Before the
Federal Trade Commission
Washington, DC 20580

In the Matter of

Petition for Withdrawal of Notice of Penalty Offenses

Consumer Healthcare Products Association

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EXECUTIVE SUMMARY

Since at least 1994, when Congress enacted the Dietary Supplement Health and Education Act (DSHEA), the American public has been promised access to safe dietary supplements, foods, over-the-counter (OTC) medication, and other consumer products that can improve their health. Congress guaranteed that American consumers could obtain truthful and non-misleading information about these products, without the need for new drug-level clinical trials.

When enacting DSHEA, Congress specifically found that "the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies." Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103–417, § 2(2), 108 Stat. 4325, 4325 (1994). Congress further declared that "clinical research has shown that several chronic diseases can be prevented simply with a healthful diet . . . with a high proportion of plant-based foods." *Id.* § 2(3)(B). Because "improving the health status of United States citizens ranks at the top of the national priorities of the Federal Government," *id.* § 2(1), Congress made sure that companies could "disseminat[e] . . . information linking nutrition and long-term good health," *id.* § 2(7), so "consumers [w]ould be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular" products. *Id.* § 2(8). Congress thus concluded that "the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers." *Id.* § 2(13).

The federal agencies responsible for regulating consumer healthcare products followed this congressional mandate. The Food and Drug Administration (FDA) issued guidance giving "manufacturers flexibility in the precise amount and type of evidence that constitutes adequate substantiation." FDA, *Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act* (Jan. 2009) ("Guidance for Industry"). Further, the FDA recognized that there is "no pre-established formula as to how many or what type of studies are needed to substantiate a claim . . . ." *Id.* While the "gold standard" for substantiation is "randomized, double blind, placebo-controlled trial[s]," the FDA directed that "trials of this type may not always be possible, practical, or ethical." *Id.* The FDA does not even require randomized controlled trials (RCTs) for OTC drugs that conform with existing OTC monographs. *See* Final Administrative Orders for Over-the-Counter Monographs, 86 Fed. Reg. 52,474, 52,475–76 (Sept. 21, 2021).

The Federal Trade Commission (FTC) also issued its own staff guidance to industry regarding dietary supplement claims. The FTC told the public that it "gives great deference to an FDA determination of whether there is adequate support for a health claim." FTC, *Dietary Supplements: An Advertising Guide for Industry* 1 (2001). The FTC further stated that it allows companies to use a "flexible" standard, and that "there is no fixed formula for the number or type of studies required . . . ." *Id.* at 9. Indeed, animal, *in vitro*, and observational studies are all to be considered. *Id.* at 10.

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Relying on this regulatory framework, thousands of companies have created and sold consumer healthcare products that have helped millions of consumers live happier and healthier lives. The Petitioners are the leading voices fighting to ensure that Americans have access to OTC medications, dietary supplements, and consumer medical devices that deliver new and better ways to get and stay healthy. The Petitioners include the Consumer Healthcare Products Association, Personal Care Products Council, United Natural Products Alliance, Food Industry Association, Natural Products Association, and American Herbal Products Association.[1]

Unfortunately, over time, the FTC began to depart from these well-settled principles and began trying to impose a new drug-level RCT requirement. *See In re The Dannon Company*, No. C-4313 (F.T.C. Jan 31, 2011) (seeking a drug-level RCT requirement); *In re Nestlé Healthcare Nutrition, Inc.*, No. C-4312 (F.T.C. Jan. 12, 2011) (same). Fortunately, when courts have analyzed the question, they have held that drug level RCTs are not required for non-drug products making non-drug claims. *United States v. Bayer Corp.*, No. 07-01(JLL), 2015 WL 5822595, at *3 (D.N.J. Sept. 24, 2015) ("Although new drugs must be pre-approved by the Food and Drug Administration, and traditionally must be supported by randomized, placebo-controlled, double-blind clinical trials, dietary supplements need not." (citations omitted)); *FTC v. Garden of Life, Inc.*, 845 F. Supp. 2d 1328, 1335 (S.D. Fla. 2012), *aff'd in part and vacated in part*, 516 F. App'x. 852 (11th Cir. 2013) (similar).

After these decisions, the FTC paused its march toward imposing RCTs for healthcare products. With a few years gone by, however, the FTC is now trying to raise the substantiation standard again. But rather than lobby Congress to amend the statute or engage in formal rulemaking, the FTC issued updated staff guidance in December 2022. FTC, *Health Products*

[1] The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing the leading manufacturers and marketers of consumer healthcare products, including OTC medicines, dietary supplements, and consumer medical devices. CHPA is committed to empowering self-care by ensuring that Americans have access to products they can count on to be reliable, affordable, and convenient, while also delivering new and better ways to get and stay healthy.

The Personal Care Products Council (PCPC), founded in 1894, is the leading national trade association representing cosmetics and personal care products companies. PCPC's 600 member companies manufacture, distribute and supply the vast majority of personal care products marketed in the U.S.

The United Natural Products Alliance (UNPA), founded in 1992, is an international association representing more than 100 best-in-class natural products, dietary supplement, functional food, and scientific, technological, and related service companies that share a commitment to providing consumers with natural health products of superior quality, benefit and reliability.

The Food Industry Association (FMI), works with and on behalf of the entire food industry to advance a safer, healthier and more efficient consumer food supply. FMI brings together a wide range of members—from retailers who sell to consumers, to producers who supply the food, as well as the wide variety of companies providing critical services—to amplify the collective work of the industry.

The Natural Products Association (NPA), founded in 1936, is the nation's largest and oldest nonprofit organization dedicated to the natural products industry. NPA represents over 700 members accounting for more than 10,000 retail, manufacturing, wholesale, and distribution locations of natural products, including foods, dietary supplements, and health/beauty aids.

The American Herbal Products Association (AHPA), founded in 1982, is the national trade association and voice of the herbal and natural products industries. AHPA is comprised of more than 350 member companies, consisting primarily of growers, processors, manufacturers and marketers of herbs and herbal products as foods, dietary supplements, cosmetics, and non-prescription drugs, and also including companies that provide expert services to the herbal trade.

Compliance Guidance (Dec. 2022). Noticeably absent from this guidance were any of the traditional statements that the substantiation standard is "flexible," that there is no set formula on the number or type of studies, or even that animal, *in vitro*, and observational studies may be sufficient. To the contrary, the new FTC guidance asserts that these types of non-randomized controlled trial evidence "may provide useful supporting or background information, but, without confirmation by human RCTs, they aren't sufficient to substantiate health-related claims." *Id.* at 14. Indeed, the guidance specifically and erroneously rejects the *Bayer* decision: "The case law both before and after *Bayer* has consistently applied an RCT standard in cases challenging health-related advertising claims as unsubstantiated." *Id.* at 38.

Now, the FTC has taken this guidance one step further. In April 2023, the FTC sent a notice of penalty offense to almost 700 companies. FTC, *Notice of Penalty Offenses Concerning Substantiation of Product Claims* (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Substantiaton-NPO.pdf ("Notice"). This Notice enclosed the updated healthcare products guidance and was accompanied by a letter stating that, if the company "engag[es] in conduct described" in the Notice, then the company "could [be] subject . . . to civil penalties of up to $50,120 per violation." FTC, *Letter re: Notices of Penalty Offenses*, 1 (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf ("Ltr."). The Notice attempts to impose a new drug-level substantiation standard for claims on foods, dietary supplement, OTC drugs, and other consumer healthcare products. Indeed, the FTC even suggests that evidence supporting a German Commission E monograph would not be sufficient for non-drug products in the U.S. *See* FTC *Health Prods. Compliance Guidance*, 19 (Dec. 2022).

Petitioners respectfully request that the Commission withdraw this Notice for three reasons. *First*, the Notice (and Health Products Guidance) attempts to impose a substantiation standard for claims on consumer healthcare products that is inconsistent with prior FTC guidance, and not permitted. *Second*, the Notice does not establish the "actual knowledge" necessary to seek civil penalties under Section 5(m)(1)(B) of the FTC Act. *Third*, enforcing the Notice would violate due process because it fails to provide any company with fair notice of what is prohibited and is so vague and standardless that it encourages discriminatory enforcement.

I. LEGAL AND FACTUAL BACKGROUND

A. The Dietary Supplement Health And Education Act And The Food, Drug, And Cosmetic Act

The Food, Drug, and Cosmetic Act ("FDCA") is designed to protect consumers from harmful products. *Perham v. GlaxoSmithKline LLC (In re Zofran (Ondansetron) Prods. Liab. Litig.)*, 57 F.4th 327, 330 (1st Cir. 2023). Recognizing the benefit of non-drug products, in 1994 Congress amended the FDCA through the enactment of the Dietary Supplement Health and Education Act (DSHEA), Pub. L. No. 103-417, 108 Stat. 4325, 4325–26. While "new drugs must be pre-approved by the Food and Drug Administration," *see* 21 U.S.C §§ 331(d), 355(a), and "traditionally must be supported by randomized, placebo-controlled, double-blind clinical trials ("RCTs"), dietary supplements need not." *Bayer*, 2015 WL 5822595, at *3 (citation omitted) (citing 21 C.F.R. § 314.126).

Instead, for dietary supplements, the only substantiation requirement is that permissible health-related claims must be "truthful and not misleading." 21 U.S.C. § 343(r)(6)(B); *see also id.* § 321(ff) (defining "dietary supplement" as any non-tobacco product "intended to supplement the diet"); *id.* § 343(r)(6)(A) (identifying types of dietary supplement claims, including structure/function claims and classical nutrient deficiency disease claims). Permissible health-related claims about food products, too, are governed by this standard. *See* FDA, *Label Claims for Conventional Foods and Dietary Supplements* (Mar. 7, 2022). At bottom, as long as the supplement is not marketed as a drug—that is, "not claim[ed] to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases," 21 U.S.C. § 343(r)(6)(C) (requiring disclaimer)—it is not regulated like a new drug.

B. Federal Agency Guidance

DSHEA does not specify what substantiation is necessary to render a claim "truthful and not misleading." Accordingly, decades ago, the FTC provided guidance, stating that the relevant standard is "competent and reliable scientific evidence." FTC, *Dietary Supplements: An Advertising Guide for Industry* (2001), at 9. The FTC defines this phrase to mean: "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." *Id.*

The prior guidance makes clear that this standard is not the new drug standard. Instead, "competent and reliable scientific evidence" is a "flexible" standard, and "[t]here is no fixed formula for the number or type of studies required . . . ." *Id.* at 8–9. Although "well-controlled human clinical studies are the most reliable form of evidence[,]" they are not necessary, and "[r]esults obtained in animal and *in vitro* studies will also be examined, particularly where they are widely considered to be acceptable substitutes for human research or where human research is infeasible." *Id.* at 10. "[R]esearch explaining the biological mechanism underlying the claimed effect" will also be considered. *Id.* Even "epidemiologic evidence may be an acceptable substitute for clinical data" in some circumstances. *Id.*

Further, studies on the precise formula used in the advertised product are not required. Rather, it can be "appropriate to extrapolate from the research to the claimed effect," even if there "are significant discrepancies between the research conditions and the real life use being promoted . . . ." *Id.* at 16. The FDA recognizes in its guidance that RCTs for dietary supplements may not be "possible, practical, or ethical." See FDA, *Guidance for Industry*.

In December 2022, however, the FTC repealed its previous guidance and issued new guidance. FTC, *Health Prods. Compliance Guidance* (Dec. 2022). The FTC's 2022 guidance is an about-face and for the first time takes the position that "[a]s a general matter, substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard." *Id.* at 12 & n.31 (collecting cases). While this guidance "do[es] not have the force and effect of law," *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 97 (2015), completely absent from the guidance is any reference to the fact that animal, *in vitro*, and other studies can provide appropriate substantiation.

C. FTC's Notice of Penalty Offenses

As part of operationalizing this new guidance, the FTC sent Notice of Penalty Offenses to nearly 700 companies. This is a novel enforcement mechanism for the Commission. For decades, the Commission's preferred method of enforcing its requirement that companies not make false or misleading statements was Section 13(b) of the FTC Act, and the FTC obtained billions of dollars in settlements under this provision. After this practice was challenged in court, however, the Supreme Court unanimously held that Section 13(b) does not authorize the FTC to seek any monetary relief. *AMG Cap. Mgmt., LLC v. FTC*, 141 S. Ct. 1341, 1351 (2021). In the aftermath of *AMG Capital*, former FTC Commissioner Rohit Chopra and his then-Advisor Samuel Levine called for a resurrection of the FTC's authority to seek civil penalties under Section 5(m). Rohit Chopra & Samuel Levine, *The Case for Resurrecting the FTC Act's Penalty Offense Authority*, 170 U. Pa. L. Rev. 71 (2021).

Not long after, the FTC began sending notice of penalty offenses on a variety of topics. *See* FTC, *Notice of Penalty Offenses Concerning Deceptive or Unfair Conduct in the Education Marketplace*, https://www.ftc.gov/system/files/attachments/penalty-offenses-concerning-education/final-notice-education.pdf (last visited Sept. 14, 2023); *see also* FTC, *Notice of Penalty Offenses Concerning Deceptive or Unfair Conduct around Endorsements and Testimonials*, https://www.ftc.gov/system/files/attachments/penalty-offenses-concerning-endorsements/notice-penalty_offenses-endorsements.pdf (last visited Sept. 14, 2023); FTC, *Notice of Penalty Offenses Concerning Money-Making Opportunities*, https://www.ftc.gov/system/files/attachments/penalty-offenses-concerning-money-making-opportunities/mmo-notice.pdf (last visited Sept. 14, 2023). These letters all threatened civil penalties for future violations.

Then in April 2023, the FTC sent letters and notices to almost 700 companies across the consumer healthcare product industry, including many members of Petitioners. The letters were mass mailers akin to junk mail and were not personalized to any of the recipients. Indeed, recipients included ingredient suppliers, retailers, and companies that have not manufactured a consumer healthcare product in years. It is unclear what source FTC used to create its list of recipients. While the letters stated that "[r]eceipt of a notice of penalty offenses puts your company on notice that engaging in conduct described therein could subject the company to civil penalties of up to $50,120 per violation," Ltr. 1, the letters did not identify any actual conduct of each recipient that the FTC believed may be unlawful. Indeed, the FTC did not even identify what products the letters addressed or claims the FTC contended were unsubstantiated, and thus it failed to give the companies any way to remedy the concerns expressed in the letter. Instead, the letters contained only a generic list of "Commission determinations in prior litigated cases that certain practices are deceptive or unfair and, thus, are unlawful under Section 5 of the [FTC] Act." *Id.* Each bulleted statement included a single footnote containing case citations to FTC administrative actions and civil cases decided in federal court. The bullets included citations to decisions as recent as 6 years ago and as old as 49 years ago. *Id.* 1–2.

II. DISCUSSION

The FTC's Notice should be withdrawn. First, the Notice and 2022 Guidance attempt to impose a substantiation standard that cannot be reconciled with DSHEA, is inconsistent with

prior FTC and Commission guidance, and is not authorized by law. Second, the Notice fails to establish that any company had "actual knowledge" that its conduct was unfair or deceptive in violation of the FTC Act, as required to obtain civil penalties under Section 5(m)(1)(B). Indeed, courts have recognized exactly that and rejected the FTC's attempts to obtain civil penalties under Section 5(m)(1)(B). *See United States v. Hopkins Dodge, Inc.*, 849 F.2d 311 (8th Cir. 1988). Third, enforcing the Notice would violate due process because it fails to provide any company fair notice of what is prohibited and is so generic and standardless as to authorize and encourage discriminatory enforcement.

A. FTC's Notice Imposes An Unlawful Substantiation Standard For Consumer Healthcare Products.

The Notice attempts to impose a substantiation standard that is not permitted by law. Both DSHEA and long-standing FDA guidance make clear that claims for non-drugs do not require drug-level RCTs.

Under the FDCA, new drugs—products intended to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases, 21 U.S.C. § 321(g)(1)—generally must be supported by at least one double-blind, placebo controlled, randomized clinical trial. 21 C.F.R. § 314.126. But this standard is not applicable to consumer healthcare products, including dietary supplements and food products. As courts have recognized time and again, through DSHEA, "Congress intended dietary supplements to escape the regulatory gauntlet that drugs must go through" and therefore adopted a lesser standard for dietary supplements. *Ferrari v. Vitamin Shoppe Indus. LLC*, 70 F.4th 64, 73–74 (1st Cir. 2023).

For dietary supplements (and other non-drug products) that make structure/function claims, manufacturers need not possess the same level of substantiation as they must for drugs. Rather than meet the RCT requirement, manufacturers of dietary supplements must ensure claims are truthful and not misleading. 21 U.S.C. § 343(r)(6)(B). After all, "there is a reason why structure/function claims may not purport to treat disease and why a product bearing such claims must expressly repudiate any intention of treating disease." *Ferrari*, 70 F.4th at 73; *see also Kaufman v. CVS Caremark Corp.*, 836 F.3d 88, 93 (1st Cir. 2016) ("FDA guidance, however, advances a commonsense interpretation of substantiation, also adopted by the Federal Trade Commission, as meaning competent and reliable scientific evidence." (cleaned up)). This same "truthful and not misleading" standard applies to health-related claims for food products. *See* FDA, *Label Claims for Conventional Foods and Dietary Supplements* (Mar. 7, 2022).

The FTC itself has long recognized that the law does not require RCTs for non-drug products and non-drug claims. Before the 2022 about-face, the FTC's own guidance made clear that RCTs are not required for dietary supplement claims: "As a general rule, well-controlled human clinical studies are the most reliable form of evidence. Results obtained in animal and *in vitro* studies will also be examined, particularly where they are widely considered to be acceptable substitutes for human research or where human research is infeasible." FTC, *Dietary Supplements: An Advertising Guide for Industry* 10 (2001).

FDA's guidance recognized this too. In 2009, the FDA published a document that interpreted 21 U.S.C. § 343(r)(6)(B). FDA, *Guidance for Industry*. While this guidance states

that "[c]ompetent and reliable scientific evidence adequate to substantiate a claim would consist of information derived primarily from human studies," it also recognizes that "[a]lthough the quality of individual pieces of evidence is important, each piece should be considered in the context of all available information; that is, the strength of the total body of scientific evidence is the critical factor in assessing whether a claim is substantiated." *Id.* The FDA's guidance thus emphasizes two key points: first, that substantiation is a fact-intensive question; and second, that *at no point* has an agency required that dietary supplement manufacturers substantiate their claims via RCTs. Nor has the FDA required RCTs for OTC drugs that conform with applicable OTC monographs. *See* 86 Fed. Reg. at 52,475–76 (detailing the FDA's OTC Drug Review process and explaining that "OTC drugs are generally recognized as safe and effective (GRASE) if they meet the conditions of an OTC monograph" and "other applicable requirements").

Even more, FDA has recognized in its guidance that RCTs for dietary supplements and foods "may not be 'possible, practical, or *ethical*.'" *Bayer*, 2015 WL 5822595, at *4 (emphasis added) (quoting FDA, *Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act* (Dec. 2008)); *see* J. De Meulemeester et al., *Many Randomized Clinical Trials May Not Be Justified: A Cross-Sectional Analysis of the Ethics and Science of Randomized Clinical Trials*, 97 J. Clin. Epidemiology 20, 24 (2018) (concluding that "RCTs should only proceed if they are scientifically and ethically justified"); J. Hébert et al., *Perspective: Randomized Controlled Trials Are Not a Panacea for Diet-Related Research*, 7 Adv. Nutr. 423, 427 (2016) (noting that, "for many dietary issues, [RCTs] are neither feasible nor ethical").[2]

Through the FDCA and DSHEA, Congress formulated a carefully balanced regulatory regime for new drugs and non-drug products. No congressional statute contemplates treating new drugs and dietary supplements the same; and doing so would violate the statutory structure carefully crafted by Congress. *See Mellouli v. Lynch*, 575 U.S. 798, 809 (2015) ("Statutes should be interpreted 'as a symmetrical and coherent regulatory scheme.'" (citation omitted)). The FTC may not now impose a contrary view on the industry in the absence of clear instruction from Congress. *See, e.g.*, *Ferrari*, 70 F.4th at 73–74 ("[C]ongress knows how to add an efficacy requirement when it wants to and intentionally excluded one from structure/function claims. . . . Needless to say, Congress intended dietary supplements to escape the regulatory gauntlet that drugs must go through.").

The FTC's attempt to establish a new substantiation standard through a mass-mailed letter and notice is not permissible under governing law and should be withdrawn.

B. FTC's Notice Does Not Establish "Actual Knowledge" Necessary To Seek Civil Penalties Under Section 5 Of The FTC Act.

The FTC's mass-mailed Notice fails to provide any basis to impose the civil penalties it threatens. Section 5(m) of the FTC Act provides that the Commission may obtain civil penalties against a company that commits a deceptive or unfair act or practice after it has "*actual*

[2] Further showing that the FTC is applying the wrong standard, FDA has recognized that, even for health claims for food that are subject to the "significant scientific agreement" standard, RCT are still not required. *See* 21 USC § 343(r)(3)(B)(i); FDA, *Guidance for Industry: Evidence-Based Review System for Scientific Evaluation Health Claims*, FDA 2007-D-0371 (Jan. 2009).

knowledge" of a final FTC "cease and desist order" declaration that the specific act or practice is unlawful. 15 U.S.C. § 45(m)(1)(B) (emphasis added). Thus, the FTC must prove that (1) the company had "actual knowledge" that *its* conduct was unfair or deceptive in violation of the FTC Act, and (2) the FTC had already issued a final cease and desist order establishing that such conduct is unfair or deceptive. *LabMD, Inc. v. FTC*, 894 F.3d 1221, 1234 (11th Cir. 2018). The Notice does not provide "actual knowledge" as the phrase has been defined by the Supreme Court, and the Eighth Circuit has already rejected the FTC's previous attempt to provide notice this way.

The Supreme Court has already explained what the phrase "actual knowledge" means, and the FTC's Notice does not come close to meeting this standard. *See Intel Corp. Inv. Pol'y Comm. v. Sulyma*, 140 S. Ct. 768, 776 (2020). As the Supreme Court explained in *Sulyma*, in "everyday speech, 'actual knowledge' might seem redundant; one who claims, 'knowledge' of a topic likely means to suggest that he actually knows a thing or two about it." *Id.* "But the law," the Court explained, "will sometimes impute knowledge—often called 'constructive' knowledge—to a person who fails to learn something that a reasonably diligent person would have learned." *Id.* It is the "qualifier 'actual' [that] creates th[is] distinction." *Id.* Thus, to have "actual knowledge" that an act or practice "is unfair or deceptive" *and* "is unlawful," one "must in fact be aware" that the specific conduct it is engaging in is illegal. *Id.*

Here, the mere receipt of the Notice could not and does not establish that any of the almost-700 companies that received the Notice have "*actual knowledge*" that any of their "act[s] or practice[s] [are] unfair or deceptive." 15 U.S.C. § 45(m)(1)(B) (emphasis added). In fact, the Notice does not identify any act or practice at all. The Notice does not identify what products are supposedly unlawfully marketed. Nor does the Notice identify what claims are supposedly not substantiated, why the recipient's substantiation is insufficient, or anything at all about the recipient or its business practices. Instead, the Notice is nothing more than a page-and-a-half mass mailer that generically states the FTC's incorrect position on the law and cites a few FTC cases. This does not put the recipient on notice of anything.

A closer look at the Notice leaves no doubt on this point. The almost 700 notices are identical in form and substance for each recipient[3] and contain an exceedingly general and vague list of five "acts or practices used in the advertising or promotion of products" that FTC "has determined . . . are deceptive or unfair and are unlawful under Section 5(a)(1) of the [FTC] Act." Notice 1. These acts or practices include making "an objective product claim without having a reasonable basis, at the time the claim is made, consisting of competent and reliable evidence," making claims "relating to the health benefits or safety features of a product without possessing and relying upon competent and reliable scientific evidence that has been conducted and evaluated in an objective manner by qualified persons and that is generally accepted in the profession to yield accurate and reliable results," and "misrepresent[ing] the level or type of substantiation for a claim." Notice 1–2. Each bullet contains a footnote that includes citations to cases and administrative decisions dating back to 1974. *See id.*

[3] FTC published the list of all recipients of this Notice on its website. FTC, *List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims*, https://www.ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf (updated May 11, 2023).

These are all just generic statements from prior cases. The Notice thus says nothing about any particular act or practice that is unlawful. Nor do the cases cited by the FTC help. The FTC cites, for example, *Automotive Breakthrough Sciences, Inc.*, 126 F.T.C. 229 (1998),[4] where the final order required two corporations to "possess competent and reliable scientific evidence to substantiate any future claims regarding the attributes, efficacy, safety or benefits of any braking system . . . in any motor vehicle." *Id.* at *1. But the consumer healthcare companies that the FTC sent the Notice to are not manufacturing braking systems or motor vehicles. Simply put, the Notice does not provide the recipients with "actual knowledge" of any unfair or deceptive act or practice.

It is not enough for the FTC to suggest that the Notice provides a general understanding of what the law requires. Under Section 5(m)(1)(B), the FTC must show that the company had actual knowledge that *its own* act or practice "is unfair or deceptive and is unlawful." *See Hopkins Dodge*, 849 F.2d at 314–15. In *Hopkins Dodge*, the Eight Circuit rejected the FTC's request for civil penalties under Section 5(m)(1)(B) because "decisions [cited] in footnotes" in the FTC notice "g[ave] no knowledge that the practices *engaged in by* [the recipient] were unfair or deceptive." *Id.* at 315 (emphasis added). Even the FTC concedes this point, stating that the Notice "does not reflect any assessment as to whether you have engaged in deceptive or unfair conduct."[5]

More still, courts have roundly rejected the FTC's attempts to trigger Section 5(m)(1)(B) and impose civil penalties through a vague notice containing unadorned citations to case law. Most notably, in *Hopkins Dodge*, the Eighth Circuit recognized the gambit FTC attempted with notices much like the Notice here. There, the court rejected the FTC's request for civil penalties pursuant to Section 5(m)(1)(B) and held that it had failed to establish "actual knowledge" where the Commission had "furnished appellees copies of four F.T.C. decisions, together with a 'synopsis' citing the said decisions in footnotes." 849 F.2d at 314 (footnote omitted). So too, on closer examination by the court, those decisions "g[ave] no knowledge that the practices *engaged in by appellees* were unfair or deceptive." *Id.* at 315 (emphasis added); *see FTC v. Sec. Rare Coin & Bullion Corp.*, 931 F.2d 1312, 1315 (8th Cir. 1991). *Hopkins Dodge* thus makes clear that the vague descriptions and scant citations provided in the Notice cannot establish "actual knowledge."

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[4] Though this case is only 25 years old, FTC's Notice cites some cases that are almost *50 years old*.

[5] The legislative history confirms what the text makes plain. As Representative McCollister explained in discussing the operation of Section 5(m)(1)(B):

> [P]enalties cannot be imposed if the defendant in good faith believes that *his conduct* is permissible. His belief may be based on lack of knowledge of the law or on a reasonable judgment that his circumstances are different from those to whom an order or rule may apply, or indeed on the view, held in good faith, that his conduct is defensible under the FTC Act for any reason.

120 Cong. Rec. E7352 (daily ed. Dec. 20, 1974) (emphasis added). Indeed, "nothing in the legislative history suggests that the knowledge requirement could be satisfied simply by showing that the defendant was aware of the relevant legal principles." David O. Bickart, *Civil Penalties Under Section 5(m) of the Federal Trade Commission Act*, 44 U. Chi. L. Rev. 761, 790 (1977).

C. Enforcing The Notice Would Violate Due Process.

The Notice also violates the Due Process Clause. Due Process mandates that "laws which regulate persons or entities must give fair notice of conduct that is forbidden or required." *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012). This constitutionally-mandated "fair notice" "requires the invalidation of laws that are impermissibly vague"—that is, statutes or regulations that "fail[] to provide a person of ordinary intelligence fair notice of what is prohibited, or [are] so standardless that [they] authorize[] or encourage[] seriously discriminatory enforcement." *Id.*; *Gen. Elec. Co. v. EPA*, 53 F.3d 1324, 1333–34 (D.C. Cir. 1995).

The FTC's Notice fails to meet this due process requirement for two reasons. *First*, the Notice fails to provide any company with notice of what is prohibited. The Notice does not tell the recipient *anything* factually about what they are doing wrong. It does not identify any product, claims, or substantiation. Rather, the Notice simply distributes vague, unclear, and contrary regulatory guidance.

The Notice is, to say the least, "unclear" regarding what acts or practices *currently engaged in* by any recipient are unlawful and fail to provide any sort of "definitive reading" of the "regulatory requirement." *Gen. Elec. Co.*, 53 F.3d at 1333–34. The Notice does not put any company "on notice" that its act or practice was unlawful. *See Gates & Fox Co. v. OSHRC*, 790 F.2d 154, 156–57 (D.C. Cir. 1986); *cf. Dravo Corp. v. OSHRC* , 613 F.2d 1227, 1232–33 (3d Cir. 1980) (rejecting agency's expansive interpretation where it did not "state with ascertainable certainty what is meant by the standards [it] ha[d] promulgated" (citation omitted)). More still, the FTC's reliance on decades-old case law in the Notice only serves to increase the due process concerns here. *See Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 158 (2012) ("[W]here, as here, an agency's announcement of its interpretation is preceded by a very lengthy period of conspicuous inaction, the potential for unfair surprise is acute.").

Second, adopting FTC's interpretation would violate due process by rendering Section 5(m)(1)(B) so standardless as to authorize and encourage discriminatory enforcement. Through an *identical* letter and Notice sent to almost 700 companies that market and sell over-the-counter drugs, supplements, foods, homeopathic products, and other consumer products, FTC purports to have put *all* those companies "on notice" that they could be subject to civil penalties of "up to $50,120 per violation." Ltr. 1. But the FTC does not explain how these companies were selected or whether the Commission conducted any investigation into the companies before sending the letter. The FTC's attempt to use a mass-mailer to satisfy a statutory requirement that triggers draconian civil penalties is precisely the type of executive overreach that the Due Process Clause forbids.

CONCLUSION & ACTION REQUESTED

Pursuant to 16 C.F.R. § 1.31, through this petition, Petitioners respectfully request that FTC withdraw the notice of penalty offenses that were sent to nearly 700 companies.

The Notice attempts to impose the drug-level standard on consumer healthcare products, even though Congress has been clear that non-drug products need not have this level of evidence. The Notice threatens civil penalties of over $50,000 *per violation* based on the theory that the

mass-mailed Notice provides "actual knowledge" under Section 5(m)(1)(B) of unlawful conduct. But as courts have recognized, a vague notice like this does not provide any actual notice of unlawful conduct. Accordingly, any attempt to enforce the Notice would be prohibited by the statute and violate due process.

Because the Notice has no legal effect, it is merely threatening companies for engaging in permissible and truthful promotion of products. The chilling effect caused by the Notice thus keeps true and not misleading scientific information away from consumers. That is exactly what Congress intended to prevent with respect to dietary supplement products through DSHEA. To stop this unlawful chilling effect, FTC should immediately withdraw the Notice.

Respectfully submitted,

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