UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Alliance for Natural Health USA, *et al*., Plaintiffs, v. United States of America, *et al.*, Defendants.	Case No. 24-cv-2989 (CRC)

PLAINTIFFS' COMBINED MEMORANDUM
IN REPLY TO DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT
AND
OPPOSITION TO DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

Plaintiffs Alliance for Natural Health USA ("ANH") and Meditrend, Inc. ("Meditrend") hereby Reply to Defendant's Opposition to Plaintiffs' Motion for Summary Judgment and Oppose Defendants' Cross-Motion for Summary Judgment, doing so in compliance with this Court's November 25, 2025 Minute Order (which reset deadlines) and in accordance with Federal Rule of Civil Procedure 56 and LCvR 7. Pursuant to this Court's July 15, 2025 Memorandum Opinion and Order, the universe of actionable claims has been narrowed to Count III of Plaintiffs' Complaint.

I. PLAINTIFFS HAVE STANDING TO SUE (ECONOMIC INJURIES SUFFERED ARE FAIRLY TRACEABLE TO THE GOVERNMENT'S ACTIONS AFFECTING HOMEOPATHIC DRUGS AND ARE REDRESSABLE BY ORDER OF THIS COURT)

The D.C. Circuit applies the tripartite test adopted in *Lujan v. Defenders of Wildlife,* 504 U.S. 555, 560-561 (1992) to determine the existence of standing necessary for subject-matter jurisdiction. *See Lin v. United States,* 177 F. Supp. 3d 242, 250 (D.D.C. 2016), *aff'd,* 690 F.

App'x 7 *(D.C. Cir. 2017)* ("the 'irreducible constitutional minimum of standing contains three elements': injury in fact, causation, and redressability"). Under *Lujan* and *Lin*, the injury must be concrete and particularized[1]; the causation must be "fairly traceable" to the challenged government action; and the injury must be redressable by a favorable decision from the court. *Lujan*, 504 U.S., at 560; *Lin*, 177 F.Supp.3d, at 242. "[F]airly traceable" does "not require that the defendant['s] [conduct] be the most immediate cause, or even a proximate cause, of the plaintiffs' injuries; it requires only that those injuries be 'fairly traceable' to the defendant." *Garnett v. Zeilinger,* 485 F.Supp.3d 206, 218 (D.D.C. 2020) (explaining further, "[t]he causation standard for Article III standing is not particularly demanding"). See also *Susan B. Anthony List*, 573 U.S. 149, 157–58 (2014)*; N. Carolina Fisheries Ass'n, Inc. v. Gutierrez*, 518 F. Supp. 2d 62, 87 (D.D.C. 2007). Traceability does not require proximate cause; it requires a "predictable chain of events leading from the government action to the injury." *Food & Drug Admin. v. All. for Hippocratic Med.*, 602 U.S. 367, 385 (2024). That standard is satisfied here. The D.C. Circuit has reasoned that "it may be enough that the defendant's conduct is one among multiple causes," relieving the Plaintiff of a need to prove a cause-and-effect relationship with certainty, reciting

[1] The first Affidavit of Richard D. Savage establishes injury in fact with specificity. Meditrend incurred over $400,000 in direct economic losses and had generated $1,670,243 in historical reseller sales from the customer group, representing revenues previously realized but now halted following the FDA's regulatory actions. (*Pls First Savage Affidavit at no. 13*). Those are concrete, quantified losses already sustained, not abstract or speculative future harms. Moreover, as the second Affidavit of Savage confirms, Meditrend has incurred price increases and source ingredient shortages since 2019 due to the Defendants' *volte face* on homeopathic safety reflected in its continuous actions against homeopathy from its 2019 withdrawal of CPG 400.400 to its 2022 denial of the AHCF petition to its site investigations questioning compliance by manufacturers of homeopathic source ingredients with requirements applicable to drugs under 21 U.S.C. § 355. Under settled precedent, the economic losses sustained suffice to establish injury in fact: "If a defendant has caused monetary injury, the plaintiff has suffered a concrete injury under Article III," *TransUnion LLC v. Ramirez,* 594 U.S. 413, 425 (2021). FDA's assertion that Plaintiffs' submissions are "entirely void" of injury contradicts the evidence before the Court.

that "substantial likelihood of the alleged causality meets the test." *Garnett v. Zeilinger,* 485 F.Supp.3d, at 206, 219; *Competitive Enterprise Institute v. NHTSA,* 901 F.2d 107, 112 (D.C. Cir. 1990).

We initially address a false assertion by Defendants at the start of their standing argument. Defendants assert that Plaintiffs abandoned Meditrend Executive Director Savage's first affidavit on standing *(Dft's cross-motion, p. 6)*. That is not true. Nowhere in Plaintiffs' brief did Plaintiffs state an intent to abandon that affidavit. They stand by it and stand by argument for representational standing for ANH, already accepted by the Court. Rather, as reflected in the Plaintiffs' footnote 2 to their Memorandum in Support of Plaintiffs' Motion for Summary Judgment, Meditrend supplied the Court "with a second affidavit," doing so precisely in response to this Court's statement in its Memorandum Opinion and Order wherein it advised that additional evidence of standing may be required as the case progresses *(Pls. SJ Mem. at 1)*.

The first affidavit from Meditrend Executive Director Savage supplied the Court with proof that FDA's revocation of the CPG 400.400 and related actions since have caused Meditrend to suffer economic injury: Whole Foods cancelled Meditrend's involvement in its "global store" initiative, which was set to expand to 500 stores across the United States and had previously netted Meditrend, Inc. on average $165,000 annually (before the anticipated 500 store expansion). The Court held that affidavit sufficient for standing at the early stage of the litigation, but stated "Meditrend will likely need to provide stronger and more specific evidence of this Court's subject-matter jurisdiction." (*Court Memo Opinion and Order at 9*).

In Plaintiffs' current motion, they supply the Court with a second affidavit from Savage providing more evidence of injury stemming from the FDA's actions. The second affidavit reveals revocation of CPG 400.400 and related FDA actions and GMP inspections ever since

have caused a reduction in the supply of and price increases for homeopathic ingredients from 2019 to the present. (*Pls Second Savage Affidavit at para. 3, Attachments A-H*). Those effects were documented from one of Meditrend's principal suppliers, Apotheca, covering the period not only immediately after the 2019 CPG 400.400 revocation but to the present (through the period in 2022 when FDA denied the American Homeopathic Consumer Freedom (AHCF) petition supported by Plaintiffs through FDA adoption of a final guidance revoking CPG 400.400 (2022) to the present as FDA site inspectors identify homeopathic source ingredients as non-compliant. (*Pls Second Savage Affidavit at para. 1; Attachments A-C*).

Against this evidence, Defendants accompany the false assertion of first affidavit withdrawal with a straw man argument: that the economic injuries suffered by Meditrend are entirely tied to FDA's 2019 withdrawal of CPG 400.400, apparently without regard to the gravamen of that withdrawal (FDA's conclusion that homeopathic drugs were not reasonably safe which resonates across time), ignoring FDA's subsequent actions reconfirming the *volte face* on homeopathic drug safety in the 2022 denial of AHCF's petition, the 2022 final ruling withdrawing CPG 400.400, and the site inspections of homeopathic ingredient manufacturers. The Defendants' position is not supported by evidence, and it is contradicted by the Savage affidavits and evidentiary support.[2]

[2] The Defendants contest without evidentiary support the evidence in the second Savage affidavit of injuries post-dating 2019 to the present. Plaintiffs' injury-in-fact arises from the economic impact on Meditrend of a continuous FDA course of action begun in 2019 and continuing to present rooted in FDA's conception of homeopathic drug lack of safety. The ACHF petition that FDA denied squarely asked the agency to reconsider its safety rationale and recognize HPUS- and GMP- compliant homeopathic drugs as safe; the FDA refused and reaffirmed its enforcement framework stemming from the 2019 withdrawal of guidance already harming Plaintiffs; indeed announcing that decision to be final in 2022. The government's actions against homeopathic safety from 2019 to the present are inextricably intertwined with, and designed to advance its position on, the safety issue before this Court and are fairly traceable to Plaintiffs' injuries, thus

In their Opposition and Cross-Motion, Defendants argue for causality more exacting than that required by precedent. They are effectively arguing for immediate or proximate causation, insisting without proof (in other words, speculating) that Plaintiffs' documented economic injuries from 2019 to present stem solely from FDA's withdrawal of its CPG 400.400 in 2019.

It is sufficient that FDA's *volte face* on safety and regulatory actions since evoked the Whole Foods' rejection of Meditrends' homeopathic line of products and comprise factors that have caused a diminution in the supply of available homeopathic source materials and an increase in the cost of source materials, as confirmed by the second Savage affidavit and supporting documents.

An order from this Court reversing and remanding FDA's safety determination as arbitrary and capricious under the APA will provide Plaintiffs needed redress by compelling the agency to examine seriously the relevant evidence establishing homeopathic drug safety that it ignored, which evidence establishes the isolated instances of injury stemming from non-adherence to the HPUS or the GMPs for homeopathic manufacturing to be atypical and non-representative.

II. THE D.C. CIRCUIT HAS RULED THE "SUBSTANTIAL EVIDENCE" TEST AND THE ARBITRARY AND CAPRICIOUS TEST "ONE AND THE SAME": CONTRARY TO DEFENDANTS' ASSERTION

Defendants misstate the governing law in their brief at note 3. They claim "substantial evidence" standard does not apply to review of *informal* adjudications under 5 U.S.C. § 706(2)(A), ignoring the D.C. Circuit decision in *Butte County, Cal. v. Hogan,* 613 F.3d

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making a remand to reconsider FDA's denial of the ACHF petition the apt remedy. See *Ellingson Drainage, Inc. v. U.S. Fish & Wildlife Serv.*, 2025 WL 2926381, at *6 (D.D.C. Oct. 15, 2025); see also *FDA v. All. for Hippocratic Med.,* 602 U.S. 367, 381 (2024).

190, 194 (D.C. Cir. 2010). In *Butte.,* the D.C. Circuit held the opposite, explaining that under Section 706 "the substantiality of evidence must take into account whatever in the record fairly detracts from its weight" and that "in their application to the requirement of factual support, ***the substantial evidence test and the arbitrary or capricious test are one and the same***" (emphasis added). Thus, contrary to Defendants' assertion, whenever this Court reviews an agency factual record under § 706, its test is indeed substantively indistinguishable from the substantial evidence test. The *Butte* Court explained:

> An agency's refusal to consider evidence bearing on the issue before it constitutes arbitrary agency action within the meaning of § 706. *See, e.g., State Farm,* 463 U.S. at 43 . . . *Comcast Corp. v. FCC,* 579 F.3d 1, 8 (D.C. Cir. 2009). This proposition may be deduced from case law applying the substantial evidence test, under which an agency cannot ignore evidence contradicting its position. "The substantiality of evidence must take into account whatever in the record fairly detracts from its weight." *Universal Camera Corp. v. NLRB,* 340 U.S. 474, 487-88 (1951) . . . Although we are dealing with the question whether agency action is arbitrary or capricious, "in their application to the requirement of factual support the substantial evidence test and the arbitrary or capricious test are one and the same." *Ass'n of Data Processing Serv. Orgs., Inc. v. Bd. of Governors of Fed. Reserve Sys.,* 745 F.2d 677, 683 (D.C. Cir. 1984); *accord Am. Radio Relay League, Inc. v. FCC,* 524 F.3d 227, 243 (D.C. Cir. 2008).

Butte Cnty., Cal., 613 F.3d at 194.

Under *Butte*, Defendants acted arbitrarily and capriciously, as explained in Plaintiffs' memorandum in support of their motion for summary judgment and further in Part IV hereinbelow. They did so by failing to take into account record evidence that fairly detracted from Defendants' position that homeopathic drugs were unsafe, evidence confirming that when manufactured in accordance with the HPUS and applicable GMPs, homeopathic drugs are demonstrably and reliably safe, and have been accepted to be so for decades by the FDA.

III. DEFENDANTS' MISREPRESENT THE RISK-BENEFIT GRAVAMEN OF THE AHCF PETITION AND ARGUE CONTRARY TO RECORD EVIDENCE

Defendants' argument misrepresents the AHCF's petition and the safety evidence of record. AHCF did not ask FDA to adopt a "single statement of enforcement policy that covers all product areas." Nor did it reject a risk-based policy for homeopathy in general. Rather, AHCF requested that FDA "ensure that the risk presented by homeopathic drugs and drug products would be properly evaluated based on past history and current science," which if done would cause homeopathic products to be in the lowest category of risk for products regulated by the FDA *(AR p. 9).* The FDA has long acknowledged homeopathic drugs listed in the HPUS are subject to defined conditions *(AR p. 29; CPG 400.400)*. The AHCF request was thus for FDA to apply a rational and risk-appropriate enforcement approach to homeopathic drugs consistent with their regulatory status and historical treatment *(AR p. 7).*

Similarly, the Defendants argument that the petition ignored the need for "numerous specific considerations for each product area" *(Dft's cross-motion, p. 9)* proceeds ignorant of the content of the AHCF petition. Recognition of that need is at the heart of the AHCF petition. The petition did not dispute that FDA may consider factors such as intended use, dosage form, manufacturing quality, or adverse events; rather, it challenged FDA's withdrawal of CPG 400.400, a settled enforcement framework that already accommodated those considerations through HPUS compliance and targeted enforcement *(AR pp. 6–7).* As Plaintiffs explained, FDA successfully regulated homeopathic drugs for decades without collapsing them all into a presumptively unlawful or uniformly high-risk category *(Pls. SJ Mem. at 3, 4, 8).* FDA's current position on homeopathic drug safety is therefore a radical departure from its decades long prior position recognizing the low risk status of homeopathic drugs made in accordance with the HPUS and applicable GMPs, a departure unsupported by reasoned explanation and record evidence.

FDA's assertion that the AHCF petition rests on a claim that homeopathic drugs are "inherently safe" *(AR p. 7218 (AR p. 36))* is specious. AHCF did not so contend; rather, the petition argued that FDA's enforcement approach should be grounded in the agency's longstanding treatment of HPUS-listed and HPUS-compliant homeopathic drugs, which historically were regulated under a distinct regulatory framework governing their formulation, dilution, and history of use precisely because of their extraordinary record of safety, while preserving FDA's authority to act against isolated instances of unsafe, adulterated, or misbranded products under extant provisions of the FDCA. *(AR p. 7).* Consistent with that framing, the petition did not dispute that "as with all drug products, the safety of homeopathic drug products… depends upon many factors, including the manufacturing quality and the identity and amount of the 'active' ingredient(s)." (*AR p. 7205*). Nor did AHCF deny FDA's authority to arrest the sale of products containing "amounts of active ingredients that could cause significant patient harm" or ingredients derived from "plants, minerals, toxic chemicals," or "healthy or diseased animal or human sources" *(AR p. 7223).* To the contrary, AHCF identified FDA's extant statutory powers against adulteration and misbranding as necessary and sufficient to act against adulterated, misbranded, or unsafe products labelled as homeopathic, stating that they are "subject to FDA enforcement action at any *time." (AR p. 32).*

Where AHCF parted ways with FDA was on FDA's unprecedented elevation of the risk level associated with homeopathic products manufactured in accordance with the HPUS and applicable GMPs, with AHCF rejecting the probative value of isolated, atypical, and unrepresentative instances of adulteration and misbranding as somehow representative of systemic homeopathic drug safety dangers, a classic hasty generalization and misapplication error. The petition explained that FDA's historical approach already addressed manufacturing

quality and ingredient concerns through HPUS standards, applicable GMPs, and targeted enforcement. As clearly explained in the petition, "an improperly manufactured homeopathic drug is a defective product just as any other product regulated by the FDA would be, and its lack of safety has no bearing on the safety of a properly manufactured and labelled homeopathic drug." *(AR p. 13).*

The Defendants further assert that the HPUS "does not limit the quantity or daily dose of active ingredient[s]" *(AR p. 7223)*, arguing that even when properly manufactured homeopathic products still cause harm. That phrasing misrepresents the HPUS and applicable GMPs. Unlike conventional pharmacology which deals with dose caps and limits, a homeopathic drug "if prepared according to the guidelines recorded in HPUS," is manufactured "by serial dilution and succussion, and consisting of only one active ingredient." *(AR p. 9).* For centuries, this method has been accepted as homeopathic good practice resulting in safe products. For decades the FDA did not find HPUS compliance itself posed a safety risk but instead emphasized enforcement against deviations from HPUS standards: "Homeopathic drug products must be manufactured in conformance with current good manufacturing practice, Section 501(a)(2)(B) of the Act and 21 CFR 211." *(AR p. 27).*

Furthermore, FDA's claim that homeopathic drugs cause patients to "forgo treatment with medical products that have been scientifically proven to be safe and effective" *(AR p. 7205)* is unsupported by record evidence, is sheer speculation. The agency cites no data demonstrating any, let alone systemic, diversion from conventional medicine to homeopathy.

Moreover, FDA's claim that FDA-approved or legally marketed drugs are uniformly "safe and effective" is a falsehood. Numerous FDA-approved pharmaceuticals, including Vioxx

(rofecoxib),[3] Fenfluramine/Phentermine (Fen-Phen),[4] Sibutramine (Meridia),[5] Phenylpropanolamine (stroke),[6] and Propoxyphene (Darvon)[7] (to mention but a few), were all granted FDA pre-market approval as safe and effective, widely prescribed, and yet withdrawn or restricted[8] on widespread evidence of serious and widespread injuries. FDA has never responded to such outcomes by declaring all drugs subject to the drug approval process categorically unsafe or ineffective. The Defendants' reasoning is thus unprecedented and not rationally explained as to why it condemns all of homeopathy as not provably safe but does not do so for any other drugs or biologics.

The administrative record on homeopathy reveals a "robust database of peer-reviewed scientific research in both clinical and preclinical investigation… demonstrating benefits in a wide range of medical conditions, with an unparalleled safety profile and patient satisfaction rates." *(AR p. 15).* This is reflected in over 54,000 public comments attesting to the perceived safety and benefits of homeopathic products *(AR pp. 7309-8962).* This is reflected in the vast majority of scientific data submitted, spanning thousands more pages than the evidence of record related to isolated adverse outcomes, confirming positive safety experiences and patient

[3] Official FDA withdrawal of Vioxx (rofecoxib): located at https: fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/vioxx-rofecoxib-quetiions-and-answers, accessed January 13, 2026.
[4] Official FDA withdrawal of Fenfluramine/Phentermine: located at https: federalregister.gov/documents/2007/01/30/E7-1414/indevus-pharmaceuticals-inc-withdrawal-of-a-new-drug-application, accessed January 13, 2026.
[5] Official FDA withdrawal of Sibutramine (Meridia): located at https: federalregister.gov/documents/2010/12/21/2010-31986/abbott-laboratories-inc-withdrawal-of-approval-of-a-new-drug-application-for-meridia, accessed January 13, 2026.
[6] Official FDA withdrawal of Phenylpropanolamine (stroke): located at https: federalregister.gov/documents/2014/02/30/2014-03596/phenylpropanolamine-withdrawal-of-13-new-drug-applications-and-46, accessed January 13, 2026.
[7] Official FDA withdrawal of Propoxyphene (Darvon): located at https: federalregister.gov/documents/2014/03/10/2014-05063/xanodyne-pharmaceuticals-inc-et-al-withdrawal-of-approval-of-8-new-drug-applications-and-46, accessed January 13, 2026.
[8] The above notes 4 to 8 are official FDA publications for which this Court may take official notice. See generally *Pharmaceutical Research and Manufacturers of America v. United States Department of Health and Human Services,* 43 F.Supp.3d 28 (D.D.C. 2014)

satisfaction. The poison-control data of record confirms products labelled "homeopathic" account for less than one percent of total calls, with 98% involving only minor or no adverse effects and "no serious adverse events, hospitalizations, or deaths attributed to properly manufactured homeopathic drugs" *(AR pp. 54, 96, 98).*

The Defendants rely on isolated safety incidents to justify a general elevation of risk not supported by the record. FDA cited "99 cases of adverse events consistent with belladonna toxicity" and reports associated with Zicam intranasal zinc products (AR p. 7205), but the AHCF petition and Plaintiffs have explained, and Defendants do not substantively dispute, that these examples involved products that were adulterated or misbranded, not homeopathic drugs manufactured in satisfaction of HPUS requirements or applicable GMPs, making them already subject to enforcement under the pre-existing law *(AR p. 12, Pls. SJ Mem. at 7, 8).* With respect to belladonna, FDA itself found the products at issue "far exceeded the labelled amounts," indicating manufacturing failure (adulteration and misbranding) not a flaw inherent in HPUS-compliant homeopathy *(AR p. 8781).* Likewise, FDA in recalling Hyland's Teething Tablets and Hyland's Baby Nighttime Teething Tables observed the presence of "significant violations of Current Good Manufacturing Practice (CGMP) regulations" which rendered the products adulterated under Section 501(a)(2)(B) *(AR p. 8784)* – precisely the type of targeted enforcement AHCF and Plaintiffs endorse.

The Defendants' brief ignores the central premise of the AHCF Petition: that safety concerns are adequately addressed through targeted enforcement of GMPs, labeling requirements, and HPUS compliance. By treating isolated, non-compliant products as representative of the safety of the entire class of homeopathic drugs, Defendants commit a classic error of law and logic – a hasty generalization that "runs counter to the evidence before

the agency" and ignores obvious, less drastic regulatory alternatives squarely presented in the petition. *(Pls. Mem. at 15, 19).*

Agency action is arbitrary and capricious when it "offer[s] an explanation for its decision that runs counter to the evidence before the agency" (*Motor Vehicle Mfrs. Ass'n v. State Farm*, 463 U.S. 29, 43 (1983); *Slash Creek Waterworks, Inc. v. Raimondo*, 2025 WL 358770, at *6 (D.D.C. Jan. 31, 2025)). That is the case here. Courts reviewing APA claims assess the whole administrative record and may not rely on post-hoc agency rationalizations to excuse profound failures to consider seriously the relevant evidence (5 U.S.C. § 706(2)(A); *FDIC v. Bank of Am., N.A.*, 783 F. Supp. 3d 1 (D.D.C. 2025). This Court may reject the Defendants' *post hoc* argument, focusing instead on the record and the FDA denial of the AHCF petition, which reveal an utter failure by FDA to account for the fact that homeopathic drugs manufactured in accordance with the HPUS and applicable GMPs have not been shown to present systemic safety risks and are, in fact, among the safest ingestible substances known to mankind, safer even than foods *(AR pp. 54, 96, 98).*

IV. FDA ARBITRARILY, CAPRICIOUSLY, AND ERRONEOUSLY PRESUMED ISOLATED FACTS OF MISMANUFACTURE AND HARM ARISING FROM PRODUCTS NOT MADE IN ACCORDANCE WITH THE HPUS AND GMPS TO BE REPRESENTATIVE OF ALL HOMEOPATHIC DRUGS, THUS VIOLATING 5 U.S.C. § 706(2)(A)

The Defendants argue based on isolated and unrepresentative instances of adulteration and harm to their general conclusion that all homeopathic drugs lack adequate safety, the capricious premise FDA relied upon to justify denial of the AHCF petition. The Defendants declare that they have evaluated the entire administrative record (despite ignoring the vast majority of it revealing homeopathic drug safety) and that they made a "reasonable" choice

(Dft's cross-motion, p. 6) (despite providing no explanation whatsoever for dismissing as irrelevant the vast majority of evidence of safety contrary to its assertion of elevated risk of harm or explaining why decades of FDA considering homeopathic drugs safe was in error). The Defendants selectively cite *FCC v. Prometheus Radio Project,* 592 U.S. 414, 423 (2021), for the proposition that this Court may not "substitute its judgment for that of the agency." The Defendants selectively cite *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983), for the proposition that so long as the Court can find a way to conclude that FDA "acted within a zone of reasonableness" and so long as it can find a way to conclude that FDA "reasonably considered the relevant issues and reasonably explained the decision" it reached, there is no basis for agency liability under Section 706. But again, its assertions are broad beyond the precedent. It is in circumstances precisely such as those present here (when an administrative agency ignores a substantial part of the record and applies examples arising from isolated and unrepresentative instances to an entire regulated class) that Courts have found agencies to have engaged in arbitrary and capricious action: on this record, to have failed to explain in a reasoned way why a market it declared for decades to be safe without need for full pre-market drug approval has somehow *sua sponte* become unsafe overnight).

Fortunately for Plaintiffs, the applicable legal standard requires that this Court not ignore the overwhelming weight of record evidence confirming homeopathic drugs made in accordance with the HPUS and applicable GMPS to be safe, or to presume illogically that isolated and unrepresentative instances of mis-manufacture or adulteration are indicative of a lack of safety for all homeopathic drugs.

In *Motor Vehicle Manufacturers Association v. State Farm*, 463 U.S. 29 (1983), the Supreme Court held in pertinent part that an agency action would violate Section 706 if the

agency "entirely failed to consider an important aspect of the problem" or "offered an explanation for its decision that runs counter to the evidence before the agency." *State Farm,* 463 U.S., at 103. The Court recognized that an agency must "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Id.* at 43, 103. In *State Farm*, comparable facts exist to those present here. The Traffic Safety Administration arbitrarily and capriciously revoked the passive restraint requirement for motor vehicles by failing to consider airbag alternatives and inadequately analyzing automatic seatbelt data, thus revealing that it ignored relevant evidence. In like manner, here, FDA denied the AHCF petition by failing to consider the overwhelming and relevant evidence that established homeopathic drug safety when products are made in accordance with the HPUS and applicable GMPs.

Repeatedly, the Supreme Court has held that agencies cannot ignore contrary record evidence when making policy decisions. See, e.g., *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 537 (2009) (Kennedy, J., concurring: "an agency cannot simply disregard contrary or inconvenient factual determinations that it made in the past, any more than it can ignore inconvenient facts when it writes on a blank slate").

And again in *Department of Homeland Security v. Regents of the University of California*, 591 U.S. 1, 30-31(2020), the Court held DHS to have acted arbitrarily and capriciously by failing to address reliance interests when rescinding the DACA program. The Court held that when an agency changes course (as it did here by holding homeopathy demonstrably and reliably safe for decades and then abruptly holding the opposite), it is obliged to remain "cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account." *Id. at* 30. When making such drastic changes, as here, it is

incumbent upon the agency to provide a full and reasoned explanation for its departure from precedent. The Supreme Court in *Encino Motorcars, LLC v. Navarro,* 579 U.S. 211, 212 (2016) held no deference appropriately given an agency because the regulation there "issued without the reasoned explanation that was required in light of the Department's change in position and the significant reliance interests involved."

In *Butte County, Cal. v. Hogen*, 613 F.3d 190, 194 (D.C. Cir. 2010), the D.C. Circuit ruled that "an agency's refusal to consider evidence bearing on the issue before it constitutes arbitrary agency action within the meaning of § 706." The Court explained that agencies cannot lawfully ignore evidence that contradicts their positions, which ignorance (whether benign or malign) constitutes arbitrary and capricious agency action. Likewise in *Genuine Parts Co. v. EPA,* 890 F.3d 304, 313 (D.C. Cir. 2018), our Court of Appeals established that "it was arbitrary and capricious for the EPA to rely on portions of studies in the record that support its position, while ignoring cross sections in those studies that do not." Here, that same practice occurs, with FDA ignoring the absence of evidence of lack of safety of properly manufactured and labeled HPUS-compliant products, while focusing its evidence of lack of safety on improperly manufactured and misbranded products. This raises a critically important and generally applicable scientific maxim, namely that "absence of evidence is not evidence of absence," which has often been applied to toxicology (e.g., Altman DG, Bland JM. "Absence of evidence is not evidence of absence". *BMJ*. 1995;311(7003):485). In the regulatory toxicology of drugs, the burden is on demonstrating safety for approval, but for existing drugs or food-related chemicals with data gaps, weight-of-evidence approaches prevail over presumptive toxicity. An example of this approach is accepted by the FDA with respect to food-contact articles. The FDA's Threshold of Regulation (21 CFR 170.39 [1995]) exempts certain food-contact substances with very low

dietary exposure (<0.5 ppb, ~1.5 μg/person/day) from full regulatory review, even without complete toxicity data. This is based on a large database of toxicological studies showing negligible risk at such exposures. It demonstrates that data gaps do not imply presumptive toxicity; rather, a conservative weight-of-evidence approach supports acceptable safety without requiring further testing.

In the case of homeopathic medicines, it is of vital importance to consider the relative lack of evidence of adverse event reports related to properly manufactured and labeled products and recognize that the overwhelming majority of adverse reports have been associated with mis-manufactured and misbranded products *(AR pp. 8781, 8814, 8844, 8846, 8864 in relation to adverse event reports, and AR pp. 8879-8962 in relation to improper manufacture)*.

A natural corollary to the requirement that evidence bear on an issue be taken into account is that the relevant data support the conclusion reached, here the relevant data did not support the conclusion reached by FDA. See generally *Texas Corn Producers v. EPA,* 141 F.4th 687 (5th Cir. 2025).

V. THE RECORD DOES NOT SUPPORT FDA'S CONCLUSION THAT HOMEOPATHIC DRUGS ARE UNSAFE, INHERENTLY OR OTHERWISE

In response to Plaintiffs' characterization of Defendants' position to be that homeopathic drugs are inherently unsafe, the Defendants assume the peculiar position that they do not hold the view that homeopathic drugs are inherently unsafe but that only certain ones are, but include as unsafe certain ones made in accordance with the HPUS and GMPs. That statement contradicts the agency's foundation for denial of the ACHF petition and the underpinnings of its revocation of CPG 400.400. The foundation was that all homeopathic products pose an elevated risk warranting elimination of the decades old CPG 400.400 safe harbor--not that just a few

homeopathic products pose that risk, but that all do. If only some homeopathic products are unsafe that should have been the gravamen of the FDA's decision without altering its risk calculus for all homeopathic products (and a rational distinguishing principle would have to have been adopted, such as HPUS-compliant and GMP compliant homeopathic products are of low risk and those not of high, which is the ACHF position). Accepting this incoherent defense as legitimate, we must conclude that the agency has not fairly taken into account the weight of evidence which contradicts its position that some homeopathic drugs are unsafe, because it has not adopted a distinguishing principle, choosing instead arbitrary and capricious unbridled discretion.

Indeed, as ACHF maintained, when made in accordance with the HPUS standards and applicable GMPs, homeopathic drugs are in fact demonstrably safe, and have historically proven to be so, a point accepted by FDA for decades.

FDA is entitled, as it sets out in its Final Guidance (2022), to prioritize enforcement against categories of homeopathic drugs that present higher risk (e.g., injectables, products claiming to treat serious diseases). FDA is also entitled to act against adulterated products and misbranded or mislabeled products, including those sold "as homeopathic" but that are not HPUS-compliant.

But, as FDA itself acknowledges ("FDA recognized that many homeopathic drugs do not raise safety concerns…[and] will fall outside the categories of products FDA intends to prioritize for enforcement", p. 13 of Opposition and Cross-Motion). Thus only a subsection of homeopathic drugs may present a safety concern. However, in its Opposition and Cross-Motion, the Defendants can produce no record evidence to define a distinguishing principle, overtly rejecting that evidence of record that GMP and HPUS-compliant products are adequately safe.

They must take that incongruent and illogical position because FDA refused to adopt the distinguishing principle, declaring all homeopathic drugs not only unapproved but also not provably safe. In attempting to justify its case, the FDA repeatedly cites cases of adulteration (in terms of deviation from the HPUS): contamination, improper manufacture, misbranding, or mislabeling. Therefore the cited record does not reflect on the safety of HPUS-compliant products manufactured under appropriate controls.

Specifically, the Opposition and Cross-Motion, posits that safety concerns arise owing to the following factors:

(1) FDA upholds that "[s]ome homeopathic drugs contain "amounts of active ingredients that could cause significant harm" justifying this by the use in homeopathy of ingredients "derived from…plants, minerals, toxic chemicals, and healthy or disease animal or human sources." As the Paracelcian principle proposes, the use, or even presence, of an ingredient that has potential toxicity has no bearing on whether its use, in its final, highly diluted, potentized form, will induce potential toxicity. FDA has not shown that "source categories" = "unacceptable risk" for properly prepared HPUS drugs; the examples in the record are dominated by manufacturing and labeling failures.

(2) FDA upholds "FDA has not shown that 'source categories' = 'unacceptable risk' for properly prepared HPUS drugs; the examples in the record are dominated by manufacturing and labeling failures." While DOJ states: "Some products sold as homeopathic could have material amounts and could harm if overdosed." That is true of all drugs, even over-the-counter ones. The "[p]otential to harm if misused or overdosed" supports enforcement against abuse, not elevation of the risk categorization for all homeopathic drugs, including the overwhelming majority that are HPUS and GMP compliant.

(3) FDA claims that people who elect to use homeopathic drugs may "Forego proven treatment / serious diseases [or] delay life-saving care." No record evidence supports this conclusion. Nothing of record corroborates that consumers cease taking prescribed treatments for homeopathic drugs.

(4) Hyland's belladonna / Zicam anosmia. Hyland's highly publicized belladonna events have clearly been demonstrated to be the result of unacceptable potency variability and poor manufacturing control. Even then, no causative evidence exists, the vast majority is associative, and the numbers may have been elevated by narrative fallacy. The Zicam cases were mislabeling/misbranding coupled with route-specific risk (intranasal toxicity caused by excessive, non-homeopathic amounts of zinc). The belladonna and Zicam cases do not provide any definitive or causative evidence for intrinsic lack of safety of compliant products. In FDA's denial of the AFHC petition (2022), only the belladonna and Zicam examples were cited (*AR p. 7205)*, as both of these cases represent the bulk of the cluster of reported adverse events. If there was a category-wide risk, FDA would not keep calling out these two outliers.

(5) FDA references the hospitalization of a product based on *Schistosoma haematobium*. This is either (a) speculative with respect to causation, or (b) an adulteration/manufacturing issue. Either way, if it is merely an association, it is not reliable evidence of causation sufficient to justify broad policy, nor does it support the categorical leap that all homeopathic drugs should be deemed not sufficiently safe. If the product genuinely delivered viable infectious material, it should be interpreted as adulteration and a manufacturing failure, not an indictment of HPUS- and GMP- compliant homeopathy.

(6) FDA provides further specific examples of high-risk uses that may induce safety concerns, namely non-sterile /high pH eye drops, and injectables with toxic ingredients that

bypass the liver/skin. It fails to establish, as it cannot but as it must, that these examples are representative of the universe of homeopathic drugs manufactured in accordance with GMPs and the HPUS.

(7) Issues of microbiological contamination in which FDA claims there have been 900+ recalls are further evidence of CGMP/quality failure, again, not shown to be typical of all homeopathic drugs.

(8) FDA raises concerns over homeopathic products based for infants or children based on nux vomica (strychnine). This is a classic case in which the intrinsic toxicity of the starting material cannot be transferred to the finished product. Nux Vomica (at potencies of 6C, 12C, 30C, 200C) lack notable safety concerns in properly manufactured, authorized/registered homeopathic products (Habs M, Koller M. *Complement Med Res.* 2021;28(1):64-84). FDA has failed again to show the examples to be representative and typical or to arise from HPUS and GMP compliant products.

In summary, Defendants rely overwhelmingly on examples of noncompliance and high-risk dosage forms—not evidence that properly manufactured and properly labeled HPUS-listed products, in low-risk dosage forms, present an elevated safety risk warranting reclassification of risk for an entire category of drugs. The FDA's cited examples do not illustrate safety risks inherent to HPUS-compliant homeopathic drugs that are properly manufactured and accurately labeled. Rather, they involve isolated instances of alleged adulteration, contamination, potency variability, misbranding, and higher-risk dosage forms—already unlawful under the pre-existing FDCA.

From these discrete enforcement actions, the FDA extrapolates to a broad, categorical conclusion regarding the safety of homeopathic drugs generally. The inference lacks support in the AR and does not provide a rational basis for denying a citizen petition that seeks a risk-based regulatory framework in recognition of the record reality: that homeopathic drugs manufactured in accordance with applicable GMPs and the HPUS are reliably safe at the lowest levels of risk of any FDA regulated products.

VI. THIS COURT SHOULD REVERSE AND REMAND THE FDA'S DENIAL OF THE ACHF PETITION, REQUIRING THAT IT TAKE INTO ACCOUNT ALL EVIDENCE DOCUMENTING HOMEOPATHIC DRUGS TO BE SAFE WHEN MANUFACTURED IN ACCORDANCE WITH THE HPUS AND APPLICABLE GMPS

As explained in the Plaintiff's memorandum in support of their motion for summary judgment and as expounded upon here, Defendants' denial of the ACHF petition should be reversed and remanded to the agency for further proceedings to take into account fully the safety data concerning the extent to which homeopathic drugs manufactured in accordance with the Homeopathic Pharmacopeia of the United States and applicable GMPs can reasonably be expected to be safe and to take such other and further action as a full accounting of the safety evidence justifies. Defendants' cross-motion on the issue of safety should be denied.

Sincerely,

/s/ Jonathan W. Emord

Jonathan W. Emord,
Counsel to Plaintiffs

Dated: January 22, 2026