IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WELLNESS PHARMACY, INC.
3401 Independence Drive, Suite 231
Birmingham, AL 35209,

WOMEN'S INTERNATIONAL PHARMACY, INC.
2 Marsh Court
Madison, WI 53718,

KEBD ENTERPRISES, LLC
d/b/a Belmar Pharmacy
231 Violet Street, Suite 140
Golden, CO 80401,

MADAME RX, LLC
d/b/a Chemistry Rx Pharmacy
829 Spruce Street, Suite 100
Philadelphia, PA 19107,

HARTLEY MEDICAL CENTER PHARMACY, INC.
113 West Victoria Street
Long Beach, CA 90805,

MEDQUEST PHARMACY, INC.
669 West 900 North
North Salt Lake, UT 84054, and

VLS PHARMACY, INC.
4402 5th Avenue
Brooklyn, NY 11220,

Plaintiffs,

v.

Civil Action No. 20-3082

ALEX M. AZAR II
in his official capacity as
Secretary of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201,

STEPHEN M. HAHN, M.D.
in his official capacity as
Commissioner of Food and Drugs
10903 New Hampshire Avenue
Silver Spring, MD 20993, and

FOOD AND DRUG ADMINISTRATION
10903 New Hampshire Avenue
Silver Spring, MD 20993,

Defendants.

COMPLAINT FOR DECLARATORY RELIEF

Plaintiffs Wellness Pharmacy, Inc.; Women's International Pharmacy, Inc.; KEBD Enterprises, LLC, doing business as Belmar Pharmacy; Madame Rx, LLC, doing business as Chemistry Rx Pharmacy; Hartley Medical Center Pharmacy, Inc.; MedQuest Pharmacy, Inc.; and VLS Pharmacy, Inc. (collectively, "Plaintiffs"), by and through their counsel Reed Smith LLP, complain against Defendants Alex M. Azar II, in his official capacity as Secretary of Health and Human Services (the "Secretary"); Stephen M. Hahn, M.D., in his official capacity as Commissioner of Food and Drugs; and the Food and Drug Administration ("FDA") (collectively, "Defendants") as follows:

NATURE OF THE ACTION

1. This is an action for declaratory relief arising from FDA's recent issuance of a final standard memorandum of understanding ("Final Standard MOU") implementing Section 503A of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 353a.

2. Section 503A addresses pharmacy compounding, which is the process by which a pharmacy combines, mixes, or alters ingredients to create medications tailored to the needs of individual patients. Traditional pharmacy compounding involves the act of dispensing: namely,

when a pharmacy provides or ships a compounded drug to an individually identified patient pursuant to a prescription for that patient.

3. In order to preserve the role of States in regulating the practice of pharmacy and protect traditional pharmacy compounding from the rigors of federal law governing drug manufacturing, Section 503A provides that certain other provisions of the FDCA do not apply to drug products compounded in compliance with Section 503A.

4. Of relevance here, Section 503A instructs the Secretary to develop a memorandum of understanding ("MOU") with States "which addresses the *distribution* of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products *distributed* outside such State." FDCA § 503A(b)(3)(B)(i) (emphasis added). However, for pharmacies located in States that do not enter into the MOU, Section 503A provides protection only in so far as the pharmacy "*distributes* (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders *dispensed or distributed* by such pharmacy . . . ." FDCA § 503A(b)(3)(B)(ii) (emphases added).

5. Moreover, Section 503A instructs that "[t]he Secretary shall issue regulations to implement this section." FDCA § 503A(c)(1).

6. Decades after the above statutory language was first enacted and without having issued any regulations implementing relevant portions of Section 503A, FDA recently issued its Final Standard MOU defining "distribution of compounded human drug products interstate" and "inordinate amounts" to include interstate dispensing of compounded human drug products even though the plain language of Section 503A clearly differentiates between dispensing and distribution. FDA has given States 365 days to decide whether to sign the Final Standard MOU.

Pharmacies such as Plaintiffs that have long engaged in traditional pharmacy compounding and which are located in States that refuse to execute the Final Standard MOU will be subject to the 5-percent limit imposed by Section 503A, causing significant harm to the pharmacies and the patients they serve. Meanwhile, pharmacies located in States that sign the Final Standard MOU will be required to expend significant resources gathering and reporting data required by the Final Standard MOU.

7. As set forth below, the Final Standard MOU is defective both procedurally and substantively. FDA's issuance of the Final Standard MOU violates Section 503A's unambiguous command that the Secretary "shall issue regulations to implement this section," which neither the Secretary nor FDA has done in relevant part prior to issuing the Final Standard MOU. FDA's issuance of the Final Standard MOU also violates various procedural requirements Congress has imposed on agencies seeking to promulgate substantive rules, including the Regulatory Flexibility Act's requirement that agencies prepare an analysis of a final rule's impact on small entities, 5 U.S.C. § 604(a). Substantively, the Final Standard MOU exceeds FDA's statutory authority by defining "distribution of compounded human drug products interstate" and "inordinate amounts" to include interstate dispensing of compounded human drug products.

PARTIES

8. Plaintiff Wellness Pharmacy, Inc. ("Wellness Pharmacy") is a corporation organized under the laws of the State of Alabama, with its principal place of business at 3401 Independence Drive, Suite 231, Birmingham, Alabama 35209. Wellness Pharmacy is properly licensed to prepare and dispense compounded drugs by the Alabama State Board of Pharmacy. Wellness Pharmacy is also properly licensed to prepare and dispense compounded drugs in 44

States and the District of Columbia, and lawfully dispenses compounded drugs to patients located in States other than Alabama.

9. Plaintiff Women's International Pharmacy, Inc. ("Women's International Pharmacy") is a corporation organized under the laws of the State of Wisconsin, with its principal place of business at 2 Marsh Court, Madison, Wisconsin 53718. Women's International Pharmacy owns and operates two compounding pharmacies, one located in Wisconsin and the other located in Arizona. Women's International Pharmacy's Wisconsin location is properly licensed to prepare and dispense compounded drugs by the Wisconsin State Board of Pharmacy. It is also properly licensed to prepare and dispense compounded drugs in 49 States and the District of Columbia, and lawfully dispenses compounded drugs to patients located in States other than Wisconsin. Women's International Pharmacy's Arizona location is properly licensed to prepare and dispense compounded drugs by the Arizona Board of Pharmacy. It is also properly licensed to prepare and dispense compounded drugs in 46 States and the District of Columbia, and lawfully dispenses compounded drugs to patients located in States other than Arizona.

10. Plaintiff KEBD Enterprises, LLC, doing business as Belmar Pharmacy ("Belmar Pharmacy"), is a limited liability company organized under the laws of the State of Colorado, with its principal place of business at 231 Violet Street, Suite 140, Golden, Colorado 80401. Belmar Pharmacy is properly licensed to prepare and dispense compounded drugs by the Colorado State Board of Pharmacy. Belmar Pharmacy is also properly licensed to prepare and dispense compounded drugs in 48 States and the District of Columbia, and lawfully dispenses compounded drugs to patients located in States other than Colorado.

11. Plaintiff Madame Rx, LLC, doing business as Chemistry Rx Pharmacy ("Chemistry Rx Pharmacy"), is a limited liability company organized under the laws of the Commonwealth of Pennsylvania, with its principal place of business at 829 Spruce Street, Suite 100, Philadelphia, Pennsylvania 19107. Chemistry Rx Pharmacy is properly licensed to prepare and dispense compounded drugs by the Pennsylvania State Board of Pharmacy. Chemistry Rx Pharmacy is also properly licensed to prepare and dispense compounded drugs in 48 States and the District of Columbia, and lawfully dispenses compounded drugs to patients located in States other than Pennsylvania.

12. Plaintiff Hartley Medical Center Pharmacy, Inc. ("Hartley Medical Center Pharmacy") is a corporation organized under the laws of the State of California, with its principal place of business at 113 West Victoria Street, Long Beach, California 90805. Hartley Medical Center Pharmacy is properly licensed to prepare and dispense compounded drugs by the California State Board of Pharmacy. Hartley is also properly licensed to prepare and dispense compounded drugs in 29 States and lawfully dispenses compounded drugs to patients located in States other than California.

13. Plaintiff MedQuest Pharmacy, Inc. ("MedQuest Pharmacy") is a corporation organized under the laws of the State of Delaware, with its principal place of business at 669 West 900 North, North Salt Lake, Utah 84054. MedQuest Pharmacy is properly licensed to prepare and dispense compounded drugs by the Utah State Board of Pharmacy. MedQuest Pharmacy is also properly licensed to prepare and dispense compounded drugs in 50 States and the District of Columbia, and lawfully dispenses compounded drugs to patients located in States other than Utah.

14. Plaintiff VLS Pharmacy, Inc. ("VLS Pharmacy") is a corporation organized under the laws of the State of New York, with its principal place of business at 4402 Fifth Avenue, Brooklyn, New York 11220. VLS Pharmacy is properly licensed to prepare and dispense compounded drugs by the New York State Board of Pharmacy. VLS Pharmacy is also properly licensed to prepare and dispense compounded drugs in 18 States, and lawfully dispenses compounded drugs to patients located in States other than New York.

15. Defendant Alex M. Azar II is the Secretary of Health and Human Services, who heads the Department of Health and Human Services ("HHS"). The Secretary is charged with administering the FDCA, including Section 503A. Although the Secretary has delegated that responsibility to FDA, the Secretary retains statutory responsibility for the agency action complained of herein. The Secretary's business address is 200 Independence Avenue, SW, Washington, District of Columbia 20201. The Secretary is sued in his official capacity only.

16. Defendant Stephen M. Hahn, M.D. is the Commissioner of Food and Drugs. In that capacity, he has the authority and responsibility for administering FDA. The Commissioner's business address is 10903 New Hampshire Avenue, Silver Spring, Maryland 20993. The Commissioner is sued in his official capacity only.

17. Defendant FDA is an operating component within HHS to which the Secretary has delegated responsibility for administering the FDCA. FDA is an "agency" within the meaning of 5 U.S.C. § 701(b)(1). FDA's business address is 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

JURISDICTION AND VENUE

18. This Court has jurisdiction over the subject matter of this action and the parties thereto pursuant to 28 U.S.C. § 1331.

19. Venue lies in this judicial district under 28 U.S.C. § 1391(e).

BACKGROUND AND FACTUAL ALLEGATIONS

20. Plaintiffs are State-licensed pharmacies that specialize in compounding human drugs. Plaintiffs provide compounded drugs to patients located within their respective States of incorporation, as well as to patients located throughout the United States where Plaintiffs are appropriately licensed as required by different state laws.

21. As required by state laws, Plaintiffs collaborate, consult, and work with practitioners and patients to prepare and dispense compounding drugs for the treatment of humans.

Pharmacy Compounding Generally

22. Traditional pharmacy compounding is the "process by which a pharmacy or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 361 (2002). "Compounding is typically used to prepare medications that are not commercially available, such as medication for a patient who is allergic to ingredients in a mass-produced product." *Id*. Compounding is a core component of the practice of pharmacy and "is taught as part of the standard curriculum at most pharmacy schools . . . . Many States specifically regulate compounding practices as part of their regulation of pharmacies." *Id*.

23. Compounded drugs fill in the gaps where, in the judgment of practitioners, there is no suitable commercially manufactured drug product available to treat a patient.

24. This unavailability occurs for many reasons. For example:

A. There is no manufactured product to accomplish the practitioner's desired or preferred medical objective;

B. A commercial product, while available, is nonetheless determined unsuitable by the practitioner because of patient allergies; drug delivery format (i.e., tablet, injectable, patch, suppository, etc.); flavoring; or combination with other drugs; and

C. A manufactured drug may not come in the dosage the practitioner determines is appropriate for a particular patient (e.g., pediatric versus adult dosage).

25. Without compounded drugs, practitioners run the risk that certain medical needs will go untreated. Therefore, after practitioners determine that there is no suitable commercially manufactured drug available, they often prescribe compounded drugs.

26. Pharmacy compounding is a vital, medically necessary, longstanding, and integral part of the delivery of health care in the United States.

27. Pharmacies prepare and dispense compounded drugs to treat cancer, autism, premenstrual syndrome, menopause, infertility, pain management, and every other conceivable condition or illness.

28. Without compounded drugs to treat conditions for which no commercially available drugs exist (or for which commercially available drugs exist, but are unsuitable), some drug therapies or treatment regimens would be unavailable altogether.

State Regulation of Compounded Drugs

29. As a traditional component of pharmacy practice, the States—and more specifically, state boards of pharmacy—historically have had oversight of most aspects of pharmacy compounding practices through state laws regulating the practice of pharmacy.

30. All 50 States address pharmacy compounding and impose rigorous registration, inspection, and safety requirements on pharmacies that provide compounding services to the patients in their respective State.

31. State pharmacy laws have registration requirements for resident and non-resident pharmacies and pharmacists; set forth the professional standards for pharmacies and pharmacists; establish labeling and purity requirements for drugs, including compounded drugs; establish licensure procedures for pharmacists as well as resident and non-resident pharmacies; and establish certain training and education requirements for pharmacists and other pharmacy providers.

32. State pharmacy laws also restrict the manner in which drugs may be compounded, including the type of order that a pharmacy or pharmacist needs to receive from a practitioner before the pharmacy or pharmacist can lawfully compound a drug.

33. For example, some States require drugs to be compounded pursuant to a prescription order for an individually identified patient (i.e., a "patient-specific" prescription).

34. On the other hand, some States permit drugs to be compounded pursuant to a health care practitioner's order or initiative in anticipation of a patient-specific prescription or for a practitioner's "office use." This permits the practitioner to keep certain compounded drugs on hand in order to immediately treat patients in his or her office, without waiting for a pharmacy to compound the drug for a specific, individually identified patient.

35. All States implement their own inspection requirements with respect to in-state and out-of-state licensed compounding pharmacies to ensure that compounding is conducted in a safe, clean environment by competent licensed pharmacists and pharmacist technicians.

36. All States further utilize their own set of enforcement and sanction mechanisms designed to ensure compliance with state pharmacy laws and regulations.

37. In addition to specific state laws and regulations, a majority of States have adopted and enforce the compounding standards set forth in the industry-recognized U.S.

Pharmacopeial Convention ("USP") General Chapters. The remaining States either model their regulations off of the standards set forth in the USP General Chapters or, in some cases, have adopted even stricter standards.

38. USP General Chapters are industry-recognized guidance chapters for compounding pharmacies that set forth good compounding practices for the preparation of non-sterile, sterile, and hazardous compounded drugs.

Federal Regulation of Compounded Drugs for Human Use

39. While States have historically regulated compounding as a traditional part of pharmacy practice, the Federal Government historically has regulated commercial drug manufacturing and distribution.

40. When first enacted in 1938, the FDCA did not address drug compounding. *See* Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–399i). Rather, Congress sought to regulate commercial drug manufacturing. The historic practice of traditional pharmacy compounding remained regulated by the States.

41. Under the FDCA, commercial drug manufacturers are required to comply with a series of rigorous, and often costly, requirements, including new drug approval ("NDA") requirements, labeling requirements, and the requirement that commercial drugs be prepared in facilities compliant with current Good Manufacturing Practices.

42. The FDCA requirements for commercially manufactured drugs, which are drugs produced on a mass scale for a general patient population, were not designed for compounded medications.

43. Compounded drugs are inherently incapable of going through the FDCA's NDA process. The NDA process is a lengthy and costly multistep process designed to approve and

manufacture one-size-fits-all drugs for mass public consumption. The NDA process typically involves years spent developing a drug in a lab, submitting an application to FDA for approval, conducting a series of human clinical trials over the course of several years, and submitting a second application following the clinical trials until one potentially receives final FDA approval. On average, it takes over a decade and at least one billion dollars to bring a new medicine to market through the NDA process.

44. The NDA process is, therefore, completely incompatible with the preparation of specialized compounded drugs prepared for specific patients' medical needs.

45. Nevertheless, in the late 1980s and early 1990s, FDA turned its focus to compounded drugs as the agency became concerned that certain compounding pharmacies were engaged in disguised and illicit drug manufacturing without going through the NDA process.

46. In 1992, FDA published Compliance Policy Guide 7132.16 (the "1992 CPG") reflecting the agency's views regarding efforts to manufacture drugs without obtaining FDA approval. At the outset, however, FDA "recognize[d] that pharmacists traditionally have extemporaneously compounded and manipulated reasonable quantities of drugs upon receipt of a valid prescription for an individually identified patient from a licensed practitioner. *This traditional activity is not the subject of this CPG*." *Id.* at 1 (emphasis added). In other words, the regulation of compounded drugs prepared pursuant to patient-specific prescriptions remained with the States.

47. The 1992 CPG set forth various factors FDA used to determine whether a pharmacy's compounding activities justified FDA enforcement under the FDCA. *See id.* at 4–5. These factors included "[d]istributing inordinate amounts of compounded products out of state." *Id.* at 5. The 1992 CPG explained that such activity was more consistent with manufacturing than

compounding, and enforcement of FDA regulations was thus necessary to prevent the "very real potential for causing harm to the public health when drug products are manufactured and distributed in commercial amounts without FDA's approval." *Id.* at 2.

48. Following the issuance of the 1992 CPG, FDA engaged in a series of enforcement actions against pharmacies that FDA believed were engaged in drug manufacturing under the guise of traditional pharmacy compounding. In response, pharmacists sought clarification from Congress regarding FDA's authority to regulate the practice of pharmacy.

49. Congress provided the requested clarification in the Food and Drug Administration Modernization Act of 1997 ("1997 Act") by creating Section 503A. Pub. L. No. 115-105, § 127, 111 Stat. 2296, 2330.

50. Section 503A continued the historical approach of leaving the regulation of traditional pharmacy compounding to the States and exempted compounded drugs from drug manufacturing requirements like the NDA process, so long as the compounded drugs met certain requirements.

51. Under Section 503A, traditional compounding pharmacies could compound drugs in either of two ways: (1) pursuant to a prescription order for an individual patient; or (2) in limited quantities in advance of receiving a prescription order for an individual patient, so long as such compounding is based upon a history of receiving prescription orders generated within an established relationship between the pharmacist and licensed practitioner. FDCA § 503A(a).

52. Section 503A also recognizes two different ways in which a compounded drug can leave the pharmacy: (1) dispensed by the pharmacy pursuant to a patient-specific prescription; and (2) distributed by the pharmacy pursuant to a non-patient-specific prescription, with the patient name later provided to the pharmacy. FDCA § 503A(a).

53. In order to assess whether a compounding pharmacy crossed the line into drug manufacturing, Congress provided in Section 503A that compounding could take place only if the compounding occurred in a State:

> (i) that has entered into a memorandum of understanding with the Secretary which addresses the ***distribution*** *of inordinate amounts of compounded drug products interstate* and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State, or
>
> (ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders *dispensed* ***or*** *distributed* by such pharmacy or physician.
>
> The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B)(i).

FDCA § 503A(b)(3)(B) (emphases added).

54. Put another way, Section 503A directed FDA to develop a standard MOU for use by States that addressed the "*distribution* of inordinate amounts of compounded drug products" shipped out of the State and that provided for "appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State." FDCA § 503A(b)(3)(B)(i). In States that did not sign the MOU, Section 503A essentially prohibited pharmacies and pharmacists from distributing compound drugs interstate in excess of 5 percent of the total prescription orders "dispensed or distributed" by the pharmacy or pharmacist. FDCA § 503A(b)(3)(B)(ii). Therefore, pharmacies or pharmacists in States that had not entered into the MOU were subject to a 5-percent cap on the interstate distribution of compounded drugs.

55. Finally, the 1997 Act included language in Section 503A instructing that "[t]he Secretary shall issue regulations to implement this section [i.e., Section 503A]." 1997 Act § 127(a), 111 Stat. at 2330 (enacting what was then FDCA § 503A(d)(1)).

56. Almost immediately following Section 503A's passage, however, Section 503A was challenged because it also banned solicitation, advertisement, or promotion of compounded drugs. *See Thompson v. W. States Med. Ctr.*, 535 U.S.C. 357 (2002). The Supreme Court of the United States ultimately found the advertising ban unconstitutional. *Id*. In light of the Court's decision in *Western States*, FDA deemed Section 503A inoperable, abandoned any attempts to draft an MOU, and reverted back to regulating traditional pharmacy compounding via the 1992 CPG for the next decade.

57. Then, in 2012, the New England Compounding Center came under scrutiny when steroid injections compounded at the facility caused an outbreak of fungal meningitis.

58. Congress responded to that outbreak by enacting the Drug Quality and Security Act, Pub. L. No. 113-54, 127 Stat. 587 (2013) ("2013 Act").

59. In relevant part, the 2013 Act revived Section 503A by striking the advertising language found unconstitutional in *Western States*. *See* 2013 Act § 106(a)(2), 127 Stat. at 598. Importantly, however, the 2013 Act left intact Section 503A's MOU language. The 2013 Act also left intact Section 503A's "shall issue regulations" command, moving it to its current location at Section 503A(c)(1). 2013 Act § 106(a)(3), 127 Stat. at 598.

Defendants' Failure to Promulgate Regulations Implementing Section 503A

60. Despite Congress's unambiguous command to issue regulations implementing Section 503A, in the nearly quarter century since Congress first enacted that command, FDA has only promulgated regulations implementing two discrete portions of Section 503A. *See* 21 C.F.R. §§ 216.23 (implementing Section 503A(b)(1)(A)(i)(III) by identifying particular bulk

drug substances that can be used to compound drug products), 216.24 (implementing Section 503A(b)(1)(C) by identifying drug products withdrawn or removed from the market for reasons of safety or effectiveness).

61. The Code of Federal Regulations itself indicates that FDA previously intended to comply with Congress's "shall issue regulations" command by promulgating regulations implementing the remainder of Section 503A.

62. In 1999, FDA created a new part 216 within title 21 of the Code of Federal Regulations. *See* List of Drug Products That Have Been Withdrawn or Removed From the Market for Reasons of Safety or Effectiveness, 64 Fed. Reg. 10,944, 10,947 (Mar. 8, 1999). Part 216 was created to house FDA's regulations addressing human drug compounding. *Id.* at 10,947.

63. Within part 216, FDA created a subpart A entitled "General Provisions." *Id.* However, FDA did not populate subpart A with regulations at that time. Instead, FDA inserted a "[Reserved]" placeholder, indicating that the agency intended to complete subpart A at a later date. *Id.* (brackets in original).

64. Subsequently, FDA's semiannual regulatory agenda periodically indicated that FDA intended to follow through and populate subpart A with the regulations required by Section 503A(c)(1). For example, in the agency's regulatory agenda for the fall of 1999, FDA described its intent to publish a notice of proposed rulemaking addressing pharmacy compounding and explained that "[e]fficient enforcement" of Section 503A "would benefit from publication of a substantive rule that interprets and applies the statutory language." Unified Agenda of Federal Regulatory and Deregulatory Actions, 64 Fed. Reg. 63,930, 63,935 (Nov. 22, 1999). FDA also noted that Section 503A "directs FDA to develop regulations, so no alternatives to regulations have been considered." *Id.*

65. As recently as its fall 2016 regulatory agenda, FDA reported its intent to "propose regulations to define and implement certain statutory conditions under which compounded products may qualify for exemptions from certain requirements." Regulatory Agenda, 81 Fed. Reg. 37,294, 37,302 (June 9, 2016). Such rulemaking, the agency acknowledged, would require the agency to conduct an analysis under the Regulatory Flexibility Act and would likely "have a significant economic impact on a substantial number of small entities." *Id.*

66. However, as reflected by the image below taken from the most recent published edition of title 21 of the Code of Federal Regulations, the "[Reserved]" placeholder FDA attached to subpart A in 1999 remains unchanged to this day:

PART 216—HUMAN DRUG COMPOUNDING

Subpart A—General Provisions [Reserved]

Subpart B—Compounded Drug Products

Sec.
216.23 Bulk drug substances that can be used to compound drug products in accordance with section 503A of the Federal Food, Drug, and Cosmetic Act.
216.24 Drug products withdrawn or removed from the market for reasons of safety or effectiveness.

AUTHORITY: 21 U.S.C. 351, 352, 353a, 353b, 355, and 371.

SOURCE: 64 FR 10944, Mar. 8, 1999, unless otherwise noted.

21 C.F.R. pt. 216 (2019).

The Final Standard MOU

67. FDA now seeks to fill this long-standing regulatory void by issuing the Final Standard MOU. *See* Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the State Board of Pharmacy or Other Appropriate State Agency and the Food and Drug Administration; Availability, 85 Fed. Reg. 68,074 (Oct. 27,

2020) ("Final Standard MOU Notice") (copy attached as Exhibit A); Final Standard MOU Addressing Certain Distributions of Compounded Human Drug Products - For Implementation, https://www.regulations.gov/document?D=FDA-2015-N-0030-8454 (Oct. 26, 2020) ("Final Standard MOU") (copy attached as Exhibit B).

68. The Final Standard MOU purports to define statutory terms at the core of Section 503A, including "inordinate amounts," "distribution," and "dispense." *See* Final Standard MOU app. A. And by FDA's own admission, the Final Standard MOU implements Section 503A. *See, e.g.*, Janet Woodcock, M.D., Dir., Ctr. for Drug Evaluation & Research, Food & Drug Admin., *FDA Announces Latest Step Toward Finalizing Memorandum of Understanding with States Addressing Compounded Drug Distribution, While Preserving Access* (May 13, 2020), https://www.fda.gov/news-events/fda-voices/fda-announces-latest-step-toward-finalizing-memorandum-understanding-states-addressing-compounded (stating that with Congress's modification of Section 503A in 2013, "FDA was able to proceed with implementing section 503A, including developing the standard MOU") (last visited Oct. 27, 2020); Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act, 85 Fed. Reg. 28,961 (May 14, 2020) (explaining that the information to be collected under the Final Standard MOU "supports [FDA] implementation of section[] 503A").

69. The Final Standard MOU establishes an agreement between a State and FDA "regarding the *distribution* of inordinate amounts of compounded human drug products interstate and the appropriate investigation by the [State] of complaints relating to human drug products compounded in [the State] and distributed outside such State." Final Standard MOU § I at 1 (emphasis added) (footnotes omitted).

70. Importantly, however, the Final Standard MOU defines the term "distribution" as follows:

> **Distribution of compounded human drug products interstate**: Means that a pharmacy or physician has sent (or caused to be sent) a compounded drug product out of the State in which the drug was compounded.

Final Standard MOU app. A at 12. In other words, FDA has defined the term "distribution" to include interstate dispensing, thereby allowing FDA to limit the amount of compound drug products a pharmacy dispenses *and* distributes interstate.

71. The Final Standard MOU then places a 50-percent threshold on all compounded drugs that leave a pharmacy by defining "inordinate amounts of compounded human drug products" as follows:

> **Inordinate Amounts**: A pharmacy has distributed an inordinate amount of compounded human drug products interstate if the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of: (i) the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year.

Final Standard MOU app. A at 12 (footnote omitted).

72. States that sign the Final Standard MOU must, on an annual basis, identify, "using surveys, reviews of records during inspections, data submitted to an Information Sharing Network, or other mechanisms available to the [State], pharmacies that distribute inordinate amounts of compounded human drug products interstate." Final Standard MOU § III.b.2 at 6. If a pharmacy is identified as having distributed inordinate amounts interstate, States must provide additional information to FDA, including:

> a. [T]he total number of prescription orders for sterile compounded human drugs distributed interstate;

b. [T]he names of States in which the pharmacy is licensed;

c. [T]he names of States into which the pharmacy distributed compounded human drug products; and

d. [W]hether the State inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients.

Final Standard MOU § III.b.3 at 6.

73. In addition, for those States that have identified a pharmacy distributing inordinate amounts, the Final Standard MOU provides that within 30 business days of such identification, States must notify FDA and provide FDA with a lengthy list of information about that particular pharmacy, including:

i. Name and address of the pharmacy that distributed inordinate amounts of compounded human drug products interstate;

ii. The number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year;

iii. The number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year;

iv. The total number of prescription orders for compounded human drug products distributed interstate during that same calendar year;

v. The total number of prescription orders for sterile compounded human drug products distributed interstate during that same calendar year;

vi. The names of States in which the pharmacy is licensed and the names of States into which the pharmacy distributed compounded human drug products during that same calendar year; and

vii. Whether the [insert State Board of Pharmacy or other appropriate State agency] inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid

> prescription orders for individually identified patients during that same calendar year.

Final Standard MOU § III.c.1.b at 8 (brackets in original).

74. The Final Standard MOU does not specify what FDA intends to do with such information obtained from States, such as whether FDA will conduct increased inspections or take enforcement action against pharmacies so identified.

75. In conjunction with issuing the Final Standard MOU, FDA announced it will wait 365 days before enforcing Section 503A's 5-percent limitation on compounding pharmacies located in non-MOU States. Final Standard MOU Notice, 85 Fed. Reg. at 68,082.

76. FDA's own estimates of how many States will not sign an MOU under Section 503A have fluctuated from 25 States to five States. *Compare* Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the States and the Food and Drug Administration; New Proposed Draft; Availability, 80 Fed. Reg. 8874, 8879 (Feb. 19, 2015) (estimating 25 States will not sign an MOU), *with* Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act, 85 Fed. Reg. 28,961, 28,962 (May 14, 2020) (estimating five States will not sign an MOU).

77. Moreover, even for those States that enter into the Final Standard MOU, FDA estimates that at least one State will terminate its participation per year. *See* 85 Fed. Reg. at 28,963. The Final Standard MOU may be terminated by a State upon just 60 days' notice. Final Standard MOU § VI.a at 10.

The Final Standard MOU Constitutes Final Agency Action Causing Current and Future Injury to Plaintiffs

78. The Final Standard MOU constitutes "final agency action" within the meaning of 5 U.S.C. § 704.

79. A significant percentage of Plaintiffs' businesses involve interstate dispensing of compounded drugs.

80. If the States in which Plaintiffs reside decline to enter into the Final Standard MOU, Plaintiffs will be severely restricted in their ability to dispense compounded medications outside of their respective home States to patients who rely on these medications.

81. Among other things, if only 5 percent of Plaintiffs' compounding practices can take place interstate, Plaintiffs will have no choice but to cut staff, downsize pharmacy facility size, space, and equipment, and eliminate most, if not all, compounding, thereby resulting in significant lost revenue.

82. Plaintiffs are nationally recognized compounding pharmacies and are sought after by prescribers and patients alike throughout the United States because they provide specialized compounded medications for unique patient populations. If Plaintiffs are severely restricted in their ability to engage in interstate dispensing, or if they are forced to eliminate their compounding businesses, patients will not be able to obtain the compounded medications they need. Compounding pharmacies are not interchangeable. They are often highly specialized, and patients cannot simply move their prescriptions to a different compounding pharmacy if the pharmacy of their choice eliminates compounding.

83. Even if Plaintiffs reside in a State that signs the Final Standard MOU, Plaintiffs will suffer increased regulatory burden and economic harm. In order for States to satisfy their data-gathering and reporting requirements under the Final States MOU, many States will pass that burden on to pharmacies themselves. All pharmacies located in States that sign the Final Standard MOU will, at a minimum, have to gather and provide information to their home States

in order for those States to establish whether such pharmacies have distributed compounded drugs in what FDA deems to be inordinate amounts.

84. If such pharmacies are found to have reached the 50-percent threshold established by the Final Standard MOU, that data-gathering and reporting increases significantly. Given the extent of information required under the Final Standard MOU, pharmacies will need to hire additional staff to handle the data-gathering and reporting requirements, and/or Plaintiffs will be forced to reallocate staff whose time would be better served focusing on the preparation of compounded medications to meet patient needs.

85. The Final Standard MOU does not state what will happen to pharmacies that are deemed to have surpassed the 50-percent threshold. This regulatory uncertainty, coupled with the increased data-gathering and reporting burden, may deter pharmacies, including Plaintiffs, from reaching the 50-percent threshold, thereby reducing patient access to compounded medication when pharmacies curtail interstate dispensing of compounded drugs.

86. Even if Plaintiffs reside in a State that signs the Final Standard MOU, it permits a State to terminate its participation with just 60 days' notice. State pharmacy board and licensing departments often change on an annual basis, which would mean a State's position on whether to continue its participation could change annually. Plaintiffs have no control over a State's decision to terminate its participation under the Final Standard MOU. As a result, Plaintiffs' economic livelihoods, and patient access to the medications they dispense, could change in just two months.

CAUSES OF ACTION

COUNT I:
FDA's Issuance of the Final Standard MOU Violates Section 503A(c)(1)'s Command that the Secretary Shall Issue Regulations Implementing Section 503A

87. Plaintiffs repeat and reallege paragraphs 1–86 as if set forth fully herein.

88. Pursuant to 5 U.S.C. § 706(2)(D), a reviewing court shall hold unlawful and set aside agency action found to be "without observance of procedure required by law."

89. Section 503A(c)(1) commands that "[t]he Secretary shall issue regulations to implement this section."

90. The Secretary and FDA have never promulgated regulations to implement Section 503A in its entirety, including the statute's requirements regarding "inordinate amounts," "distribution," "distributed," "distributes," or "dispensed."

91. The Secretary and FDA cannot circumvent Section 503A's "shall issue regulations" command through the guise of the Final Standard MOU.

92. Accordingly, the Final Standard MOU is procedurally invalid and should be set aside in its entirety.

COUNT II:
The Final Standard MOU Is a Procedurally Improper Substantive Rule

93. Plaintiffs repeat and reallege paragraphs 1–86 as if set forth fully herein.

94. Pursuant to 5 U.S.C. § 706(2)(D), a reviewing court shall hold unlawful and set aside agency action found to be "without observance of procedure required by law."

95. The Final Standard MOU is a substantive rule for which prior notice-and-comment rulemaking was required by 5 U.S.C. § 553.

96. However, FDA issued the Final Standard MOU without complying with various procedural requirements Congress has imposed on agencies seeking to promulgate substantive

rules. These requirements include the Regulatory Flexibility Act's requirement that agencies prepare an analysis of a final rule's impact on small entities. 5 U.S.C. § 604(a).

97. Accordingly, the Final Standard MOU is procedurally invalid and should be set aside in its entirety.

COUNT III:
The Final Standard MOU Exceeds FDA's Statutory Authority

98. Plaintiffs repeat and reallege paragraphs 1–86 as if set forth fully herein.

99. Pursuant to 5 U.S.C. § 706(2)(C), a reviewing court shall hold unlawful and set aside agency action found to be "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right."

100. The Final Standard MOU exceeds FDA's statutory authority under Section 503A by defining "distribution of compounded human drug products interstate" and "inordinate amounts" to include interstate dispensing of compounded human drug products.

101. Accordingly, those provisions of the Final Standard MOU should be set aside.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court:

A. Enter judgment in Plaintiffs' favor;

B. Hold unlawful and set aside the Final Standard MOU in its entirety because its issuance by FDA constitutes agency action without observance of procedure required by law;

C. Hold unlawful and set aside those portions of the Final Standard MOU whereby FDA defines "distribution of compounded human drug products interstate" and "inordinate amounts" to include interstate dispensing of compounded human drug products because both definitions exceed FDA's statutory authority under Section 503A;

D. Award Plaintiffs' their costs and attorney's fees incurred in this action pursuant to 28 U.S.C. § 2412; and

E. Award Plaintiffs such other relief as the Court deems just and proper.

Dated: October 27, 2020

Respectfully submitted,

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* *Motion for Admission Pro Hac Vice to Be Filed*