UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF COLUMBIA

ALLIANCE FOR NATURAL HEALTH USA,
211 N. Union St., Suite 100,
Alexandria, VA 22314, and

MEDITREND, INC.,
4820 Eubank Blvd.,
Albuquerque, NM 87111,

Plaintiffs,

vs.

UNITED STATES OF AMERICA
c/o Attorney General of the United States,
U.S. Department of Justice,
950 Pennsylvania Avenue, NW,
Washington, DC 20530-0001;

U.S. FOOD AND DRUG ADMINISTRATION,
10903 New Hampshire Avenue, Silver Spring, MD 20993; and

ROBERT M. CALIFF,
Commissioner of the
U.S. Food and Drug Administration,
10903 New Hampshire Avenue, Silver Spring, MD 20993,

Defendants.

Civil Action No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF RE:

(1) VIOLATIONS OF 5 U.S.C. § 706(2)(A)(C) & 5 U.S.C. § 553(b); AND

(2) VIOLATION OF THE FIFTH AMENDMENT DUE PROCESS CLAUSE AND 5 U.S.C. § 706(2)(B)

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

I. INTRODUCTION

1. Plaintiffs Alliance for Natural Health USA ("ANH") and Meditrend, Inc. ("Plaintiffs"), by counsel, hereby submit this Complaint against Defendants Robert M. Califf, Commissioner, United States Food and Drug Administration (in his official capacity); the United States Food and Drug Administration ("FDA"); and the United States of America.

2. Homeopathy is a medical art and science involving medical dilutions that assist the body's self-healing mechanisms. The United States Congress recognized homeopathy as a medical art and the Food Drug and Cosmetic Act ("FDCA") includes particular provisions that uniquely protect that art. *See, e.g.*, 21 U.S.C. 321(g)(1)(A) (recognizing homeopathic products as "drugs"); *id.* at §§ 351(b), 352(g) (adopting requirements of the Homoeopathic Pharmacopoeia of the United States when a product is labeled and offered for sale as a homeopathic drug). Similarly, the FDA has exempted homeopathic drugs from certain drug requirements and has treated them differently than conventional drugs. *See* 21 C.F.R. § 211.137(e) (exempting homeopathic drugs from expiration dating requirements); *id.* at § 211.166(c) (imposing different stability testing requirements on homeopathic drugs).

3. Homeopathy is a widely used practice, recognized by the World Health Organization,[1] dating back to the Greek physician Hippocrates, and refined thereafter through hundreds of years of medical practice, prescription, and patient experience. Millions of consumers use homeopathic drug products every day

[1] WHO, 2019. "WHO Report on Traditional and Complementary Medicine", 2019. WHO, Geneva. Available at https://iris.who.int/bitstream/handle/10665/312342/9789241515436-eng.pdf?sequence=1 (last accessed Oct. 15, 2024).

worldwide. Homeopathic drugs have a well-established safety record, and are largely available as over-the-counter ("OTC") preparations with very few adverse event reports received by the FDA annually in stark contrast to conventional drugs.

4. The Federal, Food, Drug, and Cosmetic Act of 1938 included homeopathic drugs in the general definition of "drug" products regulated by the FDA. *See* 21 U.S.C. § 321(g).[2] In recognition of inherent differences between homeopathic and conventional drugs and the extremely low incidence of adverse events associated with homeopathics compared to conventional drugs, the FDA permitted homeopathic product sales for over eighty years without requiring pre-market drug approval under 21 U.S.C. § 355 as is required for conventional drugs. Most homeopathic products have therefore been manufactured and marketed under standards and monographs in the Homoeopathic Pharmacopoeia of the United States (HPUS) for decades.

5. Homeopathics are not suited to meet the same standards as are applied to conventional drugs because they rely on fundamentally different physico-chemical and energetic properties, as well as different mechanisms of action and measures of clinical usefulness. Moreover, homeopathics lack patent protection and, so, cannot recoup the cost of conventional drug development and approval (now estimated at between $1-2 billion). The FDA filing fee alone for conventional drug approval is a seven-figure sum, beyond the means of unpatented homeopathic

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[2] The primary author of the 1938 FDCA was Royal S. Copeland, a homeopathic physician, ophthalmologist, former President of the American Institute of Homeopathy, and President of the New York City Board of Health. *See* N.Y. Medical College, Philip Capozzi, M.D., Library, Library Research Guides, NYMC Biographies, Copeland, Royal S., M.D., 1868-1938, https://guides.library.nymc.edu/RoyalCopeland (last accessed Oct. 15, 2023); Eric Foxman, *History of Homeopathy, Royal Samuel Copeland, Former U.S. Senator*, https://theaahp.org/articles/royal-s-copeland-we-know-the-name-but-do-we-know-the-man/ (last accessed Oct. 15, 2024). Copeland was a United States Senator from New York, and he sponsored the 1938 FDCA. *See id.* The Act formally recognized—and thus protected—homeopathic drugs.

products. *See* 87 Fed. Reg. 61063, 61064 (Oct. 7, 2022) (announcing Prescription Drug User Fee Amendments ("PDUFA") rates for fiscal year 2023, which includes a $1,621,013 application fee when no clinical data is required and a $3,242,026 application fee when clinical data is required).

6. After nearly 80 years of limited regulation, the FDA recently altered its policy regarding homeopathic drug products. In 2017, the FDA issued a draft guidance entitled, "Drug Products Labeled as Homeopathic," announcing the agency's shift to a so-called "risk-based approach." *See* 82 Fed. Reg. 60403 (Dec. 20, 2017) (Notice of availability of Draft Guidance). Despite decades of extensive and safe use of homeopathic OTCs, the FDA speculated without any proof that homeopathic drugs were endemically or inherently unsafe citing rare, isolated instances of mismanufacture as a basis for concluding that homeopathics posed a safety risk. The FDA issued its final guidance on December 6, 2022 (hereinafter "Final Guidance"),[3] which coincided with FDA's withdrawal of Compliance Policy Guide (CPG) 400.400 (hereinafter "CPG 400.400").[4] FDA now takes the position that, "absent a determination that a homeopathic drug product is not a 'new drug' under section 201(p), all homeopathic drug products are subject to the premarket approval requirements in section 505 of the FD&C Act[.]" *Id.* (explaining that there "are currently no homeopathic drug products that are approved by the FDA").

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[3] FDA, Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research. "Homeopathic Drug Products Guidance for FDA Staff and Industry." December 2022. Docket Number FDA-2017-D-6580. *Available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/homeopathic-drug-products-guidance-fda-staff-and-industry (last accessed Oct. 15, 2024).

[4] The CPG 400.400 governed U.S. sale of homeopathic drug products from 1988 to October 24, 2019, when it was withdrawn because it was deemed "inconsistent with the agency's risk-based approach to regulatory and enforcement action"; *see* https://www.fda.gov/news-events/press-announcements/statement-agencys-efforts-protect-patients-potentially-harmful-drugs-sold-homeopathic-products (last accessed Oct. 15, 2024).

7. By concluding in the Final Guidance that all homeopathic drugs are subject to premarket drug approval requirements, the FDA has foreclosed practical channels to market OTC homeopathic drugs. Those products are now saleable only at the whim of the FDA because the agency has provided homeopathic drugs no viable regulatory pathway to lawful marketing. In other words, FDA has rendered the FDCA's provisions recognizing the legality of homeopathic drugs of no legal force or effect whenever FDA agents in the exercise of unbridled discretion deem any single homeopathic product deserving of enforcement. That change follows decades of settled regulation and accepted pathways to market under CPG 400.400, which the Final Guidance revoked.

8. The FDA's latest policy conflicts with Congressional intent to relax—not heighten—the regulatory burdens on homeopathic drugs, particularly OTC products. Congress addressed OTC drug regulation in the Coronavirus Aid, Relief, and Economic Security Act of 2020 ("CARES Act"). In the CARES Act, Congress specifically and unequivocally exempted homeopathic OTC products from conventional drug pre-market approval requirements based on the rationale that homeopathic drugs are a "unique and separate category of drugs." *See* CARES Act § 3853 (citing and incorporating 37 Fed. Reg. at 9466 ¶25).

9. By treating OTC homeopathic drugs the same way as conventional drugs, the FDA unlawfully merges homeopathic drug with conventional drug regulation in direct contravention of the CARES Act. By regulating homeopathic drugs under the same framework as conventional drugs, the FDA threatens irreparable injury to the $6.2 billion homeopathic industry in the United States. *See* Precedence Research, *Homeopathic Products Market (By Product: Dilutions, Tincture, Tablets, and Others; By Application: Analgesic and Antipyretic, Respiratory, Neurology, Others; By Source: Animals, Plants, and Minerals) - Global*

Industry Analysis, Size, Share, Growth, Trends, Regional Outlook, and Forecast 2021 – 2030 (Nov. 2021).[5]

10. Plaintiffs ANH, a non-profit advocacy organization that defends patients' and consumers' rights of access to healthcare and health information, and Meditrend, a homeopathic drug company, bring this action challenging (a) FDA's denial of a Citizen Petition filed by the Americans for Homeopathy Choice Foundation ("AHCF"); and (b) the agency's regulation of OTC homeopathic drugs under Section 355 of the FDCA (21 U.S.C. § 355) and the Final Guidance. *See* Exh. A (AHCF Petition, Dkt. No); *see also* Exh. B (FDA Guidance, "Homeopathic Drug Products, Guidance for FDA Staff and Industry" (Dec. 2022)).

11. Under 5 U.S.C. § 706, consistent with the CARES Act, the Court should hold homeopathics not subject to Section 355 drug pre-market approval. Meditrend asks the Court to: (1) declare that homeopathic drugs marketed subject to an HPUS monograph published prior to 1938 are not "new" drugs under 21 U.S.C. § 321(p); (2) declare that OTC homeopathic drugs are exempt from "new" drug pre-market approval requirements, pursuant to 21 U.S.C. § 321(p); (3) enjoin FDA from taking enforcement action against OTC homeopathic products on grounds that such products require pre-market drug approval under 21 U.S.C. § 355; and (4) declare that FDA's Final Guidance violates the Due Process Clause of the Fifth Amendment.

II. JURISDICTION AND VENUE

12. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question jurisdiction) and 28 U.S.C. § 1346 (jurisdiction where the United States is a defendant).

13. The Court has subject matter jurisdiction under 5 U.S.C. § 706(2)(A) and (C).

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[5] *Available at* https://www.precedenceresearch.com/homeopathic-products-market (last accessed Oct. 15, 2024).

14. The Plaintiffs' requested relief is authorized under 28 U.S.C. § 2201 (declaratory relief) and 28 U.S.C. § 2202 (further relief), as well as 5 U.S.C. § 702 (Administrative Procedure Act).

15. Venue is properly vested in this Court under 28 U.S.C. § 1391(e) because the Defendants reside in this district and a substantial part of the events giving rise to this action occurred in this district.

III. PARTIES

A. Plaintiff

16. Plaintiff ANH, based in Alexandria, Virginia, works nationally to promote sustainable approaches to healthcare and defends freedom of choice in healthcare through lasting policy change and public education. ANH protects access to healthcare by lobbying Congress and state legislatures; acting as a government watchdog; filing comments in rulemakings; educating the public, press, and decision-makers about threats to consumer access to healthcare options, and initiating suits to ensure access.

17. Plaintiff Meditrend is a homeopathic drug distributor based in Albuquerque, New Mexico. For over four decades, Meditrend, through its owner Richard D. Savage, has been engaged in the development and distribution of innovative health solutions, including OTC products marketed in the United States as homeopathic drugs. Meditrend uses contract manufacturers to make its homeopathic drug products. Meditrend's homeopathic business is directly and adversely affected by the FDA's altered approach to regulation of OTC homeopathic products, including through the FDA's refusal to grant the AHCF's petition calling for regulation of homeopathic drugs outside of the pre-market approval process for conventional drugs. OTC homeopathic drug distributors, like Meditrend, face legal uncertainty following the FDA's decision to require pre-market approval for all homeopathic drug products. The FDA's stated homeopathic drug policy declares all

such products presently unlawful if sold—subject only to the FDA's "enforcement discretion." The FDA's homeopathic policy provides no viable lawful means for the continued manufacture, marketing, sale, and distribution of such products. The AHCF petition, if granted, would have provided clear standards for the lawful sale of OTC homeopathic products outside the context of pre-market approval used for conventional drugs. Meditrend is an aggrieved party under the meaning of 5 U.S.C. § 702.

B. Defendants

18. Defendant Robert M. Califf is the Commissioner of the United States Food and Drug Administration ("FDA") and is sued here in his official capacity. The Commissioner is responsible for FDA's administration of the federal Food, Drug, and Cosmetic Act ("FDCA").

19. Defendant United States created, organized, and operates the FDA as an administrative agency within the executive branch of the federal government.

IV. FACTS

A. FDA Regulation of Homeopathic Drugs

20. Homeopathy is a medical practice that uses highly diluted substances that are believed to stimulate and strengthen the body's self-healing ability. When produced by, and applied under, governing scientific principles, homeopathic drugs do not treat disease or the symptoms of disease directly, they are intended to work on multiple systems to help the body re-establish homeostatic norms (good health).

21. One of the central principles of homeopathy is that, when properly selected and prepared, only minute amounts of a drug, or even its energetic imprint, are needed to cure, treat, mitigate, and prevent various diseases.

22. The FDCA defines "drug" to include, *inter alia*, "articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them."

21 U.S.C. § 321(g)(1)(A). A conventional "new drug" requires an approved drug application filed under Section 355(b) or 355(j) before it can be marketed, i.e., introduced or delivered for introduction into interstate commerce. *See id.* at § 355(a).[6] The FDA has yet to approve a new drug application for a homeopathic drug. Nor has FDA evaluated whether any homeopathic drug is generally recognized as safe and effective ("GRAS/E").

23. Historically, OTC drugs have had pathways to market separate from "new" drugs. Those pathways include reliance on published monographs that allow OTC drugs to be marketed without proceeding through the costly new drug pre-market approval process. OTC monograph drugs have relaxed pre-market regulatory burdens because the products present little to no risk to patient health and safety in contrast to conventional prescription drugs. *See, e.g.,* 21 U.S.C. § 355h(a)(1)-(2) (an OTC drug satisfying the requirements of this section is deemed to be generally recognized as safe and effective under section 21 U.S.C. § 321(p)(1), not a "new drug" under section 321(p), and is not subject to section 353(b)(1)); 21 C.F.R. Part 333 (final OTC monograph establishing the conditions under which OTC topical acne drug products are GRAS/E, and which was later incorporated into Final Administrative Order OTC000013 on Nov. 23, 2021, OTC Monograph M006).

24. The FDA has a long history of exempting homeopathic drugs from conventional "new" drug regulations. Beginning in 1972, the FDA made GRAS/E determinations for several categories of OTC drugs pursuant to its OTC Drug Review. *See* 37 Fed. Reg. 9464 (May 11, 1972); 21 C.F.R. Part 330. The FDA formed advisory panels for OTC drugs under review. *See* 21 C.F.R. § 330.10; *see also* FDA, *Over-the-Counter (OTC) Drug Review, OTC Monograph Reform in the*

[6] A "new drug" does not include, however, a drug that, at any time prior to June 25, 1938, was subject to the Food and Drug Acts of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning conditions of use. *See* 21 U.S.C. § 321(p)(1).

CARES Act, Status of Existing OTC Monograph Products.[7] FDA published advanced notices of proposed rulemaking ("ANPR") in the Federal Register. *See, e.g.*, 42 Fed. Reg. 35346 (July 8, 1977) (ANPR for internal analgesic drug products). The ANPRs contained proposed monographs for OTC drugs, and FDA published tentative and final monographs for OTC drug categories. Drugs manufactured and labeled in compliance with an applicable OTC monograph were deemed GRAS/E and, as a result, were not required to obtain approved "new" drug status. *See* 21 U.S.C. § 321(p) (the term "new drug" does not include GRAS/E drugs).

25. The FDA excluded homeopathic drug products from this OTC drug review, deemed homeopathic drugs to be a separate category, and deferred its evaluation of those products because of the "uniqueness of homeopathic medicine[.]" *See* 37 Fed. Reg. at 9466 ("Because of the uniqueness of homeopathic medicine, the Commissioner has decided to exclude homeopathic drugs from this OTC drug review and to review them as a separate category at a later time after the present OTC drug review is complete").[8]

26. The FDA has stated repeatedly that homeopathic drugs, because of their unique properties, were not to be regulated in the same manner as conventional drugs. For example, in a 1988 article published in "FDA Consumer" magazine,[9] the agency wrote that homeopathic drugs "are exempt from the requirements of the Federal Food, Drug, and Cosmetic Act that drugs must be proven safe and effective before they can be marketed." Exh. C (*FDA Consumer* article). The FDA similarly explained at the time, in a related Talk Paper, that homeopathic products were "exempted" from FDA review. *See* Exh. D (Sept. 15, 1988 FDA Talk Paper).

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[7] *Available at* https://www.fda.gov/drugs/over-counter-otc-nonprescription-drugs/over-counter-otc-drug-review-otc-monograph-reform-cares-act (last accessed Oct. 15, 2024).

[8] The CARES Act memorialized that language when Congress ratified this clause as part of its OTC drug legislation.

[9] FDA Consumer was a magazine published by the FDA from 1967 through 2007.

27. The FDA continues to publish content for consumers online indicating that homeopathic drugs are not subject to the FDA's drug approval requirements. For example, the FDA continues to host video content explaining that homeopathic products are "sold without FDA review for safety or effectiveness…"[10]

28. Because homeopathic OTC drugs[11] were exempt from the conventional OTC drug review, those products were also excluded from certain pathways to market. Therefore, instead of evaluating homeopathic drugs under its OTC Drug review, in 1988 the FDA exercised its enforcement discretion and issued a compliance policy that established conditions under which homeopathic drugs could "ordinarily" be marketed without an approved new drug application, so long as the homeopathic drugs complied with certain requirements for labeling, manufacturing, and registration. *See* Compliance Policy Guide 7132.15, § 400.400 (1988) ("CPG 400.400").

29. The CPG 400.400 "specified the regulatory duties of manufacturers of homeopathic drugs and thus had legal consequences[.]" *See MediNatura, Inc. v. Food & Drug Admin.*, 496 F. Supp. 3d 416, 437-38 (D.D.C. 2020), *aff'd,* 998 F.3d 931 (D.C. Cir. 2021). That CPG document had the force of law thereby providing homeopathic drug manufacturers with pathways to lawfully market homeopathic drugs without undergoing "new drug" review reserved for conventional drugs. *See id.* at 931 ("By its own terms, the [CPG 400.400] thus pertains to the affirmative 'regulation' of homeopathic drugs and not just … to the exercise of enforcement discretion."). The CPG "permitted homeopathic drug companies to market their

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[10] *See* https://www.fda.gov/drugs/information-drug-class/homeopathic-products#:~:text=On%20December%206%2C%202022%2C%20FDA,the%20greatest%20risk%20to%20patients (last accessed October 15, 2024). See also FDA video "Homeopathic Drugs Warning" at: https://youtu.be/KJ21SpriY78?si=e3v-h11sV2_k8uou (last accessed October 15, 2024).

[11] OTC homeopathic drugs, as compared to prescription drugs, are intended solely for self-limiting disease conditions amenable to self-diagnosis of symptoms and treatment.

products without premarket approval, in the ordinary course, so long as they complied with the various statutory and regulatory requirements incorporated in the Policy." *Id.* at 440.[12]

30. As explained below, the FDA withdrew CPG 400.400 and replaced it with a new "risk-based" approach to enforcement and regulatory actions concerning homeopathic drugs. *See* FDA, "Homeopathic Drug Products, Guidance for FDA Staff and Industry" (Dec. 2022).[13] That "risk-based" model stripped away standards in the CPG 400.400, and instead leaves homeopathic drugs in a standardless zone, completely subject to the arbitrary whim or caprice of FDA regulators under vague and amorphous policy language. The absence of reasonable standards capable of guiding the regulated class leaves homeopathic drug manufacturers in a state of complete legal uncertainty under constant threat of arbitrary FDA enforcement.

B. CARES Act and Changes to OTC Drug Regulation

31. Congress revised the OTC Drug Review process through the CARES Act, Pub. L. No. 116-136. Under the CARES Act, an administrative process replaced notice-and-comment rulemaking for identifying OTC drugs that FDA determined to be GRAS/E, as well as issuing, revising, and amending OTC monographs. *See* 21 U.S.C. §§ 352, 355g. In short, the CARES Act overhauled the entire OTC drug approval pathway to market.

32. The CARES Act affected OTC drugs that were subject to an ongoing, non-final monograph proceeding. It brought all those outstanding proceedings to a close.

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[12] While the *MediNatura* decision mentioned the CARES Act as part of its background summary of FDA regulation (*id.* at 427), the Court was not asked to rule on whether the CARES Act Section 3853 affected the FDA's authority to regulate OTC homeopathic products. That is the question at issue in this case.

[13] *Available at* https://www.fda.gov/media/163755/download (last accessed Oct. 15, 2024).

33. The CARES Act also defaulted certain OTC drug products into the category of "new drugs" requiring pre-market approval unless and until the Administrative Order pathway created new OTC monographs under which they could then be marketed without an approved new drug application. *See* 21 U.S.C. § 355h(b). Congress therefore streamlined the OTC drug pathway but definitively did not deem drugs already subject to those pathways to be unmarketable "new drugs" subject to Section 355 approval. *See id.* at § 355h(a)(5)-(6). In effect, drugs already subject to those pathways were grandfathered.

34. In particular, Congress exempted OTC homeopathic drug products from the new OTC drug pathways. The CARES Act eliminated FDA discretion to recategorize homeopathic OTC drugs by exempting them from the new OTC portals for conventional drugs. *See* Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, § 3853, Mar. 27, 2020, 134 Stat 281, 454 (2020). Thus, the new administrative order process for recognizing GRAS/E OTC drugs does not lawfully apply to homeopathic drugs.

35. **Section 3853 of the CARES Act reconfirms the FDA Commissioner's exclusion of homeopathic drugs in 1972 from the OTC drug review and thereby memorializes the FDA's findings at that time that homeopathic drugs were "unique" and needed regulation "as a separate category."** The text of Section 3853 reads:

> **SEC. 3853. DRUGS EXCLUDED FROM THE OVER-THE-COUNTER DRUG REVIEW.**
>
> (a) IN GENERAL.—Nothing in this Act (or the amendments made by this Act) shall apply to any nonprescription drug (as defined in section 505G(q) of the Federal Food, Drug, and Cosmetic Act, as added by section 3851 of this subtitle) which was excluded by the Food and Drug Administration from the Over-the-Counter Drug Review in accordance with the paragraph numbered 25 on page 9466 of volume 37 of the Federal Register, published on May 11, 1972.

> (b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to preclude or limit the applicability of any other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

Id.

36. Because FDA has not created a separate review process for determining when an OTC homeopathic drug is marketable, OTC homeopathic drugs lack regulatory standards to govern lawful marketing. Absent a rulemaking from FDA, those products lack a legal avenue to market.

37. Under the CARES Act, Congress established that it did not intend for OTC homeopathic drugs to be regulated in the same way as conventional drugs. Although Congress indicated that other provisions of the FDCA can still apply (*see* CARES Act § 3853(b)), the regulatory exclusion in Section 3853(a) is only necessary or reasonable if Congress intended to exclude OTC homeopathic drugs from the pre-market drug approval process used for conventional drugs, 21 U.S.C. § 355.

38. The FDA has authority and flexibility to find a homeopathic drug GRAS/E subject to conditions and standards appropriate to homeopathy. *See* 21 U.S.C. § 321(p)(1) (explaining that if experts, who are qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, generally recognize a drug as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, then the drug is not a "new drug"). In Section 3853, Congress plainly sought to relax regulatory burdens on homeopathic drugs by preventing FDA from applying conventional GRAS/E standards to such drugs. Evidence specific to the art of homeopathy, such as results of homeopathic provings or compliance with an HPUS monograph, have historically been used to establish that a homeopathic drug is safe and efficacious.

C. AHCF's Citizen Petition

39. In response to the FDA's 2019 Draft Guidance, the AHCF submitted a Citizen Petition to FDA on June 5, 2020. *See* Exh. A (Dkt. No. FDA-2020-P-1510, Document ID FDA-2020-P-1510-0002 (June 5, 2020) ("Citizen Petition")).[14]

40. AHCF's Citizen Petition asked FDA "to establish a final rule setting out regulations for the manufacture and sale in the United States of homeopathic drugs and homeopathic drug products…" *Id.* at 8.

41. AHCF requested that the FDA: (1) adopt its proposed regulations;[15] (2) recognize as safe and effective homeopathic drugs that are properly manufactured and labeled, and that are listed in, or are formally pending approval for listing in, the HPUS and its supplements or addendums; (3) prohibit any homeopathic drug not listed in, or formally pending approval for listing,[16] in the HPUS or its supplements and addendums from using the term homeopathic in any form that states or implies

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[14] *Available at* https://www.regulations.gov/document/FDA-2020-P-1510-0002 (last accessed Oct. 15, 2024).

[15] AHCF's proposed regulation: (1) defines terms, such as, but not limited to, "homeopathic drug," "homeopathic drug product," "product properly labeled as homeopathic," and "product improperly labeled as homeopathic"; (2) describes the conditions under which a homeopathic drug is deemed adulterated; (3) describes the conditions under which a homeopathic drug labeled "homoeopathic" is deemed misbranded; and (4) provides standards for homeopathic drugs and homeopathic drug products. Regarding the proposed standards, they are as follows: (a) a homeopathic drug must comply with applicable cGMPs and HPUS requirements; (b) a homeopathic drug, when properly manufactured and labeled and evaluated under an appropriate risk-based policy, is recognized as inherently safe; (c) an appropriate risk-based policy requires that the risk of homeopathic drugs and homeopathic drug products be evaluated in relation to risks presented by other products; and (d) absent a determination that any specific homeopathic drug or any specific homeopathic drug product is a new drug, the FDA will treat all homeopathic drugs as generally recognized as safe and effective for their intended use (GRAS/E), subject to compliance with the regulation's provisions addressing adulteration, misbranding, and cGMPs.

[16] The Citizen Petition requested a two (2) year grace period for products, which we assume means homeopathic active ingredients, to be proposed and accepted for review for addition to the HPUS, and an additional four (4) years for the applications to be accepted or rejected by a process certified by a recognized certifying organization such as the International Standards Organization (ISO) or the American National Standards Institute (ANSI).

the product is homeopathic; (4) ensure that any drug listed in, or formally pending approval for listing in, the HPUS and its supplements and addendums is manufactured in accordance with the HPUS and current good manufacturing practices ("cGMPs"); (5) if the FDA applies a risk-based policy to drug products labeled as homeopathic, ensure that the risk-based policy is formulated and applied with generally accepted standards and procedures of risk assessment;[17] and (6) hold a public hearing if it denies the Citizen Petition. In other words, if the FDA granted AHCF's Citizen Petition, the FDA would cease applying new drug approval ("NDA") requirements to OTC homeopathic drugs, and would, in most circumstances, recognize homeopathic drugs as low-risk products that are GRAS/E.

42. ANH and Meditrend supported the AHCF's Citizen Petition and agrees that FDA cannot lawfully subject OTC homeopathic drugs to conventional drug approval requirements under Section 355. Rather, the FDA should recognize that most, if not all, OTC homeopathic drugs are GRAS/E under homeopathic principles and regulate them as such, particularly if they comply with applicable cGMP and HPUS standards. Meditrend filed a comment to the AHCF petition expressing those positions in the docket. *See* Dkt. No. FDA-2020-P-1510-0002, Comment ID FDA-2020-P-1510-29462.[18]

43. Meditrend requested that FDA allow marketing and sale of OTC homeopathic drugs without insisting on Section 355 pre-market drug approval if the active homeopathic ingredients are included or recognized within the HPUS (individually or as a class), and are manufactured consistent with homeopathic principles, HPUS guidelines, and cGMP requirements.

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[17] The Citizen Petition describes in detail what AHCF considers to be an appropriate risk-based policy. In general, the Citizen Petition describes homeopathic drug products as low risk compared to other products and encourages the FDA to regulate them as such.

[18] *Available at* https://www.regulations.gov/comment/FDA-2020-P-1510-29462 (last accessed Oct. 15, 2024).

D. FDA Final Guidance Document

44. The FDA published its final guidance regarding homeopathic drug products in December 2022. *See* 87 Fed. Reg. 75054 (Dec. 7, 2022) (announcing the availability of the final guidance). The agency declared its intention "to prioritize enforcement and regulatory actions for homeopathic drug products marketed in the United States without the required FDA approval." *See* Exh. B ("Homeopathic Drug Products, Guidance for FDA Staff and Industry") (Dec. 2022) ("Final Guidance").[19] The agency finalized its "risk-based approach" to homeopathic drugs. *Id.* at 1.

45. The FDA explained that a homeopathic drug could be subject to enforcement even if it "conforms to the HPUS dilution standards" published in the HPUS monographs. *Id.* at 1 n.3.

46. By classifying all homeopathic drugs—including OTC homeopathics—as unapproved new drugs subject to Section 355 pre-market drug approval, the FDA increased the regulatory burdens on OTC homeopathic drugs to levels much higher than those applied to conventional OTC drugs. Under the FDA's vague "risk-based approach" to homeopathic regulation, the FDA causes all such products to be subject to enforcement without notice. *Id.* at 4.

47. The FDA also concluded erroneously as a matter of law that the CARES Act requires a heightened regulatory threshold for homeopathic drug products:

> Prior to enactment of CARES, FDA had not reviewed any homeopathic drug products under the OTC Drug Review, because the Agency had placed homeopathic drug products in a separate category and deferred consideration of them. Subsequent to enactment of CARES, no GRAS/E determinations will be made for homeopathic drug products under section 505G, because section 505G does not apply to homeopathic drug products. Because at this time no homeopathic drug products have been determined by FDA

[19] *Available at* https://www.fda.gov/media/163755/download (last accessed Oct. 15, 2024).

> to be GRAS/E, all homeopathic drug products remain subject to the premarket approval requirements.

Id. at 2-3. Thus, the FDA improperly construed the CARES Act to require conventional drug approval requirements be met for homeopathic drugs when the CARES Act plainly disallows imposition of those requirements. Meditrend challenges FDA's final order, asking the Court to rule that Congress intended to protect the homeopathic OTC market from imposition of the conventional "new drug" pre-market approval requirements of 21 U.S.C. § 355.

48. The FDA's primary justification for increasing the burdens on OTC homeopathic drugs was its speculative assertion (void of evidentiary support) that homeopathics created a heightened risk of harm to patients. FDA stated: "Since the issuance of CPG 400.400, the Agency has encountered multiple situations in which homeopathic drug products posed a significant risk to patients." *Id.* at 3. But the agency identified no evidence to support the conclusion that homeopathic products are unsafe or that drug approval under Section 355 of the FDCA is required to prevent manufacturing errors.

49. The Final Guidance removed the clear standards that existed under CPG 400.400, leaving the industry without essential guidance on how to lawfully market homeopathic products.

E. FDA Denial Letter

50. Contemporaneous with the agency's publication of the Final Guidance, the FDA denied AHCF's petition on December 6, 2022. *See* Exh. E (Dkt. No. FDA-2020-P-1510, Document ID FDA-2020-P-1510-29367) (Dec. 6, 2022) ("Denial Letter").[20] The agency rejected all of AHCF's requested regulatory reforms,

[20] *Available at* https://www.regulations.gov/document/FDA-2020-P-1510-29367 (last accessed Oct. 15, 2024).

including its request to publish regulations fostering the continued marketing and sale of homeopathic drugs.

51. The FDA repeated its erroneous conclusion that the CARES Act imposed new drug approval requirements on homeopathic drugs. *Id.* at 3.

52. The FDA reiterated its concern over the safety of homeopathic products. *Id.* at 4. However, to the extent FDA identified purported safety concerns, the agency's analysis focused only on isolated instances involving manufacturing errors, not on problems endemic to homeopathic drugs themselves. *Id.* For example, the FDA acknowledged that safety concerns related to instances where the homeopathic ingredients contained in the final product "far exceeded the labeled amounts..." *Id.*

53. The FDA denied the AHCF's proposal to permit continued sale of homeopathic drugs subject to long-standing HPUS monographs. *See id.* at 6-7, 13-14. FDA therefore rejected AHCF's position that homeopathic drugs which had been sold for over eighty years are not "new" drugs under 21 U.S.C. § 321(p). Most homeopathic drug products are now defined as "new." Those products have been manufactured and marketed for decades under standards and monographs provided in the HPUS. Under 21 U.S.C. § 321(p)(1), products marketed under the HPUS are generally recognized, among experts qualified in homeopathic practice, as safe and clinically effective for their homeopathic uses. Describing a product that has been marketed and sold to consumers for generations as a "new" drug conflicts with the plain and intended meaning of the statute.

54. The FDA also rejected AHCF's proposal to permit evaluation of homeopathic drugs under homeopathic—rather than conventional—standards of review. *See* Denial Letter at 7-8, 11-12.

F. Meditrend's Comments

55. Meditrend filed comments to the AHCF petition. *See* Exh. F (Dkt. No. FDA-2020-P-1510-0002, Comment ID FDA-2020-P-1510-29462).[21] Meditrend asked FDA to grant AHCF's petition, in part, because the CARES Act would require new regulations governing the sale of OTC homeopathic products. *See id.*; *see also id.* at 27 ("Because the FDA lacks authority to require all OTC homeopathic drug products to have an approved new drug application to be lawfully marketed, Meditrend requests that the FDA partially grant the AHCF Citizen Petition and cease regulating OTC homeopathic drugs as 'new drugs' under the FDCA.").

56. Meditrend requested that FDA publish regulations allowing for the marketing and sale of OTC homeopathic drugs without new drug approval if the active homeopathic ingredients were included in or eligible for inclusion in the HPUS or prepared in accordance with HPUS provisions. *See id.* at 16. Meditrend asked FDA to memorialize provisions of the withdrawn CPG 400.400 as part of regulations governing the sale of OTC homeopathic drugs.

V. CLAIMS FOR RELIEF

COUNT ONE

FDA Violates 5 U.S.C. 706(2) by Regulating OTC Homeopathic Drugs Under 21 U.S.C. § 355(a)

57. Plaintiffs incorporate by reference all allegations contained in Paragraph 1 through Paragraph 56.

58. The FDA violates the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2)(C), by imposing pre-market new drug approval requirements on OTC homeopathic drugs. *See* Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, §§ 3851-3856, 134 Stat. 1281 (2020); *see also In re Roman Cath. Church of Archdiocese of Santa Fe*, 615 B.R. 644, 655-56 (Bankr. D.N.M. 2020)

[21] *Available at* https://www.regulations.gov/comment/FDA-2020-P-1510-29462 (last accessed Oct. 15, 2024).

(holding that agency interpretation violated CARES Act and thus 5 U.S.C. § 706(2)(C) where CARES Act spoke directly to the issue).

59. Regulating OTC homeopathic drugs under the same standards as conventional "new" drugs violates the CARES Act and contradicts its legislative intent.

60. Agency action in excess of, or in conflict with, statutory command is unlawful under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2)(A) and (C) and is entitled to no judicial deference; indeed, even were there some degree of statutory ambiguity arguably present, *Loper Bright Enterprises v. Raimondo*, 603 U.S. ___ (2024), makes it emphatically the duty of the Court, not the FDA, to determine the statutory meaning in line with the canons of statutory construction.

61. Under Section 3853(a) of the CARES Act, products "excluded" by FDA in 1972 are OTC homeopathic drugs. That statutory note is unambiguous. Congress intended through this exclusion to relax—not heighten—the premarket burdens on OTC homeopathic drugs and did not intend homeopathic drugs to be subjected to increased "new drug" pre-market approval requirements under 21 U.C.S. § 355.

62. By exempting OTC homeopathic drugs from pre-market approval requirements, Congress intended to permit the continued marketing and sale of OTC homeopathic drugs subject to the conditions defined in CPG 400.400. That interpretation is supported by Congressional intent.

63. Congress expressly adopted and ratified the FDA's language from 1972 wherein the FDA excluded OTC homeopathic drugs from premarket requirements "[b]ecause of the uniqueness of homeopathic medicine…" *See* 37 Fed. Reg. 9466 (¶25). Following that FDA-issued exemption in 1972, the FDA then permitted homeopathic products to be marketed without premarket approval for nearly fifty (50) years. By adopting the FDA's language from the Federal Register, Congress expressly acknowledged that OTC homeopathics should not be regulated the same

as conventional drugs but, instead, under a different regulatory scheme. Requiring homeopathic drugs to meet stricter standards, i.e., by eliminating the marketing pathway permitted under the CPG 400.400, FDA rejected the plain and intended meaning of the CARES Act, thus violating it.

64. Congress's language in the CARES Act is consistent with other provisions of the FDCA, including 21 U.S.C. § 360eee(13), which expressly excludes "homeopathic drugs marketed in accordance with applicable guidance under this chapter" from significant obligations imposed on conventional drugs, which are found in Section 360eee-1. Those requirements include, *inter alia*, product identifiers, manufacturing requirements, wholesale distributor requirements, dispenser requirements, repackager requirements, enhanced drug distribution requirements, and guidance documents. *See* 21 U.S.C. § 360eee-1. *See* Drug Quality and Security Act, Pub. L. 113-54 (Nov. 27, 2013), 127 Stat 587. Thus, here again, Congress chose to relax (not heighten) the regulatory requirements applicable to homeopathic drug products. Congress referenced the FDA's "applicable guidance" related to homeopathic drugs in existence at that time in 2013, i.e., CPG 400.400. Congress intended for homeopathic drug regulation to proceed in accordance with CPG 400.400.

65. The FDA's recognition that homeopathic drugs are not "new drugs" within the meaning of the FDCA for nearly eighty (80) years undermines the agency's assertion that such products must now be regulated as "new drugs" under Section 355.

66. Under the major questions doctrine, the FDA lacks a clear statutory command to increase regulatory burdens to the point of destroying the entire consumer market in homeopathic OTC drugs by imposing on it burdensome new drug regulatory requirements and the associated typical billions of dollars of cost per drug.

67. Members of Congress provided direct evidence of congressional intent in a letter to the FDA in September 2021 signed by twenty-four congresspersons. *See* Congressional Ltr. to FDA (Sep. 3, 2021).[22] Members of Congress encouraged FDA to protect homeopathic drugs consistent with the CARES Act:

> Since 1938 until 2017, the FDA consistently recognized the distinction between conventional and homeopathic drugs, and Congress has repeatedly reaffirmed this distinction as set forth in the Food, Drug, and Cosmetic Act. As discussed above, **most recently in 2020, Congress passed the CARES Act, which exempts homeopathic drugs from review under its provisions regarding pharmaceutical drugs.** In 1938, the FDA supported the decision to recognize the HPUS and its supplements as the official compendium of standards and monographs for homeopathic drug ingredients giving the Agency the tools to regulate homeopathic drugs as a unique and separate category of drugs. On several occasions, the FDA has commented on this distinction as set forth by Congress, and the Agency's policies have been in adherence with the law which, as the FDA stated in 1988, "gives no premarket review of true homeopathic dilutions."

68. *See id.* (emphasis added). Of the representatives who submitted that letter to the FDA, seventeen (17) cast votes in favor of the final CARES Act legislation.[23] The September 2021 letter represents direct evidence of congressional intent concerning the legislative text of the CARES Act. *See id.*

69. Requiring all homeopathic drugs to secure approval under Section 355 will destroy the OTC homeopathic market. Two estimates for the cost of clinical trials needed for New Drug Approvals have been estimated to average $498.9 million and $456.7 million per drug, respectively. *See,* DiMasi, J, et al., "Innovation in the pharmaceutical industry: New estimates of R&D costs," Journal of Health

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[22] *Available at*, https://homeopathychoice.org/wp-content/uploads/2021/09/9.3-Letter-to-the-FDA-regarding-Homeopathic-Guidelines.pdf (last accessed Oct. 15, 2024).

[23] An additional member, Gus Bilirakis, cast a vote for the same statutory language when it was introduced earlier under separate legislation in H.R. 7328 (Housing Innovation Act) and H.R. 269 (Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019).

Economics, 2016;47:20-23 and Wouters, O.J, et al. "Estimated research and development investment needed to bring a new medicine to market, 2009-2018." JAMA. 2020;323(9):844-853. Clinical trials required to support FDA drug approvals have a median cost of $19 million. Multiple such trials are required to satisfy the FDA's rigorous standards. Unlike conventional drugs, however, homeopathic drugs lack market exclusivity provided by patent protections, in part, because those products have been generally marketed unencumbered by the FDA for decades. The absence of barriers to market entry, coupled with widespread use of homeopathic products standardized under the HPUS, eliminate financial incentives to pursue drug approval over such products.

70. Homeopathic products are also unsuited for FDA's conventional new drug pre-market approval because new drug approval is designed for novel synthetic pharmacologically active ingredients with substantially higher safety risks non-existent with homeopathic dilutions.[24]

71. The FDA thus acts contrary to its authority, limitations, and/or statutory right. The FDA's policy regarding homeopathic OTC drugs under Section 355(a) is not in accordance with the CARES Act. *See* 5 U.S.C. § 706(2)(A), (C).

72. The Court should enjoin the FDA from taking enforcement action against any OTC homeopathic drug products on the basis that such products lack pre-market new drug approval under 21 U.S.C. § 355(a).

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[24] The FDCA was passed in 1938 primarily to address drug safety concerns in the wake of prominent drug safety failures. *See, e.g.*, FDA, *Part II: 1938, Food, Drug, Cosmetic Act*, https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-ii-1938-food-drug-cosmetic-act#:~:text=FDR%20signed%20the%20Food%2C%20Drug,adequate%20directions%20for%20safe%20use (last accessed Oct. 15, 2024) (explaining how the 1938 amendment to the FDCA was "enhanced and passed in the wake of a therapeutic disaster in 1937," which involved over 100 people dying after consuming a "sulfa wonder drug" that contained a "highly toxic analogue of antifreeze," and how the 1938 law required, *inter alia*, drugs to be labeled with adequate directions for safe use and for new drugs to be FDA approved as safe before they could be lawfully marketed).

COUNT TWO

FDA Violated 5 U.S.C. 706(2)(A) and 5 U.S.C. 553(b) by Denying AHCF's Request for a Rulemaking Regarding Homeopathic Drugs

73. Plaintiffs incorporate by reference all allegations contained in Paragraph 1 through Paragraph 72.

74. FDA erred in denying AHCF's request for regulation concerning homeopathic drug products.

75. After Congress exempted OTC homeopathic drugs from OTC drug approval pathways in the CARES Act, OTC homeopathic drugs were left without a pathway to market. Regulation of homeopathic drugs under Section 355 is legally and scientifically inappropriate.

76. Absent regulatory standards, homeopathic manufacturers lack legal protections for homeopathic products. Those manufacturers also lack recourse if the agency moves to act against them on a case-by-case basis.

77. Because homeopathic drugs are unique and function differently from conventional drugs—a fact Congress has affirmed—requiring OTC homeopathic drugs to proceed through conventional new drug pre-market approval pathways is infeasible and would destroy the homeopathic industry in the United States, an industry that Congress did not intend to destroy, but to preserve.

78. The Court has authority to overturn an agency's decision not to initiate a rulemaking where the agency has committed an error of law or incorrectly evaluated fundamental factual premises. *See, e.g., WildEarth Guardians v. U.S. E.P.A.*, 751 F.3d 649, 653 (D.C. Cir. 2014); *see also New York v. Env't Prot. Agency*, 921 F.3d 257, 261 (D.C. Cir. 2019) (the Court may set aside the agency's judgment where the agency "had not adequately explained the facts and policy concerns it relied on or that those facts did not have some basis in the record").

79. Here the FDA's decision to avoid rulemaking was based on fundamental errors of law and fact. The FDA erroneously concluded that Congress pursuant to the CARES Act intended all homeopathics (including OTC homeopathic drugs) to be regulated under 21 U.S.C. § 355. FDA also erroneously concluded that FDA lacks a statutory basis to regulate homeopathics differently. The FDA also erroneously concluded that increased regulatory oversight was necessitated by safety risks not proven endemic to homeopathics but based entirely on isolated instances of manufacturer error.

80. But most OTC homeopathic drug products are not "new" drugs under 21 U.S.C. § 321(p) because those products have been sold subject to HPUS monographs and, thus, labeled for the same conditions of use since prior to 1938. The vast majority, if not all, homeopathic drug ingredients have been on the market since before the Food and Drugs Act of 1906. The FDA therefore erred in deeming all OTC homeopathic drugs marketed subject to HPUS monographs predating 1938 to be "new drugs" under Section 321(p). The FDA's new regulations governing homeopathic drugs flatly contradict the statutory law governing those products.

(1) The Court should reverse and remand FDA's final action in its Final Guidance consistent with the Court's order, thereby necessitating that FDA maintain the status quo ante (before adoption of its Final Guidance) until such time as the FDA completes a rulemaking under 5 U.S.C. 553(b) to provide a path to market consistent with the CARES Act that mirrors conditions defined in the now-rescinded CPG 400.400.

COUNT THREE

FDA Violates 5 U.S.C. 706(2)(A) by Imposing Heightened Regulatory Burdens on Homeopathic Drugs Based on Unsupported and Misleading "Safety" Concerns

81. Plaintiffs incorporate by reference all allegations contained in Paragraph 1 through Paragraph 80.

82. FDA acted arbitrarily and capriciously by imposing heightened regulatory requirements on homeopathic drug products based on hypothesized safety concerns where the administrative record instead shows homeopathic drugs pose no cognizable safety risks to consumers.

83. Based on unsupported safety concerns, FDA arbitrarily and capriciously took adverse action against an entire industry. FDA's conclusions regarding homeopathic drug safety were unsupported by fact, and contradicted the evidence available to FDA at the time. *See* Exh. B at 3-4; Exh. E at 4. Homeopathic OTCs are much safer than conventional medicines; homeopathics are already deemed GRAS/E by the FDA.

84. In December 2022, FDA published the Final Guidance. In that guidance document, FDA stated that it "developed a risk-based approach under which the Agency intends to prioritize enforcement and regulatory actions involving certain categories of such products that *potentially* pose a higher risk to public health." Final Guidance at 1 (emphasis added). FDA ascribed generalized and hypothesized safety risks to an unspecified number of products. *See* Exh. B at 3.

85. FDA presumed homeopathic OTC drugs carry a heightened safety risk, contrary to the evidence. FDA claims that since issuance of CPG 400.400, the Agency has encountered "multiple situations" in which homeopathic drug products posed a significant risk to patients. *Id.* at 3. FDA alleged that such products either caused or "could have caused" significant harm. *See id.* at 3 (quotations added). For proof, FDA cited to the teething and Zicam products also referenced in the denial letter, and discussed by AFHC's citizen petition. *See id.* at 3 n.12; Exh. E at 4; Exh. A at 11-12.

86. FDA acknowledges that homeopathic drugs are distinct from other drugs. *See* Exh. E at 11. The only two examples offered by FDA of safety concerns

in relation to homeopathic OTCs involved labeling and manufacturing issues related to baby teething products and nasal sprays, and the quality of the data on which the FDA relied has been challenged.[25] However, the FDA identified no evidence that homeopathic products were inherently or intrinsically unsafe when manufactured or used as intended, citing instead to specific isolated instances of manufacturer error having nothing to do with endemic or intrinsic characteristics of homeopathic products. *See generally* Exh B; Exh. E.

87. The AHCF petition generated over 54,000 comments, almost exclusively in support of AHCF's request to foster continued sales of homeopathic drugs through reasonable regulation. Those comments included those from the medical community reciting detailed experiences with homeopathic product safety. *See, e.g.,* Dkt. Nos. FDA-2020-P-1510-20392 (medical doctor explaining that homeopathy is "the safest category of drugs"); -9213 (explaining that 200-year history of homeopathic use supports safety); -16385 (explaining the impracticality of proposed homeopathic regulation and highlighting the record of homeopathic safety); -19987 (homeopathic history of safe use); -2444 (Registered Nurse explaining that homeopathic drugs are "the safest and most non-toxic medicine"); -27937 ("The safety and effectiveness of homeopathy is also backed by thousands of research studies"); -10465 (safety of homeopathy compared to safety risks with conventional drugs); -23435 (homeopathy lacks side effects present with conventional drugs); -2120 (describing 200+ year history of safe homeopathic use); -26093 (describing "nontoxic and inherently safe" use of homeopathics); -54013 (explaining that homeopathic medications are safe when properly manufactured and labeled); -9154 (same); -20237 (same); -9200 (same).

88. The World Health Organization concluded that "Adverse events occurring during homeopathic treatment are rarely attributed to the homeopathic

[25] Lennihan, B. "Food and Drug Administration Action Against Homeopathic Teething Tablets Lacked Evidence Base." Alt. Compl. Therapy. 2018:24(1):19-28.

medicine itself." *See* FDA-2020-P-1510-2120 (quoting *Safety Issues in the preparation of Homeopathic Medicines*, World Health Organization (2009)). The WHO therefore determined that, where safety issues for homeopathic products arise, those are generally related to impurities in the source material or failures of good manufacturing practices. *Id.*

89. According to testimony provided to the FDA regarding the National Poison Data System (NPDS) and the American Association of Poison Control Centers (AAPCC), exposure reports to "homeopathic" products account for 1% or less of all calls to Poison Control Centers. *See* Exh. A app. 13 at 1[26] (citing 2015-N-0540-4429, presentation from Edward P. Krenzelok, Rocky Mountain Poison and Drug Center[27]). Moreover, because the NPDS reports group together dietary supplements, herbals and homeopathics, and there is often identity confusion between these three product categories, the limited reports on homeopathic products are likely overestimated and mis-attributed. *See id.* The overwhelming majority (98%) of "homeopathic" reports are nonetheless categorized as either having minor or no adverse effects, and those incidents are typically managed without the need for any medical referral. *See id.*; *see also Exh. A* app. 13 at 4 ("[I]nvestigations into homeopathic treatment including randomized controlled trials, observational studies, experimental studies, case reports, systematic reviews, worldwide literature searches, consultation with regulating authorities, and conversations with homeopathic practitioners reveal that homeopathy is an extremely safe and effective form of medicine.")

90. FDA's concerns over *potential* safety issues are, based on the evidence it cites, speculative and inflated, drawn from isolated manufacturing practices and

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[26] *Available at* https://homeopathychoice.org/app/uploads/2019/03/The-Safety-of-Homeopathic-Medicine-AFHC-Citizen-Petition-Supporting-Document-1.pdf (last accessed Oct. 15, 2024).

[27] *Available at* https://www.regulations.gov/document/FDA-2015-N-0540-4429 (last accessed Oct. 15, 2024).

labeling concerns. Pre-market drug approval under Section 355 would not have prevented cGMP-related deviations. Requiring drug approval for safety and efficacy does not address failures in good manufacturing practices. The FDA's regulation of homeopathics under the withdrawn CPG 400.400 included the requirement that homeopathic drugs meet drug GMP standards. A risk of *potential* (and demonstrably rare) GMP failures was therefore not a factually supported basis to *increase* regulatory requirements on the entire homeopathic industry when the existing CPG 400.400 had already required compliance with GMP standards.

91. FDA's imposition of heightened regulatory requirements because of alleged safety concerns was arbitrary and capricious and unsupported by the facts available to the agency at the time. Regarding the two examples cited by the FDA in both the Denial Letter and Final Guidance document cited *supra* (Exh. E and Exh. B, respectively), the FDA was unable to determine if any of the baby teething products actually caused harm, and FDA only found that belladonna alkaloids in some of the products exceeded the labeled amounts. *See* Exh. A at 11.

92. FDA's records show that homeopathic OTCs are substantially safer than conventional drug counterparts. For instance, between 1999 and 2024 (October), the FDA received a total of 1,285 adverse events in the FDA Adverse Events Reporting System (FAERS) related to homeopathic drug products. *See Homeopathics*, FDA Adverse Events Reporting System (FAERS) (current as of June 30, 2024).[28] By comparison, between the 5-year period 2019 to 2023 inclusive, the FDA received 64,664 reports for suspected adverse events linked to use of the drug

[28] *Available at* https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/45beeb74-30ab-46be-8267-5756582633b4/state/analysis (last accessed Oct. 15, 2024).

acetaminophen (the active ingredient in Tylenol®) (data current as of June 30, 2024).[29]

93. For the same 5-year period, the FDA received just 169 reports for all homeopathic products.[30] These data, from the FDA's own database, show that reports for all homeopathic drugs represented just 0.26% of the number for a single drug, namely acetaminophen (i.e., 383 times fewer reports).

94. The FDA's concerns over homeopathic drug safety are exaggerated and speculative. The FDA has speculatively observed that, "[w]hile products labeled as homeopathic are generally labeled as highly diluted, some of these products have been found to contain measurable amounts of active ingredients and therefore could cause significant harm."[31] But, as noted, the FDA has no evidence that homeopathic products have caused "significant harm" when properly manufactured and used as directed.

95. The FDA simply has no evidence that OTC homeopathic drugs are high-risk. There is no evidence that the use of homeopathic products results in a need for pre-market applications for products that have been in use for hundreds of years and are documented to be safer than conventional medicines. The FDA's elimination of the marketing pathway for homeopathic drugs in CPG 400.400, and its subsequent increased regulation of homeopathic drugs, are therefore arbitrary and capricious agency actions void of a reasonable evidentiary foundation. The FDA largely ignored, and failed to consider, the overwhelming evidence of homeopathic drug safety in the record.

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[29] *Available at* https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/45beeb74-30ab-46be-8267-5756582633b4/state/analysis (last accessed Oct. 15, 2024).

[30] *Available at* https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/45beeb74-30ab-46be-8267-5756582633b4/state/analysis.

[31] *See* https://www.fda.gov/drugs/information-drug-class/homeopathic-products#:~:text=On%20December%206%2C%202022%2C%20FDA,the%20greatest%20risk%20to%20patients (last accessed Oct. 15, 2024).

96. FDA's finding that homeopathic drugs present a risk to consumer safety also conflicts with the agency's understanding of homeopathy. The FDA understands homeopathy to involve dilution and succussion of active ingredients to form a final homeopathic product. *See* Final Guidance at 1 (defining a "homeopathic drug product" as a drug product that, inter alia, "is labeled as containing only active ingredients and dilutions (e.g., 10x, 20X) listed for those active ingredients . . ."). Those dilutions result in finished products that contain low levels of active ingredient well below the dose at which an ingredient results in toxicity.

97. To the extent FDA identifies safety issues at all, the FDA's decision to require pre-market approval over all homeopathic drug products does not address those concerns. Pre-market approval does not address manufacturing errors and cGMP violations.

98. Because the FDA predicated its revised Guidance and regulatory approach to homeopathic drugs on flawed, misleading, exaggerated, and unsupported safety concerns, the FDA acted arbitrarily and capriciously in violation of 5 U.S.C. § 706(2)(A).

COUNT FOUR

FDA's Final Homeopathy Guidance Violates the Due Process Clause of Article V of the United States Constitution by Imposing Vague and Ambiguous Conditions on the Continued Sale of Homeopathic OTC Drugs

99. Plaintiffs incorporate by reference all allegations contained in Paragraph 1 through Paragraph 99.

100. FDA's Final Guidance violates the Due Process Clause of the Fifth Amendment of the United States Constitution and the APA's prohibition on unconstitutional agency action (5 U.S.C. § 706(2)(B)) because the Guidance gives FDA unbridled discretion to remove homeopathic products from the market and fails

to provide the regulated class with fair notice of what conduct is prohibited. *See* FDA, "Homeopathic Drug Products, Guidance for FDA Staff and Industry" (Dec. 2022).[32]

101. Unlike the withdrawn CPG 400.400, the Final Guidance includes no standards for the lawful sale of homeopathic drug products. Instead, the FDA replaced those standards with a standardless "risk-based approach" giving its regulators unbridled discretion to dictate conditions for "manufacturing, distribution and marketing of homeopathic drug products[.]" *Id.* at 4.

102. CPG 400.400 provided definitions applicable to homeopathic drugs and rules governing the lawful manufacturing, labeling, and sale of same. *See* Exh. G (CPG 400.400). Those rules included compliance with "standards for strength, quality, and purity set forth in the [HPUS]." *Id.* It included reference to the types of claims that could be made on homeopathic labeling. *Id.* (citing "A Dictionary of Practical Material Medica by John Henry Clark, M.D."). The CPG 400.400 included labeling polices and provisions, including, e.g., (1) directions for use; (b) statement of ingredients; (c) documentation that must be maintained to support recognition in the HPUS; (d) the product's established name; (e) labeling exemptions for small containers; (f) language requirements; (g) net quantity of contents; (h) statement of identity; and more. *Id.* The CPG 400.400 also included provisions for both prescription and OTC homeopathic drugs. That CPG included standards for compliance with current good manufacturing practices (with certain exceptions).

103. The FDA also explained in the CPG 400.400 that firms "not in compliance with the conditions described above will be considered for regulatory follow-up." *Id.* As noted, *supra*, the CPG 400.400 imposed binding obligations and clear standards on the industry. *See MediNatura*, 496 F. Supp. 3d at 437-38. The FDA's substitute of a standardless and entirely subjective "risk-based approach"

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[32] *Available at* https://www.fda.gov/media/163755/download (last accessed Oct. 15, 2024).

deprives the regulated class of guidance sufficient to discern a reliable way to lawfully market homeopathic products, leaving the regulated class to guess as to what requirements apply, they being entirely what agency regulators select moment by moment at their whim or caprice. That void leaves Meditrend and the entire regulated class unable to determine at present and in future which homeopathic products, if any, are lawful to manufacture, distribute, and sell.

104. Although the Final Guidance cites examples of "risky" products that may have enforcement priority, the FDA reserves the right to take enforcement action against any homeopathic product without providing prior notice: "FDA is not required, and generally does not expect, to give special notice that a drug product may be subject to enforcement action." Final Guidance at 4. Critically, the FDA reserves unto itself unlimited discretion to act against any homeopathic drug product for any reason: "[T]his guidance is intended to provide notice that any homeopathic drug product that is being marketed illegally is subject to FDA enforcement action at any time." *Id.* at 5. FDA has also taken the position that all homeopathic drug products are "being marketed illegally," because the FDA now requires all homeopathic drugs to achieve new drug pre-market approval under Section 355. No homeopathic drug product has achieved that, and none will likely do so given the enormous new drug filing fees and the extraordinary multi-billion dollar cost of achieving market access for each new drug. *See id.* at 3.

105. In short, the Final Guidance deems all homeopathic drugs unlawful, and FDA fails to provide the regulated class, including Meditrend, with any standards by which homeopathic drugs can be manufactured, distributed, and sold lawfully other than through the Section 355 pre-market new drug approval requirements—the standard Congress meant to apply exclusively to drugs other than homeopathic drugs. Thus, FDA declares that it will use enforcement discretion for "risky" products that are very broadly defined. For example, these include products "that contain or purport to contain ingredients associated with potentially significant

safety concerns", those "used for the prevention of treatment of serious…diseases and conditions", and "products for vulnerable populations."[33] Although the FDA provides certain examples of risky homeopathic drugs, the FDA does not limit enforcement to those specific products. Moreover, unlike CPG 400.400, the FDA provides no reasonable method for homeopathic drug manufacturers to determine whether their product is lawfully or properly labeled. The FDA's Final Guidance therefore violates the Due Process Clause of the Fifth Amendment because it fails to give the regulated class, including Meditrend, any, let alone, reasonable, notice of the applicable legal standards governing lawful versus unlawful sales of homeopathic products.

106. Homeopathic drug companies face potential criminal penalties under the FDCA for selling products the FDA deems unapproved new drugs. *See, e.g.*, 21 U.S.C. §§ 331(a),(d), 333(a).

107. Where a regulation carries the potential for criminal enforcement, courts undertake a comparatively stricter vagueness review under the Due Process Clause. *See, e.g., All. for Nat. Health U.S. v. Sebelius*, 775 F. Supp. 2d 114, 131 (D.D.C. 2011).

108. "A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required." *F.C.C. v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012) ("This requirement of clarity in regulation is essential to the protections provided by the Due Process Clause of the Fifth Amendment.")

109. A regulation or ordinance may be unconstitutionally vague because it fails to provide fair notice of prohibited conduct, or it fails to establish minimal

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[33] "Final Guidance", "Homeopathic Drug Products Guidance for FDA Staff and Industry," p. 5. *Available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/homeopathic-drug-products-guidance-fda-staff-and-industry (last accessed Oct. 15, 2024).

guidelines to govern enforcement. *See U.S. v. Regan*, 93 F. Supp. 2d 82, 87 (D. Mass. 2000) (citing *City of Chicago v. Morales*, 527 U.S. 41, 57 (1999)). Vague regulations violate due process rights because they "neither give a party fair notice of the type of activity the regulation proscribes nor sets the standards by which government officials will enforce the regulation, permitting arbitrary and discriminatory enforcement." *See Jacobsen v. Rensink*, No. C 96-4074 MWB, 1997 WL 33833742, at *16 (N.D. Iowa Mar. 15, 1997).

110. The FDA's Final Guidance neither provides homeopathic drug manufacturers with fair notice of the standards by which OTC homeopathic drugs can be lawfully marketed, nor sets standards to govern when FDA officials will deem homeopathic drugs unsaleable.

111. The FDA had reasonable alternatives that would have avoided Due Process concerns. For more than thirty years, the FDA regulated the industry under the CPG 400.400 using standards that gave fair notice.

VI. RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request that this Court,

(2) Declare that homeopathic drugs marketed subject to an HPUS monograph published prior to 1938 are not "new" drugs under 21 U.S.C. § 321(p);

(3) Declare that OTC homeopathic drugs are exempted by the CARES Act from pre-market new drug approval requirements under 21 U.S.C. § 355(a);

(4) Enjoin FDA from taking enforcement action against OTC homeopathic products on grounds that such products require pre-market new drug approval under 21 U.S.C. § 355; and

(5) Reverse and remand the FDA's final action in its Final Guidance consistent with the Court's order, thereby necessitating that FDA maintain the status quo ante (before adoption of its Final Guidance) until such time as FDA initiates a rulemaking under 5 U.S.C. 553(b) to provide a practical pathway, consistent with

the CARES Act, for market clearance of OTC homeopathic drugs that mirrors conditions for sale stated in the now-rescinded CPG 400.400.

(6) Declare that FDA's Final Guidance violates the Due Process Clause of the Fifth Amendment and the APA's prohibition on unconstitutional agency action and against arbitrary and capricious agency action by failing to provide clear standards for homeopathic drug manufacturers.

DATED: October 21, 2024.

Respectfully submitted,

By: */s/ Jonathan W. Emord*

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CERTIFICATE OF SERVICE

I hereby certify that on October 21, 2024, the foregoing COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF was electronically filed using the Court's CM/ECF system and served* via that system on the following Defendants:

Jolene Ann Lauria
Assistant Attorney General for Administration
U.S. Department of Justice Management Division
950 Pennsylvania Avenue, N.W., Room 1111,
Washington, D.C. 20530
(receiving service by certified mail for the Attorney General of the United States for **Defendant United States of America**)

Merrick Garland
Attorney General
U.S. Department of Justice
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Washington, D.C. 20530
(receiving service by certified mail for the Attorney General of the United States for **Defendant United States of America**)

Matthew Graves
United States Attorney for the District of Columbia
Civil Process Clerk
U.S. Attorney's Office for DC
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(receiving a copy of service by certified mail for the Attorney General of the United States for **Defendant United States of America**)

Mark Raza
Chief Counsel, U.S. Food and Drug Administration
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(receiving service for Defendants **U.S. Food and Drug Administration** and **Commissioner of Food and Drugs Robert M. Califf** via OC-OCC-FDA-Litigation-mailbox@fda.hhs.gov)

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* Upon the Clerk's execution of summonses, each Defendant shall be served a copy of the summons and the complaint.

/s/ Jonathan W. Emord
Jonathan W. Emord