UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION, Plaintiff, v. GRAVITY DEFYER MEDICAL TECHNOLOGY CORP., *et. al.*, Defendants.	Case No. 1:22-cv-01464-RDM ORAL ARGUMENT REQUESTED

REPLY TO OPPOSITION TO RENEWED MOTION TO DISMISS

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INTRODUCTION

The government does not want to see the UCLA Study, the study Gravity Defyer commissioned from the Olive View-UCLA Medical Center to test its shoes, which was published in the *Journal of the American Podiatric Medical Association* and attached as Exhibit A to Gravity Defyer's Renewed Motion to Dismiss [Dkt. 15]. It does not want to see it in advertising. That, despite the fact that the FTC has admitted to Gravity Defyer that its advertising claims were valid *even without the study*. The FTC does not want Gravity Defyer to call it "the UCLA Study." (Opp'n to Renewed Mot. to Dismiss [Dkt. 15] at 2 n.3.) The FTC wants to allege "as a factual matter" that Gravity Defyer's claims are unsubstantiated (*id.* at 14), to insist that the Court accept as true its legal conclusions, and thereby obviate the need to actually engage with the study.

To support its conclusion that Gravity Defyer's advertising claims are unsubstantiated, the FTC must establish the invalidity of the study based on the study's design, its execution, its statistical analysis, and its conclusions. The FTC would have to show where the researchers (and, to be sure, peer reviewers) erred and establish that Gravity Defyer lacks the constitutional right to reference the study at all in advertising.

The agency has previously participated in the development of these standards, adopting litigation positions providing for appropriate qualification and working along with the FDA in its development of the qualified health claims regime. But now the agency has disavowed that past, suppressing speech it has agreed is valid, suppressing the study upon which the speech was based, and refusing to consider any, let alone reasonable, qualifications as a less speech restrictive alternative to outright suppression.

DISCUSSION

I. THE COURT SHOULD DISMISS COUNTS II–IV WHERE THE FTC FAILS TO PUT FORTH PLAUSIBLE ALLEGATIONS OR APPLY BEDROCK FIRST AMENDMENT STANDARDS

At the close of briefing, it remains undisputed that the FTC is seeking to ban all advertising claims "cit[ing] or otherwise rely[ing] on" the UCLA Study, whether such claims are made with qualification or not. The FTC's sole factual allegations in support of its case, at the very most, by the agency's own admission, merely "raise reasonable questions about the quality and results of [the] study." (*See* Mot. Ex. D, Letter from Maria Del Monaco to J. Kathleen Bond (Feb. 17, 2022); Opp'n at 14.) Censoring scientific research from the market solely on the basis that reasonable questions may be raised about it would surely prevent all science in the market from enjoying First Amendment protection against FTC suppression, to the profound detriment of consumers. The basis for suppression is entirely speculative and at odds with First Amendment precedent.

As the FTC has stated in comments transmitted to the FDA, case law has "ma[d]e clear" that the U.S. government may completely ban speech only when it can show the speech to be actually or inherently misleading. FTC, *Comments in the Matter of Request for Comment on First Amendment Issues*, FDA Dkt. No. 02N-0209, at 11 (Sept. 13, 2002) (citing *Pearson v. Shalala*, 164 F.3d 650, 658–59 (D.C. Cir. 1999)); *see also* Mot. at 19 n.15 (discussing FTC comments); *see generally* Opp'n (failing to address FTC comments in any form). If speech is only potentially misleading, the government must be able to show that it is "incurable by disclaimer" before "ban[ning] it outright." *FTC Comments* at 11. "[E]nforcement approaches" that integrate these bedrock principles "promote consumer welfare" by "maximizing the free flow of commercial speech." *Id.* at 2–3.

Here, the FTC has failed to allege—much less identify plausible facts that could show—that the UCLA study is so flawed that any speech based on it would be misleading. A fishing

expedition to explore "reasonable questions" about a study fails "to raise a right to relief above the speculative level," *Bell A. Corp. v. Twombly*, 550 U.S. 544, 555 (2007), and, at the same time, fails to satisfy the commercial speech doctrine.

Neither Gravity Defyer's research nor the FTC's briefing has produced any case where the FTC sought a complete speech ban based on mere speculation about "reasonable questions" that might exist as to a study's reliability. None of the precedent the FTC now cites in its latest brief comes close to justifying its novel position because, ultimately, the position cannot be justified.

A. A Legal Conclusion that a Claim Is "Unsubstantiated" Fails

The FTC contends that when "advertising claims are alleged to be unsubstantiated under the FTC Act, as they are here, they are alleged to be actually or inherently—not potentially—misleading for purposes of a First Amendment analysis." (Opp'n, at 17.) However, a bare statement that a claim is unsubstantiated is a legal conclusion, not a factual allegation. So too would be any implication, unstated at all, that speech is inherently misleading.

A court evaluating a motion to dismiss pursuant to FED. R. CIV. P. 12(b)(6) must accept all *factual* allegations as true. However, this tenet "is inapplicable to legal conclusions." *Lucas v. Guzman*, 21-cv-296, 2022 WL 2064852, at *4 (D.D.C. June 8, 2022) (cleaned up). A court should not accept as true "legal conclusions cast in the form of factual allegations." *Edwards v. Aurora Loan Services, LLC*, 791 F. Supp. 2d 144, 149–50 (D.D.C. 2011); *see also Ibanez v. Florida Dep't of Business and Prof'l Regulation*, 512 U.S. 136, 143 (1994) ("If the protections afforded commercial speech are to retain their force, we cannot allow rote invocation of the words 'potentially misleading' to supplant the [government's] burden to demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree."); *Fed. Trade Commn. v. Endo Pharm. Inc.*, 21-cv-217, 2022 WL 951640, at *12 (D.D.C. Mar. 30, 2022) (granting motion to dismiss where, in part, the FTC failed to cite legal authority to support its

position and asserted legal conclusions in the form of factual allegations); *Comm. On Ways and Means, U.S.H.R. v. U.S. Dept. of the Treas.*, 575 F. Supp. 3d 53, 62 (D.D.C. 2021), *aff'd sub nom. Comm. On Ways and Means, U.S.H.R. v. U.S. Dept. of Treas.*, 21-5289, 2022 WL 3205891 (D.C. Cir. Aug. 9, 2022) (cleaned up)

The FTC's insistence that its legal conclusions are factual allegations does not make it so. (*See, e.g.,* Opp'n at 14 (arguing the Complaint alleges "as a factual matter" that Gravity Defyer's advertising claims are unsubstantiated).) What the FTC must do is to allege sufficient factual matter to permit the Court to make a reasonable inference arriving at the FTC's legal conclusions. Whether an advertising claim is substantiated is a legal conclusion, one that may or may not be borne out by facts alleged in a complaint. Whether an advertising claim is inherently misleading is *a fortiori* a legal conclusion, one that depends on the allegation of additional facts. The Complaint in this matter simply fails to allege sufficient factual matter.

B. The First Amendment Applies to "Individualized Cases"

In another attempt to avoid pleading standards and First Amendment principles, the FTC draws a distinction between bans on "categories of speech" versus "individualized cases . . . that concern a single advertiser." (Opp'n, at 16.) The FTC admits that the First Amendment applies to regulators engaged in legislation or rulemaking to ban "categories of speech," requiring a showing first that the speech is inherently misleading. (*Id.*) However, according to the FTC, the same requirement is inapplicable when the government undertakes enforcement against "a single advertiser." (*Id.*) Drawing such a distinction is illogical and offends First Amendment principles.

In putting forth this supposed distinction, the FTC relies solely on *Kraft, Inc. v. Fed. Trade Commn.*, 970 F.2d 311 (7th Cir. 1992). *Kraft*, however, had nothing to do with the contexts in which First Amendment standards might apply. Rather, *Kraft* found that *de novo* review of First Amendment issues was warranted for a case involving a rule banning a "category" of speech, but

not for review of an "individualized FTC cease and desist order." *Id.* at 318. But this point about the appropriate standard of review on appeal in no way suggests that entities check their First Amendment rights at the door in the context of governmental enforcement. If the law were otherwise, First Amendment protections would be obliterated.

Take *Kimberly-Clark*, for instance. There, the court enjoined the District of Columbia from drafting certain regulations in a manner that would outright ban companies like Kimberly-Clark from promoting hygienic wipes as "flushable." *Kimberly-Clark Corp. v. Dist. of Columbia*, 286 F. Supp. 3d 128, 145 (D.D.C. 2017). The court found that, to justify such a ban, the government would first have to show that the claim would be inherently misleading and incurable by disclosure. *Id.* According to the FTC, an outright ban on such a "category of speech" indeed would have violated the First Amendment. However, also according to the FTC, had the District of Columbia government sought individual enforcement against Kimberly-Clark over the same claim, the same protections would be inapplicable, allowing the government to impose the same outright ban found unconstitutional. Thus, in the FTC's view, the District of Columbia government, perhaps, could have issued a letter marked "Confidential Settlement Agreement," stating that Kimberly Clark must make no "flushable" claims, qualified or not, simply because the government purported to raise "reasonable questions" about the underlying support. But, that's not the law.

The law provides that the government cannot do behind closed doors to any individual company what the First Amendment prohibits in the open, as to industries writ large. Courts correctly and routinely apply the well-settled preference for more, rather than less, information regardless of whether regulation is in the form of "individualized" enforcement, or not. *See, e.g.*, *Pearson*, 164 F.3d at 659 (involving individual company's health claim petition to FDA); *Amarin Pharma, Inc. v. Food and Drug Admin.*, 119 F. Supp. 3d 196, 225–26 (S.D.N.Y. 2015) (involving

FDA enforcement against individual drug company); *Fed. Trade Commn. v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 43–44 (D.C. Cir. 1985) (involving FTC enforcement against individual cigarette company).

C. *POM Wonderful* Illustrates How FTC Enforcement Should Operate Within First Amendment Principles

The FTC also seeks to rely on *POM Wonderful* to deny the applicability of First Amendment standards to its speech regulation. Such reliance is misplaced.

In its briefing in *POM Wonderful*, the FTC repeatedly cited *Pearson* as law the agency must consider in its regulation of speech. *See, e.g.*, *POM Wonderful v. Fed. Trade Commn*., 777 F.3d 478, 493 (D.C. Cir. 2015) (citing *In re Pom Wonderful*, 155 F.T.C. 1, 2013 WL 8364895, at *47 (2013) (citing *Pearson*, 164 F.3d at 659)). Not surprisingly then, the FTC also accepted that in order to force an end to claims that POM Wonderful juice and dietary supplements treat prostate cancer and other serious diseases, the agency had to (and did) show such speech to be actually deceptive. *See Pom Wonderful*, 2013 WL 8364895, at *44 ("Therefore, Respondents' ads were . . . actually misleading."); *aff'd POM Wonderful*, 777 F.3d 478.

Specifically, the FTC alleged, and ultimately showed, fatal flaws in the underlying studies—that certain studies lacked any statistically significant results, that one was entirely unblinded and uncontrolled, and that one constituted a small pilot study later contradicted by larger, better designed studies showing null results. Compl., *In re POM Wonderful*, FTC Dkt. 9344, 2010 WL 3799084, ¶¶ 15–17 (Sept. 24, 2010); *POM Wonderful*, 777 F.3d at 485–89, 494. Thus, rather than allege mere "reasonable questions" about POM Wonderful's studies, the FTC identified facts that could, and did, show POM Wonderful's advertising to be "actually" unsubstantiated and inherently deceptive.

Moreover, as is typical in its substantiation cases, in seeking a remedy against POM

Wonderful, the FTC never sought to prevent POM Wonderful from ever again using "advertising claims that cite or otherwise rely" on any particular study. Rather, the FTC sought an order requiring POM Wonderful to substantiate any future unqualified disease treatment or prevention claims with randomized, controlled clinical testing. *POM Wonderful*, 777 F.3d at 500–01. The FTC explained correctly that under the order, POM Wonderful could still cite in its advertising any disease-related study it chose, even those found to be unreliable, as long as it "effectively qualified" its advertising to disclose the study's limitations. *Id.* at 501; *see also e.g.*, Resp. Brief, *POM Wonderful*, No. 13-1060, 2014 WL 1231063 at *73 n.33 (Mar. 25, 2014) ("If petitioners run future ads with effectively qualified disease claims, they would be subject only to Part III of the FTC's remedial order, which does not require RCT substantiation"). Thus, rather than prove that FTC enforcement suspends the First Amendment, *POM Wonderful* demonstrates exactly how FTC regulation is supposed to operate within First Amendment standards.

D. The FTC Misstates *Pearson*

The FTC's brief, finally, misstates the *Pearson* case. The FTC summarizes *Pearson* as "invalidating sub-regulations requiring dietary supplement makers to submit health claims to the FDA for preapproval." (Opp'n, at 16, n.12.) However, far from being "invalidated," the health claims regime continues to exist. 21 U.S.C. § 343(r); 21 C.F.R. § 101.14. "Health claims," which are disease-related claims for foods or dietary supplements, continue to require FDA preapproval under the "significant scientific agreement" standard of Section 101.14(a)(1).[1]

What *Pearson* did was to create the "qualified health claims" regime. The court reasoned that because health claims failing to meet the significant scientific agreement are only potentially

[1] To provide one example, "Adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis" is an authorized health claim. 21 C.F.R. § 101.72

misleading, the FDA must consider whether disclosures or qualifications are a possible alternative to avoid a complete ban. *Id.*, 164 F.3d at 656–57.[2]

In its comments to the FDA following *Pearson*, the FTC aligned itself with the case's principles, stating "[e]mpirical evidence suggests that if consumers receive more and better information about nutrition and health, consumers are able to make better-informed choices about the food products they purchase." FTC, *Comments in the Matter of Request for Comment on First Amendment Issues*, FDA Dkt. No. 02N-0209, at 4 (Sept. 13, 2002). The FTC further characterized its own enforcement regime as "rigorous enough to attack deception, yet flexible enough to encourage accurate claims," with a "key aspect of that flexible approach [being] the emphasis on remedies that favor disclosures and qualification of claims over outright bans." *Id.*

In this case, the FTC has now wholly abandoned those principles, seeking to ban speech based on unsupported legal conclusions and an invitation to undertake a fishing expedition into what "reasonable questions" might exist as to the validity of a peer-reviewed and published, randomized, double-blind, and controlled study. As such, Counts II–IV fail to state a claim upon which relief can be granted.

[2] As an example, "Limited scientific evidence shows that by consuming 500 mg each day of cranberry dietary supplement, healthy women who have had a urinary tract infection (UTI) may reduce their risk of recurrent UTI" is an authorized qualified health claim. FDA, Letter of Enforcement Discretion, Consumption of Cranberry Products and Reduced Risk of Recurrent Urinary Tract Infection in Healthy Women, Dkt. No. FDA-2018-Q-0739 (July 21, 2020).

II. TO THE EXTENT THE COMPLAINT ALLEGES ANY FACTS, THOSE ALLEGATIONS FAIL TO SUPPORT A PLAUSIBLE CLAIM FOR RELIEF

A. Speculative Assertions as to the UCLA Study Fail to Support a Plausible Claim for Relief

Beyond the FTC's unwillingness to accept the First Amendment's restrictions on the power exercised by a government agency, the Opposition fails to rehabilitate the scant facts that are alleged in the Complaint as anything but base, implausible speculation. A plaintiff may not rely on "naked assertions" devoid of "further factual enhancement" to survive a motion to dismiss. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Mirv Holdings, LLC v. U.S. Gen. Services Administration*, 454 F. Supp. 3d 33, 41 (D.D.C. 2020) (cleaned up).

The Opposition asserts that the Complaint "provides a non-exclusive list of *seven reasons*" the FTC believes the UCLA Study to be "flawed." (Opp'n at 14; emphasis in original.) Of those supposed seven reasons, the FTC highlights four in its Opposition. (*Id.*)

Where the Complaint alleges that the UCLA Study "was only designed to measure knee pain," the FTC further elaborates that this "clearly calls into question claims that Gravity Defyer footwear relieves back, ankle, and foot pain." (Opp'n at 14.) The allegation that the study "was only designed to measure knee pain" is, however, entirely conclusory—no facts are alleged on the basis of which the conclusion that the study "was only designed to measure knee pain" can be reached. Moreover, that the study "was only designed to measure knee pain" could not possibly show that all speech based on the UCLA Study is actually unsubstantiated. The allegation, if anything, suggests that speech about knee pain should be allowed.

Where the Complaint alleges that the UCLA Study "included participants who stopped wearing the shoes," the FTC further elaborates that this "obviously calls into question the results obtained." (*Id.*) However, the FTC's own guidance advises researchers to do exactly what the

UCLA researchers did: "researchers should conduct an 'intent-to-treat' analysis that includes data from every subject initially assigned to the treatment and control groups, including subjects who dropped out during the course of the study or did not fully comply with the study protocol." FTC, *Health Products Compliance Guide* (2022). As the FTC has also known for years,[3] even after rerunning the data from the UCLA Study with a less reliable method that excluded data from the two control participants who stopped wearing their assigned shoes, the statistical results remain the same. The inclusion or not of "participants who stopped wearing the shoes" provides no basis for a plausible inference that all speech based on the UCLA Study is actually unsubstantiated.

Where the Complaint alleges that the UCLA Study "relied solely on participants' self-reported pain levels," the FTC attempts to elaborate that the study "could have included range of motion or other functional tests *of pain*." (Opp'n at 14 (emphasis added).) This misstates the original allegation. The Complaint alleges that the UCLA Study "relied solely on participants' self-reported pain levels instead of *[also] including range of motion or other functional tests*." (Compl. at 16 (emphasis added).) In addressing the original allegation, the Renewed Motion to Dismiss pointed out that "the FTC provides no factual basis at all" for concluding that "'pain levels' could possibly be an invalid measure for a pain study." (Mot. at 21–22.) The FTC, in its Opposition, appears to be responding to that point by making up new types of tests. There is no such thing as a "range of motion" or any "other functional test" *of pain*. As the name suggests, a "range of motion" test assesses range of motion, not pain. A test of any other bodily function assesses that bodily function, not pain. As a subjective state, pain must necessarily be tested using

[3] Indeed, the fact that the FTC has had years to familiarize itself with the facts in this case makes the paucity of facts in the Complaint even more notable. The Complaint grows out of the Civil Investigative Demand issued July 8, 2019. Gravity Defyer attached the CID to its Renewed Motion to Dismiss as relevant background implicated by the Complaint itself.

self-reporting, not range of motion or any other function test. This new, startling misrepresentation by the FTC fails to cure the speculative and implausible nature of the original allegation.

Where the Complaint alleges that the UCLA Study "failed to control for other treatments that participants might have received (such as medications or physical therapy)," the FTC further elaborates that this "could have affected participants' pain levels." (Opp'n at 14.) But again, this is not a factual allegation, much less a factual allegation that could plausibly show that all speech based on the UCLA Study is actually unsubstantiated. It is nothing more than pure conjecture about what "could have" happened (or what could be shown through a fishing expedition).

Accordingly, the FTC "squeezes into a single paragraph of its Complaint" seven of what it calls "substantial flaws." (Mot. at 21 (citing Compl. ¶ 27).) Further, the FTC wants the Court to rule entirely on the basis of this truncated account of the study, its "non-request that the Court exclude" the published version of the study notwithstanding. (*See* Opp'n at 8 n.6.) In spite of the fact that the study is clearly the central factual issue of this case, the FTC doesn't want the Court to see its published version—even while admitting that the percentages of pain relief experienced by the study participants are accurately reported.

Worse, the "seven reasons" are all entirely conclusory. Even when offered a second chance (or a third, as this section of the Opposition survives intact from its initial opposition (*compare* Dkt. 18, Case No. 22-1157 at 13–14 *with* Dkt. 16, Case No. 22-1464 at 13–15)) to explain these conclusions, the FTC declines—offering instead only additional conclusion, speculation, and even new ways, unknown to the world, to measure pain by testing range of motion or function. The Court should dismiss Counts II–IV where the FTC fails to state plausible allegations.

B. Threadbare and Speculative Assertions as to Testimonial Claims Fail to Support a Plausible Claim for Relief

The FTC asserts, without the support of any case law, that providing a "mere[] example" of one type of testimonial claim—a testimonial claim on back pain—entitles it to a reasonable inference that testimonials on knee pain, foot pain, and pain associated with other "conditions such as plantar fasciitis, arthritis, or neuropathy" must exist and be violative. (Opp'n at 20.) What even are the "other conditions?" Is the FTC trying to assert there might be a testimonial about footwear and cancer? Footwear and the common cold? The single testimonial and bare assertions of other testimonials out there somewhere cannot possibly provide fair notice, much less a plausible claim of relief. *See Bell A. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (a pleading fails to provide fair notice of a legally cognizable claim "if it tenders naked assertions devoid of further factual enhancement.").

In support of its position that the FTC's allegations fail, the Renewed Motion to Dismiss cited numerous cases demonstrating that it is "axiomatic that in a case alleging false advertising, the plaintiff, at a minimum, must identify relevant advertisements and explain what is false or misleading about them." (Mot. at 13.) The FTC, in its Opposition, attempts to counter that well-accepted principle by arguing that the cases cited "failed to identify the relevant advertisements at all or failed to plead why they were misleading." (Opp'n at 21.) In making this response, however, the FTC apparently fails to appreciate that Gravity Defyer cites those cases in response to the FTC's argument that it meets its burden of pleading by merely pointing at a single testimonial example and appending the phrase "among others." (*See id.* at 20.) Again, the point of the cited cases though is that no plaintiff, including the FTC, can make extremely broad, bare accusations as to all sorts of different advertising claims, but identify only one example of one type of claim in its complaint if it wishes to survive a motion to dismiss.

Equally troubling, the FTC attempts to argue that it needs no factual grounding that could show that the single testimonial ad it identified violated the 2001 Order by implying that the experience depicted represents the typical or ordinary experience of the general public. (Opp'n at 22.) In doing so, the FTC asks this court to find that the agency's own non-binding legal guidance and broad legal conclusions from two prior cases involving entirely different testimonial ads can substitute for facts. (*Id.* at 22–23 (citing FTC, *Guides Concerning Use of Endorsements and Testimonials in Advertising*, 16 C.F.R. § 2.55(b); *Fed. Trade Commn. v. Bronson Partners*, 564 F. Supp. 2d 119, 125 (D. Conn. 2008); *In re Daniel Chapter One*, No. 9329, 2009 WL 2584873, at *67 (FTC Aug. 5, 2009)).) Once again, a court should not accept "legal conclusions cast in the form of factual allegations." *see* Section I.A *supra*. The Court should dismiss Count I where the FTC fails to state plausible allegations.

III. THE FTC LETTER IS ADMISSIBLE AND PROPERLY BEFORE THE COURT

Gravity Defyer attached to its Renewed Motion to Dismiss a letter sent from FTC counsel Maria Del Monaco to Gravity Defyer counsel Katie Bond on February 17, 2022 in which the FTC expressed its desire "to make clear, however, that we believe there are claims that Gravity Defyer could make moving forward, including a number of advertising claims that Gravity Defyer has made in the past." (Mot. Ex. D at 1.) These claims included that Gravity Defyer shoes "absorb harmful shock, reducing pain and discomfort," "absorb harmful energy from hard surfaces," and allow people to "stay active and on their feet all day without pain." (*Id.* at 1–2.) Although the letter "conspicuously," as the FTC would have it, bears a header pronouncing it to be a "confidential settlement communication," it in fact does not fall within the ambit of FED. R. EVID. 408 because it is not an offer of a valuable consideration to compromise a claim.

FED. R. EVID. 408 provides that offering a valuable consideration in attempting to compromise a claim is not admissible to prove the validity of the claim. It is widely recognized that the

purpose of the rule is to encourage "full and frank disclosure between the parties" to promote settlement discussions, and courts must consider the purpose of the rule in determining whether evidence should be excluded pursuant to its strictures. *Sikkelee v. Precision Airmotive Corp.*, 522 F. Supp. 3d 120, 143–44 (M.D. Pa. 2021).

While the rule does not distinguish between public and private parties, the policy rationales are clearly quite different where the party making the putative compromise offer is the government. Government counsel pursuing enforcement actions do not pursue ordinary "claims," as enforcement is ethically required to advance the interests of justice rather than the interests of a particular party. 23 FED. PRAC. & PROC. EVID. § 5303 (2d ed.) (2022). If enforcement counsel brings claims that are unsupported by the evidence or offers deals that are inconsistent with the interests of justice, there is no policy rationale for obscuring evidence of such misconduct from a court. *Id.*

This is essential because, although the judicial branch will prevent the FTC from obtaining unmerited relief, it cannot prevent the severe damage to a business that results from a legal tangle with the agency. The agency itself is aware of the substantial power it wields in publicizing its litigation, announcing every complaint it files through widely circulated press releases. It hopes to use this power to cow its party opponents into accepting a quick settlement so as to try and salvage what remains of their business. Where the FTC is concerned, it is very often true that you may beat the rap, but you can't beat the ride.

Here, most obviously, the relevant statements in the February 17 letter concern the FTC's beliefs regarding "[advertising] claims that Gravity Defyer could make moving forward," i.e., advertising claims that have not yet been made and so are not the subject of this litigation. Expressing a position regarding the substantiation of advertising claims to be made in the future is

not offering to compromise enforcement regarding advertising claims made in the past, and so falls outside of the reach of Rule 408.[4]

Second, because the FTC is acting in an enforcement capacity, it has no claims in this case. Its obligation is to enforce the laws and seek justice, not to advance the interests of the United States. Because the FTC has no claims in this case, any offer it made in settlement discussions would fall outside of the bounds of Rule 408. Further, it falls outside the zone of policy concern embodied in Rule 408, as it requires no protection or encouragement to reach settlement agreements consistent with the demands of justice.

Third, even if it had claims in this case, the FTC could not have offered to compromise those claims. To accept the FTC's interpretation of the February 17 letter (Opp'n at 9) is to accept that the FTC offered to permit Gravity Defyer to break the law "moving forward" in exchange for Gravity Defyer's acquiescence to the settlement terms demanded by the FTC. But the agency lacks any authority to allow a company to make claims deceptive under the FTC Act; it can only assent to the making of lawful claims (otherwise, it would be complicit in the very actions the FTC Act prohibits). Because this interpretation of the letter cannot be sustained consistent with the FTC's statutory obligations and the ethical obligations of its counsel, it must be rejected and the conclusion drawn that the FTC did not offer to compromise the relevant claims. Indeed, to refuse consideration of the letter would withhold material evidence revealing the Complaint's assertions of deceptive advertising to themselves be an act of deception (conveyed without admission that the FTC had already decided—and had communicated to the accused—that several of its strongest advertising representations challenged here had previously been found unobjectionable to the agency).

[4] The FTC's argument that it can offer to settle a controversy regarding future claims because it seeks a permanent injunction in the present litigation (Opp'n at 10 n.8) is, to the extent it is intelligible at all, a *non sequitur*.

Fourth, without the possibility of offering this sort of a grant to withhold material evidence from the Court, it is not clear what "valuable consideration"—as required for the application of Rule 408—the FTC could have been offering in the February 17 letter. The language of the letter did not state, for instance, that the FTC would forgo justified enforcement against certain advertising claims in order to reach a settlement as to other claims. Instead, it stated that "we believe there are claims that Gravity Defyer could make moving forward, including a number of advertising claims that Gravity Defyer has made in the past." Nothing in this language contemplates any sort of "valuable consideration" offered to compromise a claim—rather, it states a position as to the existing substantiation for Gravity Defyer's advertising.

What is shown by the letter is an approved "other purpose" contemplated by Rule 408—to show that the FTC filed its Complaint in bad faith, in retaliation for Gravity Defyer's refusal to accept the settlement terms offered. Courts have refused to exclude evidence of settlement discussions where those discussions were offered as evidence of the plaintiff's bad faith in maintaining a claim. *See, e.g., Princeton Digital Image Corp. v. Off. Depot Inc.*, 13-cv-239, 2017 WL 3420947, at *2 (D. Del. Aug. 9, 2017) (settlement evidence admissible to show bad faith); *ADR Tr. Corp. v. Blasdell*, 154 F.R.D. 675, 681 (D. Ariz. 1993) (settlement evidence admissible to show that complaint was filed in retaliation for defendants' refusal to settle on terms offered).

The letter is also a fundamental part of the FTC's violation of Gravity Defyer's First Amendment Rights. In refusing to allow Gravity Defyer to make *any* advertising claims that rely on the UCLA, regardless of the qualifying language accompanying the citation or reliance, the FTC violates the First Amendment standards discussed above. *Cf. Basic Research, LLC v. Fed. Trade. Commn.*, 807 F. Supp. 2d 1078, 1084 (D. Utah 2011) (FTC stating during negotiations with advertiser that "eat all you want and still lose weight" language could be qualified with additional

language regarding appetite suppression properties of product). The government cannot immunize itself from a challenge to its violation of a party's constitutional rights by committing that violation within the context of a settlement communication. *Carney v. American Univ.,* 151 F.3d 1090, 1095 (D.C. Cir. 1998); *Desmond v. Gonzales*, No. 03-cv-1729, 2007 WL 9770144, at *2 (D.D.C. Feb. 20, 2007); *see also United States v. Zinnel*, 725 Fed. Appx. 453, 459 (9th Cir. 2018) ("Rule 408 is 'inapplicable when the claim is based upon some wrong that was committed in the course of the settlement discussions.'") (quoting *Uforma/Shelby Bus. Forms, Inc. v. NLRB*, 111 F.3d 1284, 1293 (6th Cir. 1997)); *Zurich Am. Life Ins. Co. v. Nagel*, 538 F. Supp. 3d 396, 401 (S.D.N.Y. 2021) (Rule 408 does not bar admission of an email which itself was alleged to be a commission of a breach of contractual and fiduciary duties).

As in these cases, so here, Gravity Defyer does not offer the February 17 letter as circumstantial evidence of the FTC's awareness of the wrongfulness of its conduct. Rather, by refusing to consider any qualifying language to accompany Gravity Defyer's use of the UCLA Study, the FTC abridged Gravity Defyer's First Amendment rights. The February 17 letter is not circumstantial evidence of the FTC's doubts about the validity of its claim, but rather a fundamental part of the FTC's First Amendment violation. As such, it falls outside of the reach of Rule 408, and is properly considered by the Court in evaluating Gravity Defyer's Motion.

IV. THE EXPIRED 2001 ORDER IS UNENFORCEABLE

Section 5(*l*) provides that "[a]ny person, partnership, or corporation who violates an order of the Commission after it has become final, and while such order is in effect, shall forfeit and pay to the United States a civil penalty." 15 U.S.C. § 45(*l*). The FTC suggests that 5(*l*) could be read one of two ways: that one "shall forfeit and pay . . . a civil penalty" only while an order "is in effect" or that one "shall forfeit and pay . . . a civil penalty" for any violations that occurred "while such order [was] in effect." The FTC repeatedly contends that the latter "reading" is "best." (Opp'n

at 26.) But, that "reading" conflicts with the plain language of the statute that requires that an order "is in effect," not "was" in effect, to be enforceable. *See AMG Cap. Mgmt., LLC v. Fed. Trade Commn.*, 41 S. Ct. 1341, 1344 (2021) (the FTC cannot read its enabling statutes "as allowing what they do not say"). That reading also conflicts with 108 years of agency practice.

Since its establishment by statute in 1914, the FTC has had the ability to issue administrative orders and take enforcement action based on such orders. *See* 38 Stat. 719–20, §5 (Sept. 19, 1914). However, even as enacted in its original form in 1914, Section (5) of the FTC Act included similar "in effect" language. *Id.* (If a person "fails or neglects to obey such order of the commission *while the same is in effect*, the commission may apply to the circuit court of appeals of the United States . . .for the enforcement of its order . . .") (emphasis added).

With the 1938 Wheeler-Lea amendments, Congress added Section 5(*l*), allowing for civil penalties in addition to equitable remedies for violation of a prior administrative order. 52 Stat. 111, §5(*l*) (Mar. 21, 1938). In doing so, Congress revised the "in effect" language only slightly and non-substantively, to "while such order is in effect." *Id.* (emphasis added); *see also* 15 U.S.C. § 21(*l*) (allowing FTC to pursue civil penalties for violations of certain competition orders where "such order has become final, and while such order is in effect"); *United States v. J. B. Williams Co., Inc.*, 498 F.2d 414, 427 (2d Cir. 1974) (noting that in 1959 "Congress followed the model of the [1938] Wheeler-Lea amendments almost to the letter, including the civil penalty provision, which became 15 U.S.C. § 21(*l*)").[5]

[5] In addition to allowing civil penalties, the Wheeler-Lea Act expanded Section 5 to apply to unfair and deceptive acts and practices, in addition to unfair methods of competition. The legislative history focuses primarily on that relatively dramatic expansion, noting only that "[t]he other amendments to section 5 of the present law are procedural in character, and are designed to expedite and to lessen the expense of proceedings to review or to enforce the Commission's orders in the courts." Sen. Rep. 75-221, at 3 (March 19, 1937).

The FTC has not identified, and Gravity Defyer is unaware of, any other instance that the FTC has taken enforcement action under the original Section 5, Section 5(*l*), or its similar authority under 15 U.S.C. § 21(*l*), based on an order that is no longer "in effect." The FTC likewise can offer nothing but conclusory aspersions to dispute the many examples cited in the Motion of courts and the agency acknowledging and abiding by the "is in effect" limitation on enforcement. (Mot. at 30–31.) "While Commission practice does not constitute conclusive proof of legislative intent, consistent adherence to [a procedure] indicates, at the very least, that the Commission and the Attorney General consider it an extremely effective and practical means for enforcing the Commission orders." *United States v. St. Regis Paper Co.*, 355 F.2d 688, 698–99 (2d Cir. 1966) (upholding 5(*l*), 15 U.S.C. § 45(*l*), statutory procedure requiring FTC referral to the U.S. Attorney); *see also United States v. Standard Distributors, Inc*., 267 F. Supp. 7 (N.D. Ill. 1967) (finding twenty years of FTC practice "persuasive authority for the proposition that Congress intended [5(*l*)] to apply to all final orders," despite respondents' arguments otherwise).

The FTC is correct that a Federal Register footnote on its sunset policy allowed that it might be "conceivable that the government could file a complaint up to five years after an order has terminated challenging violations that occurred while the order was in force." (Opp'n at 28 (citing 60 Fed. Reg. 42,571, n.8 (Aug. 16,1995)).) But, by the time the FTC issued its final "sunset rule," it ended any such speculation, again confirming that its "authority pursuant to Section 5(*l*) of the FTC Act" allows it to seek civil penalties only "for violations of an order *that remains in effect*." Final Rule, 60 Fed. Reg. 58,514, at 58,514, n.2 (Nov. 28, 1995) (emphasis added).

The FTC is also correct that the terms of the 2001 order provide that filing of a complaint "after the order has terminated" "will not affect the duration of the order." (Opp'n at 27–28 (citing 2001 Order, at Part X.C).) What the agency overlooks is that such filing would be *ultra vires* where

the order would no longer be "in effect" for the purposes of Section 5(*l*). The order language simply reiterates when and how a complaint filing will reset the 20-year duration of the order—if it is filed while the order is still "in effect," not after. The order language does not and could not grant the FTC statutory authority is does not have.

The general federal statute of limitations for civil penalty actions provides as follows:

> Except as otherwise provided by Act of Congress, an action, suit or proceeding for the enforcement of any civil fine, penalty, or forfeiture, pecuniary or otherwise, shall not be entertained unless commenced within five years from the date when the claim first accrued if, within the same period, the offender or the property is found within the United States in order that proper service may be made thereon.

28 U.S.C. § 2462. With the language "[e]xcept as otherwise provided by Act of Congress," that provision "provides a catch-all statute of limitations in situations where Congress did not specifically include a time limitation in the statute." *Fed. Elec. Commn. v. Nat'l Republican Senatorial Comm*., 877 F. Supp. 15, 17 (D.D.C. 1995). Where Section 5(*l*) limits filing a civil penalty enforcement action, based on a prior FTC order, to the period "while such order is in effect," Congress has already spoken and the catch-all five-year cannot extend the time to file.[6] The Court should dismiss Counts I–II where the underlying 2001 Order is expired and no longer enforceable.

V. THE EXPIRED 2001 ORDER NEVER APPLIED TO GRAVITY DEFYER OR FOOTWEAR

A. The Expired 2001 Order Never Applied to Gravity Defyer

In its Motion, Gravity Defyer argues the 2001 Order cannot be enforced against it because it is not named in the Order. (*Id.* at 24–26.) Gravity Defyer is not a "successor or assign" of Gadget Universe, nor is it "merely a disguised continuance" of that company. (*Id.* at 25–26.) Unlike the situation in *Washington Metro. Area Transit Comm'n v. Reliable Limousine Serv., LLC*, 776 F.3d

[6] By contrast, where 5(*l*) provides no limit on how far in the past civil penalties may be assessed, the general statute of limitations applies, limiting the period to five years. *See, e.g.*, *Fed. Trade Commn. v. Lukens Steel Co*., 454 F. Supp. 1182, 1185 n.2 (D.D.C. 1978).

1 (D.C. Cir. 2015), Gravity Defyer was not started as an attempt to elude the terms of an order, but rather to contribute to society in the conduct of a completely different line of business. Gravity Defyer does not advertise technology, it makes shoes.

In its Opposition, the FTC responds that the 2001 Order can be enforced against Gravity Defyer because of its "identify of interest" with Mr. Elnekaveh and because it acted in concert and participation with him. (*Id.* at 32.)[7] In making this argument, the FTC relies heavily on *Reliable Limousine*. That is a mistake, however, as that decision explicitly states that common ownership is not sufficient to bind an entity to the terms of an order. *Reliable Limousine*, 776 F.3d at 30. Instead, there must be a close relationship "*as to the specific conduct proscribed by the Order*." *Id.* at 31 (emphasis added). No such relationship exists here, nor could it—because the terms of the 2001 Order proscribe any breach of the laws enforced by the FTC.

"No court may lawfully enjoin the world at large." *Whole Woman's Health v. Jackson*, 142 S. Ct. 522, 535 (2021) (cleaned up). Nor may it enforce an order that fails to "describe in reasonable detail—and not by referring to the complaint or other document—the act or acts restrained or required." FED. R. CIV. P. 65(d)(1)(C). Many courts have expressed skepticism about the enforceability of broad, "obey-the-law" injunctions, orders that do "little more than order the defendant to obey the law." *Securities and Exch. Commn. v. Goble*, 682 F.3d 934, 949 (11th Cir. 2012); *see also Securities and Exch. Commn. v. Savoy Industries, Inc.*, 665 F.2d 1310, 1318–19 (D.C. Cir. 1981); *Securities and Exch. Commn. v. Graham*, 823 F.3d 1357, 1362 n.2 (11th Cir. 2016) (collecting cases); *Securities and Exch. Commn. v. Smyth*, 420 F.3d 1225, 1233 n.14 (11th Cir. 2005)

[7] The reach of the FTC's position here is breathtaking. Executives are often awarded stock options to create an "identity of interest" with the companies they work for; would the FTC seek to enforce the 2001 Order against a hypothetical company that hired Mr. Elnekaveh as Chief Operating Officer? The FTC would apparently extend its orders to any company touched by an individual during the time he remains under order.

(collecting cases); *United States v. Corn*, 836 F.2d 889, 892 & n.6 (5th Cir. 1988). While this case law involves orders sought by the Securities and Exchange Commission, the terms of the "obey-the-law" injunctions criticized there are identical to those in the 2001 Order—which do "little more than order the defendant to obey the law." *See also Fed. Trade Commn. v. Washington Data Resources*, 09-cv-2309, 2012 WL 2075827, at *5 (M.D. Fla. June 8, 2012) (describing an obey-the-law provision requested by the FTC as "insufficiently specific, the provision essentially informs the defendants not to violate Section 5 of the FTC Act, 15 U.S.C. § 45(a), which prohibits 'unfair or deceptive acts or practices in or affecting commerce,' a prohibition of boundless proportion.").

The reason for courts' reluctance to enforce these sorts of orders is that they "embrace nearly any sort of violation" of the laws enforced by the agency, subject a party to sanctions for violating an order for acts "completely unrelated" to past lawbreaking, and are "so vague as to put the whole conduct of a business at the peril of a summons for contempt. *Savoy*, 665 F.2d at 1318–19. Courts have condemned "obey-the-law" orders more generally "because they lack specificity and deprive defendants of the procedural protections that would ordinarily accompany a future charge of a violation." *Goble*, 682 F.3d at 949.

Here, the FTC seeks to go even farther, not simply attempting to enforce an overly broad obey-the-law injunction, but attempting to enforce it against an unnamed company in a different line of business. The only connection between Gravity Defyer and Gadget Universe is common ownership which, as in *Reliable Limousine*, does not bind Gravity Defyer to an Order issued against Gadget Universe. Although the FTC insists that the conduct proscribed by the 2001 Order is "remarkably like" the conduct alleged in this case (Compl. at 2), advertising fuel savings technologies for cars and designing orthopedic shoes are, in fact, entirely different industries. Publishing an advertisement for a third-party seller of fuel saving technology and engaging in painstaking,

exhaustive research and development to design pain relieving shoes are, in fact, wholly different courses of conduct.

Even had Gravity Defyer not created a shoe that provides pain relief, even had Gravity Defyer not commissioned a reputable study whose results substantiate pain relief claims, the FTC is simply wrong that it can impute to Gravity Defyer knowledge of conduct proscribed by the 2001 Order where the order itself fails to describe any advertising germane to the sale of orthotics such that a reasonable person could anticipate how specific content for that entirely unrelated advertising would be affected by the 2001 Order. Instead, according to the FTC's reading of the order, the order proscribes deceptively advertising a specific class of products—fuel-line magnets or other purported fuel-saving or emissions-reducing products—and also any other advertising in violation of the FTC Act. Where a broad, obey-the-law order fails to describe in reasonable detail the conduct it proscribes, it fails to put a party allegedly acting in concert with a named party on notice of the proscribed conduct. Where such notice is lacking, the 2001 Order cannot be enforced by an Article III court. Thus, Counts I–II, based on the 2001 Order, should be dismissed as to Gravity Defyer.

B. The Expired 2001 Order Never Applied to Footwear

The Renewed Motion to Dismiss argued that, based on the parties' intent, Parts III and IV of the 2001 Order reach only "fuel-line magnet[s]" and any other "purported fuel-saving or emissions-reducing product for use in conjunction with a motor vehicle," not footwear. (Mot. at 27–30.) The FTC, once again, adopts the tactic or arguing that the Court must accept its preferred interpretation of the Order's language for the purposes of a motion to dismiss—all the while insisting that it is not asking the court to assume anything. (Opp'n at 30.)

As above, however, while the Court does assume the truth of factual assertions in the Complaint for purposes of ruling on a motion to dismiss, the same is not true of legal conclusions,

including those related to the FTC's preferred reading of the Order's language. The FTC's interpretation runs aground at the point where the "reasonably related" doctrine applicable to "fencing in" relief enlightens the parties' intent as to an ambiguous term. The ambiguous term "any product" in Parts III (prohibiting misleading testimonials) and IV (prohibiting misleading claims about testing) could mean "any product" ever developed or simply "any product" that is similar to the products that were the sole focus of the enforcement matter and identified in Part I. But this is not an unresolvable ambiguity, because only one of these interpretations bears any modicum of legal plausibility. It is not that favored by the FTC.

As discussed in the Renewed Motion to Dismiss, when assessing the validity of so-called "fencing-in relief" that prohibits more than the alleged violative behavior, courts consider whether the relief sought is "reasonably related" to the alleged violations. *See, e.g., Litton Industries, Inc. v. Fed. Trade Commn.*, 676 F.2d 364, 371–72 (9th Cir. 1982); *In re ECM Biofilms, Inc.*, No. 9358, 2015 WL 575402, at *219 (FTC Jan. 28, 2015). In determining whether an order's prohibitions are "reasonably related" to alleged violations, a court assesses not only the logical relationship between the violative conduct and the fenced-in conduct, but also the deliberateness of the violation, the seriousness of the violation in terms of consumer harm, the violator's past record, and the transferability of the unfair practice to other products. *See, e.g., In re Sanctuary Belize Litig.*, 482 F. Supp. 3d 373, 467 (D. Md. 2020); *Removatron Int'l Corp. v. Fed. Trade Commn.*, 884 F.2d 1489, 1499 (1st Cir. 1989); *Sterling Drug, Inc. v. Fed. Trade Commn.*, 741 F.2d 1146, 1154 (9th Cir. 1984) (citing *Fed. Trade Commn. v. Colgate-Palmolive Co.*, 380 U.S. 374, 392 (1965)); *Fed. Trade Commn. v. SuperTherm Inc.*, No. CV-20-08190-PCT-DWL, 2021 WL 3419035, at *9 (D. Ariz. Aug. 5, 2021).

There is no dispute that it is well-settled that "multi-product orders should be used with caution 'because they alter the scheme of penalties and enforcement procedures defined by the [FTC] Act.'" *Litton Industries*, 676 F.2d at 371–72 (quoting *Standard Oil Co. v. Fed. Trade Commn.*, 577 F.2d 653, 661 (9th Cir. 1978)); *see also Am. Home Prod. Corp. v. Fed. Trade Commn.*, 695 F.2d 681, 705 (3d Cir. 1982). There is likewise no dispute that in the enforcement matter leading to the 2001 Order, the FTC offered a no-money settlement to Esrim Ve Sheva Holding Corp. (d/b/a Gadget Universe) and Mr. Elnekaveh, versus the $4.2 million settlement offered to the creators of the fuel device that was at issue. There is likewise no dispute that the allegations against Esrim Ve Sheva Holding Corp. and Mr. Elnekaveh involved but three advertisements: a single, one-page internet ad and two catalog ads. Beyond there being little if any logical connection between "fuel-line magnet[s]," "purported fuel-saving or emissions-reducing product," and orthotic footwear there is simply not any deliberate or pervasive deception that would have warranted such broad fencing-in relief reaching "any product."

The parties clearly agreed to a consent order as to "fuel-line magnet[s]," and "purported fuel-saving or emissions-reducing product[s]," not any type of product that existed then or could have been developed in the 21 years since 2001. The Court should dismiss Counts I–II where the underlying 2001 Order never applied to footwear.

CONCLUSION

For the foregoing reasons, Gravity Defyer and Mr. Elnekaveh's Renewed Motion to Dismiss should be granted, along with such other and further relief as the Court deems just and proper.

Dated: April 28, 2023

Respectfully submitted,

/s/ J. Kathleen Bond
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CERTIFICATE OF SERVICE

I hereby certify that, on April 28, 2023, I electronically filed the foregoing paper with the Clerk of the Court using the ECF system that will send notification of such filing to all parties whose counsel has entered an appearance in this matter.

/s/ *J. Kathleen Bond*