IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WELLNESS PHARMACY, INC., *et al.*, Plaintiffs, v. NORRIS COCHRAN,* *et al.*, Defendants.	Civil Action No. 20-3082 (CRC)

UNOPPOSED MOTION OF ALLIANCE FOR PHARMACY COMPOUNDING, CENTRAL ADMIXTURE PHARMACY SERVICES, INC., PROFESSIONAL COMPOUNDING CENTERS OF AMERICA, NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, NUTRISHARE, INC., AND MEDISCA USA FOR LEAVE TO FILE AMICUS CURIAE BRIEF IN SUPPORT OF PLAINTIFFS

Pursuant to Local Civil Rule 7(o), the Alliance for Pharmacy Compounding, Central Admixture Pharmacy Services, Inc., Professional Compounding Centers of America, National Community Pharmacists Association, Nutrishare, Inc., and Medisca USA ("Proposed Amici") respectfully request leave to file an amicus curiae brief in support of Plaintiffs' Motion for Partial Summary Judgment, ECF No. 12. Good cause exists to grant the requested relief, in support of which Proposed Amici state as follows:

1. The Alliance for Pharmacy Compounding ("APC") is a national trade association advocating on behalf of millions of patients who benefit from compounded medications. APC's

* Pursuant to Rule 25(d) of the Federal Rules of Civil Procedure, the successors of the two public-officer defendants named in this action are automatically substituted as parties: (1) Norris Cochran, in his official capacity as Acting Secretary of Health and Human Services, is substituted for Alex M. Azar II; and (2) Janet Woodcock, M.D., in her official capacity as Acting Commissioner of Food and Drugs, is substituted for Stephen M. Hahn, M.D.

members are compounding pharmacists, pharmacy technicians, educators, students, researchers, and suppliers, but APC also represents the interests of physicians, veterinarians, nurse practitioners, and other medical professionals. APC works to ensure the availability of—and access to—customized medications for patients for whom manufactured drugs are not suited. Its mission is to preserve the rights of physicians to prescribe, of pharmacists to prepare, and of patients to take personalized medication solutions to meet their unique healthcare needs for a range of issues, including women's health, autism, oncology, dermatology, ophthalmology, pediatrics, and others.

2. Central Admixture Pharmacy Services, Inc. ("CAPS") is the nation's largest network of outsourcing admixture pharmacies. CAPS' network includes 22 regional pharmacies across the United States that dispense needed customized, patient-specific compounded medications in accordance with Section 503A of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, Pub. L. No. 75-717, 52 Stat. 1040 (1938). 21 U.S.C. § 353a. CAPS provides both custom and standard solutions to hospital and outpatient providers pursuant to individual prescriptions nationwide from its locations across the United States. Importantly, CAPS is the only national compounder of neonatal parenteral nutrition ("PN"), providing over 70,000 interstate, specialized, compounded PN solution prescriptions annually.

3. Professional Compounding Centers of America ("PCCA") supports the creation of personalized medicine and innovative products that make a significant difference in patients' lives. A complete resource for compounding pharmacists and health systems, PCCA provides high-quality products, education, and support to a network of more than 8,000 compounding pharmacies worldwide.

4. Founded in 1898, the National Community Pharmacists Association ("NCPA") is the voice for the community pharmacist, representing more than 21,000 pharmacies that employ 250,000 individuals nationwide. Community pharmacies are rooted in the communities where they are located and are among America's most accessible healthcare providers. According to the 2020 NCPA Digest, 49% of NCPA members provide compounding services and serve a vital role in meeting patient needs.

5. Nutrishare, Inc. ("Nutrishare") is a home-infusion pharmacy specializing in Home "TPN" (IV nutrition), or Total Parenteral Nutrition, for the past 30 years. Nutrishare's pharmacies are located in Sacramento, California and Louisville, Kentucky, and its patients are located in about 40 states scattered throughout the country including Hawaii and Alaska. Nutrishare's patients depend on its clinical and service expertise, which reduce adverse clinical outcomes. Most of its formulations are shipped out of state. Nutrishare's interstate services also meet patients' needs when they need to travel out of state for medical care otherwise. Over the past 30 years, Nutrishare has sent interstate over a million bags of TPN to patients, not one of which has been contaminated.

6. Medisca USA ("Medisca")—for over 30 years—has provided turnkey solutions to the pharmaceutical compounding industry and allied healthcare professionals worldwide. Through its global partners, Medisca supports prescribers, pharmacists, and pharmacy technicians engaged in pharmacy compounding and personalized medicine by offering quality products, educational trainings, and technical support services.

7. Proposed Amici and their respective members, as applicable, have a substantial interest in the lawful implementation of Section 503A of the FDCA, as Proposed Amici are composed of specialty compounders, traditional compounding pharmacies, compounding

suppliers and service providers, and prescribers of compounded medicines that are dispensed interstate to patients throughout the United States. All six of the Proposed Amici advocate on behalf of patients that rely on compounding services for critical, life-saving treatments that are otherwise unavailable—and unlikely to ever be available—commercially, or solely within the confines of each state such that they are available through intrastate shipments or distributions.

8. Proposed Amici submit this brief to address the U.S. Food and Drug Administration's ("FDA" or the "Agency") continuing refusal to regulate the compounding industry pursuant to lawfully implemented regulations. Historically, FDA has governed compounding through a series of non-binding guidance and interpretive materials. FDA seeks to continue this practice by unlawfully limiting compounding and access thereto through its use of guidance and interpretative materials in total disregard of the required procedural requirements imposed by the administrative rulemaking process required by Section 503A, 21 U.S.C. § 353a(c), and the Regulatory Flexibility Act, Pub. L. No. 96-354, 94 Stat. 1164 (1980), 5 U.S.C. §§ 601-612.

9. FDA published a Final Memorandum of Understanding ("MOU") on October 27, 2020, 85 Fed. Reg. 68,074; this MOU is in fact a "rule" as defined under the Administrative Procedure Act ("APA"), 5 U.S.C. § 551 *et seq.*, Pub. L. No. 79-404, 60 Stat. 237 (1946), which, in turn, constitutes a "rule" under the Regulatory Flexibility Act. *See* 5 U.S.C. § 601(2) (defining "rule" in terms of an APA rulemaking). The effects of FDA's implementation of Section 503A through the promulgation of an MOU—without engaging in the required procedures set forth in Section 503A and the Regulatory Flexibility Act—extend beyond the scope of that MOU to substantially affect the interests of compounders, prescribers, and patients, including those in states that do not sign the MOU. FDA's decision to, yet again, govern the

compounding industry through something other than the regulations required by Section 503A imposes significant burdens on Section 503A compounders, patients, and prescribers without consideration of their affected rights—in particular compounders that are small businesses—including the denial of patient access to life-saving medications.

10. The MOU also conflates the terms "dispensing" and "distribution" to have the same meaning, in stark contrast to state laws addressing these terms. The memorandum of Proposed Amici addresses the difference between state laws, all of which are consistent with each other and have traditionally regulated pharmacy compounding, the federal law (FDCA § 503A(b)(3)(B)), and the MOU.

11. Further, Proposed Amici are concerned more generally about the impact of the lack of legal certainty in the compounding industry on Proposed Amici's legal rights and responsibilities. This is more than a single, discrete issue limited to the publication of the MOU. Instead, it is representative of FDA's ad hoc approach to regulating compounding notwithstanding the rulemaking provisions of the APA, related sections of the Regulatory Flexibility Act, and Section 503A's plain mandate requiring FDA to undertake rulemaking. As such, the proposed amicus brief provides the Court with additional insight into the impact of both the MOU *and* the improper proliferation of a violative compounding regulatory scheme on prescribers and compounders throughout the United States.

12. As prescribers, traditional compounding pharmacies, specialty compounders, and compounding suppliers and service providers, Proposed Amici are uniquely vulnerable to the consequences suffered by compounding pharmacies located in those states that do not enter into the MOU with FDA. APC, for example, is dedicated to facilitating and preserving access to compounded medicines. Because its membership likely comprises a majority of the traditional

pharmacy compounding industry, these members are directly affected by the limitations set forth in the MOU effectively precluding interstate distribution and interstate dispensing of compounded medications in non-MOU states. Similarly, NCPA advocates for its thousands of pharmacy members nationwide, many of whom provide compounding services, and is dedicated to ensuring the ability of independent pharmacists to compete in a fair marketplace. CAPS, comprised of its many specialty pharmacies throughout the country, provides, among other formulations, compounded medications for a very specific and unique population: neonatal patients. Without the ability to dispense (greater than 5% of its compounded medications) interstate, CAPS interstate neonatal patients will only have access to approximately 44-49% of the compounded neonatal PN solutions prescribed. Given that so few facilities compound PN solutions, neither *intrastate* compounding pharmacies nor pharmaceutical companies have the expertise to fill the remaining 51% void, which will likely leave infant patients without access to needed medications. Nutrishare also provides specialized parenteral nutrition for home use and provides its prescription formulations to patients across the United States. And, PCCA supports the creation of personalized medicines for patients by compounding pharmacies across the United States by supplying ingredients, formulations, innovative products, education, and consulting expertise. Finally, as a supplier, Medisca provides active pharmaceutical ingredients to thousands of compounding pharmacies, which, in turn, treat patients located across the country. Customers of these amici in non-MOU states (i.e., states that do not sign the MOU) will be adversely affected by the resulting limitations on interstate distribution and dispensing of compounded medications.

13. All of these interests are distinct from Plaintiff Pharmacies, as the Proposed Amici encompass a significant number of industry participants—including certain patient

populations and providers—not within the plaintiff group that FDA may not have fully considered when finalizing the MOU. Indeed, a significant consideration in evaluating any agency action is the impact of the imposition of a requirement not only on regulated industry, but also on the general public. FDA's mission is first and foremost to protect the public health by assuring both the safety and efficacy of drugs, but also to facilitate access. FDA must ensure that the promulgation of mechanisms to enforce provisions of Section 503A occur as Congress intended—through appropriately issued regulations. Yet, FDA refuses to use the appropriate administrative pathway, as it has refused to do so over its decades-long history regulating compounding through non-binding guidance documents. The parties have not fully addressed this history nor have they fully addressed the impact of the MOU on patient access and specialty pharmacies. Those views, including further explanation of the significant burden imposed by FDA's improper restraint on access, should be considered by this Court, in addition to whether the narrowing of the Section 503A statutory exemptions, as set forth in FDA's MOU, constitutes a rulemaking requiring a regulatory flexibility analysis. Because Proposed Amici can provide insight to the Court that is not found in the parties' briefs—specifically the viewpoint of specialty pharmacies, patients, and suppliers and service providers—the matters asserted in the Proposed Amicus Curiae Brief are relevant to the disposition of the case. *See District of Columbia v. Potomac Elec. Power Co.*, 826 F. Supp. 2d 227, 237 (D.D.C. 2011) (permitting proposed intervenors to participate as amici curiae because "the Court finds that it may benefit from their input" due to their "relevant expertise and a stated concern for the issues at stake in this case.")

14. In accordance with Local Civil Rule 7(o)(2), on February 12, 2021, undersigned counsel advised counsel for the parties of Proposed Amici's intent to seek this Court's

permission on or before February 12, 2021, to submit an amicus brief in support of Plaintiffs' Motion for Partial Summary Judgment. Counsel for the parties promptly advised the undersigned that they did not oppose or took no position on Proposed Amici's request.

15. WHEREFORE, the Proposed Amici respectfully assert that this Court should grant them permission to submit an amicus brief in this case. In accordance with Local Civil Rule 7(o)(2), a proposed order granting the requested relief is submitted as Exhibit 1.

Dated: February 17, 2021

Respectfully submitted,

By: /s/ Karla L. Palmer

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CERTIFICATE OF SERVICE

I, Karla L. Palmer, hereby certify that I caused the foregoing Motion for Leave to File Brief of Amicus Curiae and supporting documents to be served via the District Court's Electronic Case Files (ECF) System upon counsel for the parties:

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This 17th day of February 2021.

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