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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 **Defendants' Reply to Plaintiff's Response to Motion to Dismiss** Hearing Date: March 23, 2023 Time: 1:00 PM, In Person **Related ECF No.: 21**

INTRODUCTION

Plaintiff's First Amended Complaint ("FAC") (Dkt. 15) should be dismissed against Defendants Precision Patient Outcomes, Inc. ("PPO") and Margrett Priest Lewis ("Ms. Lewis") (collectively "Defendants") pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6).[1]

Plaintiff's Response to Defendants' motion to dismiss only underlines the FAC's failure to state a claim or put Defendants on notice of the claims against them. *First*, FTC has made admissions in its Response that require portions of the FAC to be struck. Further, FTC's decision to conflate allegations regarding one product, COVID Resist (which was never sold), with those related to a separate product, VIRUS Resist, renders the FAC unintelligible regarding the "who, what, when, where, and how" of FTC's allegations. So much so that for the first time after months of investigation and *two* complaints, FTC makes the implausible claim that "it is reasonable to infer that Defendants' advertising claims for COVID Resist did lead to purchases of the same product under the VIRUS Resist label." Response at 7, Dkt. 25. This unalleged, unsupported, and implausible allegation was not pled with particularity. At a minimum, the FAC must be struck and repled to intelligibly state, and put Defendants on notice of, which allegations pertain to COVID Resist and which allegations pertain to VIRUS Resist. They are two discrete products and nowhere does FTC say the marketing for one product caused sales of the other product.

Second, FTC's structure is unconstitutional, so it is without power to bring this case. The cases FTC relies on do not show otherwise, and instead support Defendants' arguments. *Finally*, Congress deliberately protected dietary supplement producers in specific ways. FTC cannot ignore those protections by establishing its own standards without congressional authorization.

[1] In its Response, FTC makes no distinction between Defendants' claims under Rules 12(b)(1) and 12(b)(6).

ARGUMENT

I. FTC FAILED TO PLEAD ITS CLAIMS UNDER FED. R. CIV. P. 12(b)(6)

A. FTC's Admissions Require Striking Certain Portions of the FAC

FTC has made several admissions that require striking certain portions of the FAC. First, it concedes that labeling a product is distinct from marketing a product, and that labeling falls within the jurisdiction of the Food and Drug Administration ("FDA"). Response at 13-14.[2] The following FAC allegations and exhibits must be struck because they deal solely with labeling and not marketing: FAC ¶¶ 2 ("labeled"), 9 ("labeling"), 39(D), and Exhibits 3 and 4. These items are only about labeling, and even under the FTC's position that is the FDA's bailiwick.

Next, FTC concedes it is seeking "civil penalties pursuant to the COVID-19 Act not consumer redress." Response at 7. This admission requires all allegations of consumer injury to be struck. Section 19 of the FTC Act, 15 U.S.C. § 57b, requires consumer injury. FAC ¶ 1 ("brings suit under … 57b"); Prayer for Relief (requesting relief "pursuant to … 57b"). This also includes Paragraph 63, which alleges "Consumer Injury" in a conclusory manner (without describing such injury or identifying even a single injured consumer).

Finally, FTC concedes that are no violations alleged after June 2022 (and none regarding COVID Resist after January 2022). Response at 10; FAC ¶ 37. That admission alone should end any request to this Court for a permanent injunction under section 13b of the FTC Act, 15 U.S.C. § 53(b). FTC's argument for retaining jurisdiction based on its seeking injunctive relief is barebones. FTC admits that the challenged activity ceased before it sued. *Id.* at 11. FTC also admits that it became aware of the product because the Defendants wrote to FTC seeking its review before selling COVID Resist. FAC Ex. 1. FTC rests its entire injunction pleading on the allegation

[2] Defendants reject that FTC has any jurisdiction over dietary supplements, but FTC must be bound by its admissions.

that there were violations, that the company still exists, that Ms. Lewis is still involved with the company, and that it still sells dietary supplements. Response at 11. FTC states that it should be granted unfettered authority to determine who is likely to restart challenged conduct. *Id.* at 12. But a complaint needs to state facts sufficient to sustain the proposition that Defendants, who have stopped selling and abandoned the trademark for both challenged products, are likely to restart the challenged conduct. Mot. to Dismiss at 11 n.2, Dkt. 21. FTC's argument makes no sense. If Defendants are likely recidivists, as FTC supposes, then why did they affirmatively seek FTC's pre-market input regarding their products and statements? FAC Ex. 1. Why did they rename and relabel COVID Resist? FAC ¶ 23. Why did they cease selling VIRUS Resist? FAC ¶ 37. Indeed, the Defendants' actions in the FAC reveal a small business trying to comply with the law and do not plausibly imply that any of the alleged violations are likely to recur. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007) (claims must cross "the line from conceivable to plausible").

FTC did not send Defendants a warning letter, which is its usual practice. As FTC has noted, its warning letters are immediately effective at having companies "come into compliance with the law." *FTC Coronavirus Warning Letters to Companies*, Fed. Trade Comm'n https://www.ftc.gov/news-events/features/coronavirus/enforcement/warning-letters (last visited Feb. 23, 2023).

It is simply beyond any plausible inference that a threat of further injury remains (especially when FTC admits it is seeking penalties, not redress of consumer injury). FTC seeks a permanent injunction. On the facts alleged, it is not entitled to one. As the Response acknowledges, and Defendants agree, *FTC v. Evans Products Co*., 775 F.2d 1084 (9th Cir. 1985), is binding on this Court. But, notably, that case denied a *preliminary* injunction. *Id.* at 1089. Defendants "gesture," Response at 11, at *FTC v. Shire ViroPharma, Inc.*, 917 F.3d 147 (3d Cir.

2019), because it is a *permanent* injunction case, and that is what the FAC seeks. Also, because *Shire* has not been rejected by the Ninth Circuit and is persuasive. But what is alleged here is exactly what the Ninth Circuit found wanting in *Evans*. As that court observed, "[t]he gravamen of the FTC's complaint is that Evans engaged in misrepresentations and false advertisements during 1979–1982. The FTC does not contend that these misrepresentations and advertisements are presently occurring." *Evans*, 775 F.2d at 1088. And Defendants have the added fillip that FTC admits it's seeking penalties and not consumer redress. So, what has FTC alleged to show further violations are "likely?" Only that past alleged violations are likely to recur because PPO still exists and Ms. Lewis still runs it. Response at 11. That is far too thin a reed to carry the heavy weight of a permanent injunction. *See, e.g., FTC v. LendingClub Corp.*, No. 18-cv-02454, 2018 WL 11436309, at *10-11 (N.D. Cal. Oct. 3, 2018) (refusing to strike injunctive claim because it was "plausible to infer that the conduct [was] *ongoing*" when there was no claim the conduct had stopped (emphasis in original)). Here the admissions in the FAC and the Response wholly foreclose any "likelihood" of reoccurrence. All FTC has alleged is that a reoccurrence is not physically impossible—but that means it is only conceivable, not plausible as *Twombly* demands.

B. The FAC Does Not Plead Fraud with Particularity, so It Is Impossible to Determine What Is Alleged Regarding Each Product

FTC admits that no COVID Resist was sold and that it is not seeking consumer redress, but it nonetheless contends that COVID Resist was somehow "offered for sale" and that this allows it to impose penalties of more than $50,000 for speech that could not induce any action by consumers. The FAC attaches a letter from PPO stating "We are planning to launch COVIDresist™…" FAC Ex. 1. In connection with this letter, Defendants took preliminary steps that are explained. In support of its allegations, FTC also attached Exhibit 5, which is an *empty* shopping cart on the website. It is labeled "empty" and was empty because COVID Resist was

never practicably "offered for sale" as shown by the *factual* allegations of the FAC. Defendants do not contest that FTC kept the words "offered for sale" in the FAC. But FTC did not plead any facts that allow the Court to come to that conclusion. The pled facts and attachments stating "we are planning" and every other fact in the FAC and in the Response are clear no COVID Resist was offered for sale or sold. Indeed, FTC's pleading is confusing because it conflates COVID Resist and VIRUS Resist throughout. *See, e.g.*, FAC ¶¶ 3, 26, 27, 29, 39, 40, 45, 53, 58, 60 (referring to the products as "COVID Resist/VIRUS Resist"). This sloppy and misleading phrasing is unintelligible and obscures the "who, what, when, where, and how" of FTC's allegations. *See Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003). This confusing phrasing is also likely why it is not until FTC's Response that it first alleges that consumers who may have viewed COVID Resist marketing may have bought VIRUS Resist. Response at 7. But FTC did not plead that allegation, and the Court ought not countenance such an unalleged and counterintuitive assertion to be "inferred." Plausible inferences are allowed on pled facts under *Twombly*, but implausible and counterintuitive claims must be clearly stated.

FTC chose to conflate COVID Resist and VIRUS Resist to make the FAC unintelligible. The Response admits that FTC's action is directed at the marketing of a product. Response at 14. While FTC alleges that the ingredients of COVID Resist and VIRUS Resist are the same, it admits that the two were different products (which is why there were trademarks for each). FAC ¶¶ 30, 31. By intentionally styling the separate products as a single product, *i.e.*, COVID Resist/VIRUS Resist, what specifically was said as to each product, and where and when it was said is obscured. A complaint can be struck if it is confusing, ambiguous, or unintelligible. *Schmidt v. Hermann*, 614 F.2d 1221, 1224 (9th Cir. 1980). This one is all of the above. Neither Defendants nor the Court can read the FAC and determine what is being alleged as to each product or which statements

induced a "reasonable consumer" to purchase which product. FTC's assertion that COVID Resist marketing caused people to buy another product is not discernible from the FAC. Neither the Defendants nor the Court should have to decipher what is being pled as to each product. *See Rosales v. U.S. Dep't of Interior*, No. 20-cv-00521, 2022 WL 2052639, at *3 (E.D. Cal. June 7, 2022) ("Confusing complaints unnecessarily burden the courts who must spend time deciphering them and then managing the needless pretrial motion practice and uncertainty those pleadings create." (citing *McHenry v. Renne,* 84 F.3d 1172, 1179-80 (9th Cir. 1996)). In claims involving multiple products, failure to properly identify the allegations regarding each requires striking those claims. *See, e.g., Cont'l Circuits LLC v. Intel Corp.*, No. CV16-2026, 2017 WL 679116, at *6 (D. Ariz. Feb. 21, 2017) (granting motion to dismiss in patent case where descriptions and allegations of certain products were not sufficient even when allegations regarding other products were).

The Response asserts that penalties can be assessed for COVID Resist if it was "offered for sale" but induced no action. As noted, the FAC does not actually plead facts that it was "offered for sale." In the Defendants' moving brief, they set out the First Amendment argument that that assertion is not supportable by any case law. Mot. to Dismiss at 8-9. FTC has failed to cite any case where a Court has allowed a penalty with no sales. *See* Response at 6-7. FTC is seeking penalties for pure speech as to COVID Resist. FTC has not countered the cases regarding free speech, which induces no action and harms no consumer, except to say it can seek penalties, but it cites no case that has ever allowed it to do so when no product was sold. All claims regarding COVID Resist should be dismissed.

Regarding particularity, Defendants still do not know what "numerous instances" are alleged in paragraphs 53 and 58. Are these different from what is alleged in paragraphs 39-41? The Defendants and the Court should not have to guess. FTC squirms a little about whether fraud

must be pled with particularity on its claims, but seems to agree it must meet those standards. Response at 7-10. It has not. When it is not clear in a fraud complaint which products were purchased and when, courts in this Circuit have dismissed the complaint under 9(b). *See Beckman v. Ariz. Canning Co.*, No. 16cv02792, 2017 WL 4227043, at *5 (S.D. Cal. Sept. 21, 2017) (class action misrepresentation claim dismissed because it was "unclear which bean products" were purchased). Finally, FTC states that the number of violations can be determined in discovery. But the FAC sounds in fraud. It seeks what appear to be substantial penalties. The Defendants are left in the dark about how many times they allegedly violated the Covid-19 Act and what FTC is seeking in penalty. This is lack of specificity in the extreme.

C. The FDA Act Regulates Supplements and the FTC Act Doesn't

FTC has a bad habit of treating its preferred policies as law. Its guidance documents are not law. Its longstanding practices are not law. *AMG Cap. Mgmt., LLC v. FTC*, 141 S. Ct. 1341, 1346, 1352 (2021) (rejecting FTC's longstanding practice of seeking "equitable monetary relief" under section 13(b)). It is black letter law that agencies only possess powers Congress affirmatively chooses to delegate to them. *La. Pub. Serv. Com'n v. FCC*, 476 U.S. 355, 374 (1986). As the moving brief's unrebutted description of DSHEA demonstrates, Congress intentionally prevented the type of substantiation standard FTC seeks to apply here. Mot. to Dismiss at 13. The FDA also regulates advertising for pharmaceuticals, and it is a crime to advertise with something not on the label. *But see United States v. Caronia*, 703 F.3d 149, 168-69 (2d Cir. 2012) (striking down criminal penalty for pure speech). That is what Congress was trying to prevent. FTC cannot just make up its own powers as it attempts here. That FTC brings cases and puts out guidance is irrelevant to whether it has this power that is not in the FTC Act but is in the FDA Act. *See* Response at 12, 14. No MOU or claim of undelegated power can change that.

Regarding dietary supplements, Congress expressly provided FDA with jurisdiction over claims and said that the "prevent disease" is not actionable. Mot. to Dismiss at 12-15. Worse, in this case, in addition to sending no warning letter and filing an action after the Department of Justice ("DOJ") refused, FTC also failed in its statutory obligations to Defendants, a small business. Defendants wrote a letter to FTC requesting that the Commission provide them with "information on, and advice about, compliance with such statutes and regulations" regarding their product and sought guidance "interpreting and applying the law to specific sets of facts supplied by" them. Small Business Regulatory Enforcement Fairness Act of 1996 ("SBREFA"), Pub. L. No. 104-121, tit. II, § 213(a), 110 Stat. 847, 858-59; *see* FAC Ex. 1. In defiance of SBREFA, FTC declined to do so, stating that it "does not pre-review advertising materials to opine on their compliance with the FTC Act or any other applicable laws" and proceeded instead to direct Defendants to review hundreds of pages of guides, policy statements, "roughly 400" warning letters to third parties, and a recently filed complaint. FAC Ex. 2.

While FTC argues this letter provided "detailed information about the legal requirements[,]" Response at 1, 10, it did anything but. FTC's response does not comply with section 13(a) of SBREFA, nor does it rely on any delegation from Congress to FTC that would permit the Commission to create a substantiation standard for dietary supplements. Further, FTC has never used its limited rulemaking power, *see* 15 U.S.C. § 57a, to issue such a binding standard, relying instead on case-by-case enforcement actions and interpretative rules, *i.e.*, guides and policy statements. But, the "convenience" of interpretive rules "comes at a price" because such rules "do not have the force and effect of law and are not accorded that weight in the adjudicatory process." *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 97 (2015) (citation and internal quotation omitted). Hence, FTC's non-binding substantiation standard cannot form the basis of a violation

of the FTC Act, at least not without running afoul of due process and fair notice considerations. *Cf. Landgraf v. USI Film Prod.*, 511 U.S. 244, 265 (1994) ("Elementary considerations of fairness dictate that individuals should have an opportunity to know what the law is and to conform their conduct accordingly[.]"); *Gutierrez-Brizuela v. Lynch*, 834 F.3d 1142, 1152 (10th Cir. 2016) (Gorsuch, J., concurring) ("Transferring the job of saying what the law is from the judiciary to [an agency] unsurprisingly invites … due process (fair notice) and equal protection concerns."). The substantiation allegations must be struck.

This Complaint alleges substantiation violations that are different from anything in the FDA Act and have never been made into a binding regulation by FTC.

II. FTC COMMISSIONERS ARE NOT REMOVABLE AT WILL BY THE PRESIDENT SO FTC LACKS POWER TO BRING THESE CLAIMS AND THIS COURT IS WITHOUT SUBJECT-MATTER JURISDICTION UNDER FED. R. CIV. P 12(b)(1)

The Response is quite candid that FTC Commissioners are not removable at will by the President. Response at 2 (Commissioners are appointed for seven-year terms). It also acknowledges that Defendants are not asking this Court to weaken *Humphrey's Executor* but to follow it in light of the other, more recent, binding precedent from the Supreme Court. FTC butchers what that precedent is because it cites cases for the proposition that *Humphrey's Executor* has been bolstered when in fact no one asked for that precedent to be overruled and so the Supreme Court was never given the opportunity to do so. Response at 2-3.

Supreme Court rules only allow it to consider "the questions set out in the petition, or fairly included therein." Sup. Ct. R. 14(1)(a); *see also Boynton v. Com. of Va.,* 364 U.S. 454, 457 (1960) ("Ordinarily we limit our review to the questions presented in an application for certiorari."). FTC tries to bolster its claims that its structure and its filing here are constitutional by citing cases that did not consider that question. In *Free Enterprise Fund v. PCAOB*, 561 U.S. 477, 483 (2010), the Court cited *Humphrey's Executor* among others and stated that "[t]he parties do not ask us to

reexamine any of these precedents, and we do not do so." In *Collins v. Yellen*, 141 S. Ct. 1761 (2021), *amici* expressed concern that the case would imperil agencies structured like FTC. But the Court noted that those agencies were not before the Court and that it was "not comment[ing] on the constitutionality of any removal restriction that applies to their officers." *Id.* at 1787 n.21. Despite this, *Humphrey's Executor*'s days may well be numbered. *See Seila Law LLC v. CFPB*, 140 S. Ct. 2183, 2198 n.2 (2020) ("The Court's conclusion that the FTC did not exercise executive power has not withstood the test of time."); *see also id.* at 2211-12 (Thomas, J., concurring) (noting that the *Seila Law* decision "has repudiated almost every aspect of *Humphrey's Executor*").

FTC misunderstood the opening brief's explanation of DOJ's decision not to prosecute this case. All Executive Power, including the power to "take Care that the Laws be faithfully executed[,]" is vested in the President. U.S. Const. art. II, §§ 1, 3. DOJ is an indisputably constitutional agency. As explained in the moving brief and not rebutted by FTC, by filing this action, FTC has taken an opposite position from DOJ in litigation. Attorney General Merrick Garland is removable at will by the President, as is the head of the FDA. Chair Lina Khan and the other FTC Commissioners are not. As the President lacks this necessary control over FTC, the Commission cannot maintain an action, like this, that constitutes executive power. In its Response, FTC calls itself a law enforcement agency. Response at 14. But law enforcement is neither "quasi-judicial" nor "quasi-legislative." It is squarely executive. And yet FTC's Commissioners cannot be removed at will by the President. FTC had to vote at least once to send the case to DOJ for consideration, and likely again to file this case. In between, DOJ decided not to bring it. FTC is wielding pure executive power here. But Section 41 of the FTC Act precludes it from doing so because it makes the Commissioners unremovable.

CONCLUSION

For the foregoing reasons, the FAC should be dismissed.

February 24, 2023

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 24, 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/ Fredrick A. Hagen
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