exercise that discretion fairly or logically. *See supra* notes 256–262 and accompanying text. In *Franck's Lab*, the FDA's action forced the pharmacy out of business, when the undisputed facts showed that the pharmacy had done nothing it was not permitted to do under state law. *See* United States v. Franck's Lab, Inc., 816 F. Supp. 2d 1209, 1214–15 (M.D. Fla. 2011) (finding, on the record, that Franck's complied with all state compounding laws), *vacated as moot on voluntary dismissal of appeal*, No. 11-15350 (11th Cir. Oct. 18, 2012); Joint Motion to Vacate and Dismiss as Moot at 3, United States v. Franck's Lab, Inc., No. 11-15350 (11th Cir. Nov. 1, 2012) (noting that Franck's was forced out of business).

279. *See* Deacon & Litman, *supra* note 36, at 1049, 1050–51 (claiming the doctrine allows political actors to create controversy, in order to "make an issue 'major,'" thus enabling judicially-created exceptions and amendments to "broad statutory grants of authority," and promoting politically motivated judgments over "formal lawmaking").

But, while these broader arguments might hold greater sway in other contexts, when applied to pharmacy compounding from bulk drug ingredients for nonfood animals, it lacks persuasiveness and, instead, promotes absurdity.[280] The FDA argues that it has authority over all drugs, regardless of how, where, or by whom they are created, and, because pharmacy compounded animal drugs lack FDA approval, they are "unsafe" and "illegal."[281] But, the Court rejected a similarly overbroad FDCA interpretation in *FDA v. Brown & Williamson Tobacco Corp.*, where the FDA promoted an "expansive construction" of its authority to ban or limit tobacco products on the basis that they technically fit within the FDCA's definitions of "drugs" and "devices."[282] As the Court echoed in *West Virginia v. EPA*, a merely "colorable textual basis" will not suffice when statutory "context" and "common sense" do not support congressional delegation of authority.[283] Here, the FDA has admitted and numerous federal courts—including the Supreme Court—have confirmed, that pharmacy compounds cannot meet the rigorous and expensive new animal drug approval process, and that requiring them to do so would eradicate this desirable and much needed pharmacy practice.[284] Despite these realities, the FDA has refused to cede "authority," both because it does not believe it would be prudent to do so,[285] and, as industry stakeholders have pointed out, because of significant lobbying efforts by the big pharmaceutical manufacturers.[286]

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280. *See supra* Part IV.B.2.

281. *See supra* note 171 and accompanying text.

282. 529 U.S. 120, 160 (2000).

283. 142 S. Ct. 2587, 2609 (2022); *see also id.* at 2614 ("[S]horn of all context . . . [a word] is an empty vessel.").

284. *See supra* notes 252–257, 263–266 and accompanying text; Thompson v. W. States Med. Ctr., 535 U.S. 357, 369 (2002) (citing government's admissions).

285. *See* 1989 Memorandum, *supra* note 111, at 4 ("[W]e must assert, if asked, that our jurisdiction extends to all products . . . . [W]e cannot . . . concede a lack of jurisdiction . . . ."); COMPOUNDING FOR ANIMALS, *supra* note 212, at 3 ("FDA states that they do not want to concede that some compounding from bulk pharmaceutical ingredients is acceptable because it weakens their case against the types of compounding they want to limit . . . .").

286. *See* COMPOUNDING FOR ANIMALS, *supra* note 212, at 3 (addressing "why" the FDA is so concerned about bulk drug compounding for nonfood animals, and explaining that the Agency is reacting to pressure from big pharmaceutical manufacturers). Thus, the concern that interested parties

Neither the FDA's nor the pharmaceutical manufacturers' position make logical or medical sense. On the one hand, a sufficient number of FDA approved, manufactured drugs do not exist for veterinarians to use to meet animal patient needs, and thus compounding is "an essential tool in veterinary medicine."[287] On the other hand, drug manufacturers do not have a sufficient economic incentive to create them. The time, effort, and cost to bring an animal drug to market, which requires almost seven years and more than $22 million,[288] can prove "insurmountable" and "limit[] the development of new animal drugs."[289] The American Veterinary Medical Association states that time and cost are the primary reasons for fewer approved animal drugs, as "the return on investment for animal drug products is small compared with that for human drug products."[290]

Finally, a determination that the FDA lacks authority to ban or limit bulk drug pharmacy compounding for nonfood animals suffers from none of the broad criticisms leveled against application of the major questions doctrine.[291] Rather than showing agency flexibility, the FDA continues to take a hardline stance on illegality, despite no logical reason existing to distinguish between compounding for humans and compounding for nonfood animals. FDA former officials have admitted the absurdity of this dubious distinction,[292] thus demonstrating that it is not reflective of any alleged agency expertise.[293] The FDA also patently ignores that, when faced with its "contention" that bulk drug compounding was illegal for

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may influence law by "creating" controversy actually works both ways. *See supra* note 279 and accompanying text. "Powerful special interests" are also "'uniquely' suited to influence" agency agendas, thus drowning out "wide social consensus." *West Virginia*, 142 S. Ct. at 2618 (Gorsuch, J. concurring).

287. *See* Alexandria Gochenauer & Lauren Forsythe, *What You Should Know About Compounding*, TODAYS VETERINARY PRAC., July/Aug. 2021, at 93, 93, https://perma.cc/E963-ZJC6 (PDF) (noting the special need for bulk drug compounded medications for small animals to ensure proper treatment dosages).

288. *See supra* note 172 and accompanying text.

289. Gochenauer & Forsythe, *supra* note 287, at 93.

290. *Id.*

291. *See supra* notes 272–279 and accompanying text.

292. *See supra* notes 189–191 and accompanying text.

293. *See supra* note 277 and accompanying text.

human drugs, Congress overrode the FDA's mistaken claim of authority.[294]

The FDA's current position with regard to nonfood animals does not reflect an agency's attempt to flex and adapt to changing times, but rather it demonstrates an agency's stubborn refusal to adjust its irrational and legally flawed position.[295] If the FDA's position is correct, then Congress intended to grant the FDA authority to require new drug approval for all nonfood animal drugs but declined to grant that same authority for human drugs, a position which is "simply too much for a public health statute like the FDCA to bear."[296] Any political motivation that exists rests squarely with the FDA and its faithfulness to big pharmaceutical manufacturers,[297] as the desire to allow pharmacy compounding of much needed medications for nonfood animal pets is, most assuredly, a largely apolitical matter for their owners and their medical providers.[298]

C. *The Solution: Clarifying Federal Law*

Given the importance of companion animals' health and wellbeing—to their owners, medical providers, and the animals

294. *See supra* Part III.B.1.

295. *See supra* note 189–190 (recounting FDA Chief Counsel Troy's description of the FDA's position as imbued with "a religious fervor" and statutorily unsupportable).

296. United States v. Franck's Lab, Inc., 816 F. Supp. 2d 1209, 1250 (M.D. Fla. 2011), *vacated as moot on voluntary dismissal of appeal*, No. 11-15350 (11th Cir. Oct. 18, 2012).

297. *See supra* note 286 and accompanying text.

298. Notably, the Court has applied the major questions doctrine in "all corners of the administrative state." West Virginia v. EPA, 142 S. Ct. 2587, 2608 (2002). Even if the *Chevron's* standard were to apply, however, the conclusion reached here likely would not change. Although Congress has not spoken directly to bulk drug compounding for companion nonfood animals, it has done so for the human nonfood animal species, and it has chosen to allow compounding from bulk, within generous parameters. *See* 21 U.S.C. § 353a; *see also* Chevron U.S.A., Inc. v. Nat'l Res. Def. Council, Inc., 467 U.S. 837, 842 (1984) (stating *Chevron* step one is whether Congress has directly spoken to the issue). Similarly, while conducting *Chevron* analysis, at least one federal court has held that Congress did not give the FDA regulatory authority over traditional pharmacy compounding from bulk for nonfood animals. *See generally Franck's Lab*, 816 F. Supp. 2d 1209. In sum, the FDA's 2022 policy is statutorily unsupportable and "arbitrary [and] capricious." *Chevron*, 467 U.S. at 844.

themselves—the time has come to address the FDA's misplaced claim that it may unnecessarily limit their health options. The United States alone takes the antithetical position that pharmacies may not compound bulk drug substances for nonfood animals.[299] Yet, the vast number of different species requiring therapeutic treatment presents a complex problem, as neither sufficient availability nor incentive exists to address all of their unique medical needs.[300] And, while the 2022 GFI's policy requiring pharmacists to extract the API from an approved drug source may benefit drug manufacturers' bottom lines,[301] the requirement increases both the risk of harm to animal patients[302] as well as their owners' medication costs.[303]

As discussed above, judicial review of the FDA's policy likely would result in its rejection under the major questions doctrine.[304] Absent a determination that the states alone regulate traditional pharmacy compounding for nonfood animals, however, pharmacists, veterinarians, and pet owners will still face regulatory limbo.[305] This subpart proposes two solutions: (1) amend the FDCA to make clear that its "new drug" approval process does not apply to traditional pharmacies that compound drugs for nonfood animals, or (2) create a statute similar to FDAMA for pharmacy compounding for nonfood animals.

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299. *See* Davidson, *supra* note 85, at 4–5 (noting that no other country appears to have this prohibition).

300. *See id.* at 6–7 (describing significant anatomical differences and susceptibilities to toxicities that vary greatly among the various species); *see also supra* notes 287–290 and accompanying text.

301. *See supra* notes 213, 286 and accompanying text.

302. See *supra* notes 161, 163, 165, 214–215 for sources showing that compounding from finished drugs poses dangerous unknowns and results in medications with less accurate potency and purity than compounding from bulk drug substances.

303. *See supra* notes 86–88, 216–217 and accompanying text.

304. *See supra* Parts IV.A–B. The policy also would likely fail under a *Chevron* analysis. *See supra* note 298.

305. *See* Davidson, *supra* note 85, at 5 (highlighting this regulatory void and hoping for legislative "clarity" in this "country where more than 6 million compounds are prepared for animals annually").

1. Amending the "New Drug" Approval Provision

Under the FDCA, traditional pharmacies that compound in compliance with state law, pursuant to a prescription, and in the course of their professional practice, need not register with the FDA or undergo the FDA factory inspection designed to uncover adulteration, misbranding, and other chapter violations.[306] Enacted in 1962, these provisions clearly differentiate state-licensed pharmacy professionals from drug manufacturers.[307] Yet, the FDA has contended that, through the "new animal drug" provision,[308] which triggers the adulteration and misbranding provisions,[309] traditional pharmacies who compound from bulk drug substances for nonfood animals violate the Act, even if they comply with the FDCA's practice of pharmacy provision.[310] Its position creates statutory conflict.

To correct the FDA's contorted position, Congress should amend 21 U.S.C. § 360b to make clear that nonfood animal drug compounds prepared by pharmacists in compliance with state law, pursuant prescriptions, and in the course of their professional practice, shall not be subject to the "new animal drug" approval process.[311] This change would enable the bulk drug compounding necessary to meet the unique needs of many nonfood animal species,[312] and it would preserve the federalism balance Justice Gorsuch sought to protect in *West Virginia*.[313]

306. *See supra* notes 102–107, 229 and accompanying text.

307. *See* United States v. Franck's Lab, Inc., 816 F. Supp. 2d 1209, 1250 (M.D. Fla. 2011) (stating that these 1962 FDCA provisions, alone, mentioned "compounding," and they "expressly distinguish drug manufacturers"), *vacated as moot on voluntary dismissal of appeal*, No. 11-15350 (11th Cir. Oct. 18, 2012).

308. *See* at 21 U.S.C. § 360b(a)(1)(A) (stating a new animal drug is "unsafe" absent an approved application).

309. *See id.* § 351(a)(5) (providing that an "unsafe" animal drug is also "adulterated"); *see also id.* § 352(f)(1) (premising misbranding on lack of approved labeling).

310. *See* 2022 GFI, *supra* note 8, at 8.

311. *See* Thompson v. W. States Med. Ctr., 535 U.S. 357, 369 (2002) ("[I]t would not make sense to require compounded drugs . . . to undergo the testing required for the new drug approval process.").

312. *See supra* note 300 and accompanying text.

313. *See* West Virginia v. EPA, 142 S. Ct. 2587, 2618 (2022) (Gorsuch, J., concurring) (warning against "agencies moving into areas where state authority has traditionally predominated").

2. Creating a Statute Similar to FDAMA for Nonfood Animals

As a second option, Congress could create a statute similar to FDAMA for nonfood animal drug compounding. The policies Congress animated in FDAMA are strikingly similar because, as with compounded drugs for humans, compounded drugs for nonfood animals "do[] not ordinarily pose a threat to the public health."[314] Like FDAMA, the new statute would allow compounding by state-licensed pharmacists pursuant to prescriptions for individual animal patients.[315] And notably, like FDAMA, the statute would permit compounding from bulk drug substances. Under FDAMA, a pharmacist may compound using any bulk drug substance that (1) complies with a USP or NF monograph, (2) is a "component" of an FDA-approved drug, or (3) "appear[s] on a list developed by the [FDA] through regulations."[316] This capacity to create an additional list particularly benefits nonfood animals, as some drug ingredients that are highly effective for them have been withdrawn or removed from use in human drugs.[317] And, the statute's capacity for drug listing works both ways. For example, a listing provision for drugs withdrawn or removed from the market as unsafe or ineffective could be used in the nonfood animal drug compounding statute to ensure that the anatomical differences and susceptibilities to toxicities among the various species are taken into account.[318]

Finally, a nonfood animal drug compounding statute similar to FDAMA would not upset the balance between federal and state government. Like FDAMA, the animal drug

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314. 21 C.F.R. § 530.30(a); *cf. id.* § 530.21(a) (discussing unique public health concerns, such as drug withdrawal timeframes, for medications prepared for *food*-producing animals).

315. *See* 21 U.S.C. § 353a(a) (describing traditional compounding, which distinguishes it from drug manufacturing, under FDAMA).

316. *Id.* § 353a(b)(1)(A); *see id.* (requiring, also, under FDAMA, that the bulk drug substance comes from an FDA-registered manufacturer with a certificate of drug analysis).

317. *See* Davidson, *supra* note 85, at 2–3 (citing, as an example, potassium bromide, which was removed from the human drug market in the 1970s, but which is commonly prescribed for dogs with epilepsy).

318. *See* 21 U.S.C. § 353a(b)(1)(C) (providing for this drug listing in FDAMA); *see also supra* note 300 and accompanying text.

compounding statute should expressly provide for primary state regulation of pharmacy compounding, but with a mechanism for states to work cooperatively with the FDA when the scope of a pharmacy's compounding more closely resembles drug manufacturing.[319] In sum, the impetus and policy foundations for the two statutes are the same. Congress enacted FDAMA when the FDA attempted to regulate too harshly in relation to compounded drugs for human use,[320] and it should do the same thing, now, for nonfood animals.

CONCLUSION

Bulk drug compounding plays a critical role in veterinary and pharmacy treatment of nonfood animals. Because of the idiosyncrasies that exist among animal types, and the lack of available approved drugs or the incentive to create them, compounding from bulk drug substances must be allowed to fill the therapeutic gap. The FDA's 2022 GFI declaring bulk drug compounding for nonfood animals to be illegal finds no purchase in law, logic, or medicine. Congress did not design the FDCA to regulate the medical practices, which are traditionally controlled by the states; Congress's subsequent statutes confirmed this policy decision; and the FDA abided by Congress's choice for more than half a century. The FDA's 2022 GFI only serves to increase these animals' health risks and their owners' economic costs by requiring compounding from manufacturers' approved drugs, rather than bulk drug ingredients that can be safer for individualized drug preparations. Congress and stakeholders consistently have pushed back against the FDA's unauthorized policy, which will impact the livelihoods and reputations of veterinarians, pharmacists, and the 70 percent of households that own pets. And, importantly, the value of our companion animals' health distills not only to political and economic debates, but to our emotions. For many of us, companion animals, like my cat Patch, play a vital role as beloved family members. Their health and wellbeing is, most decidedly, a major issue in our lives, and,

319. *See* 21 U.S.C. § 353a(b)(3)(B) (providing for a memorandum of understanding between the FDA and each state to accommodate this concern, pursuant to FDAMA).

320. *See supra* notes 124–128 and accompanying text.

if the FDA will not change its position, then the courts or Congress should force it to do so.