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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

FEDERAL TRADE COMMISSION, Plaintiff, vs. PRECISION PATIENT OUTCOMES, INC., a corporation; and MARGRETT PRIEST LEWIS, Individually and as CEO of Precision Patient Outcomes, Inc., Defendant(s).	Case No. 3:22-cv-7307 **NOTICE OF MOTION TO DISMISS COMPLAINT AND MEMORANDUM IN SUPPORT UNDER RULES 8, 9(b), 12(b)(1) AND 12(b)(6) OF THE FEDERAL RULES OF CIVIL PROCEDURE** Date: March 16, 2023 Time: 10:00 a.m. (Zoom) **Related ECF No.: 15**

NOTICE OF MOTION

PLEASE TAKE NOTICE that on March 16, 2023, at 10:00 a.m., before the Honorable Vince Chhabria of the United States District Court for the Northern District of California, Defendants Precision Patient Outcomes, Inc. ("PPO") and Margrett Priest Lewis ("Ms. Lewis") (collectively "Defendants") will move the Court to dismiss the First Amended Complaint ("FAC"), ECF No. 15, pursuant to Rules 8, 9(b), 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure.

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INTRODUCTION

This case comes before the Court after Defendants' good-faith efforts to engage with the Federal Trade Commission ("FTC" or "Commission") and comply with FTC's view of the law in connection with marketing Defendants' product "COVID Resist," a dietary supplement that Defendants had developed but not yet offered for sale. FTC declined to provide any feedback on Defendants' product or marketing materials but eventually initiated the present deception action, including allegations concerning COVID Resist, notwithstanding the undisputed fact that Defendants independently abandoned the COVID Resist trademark and never sold a single unit of COVID Resist.

FTC's claims against Defendants for alleged violations of the Federal Trade Commission Act ("FTC Act") and the COVID-19 Consumer Protection Act ("COVID-19 Act") fail. First the FTC's initiation and prosecution of this lawsuit violates the Constitution's separation of powers, as the FTC Commissioners—shielded from at-will removal by the President—are unconstitutionally exercising Article II powers solely reserved to officers accountable to the President. Second, FTC fails to allege any set of facts sufficient to support its deception claims against Defendants. As FTC concedes, not a single person purchased even one unit of COVID Resist, nor was it ever offered for sale. Even for Defendants' subsequent VIRUS Resist product, FTC failed to plead its claims with the particularity required by Rule 9(b). Third, FTC's request for injunctive relief against Defendants is unfounded given that Defendants never offered COVID Resist for sale in the first place and ceased all marketing and sales of VIRUS Resist in June 2022. Finally, the Food and Drug Administration ("FDA"), not FTC, has jurisdiction over what dietary supplement purveyors can say about their products.

ARGUMENT

I. FTC MAY NOT EXERCISE THE EXECUTIVE POWER BY INITIATING AND PROSECUTING THIS LAWSUIT

"A motion to dismiss for lack of subject matter jurisdiction may either attack the allegations of the complaint or may be made as a 'speaking motion' attacking the existence of subject matter jurisdiction in fact." *Thornhill Pub. Co. v. Gen. Tel. & Elecs. Corp.*, 594 F.2d

730, 733 (9th Cir. 1979). Here, FTC does not have the constitutional power to bring this action in this Court and has no power to bring a claim given to FDA, so it is a facial attack on the complaint. "To survive [a motion to dismiss under Rule 12(b)(6)], a motion must allege enough facts to be plausible on its face." *Retail Prop. Trust v. United Bhd. of Carpenters & Joiners of Am.*, 768 F.3d 938, 945 (9th Cir. 2014) (cleaned up). For the reasons set out below, the FAC should not survive.

The Constitution sets out the three branches of government and vests each with a different power—legislative, executive, and judicial. *See* U.S. Const. art. I, § 1, art. II, § 1, cl. 1, art. III, § 1. Article II vests "[t]he executive Power" in the "President of the United States of America." § 1, cl. 1. To exercise that power, the Constitution directs the President to "take Care that the Laws be faithfully executed." *Id.* § 3. Initiating a lawsuit is the essence of "tak[ing] Care that the Laws be faithfully executed," and that responsibility is entrusted to the President. *Buckley v. Valeo*, 424 U.S. 1, 138 (1976); *see also Cunningham v. Neagle*, 135 U.S. 1, 64 (1890) (that the laws be faithfully executed refers to the President's "enforcement of acts of [C]ongress"). "The entire 'executive Power' belongs to the President alone," and it includes the power to initiate lawsuits. *Seila Law LLC v. CFPB*, 140 S. Ct. 2183, 2197 (2020). The President cannot fulfill his role of "faithfully" initiating lawsuits without assistance. He must "select those who [are] to act for him under his direction in the execution of the laws." *Myers v. U.S.*, 272 U.S. 52, 117 (1926); *Cunningham*, 135 U.S. at 63-64.

The President's selection of administrative officers is essential to his execution of the laws. *Myers*, 272 U.S. at 117. Equally essential is his power to remove those officers. *Id.* "[T]o hold otherwise would make it impossible for the President … to take care that the laws be faithfully executed." *Id.* at 164; *see also Free Enter. Fund v. PCAOB*, 561 U.S. 477, 483 (2010) ("Since 1789, the Constitution has been understood to empower the President to keep [his] officers accountable—by removing them from office, if necessary.").

The FTC's initiation of this lawsuit—and the statutes authorizing it—unconstitutionally usurp the President's Article II powers because commencing civil litigation is an act of executive power. Lest there be any doubt that FTC exercises a truly executive, rather than

"quasi-legislative" or "quasi-judicial" function, the Commission has taken legal stances directly contrary to those advanced by the Executive Branch. For example, in *FTC v. Qualcomm Inc.*, 969 F.3d 974 (9th Cir. 2020), FTC said Qualcomm's patent licensing policies violated antitrust laws. The Department of Justice ("DOJ") took the opposite view. Despite DOJ expressing its position early on and supporting Qualcomm's motion to stay the district court's (eventually reversed) order, *see FTC v. Qualcomm Inc.*, 935 F.3d 752 (9th Cir. 2019), FTC continued its prosecution, *see also FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (mem.) (denying FTC's petition for certiorari that the United States opposed as *amicus curiae*). FTC drove the district court into error, despite being totally outside the chain of executive command. Though Qualcomm was vindicated and FTC's jejune understanding of patent law repudiated, millions of dollars in legal fees and reputational damage accumulated for years. Yet, the Commissioners who authorized that action were not Article II executive officers accountable to the President, nor are the Commissioners who approved this action. *See Humphrey's Ex'r v. U.S.*, 295 U.S. 602 (1935). Vesting FTC with the power to bring enforcement actions while challenging presidential authority to "take Care that the Laws be faithfully executed," U.S. Const. art. II., § 3, contradicts the constitutional structure the Framers designed and set out in the Constitution's text, *see Free Enter. Fund*, 561 U.S. at 484 ("The President cannot 'take Care that the Laws be faithfully executed' if he cannot oversee the faithfulness of the officers who execute them.").

Under Section 16(a)(1) of the FTC Act, FTC must notify DOJ in writing and "consult with the Attorney General" before filing actions like this. 15 U.S.C § 56(a)(1). The Commission can only commence an action in its own name, as it is doing here, if DOJ declines to bring the case. *Id.* § 56(a)(1)(B). In contrast to FTC Commissioners, the Attorney General, as a top Cabinet member, is appointed and removable by the President. DOJ bills itself as "the world's largest law office," and it helps the President take care that the laws are faithfully executed. *Office of Attorney Recruitment & Management*, Dep't of Justice, https://www.justice.gov/oarm (last visited Jan. 31, 2023). Here, by declining to bring an action, it did so.

In *Humphrey's Executor*, the Supreme Court upheld against a constitutional challenge the provisions of the FTC Act that made Commissioners removable only "for cause." 295 U.S.

at 629. But that decision was narrow. *First*, the Supreme Court did not doubt the Executive's Article II power to terminate executive officers' employment, which the Court characterized as "exclusive and illimitable." *Id.* at 627. As the Supreme Court explained, "*Humphrey's Executor* reaffirmed the core holding of *Myers* that the President has 'unrestrictable power … to remove purely executive officers.'" *Seila Law*, 140 S. Ct. at 2199 (quoting *Humphrey's Ex'r*, 295 U.S. at 632). *Second*, in analyzing the actual role Congress assigned FTC, the Court concluded that the Commission's 1935 iteration exercised "no part of the executive power vested by the Constitution in the President." *Humphrey's Ex'r*, 295 U.S. at 628. To the contrary, the Court concluded that "[i]n administering the provisions of the statute in respect of 'unfair methods of competition,' … the commission acts in part quasi legislatively and in part quasi judicially," and that "[t]o the extent that it exercises any executive function, as distinguished from executive power in the constitutional sense, it does so … as an agency of the legislative or judicial departments of the government." *Id.* But bringing and prosecuting this suit is ur-executive.

As current law, *Humphrey's Executor* binds this Court, but there is an evolving debate regarding the continuing viability of that precedent given the functional differences in FTC's authority and operations then versus now. As the Supreme Court has noted, the "conclusion that the FTC did not exercise executive power has not withstood the test of time." *Seila Law*, 140 S. Ct. at 2198 n.2. In applying *Humphrey's Executor* to the present dispute, this Court need not overrule that decision, nor could it. *See State Oil Co. v. Khan*, 522 U.S. 3, 20 (1997). But it can and should faithfully apply *Humphrey's entire* logic to this case in light of the FTC Act's structure, FTC's powers today, and recent Supreme Court separation-of-powers pronouncements.

When *Humphrey's* was decided, FTC did *not* possess the power to initiate suits or seek any penalties. FTC gained this core executive power only in the 1970s. Yet, as Congress added these provisions, *see* 15 U.S.C. §§ 45(m), 53(b), 57b, it left for-cause removal intact, *id.* § 41 (permitting removal for "inefficiency, neglect of duty, or malfeasance in office").

This Court must decide whether Congress violated separation of powers by authorizing the Commissioners to commence lawsuits while shielding them from at-will removal by the President. The Supreme Court's blessing of the FTC of yesteryear, with vastly different powers, does not imply an endorsement of the Commission's newer minted executive powers. *See Consumers' Rsch. v. CPSC*, 592 F. Supp. 3d 568, 584 (E.D. Tex. 2022) ("[T]he Court must consider 'the set of powers the [Supreme] Court considered as the basis for its decision' in *Humphrey's Executor*, and 'not any latent powers that the agency may have had not alluded to by the Court.'") (quoting *Seila Law*, 140 S. Ct. at 2200 n.4), *appeal docketed*, No. 22-40328 (5th Cir. May 18, 2022). That blessing "has not withstood the test of time." *Seila Law*, 140 S. Ct. at 2198 n.2. Because FTC is now vested with core executive powers, any limit on the President's ability to remove Commissioners violates separation of powers.

Notably, in the decades since deciding *Humphrey's Executor*, the Supreme Court has approved of limits on the Presidential removal power only twice. *See Morrison v. Olson*, 487 U.S. 654 (1988); *Wiener v. U.S.*, 357 U.S. 349 (1958). In neither case was the power of the protected officer sufficiently like the powers exercised by the FTC Commissioners. In *Morrison*, the Supreme Court upheld a statute granting good-cause tenure protection to an Independent Counsel appointed to investigate and prosecute alleged crimes by high-ranking government officials because the independent counsel was "an inferior officer … with limited jurisdiction and tenure and lacking policymaking or significant administrative authority." 487 U.S. at 691.[1] The logic of *Morrison*—permitting an exception to the Executive's at-will termination power—does not apply to FTC. Unlike an Independent Counsel who (in the Supreme Court's view) lacked policymaking or administrative authority, the FTC's duties are far from limited. The Commission administers multiple statutes covering broad swaths of the economy, and it claims more authority than Congress has given it. *Seila Law*, 140 S. Ct. at 2200. Furthermore, unlike an Independent Counsel whose jurisdiction is limited by specific

[1] It remains unclear if *Morrison* was overruled. *See* Richard Samp, *Good-bye*, Morrison v. Olson, Law & Liberty (Sept. 7, 2021), https://lawliberty.org/good-bye-morrison-v-olson/; *see, e.g., Justice Kagan and Judges Srinivasan and Kethledge Offer Views from the Bench*, 92 Stan. Law. In Brief (2015), https://stanford.io/3qw1UuM.

grant, *see Morrison*, 487 U.S. at 672, FTC is empowered to "prevent persons, partnerships, or corporations … from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce," 15 U.S.C. § 45(a)(2). Such broad authority, if construed without proper constitutional and statutory limits, is difficult to imagine. And that is just *one* of FTC's powers. *Morrison* cannot be relied on to sustain FTC's modern structure and powers. *Wiener* is similarly unhelpful because the War Claims Commission possessed no executive powers but, instead, was "established as an adjudicating body with all the paraphernalia by which legal claims are put to the test of proof." 357 U.S. at 345-55.

Recently, the Ninth Circuit has recognized that "*Lucia* [*v. SEC*, 138 S. Ct. 2044 (2018)] was a watershed decision that created new issues and questions for federal agencies." *Cody v Kijakazi*, 48 F.4th 956, 961 (9th Cir. 2022). The authority of every agency's decision-making officers must be considered anew post-*Lucia*. So, this Court should grapple with the questions before it with a keen eye on the Supreme Court's recent appointments and termination cases.

Turning to first principles, Article II vests the executive power in the President, who must "take Care that the Laws be faithfully executed." *See, e.g.*, *Humphrey's Ex'r*, 295 U.S. at 627 (citing the "illimitable power of removal by the Chief Executive"); *Free Enter. Fund*, 561 U.S. at 492 (citing the Take Care Clause); *Seila Law*, 140 S. Ct. at 2197 (same). The President cannot effectively fulfill that duty when Congress restricts his removal power. *Myers*, 272 U.S. at 164 ("[T]o hold otherwise would make it impossible for the President, in case of political or other difference with the Senate or Congress, to take care that the laws be faithfully executed."); *Free Enter. Fund*, 561 U.S. at 492 (same); *Seila Law*, 140 S. Ct. at 2197 (same). Thus, an unrestricted removal power is "the general rule." *Seila Law*, 140 S. Ct. at 2198. The President cannot readily remove FTC Commissioners, so their decisions are unreviewable and uncorrectable by him. *Cf. U.S. v. Arthrex*, 141 S. Ct. 1970, 1981 (2021). This is unacceptable.

II. NO COVID RESIST WAS SOLD, NOR DOES THE AMENDED COMPLAINT ALLEGE THAT IT WAS SOLD, SO FTC CANNOT MAINTAIN A SUIT ASSERTING SUCH A CLAIM

The Amended Complaint has removed any allegation that Defendants sold any product called COVID Resist. As the FAC relates, Defendants were "planning to launch

COVIDresist™" and wrote to FTC before doing so. FAC ¶¶ 11-15. Upon receiving FTC's response, Defendants abandoned the trademark, changing the product's name to remove "COVID" from it. *See* FAC ¶ 23. That's it. There is nothing more any Defendant did with anything called "COVID Resist." No member of the public bought such a product, as it was never provided nor offered for sale, and there is no allegation to the contrary in the FAC.

If FTC does not have to show that any actual person was deceived in an FTC deception action, that plainly poses serious due process concerns. However, to maintain a deception claim, FTC must show, at the very least, that a product was actually purchased. *See FTC v. Figgie Int'l, Inc.*, 994 F.2d 595, 605-06 (9th Cir. 1993) ("A presumption of actual reliance arises once the Commission has proved that the defendant made material misrepresentations, that were widely disseminated, *and that consumers purchased the defendant's product*" (emphasis added)). Here, no sale of the product "COVID Resist™" occurred, and the FAC does not so allege. Thus, FTC can present no proof of reliance upon any misrepresentation that the FAC alleges. As *Figgie* establishes and as the basic law of deception requires, to be actionable a misstatement must also be material. No statement that fails to induce a sale could be relied upon by anyone or be material.

Besides, "[f]raud statutes must be precisely crafted to target only specific false statements that are likely to cause a bona fide harm." *U.S. v. Alvarez*, 617 F.3d 1198, 1211 (9th Cir. 2010). The Ninth Circuit has been crystal clear that even false statements are protected speech and cannot be punished except under circumstances not alleged in the FAC, stating:

> [I]n a properly tailored fraud action the State bears the full burden of proof. False statement alone does not subject a [speaker] to fraud liability.... [T]o prove a defendant liable for fraud, the complainant must show that the defendant made a false representation of a material fact knowing that the representation was false; further, the complainant must demonstrate that the defendant made the representation with the intent to mislead the listener, *and succeeded in doing so.*

Id. (emphasis added) (quoting *Ill. ex rel. Madigan v. Telemarketing Assocs., Inc.*, 538 U.S. 600, 620 (2003)). Under the facts and FAC allegations here, no sale of any product called COVID Resist occurred to anyone, so there can be no allegation that Defendants "succeeded" in inducing anyone's reliance. Even if "commercial speech" is less protected by the First

Amendment, speech that induces no conduct is protected. *See, e.g., Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 68-70 (1983) ("[S]ubstantial protection accorded commercial speech"); *see also IMDB.com, Inc. v. Becerra*. 962 F.3d 1111, 1122-23 (9th Cir. 2020) (states should prohibit "unlawful conduct" not speech). The Constitution forbids punishing written words that could not be relied upon. *Alvarez*, 617 F.3d at 1212. To hold otherwise would allow FTC to "chill" protected speech that even the Court's commercial speech jurisprudence cautions against. *See, e.g., Am. Beverage Ass'n v. City & Cnty. of San Francisco*, 916 F.3d 749, 757-58 (9th Cir. 2019) (citing *NIFLA v. Becerra*, 138 S. Ct. 2361, 2377-78 (2018)). Undersigned counsel has found no case under Sections 5 or 19 of the FTC Act, nor under the new COVID-19 Act, finding liability without a sale. All claims against Defendants involving COVID Resist must be dismissed.

III. FTC HAS FAILED TO PLEAD FRAUD WITH PARTICULARITY UNDER RULE 9(B) AND FAILED TO STATE A CLAIM UNDER RULE 8, SO THOSE CLAIMS SHOULD BE DISMISSED

Counts I and II of the FAC sound in fraud, not unfairness, so both must be pled with particularity in this Circuit and district. *FTC v. D-Link Systems, Inc.*, No. 17-cv-00039-JD, 2017 WL 4150873, at *1-2 (N.D. Cal. Sept. 19, 2017) (noting complaint sounded in fraud and under *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1103-04 (9th Cir. 2003), must be pled with particularity). This heightened pleading standard has teeth. *FTC v. Lights of Am., Inc.*, 760 F. Supp. 2d 848, 854 (C.D. Cal. 2010) (dismissing FTC complaint for failing to meet Rule 9(b) standard and allege the "who, what, when, where, and how" of defendants' conduct). Courts have noted that the Ninth Circuit applies Rule 9(b) searchingly:

> Fraud allegations elicit a more demanding standard. "In alleging fraud …, a party must state with particularity the circumstances constituting fraud[.] Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). This means that "[a]verments of fraud must be accompanied by the 'who, what, when, where, and how' of the misconduct charged." *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003). "The plaintiff must [also] set forth what is false or misleading about a statement, and why it is false." *Id.* (cleaned up). Like the basic "notice pleading" demands of Rule 8, a driving concern behind Rule 9(b) is that defendants be given fair notice of the charges against them.

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Leventhal v. Streamlabs LLC, No. 22-CV-01330-LB, 2022 WL 17905111, at *5 (N.D. Cal. Dec. 23, 2022). The FAC fails in this respect. In paragraphs 53 and 58, FTC alleges that, "in numerous instances," Defendants have stated or implied that one of the products "can treat, prevent or mitigate Covid-19." Putting aside paragraphs 39-41, which claim to allege particular incidents, Defendants are not on notice of in what other "instance" they said what to whom or inducing what result. FTC even fails to allege with specificity when the alleged violations listed in paragraphs 39-41 occurred, that any consumer saw them, or that they induced any purchases.

The FAC also wholly fails to specify any alleged "consumer injury." Under *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), and *Bell Atlatntic Corp. v. Twombly*, 550 U.S. 544 (2007), it is not sufficient to plead boilerplate statements of the cause of action. No consumer purchased COVID Resist, and the FAC does not allege that they did. There is thus no colorable injury alleged for that "product," and the FAC must be dismissed for all claims regarding COVID Resist. The FAC alleges VIRUS Resist statements were made on a website or other social media, but other than a boilerplate statement that "consumers were harmed," it does not allege "who," "when," "how much," or "how many times." The FAC simply identifies statements FTC claims are false and misleading, while failing to plead *facts* that demonstrate "justifiable reliance" or "resulting damage." *See Lights of Am.*, 760 F. Supp. 2d at 853. The FAC requests "civil penalties from Defendants for *each* violation of Section 5(a) of the FTC Act pursuant to the COVID-19 Act." FAC Prayer for Relief "C" (emphasis added). The FAC should at least allege how many violations ¶¶ 53 and 58 contain and when they occurred.

This case alleges no consumer complaints concerning Defendants' products. It rests on FTC's disagreement with Congress and Defendants about the nature of dietary supplements and their benefits. It posits an imaginary consumer who, in FTC's mind, is harmed. Defendants are entitled under Rule 9(b) to know how many violations allegedly occurred and when, given the enormous sums FTC claims per "violation." FAC ¶ 52 (FTC Act "authorizes this Court to award monetary civil penalties of not more than $50,120 for each violation of the COVID-19 Act").

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IV. FTC HAS FAILED TO PLEAD A CONTINUING VIOLATION OR FACTS SUPPORTING FUTURE VIOLATION, SO CLAIMS FOR INJUNCTIVE RELIEF SHOULD BE DISMISSED

The FAC explicitly states the period of the alleged statements as March 2, 2021 to June 2022. FAC ¶¶ 30, 37. It alleges no continuing violation. The Court can take judicial notice that Defendants abandoned VIRUS Resist's trademark on November 25, 2022.[2] As the FAC alleges, Defendants ceased marketing or selling VIRUS Resist in June 2022. FAC ¶ 37. The FAC's claim to enjoin Defendants is thus insupportable. *FTC v. Shire ViroPharma, Inc.*, 917 F.3d 147, 156-57 (3d Cir. 2019) (injunctive relief unavailable to FTC unless Defendant "is violating, or is about to violate" the FTC Act). At least one district court in this Circuit has criticized *Shire*. *See U.S. v. Mylife.com Inc.*, 499 F. Supp. 3d 757, 766-67 (C.D. Cal. 2020) (finding *Shire* is not Ninth Circuit law but also factually distinguishing the case).[3] This *Shire* critique is predicated on *FTC v. Evans Prod. Co.*, 775 F.2d 1084 (9th Cir. 1985), which still establishes that injunctive relief under Section 13(b) of the FTC Act—crucially—requires a showing that the violation is "likely to recur" and that such a showing fails when the violative conduct has ceased. *Id.* at 1087.

FTC did not sufficiently plead that Defendants will likely offend again. FTC's bald statement about continuing consumer injury, FAC ¶ 63, when the alleged conduct ceased, is not enough under *Iqbal* and *Twombly* to allege a case for injunctive relief. The FAC alleges that Defendants wrote to FTC to determine its view of their statements. FAC Ex. 1. Upon receiving FTC's response, Defendants ceased to market, and *never* provided, COVID Resist for sale. FAC ¶¶ 22, 34. They then sold and marketed VIRUS Resist only until June 2022. All subsequent allegations are in the past tense. FAC ¶¶ 37, 53 ("Defendants have represented . . . "). FTC has not pled any fact showing a future violation is likely, so its injunctive relief request should be dismissed.

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[2] *See Trademark Electronic Search System (TESS)*, U.S. PTO (Feb. 3, 2023), https://tmsearch.uspto.gov/bin/gate.exe?f=searchss&state=4810:4dj3dp.1.1 (search "Virus Resist")).

[3] *Shire* has been favorably cited by the 7th Circuit. *FTC v. Credit Bureau Ctr., LLC*, 937 F.3d 764, 779 (7th Cir. 2019).

V. THE FDA ACT REGULATES SUPPLEMENTS, BUT FTC HAS NO AUTHORITY TO BRING CASES UNDER IT AND CANNOT ALLEGE A STANDARD THAT DIFFERS FROM IT

FTC has no agency competence in what dietary supplements can and cannot do. It does not have medical professionals or dieticians on staff. It is not competent to determine claims about vitamins. Congress has explicitly granted FDA the ability to set the standard of what can and cannot be said about dietary supplements in a statute that delegates no authority to FTC, and which the FAC fails to mention. The FAC must be dismissed both because it fails to state the proper statute and standard prescribed by Congress for evaluating statements concerning dietary supplements, but also because it has no delegated authority whatsoever under that statute.

FTC filed its complaint under the novel COVID-19 Act, which does not amend the Dietary Supplement Health & Education Act of 1994 ("DSHEA") in any important respect.[4] "Administrative agencies are creatures of statute. They accordingly possess only the authority that Congress has provided." *See NFIB v. OSHA*, 142 S. Ct. 661, 665 (2022). FTC may not change one jot or tittle of DSHEA to punish dietary supplement purveyors for saying things it dislikes but that Congress approves and over which FTC lacks authority. This Circuit recognizes DSHEA is part of Congress' express intent as to dietary supplement labeling and advertising:

> In 1990, Congress amended the FDCA with the Nutrition Labeling and Education Act ("NLEA"), 21 U.S.C. § 343 *et seq.*, and established new requirements governing the labeling of food, including dietary supplements. In 1994, Congress further amended the FDCA with [DSHEA], Pub. L. No. 103-417, 108 Stat. 4325. The NLEA and DSHEA together established a new category of food products—specifically, dietary supplements—that have unique safety, labeling, manufacturing, and other related standards. All proceedings "for the enforcement, or to restrain violations, of" the FDCA must "be by and in the name of the United States." 21 U.S.C. § 337(a).

Kroessler v. CVS Health Corp., 977 F.3d 803, 808 (9th Cir. 2020). DSHEA provides many protections for purveyors of dietary supplements. *See, e.g.*, 21 U.S.C. §§ 343-1 (preemption of

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[4] The Consolidated Appropriations Act of 2023 amends certain sections of the Federal Food, Drug, and Cosmetic Act (later amended by DSHEA for regulating dietary supplements), none of which relate to dietary supplements or definitions and protections in the DSHEA noted above. Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, 136 Stat. 4459.

state labeling laws as to dietary supplements), 343-2 ("Dietary Supplement Labeling Exemptions"), 343(r)(6) (safe harbor for statements).

Specific protections for dietary supplements were prescribed by Congress because proposed legislation would have subjected dietary supplements to the same "double blind" studies and costly, exhaustive procedures, including showing "significant scientific agreement," that new drugs must meet to be sold in the United States. *See* Francis Wilkinson,*None-a-Day*, Rolling Stone Mag. (Jan. 27, 1994), https://www.rollingstone.com/politics/politics-news/none-a-day-176027/ (describing the contemporaneous controversy and efforts in passing DSHEA). The legislative history bares out these concerns. For instance, Senator Larry Pressler noted that he was co-sponsoring DSHEA because his constituents, health food storeowners and consumers, feared that supplements would be done away with under the new law. He decried the FDA's being able to impose a standard on what could be said about supplements unless "significant agreement on them did not exist within the scientific community." 139 Cong. Rec. S21741 (daily ed. Sept. 20, 1993). He added that "FDA wants to hold food supplements to the same standards it applies to prescription drugs," which was not "appropriate" because "[f]ood supplements are used to prevent disease," not to cure it. *Id.* Senators Ted Kennedy and Orrin Hatch called DSHEA a bipartisan "victory for consumers who want to lead healthy lifestyles." 140 Cong. Rec. 28961 (1994). DSHEA's congressional findings bear this out stating, *inter alia*, that "(2) the importance of nutrition and the benefits of dietary supplements to health promotion and *disease prevention* have been documented increasingly in scientific studies" and "(8) consumers should be empowered to make choices about preventative health care programs based on data from scientific studies of health benefits related to particularly dietary supplements." Pub. L. No. 103-417, § 2(2), (8), 108 Stat. at 4325-26..

The FAC adopts the standard explicitly rejected by Congress through DSHEA. It alleges: "There are no competent and reliable human clinical studies substantiating that COVID Resist/Virus Resist is effective in treatment, prevention, or mitigation or COVID-19." FAC ¶ 40. This is not a statement cognizable as a violation of anything under DSHEA or the FTC Act. There is no requirement for such clinical studies for any dietary supplement. Every statement

alleged in the FAC is about the product's ingredients. Not one of Defendants' statements listed in the FAC claims the product treats COVID-19. Each claims to boost the body's immune system, as Vitamin D is thought to do. The attempt to import FDA's prescription drug requirements—particularly double-blind clinical studies—is the precise barrier to entry Congress rejected. FTC cannot apply a standard Congress never approved nor delegated authority to FTC to administer. FTC's attempt to flip the burden of proof to Defendants thus lacks merit.

No statutory authority cited in the FAC mentions dietary supplements. DSHEA does so in detail. Regulated entities have a due process right to fair notice of a regulator's requirements. *U.S. v. AMC Entm't, Inc.*, 549 F.3d 760, 768-70 (9th Cir. 2008); *see also Montgomery Ward & Co. v. FTC*, 691 F.2d 1322, 1332 (9th Cir. 1982). The burden to show such standards exist under the law is on the agency. *U.S. v. Trident Seafoods Corp.*, 60 F.3d 556, 559 (9th Cir. 1995). DSHEA—not the FTC Act, nor the COVID-19 Act—provides the relevant standards here. FTC may not rely on a vague, nearly standardless "deception" claim to govern over explicitly detailed statutory standards and protections. Further, FTC alleges that statements by Defendants were "false or misleading, *or were not substantiated at the time the representations were made*." FAC ¶ 55 (emphasis added). This language is found nowhere in the FTC or COVID-19 Acts, does not provide the notice required for due process, and is a blatant attempt to shift the burden of proof to Defendants. It is FTC's burden to prove a statement false or misleading; not just that some scientist disagrees with it. DSHEA explicitly rejected that standard, and FTC cannot smuggle it in through the backdoor of the FTC Act or COVID-19 Act against Congress's express wishes while still complying with the due process duty to provide fair notice. If two statutes conflict, the more specific statute usually controls. *U.S. v. Hernandez-Garcia*, 44 F.4th 1157, 1164-65 (9th Cir. 2022) (agreeing that statutes conflict and applying more specific one).

Even if the statutes FTC relies upon here do not directly conflict, FTC cannot simply elide the protections that Congress provided pertaining to dietary supplements as if they are a nullity. *See Pom Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 112 (2014) (no conflict

between DSHEA and the Lanham Act). The FTC Act must be interpreted *in pari materia* with DSHEA, or all of the protections for what dietary supplement purveyors can say about their products would simply be voided. A maker of dietary supplements could wholly comply with DSHEA's requirements on supplements but run afoul of some FTC Commissioner who disagrees with Congress's decision. It makes no sense for FTC to have standalone authority to maintain a case against a dietary supplement that fully complies with DSHEA. In failing to even mention DSHEA, the FAC purports to impose its own standards governing labels and statements concerning dietary supplements that Congress has explicitly rejected. Neither the FTC Act nor the COVID-19 Act amended DSHEA. The FAC must be dismissed.

CONCLUSION

For the foregoing reasons, the FAC should be dismissed.

February 3, 2023

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 3, 2023, I electronically filed the foregoing Notice of Motion to Dismiss and accompanying points and authorities with the Clerk of the Court using the CM/ECF system, which sent notification of such filing to all counsel of record.

/s/ Frederick A. Hagan
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