UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	
POM WONDERFUL LLC and	)	
ROLL GLOBAL, as successor in interest	)	
to Roll International companies, and	)	**Docket No. 9344**
	)	**PUBLIC**
	)	
STEWART A. RESNICK,	)	
LYNDA RAE RESNICK, and	)	
MATTHEW TUPPER, individually and	)	
as officers of the companies.	)	
	)	

RESPONDENTS' PRETRIAL BRIEF
CORRECTED COPY

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I. SUMMARY OF THE CASE

A. Overview

Unlike many false advertising cases where respondents have little or no evidence to support their claims, Respondents have developed and rely on a truly unprecedented amount of scientific research—conducted by leading researchers and scientists—to support their belief that their products, 100% Pomegranate Juice and an extract of pomegranates in pill and liquid form, have significant health benefits. Respondents confidently submit that the level of research they have developed and rely upon meets the traditional "competent and reliable scientific evidence" standard applied by the Federal Trade Commission ("FTC" or "Complainant"), and that the claims they have made for their products are substantiated and non-deceptive. However, notwithstanding the unprecedented level of research sponsored by Respondents, Complaint Counsel, by this action, are aggressively seeking to obtain new legal ground against advertisers making health claims—including those who, like POM Wonderful ("POM"), have ample credible scientific evidence to support their claims—contrary to law, and to the detriment of consumers. This should not be permitted.

First, Complaint Counsel are trying to apply a pharmaceutical "drug" standard to food products. This position is both scientifically and legally unsound. Ample scientific evidence exists that the large randomized trials used to support the approval of pharmaceutical drugs are not scientifically superior for foods or nutrients. Nor can Complaint Counsel cite a single case where the FDA standard for drug approval has been applied to foods. Yet, if successful, in applying the "drug" standards to food, the FTC will effectively prevent the dissemination of information regarding any emerging science on the health benefits of wholesome food products.[1]

[1] The White House and public officials all over the world recognize the link between diet and disease. The 2010 Dietary Guidelines for Americans explicitly encourage consumers to make healthy dietary choices to help reduce

Second, as a remedy in this case, Complaint Counsel are also seeking to impose on Respondents, for the first time in agency history, the requirement that Respondents seek and obtain prior approval by the FDA before making certain health claims in future advertising. Complaint Counsel thereby invoke a prior restraint on speech, in stark contrast to previous matters it has brought before this Court. This maneuver is contrary to the entire regulatory and statutory framework under the Federal Trade Commission Act ("FTCA") (15 U.S.C. § 41, *et seq.*) and Food, Drug, and Cosmetic Act ("FDCA") (21 U.S.C. § 301, *et seq.*). It exceeds the FTC's jurisdiction, and contravenes well-established commercial speech standards limiting prior restraints on speech. Despite its unprecedented legal maneuvers, Complaint Counsel tiptoe around these issues, spending a mere two (2) pages on the "standard" and on what "competent and reliable" evidence means.

Last, Complaint Counsel take an extremely aggressive view of what POM's advertising actually conveys, and construe all advertising regarding health as conveying the message that the products are "clinically proven" to reduce the risk of, prevent or treat disease or that its consumption is a "silver bullet" against disease. These messages have certainly not been conveyed in the ads. There are clear distinctions with a difference between saying that a product is good for you, or even that it may assist in the reduction of risk of disease, and saying that it is a "silver bullet" against disease. Notwithstanding these distinctions and the fact that Respondents have not made "silver bullet" health claims, there does exist significant scientific evidence, competently and reliably executed, that POM's products are good for you and may reduce the likelihood of disease.

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obesity and the risk of diet-related disease, such as cancer, heart disease, and diabetes. It then follows that food companies should, like POM, invest in the scientific research of their foods or food components to build on the current sizeable evidence suggesting that plant foods and phytonutrients have health promoting benefits.

The pomegranate is a safe, wholesome food product. There is significant credible evidence, including numerous well-designed, controlled clinical studies, indicating that the fruit and its derivative products provide numerous health benefits, including benefits to the heart, prostate and erectile function. Complaint Counsel certainly cannot meet their burden of showing that Respondents had no reasonable basis for their health claims at issue in this case. Moreover, at a minimum, to prevail under the FTCA on their "falsity" theory, Complaint Counsel must affirmatively present evidence establishing the claims are actually false—that the claimed health benefits do not in fact exist. Complaint Counsel cannot possibly meet that burden, and have not designated a single expert to support this allegation.

Although the appropriate legal and scientific "standards" are certainly dominant issues in this case, Respondents can satisfy all applicable standards, including the FTC's "competent and reliable" standard, which is admittedly the most vague and, now, rigid of the potentially applicable legal standards. The totality of scientific evidence supporting the health benefits of POM's products is ample proof of the advertising representations made. In the face of this science, the applicable policy endorsed by the Supreme Court, the Court of Appeals for the D.C. Circuit, and the D.C. District Court is to prefer disclosure over suppression of the advertised information. *See Bates v. State Bar of Arizona*, 433 U.S. 350, 375; 97 S.Ct. 2691, 2700-01 (1977); *Pearson v. Shalala*, 164 F.3d 650, 656-58 (D.C. Cir. 1999) ("*Pearson I*"); *Alliance for Natural Health v. Sebelius*, 714 F. Supp. 2d 48, 52-53 (D.D.C. 2010). That policy is particularly applicable where, as here, the product creates no material risk of harm. *Pearson I, supra*, at 656; *Whitaker v. Thompson*, 248 F. Supp. 2d 1, 15-16 (D.D.C. 2002) ("*Whitaker I*"). Complaint Counsel should not be allowed to thwart the dissemination of potentially helpful information regarding the potential and actual health benefits of 100% fruit-derived products.

B. An Unworkable New "Substantiation" Standard For Food And Food Derivatives

Although referred to as a false advertising case, this case really turns on whether POM's science, which is obviously extensive, is also of the specific type and character that the FTC desires for all health claim advertising, without regard to the type of claim being made or the product. The FTC, in fact, has never before litigated a false advertising case in connection with so natural a food product as POM Wonderful's 100% Juice, and with the level of scientific support POM marshals in support of its products' health claims. Ironically, that is precisely why this case is being brought: if the FTC is successful in its efforts to require POM to support its health claims with the massive clinical studies often required for the approval of pharmaceutical drugs, then the FTC would succeed in widely restricting the advertising of all non-drug products, including against companies, like POM, who have significant credible scientific evidence to support their claims, yet who do not have the several large human clinical randomized placebo-controlled trials ("RCTs") used by large drug manufacturers. The public, however, should not be deprived of important scientific information on nutrition, which is the most significant consequence of the FTC's new mandate.

Complaint Counsel argue, contrary to *In re Pfizer Inc.*, 81 F.T.C. 23 (1972), that only RCTs can support a health claim, regardless of the type of product or claim at issue. Specifically, Complaint Counsel wrongly assert that POM's natural food products should be held to the same scientific standard typically required for pharmaceutical drugs and high-risk products. To this end, Complaint Counsel have asked four experts to support its "one size fits all" legal argument, *scientifically*, and testify that only RCT studies matter. However, Complaint Counsel's argument is not supportable scientifically, economically, or legally.

First, Complaint Counsel's argument that only RCTs matter is not supported scientifically. Leading nutrition researchers, including the FTC's only expert on nutrition, argue just the opposite: in the nutrient context, the conventional RCTs used effectively for drugs are not an efficient or even effective scientific model by which to test nutrients or whole food products. There are several reasons for this, including that drug effects can be tested against a non-exposed (placebo) contrast group, whereas it is impossible and/or unethical to attempt a zero intake group for nutrients; and therapeutic drugs are intended to be efficacious within a relatively short term while the impact of nutrients on the reduction of risk of chronic disease may require decades to demonstrate—a difference with significant implications for the feasibility of conducting pertinent RCTs in foods. Yet, Complaint Counsel, with their singular focus on applying the "drug" standard to POM's products, ignore these scientific facts entirely. Complaint Counsel never offer an expert opinion on this subject, and their sole nutritionist, their only expert who is qualified to testify on this subject, Dr. Meir Stampfer, has testified that RCTs are not the required practice for evaluating nutrients or foods.

Second, the FTC's proposed new standard is economically unworkable. For example, Complaint Counsel contend that before one can advertise that a product prevents prostate cancer, one must conduct an RCT involving more than 10,000 men over the course of four to seven years. *See* Compl. Counsel's Br. at 74. At a cost of $5,000 to $10,000 per participant, one RCT alone would cost up to $700,000,000. The FTC's novel pharmaceutical standard would, economically speaking, end all commercial speech in this area, including truthful speech that cannot be economically supported by the requisite RCTs. The economics of the FTC's position is not a mere side note, but directly relevant and required analysis under *Pfizer*.

Third, Complaint Counsel's legal argument that only RCTs matter is also not legally sustainable for at least the following reasons:

1. Complainant's argument that "one size fits all" is contrary to the "reasonable basis" test under *Pfizer* that requires the Court to consider, among other things, the type of "product" at issue and to engage in a cost-benefit analysis to determine whether a "reasonable basis" exists for the claim.

2. Complainant's interpretation of the *Pfizer* factors, which ignores the food vs. drug distinction, tacitly permits the FTC to dictate, in effect, a rigid legal standard requiring RCTs, subsuming all the other *Pfizer* factors, merely by retaining testifying experts who work almost exclusively in the pharmaceutical drug arena, and who recognize only RCTs. This interpretation of the *Pfizer* factors would turn the "reasonable basis" test on its head, violate the commercial speech cases of *Pearson v. Shalala* discussed further below, and allow testifying pharmaceutical scientists, to dictate a legal standard retroactively, violating Respondents' due process rights under the Administrative Procedures Act ("APA") (5 U.S.C. § 500, *et seq.*) and the Fifth Amendment.

3. Complainant's argument represents a complete turnabout from its own previously issued policy statements. The FTC previously conceded that the rigid standard now advocated here improperly implicates the First Amendment.

4. Separate and apart from Complainant's position on *Pfizer*, this Court must be guided by the commercial speech doctrine line of cases under, *Pearson v. Shalala*, 130 F. Supp. 2d 105 (D.D.C. 2001) ("*Pearson II*"), *Pearson v. Thompson*, 141 F. Supp. 2d 105 (D.D.C. 2001) ("*Pearson III*"), *Whitaker v. Thompson*, 248 F. Supp.

2d 1 (D.D.C. 2002) ("*Whitaker I*"), *Whitaker v. Thompson,* 239 F. Supp. 2d 43 (D.D.C. 2003) ("*Whitaker II*"), and *Alliance for Natural Health, supra,* 714 F. Supp. 2d 48. These cases, following *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York,* 447 U.S. 557, 100 S.Ct. 2343 (1980), insist that the determination of whether commercial speech is "false or misleading" cannot depend on whether there exists significant scientific agreement in support for the claim; *i.e.* speech cannot be deemed false or misleading merely because experts do not agree, as that standard would require commercial actors to show the statements are in fact true (although POM can show this in any event), and go well beyond what is required to show the speech is not "false or misleading." Instead, it is enough, under these cases, that there exists "credible evidence" for a claim. This Court's construction of *Pfizer's* "reasonable basis" test, as well as the FTC's own competent and reliable test, should be applied, if at all, consistent with the *Pearson v. Shalala* line of cases.

C. The FTC's Adoption Of The FDA's Prior-Approval Mechanism

Just as significant, Complaint Counsel seek to implement, for the first time, a radically new mechanism in its proposed order against POM that incorporates the FDA's prior approval system. This would require POM to obtain prior approval by the FDA before making certain health claims in advertisements. This blatant attempt to prevent reoccurrence of the agency's loss in the district court in *Lane Labs*[2] is unsustainable for at least the following reasons:

1. Complainant's requirement that Respondents obtain prior FDA-approval before making certain health claims in advertising bears no rational relationship to the

[2] *See FT. v. Lane Labs-USA, Inc.*, 2009 WL 2496532 (D.N.J. Aug. 11, 2009), aff'd and rev'd in part, by *FTC v. Lane Labs-USA, Inc.*, 624 F.3d 575 (3d Cir. 2010).

conduct challenged in the complaint. Although Complaint Counsel may seek a remedy deemed adequate to cope with alleged unlawful practices, the remedy must have a "reasonable relation to the unlawful practices found to exist." *Standard Oil Co. v. FTC*, 577 F.2d 653, 662 (9th Cir. 1978). Here, by requiring prior FDA approval, Complaint Counsel are stifling Respondents' ability (and right) to make any health claims regarding a fruit juice (and its derivatives) given the FDA's stringent requirements for approving a new drug. This restriction is not narrowly tailored and bears no reasonable relation to the conduct alleged in this case.

2. In addition, the requirement to obtain prior approval by the FDA before making health claims constitutes an impermissible shift of the government's burden to justify its restrictions on speech. *See Thomas v. Chcagoi Park Dist.*, 534 US 316, 122 S. Ct 775; 151 L.Ed. 2d 783 (2002); *United States v. Playboy Entm't Group, Inc.* 529 US 803, 120 S.Ct. 1878; 146 L.Ed. 2d 865 (2000). The D.C. Court of Appeals in *Pearson v. Shalala* (and in the progeny of that case) make clear, however, that independent of the Nutrition Labeling and Education Act ("NLEA"), Pub.L. No. 101-535, 104 Stat. 2353 (1990) (21 U.S.C. § 343 *et seq.*), the FDA (and, indeed, every agency of this government that would presume to restrict health claims) may not impose a prior restraint on nutrient-disease claims unless it first carries the burden of establishing that no qualification of the claim is sufficient to eliminate its alleged misleadingness. *See Pearson I*, 164 F.3d at 659; *Pearson II* 130 F.Supp. 2d at 112-13, 118-19; *Pearson III*, 141 F.Supp. 2d at 112;

Alliance for Natural Health, 714 F.Supp. 2d at 53, 62, 65; *Whitaker I*, 248 F.Supp. 2d at 14;.

3. The FTC lacks jurisdiction to enforce the FDCA.

II. FACTUAL AND PROCEDURAL BACKGROUND

A. Factual Background

1. The Parties

a. The Pomegranate

Pomegranates have been safely consumed since the beginning of recorded history. They have been known (and eaten) since Biblical times and probably even before that. In the Bible, the Song of Solomon 4:3 refers to pomegranates, and Jerusalem's silver shekel minted between 143 and 135 B.C. bears an engraving of three pomegranates. The Koran describes paradise as having gardens with trees bearing pomegranates and other fruit. Buddha gave the female demon Hariti a pomegranate which cured her of evil. Ancient jewelry from India featured pomegranates.

Pomegranates were used medicinally by Egyptians, Persians, Assyrians, Babylonians, Greeks and Romans. For example, Hippocrates used pomegranates to treat eye infections. Likewise, the Greek physician Dioscordes featured pomegranates as a cure for many ailments in his ancient text. In Egypt, pomegranates trees were known as the tree of life, and King Tut took a pomegranate vase with him to the afterlife.

In the 16th Century, the Royal College of Physicians adopted a coat of arms featuring a pomegranate. That fruit was also on the coat of arms of Catherine of Aragon, the daughter of Ferdinand and Isabella and the first wife of Henry VIII.

In all of these places, over all of these centuries, pomegranates have been safely consumed.

b. Corporate Respondents: POM and Roll

POM is the largest grower and distributor of pomegranates and pomegranate juice in the United States. POM produces, markets, and sells fresh pomegranates (known as the "Wonderful" variety and grown in California's San Joaquin Valley), pomegranate juice, and other pomegranate-based products containing POMx, a proprietary and antioxidant-rich extract developed from the pomegranate juicing process.

In 2002, POM first launched POM Wonderful 100% Pomegranate Juice, the first premium, all-natural pomegranate juice made from pomegranates grown from POM's own orchards. In 2006, POM developed and marketed POMx Pills, a dietary supplement containing the POMx extract, as well as POMx Liquid, a liquid form of the POMx Pills. These products, however, were not available for sale until 2007. POM is a Delaware limited liability company with its principal place of business in Los Angeles, California.

Roll Global LLC ("Roll Global"), the successor in interest to Roll International Corporation ("Roll"), is a privately held company with diverse business interests, including agriculture, consumer packaged goods, and floral services, among others. Roll Global is a Delaware limited liability company with its principal place of business in Los Angeles, California.[3]

[3] POM and Roll Global are independent companies that strictly abide by corporate formalities, and operate at an arms-length basis. Considering the evidence, including the depositions of the Chief Financial Officers of POM and Roll, as well as the multi-factored legal standard on common enterprise liability, it is clear that there is insufficient evidence to support a finding that POM and Roll, and now Roll Global, operate as a common enterprise.

c. Individual Respondents: Stewart Resnick, Lynda Resnick, and Matthew Tupper

Respondent Stewart Resnick is the Chairman of POM. Mr. Resnick also serves as the Chairman and President of Roll Global. For more than 50 years, Mr. Resnick has owned, managed, and pursued a wide array of business concerns. For the past 30 years, Mr. Resnick's business activities have focused on the production, marketing, and sale of consumer goods. Respondent Lynda Resnick is the Vice-Chairman of Roll. Respondent Matthew Tupper is the President and Chief Operating Officer of POM.

There is no reason to believe as Complaint Counsel blindly assert, that the FTC can make any showing suggesting that an injunction is needed as to the individual Respondents. The Respondents have been, and will continue to be, good individual and corporate citizens. Indeed, their communications regarding the healthful benefits of pomegranate juice are not merely legally appropriate, but consistent with their long-held personal beliefs, supported by science that the health benefits of pomegranate juice are real.

2. POM's Research Program

For more than a decade, POM and its founders have been committed to funding scientific research that adheres to the highest level of scientific integrity and have been dedicated to exploring the health benefits of the pomegranate. Respondents[4] have established a state-of-the-art research program involving the participation of the most renowned researchers in the world, affiliated with the most respected institutions, using the most advanced technology around the globe.

Respondents' interest in pomegranates first began in 1986 after acquiring 120 acres of pomegranate trees as part of a larger agricultural purchase. Initially, Respondents only sold the

[4] In the context of funding research, the term "Respondents" generally excludes individual respondent Matthew Tupper, Roll, and Roll Global.

fresh pomegranate fruit, and it was not until 2002 that Respondents began selling pomegranate juice. From the time of the initial purchase to the mid 1990s, Respondents planted another 6,000 acres. As the sales of the fruit grew and became a larger part of POM's business, Respondents became fascinated with the mythological and historical allure of pomegranates, and Respondents set out to learn more about the fruit and to assess whether there might be any scientific evidence to support its legendary reputation as a powerful contributor to health.

In 1996, Respondents and their medical advisor, Dr. Leslie Dornfeld, approached Dr. Michael Aviram, an Israeli scientist who had done groundbreaking work exploring the antioxidant properties of red wine, and asked Dr. Aviram to begin researching the antioxidant potency of pomegranates. Additionally, Respondents sponsored compositional research on pomegranate juice at the University of California, Davis in the late 1990s. Those scientists concluded that pomegranate juice extracted from the whole fruit contained much higher antioxidant levels when compared to any of the other beverages in the study and published the study in the *Journal of Agricultural Food and Chemistry*, a leading food chemistry journal. From both the research of Dr. Aviram and this basic seminal discovery by the University of California, Davis, Respondents grew a cutting-edge research program to further investigate the lore that accompanied the pomegranate's history and to explore other prospective health benefits that might accompany the juice's potent antioxidant activity.

Respondents have now investigated the health benefits of pomegranates for more than a decade, funding both clinical and non-clinical studies at world-class institutions like the University of California, Los Angeles ("UCLA") and San Francisco ("UCSF"), Johns Hopkins,

Columbia, Washington University, The Technion – Israel Institute of Technology,[5] University of Naples in Italy, and University of Glasgow in Scotland. Respondents have worked with some of the most esteemed researchers in the world, including a Nobel Laureate attributed with Viagra, and spent well over $35 million[6] to support its extensive scientific research program on pomegranates. Accordingly, since 1998, Respondents have sponsored or participated in more than 90 scientific investigations, with over 65 studies on POM products, including 17 clinical trials that have been published in top peer-reviewed scientific journals.

Respondents have sponsored studies testing pomegranate benefits in the areas of antioxidant activity, cardiovascular health, erectile health, prostate health, cancer, skin care, sports physiology, immunity, inflammatory disorders, and cognitive function. More than 20 research studies have focused solely on cardiovascular health (as distinguished from studies focusing more generally on basic mechanisms of action within the body, including the cardiovascular system). The findings from the entire body of research show that POM products have many dynamic and positive effects on the human cardiovascular system, including anti-atherogenic properties, increased blood flow to the heart, and reduction in blood pressure.

POM has also uncovered a strong connection between pomegranates and human prostate health due to the fact that consumption of pomegranate juice has been found to nearly triple the prostate specific antigen ("PSA") doubling time in 50% of men following radical prostatectomy. PSA doubling time has been shown to be an indicator of the risk and time to clinical recurrence of prostate cancer following radical treatment.

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[5] The Technion – Israel Institute of Technology, founded in 1912, is an institute of engineering and sciences located in Haifa, Israel. Dr. Arnold Melman, the FTC's expert in the field of erectile dysfunction, regards the Technion as a "terrific institution." Melman Dep. Tr. at 106:17-18; PX0360.

[6] This figure excludes significant internal costs and overhead.

Respondents' research has also revealed that the consumption of pomegranate juice has positive effects on erectile function due in part to the fruit's strong antioxidant components and its impact on nitric oxide levels, which trigger the chemical cascade that causes the smooth muscle relaxation necessary to achieve penile erection.

Taken in its totality, Respondents have created a significant body of research showing that a definitive and significant connection exists between the consumption of pomegranate and the maintenance of human health. Indeed, this body of research provides evidence that pomegranates are beneficial to heart, prostate, and erectile health, and that the consumption of the 100% Juice or the extracts may affirmatively reduce the risk of disease.[7]

While POM has been committed to marketing and selling its pomegranate products, unlike other companies advertising health benefits, POM has discriminated among the areas of research it has funded and refrained from marketing many areas of research in which it has invested substantial sums. Regardless, POM remains steadfast in its dedication to expanding its research program and encouraging an open dialogue about the health benefits of pomegranates.

3. POM's Advertisements

Over the past eight years, based on significant and substantial scientific research on the health benefits of pomegranate juice, POM has publicized the health benefits of pomegranate juice in a variety of media, including, among others, print (e.g., magazine ads), online (e.g., POM website and internet banners), out-of-home ("OOH") (e.g., billboards, transit shelters and gym posters) and point-of-sale ("POS") (e.g., hang tags). Many of POM's advertisements promoting the juice's "Antioxidant Superpowers" are puffery or pure hyperbole: "Drink it daily. Feel it forever." (circa 2008), "It's been around for 5,000 years. Drink it and you might be too."

(circa 2009) and "Forever young." (circa 2009-2010). *See* Deposition of David W. Stewart, Ph.D. at 138:14-15 ("I think the "live forever" is a good example of -- of puffery, of hyperbole.").[8] Other POM advertisements only make health claims in areas that are supported by competent and reliable scientific evidence. At worst, POM's ads conveyed pomegranate juice as promoting heart, prostate and erectile "health," but never claimed that POM pomegranate juice is "proven" to "prevent," "treat," or "cure" any disease.

When POM first began marketing its juice in late 2003 and early 2004,[9] POM advertised the health benefits of antioxidants generally. For example in 2004, POM's "Drink and be healthy" advertisement depicted a picture of a bottle of POM juice, a fresh pomegranate, and a small chart showing that its juice had more antioxidant power than red wine, blueberry juice, cranberry cocktail, orange juice and green tea. It contained the following antioxidant message:

> 100% all-natural pomegranate juice. The delicious, refreshing antioxidant superpower.
>
> More naturally occurring antioxidant power than any other drink, including red wine, blueberry juice, cranberry juice, orange juice and green tea. Antioxidants guard your body against harmful free radicals that can cause heart disease, premature aging, Alzheimer's disease, even cancer . . . Medical studies have shown that drinking 8 oz. of POM Wonderful pomegranate juice daily minimizes factors that lead to atherosclerosis (plaque buildup in the arteries), a major cause of heart disease.

These early types of ads, however, were low-circulation and clearly have little or no relevance in that they were published more than five years before the Complaint was filed, and six to seven years before the trial date. Additionally, they were extremely short-lived because POM's marketing and advertising campaign quickly evolved to a more light-hearted, comical,

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[8] Professor Stewart, one of the FTC's expert witnesses, is the dean and a professor of management at the School of Business Administration at the University of California, Riverside.

[9] For the reasons set forth in Respondents' Motion *in Limine*, POM's earlier ads are inadmissible and cannot be the basis for liability.

and tongue-in-cheek approach. Even in 2004, POM conveyed humor in its antioxidant message with headlines like "Some people love their bodies. Others worship." and "With curves like this, it's got to be good for the body." Because these ads were discontinued many years ago, they do not demonstrate that Respondents are currently violating the law.

Moreover, humor and wit quickly resonated with POM's marketing department. Since late 2004 and early 2005, POM's advertising campaign progressed towards what became the Dressed Bottle (2005-2008 and 2010) and Super Hero (2008-2009) campaigns. This humorous, irreverent, tongue-in-cheek advertising style is the heart of POM's marketing and advertising strategy, and is central to the landscape of this case.

The Dressed Bottle campaign utilized a white background with a POM juice bottle "dressed up" to match the headline and its short-lived precursor featured the "dressed up" juice bottle against a pastel-colored background. For example, a 2005 "Extreme Makeover" advertisement depicted POM's juice bottle sitting under a retro-style hair dryer chair with the following copy:

> Nips and tucks are so last year. For a whole new you from the inside out, drink luscious POM Wonderful Pomegranate Juice. With more naturally occurring antioxidants than any other drink, POM Wonderful neutralizes free radicals, ugly little molecules that can cause premature aging, heart disease, Alzheimer's, even cancer. Eight ounces a day is all it takes to absolutely transform you.

In a 2007 "Decompress" ad featuring a POM juice bottle wrapped in a blood pressure cuff, the copy read:

> Amaze your cardiologist. Drink POM Wonderful Pomegranate Juice. It helps guard your body against free radicals, unstable molecules that emerging science suggests aggressively destroy and weaken healthy cells in your body and contribute to disease. POM Wonderful Pomegranate Juice is supported by $23 million of initial scientific research from leading universities, which has

> uncovered encouraging results in prostate and cardiovascular health. Keep your ticker ticking and drink 8 ounces a day!

Similarly, in 2008, POM advertised its juice as the "Guardian Angel" and featured a POM juice bottle cloaked with white angel wings and a halo with the following copy:

> Want to have your own personal miracle worker? Drink POM Wonderful 100% Pomegranate Juice. It helps guard your body against free radicals, unstable molecules that emerging science suggests aggressively destroy and weaken healthy cells in your body and contribute to disease. POM Wonderful 100% Pomegranate Juice is supported by $23 million of initial scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health. Eight ounces a day is all you need to keep your body absolutely heavenly.

In 2008, POM took humor and wit to a further level when it launched the Super Hero campaign. In these series of comic book style advertisements, POM juice is depicted as a superhero that saves the world. For example, in a 2009 cartoon image of a POM juice bottle blasting off like a rocket with the headline "I'm off to save PROSTATES!", the copy read:

> Man by man, gland by gland, The Antioxidant Super power is 100% committed to defending healthy prostates. Powered by pure pomegranate juice. . . backed by $25 million in vigilant medical research* . . . there's no telling just how far it will go to improve prostate health in the future.

A 2009 POS piece – a "SUPER HEALTH POWERS!" hang tag (i.e., a small tag that hangs from the neck of the POM juice bottle) – stated on the inside of the tag:

> 100% PURE POMEGRANATE JUICE. It's 100% pure! It's heroically healthy! It's the Antioxidant Superpower, POM Wonderful 100% authentic pomegranate juice.
>
> Backed by $25 million in medical research. Proven to fight for cardiovascular, prostate and erectile health. Committed to keeping you healthy for a good, long time!

For more than the past several years, and certainly since the inception of the Dressed Bottle campaign, most of POM's advertisements conveyed that scientific studies showed results

that were merely "promising," "encouraging" or "hopeful" for "prostate, cardiovascular and erectile health." The advertisements never promised to prevent, treat or cure a disease. Nor did any advertisement ever suggest that POM was a "silver bullet" or otherwise suggest that it in some way was an absolute means to health. Even the results that were "promising," "encouraging" or "hopeful" did not relate to preventing, treating or curing any disease, but only to achieving such general goals as "prostate, cardiovascular or erectile health," a very different concept. This was true despite the fact that the scientific evidence certainly supports much stronger health benefit statements.

B. Legal Background

This Court is well aware of the legal framework under which the FTC has the burden to prove that Respondents' claims violate the FTCA. Complaint Counsel are advocating—with regard to both substantiation and remedy—a standard borrowed from the FDA's drug approval methodology. Below is an overview of the FTC's role in regulating health benefit claims and a discussion of the evolution of the FTC's approach to regulating health benefit claims.

1. The FTC And FDA's Respective Roles In Regulating Health Benefit Claims.

The FTC's authority to regulate health benefit claims for food, such as the ones at issue here, derives from the FTCA, which prohibits false and misleading advertising. In addition to the FTC, another federal agency, namely the FDA, may also regulate health benefit claims for food under the authority provided in the FDCA. While both the FDCA and FTCA give the FDA and FTC overlapping jurisdiction over food labeling and advertising, the FDA and FTC proceed under a longstanding liaison agreement under which the FDA regulates food labeling – the actual package label and any written, printed, or graphic matter that accompanies the sale of the food –

and the FTC regulates food advertising, including non-labeling marketing communications, such as television and print advertising.[10]

The FTC's and FDA's respective regulation of health benefit claims differ in several important respects. For example, in addition to its authority to determine whether labeling renders a food misbranded, the FDA may also look to claims made in advertising as evidence of a company's intended use for its food, because, under the FDCA, articles are defined by their intended use, as evidenced by marketing claims. Thus, the FDA's approach to health benefit claims for food is driven in large measure by the definition of a "drug" under the FDCA, which includes "articles intended for use in the ... cure, mitigation, treatment or prevention of disease in man or other animals." 21 U.S.C. 321(g)(1). Under the FDA's approach, claims that state or imply that a food is intended for such a use will be deemed by the FDA to be drug claims not permitted for food, even if they are true and substantiated by evidence. *See Wallach v. Crawford*, No. 04-CV-216 BTM, 2005 WL 6054963, at *5-6 (S.D. Cal. Mar. 29, 2005). The FDA takes the position that such claims, whether made in food labeling or advertising, may render the food an unapproved new drug being marketed in violation of the FDA's new drug approval requirements.

In contrast to the FDA, the FTC's enforcement mandate is not based on the rigid categories of "food" or "dietary supplement" versus "drug," set forth in the FDCA. Instead, the FTC evaluates whether claims are truthful, non-misleading, and substantiated. This approach is derived from the FTCA, which grants the FTC the statutory authority to regulate only those claims that are false or misleading. Thus, if a claim is truthful, non-misleading, and

[10] *Working Agreement Between FTC and Food and Drug Administration*, 4 Trade Reg. Rep. (CCH) ¶ 9,850.01 (1971) (hereinafter "Memorandum of Understanding").

substantiated by evidence, the FTC cannot prohibit the claim (even if the FDA determines that such claims should be prohibited under its separate regulatory scheme).

Moreover, unlike the FDA, which pre-approves health claims for food,[11] the FTC does not pre-approve advertising claims, but instead takes post-market enforcement action against false, misleading, or unsubstantiated claims. The FTC's post-market review of advertising claims and application of tailored remedies in advertising cases have been essential to the FTC's goal of "curb[ing] deception without overly restricting truthful commercial speech, thus promoting the goals embodied in the First Amendment."[12] Indeed, in the past, the FTC's Bureau of Consumer Protection has urged the FDA to adopt an approach to health claim regulation that would allow for dissemination of information to consumers and has noted that the pre-market approval approach may prohibit claims even if substantiated by evidence, and had the potential to discourage the dissemination of useful information to consumers.[13]

2. The FTC's Traditional Approach In Evaluating Health Benefit Claims

The FTC's 1972 decision in *Pfizer*, established the basic requirements for advertising substantiation. In that decision, the FTC identified various factors used to determine the amount of substantiation necessary to determine whether an advertiser has a reasonable basis for a particular claim, including (1) the type and specificity of the claim made—*e.g.*, safety, efficacy, dietary, health, or medical; (2) the type of product— *e.g.* food, drug, potentially hazardous consumer product; (3) the possible consequences of a false claim—*e.g.*, personal injury, property

[11] Since the implementation of the NLEA, food labels may bear claims characterizing the relationship of a food or nutrient in food to a disease or health-related condition, but such claims require prior approval or authorization by the FDA.

[12] *In the Matter of Request for Comment on First Amendment Issues,* Docket No. 02N-0209: *Comments of the Staff of the Bureau of Economics, the Bureau of Consumer Protection, and the Office of Policy Planning of the Federal Trade Commission.*

[13] *Id.*

damage; (4) the case and cost of developing substantiation for the claim; (5) the degree of reliance by consumers on the claims; and (6) the level of substantiation experts would agree is reasonable. *Id.* at 30. The FTC's approach to evaluating advertising claims was later memorialized in the FTC's Deception Policy Statement[14] and Substantiation Policy Statement.[15]

To determine whether a particular advertising claim is substantiated, the FTC has historically applied a flexible standard governed in large part by the way the claim is presented.[16] For claims relating to health and safety, as well as some claims of product efficacy, the FTC has defined the reasonable basis requirement as "competent and reliable scientific evidence," which the FTC defines as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results."[17] This definition, while subject to criticism, recognizes that different claims require different levels of substantiation. The standard does not require a fixed number or type of studies. However, it does allow experts to determine the nature and quantity of evidence that an expert in the relevant field would believe is needed to substantiate the claim being made.[18] This standard does not require FDA-like protocols and clinical trials, with the

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[14] FTC Policy Statement on Deception ("FTC Deception Policy Statement"), appended to *In the Matter of Cliffdale Associates, Inc.*, 103 F.T.C. 110, 174 (1984).

[15] FTC Policy Statement Regarding Advertising Substantiation ("FTC Substantiation Policy Statement"), appended to *In the Matter of Thompson Medical Co.*, 104 F.T.C. 648, 839 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987).

[16] *See, e.g.,* Dietary Supplements: An Advertising Guide for Industry (internal quotes omitted).

[17] *Id.*

[18] *See, e.g., FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008) ("Nothing in the Federal Trade Commission Act...requires placebo-controlled, double-blind studies. The Act forbids false and misleading statements, and a statement that is plausible but has not been tested in the most reliable way cannot be condemned out of hand. The burden is on the Commission to prove that the statements are false. (This is one way in which the Federal Trade Commission Act differs from the Food and Drug Act.)").

narrow exception of cases in which a marketer makes an establishment claim (such as that a particular product is "clinically proven" to result in certain, specified health benefits).[19]

3. The FTC's New Approach In Evaluating Health Benefit Claims

In stark contrast to the FTC's historical, flexible approach to advertising substantiation, the FTC's Bureau of Consumer Protection has begun, in recent months, to advocate a new standard for health claim regulation that is akin to the standard used by the FDA in approving new drugs. As noted, the genesis of the FTC's effort to implement a new standard came on the heels of its loss before the district court in the *Lane Labs* case. Almost immediately after the district court's decision in *Lane Labs*, the FTC announced a new standard for advertising substantiation that would require two well-controlled clinical trials for health benefit claims. The FTC was not shy in stating that its new approach was intended to mimic the FDA's approach to claims regulation.[20] Indeed, the FTC has made it clear that nothing short of the expensive, onerous, and rigorous, FDA-required testing will satisfy its new standard. For example, Consumer Protection Bureau Director David Vladeck has stated that even an "outlier study," if well conducted, would not be sufficient basis for a health claim.[21]

The FTC has gone to lengths to try to package its standard for substantiation so as to obscure from the completely new and unprecedented approach that it is advocating. For example, the FTC has frequently referred to its new approach to substantiation as merely a "short cut" and has indicated that it will reference FDA standards in some cases for determining

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[19] *See, e.g., Thompson Medical,* 104 F.T.C. 648, 842-43 (1984), *aff'd,* 791 F.2d 189 (D.C. Cir. 1986), *cert. denied,* 479 U.S. 1086 (1987).

[20] David C. Vladeck, Director, Bureau of Consumer Protection, Fed. Trade Comm'n, Remarks Before the Council for Responsible Nutrition's Annual Symposium for the Dietary Supplement Industry, Priorities for Dietary Supplement Advertising Enforcement (Oct. 22, 2009), available at http://www.ftc.gov/speeches/vladeck/091022vladeckcrnspccch.pdf.

[21] *Id.*

whether certain claims are substantiated, instead of applying the multi-factor *Pfizer* analysis.[22] The consequence of the FTC's "short cut" is that the FTC is asking that courts no longer undertake a full review of claims, expert evidence, and the science behind such claims to determine whether they are supported under the FTC's historical substantiation standard, but rather it is advocating that courts consider only whether a particular advertiser has undertaken FDA-like studies.[23] In their brief, Complaint Counsel have also attempted to avoid any suggestion that their approach to health claim substantiation is, in fact, new by relying on the 1994 Enforcement Policy Statement on Food Advertising. Federal Trade Commission Enforcement Policy Statement on Food Advertising. (May 1994); Compl. Counsel's Br. at 84-86. Complaint Counsel's suggestions in this respect are incorrect.

The FTC has obtained consent orders from Iovate Health Sciences, Nestlé HealthCare Nutrition, Inc., and The Dannon Company, Inc. illustrating its new philosophy, but has not yet litigated the legitimacy of this new approach in any matter.[24] If judicially sanctioned, this new approach will result in the suppression of vast quantities of health information in the market indispensable to informed consumer choice, as consumers will be deprived of truthful and non-deceptive health information. Moreover, application of this new standard also exceeds the FTC's authority under the FTCA. While the FTCA empowers the FTC to regulate false and misleading health claims, the FTC is not empowered impose a prior restraint on prospective

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[22] *See* Mary Engle, FDLI Webinar on FTC's Recent Advertising Orders, Oct. 28, 2010, *available at* http://www.ahpa.org/Portals/0/members/10_1029_FTCWebinar.pdf (last visited May 9, 2011) at slide 6; *see also* Presentation by Mary Engle, Associate Director of Advertising Practices, FTC's Recent Food and Supplement Advertising Orders, available at http://www.ftc.gov/bcp/guides/Engle-Advertising-Substantiation-2010.pdf (last visited May 9, 2011).

[23] *Id.*

[24] *In the Matter of Nestlé HealthCare Nutrition, Inc.,* Consent Agreement, FTC File No. 092 3087 (July 14, 2010), available at: http://www.ftc.gov/os/caselist/0923087/110118nestledo.pdf.; *FTC v. Iovate Health Sciences, Inc.*, Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief, Case No. 10-CV-587 (July 29, 2010), available at: http://www.ftc.gov/os/caselist/0723187/100729iovatestip.pdf.; *In the Matter of The Dannon Company, Inc.*, Decision and Order, Case No. C-4313 (Jan. 31, 2011), available at: http:// http://www.ftc.gov/os/caselist/0823158/110204dannondo.pdf.

nutrient disease claims by adopting the FDA's NLEA health claim approval process as a proxy for FTC deceptive advertising determinations.

As noted above, Respondents in this case have amassed a large amount of science that provides more than a reasonable basis of substantiation for their advertising claims. That science should not be disregarded by the Court simply because it does not meet the requirements of studies required by the FDA for new drug approval.

III. COMPLAINT COUNSEL FAIL TO SATISFY THEIR BURDEN OF PROVING THAT RESPONDENTS VIOLATED THE FTCA.

To find that an advertisement is deceptive, Complaint Counsel bear the burden of proving that claims (1) are conveyed in the advertisement; (2) [are] "false or misleading;" and (3) "material to prospective consumers." *In re Kraft, Inc.*, 970 F.2d 311, 314 (7th Cir. 1992).

A. Complaint Counsel Fail To Meet Their Burden To Prove That The Challenged Advertisements Convey The Alleged Claims

Intent on applying the FDA's drug-approval standards to Respondents' advertising, Complaint Counsel's fundamental claim is that "Respondents Represent That the Challenged Products Effectively Prevent, Reduce The Risk of, and/or Treat Heart Disease, Prostate Cancer, and Erectile Dysfunction, and That Their Research Proves the Efficacy of Those Products." Compl. Counsel's Br. at 31. Instead of assessing which claim is made with particularity by each ad—is it prevent, reduce the risk of, or treat—Complaint Counsel conflate the three as if they were one indivisible unity, none of which can be substantiated. Likewise, in defining its case by reference to what it calls the "Challenged Products" rather than the challenged advertising, Complaint Counsel awkwardly attempt to mimic the FDA's regulatory authority (that focuses on product type) over pharmaceutical products. As discussed below, Complaint Counsel's efforts to treat an advertising case as if it were pharmaceutical litigation contravene both the governing law

and the applicable science. POM's advertisements do not convey the convoluted claims that Complaint Counsel, focused on FDA drug regulations, attempts to shoehorn into them.

1. The Legal Standard For Proving What Claims Are Conveyed In An Advertisement

Advertisements may convey two kinds of claims, express and implied. Because express claims unequivocally state a representation, that representation itself constitutes the meaning of the claim. No further proof about the meaning of an express claim is necessary because the express claim itself (rather than a paraphrase about what it "implies") is explicitly stated. *See* Deception Policy Statement, 103 F.T.C. at 176; *Thompson Medical Co.*, 104 F.T.C. at 788.

By contrast, implied claims are claims that the advertisement communicates to reasonable consumers that are not expressly stated. *See In re Kraft, Inc.*, 114 F.T.C. 40, 120 (1991), *aff'd*, 970 F.2d 311 (7th Cir. 1992), *cert. denied*, 507 U.S. 909 (1993); *Thompson Medical Co.*, 104 F.T.C. at 789. Because such claims are not stated explicitly, the FTC must find that they are likely conveyed to a significant portion of reasonable consumers. In determining if reasonable consumers are likely to take an implied claim, the FTC looks at the net impression created by the ad as a whole. *See* Deception Policy Statement, 103 F.T.C. at 179 & n.32; *In re Stouffer Foods Corp.*, 118 F.T.C. 746, 799 (1994). The FTC examines "the entire mosaic, rather than each tile separately." *FTC v. Sterling Drug,* 317 F.2d 669, 674 (2d Cir. 1964).

When an implied claim is not clear enough to permit the FTC to determine its existence by examining the advertisement alone, extrinsic evidence may be required. *See Stouffer Foods Corp.*, 118 F.T.C. at 798-99. In all cases, if extrinsic evidence is available, the FTC will consider it, taking into account its relative quality and reliability. *See Kraft*, 114 F.T.C. at 121.

2. Complaint Counsel Improperly Substitute Legal Assertions About POM's Advertising For The Reasoned Analysis And Empirical Evidence Required To Establish What Claims The Advertising Conveys To Consumers.

Most of Respondents' ads in the last few years conveyed the restrained message that scientific studies show results that are merely "promising," "encouraging" or "hopeful" for "prostate, cardiovascular and erectile health." They do not expressly claim that POM's products are a "silver bullet" or proven to prevent or cure a disease. Even the results that are said to be "promising," "encouraging" or "hopeful" do not relate to preventing or curing any disease, but only to achieving such general goals as "prostate, cardiovascular or erectile health." The advertisements typically include humorously exaggerated headlines and imagery.

Complaint Counsel, however, contend that POM's products are advertised as drugs, as the FDA defines them, and therefore insists that POM's advertising makes what it calls "Prevention, Reduction of Risk, and Treatment Claims." Compl. Counsel's Br. at 38, 43, 47 (cardiovascular, prostate, and erectile dysfunction claims). Complaint Counsel allege that these claims are made "expressly or by implication." *Id.* Complaint Counsel's efforts to argue this strain credulity.

Complaint Counsel first address cardiovascular disease. Complaint Counsel contend that POM improperly posts on its website scientific articles that report on the health benefits of pomegranate juice. Compl. Counsel's Br. at 39-40. This, according to Complaint Counsel, should be suppressed because it constitutes the making of misleading drug claims. To the contrary, posting legitimate, peer-reviewed, scientific articles, written by prominent experts in the field, does not constitute "making drug claims." Indeed, the articles, presented in full, are constitutionally protected scientific speech protected from government suppression by strict

scrutiny. *See Edwards v. District of Columbia*, --- F.Supp. 2d ---, 2011 WL 667950, at *6 (D.D.C. Feb. 25, 2011).

Complaint Counsel do not explain what, exactly, are the implied claims that this research communicates to consumers, instead implying that the mere act of posting published science regarding potential health benefits from pomegranate juice is equivalent to claiming that the food in question has been proven to operate as an efficacious drug. That is an untenable approach to analyzing advertising claims. As discussed below, federal courts have consistently held that the government cannot depict legitimate scientific research as "deceptive" on the theory that consumers might draw misleading conclusions from it. Scientific speech, such as the publication of full scientific journal articles for the edification of the public, even when sponsored by commercial enterprises, does not cause the speech in question to lose its heightened First Amendment protection. *See Wallach*, 2005 WL 6054963, at *8-9; *see also Edwards*, 2011 WL 667950, at *6; *Enten v. District of Columbia*, 675 F. Supp. 2d 42, 50 (D.D.C. 2009) ("the degree of First Amendment is not diminished merely because...speech is sold rather than given away"); *City of Lakewood v. Plain Dealer Publ'g Co.*, 486 U.S. 750, 756 n.5 (1988). The articles are independent, peer-reviewed, scientific journal publications, the communication of which is a right for commercial and non-commercial speakers alike. The mere posting of the articles is not advertisement.

Focusing almost entirely on print advertisements from 2003-2004 – because, by comparison, it has so little to seize upon in POM's advertisements over the last five years – Complaint Counsel further contend that POM's print advertising claimed "that drinking POM Juice prevents, reduces the risk of, and/or treats heart disease." Compl. Counsel's Br. at 40-42. That purported summary is, in fact, contrived. It is not what the advertisements actually say, and

Complaint Counsel present no evidence that consumers understand this message to be implied. The advertisements only state qualified claims about specific scientific research. Rather than identifying what each advertisement actually conveys by such statements, Complaint Counsel automatically equate them with their legal boilerplate, arguing that "[i]n each advertisement, the interplay of all of these factors unmistakably creates the net impression that daily consumption of POM Juice prevents, reduces the risk of, or treats heart disease and that clinical studies, research, and/or trials prove it." *Id.* at 42. That is not apparent from the face of the advertisements, and there is absolutely no evidence of it. Indeed, the language is derived from the FDCA's definition of a drug (21 U.S.C. § 321(g)), legalistic language one would not reasonably presume is in a consumer's common lexicon.

With respect to claims about prostate cancer, Complaint Counsel take the same defective approach. POM's website is criticized, particularly the scientific articles posted on it, with the implication that posting such scientific articles is the same thing as making impermissible drug claims. Compl. Counsel's Br. at 43-44. Essential to Complaint Counsel's criticism is a fact nowhere present in the scientific articles POM posts: that the treatment or preventative effects of pomegranates are scientifically proven beyond peradventure of doubt. Complaint Counsel's attack thus rests on a *non sequitur*. The articles do not represent that pomegranates are proven treatments or cures for disease. They instead reveal the presence of on-going research into the potential role of nutrients within pomegranates in maintaining good health, but even that association is qualified in the articles. The articles thus do not form a proper foundation for the notion that POM's reposting of them expressly or impliedly (1) promotes POM's products as treatments for disease or (2) represents POM's products to be proven treatments for disease. Indeed, by posting these scientific articles, POM is being forthright, enabling the consumer to

appreciate the actual science and debate concerning it and to exercise informed choice. It is far better for the consumer to have access to such independent, peer-reviewed journal articles than to be deprived of them by force of law, lessening the consumer's intellectual basis for exercising informed choice.

The FTC's approach reflects the same paternalistic assumption of consumer ignorance used to justify the restraint on speech of emerging science that the Court called "simplistic" and "frivolous" in *Pearson I*. *See Pearson I*, 164 F.3d at 655 ("[i]t would be as if the consumers were asked to buy something while hypnotized, and therefore they are bound to be misled"). There is no evidence that consumers take away from the scientific articles the message presumed by Complaint Counsel. Nor could such a finding be consistent with the First Amendment precedent holding that the government may not aggressively suppress the publication of nutrition science on the theory that the science itself may mislead consumers, or when a qualification of some form is sufficient.

Complaint Counsel cite POM's print advertising relating to prostates, and baldly assert that "[t]he net impression of such references to 'prostate health,' 'men treated for prostate cancer,' and 'significantly longer PSA doubling times' inexorably communicates the claim that POM Juice treats, prevent, and/or reduces the risk of prostate cancer and that it's scientifically validated." Compl. Counsel's Br. at 45. Stating these phrases and vaguely alluding to the alleged "inexorab[ility]" of an inference does not constitute reasoned proof that consumers in fact leap from "significantly longer PSA doubling times" to "cures cancer." Moreover, since the underlying science does show that PSA doubling times were prolonged, Complaint Counsel bear a heavy burden to prove that such an accurate statement of the research is misleading due to the supposed "inexorability." There is no evidence that a significant portion of consumers took

away such dramatic drug messages, in contravention of the qualified statements actually contained in the advertisements.

For erectile function, Complaint Counsel cite POM's website, but fail to identify anything more than summaries of scientific research. Compl. Counsel's Br. at 47-48. The posting and description of such scientific research was, in Complaint Counsel's unsupported view, equivalent to making express or implied claims that POM has been proven efficacious as a drug that prevents, treats, or cures erectile dysfunction. Complaint Counsel have no evidence that consumers leap to such conclusions, and fail to identify any express statements that make such claims.

For print advertising bearing on erectile function, Complaint Counsel cite only to a single POMx print advertisement, and nothing for POM pomegranate juice. Compl. Counsel's Br. at 49. The quoted portion of the advertisement consists of a highly-qualified reference to a particular study, identified as "preliminary," and including the statement that "further studies are warranted." Repeating its overreaching methodology, however, Complaint Counsel leap from this to arguing that consumers must take away implied claims that POMx (and Respondents' other products more generally) are proven to cure erectile dysfunction. Consistent with Complaint Counsel's overall theme, no empirical evidence of this is cited.

Moreover, Complaint Counsel also ignore completely the puffery that is implicit in some of the ads, which will be demonstrated at trial and in the administrative record. The FTC has long recognized that highly subjective claims that consumers are not likely to take seriously are non-actionable "puffery." *See, e.g., In the Matter of Bristol-Meyers Co*, 102 F.T.C. 21, 321 (1983), *aff'd.* 738 F.2d 554 (2d. Cir. 1984). The record in this case will show that Respondents have not in fact made the claims asserted by Complaint Counsel.

Complaint Counsel rely on blunt, unproveable assertions about what consumers "must" have taken away from POM's advertising. Complaint Counsel did not attempt to shore up their deficient facial arguments with empirical analysis, such as consumer surveys. Although the FTC is empowered to conduct facial analysis regarding what claims are conveyed, Complaint Counsel treat that power as if it constitutes free license to avoid proving its case. It does not.

B. POM's Health Claims Are Neither False Nor Lacking In A Reasonable Basis

1. Complaint Counsel Cannot Show That POM's Ads Are False

The FTC appears to argue that it need not rely on any implied claims, and rather, undertakes the heavy burden of proving that all of the alleged claims are expressly conveyed in the ads. Complaint Counsel, however, certainly cannot meet this burden and have not designated a single expert to support this *pro forma* allegation.[25]

2. Complaint Counsel Cannot Show That POM's Ads Lack A Reasonable Basis

a. Complaint Counsel Fail To Apply The *Pfizer* Factors, Which Require That The Claims Against Respondents Be Rejected

Complaint Counsel completely ignore the considerations and cost benefit analysis required by *Pfizer Inc.*, *supra*, 81 F.T.C. 23, including the type of product at issue, the possible consequences of a false claim, and the cost of developing substantiation for the claim. A careful weighing of the relevant factors is not at all what Complaint Counsel advocate. Nor is it the position taken by their experts. Indeed, Complaint Counsel would provide no health information to the public that is not backed by RCT studies, no matter how great the cost of those studies, or

[25] Unable to offer any evidence of falsity, Complaint Counsel points to a 2005 inquiry by the National Advertising Division ("NAD") to argue that Respondents knew and disregarded the standards on the level of substantiation. *See* Compl. Counsel's Br. at 27-28. The NAD is a private organization that purports to self-regulate the advertising industry. The review process is voluntary and the recommendations are non-binding. Contrary to Complaint Counsel's conclusory allegations that Respondents refused to abide by the NAD's recommendations, the evidence will show that Respondents cooperated fully in the voluntary review process, and, although POM disagreed with the NAD, took appropriate actions to address the NAD concerns. Indeed, even Complaint Counsel acknowledge that POM's ads took on a different tone after 2004-2005. *See id.* at 12-13.

how slight the risk of harm, or what other forms of science support the information. Based on this obvious fact alone—that Complaint Counsel have ignored the required cost benefit analysis under *Pfizer*—their claims against Respondents should be rejected.

Moreover, in this analysis, this Court should prefer "disclosure over outright suppression." *Pearson I, supra*, 164 F.3d at 657. Where there is doubt as to the completeness or accuracy of an ad, the courts should favor providing the information to the public over suppressing it. *Id.* This policy has also been endorsed by federal courts following the command in *Pearson I* stating "that, under the First Amendment commercial speech doctrine, there is a 'preference for disclosure over outright suppression.'" *Alliance for Natural Health*, 714 F.Supp.2d at 52-53; s*ee also Whitaker I*, 248 F.Supp.2d at 9 ("in finding that speech is misleading, the government must consider that 'people will perceive their own best interests if only they are well enough informed, and . . . the best means to this end is to open the channels of communication, rather than to close them.").

In addition, in applying the *Pfizer* criteria, the Court should consider, when confronted with an abrupt change in Complaint Counsel's preferred standard of review, the ultimate outgrowth of Complaint Counsel's position, wherein they and their experts engage in the absurdity of insisting on huge 10,000 person multi-year RCTs—studies are not even consistently required for approval of a drug, and which are not necessarily a superior method for determining the health benefits of a nutrient or food product—for POM's products (which are obviously safe and do not pose the risk of harm or serious side effects from their consumption). Complaint Counsel would require POM to spend up to $700 million dollars before disseminating potentially very helpful information regarding the potential health benefits of a fruit. Complaint Counsel's

position goes too far and departs from their own published policy, to the detriment of consumers. *See* FTC Enforcement Policy Statement. on Food Advertising., at 6-7.

An approach that equates food to drugs makes communicating truthful information regarding the potential health benefits of a food economically impossible to "substantiate." Unlike a drug, wherein the manufacturer receives patent protection and market exclusivity in return for cost intensive research, producers of natural food products receive no comparable compensation for their investment. Requiring RCTs here will necessarily suppress truthful information. In stark contrast, where the product at issue is a potentially harmful drug, and its expected patent rights and likely high price justifies the massive expense of RCTs, requiring two such studies before informing the public of the drug's potential benefit may be appropriate. For example, Bristol Myers' new melanoma drug Yervoy creates a serious danger of death. Its patent gives the company a monopoly, and the treatment costs $120,000. Under such circumstances, the FDA may have good reasons for requiring RCTs.

On the other hand, where we are dealing with a pure food or juice that creates no risk of harm, has no patent protection, and sells for a few dollars, requiring two enormously costly RCTs, as the only way the public can be given information about the product's health benefits, is contrary to the FTC's announced position and is manifestly bad public policy. As summarized in *Pearson I*, 164 F.3d at 656 and n.6, the courts should distinguish between products (*e.g.*, dietary supplements) that do not "in any fashion threaten consumer's health and safety" and "drugs," which "appear to be in an entirely different category," *e.g.*, "wherein the potential harm presumably is much greater."

As the Court in *Whitaker I*, reasoned:

> It is important to recognize that, in the present case, the potential harm to consumers from deception is severely limited . . . . At

> worst any deception resulting from plaintiff's health claim will result in consumers spending money on a product that they might not otherwise have purchased. This type of injury, while obviously not insignificant, cannot compare to the harm resulting from the unlawful suppression of speech.

248 F. Supp.2d at 16.

Respondents' experts in each field support the distinction drawn by the Court of Appeals in *Pearson I* and by the District Court in the subsequent *Pearson II* case and in *Whitaker*. For example, Dr. Denis Miller,[26] an esteemed pediatric oncologist has testified that where the product is absolutely safe, like POM, and where the claim or advertisement does not suggest that the product be used as a substitute for conventional medical care or treatment, then it is appropriate to favor disclosure, and credible evidence is enough. RCT's are not required or even necessarily superior. Notably, Dr. Miller previously testified as an expert for the FTC in the *Daniel Chapter One* case, where the respondent urged consumers to use its product to treat cancer in place of recommended medical treatment. However, Dr. Miller recognizes that this case—involving pure fruit juice or pomegranate derived products, threatening no material risk of harm—is eminently distinguishable. He has testified that no such costly tests should be required as a barrier to providing information as to the likely health benefits of pomegranate products to the public.[27]

The "cost" factor similarly militates in favor of public disclosure without requiring expensive RCTs. The select study referred to by Complaint Counsel's expert cost $25 million. The well-known Women's Health Study cost $600 million and produced inconclusive results. Sixty-Five peer-reviewed, scientific studies to obtain the information about the potential health

[26] Dr. Denis Miller is the Global Therapeutic Area Leader of Oncology/Hematology at PAREXEL International, one of the world's leading contract research organizations, and Clinical Professor of Pediatrics) at Robert Wood Johnson School of Medicine (New Brunswick, NJ).

[27] This view is also discussed in an as yet unpublished article "In Support of the Pfizer Factors," attached as Exhibit "A" to this brief.

benefits of their product have already cost Respondents $35 million. The economics of the business pose a serious barrier to performing more expensive studies. Unlike Bristol-Myers' Yervoy, a drug which will cost $120,000 per patient, POM sells its juice for only $4.00 on average.

In addition, as explained further below, exclusive or heavily weighted reliance on an RCT in the nutrient context does not make sense scientifically. Unlike a xenobiotic substance, such as a synthetic drug, which can be identified and readily traced in the body, single nutrients enter the body and merge with others forming a milieu that does not lend itself to conclusive results in RCTs.[28] That is true of antioxidants, where even the federal government recognizes their potential to help sustain normal cellular growth and reproduction, diminishing the risk of vascular disease and cancer. It must be remembered that scientific evaluation of the extent to which Vitamin C reduced the incidence of scurvy and the extent to which Vitamin D reduced the incidence of rickets were based primarily on *in vitro* experimentation and epidemiologic observation, not RCTs. Indeed, even more recently, the role of folic acid in reducing the incidence of neural tube defect births was a point supported almost exclusively on non-RCT data, because to perform a clinical trial in which women would be deprived of folic acid would be unethical given the very real potential that it could increase the risk of a neural tube defect. *See Pearson I*, 164 F.3d at 658-59 (observing that the FDA rejected scientific evidence drawn from foods and other sources imply because the agency "concluded that the scientific literature does not support the superiority of any one source of folic acid over others") (*internal citations and quotations omitted*).

[28] *See* Andrew Shao, PhD and Douglas Mackay, ND, A Commentary on the Nutrient-Chronic Disease Relationship and the New Paradigm of Evidence-Based Nutrition, Natural Medicine Journal 2010; 2(12):10-18, at 11.

Considering all of the relevant factors, RCTs should not be arbitrarily required from Respondents as the only way to justify future advertising about potential nutrient disease effects of pomegranate products. Basic science, *in vivo* and *in vitro* laboratory tests and clinical studies, even if not costly RCT studies, are sufficient. That view is supported by the expert testimony of distinguished scientists in each medical field at issue.[29]

b. Complaint Counsel Improperly Interpret The "Competent And Reliable Scientific Evidence" Standard As Requiring Drug-Level Proof For Claims Regarding The Health Benefits Of Foods

Complaint Counsel cite the FTC's 1994 Statement on Food Advertising as imposing a "competent and reliable scientific evidence" standard for evaluating health claims regarding food. Compl. Counsel's Br. at 84. As discussed below, Respondents rely on extensive scientific evidence, including *in vitro* studies, animal studies, and clinical studies, that supports the contents of POM's advertising. Thus, Respondents have satisfied this test.

Yet, Complaint Counsel further claim, in contravention of mainstream nutritional science, that such "competent and reliable scientific evidence" requires randomized double-blind, placebo-controlled trials. *Id.* Complaint Counsel thereby commit plain scientific and legal error. The question of whether competent and reliable scientific evidence supports a claim about

[29] Certain research agencies of the United States government and internationally recognized academic institutions have participated in and publicized their research addressing some of the very same health benefit topics and diseases that Respondents have also explored. For example, the Agricultural Research Service, which is the U.S. Department of Agriculture's chief scientific research agency, has investigated and funded research on fruits, vegetables, and nuts. Its publicized studies have examined various foods and their potential impact on various human ailments such as cancer, cardiovascular disease, inflammatory diseases, and cognitive function. Like the research sponsored by Respondents, the investigators used in vitro, animal, and small-scale human models as the bases for their scientific inquiries These studies, which would not meet Complainant Counsel's rigid "competent and reliable" standard, are the bases for many of the nutritional recommendations made by the U.S.D.A. In effect, Respondents are being held to a legal standard that not even another branch of government would be able to satisfy.

the health benefits of food must be analyzed by nutrition science – not by whether the claim complies with a formal drug approval testing regimen, as Complaint Counsel would have it.

In the field of nutritional epidemiology, which analyzes the connections between nutrition and disease, it is well-accepted that RCTs are not the best source of valid and reliable information on nutrition. There are multiple reasons for this consensus. Ethical principles do not permit randomizing individuals to diets that may have negative health effects. It is very difficult to ensure that large numbers of participants adhere to an altered diet over long-term periods. The cost of such studies forms an almost insurmountable barrier, given that no exclusive intellectual property rights (like a pharmaceutical patent) will result from a nutritional trial. If RCTs were required before it could be said that scientific evidence supports a particular claim about the health benefits of food, the field of nutrition science would be almost eliminated.

Accordingly, scientists who specialize in analyzing the connections between nutrition and disease routinely rely on data from observational studies, animal research, and basic science. Respondents' expert, Dr. David Heber,[30] will testify about this. Indeed, Complaint Counsel's only expert witness in this area, Dr. Meir Stampfer, openly concedes that observational research is often superior as the basis for nutritional recommendations, because large RCTs are impractical for assessing nutritional benefits. *See* Stampfer Dep. Tr. 74:5-79:6; PX0362 ("That observational studies are superior to randomized trials depends on the context .... In principle, they would not be, if there is no limitation of resources, and feasibility issues .... There are feasibility limitations ... in principle, the randomized trials are best, but as a practical matter, we have to rely on observational studies because of all the constraints that we discussed.") Dr.

[30] Dr. Heber is a Professor of Medicine and Public Health, and Director of the UCLA Center for Human Nutrition, David Geffen School of Medicine.

Stampfer even goes so far as to concede that "there are situations where you would determine causality in the absence of a randomized trial," (*id.* 73:6:-14), and that a randomized, double-blind, and placebo-controlled clinical trial is not required to conclude a causal link regarding a nutrient and disease. *Id.* at 98:8-18. This point is consistently recognized by the literature addressing the level of *scientific* evidence required to indicate connections between nutrition and disease.

Casting the applicable science aside, however, Complaint Counsel argue that "competent and reliable scientific evidence" for evaluating the health benefits of a food must consist of the same type of double-blind placebo-controlled trial used for drugs. According to Complaint Counsel, "[i]n fact there is no different rule for foods." Compl. Counsel's Br. at 84. But the issue is whether there is competent and reliable scientific evidence for a particular claim, a point that is determined by the science specific to that claim (here a nutritional claim about food), not by rote bureaucratic convention; by the totality of scientific evidence in the relevant field, not by dogmatic insistence on a set number or specific kind of test. As Complaint Counsel's own expert concedes, "I believe that it may be appropriate to use evidence short of randomized clinical trials for crafting public health recommendations regarding nutrient guidelines even when causality cannot be established, because everyone eats and the public should be given advice based on the best evidence available." Stampfer Report at pp. 29-30; PX0300. Complaint Counsel are mistaken in maintaining the contrary. There is a key difference between drugs and nutrients.[31] Indeed, an expert in the field of nutritional epidemiology could not opine differently, because public health recommendations regarding nutrition are normally based on the totality of scientific evidence – not RCTs.

[31] *See, e.g.,* Heaney RP. Nutrients, endpoints, and the problem of proof. *J. Nutr.* 2008; 138(9): 1591-1595, 1592. ("[T]he success of the RCT [randomized controlled trial] in evaluating medical treatments has, perhaps, blinded nutritionists, regulators, and editors to the fact that it is a method ill-suited for the evaluation of nutrient effects.").

In distancing themselves from the methods of nutritional science, Complaint Counsel do not ask this Court to assess the "competent and reliable scientific evidence" test as a scientist would. Rather, Complaint Counsel misconstrue the test for all nutrient disease relationship claims in advertising, requiring "competent and reliable scientific evidence" to include randomized, placebo-controlled, double-blind studies. That is not the law. Although the FTC has required such tests in narrow circumstances for establishment claims regarding disease (especially in the context of over-the-counter prescription medications and ointments), *see e.g., Thompson Medical*, 104 F.T.C. 648, 842-43 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987), the FTC and courts have never required such tests for all nutrient disease relationship claims in advertising—and have certainly not required them for claims regarding nutritious foods, such as the Challenged Products in this case. *See, e.g., FTC v. QT, supra,* 512 F.3d at 861. Indeed, the standard should be a flexible one that considers the nature of the claims made, the totality of the science conducted, and the product at issue. *See, e.g., Pfizer, supra*, 81 F.T.C. at 30.

To shore up its scientifically-invalid position that RCTs are the only sufficient type of evidence, Complaint Counsel cite various court decisions for the proposition that "federal courts have required clinical studies for cancer, heart disease, and erectile dysfunction claims for dietary supplements, which are types of foods." Compl. Counsel's Br. at 85. Complaint Counsel's citations are misplaced (and, furthermore, contrary to their own assertions in this litigation that supplements cannot be foods). For example, Complaint Counsel appear to cite the district court decision in *FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 285 (D. Mass 2008) for the proposition that double-blind, placebo controlled studies are required for health claims. However, the First Circuit, when reviewing the district court's opinion, expressly noted that,

although the FTC had argued and produced expert testimony that the claims at issue should be substantiated by double-blind, placebo-controlled studies, "there may be other scientific evidence that could be sufficient, and we may assume for these purposes that a double-blind study is not necessarily required." 624 F.3d 1, 9 (1st Cir. 2010) (emphasis added). The court did not deny the possibility of a defendant relying upon competent and reliable science other than double-blind studies.

Other cases cited by Complaint Counsel are equally unavailing. The court in *FTC v. National Urological Group, Inc.*, 645 F. Supp.2d 1167 (N.D. Ga. 2008) did not hold that claims for erectile dysfunction "required" double-blind placebo-controlled studies, as Complaint Counsel suggest; rather, the court noted that the defendants in that case had not countered the FTC's expert evidence that such studies were required and granted summary judgment on that basis. *Id.* at 1202.[32] Had defendants in that case relied on other competent and reliable evidence, as Respondents do here, the court may well have rejected Complaint Counsel's insistence on well-controlled human studies.

Further, this Court's Initial Decision in *Daniel Chapter One*, also cited in Complaint Counsel's Pre-Trial Brief, did not stand for the proposition that controlled clinical testing is required for all health benefit claims. In that case, the Court specifically noted that Respondents in that case "did not possess or rely upon any adequate substantiation for their claims that the Challenged Products prevent, treat, or cure cancer." Initial Decision at 109 (emphasis added); PX0531. Indeed, the Court noted that "Respondents had no studies whatsoever of the effects of the Challenged Products themselves." *Id.* The facts of *Daniel Chapter One* are in stark contrast to the situation here, where Respondents have a vast body of scientific research and literature

[32] The court expressly noted that it would rely on FTC's expert testimony because the "defendants have not countered the testimonies of the FTC's experts regarding what level of substantiation is required for the claims made in this case." *Id.*

supporting their advertising claims, including published peer-reviewed clinical studies.[33] Not only do the court decisions cited by Complaint Counsel fail to support their position in this case, not one of the decisions cited concerned a 100% fruit product, such as the pomegranate products at issue here.

Complaint Counsel's reliance on the FTC's 1994 Enforcement Policy Statement on Food Advertising is also misplaced. The Statement on Food Advertising did not disturb the FTC's well-settled, flexible approach to evaluating advertising substantiation. First, although the Statement indicates that the FTC will consider the "scientific agreement" standard adopted by the FDA in determining whether a claim is substantiated, it expressly states that the FTC "does not require food advertisers to establish that there is scientific consensus in support of claims." The Statement also provides that there will be some instances in which it is possible for an advertiser to craft a qualified, truthful, and non-misleading claim even if the claim does not meet the FDA's standards for regulation.

To the extent that the Statement mentions that it is "likely that the Commission will reach the same conclusion as FDA as to whether an unqualified claim about the relationship between a nutrient or substance in a food and a disease or health-related condition is adequately supported by the scientific evidence," this pronouncement cannot be taken to mean that the FTCA requires an advertiser to rely on double-blind, placebo-controlled tests, as opposed to other competent and reliable science, as Complaint Counsel suggest. Indeed, the Statement merely notes that, to the extent that the FDA concludes that an advertiser can make a health claim on its label, the FTC will likely agree with the FDA's conclusion. Obviously, if the FDA expressly permits a health claim after its lengthy regulatory review, the FTC would hardly be in a position to criticize advertisers who market the claim. The Statement, however, does not suggest that the FTC

should categorically apply the FDA's methodology when determining whether a claim is false or misleading. As explained above, such categorical reliance is inconsistent with the FTC's authority under the FTCA, as well as the governing scientific standards with which Complaint Counsel purport to comply.

Ironically, the rigid standard Complaint Counsel advocate here is actually more stringent than that applied by the FDA. In many instances, even the FDA approves pharmaceutical products without requiring the type of rigorous clinical trials the FTC would require of a safe food product. *See, e.g.*, Expert Report of Denis Miller at 8-9.[34] In addition, from 1973 through 2006, the FDA approved 31 oncology drugs without a randomized trial using the Accelerated Approval and Priority Review Program ("Fast Track Program").[35]

As noted in the sections that follow, Complaint Counsel cannot meet their burden of showing that Respondents lack competent and reliable scientific evidence for their claims. The proper standard for substantiation in this case should be determined under the FTC's flexible standard, which evaluates whether Respondents possessed adequate competent and reliable scientific evidence to support their advertising claims. Complaint Counsel err by insisting that such evidence must consist of large, well-controlled human clinical trials, especially given the vast array of evidence that Respondents rely on here.

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[34] *See also* Irving Kirsch, *et al.*, "The Emperor's New Drugs: An Analysis of Antidepressant Medication Data Submitted to the U.S. Food and Drug Administration," *Prevention & Treatment*, 2002; 5(23) (explaining that the FDA's approval of the six most widely prescribed antidepressant drugs was based on "clinically negligible" data produced by RCTs and, therefore, "alternative experimental designs are needed for the evaluation of antidepressants")

[35] *See http://jco.ascopubs.org/content/27/36/6243.abstract* (last visited, May 11, 2011); *see also http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm* (last visited, May 11, 2011) (FDA guidance explaining the Fast Track Program); *http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/speedingaccesstoimportantnewtherapies/ucm128291.htm* (last visited, May 11, 2011) (explaining that "Fast Track" drugs may receive approval based on "an effect on a surrogate, or substitute endpoint reasonably likely to predict clinical benefit"); 21 CFR § 314.510 (allowing approval based on a surrogate endpoint or on an effect on a clinical endpoint other than survival or irreversible morbidity).

c. The Constitution Defines The Limits Of The Reasonable Basis Standard.

i. Scientific Agreement Is Not Required – The Government Cannot Ban Claims That Are "Inconclusive" Or Are Supported By "Credible" Evidence.

Complaint Counsel's resort to the FDA's drug approval standard is also invalid because it conflicts with well-established First Amendment limits on government power to restrict protected speech. In a recent series of seminal decisions, federal courts have emphatically held that the government may not suppress commercial speech by requiring excessively high levels of supporting scientific evidence and that a claim may not be barred "simply because the scientific literature is inconclusive." *Pearson III*, 141 F. Supp. 2d at 110. In addition, even if some studies show a likely benefit, the fact that other studies may produce no such result does not justify suppression of the information. *See Whitaker I*, 248 F. Supp. at 13 (where only one-third of studies show claimed benefit and were criticized as procedurally flawed, the court held that suppression of information was improper.) The *Whitaker I* court further stated that because there was "some" evidence, "a complete ban of the [c]laim cannot be justified." 248 F. Supp. at 13.

The FDA, in particular, has fallen on the wrong sides of these federal court decisions, and the FTC now seems determined to follow the FDA's wayward lead. The NLEA amended the FDCA to create a "'safe harbor' from the 'drug' designation for foods . . . labeled with health claims." *Alliance for Natural* Health, 714 F. Supp. 2d at 51. For labeling to bear such health claims under the NLEA, the FDA required "that 'significant scientific agreement,' based on the 'totality of publicly available scientific evidence' support the claim." *Id.* Because the NLEA did not provide for approval of health claims that are based on less than significant scientific agreement, the FDA previously declined to approve health claims that were supported by

credible, but inconclusive scientific evidence: "The problem with these claims, according to the FDA, was not a dearth of supporting evidence; rather, the agency concluded that the evidence was inconclusive for one reason or another and thus failed to give rise to 'significant scientific agreement.'" *Pearson I*, 164 F.3d at 653.

The FDA was wrong. In the landmark *Pearson I* case, the D.C. Circuit applied the commercial speech test in *Central Hudson*, 447 U.S. at 557, to invalidate the FDA's position:

> that health claims lacking "significant scientific agreement" are *inherently* misleading and thus entirely outside the protection of the First Amendment; and second, that even if the claims are only *potentially* misleading, . . . the government is not obliged to consider requiring disclaimers in lieu of an outright ban on all claims that lack significant scientific agreement.

Pearson I, 164 F.3d at 655. *Pearson I* held that the claim qualification requirement was the government's burden. It was not incumbent upon a claim proponent to establish a suitable qualification as a condition precedent to speech. Rather, it was incumbent on the government to prove that no qualification would suffice as a less speech restrictive alternative to outright claim suppression. 164 F.3d at 659. Furthermore, in *Pearson III,* in the context of the FTC's enforcement action, the district court identified the relevant burden on the administrative agencies:

> [T]he FDA [may] impos[e] an outright ban on a claim where evidence in support of the claim is *qualitatively* weaker than evidence against the claim-for example, where the claim rests on only one or two old studies or where the evidence in support of a claim is outweighed by evidence against the claim. *Pearson II* fleshes out the term "against": The mere absence of significant affirmative evidence in support of a particular claim ... does not translate into negative evidence "against" it.

Id. at 112 (citing *Pearson I*, 164 F.3d at 660 & n.10; *Pearson II*, 130 F. Supp. 2d at 115) (internal citations omitted; emphasis added). Accordingly, the "question which must be

answered under *Pearson[I]* is *whether there is any 'credible evidence.'*" *Pearson II*, 130 F .Supp. 2d at 118 (emphasis added).

More recently, in *Alliance for Natural Health*, the district court overturned the FDA's rejection of various health claims regarding the role of the nutrient mineral, selenium, in the prevention of various cancers, based on evidence of selenium's antioxidant effects (among others) that was credible but not conclusive. 714 F. Supp, 2d at 70-71.

Accordingly, *Pearson I* and its progeny unequivocally demonstrate that courts will not permit government agencies to play fast-and-loose when determining whether credible scientific evidence supports a health claim. The standard cannot be overwritten by pseudo-scientific requirements that effectively impose a heightened burden of proof on the advertiser. Here, Complaint Counsel inappropriately seek to do just that, and such conduct should not be condoned.

3. Some Of The "Advertisements" Complaint Counsel Allege Are Not Actually Advertisements.

Rather than confine themselves to POM's conventional advertisements, Complaint Counsel also allege as violations of the FTCA a handful of media interviews given by Mrs. Resnick and Mr. Tupper. In doing so, however, Complaint Counsel have overstepped their jurisdiction. For "unless [an] advertisement can be classified as commercial speech it is not subject to the Commission's jurisdiction." *In re RJ Reynolds*, FTC Docket No. 9206 (Mar. 4, 1988), Order at 3.

As a preliminary matter, this Court correctly recognized in *Daniel Chapter One* that "'[a]dvertisement' is not defined in the FTC act." FTC Docket 9329 (2009), Initial Decision at p. 79. Curiously, the parties do not appear to have briefed the issue. Nevertheless, it was sufficient there for the Court to rely on straightforward dictionary definitions of advertising

because the respondents' conduct was not even a close call. They hosted a daily, two-hour radio program during which they counseled listeners who identified themselves as cancer patients to use respondents' products as cancer treatments. The respondents also broadcast a toll-free phone number for listeners to order their products.

By contrast, Complaint Counsel's allegations here revolve around minutes-long, one-off, non-commercial interviews on matters of public interest: (1) Mrs. Resnick's television appearance on Martha Stewart's cooking program to share personal recipes for a POMtini cocktail and Thanksgiving stuffing; (2) an interview of Mrs. Resnick in *Newsweek* magazine discussing the economy, her business acumen, and promoting the sale of her book, *Rubies in the Orchard*; and (3) a television interview of Mr. Tupper on Fox Business discussing the newest "hot" wave in foods—the pomegranate, and the pomegranate juice industry. None of these fleeting, sporadic interviews is akin to the *Daniel Chapter One* respondents' daily infomercial.

Long before *Daniel Chapter One*, the FTC stated that it "understand[s an advertisement] to mean a notice or announcement that is publicly published or broadcast and is paid-for." *RJ Reynolds*, Order at 3. Using the FTC's own "understanding," the individual respondents' unpaid-for media appearances do not constitute actionable advertising. That alone should end the inquiry. But Complaint Counsel's overreaching also fails under a more rigorous commercial speech inquiry.

In *Koch v. FTC*, 206 F.3d 311 (6th Cir. 1953), the respondent sold medicinal preparations as cancer treatments, which he promoted through traditional advertisements, in a book that elaborated on his medical philosophy, and in at least one public address. The FTC enjoined all these avenues of communication, but the Sixth Circuit reversed as to the latter two. The court concluded that because the book "sets forth primarily matter of opinion," "prohibiting

dissemination of such a book . . . would violate the First Amendment. . . ." *Id.* at 317-18. The court also concluded that neither the book nor a public address were "advertisement[s] covered by Sections 5, 12, or 15(a)" of the FTCA. *Id.*

Other than the public address in *Koch*, courts do not appear to have analyzed whether public addresses or media interviews constitute advertising or commercial speech under the FTCA. But courts have done so in construing Section 43(a) of the Lanham Act, which has a similar "commercial advertising or promotion" jurisdictional prerequisite that is not statutorily defined. *See Oxycal Labs., Inc. v. Jeffers*, 909 F. Supp. 719, 722, 723 (S.D. Cal. 1995) ("to even fall within the category of commercial advertising and promotion, the communications must first be found to be commercial speech."). They routinely find that media interviews do not constitute actionable commercial speech.

For example, in *Galerie Gmurzynska v. Hutton*, 355 F.3d 206, 210 (2d Cir. 2004), an art gallery sued another gallery under the Lanham Act, alleging that the defendant had conspired with art experts to question the authenticity of the plaintiff's artwork and to convince an art journalist to write an article about it. The trial court dismissed the case on a 12(b)(6) motion. The Second Circuit affirmed, reasoning that "[t]he journalist's article is not commercial advertising, commercial promotion, or commercial speech. Rather, it is speech that is traditionally granted full protection under the First Amendment." *Id.* at 210-11.

Galerie Gmurzynska cited with approval the Second Circuit's earlier decision in *Boule v. Hutton*, 328 F.3d 84 (2d Cir. 2003), which recognized an instructive, though not dispositive, distinction between proactive and reactive speech. *Id.* at 91; *Boule v. Hutton* 70 F. Supp. 2d 378, 390 (S.D.N.Y. 1999) (the Lanham Act "does not cover a response to an unsolicited inquiry by a

magazine reporter seeking comment on a topic of public concern.").[36] Wholly apart from that distinction, the Second Circuit affirmed because the defendant's "statements were inextricably intertwined with the reporter's coverage of the topic and related to the reporter's discussion of an issue of public importance," and "occur[ed] in a forum that has traditionally been granted full protection under the First Amendment." *Boule*, 328 F.3d at 91.

Even when non-commercial speech is tinged with commercial speech, the entirety is nonetheless treated as non-commercial speech, provided the latter is the "main purpose" and is "not merely a mask for the essentially commercial nature. . . ." *Oxycal*, 909 F. Supp. at 725-26. *See also Edwards v. District of Columbia*, 2011 WL 667950, at *6 (D.D.C. Feb. 25, 2011) (addressing the distinction between "speech-for-profit" and commercial speech, the latter subjected to lesser protection under the First Amendment); *City of Lakewood v. Plain Dealer Publ'g Co.*, 486 U.S. 750, 756 n.5 (1988) ("the degree of First Amendment protection is not diminished merely because the newspaper or speech is sold rather than given away").

Under either the FTC's own understanding of advertisement as a paid-for communication, or under a more comprehensive First Amendment commercial speech analysis, Mrs. Resnick's and Mr. Tupper's media interviews on matters of public concern and to which they offered "reactive" statements are not actionable under the FTCA.

4. POM's Advertisements Are Extensively Substantiated By Rigorous, Competent And Reliable Science.

Respondents are not *Daniel Chapter One* relying solely on pseudo-religious sanction and urging people to use their product instead of proper medical treatment. Respondents have spent $35 million on science – real science – at 44 different major universities, hospitals and science

[36] This distinction exists for good reason. As Mr. Tupper explained: "I can't tell you what was exactly going through my head at that period of time, especially with a television camera staring you in the face and the adrenalin coursing through your body. . . ." Matthew Tupper Depo. Tr. at 70:2-5.

centers. Their efforts and involvement have generated 65 peer-reviewed, published articles on the results of their scientific studies. This included analysis founded on basic science, numerous *in vitro* and *in vivo* studies, as well as clinical studies (some RCT), performed by distinguished scientists at such institutes as Johns Hopkins and the University of California.

This case is qualitatively different from other enforcement actions brought by the FTC. In past actions, the FTC has brought enforcement actions against fraudsters with little to know science supporting the advertised claims. For example, *In the Matter of Daniel Chapter One*, FTC Docket No. 9329, Initial Decision (Aug. 5, 2009), PX0531, was an enforcement action concerning various shark cartilage products. These products contained numerous undisclosed ingredients, very little of which was actual shark cartilage. Among other claims, the sellers promoted these products as effective in the treatment of cancer, and superior to medical treatment like radiation and chemotherapy. *Id.* at 1. The vast majority of the materials relied upon by the sellers were not peer-reviewed studies, and constituted mere author opinions and review of literature on the use of herbal medicine in general. *See id.* at 58-66. Likewise, *FTC v. QT, Inc.* was an enforcement action brought in district court against the sellers of a bracelet that allegedly provided pain relief. The company that manufactured and sold these bracelets did not employ scientists on its staff, but relied exclusively on 7 non-peer reviewed studies—many of which were not conducted on the product at issue. Indeed, some of the studies did not even include any underlying data, and none of the studies were conducted by credible researchers or credible institutions. 448 F. Supp. 2d 908, 932-36 (N.D. Ill. 2006).

In addition to the research sponsored by Respondents, other national and international institutions have conducted and published research exploring some of the very same health benefit properties as Respondents. Like Respondents, these institutions have published clinical

and non-clinical research on pomegranates investigating the fruit's benefits with respect to cancer, bioavailability, immunity, cardiovascular health, prostate health, inflammatory disorders, antioxidant capacity, and reproductive health. The findings of these studies have also been published in top peer-reviewed journals adhering to the same level of scientific scrutiny as those sponsored by Respondents.

i. General Health Benefits Of Pomegranates.

Pomegranate, *Punica granatum*, is a fruit-bearing plant native to high-altitude regions of Central Asia. Humans have consumed pomegranates for thousands of years as a safe and nutritious food. The FDA identifies pomegranate as being "generally recognized as safe" for human consumption. See generally 32 U.S.C. § 231(s); 21 C.F.R. § 182.20.

Scientific studies have revealed that specific compounds found in pomegranate juice have exceptional antioxidant effects and bioavailability, relative to other compounds commonly referred to by the generalized term "antioxidants." To provide expert testimony on this point at trial, Respondents will present David A. Heber, M.D., Professor of Medicine and Public Health, and Director of the UCLA Center for Human Nutrition, David Geffen School of Medicine.

Human beings are constantly exposed to oxidative stress. (Heber Report, pp. 14-17; PX0192.) Normal aerobic metabolism produces as its by-products various highly reactive molecules, collectively termed "oxidants." These oxidants, known as free radicals, include a variety of different chemicals which, like oxygen, are capable of inflicting oxidation damage. Over the long term, the human body cannot eliminate oxidative damage by relying on its own antioxidant defenses. Net oxidative damage accrues, contributing to aging and age-related diseases like cancer and cardiovascular disease.

Laboratory testing has shown that pomegranate juice has exceptionally powerful antioxidant effects. (Heber Report, pp. 16-19; PX0192.) Similarly, POMx has exceptional antioxidant power. (Heber Report, p. 20; PX0192.) Pomegranate's antioxidant properties are attributable to multiple polyphenols including hydrolyzable tannins, and ellagic acid. Most notably, punicalagin is a unique compound named after the pomegranate. (Heber Report, p. 12; PX0192.) Punicalagin is the largest known polyphenol antioxidant molecule. The potent antioxidant effects measured for POMx are consistent with scientific research finding that tannins like punicalagin, rather than anthocyanins, are the major active antioxidant component of pomegranates.

Dr. Heber will further testify that a great deal is known about the absorption and metabolism of the unique hydrolysable tannins found in pomegranate juice. (Heber Report, pp. 20-21.) Studies on the human metabolism of pomegranate juice demonstrate that the antioxidants found in pomegranate juice are bioavailable to a much greater degree than other substances commonly described as "antioxidants."

As Dr. Heber will testify, antioxidation is not a single "drug target," but rather is a physiologically important variable characterizing diets that are either rich or poor in antioxidant intake. Consuming foods with increased antioxidant potency (which also have varied physiological effects) promotes overall health in a number of organ systems by different mechanisms. These benefits are defined by the best available nutrition science.

Scientific studies have investigated the basic biological mechanisms by which pomegranate juice and pomegranate juice extract act upon the human body. Understanding these mechanisms of action, which Dr. Heber will testify about at trial, serves to support and explain

the results of the studies that have shown potential health benefits from pomegranate juice and pomegranate juice extract.

ii. POM's Heart Health Claims Are Substantiated.

Taken as a whole, the preponderance of the scientific evidence from basic scientific studies, animal research, and clinical trials in humans reveals that the pomegranate in its various forms (including POM Wonderful 100% Pomegranate Juice, POMx Pills, or POMx Liquid) is likely to be beneficial in maintaining cardiovascular health and is likely to help reduce the risk of cardiovascular disease. Specifically, the universe of existing science provides significant evidence that pomegranate juice is likely to, among other things, reduce arterial plaque, improve blood flow, and reduce blood pressure. Importantly, the consumption of pomegranate juice or its derivatives is not a "silver bullet" or a substitute for conventional treatments for heart disease, and Respondents do not and have never suggested otherwise.

As set forth in the expert report of Dr. Dean Ornish,[37] Respondents' expert in the field of cardiovascular health, in evaluating whether a food, is beneficial in maintaining cardiovascular health and in lessening the risk of cardiovascular disease, the totality and preponderance of the evidence should be examined, given that: (1) pomegranate juice and its extract are safe; and (2) no one suggests that pomegranate juice or extract should be offered in lieu of conventional medical treatment or surgery.

Dr. Frank Sacks, Complaint Counsel's cardiovascular health expert, however, would have the Court believe that a fruit juice should be held to the same scientific evidentiary standard as a new drug when evaluating a juice's clinical efficacy on the cardiovascular system. Thus, according to Dr. Sacks, only evidence from randomized, double-blind, placebo-controlled trials

[37] Dr. Dean Ornish is the Founder and President of the non-profit Preventive Medicine Research Institute in Sausalito, California. He also serves as a Clinical Professor of Medicine at UCSF.

in humans can be considered in evaluating the therapeutic value of a food. Dr. Sacks is mistaken.

Instead, as Dr. Ornish observes, much of what physicians provide patients in their clinical practices has not been proven to be beneficial in RCTs. It is unreasonable to require that pomegranate juice meet a standard that is not met by many of the drugs and surgical treatments used every day by physicians. For example, RCTs have shown that angioplasties and stents do not prevent heart attacks or prolong life, yet the number of these procedures performed is greater than ever.

In addition, while it may not be possible to extrapolate findings from animal and *in vitro* studies to human studies in all cases, it is scientifically wrong to adopt the extreme position that these studies have no value in determining the therapeutic value of a fruit juice or its byproducts. Instead, the more valid and scientifically accepted approach is to carefully examine the totality of scientific evidence in analyzing therapeutic efficacy on cardiovascular health. This includes, but is not limited to, RCTs that are perfectly conducted (truth be told, perfection is not possible to achieve).

Finally, pomegranates should not (and cannot) be held to the same scientific evaluation process required for a new drug. As Dr. Ornish and others have observed, the benefits of pomegranates have been described since Biblical times over thousands of years. The body of modern science also confirms that pomegranates are safe for human consumption. *See, e.g.,* 21 CFR § 182.20. As such, studying pomegranate juice is different than studying a new drug, in which harmful side-effects, both short-term and long-term, are the rule rather than the exception. For these reasons, the totality of the evidence -- basic *in vitro* research, animal studies, and clinical trials (even where the protocols can be nit-picked) -- should be examined in evaluating

whether a food, such as the pomegranate (or its extracts), is beneficial in maintaining cardiovascular health and in lessening the risk of cardiovascular disease.

Over the past decade, Respondents have sponsored extensive research—at the cellular, animal, and human levels—from many of the world's most respected researchers and institutions to investigate the effects of polyphenol antioxidants found in pomegranates on cardiovascular health. Studies conducted by respected scientists such as Dr. Ornish, Dr. Michael Aviram,[38] and Dr. Michael Davidson[39] found that, among other things, the consumption of pomegranate juice or its derivatives: (1) decreased susceptibility to the aggregation and retention of LDL, or "bad", cholesterol; (2) positively affected certain biomarkers, such as serum paraoxonase (known as "PON1") and angiotensin converting enzyme (referred to as "ACE"); (3) improved blood flow in patients with stress-induced myocardial ischemia (narrowing of the arteries); and (4) reduced carotid intima-media thickness ("CIMT") in subjects with carotid artery stenosis (narrowing of carotid arteries).

In short, based on the totality of the scientific studies conducted on the cardiovascular system, competent and reliable evidence exists to show that pomegranate juice in its various forms is likely to be beneficial in maintaining cardiovascular health and is likely to help reduce the risk of cardiovascular disease.

iii. POM's Prostate Health Claims Are Substantiated.

[38] Dr. Aviram is a Professor at the Technion Faculty of Medicine, Rappaport Institute for Research in the Medical Sciences and Rambam Medical Center, in Haifa, Israel. Dr. Aviram is widely regarded as one the leading experts in the world on cholesterol, lipid oxidation, and the protective role of dietary antioxidants related to cardiovascular disease.

[39] Dr. Michael Davison is a Clinical Professor of Medicine and Director of Preventive Cardiology at the University of Chicago Medical Center. Dr. Davidson is a nationally recognized expert on statins, novel lipid-lowering drugs and the reduction of coronary artery disease risk through diet and exercise.

PSA doubling time, a measure of the time it takes the levels of PSA (a protein made by prostate cells) to double in a man's blood, is currently the best marker for recurrence of prostate cancer following radical prostatectomy or radiation therapy. Generally, the shorter the doubling time the greater the risk of recurrence of cancer. As studied and demonstrated in multiple peer-reviewed articles, PSA doubling time accurately reflects prostate cancer cell behavior. For example, in a study by Pound, *et al.* (JAMA 1999), the investigators found a correlation between the length of the PSA doubling time after radical prostatectomy biochemical recurrence and the expected clinical recurrence. Similarly, in a study by Patel, *et al.* (Journal of Urology 1997), the authors found that PSA doubling time was correlated with the risk of clinical recurrence. In yet another study by Tollefson, et al. (Mayo. Clin. Proc. 2007), the authors found that PSA doubling time correlated with recurrence and survival. And a recent study by Teeter, et al. (Urology 2011) similarly correlated length of PSA doubling time with risk of mortality.[40] [41]

In a 2006 study published in the prestigious Clinical Cancer Research Journal, Dr. Pantuck, *et al.*, studying men that had undergone radical prostatectomy or radiotherapy, found that drinking 8 ounces of POM pomegranate juice daily materially lengthened PSA doubling time in nearly 50% of men after 18 months - in fact it almost tripled. They also found that when POM's juice was tested *in vitro* on prostate cell assays, it was found to both decrease prostate cancer cell proliferation by 12% and stimulate prostate cancer cell apoptosis (cell death) by 17%. Additionally, serum nitric oxide increased by 23% in men that consumed POM. Nitric oxide is a molecule that has been found to inhibit inflammation, which is correlated with higher risk of cancer[redacted]

[40] A multitude of additional peer-reviewed articles only confirm these findings.
[41] Dr. Eastham, Complaint Counsel's expert, challenges the appropriateness of this marker as a surrogate for prostate cancer clinical recurrence or survival but admits that he himself uses it for just such a purpose. Expert Report of Dr. James Eastham, at 10-11.

[redacted]

These studies were consistent with earlier pre-clinical laboratory and animal studies that showed a robust effect of POM pomegranate juice on prostate cancer in *in vitro* and *in vivo* mouse models. Despite this tidal wave of published research showing a profound effect of POM pomegranate juice on prostate cancer, Complaint Counsel challenge the science supporting the likely beneficial effects of pomegranate juice on prostate heath and prostate cancer. In doing so, Complaint Counsel ignore, as they must, the significant basic and pre-clinical science performed on antioxidants and pomegranate juice, and then apply a scientific standard used only with drugs in order to downplay the clinical research showing a significant benefit. In essence, Complaint Counsel's criticism is that research performed on pomegranate juice with regard to prostate cancer was not done to the standard of the FDA and that of a drug. But such a standard is simply misplaced in the context of a food, as previously discussed. Particularly in the context of prostate cancer, which can take decades to clinically affect or ultimately kill the patient, the FTC's position would almost certainly discourage or eliminate altogether the dissemination to the public of any information regarding food that may potentially affect prostate health or prostate cancer progression.

As discussed in the expert report of Dr. deKernion,[42] Respondents' prostate expert, the scores of published literature analyzing the effects of antioxidants on the inflammatory pathway, the basic science showing a direct effect of POM on prostate cancer cell apoptosis and

[42] Dr. Jean deKernion is currently the Chairman of the Department of Urology and Senior Associate Dean for Clinical Affairs in the David Geffen UCLA School of Medicine. He has multiple responsibilities at UCLA, including overseeing the urological clinical and research education of students, residents and fellows, and maintains a busy practice in urologic oncology, primarily related to prostate cancer. He also oversees the department's large and diverse research programs. He has co-authored over 133 research chapters in urologic cancer research and has published over 228 papers in peer-reviewed journals. He also co-authored the first book on urologic oncology, which includes prostate cancer.

proliferation and serum nitric oxide levels, when combined with the clinical research showing POM pomegranate juice materially lengthened PSA doubling time, is "very convincing" science that POM has an inhibitory effect on prostate cancer. In fact, Dr. deKernion is clear that, based on the above science, POM also likely aids in the prevention and recurrence of prostate cancer and, at the very least, can delay very invasive and more radical treatments and their concomitant severe side-effects.

In sum: (1) POM pomegranate juice is non-toxic; (2) it is supported by peer-reviewed studies published in reputable journals; (3) basic science supports the clinical findings of effect on prostate cancer; (4) PSA doubling time is the best marker and indicative of tumor behavior; (5) POM is not a drug and therefore should not be governed by an FDA drug standard; and (6) given the above, there is competent and reliable scientific evidence that POM likely benefits prostate health and the progression of prostate cancer and the public has a right to have this information.

iv. POM's Erectile Health Claims Are Substantiated.

Proclaimed "Molecule of the Year" by Science magazine in 1992, nitric oxide plays a critical role in cardiovascular and erectile health. Nobel-prize-winner Dr. Louis Ignarro, whose discoveries concerning nitric oxide enabled the development of Viagra, conducted an *in vitro* study to evaluate pomegranate juice's capacity to protect nitric oxide against oxidative destruction. Pomegranate juice, a rich source of potent flavonoid antioxidants, was found to possess more antioxidant activity than grape juice, blueberry juice, red wine, and ascorbic acid. Based on a series of studies that were performed on vascular endothelial cells, Dr. Ignarro concluded that pomegranate juice possesses potent antioxidant activity that results in marked protection of nitric oxide against oxidative destruction, thereby augmenting the biologic actions

of nitric oxide. Other *in vitro* studies further demonstrate pomegranate juice's antioxidative powers in enhancing and preserving nitric oxide.

Using an animal model, Dr. Azadzoi *et al.* found that long-term pomegranate juice intake increased intracavernosal blood flow in the penis, improved erectile responses, improved smooth muscle relaxation, and decreased erectile tissue fibrosis. Dr. Azadzoi and his team of researchers concluded that arteriogenic erectile dysfunction accumulates oxidative products in erectile tissues and that oxidative stress is an important pathophysiologic factor of erectile dysfunction. Antioxidant therapy may be useful as a prophylactic for preventing smooth muscle dysfunction and fibrosis in erectile dysfunction. Consumption of pomegranate juice had the highest free radical scavenging capacity of a series of fruit juices and other known antioxidant beverages.

Dr. Arthur Burnett of Johns Hopkins University Medical School,[43] Respondents' expert regarding nitric oxide, testified in his deposition that these basic scientific studies alone "provide a powerful support for pomegranate juice . . . as antioxidants; that they work with very potent effects on the nitric oxide regulatory mechanism" and that "there's good basic science support that pomegranate juice is a very effective agent factor . . . in vascular function;" Burnett Dep. Tr. at 116:12-117:6.

Building on this strong basic scientific foundation, Forest and colleagues performed a randomized, double-blind, placebo-controlled cross-over design trial of Wonderful variety pomegranate juice versus placebo. The study engaged 53 completed subjects with mild-to-moderate erectile dysfunction who underwent two four-week treatment periods separated by a

[43] Dr. Burnett is the Patrick C. Walsh Professor of Urology serving on the faculty of the Department of Urology at the Johns Hopkins University School of Medicine/Johns Hopkins Hospital. He also holds a faculty appointment in the Cellular and Molecular Medicine Training Program of the Johns Hopkins University School of Medicine and is the Director of the Basic Science Laboratory in Neuro-urology of the James Buchanan Brady Urological Institute and Director of the Male Consultation Clinic/Sexual Medicine Division of the Department of Urology at Johns Hopkins. Dr. Burnett has authored and published over 180 original peer-reviewed articles and 40 book chapters. His research on nitric oxide is world renowned.

two-week washout. Using a global assessment question ("GAQ"), Forest *et al.* found that participants rated pomegranate juice 50% more effective than placebo at improving erections. The GAQ results achieved a probability value of 0.058, meaning that the positive results of the study were 94.2% likely to be the result of something other than "chance." Complaint Counsel's erectile function expert, however, argues that because this "p-value" was a few thousandths of a percentage point shy of an arbitrary 95% threshold,[44] the study is "not entitled to any weight;" Melman Dep. Tr. at 63:15-16. Respondents' expert in the clinical aspects of erectile health, Dr. Irwin Goldstein,[45] rejects Complaint Counsel's myopic view. Instead, Dr. Goldstein opines that the study is "clinically significant because it supports the conclusion that the positive results in the basic science are borne out in human function;" Goldstein Dep. Tr. at 108:10-13.

Not surprisingly, against this scientific backdrop, Dr. Goldstein concludes that "competent and reliable scientific evidence exists upon which clinicians who treat men with erectile health concerns would rely in concluding that pomegranate juice promotes erectile health;" Goldstein Expert Report at 14; PX0189. Further, Dr. Goldstein concludes that since pomegranate juice is a neutraceutical and not a pharmaceutical drug, physicians who treat patients concerned with erectile health would not hold pomegranate juice to the standards of safety and efficacy traditionally required by the FDA for approval of a pharmaceutical drug before recommending pomegranate juice to their patients.

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[44] Common levels of statistical significance are 10% (0.1), 5% (0.05), 1% (0.01) and 0.1% (0.001). Choosing a significance level is technically an arbitrary task, but for many applications a level of 5% is chosen, for no better reason than that it is conventional.

[45] Dr. Goldstein has been practicing medicine since 1976 and has been certified by the American Board of Urology since 1982. He was Professor of Urology and Professor of Gynecology at the Boston University School of Medicine from 1990-2005 and 2002-2005, respectively. He was Director of the Institute for Sexual Medicine at the Boston University School of Medicine from 2002-2005. He is currently Director of San Diego Sexual Medicine, APC; Director, Sexual Medicine, Alvarado Hospital, San Diego, California; and Clinical Professor of Surgery, University of California, San Diego. Dr. Goldstein has published over 250 original peer-reviewed manuscripts in male and female sexual medicine. He is one of the only physicians in the United States who focuses his practice on the sexual medicine aspects of urology.

C. In Any Event, Consumers Do Not Buy POM Products Because They Believe That The Products Will Prevent, Treat, Or Reduce The Risk Of Disease

"A 'material' misrepresentation or practice is one which is likely to affect a consumer's choice of or conduct regarding a product. In other words, it is information that is important to consumers." *FTC Policy Statement on Deception*, appended *to In re Cliffdale Assocs.*, 103 F.T.C. 110, 182 (1984). Although the FTC is entitled to apply, within reason, a presumption of materiality to express claims, deliberately made implied claims and claims that involve significant health concerns, *id.* at 182, the "[FTC] will always consider relevant and competent evidence offered to rebut presumptions of materiality." *Id.* at 182 n.47.

Here, to rebut the presumption that the alleged health benefit claims are material, Respondents submit Dr. Reibstein's Survey of POM Wonderful 100% Pomegranate Juice Users ("Reibstein Survey"),[46] which is both relevant and competent. The Reibstein Survey directly addresses materiality, which "is a test of the likely effect of the claim on the conduct of a consumer who *has* been reached and deceived." *Id.* at 182-83.

[redacted]

[46] Dr. Reibstein is POM's marketing research and consumer behavior expert. He is a William S. Woodside Professor of Marketing at The Wharton School at The University of Pennsylvania.

[redacted]

The Reibstein Survey accordingly directly rebuts the initial presumption of materiality.

IV. ALTHOUGH POM CAN SATISFY THE *PFIZER* FACTORS AND THE COMPETENT AND RELIABLE STANDARD, ANY CRITERIA REQUIRING "SCIENTIFIC AGREEMENT" IS UNCONSTITUTIONAL

Complaint Counsel's attempt to construe "the level of substantiation experts would agree is reasonable" as requiring scientific agreement or consensus at the level required for FDA drug approval would render this *Pfizer* factor unconstitutional for several reasons. First, it is inherently and impermissibly vague, such that it violates the First and Fifth Amendments, as well as the APA. There currently exists no objective legal standard against which to measure health benefit claims of foods. Rather, "scientific agreement" is applied, and scientific opinion provided on an *ad hoc* basis only after litigation has ensued. The test is then applied retroactively to measure the appropriateness of past conduct. Although Respondents can no doubt meet a reasonable "scientific agreement" standard here, the rule certainly provides no meaningful prospective guidance to advertisers, and its enactment as a criteria, especially as construed by the FTC, wherein it subsumes all other criteria under the *Pfizer* factors, as well as the "competent and reliable" rule, renders the test unconstitutional.

Second, the "scientific agreement" standard also violates the First Amendment as well as the line of cases led by *Pearson I*, as discussed elsewhere, and its progeny because it requires the advertiser to "prove" its claim, which is more than what is required to show that the claim was non-deceptive. *See Pearson I*, 164 F.3d at 655.

V. THE REMEDY COMPLAINT COUNSEL SEEK EXCEEDS THE FTC'S AUTHORITY AND VIOLATES THE CONSTITUTION

Complaint Counsel cannot meet its burden of proving that the draconian remedy provisions set forth in the Notice Order -- which are novel and raise serious issues under the First Amendment and the FTC's authority under the FTCA -- are justified. Although the FTC has discretion in proposing injunctive remedies, a broad "fencing-in" order must bear a reasonable relation to the alleged conduct, and must also comply with First Amendment standards. Here, Complaint Counsel's indiscriminate fencing-in order falls far short of those requirements, and, if adopted, would also exceed the FTC's authority under the FTCA. What Complaint Counsel seeks is not injunctive relief narrowly tailored to prevent future violations, but rather to chill commercial speech about the potential health benefits of food, effectively limiting speech to statements pre-approved by the FDA. The proposed relief should be denied.

A. The Novel FDA Pre-Approval Requirement Sought By Part I Of The Notice Order Exceeds The FTC's Authority And Is Not Reasonably Related To The Conduct At Issue.

In Part I of the Notice Order, Complaint Counsel ask this Court to require that Respondents obtain FDA approval before making any future nutrient-disease advertising claim concerning POM's products. This imposition of the FDA's NLEA prior restraint as a proxy for a finding of deceptive advertising by the FTC exceeds the FTC's jurisdiction.

The FTCA empowers the FTC to prohibit false, misleading, deceptive and unfair advertising practices. The Act does not, however, allow the Commission to prohibit through a prior restraint, advertising practices that may not meet FDA NLEA approval standards, but which are nevertheless truthful or substantiated.

Part I of the Order would impose a categorical restriction on several types of future claims, regardless of how truthful they may be, if such claims are not pre-approved by the FDA.

The FTC is using the enforcement provisions of the FDCA in requiring FDA approval before allowing Respondents to make nutrient-disease claims in advertising -- even if truthful and substantiated. This exceeds the FTC's authority because the FDCA mandates that only the "United States," and not other agencies, may bring actions to enforce provisions of the statute.

To distract from its unprecedented power grab nature, Complaint Counsel rely on the FTC's decision in *Thompson Medical* where the FTC determined that the proper level of substantiation for the respondents' advertising claims consisted of two well-controlled clinical trials, which was consistent with the FDA's standards. But nowhere in the *Thompson Medical* decision did the Commission seek to impose a requirement that respondents obtain the FDA's pre-approval before making nutrient-disease claims in advertising. In that case, which, notably, involved an over-the-counter medicinal cream and not a 100% fruit product, the FTC merely stated that requiring two well-controlled studies for the health benefit claims at issue there was appropriate. Nowhere in *Thompson Medical* or in any other litigated case have the FTC or courts required a marketer to receive pre-approval from the FDA to make truthful and non-misleading health claims under the FTCA. Indeed, Complaint Counsel has not cited a single case in which this Court or any other has upheld the rigid and onerous restraints proposed by Part I of this Notice Order.

Complaint Counsel seek to require Respondents to obtain prior FDA approval for health claims related to heart disease, prostate cancer, or erectile dysfunction that are not reasonably related to the conduct challenged here. Although the FDA and FTC often regulate the same products, the FDA's approach to regulation differs in several important respects from the FTC's authority to regulate health claims. Complaint Counsel—in a footnote—attempts to argue that the proposed relief is reasonably related to the challenged conduct because it contends that the

standards applied by the FDA under the NLEA and the FTC under its various policy statements are similar. Compl. Counsel's Br. at n. 69. However, Complaint Counsel completely mischaracterize the process by which the FDA regulates health claims. In sharp contrast to the FTC's historical practice of encouraging dissemination of truthful consumer information, the FDA has a history of unduly restricting health claims through prior restraint. Indeed, in the nearly 20 years since the NLEA's implementation, the FDA has only approved 12 health claims. By requiring Respondents to obtain FDA approval before making certain health claims about the Challenged Products, Complaint Counsel are, in effect, halting altogether Respondents' ability to make any health claims. This broad restriction bears no reasonable relation to the conduct alleged in this case and is not justified under the law.

B. The Order's Fencing-In Provisions Are Impermissibly Overbroad.

1. The Three-Factor Test For Finding A Reasonable Relationship.

The FTC is authorized to order a party to "cease and desist" from engaging in prohibited acts or practices. *See* 15 U.S.C. § 45. The FTC may issue a fencing-in order that extends to other products sold by a respondent, but the scope of such an order must bear a "reasonable relationship" to the violation it is intended to remedy. *See FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 394-95 (1965).

Three factors bear on whether a fencing-in order has the required "reasonable relationship": (1) the seriousness and deliberateness of the violation; (2) the ease with which the violative claim may be transferred to other products; and (3) whether the respondent has a history of prior violations. *See Stouffer Foods Corp.*, 118 F.T.C. 746, 811 (1994); *Sterling Drug, Inc. v. FTC*, 741 F.2d 1146, 1155 (9th Cir. 1984); *Sears Roebuck & Co. v. FTC*, 676 F.2d 385, 391-392 (9th Cir. 1982); *Standard Oil Co. v. FTC*, 577 F.2d 653, 662 (1978) ("Among the

circumstances which should be considered in evaluating the relation between the order and the unlawful practice are whether the respondents acted in blatant and utter disregard of the law, and whether they had a history of engaging in unfair trade practices."). As discussed below, all three factors weigh heavily against the relief sought in the Notice Order.

2. The Order's Fencing-In Provisions Lack A Reasonable Relationship To POM's Alleged Advertising Violations.

The Notice Order includes extremely broad fencing-in provisions (Parts II and III) directed against a broad range of the Respondents' business activities, despite the fact that such relief is not reasonably related to the narrow conduct in dispute here. Respondent Roll Global operates a wide range of different companies. Current Roll Global companies include, inter alia:

- Teleflora (floral wire service)
- FIJI Water (bottled artesian water)
- Paramount Citrus (citrus fruits)
- Suterra (pheromone-based pest control)
- Paramount Farms (nuts and nut processing)
- POM Wonderful (pomegranate products)
- Neptune Pacific Line (commercial shipping services)
- Justin Vineyards (winery)

POM is a relatively recent addition to this family, and constitutes a minority component. None of the other Roll companies have any plausible connection to POM's alleged advertising violations. Yet, Parts II and III of the Notice Order seek to impact all Respondents (including Roll Global) from making representations regarding food products. These proposed prohibitions would apply to Respondents' actions "directly or through any corporation, partnership, subsidiary, division, trade name, or other device."

None of the three factors for the required "reasonable relationship" support Complaint Counsel's request for this expansive fencing-in relief. POM funded many millions of dollars of scientific research by renowned scientists, resulting in over 65 peer-reviewed publications. POM rightfully believed in the merits of this science. While it does not include the $700 million type drug trials that Complaint Counsel incorrectly insists are required, that does not establish that POM acted as a deliberate false advertiser. Likewise, Complaint Counsel contend that the alleged false advertising was "serious" because it involved health issues. However, Complaint Counsel do not allege, nor can they, that any consumer suffered adverse health effects from the alleged false advertising. Instead, consumers purchased pomegranate juice, a nutritious and safe food product.

In addition, even if POM had acted wrongfully and publicizing its medical research, there exists no "reasonable relationship" with the alleged harm and chosen remedy against all the companies. The second factor asks whether a "reasonable relationship" exists to justify transferring the prohibition of speech to other products. However, the "violative claims" alleged in this dispute could not possibly be transferred to other food products. No other Roll company is involved in the large or sophisticated research program that POM is engaged in and there certainly is no history of past false advertising by other Roll companies. Complaint Counsel's suggestion that Respondents will suddenly transfer their claims over to other food products is without merit.

The third factor, a history of prior violations, again cuts powerfully against finding a "reasonable relationship." The five Respondents have no history of prior violations, despite the collective scale of their respective business activities over the past several decades. Although Complaint Counsel rely on unsupported speculation about what Respondents might do in the

future, Respondents' various businesses have operated for decades in a manner unrelated to the violations at issue here, without running into any regulatory issues. Even if everything Complaint Counsel alleged was true, POM would be an isolated outlier.

Complaint Counsel fail to justify its request for fencing-in relief, which should be denied. *See, e.g., Grove Laboratories v. FTC*, 418 F.2d 489 (5th Cir. 1969); *American Home Products Corp. v. FTC*, 402 F.2d 232 (6th Cir. 1968).

Rather than proposing injunctive relief that is *rationally* related to the *violations at issue*. Complaint Counsel seek to punish a broad range of companies. The intended effect is to chill all these companies' speech about food, reserving such speech solely for the FDA. Part II of the Notice Order is particularly disturbing because it bars misrepresentations relating to **any** studies or research, regardless of whether the research has anything to do with health claims. For example, Respondents would theoretically be at risk when discussing new scientific research on the pesticide resistance of new varieties of pistachios. Respondents would potentially be barred from citing the public health pronouncements made by Complaint Counsel's own nutritional epidemiology expert, Dr. Stampfer, regarding the health benefits of wine consumption, because those recommendations were made on the basis of observational studies (rather than the double-blind placebo-controlled trials that Complaint Counsel erroneously insist are required for making such recommendations). Although citing Dr. Stampfer's statements about the health benefits of alcohol would be completely acceptable by the standards of nutritional science, the Notice Order would suppress such speech.

Notably, fencing-in orders should be used with caution because they impose new legal obligations on the respondents, rather than just restating the general legal principle that false advertising is prohibited. "Multi-products orders should be used with caution because they alter

the scheme of penalties and enforcement procedures defined by the Act. Violations of a cease and desist order are heard in the district courts, rather than before the FTC. A company alleged to have violated such an order is therefore not entitled to a full hearing before the FTC." *Litton Industries, Inc. v. F.T.C.*, 676 F.2d 364, 371-72 (9th Cir. 1982) (*citing Standard Oil Co. v. FTC*, 577 F.2d at 661; *Colgate-Palmolive Co.*, 380 U.S. at 394) (internal quotations omitted).

C. The Order's Proposed Restrictions Do Not Pass First Amendment Scrutiny

The First Amendment limits the scope of injunctive relief that the FTC could obtain in this action. The FTC may not prospectively enjoin Respondents from engaging in speech on the basis that the FDA's NLEA prior restraint has not been satisfied, but must instead prove that no qualification is capable of rendering the future nutrient-disease advertising claims non-deceptive on a claim-by-claim basis. *See FTC v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 45 (D.C. Cir. 1985) (explaining that FTC injunction violated First Amendment because it prevented B&W from advertising using information "in sufficient quantity to allow consumers to make informed decisions" and "[s]ince [that] would eliminate consumer confusion ... the FTC must bear the affirmative burden of demonstrating any inadequacy, and thus deceptiveness ..."); *Peel v. Attorney Registration and Disciplinary Com'n of Illinois*, 496 U.S. 91 at 109-11 (holding that burden is on the government, not the advertiser, to come up with a less restrictive regulation); *Kraft*, 970 F.2d at 325 (collecting cases).

The government is prohibited from keeping the public in the dark simply because there is a lack of scientific agreement on a particular health issue. The freedom of speech includes the freedom to communicate potential health benefits, appropriately qualified, not solely those that the government believes proven beyond doubt. As the D.C. Circuit explained in *Pearson I*:

> As best we understand the government, its first argument runs along the following lines: that health claims lacking "significant scientific agreement" are inherently misleading because they have such an awesome impact on

> consumers as to make it virtually impossible for them to exercise any judgment at the point of sale. It would be as if the consumers were asked to buy something while hypnotized, and therefore they are bound to be misled. We think this contention is almost frivolous. We reject it.

Pearson I, 164 F.3d at 655-56; *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996) ("[t]he First Amendment directs us to be especially skeptical of regulations [of indisputably non-misleading information] that seek to keep people in the dark for what the government perceives to be their own good").

Complaint Counsel have made no effort to satisfy their heavy burden in this context. For example, they have alleged that studies did not support POM's claims because they "consisted of results from an unblinded, uncontrolled study; and the study report stated that it is 'controversial whether modulation of PSA levels represents and equally valid clinical end point,' and that 'further research is needed to ... determine whether improvements in such biomarkers ... are likely to serve as surrogates for clinical benefit.'" Compl., ¶ 15. Complaint Counsel's Order, however, presumes that the appropriate remedy is to require NLEA approval from the FDA for all such claims, rather than to require reasonable disclaimers or qualifications. Under *Pearson I* and its progeny, unless the FTC can prove that consumers will not understand the limits of scientific evidence bearing qualifications, it may not impose such a prior restraint instead. *See Pearson I*, 164 F.3d at 658 ("[a]lthough the government may have more leeway in choosing suppression over disclosure as a response to the problem of consumer confusion where the product affects health, it must still meet its burden of justifying a restriction on speech"); *Ibanez v. Florida Department of Bus. and Prof. Reg.*, 512 U.S. 136, 146 (1994) ("[i]f 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");

Edenfield v. Fane, 407 U.S. 761, 771 (1993) (concerning ban on solicitation by accountants and stating that the government "present[ed] no studies that suggest personal solicitation of prospective business clients by CPA's creates the dangers. . . .").

When imposing a prior restraint, the FTC cannot meet its constitutional burden based on speculative assertions that the evidence presented is unacceptable for one reason or another. To meet its burden, Complaint Counsel must instead establish (1) that there is "no [scientific] evidence in support of the claims," or (2) that the "evidence in support of the health claim is qualitatively weaker than the evidence against the claim." *Id.* The *Pearson III* court explained that the "mere absence of significant affirmative evidence in support of a particular claim ... [is not] negative evidence 'against' it." 141 F. Supp. 2d 105 (*citing Pearson I*, 164 F.3d at 660). Nonetheless, even if Complaint Counsel demonstrate (1) or (2), the FTC must still permit the claim unless it also proves that disclaimers "would bewilder consumers and fail to correct for deceptiveness." *Whitaker I*, 248 F. Supp. 2d at 10. Without satisfying each of those elements – which it cannot here – the FTC is constitutionally barred from imposing a prior restraint on Respondents' future advertising.

* * *

Respondents respectfully submit that they will prove at trial that other aspects of the proposed Notice Order are inappropriate, including (without limitation) provisions relating to individual Respondents. Respondents reserve the right to include additional argument with regard to the Proposed Order at trial and in post-trial briefing.

VI. MATTHEW TUPPER SHOULD BE DISMISSED AS A RESPONDENT

Matthew Tupper has filed a separate Pretrial Brief explaining why he should be dismissed as a respondent. Respondents hereby incorporate by reference his Pretrial Brief.

VII. CONCLUSION

Setting aside for the moment the constitutional issues, it is clear that Respondents have abundant competent and reliable preclinical and clinical evidence to support their claims—even if this Court were to adopt Complaint Counsel's argument that claims beyond supportive health have been made. As summarized in *Whitaker* and *Pearson*, and their progeny, while a complete ban would be reasonable where there was no evidence to support a claim or if there were only "qualitatively weak support" in "one or two old studies," where, as here, there exists ample, significant and credible evidence to support the claim, more disclosure rather than less is the preferred approach. POM's studies are rigorous, scientifically executed studies, published in peer-reviewed scientific journals, which certainly show health benefits from the consumption of POM's pomegranate products. The claims are supported under *Pfizer* and the FTC's "competent and reliable" standard—even those claims which Respondents dispute were conveyed by the advertisements. The advertisements, however, do not convey that the products are "silver bullets" against disease as alleged by the FTC. Consequently, the proposed order against Respondents, including its definition of "Covered Products" is not supportable.

In addition, the mechanism in the order requiring FDA prior approval is not appropriate or warranted by the facts of this case, and is constitutionally flawed. This requirement should be barred outright.

Respectfully submitted,

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UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

COMMISSIONERS: Jon Leibowitz, Chairman
William E. Kovacic
J. Thomas Rosch
Edith Ramirez
Julie Brill

In the Matter of	)	
	)	
POM WONDERFUL LLC and	)	
ROLL INTERNATIONAL CORP.,	)	
companies, and	)	Docket No. 9344
	)	PUBLIC
	)	
STEWART A. RESNICK,	)	
LYNDA RAE RESNICK, and	)	
MATTHEW TUPPER, individually and	)	
as officers of the companies.	)	

CERTIFICATE OF SERVICE

I hereby certify that this is a true and correct copy of the Respondents' **PUBLIC PRE-TRIAL BRIEF – CORRECTED COPY**, and that on this 20th day of May, 2011, I caused the foregoing to be served by hand delivery and FTC E-File on the following:

Donald S. Clark
The Office of the Secretary
Federal Trade Commission
600 Pennsylvania Avenue, NW
Rm. H-159
Washington, DC 20580

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Avenue, NW
Rm. H-110
Washington, DC 20580

I hereby certify that this is a true and correct copy of the Respondents' **PUBLIC PRE-TRIAL BRIEF – CORRECTED COPY**, and that on this 20th day of May, 2011, I caused the foregoing to be served by e-mail on the following:

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Dated: May 20, 2011

EXHIBIT A

REDACTED

Slip Copy, 2009 WL 2496532 (D.N.J.), 2009-2 Trade Cases P 76,708
(Cite as: 2009 WL 2496532 (D.N.J.))

NOT FOR PUBLICATION

United States District Court,
D. New Jersey.
FEDERAL TRADE COMMISSION, Plaintiff,
v.
LANE LABS-USA, INC., Cartilage Consultants, Inc., corporations, and I. William Lane and Andrew J. Lane, individuals, Defendants.

Civil Action No. 00-cv-3174 (DMC).
Aug. 11, 2009.

West KeySummary**Federal Civil Procedure 170A ⚖2397.6**

170A Federal Civil Procedure
170AXVII Judgment
170AXVII(A) In General
170Ak2397 On Consent
170Ak2397.6 k. Compliance; Enforcement. Most Cited Cases

A supplier of dietary supplements acted in accordance with the spirit of a consent order and thus it was not in civil contempt. The consent order required the supplier, in making claims about the health benefits of a product, to possess competent and reliable scientific evidence that substantiated their claims. The supplier found two new products, a patented calcium supplement and a male fertility dietary supplement, and obtained scientific evidence that the products were efficacious. The supplier then consulted experts who opined that the research supporting the products and the products themselves were good. Of concern was the notion that a lay person should have to do more than could reasonably be expected when confronted with both reliable and/or peer reviewed studies and articles.

Amanda Christine Basta, Constance Marie Vecellio, Elsie Bennett Kappler, Federal Trade Commission, Washington, DC, Susan J. Steele, United States Attorney's Office, Newark, NJ, for Plaintiff.

Jack Wenik, Theodora T. McCormick, Sills, Cummis & Gross, PC, Newark, NJ, Paul F. Carvelli, McCusker, Anselmi, Rosen, Carvelli & Walsh, PA, Chatham, NJ, for Defendants.

OPINION

DENNIS M. CAVANAUGH, District Judge.

***1** This matter comes before the Court upon motion by Plaintiff, the Federal Trade Commission ("FTC") for a finding that Defendants Lane Labs-USA, Inc. ("Lane Labs"), Andrew Lane, and Dr. I. William Lane (collectively, "Defendants") are in violation of Orders agreed to by the parties and entered by the Honorable William G. Bassler, U.S.D.J. on June 30, 2000. The FTC seeks to have this Court find that Defendants are in contempt as a result, and to fine Defendants twenty-four million dollars and to have any monies levied turned over to the FTC to be disbursed to consumers allegedly injured by Defendants' actions.[FN1] Beginning on April 20, 2009, this Court conducted an evidential hearing lasting five days. After carefully considering the complete record, and based upon factual findings below, this Court concludes that the FTC has not sustained its burden of proof. Accordingly, the FTC's motion is **denied.**

FN1. It should be noted that the alleged injuries consist of consumers paying premium prices as a result of false claims and not for any personal injuries suffered as a result of ingesting Defendants' products. In any event, Defendants challenge the damages amount arguing that the amount proposed by the FTC is excessive and inaccurate.

I. *FACTUAL FINDINGS*

The FTC's contempt motion arises out of claims made regarding Lane Labs' AdvaCAL and Fertil Male products. Lane Labs USA Inc., founded in 1994 by Andrew Lane is a supplier of dietary supplements. Dr. William Lane, as well as being

Andrew Lane's father, is a researcher, educator, and author on the subject of alternative medicine. Dr. William Lane has doctoral degrees in biochemistry and nutrition from Rutgers University. In 2000, Defendants entered into Consent Orders with the FTC in connection with two totally unrelated products (Skin Answer and Benefin). The Consent Orders preclude Defendants from making representations regarding the effect of any health product without being able to support those claims with reliable scientific evidence. Claiming Defendants violated the Orders, the FTC filed this motion on January 11, 2007, seeking to hold Defendants in contempt. Following extensive discovery, this Court conducted an evidentiary hearing over the course of five days commencing on April 20, 2009. The Court also considered pre and post hearing submissions filed on behalf of all parties.

The Hearing

AdvaCAL or "AAACa" is a patented calcium supplement derived from oyster shells that are smelted at extremely high temperatures. The smelting process changes the chemical form of the shells from calcium carbonate to calcium hydroxide and calcium oxide. In addition, small amounts of heated algae ingredient ("HAI") are added to the calcium for increased absorbability into the body. According to Defendants, AdvaCal is the only calcium hydroxide and calcium oxide supplement available in the United States.

Fertil Male is a dietary supplement derived from a Peruvian plant known as "Maca" or Lepidicum meyenni. Defendants claim Fertil Male is a supplement that can improve male fertility parameters.

The FTC's motion is predicated on a number of claims made by Defendants which the FTC believes violate the prior Orders. A representative selection of these claims are:

• AdvaCAL has been "clinically shown to be three times more absorbable than other calci- ums;"

***2** • AdvaCAL is "absorbed three times better than typical calcium carbonate/coral calcium supplements;"

• AdvaCAL is the "only" calcium that can increase bone mineral density;

• AdvaCAL produced a 3 percent per year increase in bone density "over a period of years;"

• Results from a "group" study demonstrates that AdvaCAL caused a 13.5% increase in bone density over two years;

• AdvaCAL has been shown in clinical tests to increase bone density in the hip;

• In an infomercial for AdvaCAL produced in 2003, Lane Labs included a testimonial from a 25 year old woman named "Michelle C." who claimed that after taking AdvaCAL, her bone density increased by 50% in six months.

Additionally, the FTC challenges four statements made by Dr. Lane regarding AdvaCAL:

• AdvaCAL "is the only calcium I've seen that has been shown over and over to build bone density"

• AdvaCAL "is the only calcium I know that can increase bone density"

• "Most of the supplements out there don't have available, digestible calcium"

• Calcium is so hard that the body "cannot absorb it-like a rock!" "It goes in one end and out the other"

With respect to Fertil Male, the FTC challenges Defendants' general claim that Fertil Male has been "clinically-shown" to increase sperm production, sperm motility, and semen production.

The claims at issue appeared over a number of years, since 2000 for AdvaCAL and 2003 for Fertil Male, in Lane Labs' CompassioNet catalogs, the Lane Labs CompassioNet and product specific

websites, direct mailing packages, national magazines, national trade publications, national publications directed at health care providers, and infomercials that were broadcast and distributed as CD-Roms.

Defendant Andrew Lane testified at length regarding the steps he personally took and efforts taken by others at Lane Labs to ensure compliance with the Orders. Mr. Lane testified that he traveled to meet with researchers and to see how different products were made. Mr. Lane further testified that a process was established to vet every claim in an advertisement and that a file was kept of all substantiation for each advertisement or claim. Mr. Lane explained how at times multiple reports or studies were combined to make a given claim or to produce an advertisement, but that someone with knowledge in the field checked to make sure every advertisement and/or claim was not misleading. The Court found Mr. Lane to be forthcoming and credible, and considers his testimony to be evidence of the efforts undertaken by Defendants to comply with the Orders.

At the hearing, the FTC offered two expert witnesses, Dr. Robert P. Heaney regarding AdvaCAL and Dr. Craig Niederberger regarding Fertil Male. The Defendants offered two experts witnesses as well, Dr. Michael Frank Holick regarding AdvaCal and Dr. Machelle M. Seibel regarding Fertil Male. The Court will address each of these witnesses individually.

Dr. Robert P. Heaney

***3** Dr. Heaney is a physician trained as an internist-endocrinologist and is on the faculty of Creighton University in Omaha, Nebraska. Dr. Heaney is the principal scientist in Creighton's Osteoporosis Research Center. Dr. Heaney has been on Creighton University's faculty for fifty-two years. At the time of the hearing Dr. Heaney held the administrative position of Interim Vice President for Health Sciences at Creighton. Dr. Heany held this position until August 3, 2009, when he was named Creighton University's Vice President of Research. The Court recognized Dr. Heaney as an expert in the field of calcium research.

Dr. Heaney was originally hired by Lane Labs prior to the FTC's contempt claims, to assess AdvaCAL and specifically, to compare the absorbability of calcium from AdvaCAL to Citracal,[FN2] another calcium supplement. Dr. Heaney applied the pharmacokinetic method which measures the amount of calcium absorbed from the intestine into the bloodstream. In studying the data produced from his comparative study, Dr. Heaney concluded that AdvaCAL is absorbable and that it is a good source of calcium. Dr. Heaney further concluded that AdvaCAL is inferior to Citracal by approximately twenty percent. Dr. Heaney testified that absorbablility is the critical measure because there is currently no means known to science for a calcium source that is not absorbed as well as another to nevertheless cause superior results. After communicating his conclusions to Lane Labs Dr. Heaney proposed a larger study. Lane Labs decided not to fund the larger study. Subsequent to working with Lane Labs, Dr. Heaney was retained by the FTC to review Lane Labs' AdvaCAL advertising and to testify as an expert in this matter.

> FN2. Citracal is brand-name product that contains calcium citrate which is a calcium salt often used as a calcium supplement.

Dr. Heaney testified that it is general practice when comparing one product to another to ensure two components: "randomization on the one hand, and complete follow-through or obtaining the information on all the subjects that you have randomized to the treatments." Dr. Heaney added that "different products have to be tested side by side in the same population." Dr. Heaney was asked his opinion as to whether the evidence provided by Lane Labs in support of its claims pertaining to AdvaCAL provided substantiation. The witness responded that in his opinion, Lane Labs' claims were not substantiated by competent and reliable scientific evidence as defined in the Orders. Dr. Heaney further discussed formulation and how

changing the formulation of a product effects the relevance of information based on the old formulation. Specifically, Dr. Heaney was asked about and discussed inert excipients, which, although not active ingredients, can change the effect of active ingredients. Dr. Heaney also discussed individual reports and studies relied upon by Lane Labs and explained why he believes these studies and reports do not constitute reliable scientific evidence. The Court notes that Dr. Heaney, a very capable researcher, was critical of most studies and held these studies to a standard that would be difficult to obtain.

***4** On cross-examination by defense counsel, Dr. Heaney acknowledged that a good calcium source can be expected to produce the benefits of calcium and that AdvaCAL is a good source of calcium. Specifically, Dr. Heaney testified that calcium literature and studies about other forms of calcium can be used to support claims for AdvaCAL. Dr. Heaney testified that if he had the original data for any study on calcium or osteoporosis he could "almost certainly" find a flaw with that study. Dr. Heaney additionally testified that the half life for medical publications is approximately four or five years. Meaning, after four or five years there is superceding, additional, better, or contrary information. Dr. Heaney agreed that once an article, notwithstanding the fact that he might disagree with it, has been published in a peer-reviewed publication, such an article can provide substantiation. Dr. Heaney explained that a company could rely on the facts of a publication but not necessarily the authors' opinion. Dr. Heaney further stated that a company wishing to rely on the facts of a study must also analyze whether the study was conducted properly. He explained that a professional could and should perform this service as a consultant. Dr. Heaney stated that he would not fault a manufacture who took a peer reviewed study, tried to determine if the study was conducted properly, and then relied on that study. The Court finds these views somewhat unreasonable.

On redirect, Dr. Heaney testified that "the New England Journal [of Medicine], which would be considered one of the premier journals for the publication of clinical results whether you live in New England or the rest of the U.S. or Europe, for that matter, published a communication from the editors looking back over their own experience with peer-reviewed publications and [state] that something on the order of [50%] of the papers [printed] in retrospect have been significantly flawed."

Dr. Craig Stuart Niederberger

Dr. Niederberger is a physician and researcher in the area of andrology (male reproductive medicine) and urology. Since in 1993, Dr. Niederberger has been on the faculty of the College of Medicine and the College of Engineering in the Department of Bioengineering at the University of Illinois at Chicago, where he is currently the Chairman of the Department of Urology. Dr. Niederberger was recognized by the Court as an expert in the field of urology.

Dr. Niederberger opined that there is no evidence to support Lane Labs' claim that Fertil Male optimizes male fertility. Dr. Niederberger explained his understanding of what constitutes "competent reliable scientific evidence." Dr. Niederberger implied that evidence relied upon must result from tests that are objective/non-biased. Dr. Niederberger stated that bias is removed by incorporating randomization and a placebo.

Dr. Niederberger explained how he assesses fertility. He testified that semen analysis is an imperfect test but is the principle basic test. Semen has several components, the volume of the ejaculate, the amount of liquid in the ejaculate, the sperm count, and the motility (how the sperm moves) of the sperm. Dr. Niederberger also discussed the relevancy of sperm morphology which compares what sperm actually looks like to what it should look like. Dr. Niederberger testified that he is aware of five studies that discuss the effect of Maca on fertility; a 2001 study in the Asian Journal of Andrology using rats as subjects, a 2001 study on nine men, a

2004 rat study in the Journal of Endocrinology, an unpublished manuscript, and a doctoral thesis. While stating the obvious, that in normal circumstances a man has to be able to have sex to impregnate a women, Dr. Niederberger explained that sexual activity or impotency is a separate and distinct issue from infertility. Dr. Niederberger explained why he believes that the five studies mentioned above do not constitute competent reliable scientific evidence for the proposition that Fertil Male promotes male fertility. Dr. Niederberger based his opinion on criticisms that the studies were under powered (did not have enough participants), utilized inaccurate measuring techniques, and/or the fact that the test subjects in two of the studies were rats as oppose to humans.

***5** Dr. Niederberger further testified that if a dietary supplement caused no harm but could do some good he would have no problem with a doctor advising a client to take the supplement. Dr. Niederberger added that Maca has not been shown to have a benefit and that he believes there is some evidence that Maca might cause harm so he would not support advising a client to take Maca based on the above rational. Dr. Niederberger stated that he would want the best evidence that an agent improves fertility before he would advise a patient to ingest the agent.

Dr. Michael Frank Holick

Dr. Holick is a professor of medicine, physiology, and biophysics at the Boston University Medical Center. He is Director of the General Clinical Research Center and the Bone Health Care Clinic. Dr. Holick holds both a Ph.D. and an M.D. Dr. Holick was qualified as an expert in calcium, vitamin D metabolism, and bone health. He was called as a defense expert witness.

Dr. Holick testified that the studies he reviewed dealing with AdvaCAL or its active ingredients used research structures discussed by Dr. Heaney, randomization and placebo/control groups. Dr. Holick discussed many of the documents presented by Lane Labs and criticized by Dr. Heaney. Dr. Holick provided a different interpretation of these documents. Dr. Holick testified that while researchers do not like to see test subjects who initially took part in a study not complete the study or rather "dropout" of the study group, the effect of dropouts on a study can be dealt with by statistical analysis and by asking the author to explain why a subject dropped out of the study group. Dr. Holick explained how research not specifically on point with a claim can still be used to substantiate that claim. For example, if you have a study that says a product will increase bone density, that study can be used as a surrogate to substantiate a claim that the product will reduce risk of fracture because better bone density reduces risks of fractures.

Dr. Holick testified that Dr. Heaney's comparative study of AdvaCAL and Citracal was flawed because of the use of 25-hydroxyvitamin D. Dr. Holick further testified that Dr. Heaney's data does not necessarily mean that Citracal is absorbed better than AdvaCAL as concluded by Dr. Heaney. Dr. Holick testified that in his opinion there is reliable scientific evidence that AdvaCAL reduces fracture risk better than calcium carbonate and that AdvaCAL is better absorbed or more bioavailable than calcium carbonate. Dr. Holick testified that while dramatic bone density increases over a relatively short period of time resulting from regulating a patient's calcium and vitamin D levels is unusual, he has seen it occur. Dr. Holick explained that he would want to know more about the medical condition of the patient, but he would not dismiss a dramatic increase in bone density as error.

Dr. Machelle Seibel

Dr. Seibel is a medical doctor and is a professor at the University of Massachusetts Medical School. Before holding this position Dr. Seibel was on the faculty of Harvard Medical School for nineteen years where he oversaw the reproductive endocrinology labs and was Chief of the Division of Reproductive Endocrinology. Although Dr. Seibel is not a urologist, he has treated male patients for infertility. Dr. Seibel serves part-time as the Medical

Director for a publicly traded company. In his capacity as Medical Director, Dr. Seibel is responsible for the supplements that the company produces. As a result of the various positions Dr. Seibel holds, he has reviewed many studies. Dr. Seibel was qualified as an expert regarding fertility.

***6** Dr. Seibel discussed several studies offered by Lane Labs to substantiate its claims pertaining to Fertil Male. Dr. Seibel testified to the relevancy of studies where the subjects are rats and the use of randomization. He stated that while having a placebo group is optimal, it is not uncommon for studies in this area to not use placebo groups. Dr. Seibel explained why he believes that the studies offered by Lane Labs are reliable competent scientific substantiation of Lane Labs' claims regarding Fertil Male. Dr. Seibel stated that "half of the things on the shelf have no studies ..." and that it is "so unusual to have [ ] studies that it is refreshing." Dr. Seibel testified that he is of the opinion that there is competent and reliable scientific evidence that Fertil Male is clinically shown to promote sperm count, motility, and production. Dr. Seibel further testified that he has no hesitation about offering Fertil Male to his patients if other treatments are not working.

All four expert witnesses were credible and knowledgeable in their respective fields of expertise. This Court however, was more impressed by the testimony of Defendants' experts because their testimony and approach to the subject matter seemed more reasonable and in accordance with the Consent Orders. In considering the testimony offered by all of the experts the difference between the FTC's experts and the Defendants' experts came down to a difference of opinion-not necessarily matters of right and wrong. Defendants clearly offered support and substantiation for the claims regarding their products.

II. *STANDARD OF REVIEW*

A. Civil Contempt

"The exercise of the power to find and to punish for contempt is [ ] discretionary, and should be undertaken with the utmost sense of responsibility and circumspection." *Thompson v. Johnson,* 410 F.Supp. 633, 640 (E.D.Pa.1976), aff'd 556 F.2d 568 (3d Cir.1977). For a party to be held in civil contempt, a plaintiff must show that "(1) a valid court order existed, (2) the defendant had knowledge of the order, and (3) the defendant disobeyed the order." *John T. v. Delaware County Intermediate Unit,* 318 F.3d 545, 552 (3rd Cir.2003) (quoting *Harris v. City of Philadelphia,* 47 F.3d 1342, 1326 (3rd Cir.1995)). The burden then shifts to the alleged contemnors to show why they were unable to comply with the order. *FTC v. Affordable Media, LLC,* 179 F.3d 1228, 1239 (9th Cir.1999), cert. denied *sub nom Lawson v. FTC,* 534 U.S. 1042, 122 S.Ct. 620, 151 L.Ed.2d 542 (2001); *In re Affairs with a Flair,* 123 B.R. 724, 727 (Bankr.E.D.Pa.1991).

To establish contempt the movant bears the burden of proving by clear and convincing evidence that the respondent violated a court order. *Roe v. Operation Rescue,* 54 F.3d 133, 137 (3d Cir.1995). This standard is not satisfied unless the evidence "produce[s] in the mind of the trier of fact a firm belief or conviction as to the truth of the allegations sought to be established, evidence so clear, direct and weighty and convincing as to enable [a court] to come to a clear conviction without hesitancy, of the truth of the precise facts." *U.S. v. Askar,* 222 Fed. Appx. 115, 119 (3d Cir.2007) (quoting *In re Jobes,* 108 N.J. 394, 529 A.2d 434 (1987)). Where there is any reason to doubt the wrongfulness of the respondents conduct, a court should not find contempt. *Paul T.V. Delaware County Intermediate Unit,* 318 F.3d 545, 552 (3d Cir.2003). Willfulness is not an element of contempt, nor does evidence of good faith bar a conclusion that a defendant acted in contempt. *Robin Woods, Inc. v. Woods,* 28 F.3d 396, 399 (3rd Cir.1994).

***7** Moreover, substantial compliance with a court order is a defense to civil contempt. "[A] de-

fendant may not be held in contempt as long as it took all reasonable steps to comply." *Harris v. City of Philadelphia,* 47 F.3d 1311, 1324 (3d Cir.1994) (citations omitted). If a respondent "has made in good faith all reasonable efforts to comply" with a court order, "technical or inadvertent violations of the order will not support a finding of civil contempt ." *Raza v. Biase,* 2008 U.S. Dist. LEXIS 20526 *12 (D.N.J. March 14, 2008).

III. *DISCUSSION*

The first two elements of civil contempt are uncontested in this case. The Consent Orders were and are valid and controlling. Andrew Lane testified that he knew of the Orders, posted the Orders easily viewable in his office, and distributed the Orders to senior members of his staff. The third element, whether the Defendants' disobeyed the Orders, and the defense of Substantial Compliance are the dispositive issues in this case.

A. The Consent Orders

The FTC asserts that Defendants violated Sections III, IV and IX of the Consent Orders. Section III requires Defendants, in making claims about the health benefits of a product, to possess competent and reliable scientific evidence that substantiates their claims. "Competent and reliable scientific evidence" is defined in the Orders as: tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate results. Section IV bars Defendants from misrepresenting "the existence, contents, validity, results, conclusions, or interpretations of any test, study or research." Section 5 of the FTC Act provides a standard for determining whether a statement is deceptive. The Act details that the net impression created by the advertisement as a whole is the controlling factor. "The impression created by the advertising, not its literal truth or falsity, is the desideratum." *American Home Products v. FTC,* 695 F.2d 681, 687 (3rd Cir.1982). Section IX of the Consent Orders requires Defendants to maintain adequate records.

B. Section III

The FTC argues that Defendants did not rely upon competent reliable scientific evidence. In support of this contention, the FTC offered two expert witnesses, Dr. Heaney who testified regarding AdvaCAL and Dr. Niederberger who testified regarding Fertil Male. In response, Lane Labs presented two experts, Dr. Holick regarding AdvaCAL and Dr. Seibel regarding Fertil Male. Both of Defendants' witnesses testified that Lane Labs did have competent reliable scientific evidence to support its claims. As stated above, the Court was more swayed by the defense experts. The result of both the FTC's and Defendants' considerable efforts is that this case has become a battle of the experts.

***8** The Court found all four of the above identified experts to be credible and their testimony to be informative. Of critical importance is the fact that Dr. Heaney testified that AdvaCAL is a good source of calcium and that Dr. Niederberger merely questioned what can be determined from the studies pertaining to Maca, the active ingredient in Fertil Male. Neither of the FTC's experts stated that the supplements marketed by Lane Labs are not effective [FN3] or constitute a health risk to the public. Further, Lane Labs' experts testified that they believe that the supplements do indeed have beneficial effects and that they would not hesitate in advising their clients to take them when appropriate.

> FN3. The Court recognizes that Dr. Niederberger testified that Maca, the active ingredient in Fertil Maile, has not been shown to have a benefit. Dr. Niederberger's statement, however, is predicated upon his belief that the substantiation provided by Defendants is inconclusive and not upon research undertaken by Dr. Niederberger personally or research evidencing that Maca is ineffective.

In support of its motion, the FTC engaged in

significant discovery and presented a nuanced case that delved into the details of every piece of substantiation offered by Lane Labs. While the FTC's experts identified several questionable aspects to the studies and reports offered by Lane Labs, Lane Labs' experts explained why these concerns do not negate the value of the studies and reports. Additionally, the Court considers the fact that Lane Labs did what they were suppose to do, what Dr. Heaney suggested a lay person should do. That is, before relying on scientific articles Lane Labs sought expert advice. This is not a case of a company making claims out of thin air. Of concern to the Court is the notion that a lay person should have to do more than can reasonably be expected when confronted with both reliable and/or peer reviewed studies and articles. Lane Labs found a product and obtained scientific evidence that the product is efficacious. Lane Labs then consulted experts who opined that the research supporting the product and the product itself were good. Lane Labs acted in accordance with the spirit of Judge Bassler's Orders.

In a further effort to comply with the Consent Orders, Lane Labs submitted to the FTC multiple voluminous compliance reports between 2001 and 2006 [FN4]. Lane Labs under took efforts to verify the claims it had made and intended to make about the products at issue. Additionally, Lane Labs hired a compliance officer, Jennifer Morganti from 2001 to 2004. During the hearing, Lane Labs provided credible expert testimony in support of both the claims it made and the substantiation it provided in support of those claims. As a result, the Court is satisfied that Lane Labs complied with Section III of the Consent Orders.

> FN4. It has not gone unnoticed by the Court that the Defendants submitted substantiation and multiple compliance reports in a timely manner during the years of 2001 through 2006, as required by the Consent Orders. By submitting compliance reports, Defendants basically informed the FTC of their plans in advance. In spite of these submissions, the FTC never contacted or advised Defendants of a compliance issue until January 12, 2007. In the Court's view, Defendants acted reasonably and appropriately in assuming that they were in compliance since they heard nothing to the contrary for years.

C. Section IV

The primary issue here is what impression was created by the advertising distributed by Lane Labs. *American Home Products,* 695 F.2d at 687. The FTC presented many pieces of advertising that were created and circulated by Defendants. These advertisements, as could be expected, strongly encouraged consumers to buy Defendants' products.

During the hearing, the FTC provided evidence that some of the statements contained in the advertising claims made by Defendants were incorrect. Mr. Lane admitted during his testimony that some things slipped through the cracks and that errors were made over a number of years. This notwithstanding, the impression created by Defendants' advertisements is that both supplements are good products that will most likely help the people who take them. While the FTC believes this is a false impression, as stated above, even the FTC's experts do not go as far as to say that the products do not work and Dr. Heaney acknowledged that AdvaCAL is a good source of calcium. Moreover, Defendants provided credible medical testimony that the products in question are good products and could have the results advertised by Defendants. Therefore, the FTC has not carried its burden of demonstrating that Lane Labs has created a false impression in violation of Section IV of the Consent Orders.

D. Section IX

***9** The FTC argues that Defendants have not complied with their obligation to maintain records regarding all of the claims they made in their advertisements. While this issue was not initially identified in the FTC's trial brief, at trial it became evident that an early poster presentation obtained

and relied upon by Defendants and a version of an advertisement were not submitted to the FTC as required by the Consent Orders. Given the amount of material that has been kept, and the fact that the poster was created and obtained by Lane Labs prior to the issuance of the Orders, it appears that Defendants have made every reasonable effort to comply with the record keeping requirement and certainly did not intentionally discard covered materi- al.

E. Substantial Compliance

Defendants argue alternatively that even if there are technical issues regarding their actions, they have made a good faith effort to substantially comply with the Consent Orders. In response, the FTC argues that the issues it raises are not technical or inadvertent and that Defendants have not taken all reasonable steps to comply with the Consent Orders and therefore, Defendants cannot argue substantial compliance.

As detailed above, the Defendants have undertaken considerable efforts to learn about the products at issue and to make claims that they believed were supported by credible evidence. More to the point, Defendants have exerted considerable effort to comply with the Consent Orders including seeking expert advise and hiring a compliance officer. Based on the evidence offered by the FTC, it is evident that the materials relied upon by Defendants are in hindsight not perfect. This however, does not negate Defendants' efforts to obtain good information and expert advice.

The application of the substantial compliance defense is further supported by Defendants submission of compliance reports for years which the FTC ignored until preparing to commence this action. Defendants submitted lengthy reports which evidence the fact that they exerted great effort to try and comply with the Orders.

Moreover, Defendants' submissions raise a significant issue of fundamental fairness. The FTC addresses this issue by arguing that Defendants are trying to avail themselves of the defense of laches. The FTC argues that allowing Defendants to rely upon this defense would turn the Orders on their head because it would allow Defendants to "wantonly violate the Orders unless and until the FTC took action." The FTC further argues that the laches defense fails as a matter of law because "[a]s a general rule laches or neglect of duty on the part of officers of the Government is no defense to a suit by it to enforce a public right or protect a public interest." *Nevada v. United States,* 463 U.S. 110, 141, 103 S.Ct. 2906, 77 L.Ed.2d 509 (1983); *Mudric v. Atty. Gen. of the United States,* 469 F.3d 94, 99 (3d Cir.2006).

The FTC mis-conceptualizes the issue. The issue here is not that Defendants broke the law and the FTC did nothing to stop it. At issue is whether Defendants were compliant with the Consent Orders. Defendants thought they were compliant and undertook significant efforts to be compliant. In the Court's view, Defendants' voluminous submissions to the FTC which detail all of the substantiation Defendants obtained along with Defendants' other actions such as hiring a compliance officer, justify Defendants' belief that they were compliant with the Orders. In this Court's opinion, to tell Defendants that their efforts were not good enough years after not advising them of any compliance issues is disingenuous and is highly relevant to the inquiry into whether Defendants should have done something different in the first instance. Moreover, the Court notes that there has been no physical harm to the public. The FTC seeks to have the Court fine Defendants to allow the FTC to distribute the monies collected to consumers to cure consumer injury resulting from alleged over payment for Defendants' products. Despite the FTC's claims, the FTC provides no evidence that consumers have complained that they were physically harmed by the use of either supplement. This compounds the fundamental fairness issues in this case.

***10** The issues raised by the FTC in this action are subject to interpretation. The differences

between the expert opinions evidences this fact. The Orders do not specifically require that which the FTC is arguing was and is required. If the Defendants were not able to present justification for its claims and actions, then the FTC's laches argument might be relevant, however, Defendants have support for their position. Given that Defendants obtained and provided scientific evidence that experts in the field said could be relied upon and they were never told otherwise, it would be fundamentally unfair to now say that they have been violating the Orders and therefore must pay a prohibitive penalty. The facts presented by Defendants and the failure of the FTC to timely consider Defendants' compliance reports suggest that Defendants took all reasonable steps to substantially comply with the Consent Orders.

IV. *CONCLUSION*

For the reasons stated, the FTC's motion for a finding of contempt is **denied.** An appropriate Order accompanies this Opinion.

D.N.J.,2009.
F.T.C. v. Lane Labs-USA, Inc.
Slip Copy, 2009 WL 2496532 (D.N.J.), 2009-2 Trade Cases P 76,708

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Not Reported in F.Supp.2d, 2005 WL 6054963 (S.D.Cal.)
(Cite as: 2005 WL 6054963 (S.D.Cal.))

United States District Court,
S.D. California.
Joel D. WALLACH, D.V.M., N.D., an individual, and American Longevity, Inc., a California Corporation, Plaintiffs,
v.
Lester M. CRAWFORD, D.V.M., in his official capacity as Acting Commissioner of the United States Food and Drug Administration; the Food and Drug Administration; Tommy G. Thompson, in his official capacity as Secretary of the Department of Health and Human Services; the Department of Health and Human Services; and the United States of America, Defendants.

No. 04CV216 BTM (WMC).
March 29, 2005.

Jonathan W. Emord, Andrea G. Ferrenz, Kathryn E. Balmford, Emord and Associates, Reston, VA, Steven W. Haskins, Haskins and Associates, Bonita, CA, for Plaintiffs.

U.S. Attorney CV, U.S. Attorneys Office Southern, San Diego, CA, for Defendants.

ORDER DENYING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT; GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISMISS AND DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

BARRY TED MOSKOWITZ, District Judge.

***1** On February 3, 2004, Plaintiff Dr. Wallach and American Longevity, Inc. (collectively "Plaintiffs") filed a complaint against the Food and Drug Administration ("FDA"), Commissioner Lester Crawford, the Department of Health and Human Services, Secretary Tommy Thompson and the United States (collectively "Defendants"). On April 23, 2004, Plaintiffs amended their Complaint alleging two primary causes of action: (1) that 21 U.S.C. § 343-2(a)(2-5) on its face violates the First Amendment to the United States Constitution; and (2) that the FDA's enforcement policy, which construes all scientific literature distributed by a supplement manufacturer as evidence of the manufacturer's intent to sell an unapproved new drug *even if* the distribution squarely falls under the § 343-2(a) labeling exemption, also violates the First Amendment.

On May, 13, 2004, Plaintiffs filed a motion for summary judgment moving the Court to find that 21 U.S.C. § 343-2(a)(2-5) and the FDA's enforcement policy regarding scientific literature violate the First Amendment as a matter of law. On August 9, 2004, Defendants conjunctively opposed Plaintiffs' summary judgement motion and filed a motion to dismiss and an alternative cross-motion for summary judgment. Defendants contend that Plaintiffs lack standing to sue and that in any case, both § 343-2(a) and the FDA's enforcement policy do not violate the First Amendment as a matter of law.

I. *FACTUAL BACKGROUND*

Plaintiffs American Longevity and its president, Dr. Wallach, distribute dietary supplements and food products to a network of United States distributors who, in turn, sell Plaintiffs' products to customers. Plaintiffs sell more than 50 different dietary supplements and food products including 14 different supplements containing magnesium.

Plaintiffs seek to send a "Magnesium Package" to their distributors which includes the following materials: (1) a cover letter inviting the distributors to purchase Plaintiffs' magnesium dietary supplements; (2) a reprint of the Physicians Desk Reference describing magnesium's effect on health and disease, as well as magnesium's use for treating certain medical conditions; (3) a listing of Plaintiffs' supplements containing magnesium, prices, and ordering information; and (4) stickers which are af-

fixed to every page of the package bearing the American Longevity name and logo and the statement "To Order Call American Longevity 1-800-982-3197." (*See* Pls.' First. Am. Compl., Ex. 1.)

The Physicians Desk Reference ("PDR") chapter on magnesium is a peer-reviewed, scientific reference text published by Medical Economics Company, Inc. The chapter contains basic nutrient information about magnesium and also includes information on how magnesium is currently used to treat to certain diseases. (*See* Pls.' Statement of Material Facts, Ex. 5.)

Plaintiffs have refrained from distributing the Magnesium Package to its distributors and sales force fearing that the Package fails to qualify for a 21 U.S.C. § 343-2(a) labeling exemption and will therefore invoke an adverse FDA enforcement action against American Longevity. Plaintiffs also fear that the FDA will invoke its intended use enforcement policy regardless of whether their distribution of the Magnesium Package meets the criteria of 21 U.S.C. § 343-2(a) and construe Plaintiffs' magnesium supplements as unapproved new drugs. To date, the FDA has taken no affirmative enforcement action against Plaintiffs.[FN1] Plaintiffs move this Court to declare 21 U.S.C. § 343-2(a)(2-5) and the FDA's enforcement policy unconstitutional, and to enjoin the FDA from restricting Plaintiffs' planned distribution of the Magnesium Package.

> FN1. Plaintiff states that they sent the FDA a letter regarding the legality of their planned Magnesium package distribution, but received no reply. (*See* Pls.' Surreply at 1.)

II. *STATUTORY BACKGROUND*

***2** The Food and Drug Administration is established within the Department of Health and Human Services. 21 U.S.C. § 393(a). The FDA's statutory mission, in part, is to promote and protect the public health by promptly reviewing clinical research and ensuring that foods and drugs are safe and properly labeled, and there is reasonable assurance of the safety and effectiveness of devices intended for human use. 21 U.S.C. § 393(b).

The Food, Drug and Cosmetics Act ("FDCA") regulates and defines dietary supplements, drugs, and their labeling. *See generally* 21 U.S.C. § 301-97. In 1990, Congress passed the Nutrition Labeling and Education Act ("NLEA") which amended the FDCA to specifically authorize certain types of claims in dietary supplement labeling without triggering formal drug regulations. *See* 21 U.S.C. §§ 343(r)(1)(B), (r)(5)(D); 21 C.F.R. §§ 101.14, 101.70. In 1994, Congress enacted the Dietary Supplement Heath and Education Act ("DSHEA"), PUB.L. NO. 103-417, 108 Stat. 4325, which established a new regulatory category for "dietary supplements" defining them as a product (other than tobacco) intended to supplement the diet that contains vitamins, minerals, herbs or other botanical, amino acid, or dietary substances for use by humans to supplement their diet. 21 U.S.C. § 321(ff)(1).

In drafting the DSHEA, Congress for the first time defined a "dietary supplement" so as to differentiate it from a "drug." S.Rep. No. 103-410 at 34-35. Moreover, the DSHEA established "dietary supplements as a separate category of product under the Federal Food, Drug and Cosmetic Act." *Id.* at 35. Congress understood that "if a product meets the new definition of a dietary supplement, it is not a drug under ... the Act (unless its labeling makes disease claims prohibited by the Act)." *Id.* (parenthetical in original). The Senate Report noted that "under current law [pre-DSHEA and § 343-2(a)], any literature used in connection with the sale or distribution of a product becomes 'labeling' for that product, meaning that any claims contained in that literature are considered as if they were printed on the label of the product." S.Rep. No. 103-410 at 36.

Congress amended the law to exclude truthful scientific literature from the definition of labeling such that "any claims found in scientific reports, for

example, would not be attributed to the person who sold or distributed a supplement described in that report." *id.* Specifically, the DSHEA amended the FDCA to include 21 U.S.C. § 343-2(a) which creates a dietary supplement labeling exception for certain qualified publications. The DSHEA also added § 343(r)(6) to the FDCA which lists requirements and allowable statements for disease/health related claims in labeling that fall under § 343(r)(1)(B).

III. *DISCUSSION*

Plaintiffs essentially argue that both 21 U.S.C. § 343-2(a)(2-5) and the FDA's enforcement policy regarding distribution of scientific literature violate the First Amendment. Defendants contend that Plaintiffs lack standing and that neither 21 U.S.C. § 343-2(a)(2-5) nor the FDA's enforcement policy violate the First Amendment.

A. *STANDING*

***3** Article III of the United States Constitution requires that a party have standing to bring an action in federal court. *Luian v. Defenders of Wildlife,* 504 U.S. 555, 560, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992) ("[T]he core component of standing is an essential and unchanging part of the case-or-controversy requirement of Article III."). The doctrine of standing contains three elements: (1) plaintiff must have suffered an injury in fact; (2) the injury must be fairly traceable to the challenged action of the defendant; and (3) it must be likely that the injury will be redressed by a favorable court decision. *Id.* at 560-61 (citations omitted). The party invoking federal jurisdiction bears the burden of establishing these elements. *Id.* at 561 (citations omitted). "Since they are not mere pleading requirements but rather an indispensable part of the plaintiff's case, each element must be supported in the same way as any other matter on which the plaintiff bears the burden of proof ...." *Lujan,* 504 U.S. at 561.

1. *PLAINTIFFS' FIRST CAUSE OF ACTION*

Plaintiffs first claim that 21 U.S.C. § 343-2(a)(2-5) violates the First Amendment as an undue burden on speech. Defendants contend that Plaintiffs lack standing to challenge 21 U.S.C. § 343-2(a)(2-5) as unconstitutional because § 343-2(a) on its face is not a prohibitive statute. Defendants point to the fact that failing to meet the criteria of § 343-2(a) does not create any violation under the FDCA or authorize the FDA to prohibit or sanction any speech. Moreover, Defendants contend that § 343-2(a) is merely a "safe harbor" provision that exempts certain scientific literature from the FDCA "labeling" definition, and therefore, § 343-2(a) in and of itself cannot serve as an injury in fact that is fairly traceable to Defendants. Plaintiffs maintain that they have standing to raise a First Amendment pre-enforcement challenge of § 343-2(a)(2-5) because these subsection requirements have a clear speech suppressive impact when read in context with the FDCA enforcement scheme as a whole. The Court agrees.

On its face, § 343-2(a) does not prohibit or sanction any speech or conduct. Nor does it create an express violation for non-qualifying scientific literature. 21 U.S.C. § 343-2(a) reads:

> A publication, including an article, a chapter in a book, or an official abstract of a peer-reviewed scientific publication that appears in an article and was prepared by the author or the editors of the publication, which is reprinted in its entirety, shall not be defined as labeling when used in connection with the sale of a dietary supplement to consumers when it-
>
> (1) is not false or misleading;
>
> (2) does not promote a particular manufacturer or brand of a dietary supplement;
>
> (3) is displayed or presented, or is displayed or presented with other such items on the same subject matter, so as to present a balanced view of the available scientific information on a dietary supplement;
>
> ***4** (4) if displayed in an establishment, is physic-

ally separate from the dietary supplements; and

(5) does not have appended to it any information by sticker or any other method.

21 U.S.C. § 343-2(a)(1)-(5).

Clearly, this section exempts qualified publications from being construed as labeling. *Id.* However, § 343-2(a) is not immune from constitutional attack merely because the statute, read in vacuum, does not create an express violation for failure to meet its criteria or independently authorize the FDA to restrict speech. To fully understand § 343-2(a)'s speech implications, the Court must necessarily look to its interplay with the other FDA statutes and regulations regarding labeling. As Plaintiffs point out, § 343-2(a) should be read together with the FDA's definitions of labeling, drugs, and the prohibition against the sale of unapproved and/or misbranded drugs. In this light, Section 343-2(a) clearly has speech restrictive implications when viewed in conjunction with the overall FDA enforcement scheme. Simply put, if Plaintiffs' promotional Magnesium Package fails to qualify for a § 343-2(a) labeling exemption, it will be construed as labeling thereby exposing Plaintiffs to heightened regulations and a clear threat of enforcement. Indeed, the Magnesium Package, construed as labeling, could transform Plaintiffs' magnesium supplements themselves into unapproved new drugs in terms of FDA enforcement. This constitutes a patent chilling effect on Plaintiffs' speech which effects their day to day operations.[FN2]

FN2. *Cf., e.g., National Park Hospitality Ass'n v. Department of Interior,* 538 U.S. 803, 810, 123 S.Ct. 2026, 155 L.Ed.2d 1017 (2003) ("conclud[ing that] the case was not ripe for judicial review because the impact of the regulation could not 'be said to be felt immediately by those subject to it in conducting their day-to-day affairs' ") (quoting *Toilet Goods Ass'n. Inc. v. Gardner,* 387 U.S. 158, 164, 87 S.Ct. 1520, 18 L.Ed.2d 697 (1967)); *Municipality of Anchorage v. United States,* 980 F.2d 1320, 1326 (9th Cir.1992) ("[P]laintiffs have failed to show that they will suffer any immediate, direct, or significant hardship ... [where the policy] imposes no present, affirmative duties on plaintiffs, requires no immediate changes in plaintiffs' conduct, and does not impact, in any way, plaintiffs' day-to-day affairs.").

"Labeling" is defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). The Supreme Court, in *Kordel v. United States,* expanded the definition of labeling by holding that "the phrase 'accompanying such article' is not restricted to labels that are on or in the article o[r] package that is transported." 335 U.S. 345, 349, 69 S.Ct. 106, 93 L.Ed. 52 (1948). The Court in *Kordel* held that promotional pamphlets and circulars distributed by the drug manufacturerto its vendors, though *separate* from the drug product, nevertheless constituted "labeling" thereby rendering the product misbranded.[FN3] *Id.* at 346-49.

FN3. *Kordel* reasoned that the "products and the literature were interdependent" because "the drugs and the literature had a common origin and a common destination ... [t]he literature was used in the sale of the drugs ... it explained their uses ... [n]owhere else was the purchaser advised how to use them [and] ... it constituted an essential supplement to the label attached to the package." *Kordel.* 335 U.S. at 348.

A "drug" is defined as:

(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) art-

> icles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

21 U.S.C. § 321(g)(1). Section 321(g)(1) goes on to specifically provide that a dietary supplement's label containing a claim that links a nutrient to a disease or health related condition will not render the supplement a "drug" if the claim otherwise complies with 21 U.S.C. § 343(r). *See id.* Importantly, 21 U.S.C. § 343(r)(5)(D) provides that a dietary supplement with such a disease/health claim in its labeling is not subject to § 343(r) (1)(B)'s pre-publication FDA approval process.[FN4]

> FN4. *See also* 21 U.S.C. § 343(r)(6) (delineating the FDA pre-approval requirements to make such a claim under § 343(r)(1) (B)); 21 C.F.R. 101.14(a)(1) (defining a "health claim" made in the labeling of a dietary supplement).

***5** However, under § 343(r)(5)(D), the dietary supplement with a disease/health claim in its labeling remains "subject to a procedure and standard, respecting the validity of such claim, established by regulation of the Secretary." 21 U.S.C. § 343(r) (5)(D).[FN5] Here, the FDA still requires a pre-authorization process. *See* 21 C.F.R. §§ 101.14, 101.70. Moreover, a disease/health claim in a dietary supplement's labeling will not render the underlying supplement a drug only if the FDA, after reviewing appropriate scientific evidence, promulgates a specific regulation authorizing such a claim. 21 C.F.R. § 101.14(c).[FN6]

> FN5. *See also* 21 U.S.C. § 321(d) ("The term 'Secretary' means the Secretary of Health and Human Services.").

> FN6. Specifically, 21 C.F.R. § 101.14(c) provides that the FDA "will promulgate regulations authorizing a health claim *only when* it determines, based on the totality of publicly available scientific evidence ... that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence." *Id.* (emphasis added). *See also id.* § 101.14(a), (d).
>
> Oddly, § 101.14(c) is identical to the § 343(r)(3)(B)(i) pre-authorization requirement that § 343(r)(5)(D) expressly exempts dietary supplements from in the first place. *Compare* 21 U.S.C. § 343(r)(3)(B)(i) *with id.* § (5)(D) *and* 21 C.F.R. § 101.14(c). Thus, it appears that the FDA has avoided § 343(r)(5) (D) s express exemption for dietary supplements (from § 343(r)(3)'s pre-approval regulation) by placing the same subparagraph (3) pre-approval regulation as a backdoor requirement pursuant to § 343(r)(5)(D). In any case, the point remains the same-heightened regulation exists if a dietary supplement publication is deemed labeling.

Thus, if Plaintiffs' Magnesium Package publication is considered labeling, the health/disease claims in the PDR section will subject Plaintiffs to pre-approval regulations and restrictions established by the FDA. *See* 21 U.S.C. § 343(r)(5)(D); 21 C.F.R. §§ 101.14, 101.70. Indeed, Defendants themselves state that the FDA imposes these requirements on dietary supplement labeling via "the pre-authorization requirement for health claims and the postmarket notification requirement for structure/function and classic nutrient deficiency disease claims." (Def.'s Reply at 5; *see also* Def. Mem. in Support of Motions at 6-7.) Defendants further agree that these two restrictions require prior submission to the FDA. (*Id.*)

The FDCA itself also provides that a dietary supplement will be deemed misbranded if its *labeling* fails to contain certain minimum requirements. *See* 21 U.S.C. § 321(s)(2)(A)(E). Thus, if

the Magnesium Package is considered labeling, Plaintiffs will then be subject to heightened regulations and restrictions established under 21 U.S.C. § 321(s) to ensure that the magnesium supplements are not misbranded or sold as an unapproved new drug.

Under the FDCA, a dietary supplement's labeling can readily transform the supplement into a "drug" pursuant to the "intended use" drug definition. *See* 21 U.S.C. 321(g)(1) (defining a drug, in part, as "articles *intended for use* in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals ... and articles (other than food) *intended* to affect the structure or any function of the body of man or other animals") (emphasis added). If a manufacturer's publication is considered labeling, then the claims in the publication/label may be construed as evidence of the manufacturer's "intended use" of its supplement as an unapproved new drug. *See id. Accord Kordel,* 335 U.S. at 350; *National Nutritional Foods Ass'n v. Mathews,* 557 F.2d 325, 334 (2nd Cir.1977); *U.S. v. Article Consisting of 36 Boxes, More or Less, Labeled "Line Away Temporary Wrinkle Smoother, Coty",* 415 F.2d 369, 371 (3d Cir.1969); 21 U.S.C. § 321(g)(1). Moreover, any promotional publication that fails to qualify for a § 343-2(a) labeling exemption, will expose the manufacturer to heightened regulation over the claims in the publication/label as well as the underlying supplement the manufacturer distributes, which could then be defined as a drug. Thus, if the Magnesium Package is construed as labeling because it fails to qualify for a § 343-2(a) exemption, then the claims within the PDR chapter could transform Plaintiffs' magnesium supplements into unapproved new drugs. *See* 21 U.S.C. § 321(g)(1). At oral argument, Defendants admitted that FDA enforcement would no doubt follow such a scenario.

***6** As such, failing to meet the criteria of § 343-2(a)-which exempts qualified publications from the definition of labeling-serves to restrict Plaintiffs' speech by imposing heightened regulation via coexisting statues within the interdependent enforcement scheme. Plaintiffs submit that their planned distribution of the Magnesium Package does not comply with § 343-2(a) and therefore is ineligible for a labeling exemption. Thus, Plaintiffs' planned distribution of the Magnesium Package will be construed as labeling under *Kordel* and therefore subject Plaintiffs to heightened FDA regulation and a imminent threat of enforcement action. *See Abbott Laboratories v. Gardner,* 387 U.S. 136, 152-56, 87 S.Ct. 1507, 18 L.Ed.2d 681 (1967) (holding that a pre-enforcement challenge to drug labeling regulations was ripe for review where the impact of the regulations upon the petitioners was sufficiently direct and immediate). Indeed, distributing the promotional publication as labeling would inevitably be evidence of Plaintiffs' intended use of their product as a drug, which could potentially render their underlying magnesium supplements "drugs" under 21 U.S.C. § 321(g) (1). The chilling effect on Plaintiffs' speech here is obvious.

Taken together, the role that § 343-2(a) plays within the overall FDA enforcement scheme constitutes a "concrete and particularized" injury in fact that is "not conjectural or hypothetical." *Lujan,* 504 U.S. at 560. Furthermore, Plaintiffs face a direct threat of enforcement that affects their day to day business as well as their vendor and customer relationships. *See Abbott Labs.,* 387 U.S. at 152-53. This injury is fairly traceable to Defendants. *See Luian,* 504 U.S. at 560. Indeed, the Court could remedy Plaintiffs' alleged injury by striking certain provisions of § 343-2(a) thereby permitting Plaintiffs' Magnesium Package to qualify for the labeling exemption. *See Gonzales v. Gorsuch,* 688 F.2d 1263, 1267 (9th Cir.1982) ("It is a prerequisite of justiciability that judicial relief will prevent or redress the claimed injury, or that there is a significant likelihood of such redress."). Accordingly, the Court finds that Plaintiffs have standing to challenge § 343-2(a)(2-5) as violating the First Amendment.

2. *PLAINTIFFS' SECOND CAUSE OF ACTION*

Plaintiffs next claim that the FDA's enforcement policy of using promotional scientific literature exempted from labeling under § 343-2(a) as evidence of a manufacturer's intent to distribute an unapproved new *drug* rather than just a dietary supplement violates the First Amendment. Plaintiffs contend that if a manufacturer's publication qualifies for a § 343-2(a) labeling exemption, the FDA can no longer construe it as evidence of the manufacturer's intended use to market an unapproved new drug instead of a dietary supplement under 21 U.S.C. 321(g)(1).

Plaintiffs, however, concede that their Magnesium Package does not satisfy § 343-2(a)'s criteria and therefore does not qualify for a labeling exemption. (*See* Pls.' Mot. for Summ. J. at 6; Pls.' Statement of Material Facts at 4.) Furthermore, Plaintiffs do not contest the FDA's intended use enforcement policy regarding manufacturer publications that do *not* qualify for a § 343-2(a) labeling exception.[FN7]

> FN7. Indeed, in arguing that Plaintiffs have standing to challenge § 343-2(a), Plaintiffs contend that the FDA may properly look to third party literature distributed by the manufacturer, which fails to qualify for a labeling exemption, as evidence of that manufacturer's intended use for its product. *Cf. United States v. Lane Labs-USA, Inc.*, 328 F.Supp.2d 547, 568-69 (D.N.J.2004) (holding that promotional third party literature distributed by the defendant manufacturer did not qualify for a § 343-2(a) labeling exemption and thus construing the publications as the manufacturer's intended use for its product).

***7** The Magnesium Package, as presented to this Court, patently fails to meet § 343-2(a)(2), (3), and (5).[FN8] Plaintiffs admit that their planned distribution of the Magnesium Package does not qualify for a § 343-2(a) labeling exception and have thus refrained from sending it out. While Plaintiffs submit that they will include a disclaimer on the Package if necessary, Plaintiffs do not contend that they will or can change the Package itself to comply with § 343-2(a)(2-5). Thus, the FDA's enforcement policy of construing publications that meet § 343-2(a) as evidence of intended use, cannot be invoked against Plaintiffs because their Package does not and cannot meet § 343-2(a) as it currently stands. *See Citizens for Honesty and Integrity in Regional Planning v. County of San Diego,* 399 F.3d 1067, 2005 WL 433598, *1 (9th Cir. Feb 25, 2005) (finding no basis for federal jurisdiction, in part, where "there [was] no threat of prosecution, imminent or otherwise, or evidence that the County intend[ed] to employ the local definition against [the plaintiffs]"); *Black Faculty Ass'n of Mesa College v. San Diego Community College Dist.,* 664 F.2d 1153, 1155 (9th Cir.1981) (the plaintiff must "show a direct, individualized injury") (citation omitted). Moreover, the FDA's contested enforcement policy at issue here does not even apply to Plaintiffs' Magnesium Package in this case. *See Warth v. Seldin,* 422 U.S. 490, 501, 95 S.Ct. 2197, 45 L.Ed.2d 343 (1975) (Article III requires that "the plaintiff ... must allege a distinct and palpable injury to himself"). At best, Plaintiffs' allegations here are generalized, conjectural and hypothetical. *Lujan,* 504 U.S. at 560. This does not amount to a concrete injury in fact sufficient to confer Article III standing. *See id. See also City of Los Angeles v. Lyons,* 461 U.S. 95, 101, 103 S.Ct. 1660, 75 L.Ed.2d 675 (1983) ("Plaintiffs must demonstrate a 'personal stake in the outcome' in order to 'assure that concrete adverseness which sharpens the presentation of issues' necessary for the proper resolution of constitutional questions.") (quoting *Baker v. Carr,* 369 U.S. 186, 204, 82 S.Ct. 691, 7 L.Ed.2d 663 (1962)); *Whitmore v. Arkansas,* 495 U.S. 149, 155-156, 110 S.Ct. 1717, 109 L.Ed.2d 135 (1990) (the injury in fact "must be concrete in both a qualitative and temporal sense"). As such, Plaintiffs lack standing to bring their second claim and the Court dismisses it on that ground.[FN9]

> FN8. Plaintiffs submit that the Magnesium Package also fails to meet § 343-2(a)(4)

> Because the Package has not been distributed, the Court cannot determine its compliance with § 343-2(a)(4) at this time. As to § 343-2(a)(1), Plaintiffs do not contest its validity and contend that the Magnesium Package meets this requirement.
>
> FN9. *See Whitmore* 495 U.S. at 155-156 ("A federal court is powerless to create its own jurisdiction by embellishing otherwise deficient allegations of standing."). If the Court were to alter § 343-2(a) by striking sub-sections (2) through (5) as unconstitutional (as Plaintiff requests), then, and only then, would Plaintiffs' Magnesium Package potentially comply with § 343-2(a) (as severed) thereby triggering the FDA's "intended use" enforcement policy as to them. However, this protracted scenario, dependent on future action by this Court, does not constitute a concrete injury in fact. *See Lyons,* 461 U.S. at 102 ("Abstract injury is not enough. The plaintiff must show that he has sustained or is immediately in danger of sustaining some direct injury as the result of the challenged official conduct ....") (internal quotation marks omitted).

B. *WHETHER 21 U.S.C. § 343-2(A)(2-5) VIOLATES THE FIRST AMENDMENT*

Plaintiffs contend that 21 U.S.C. § 343-2(a)(2-5) violates the First Amendment as an undue burden on speech. Specifically, Plaintiffs purport to argue that subsections (2) through (5) do not comply with the legislative intent behind § 343-2(a). Further, they argue that those subsections fail the " *Central Hudson* " test because they are irrational requirements that do not directly advance the government's substantial interest in protecting the public health and ensuring the accuracy of information in the marketplace. *See Central Hudson Gas and Elec. Corp., v. Pub. Serv. Comm'n,* 447 U.S. 557, 100 S.Ct. 2343, 65 L.Ed.2d 341 (1980). Thus, Plaintiffs argue that because the subsection provisions (2) through (5) are severable, they should therefore be stricken leaving only § 343-2(a)(1).[FN10]

> FN10. Basically, Plaintiffs would have § 343-2(a) read as follows:
>
> > A publication, including an article, a chapter in a book, or an official abstract of a peer-reviewed scientific publication that appears in an article and was prepared by the author or the editors of the publication, which is reprinted in its entirety, shall not be defined as labeling when used in connection with the sale of a dietary supplement to consumers when it-
> >
> > (1) is not false or misleading.
>
> (*See* Pl.'s Mot. for Summ. J. at 23.) *Cf.* 21 U.S.C. § 343-2(a)(1)-(5).

***8** The Court does not find § 343-2(a) unconstitutional on its face. Moreover, the Court concludes that subsections (2) through (5) clearly effectuate the legislative intent and constitute rational requirements that directly advance the government's interest under the established *Central Hudson* test.

1. *THE CENTRAL HUDSON TEST: REGULATING COMMERCIAL SPEECH*

Scientific literature distributed by a manufacturer in connection with the sale of dietary supplements is commercial speech. *Cf. Bolger v. Youngs Drug Prods. Corp.,* 463 U.S. 60, 67-68, 103 S.Ct. 2875, 77 L.Ed.2d 469 (1983); *Pearson v. Shalala,* 164 F.3d 650, 655 (D.C.Cir.1999). "Although commercial speech is protected by the First Amendment, not all regulation of such speech is unconstitutional." *Thompson v. Western States Medical Center,* 535 U.S. 357, 367, 122 S.Ct. 1497, 152 L.Ed.2d 563 (2002) (citing *Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.,* 425 U.S. 748, 770, 96 S.Ct. 1817, 48 L.Ed.2d 346 (1976)). *See also Central Hudson,* 447 U.S. at 561 ("The First Amendment ... protects commercial

speech from unwarranted governmental regulation.") (citation omitted). The Supreme Court in *Central Hudson* established a four prong test to determine whether a particular commercial speech regulation is constitutionally permissible. 447 U.S. at 562-563. *See also Thompson,* 535 U.S. at 367. The first prong involves a threshold inquiry into whether the communication is misleading or related to an unlawful activity. *Central Hudson,* 447 U.S. at 563-64. If so, the government may ban the speech without "constitutional objection." *id.* at 563. If the commercial speech is neither misleading nor related to an unlawful activity, then the "government's power is more circumscribed." *Id.* at 564. In this event, the government may only restrict the speech if: (1) the government interest is substantial; (2) the regulation directly advances the government interest involved; and (3) the regulation is no more extensive than necessary to serve the interest. *Id.* The government, as "[t]he party seeking to uphold a restriction on commercial speech carries the burden of justifying it." *Bolger,* 463 U.S. at 71, n. 20. *See also Edenfield v. Fane,* 507 U.S. 761, 770, 113 S.Ct. 1792, 123 L.Ed.2d 543 (1993).

a. *THRESHOLD INQUIRY: MISLEADING OR RELATED TO UNLAWFUL ACTIVITY*

Plaintiffs claim that the Magnesium Package pertains to the lawful activity of selling their magnesium supplements. Plaintiffs contend that the Magnesium Package consists primarily of the PDR chapter on magnesium and therefore is commercial speech of a very high order.[FN11] Defendants, on the other hand, argue that the Magnesium Package is misleading because the PDR chapter contains drug related claims. Furthermore, Defendants argue thatthe drug use claims turn Plaintiffs' planned distribution of the Package into an effort to market unapproved new drugs rather than magnesium supplements. As such, Defendants submit that the Magnesium Package relates to unlawful activity and warrants no constitutional protection.

FN11. The First Amendment protects scientific speech and expression. *See Miller v. California,* 413 U.S. 15, 34, 93 S.Ct. 2607, 37 L.Ed.2d 419 (1973); *Kevishian v. Board of Regents,* 385 U.S. 589, 603, 87 S.Ct. 675, 17 L.Ed.2d 629 (1967); *Board of Trustees of Leland Stanford Jr. Univ. v. Sullivan,* 773 F.Supp. 472 (D.D.C.1991).

***9** The government may ban *inherently* misleading speech outright. *See In re R.M. J.,* 455 U.S. 191, 203, 102 S.Ct. 929, 71 L.Ed.2d 64 (1982). However, the government "may not place an absolute prohibition on certain types of *potentially* misleading information ... if the information also may be presented in a way that is not deceptive." *Id.* (emphasis added). The Magnesium Package is not inherently misleading. The cover page states that the Package includes a reprinted chapter on magnesium from the PDR. While the Package is distributed in connection with the sale of a dietary supplement (not a drug), the PDR chapter does make repeated drug related claims. Specifically, the PDR chapter states that magnesium is used to treat certain diseases and makes other disease/health claims. However, the PDR chapter has its own disclaimer page on the cover. Furthermore, Plaintiffs attest to their willingness to put any disclaimer on the package necessary to cure any perceived ambiguity regarding their intent to distribute non-treating supplements. At worst, the Magnesium Package is only potentially misleading. Plaintiffs have demonstrated that the Package can be presented in a non-deceptive fashion by utilizing disclaimers.

As to being related to unlawful activity, Defendants' circular argument-that distributing the Magnesium Package is unlawful and therefore Plaintiffs cannot challenge the statutes that make it unlawful-should not bar a full-blown constitutional analysis under *Central Hudson.* Plaintiffs lawfully manufacture and distribute magnesium supplements. The fact that Plaintiffs seek to distribute the Magnesium Package to their distributors and sales force does not make their otherwise lawful activities unlawful. Plaintiffs have not distributed the

Magnesium Package nor has the FDA, in reply to Plaintiffs' letter, stated that they hold the Package as violating the law. While Defendants argue that the Package will render Plaintiffs' magnesium products "drugs" underthe intended use definition, the FDA has not formally taken any action. Plaintiffs' plan to distribute the Package does not relate to unlawful activity.

Accordingly, the Magnesium Package is not inherently misleading nor does it pertain to unlawful activity per se. Thus, the government may not place a absolute ban on Plaintiffs' proposed distribution of the Package.[FN12] The Court must move to the second prong of the *Central Hudson* test. *In re R.M.J.*, 455 U.S. at 203 ("Even when a communication is not misleading, the State retains some authority to regulate.").

> FN12. In any case, § 343-2(a)(2-5) does not place an absolute ban on Plaintiffs' proposed speech. *See In re R.M. J.*, 455 U.S. at 203. If the Magnesium Package failed to qualify for a § 343-2(a) labeling exemption, then Plaintiffs would be exposed to heightened regulation and pre-approval restrictions under the FDCA. At worst, the Magnesium Package's drug claims could render Plaintiffs' underlying products drugs under the intended use definition thereby subjecting Plaintiffs to the formal FDA drug approval process. Even so, § 343-2(a)(2-5) is not an absolute ban on Plaintiffs' speech.

b. *THE GOVERNMENT INTEREST*

The FDA's mission is to promote and protect the public health. 21 U.S.C. § 393(b). Plaintiffs concede that the government has a substantial interest in protecting the public health and safety. (*See* Pl.s Mot. for Summ. J. at 9.) Furthermore, they admit that the government has a substantial interest in protecting the public from harm. (*Id.*)

The Supreme Court has said "there is no question that [the government's] interest in ensuring the accuracy of commercial information in the marketplace is substantial," *Edenfield,* 507 U.S. at 769, and that government has a substantial interest in "promoting the health, safety, and welfare of its citizens," *Rubin v. Coors Brewing Co.,* 514 U.S. 476, 485, 115 S.Ct. 1585, 131 L.Ed.2d 532 (1995). "At this level of generality, therefore, a substantial governmental interest is undeniable." *Pearson v. Shalala,* 164 F.3d 650, 656 (D.C.Cir.1999).

c. *DIRECT ADVANCEMENT OF THE GOVERNMENT INTEREST*

***10** The Supreme Court has "declined to uphold regulations that only *indirectly* advance the state interest involved." *Central Hudson,* 447 U.S. at 564-565 (emphasis added). In *Bates v. State Bar of California,* the Court overturned an advertising prohibition that was designed to protect the "quality" of a lawyer's work because the "restraints on advertising ... [were] an ineffective way of deterring shoddy work." 433 U.S. 350, 378, 97 S.Ct. 2691, 53 L.Ed.2d 810 (1977). The regulation must *directly* advance the government interest. *Central Hudson,* 447 U.S. at 566; *Pearson,* 164 F.3d at 656.

Here, both Plaintiffs' and Defendants' arguments miss the mark. Plaintiffs purport to argue that § 343-2(a)(2-5) fails to comply with the underlying congressional intent and therefore does not directly advance the government's substantial interest. Defendants argue that the FDCA *drug approval requirement* directly advances the government interest instead of addressing the subsection regulations found in § 343-2(a) itself.

i. *CONGRESSIONAL INTENT*

As a threshold issue, Defendants argue that the Court should not even resort to an analysis of congressional intent because Plaintiffs have failed to meet their initial burden to demonstrate any ambiguity in § 343-2(a). (Def.'s Reply at 4.) *See Church of Scientology v. Dep't of Justice,* 612 F.2d 417, 421 (9th Cir.1979) ("If the language of a statute is clear and there is no ambiguity, then there is no need to interpret the language by resorting to the legislative history or other extrinsic aids."); *Califor-*

nia v. Montrose Chemical Corp., 104 F.3d 1507, 1514-15 (9th Cir.1997) (party claiming that statutory language is ambiguous bears the burden to show it). Insofar as Plaintiffs contest the constitutionality of § 343-2(a)(2-5), Plaintiffs have not demonstrated any ambiguity in the language of the statute or its individual subsection requirements. Section 343-2(a) is clear on its face in what it requires for a labeling exemption. *See* § 343-2(a)(1)-(5). Thus, the Court need not belabor an inquiry into the congressional intent as it applies to Plaintiffs' first cause of action.[FN13] *Rubin v. U.S.*, 449 U.S. 424, 430, 101 S.Ct. 698, 66 L.Ed.2d 633 (1981) ("When we find the terms of a statute unambiguous, judicial inquiry is complete, except in rare and exceptional circumstances [and] ... [n]o such circumstances are present here, for our reading of the statute is wholly consistent with the history and the purposes of the Securities Act of 1933.") (internal quotation marks and citations omitted).

> FN13. The Court notes that some ambiguity exists as to whether a § 343-2(a) labeling exemption also provides a shelter from the intended use definition of a drug. *See* 21 U.S.C. § 321(g)(1). However, this ambiguity only applies to Plaintiffs' second cause of action regarding the validity of the FDA's intended use enforcement policy, for which they lack standing. This ambiguity does not reach Plaintiffs' first cause of action challenging § 343-2(a) it- self.

However, even assuming that § 343-2(a) is ambiguous at some level, the Court finds that the legislative intent behind § 343-2(a) overwhelmingly supports the statute as it currently stands. In interpreting the meaning of a statute, a court must first look to the language of the statute itself. *See U.S. v. Ron Pair Enterprises, Inc.*, 489 U.S. 235, 241, 109 S.Ct. 1026, 103 L.Ed.2d 290 (1989) ("The task of resolving the dispute over the meaning of [a statute] ... begins where all such inquiries must begin: with the language of the statute itself."). Under this first, cardinal canon of construction, the Supreme Court has "stated time and again that courts must presume that a legislature says in a statute what it means and means in a statute what it says there." *Connecticut Nat. Bank v. Germain*, 503 U.S. 249, 253-54, 112 S.Ct. 1146, 117 L.Ed.2d 391 (1992) (citations omitted).

***11** Here, § 343-2(a) is sufficiently clear on it-face. The subsection provisions (1)through (5) are likewise clear in what they expressly mandate as prerequisites for exemption. *See* 21 U.S.C. § 343-2(a)(1)-(5). Plaintiffs have not demonstrated that the statute *does not mean what it says* in 4 out of its 5 subsection requirements. Moreover, "when the words of a statute are unambiguous, then, this first canon is also the last: 'judicial inquiry is complete.' " *Germain*, 503 U.S. at 253-54 (quoting *Rubin*, 449 U.S. at 430). *See also Ron Pair Enterprises*, 489 U.S. at 241 (although the party claimed that legislative history pointed to a different result, the court held that "judicial inquiry" into the applicability of the statute "begins and ends with what [the statute] does say").

A deeper examination into the legislative history as well makes clear that § 343-2(a)(2-5) directly advances the government's interest and Congress' intent in passing the statute to begin with. Congress essentially intended § 343-2(a) to provide a labeling exemption for "the use of certain types of third party literature in direct connection with the sale of dietary supplement products." S.Rep. No. 103-410 at 25.[FN14] However, Congress expressly cautioned that:

> FN14. *See also* S.Rep. No. 103-410 at 36 (Congress intended to create a labeling exception for "truthful scientific literature [used] in connection with the sale or distribution of dietary supplements."). This overall intent is clearly reflected in the plain words of the statute itself. *See* 21 U.S.C. § 343-2(a).

The literature would need to meet certain criteria

that would generally establish the independence and reliability of the material, i.e. the bill would require (a) that any such item would need to be "not false or misleading," (b) that it "not promote a particular brand of dietary supplement," (c) that it be displayed or presented so as to present a "balanced view" of the available information, and (d) that if displayed in a location in an establishment, it be displayed "physically separate" from the dietary supplements.
Id. See also id. at 36, 47. No doubt, Congress intended these requirements to advance the substantial government interest in promoting and protecting the public health and safety. Importantly, this summary report of the legislative intent behind the § 343-2(a) labeling exemption is nearly identical to the final version of the statute. *See* 21 U.S.C. § 343-2(a). As Plaintiffs themselves point out, "[t]he only difference between the summary appearing in the Senate Report and the statute is that the summary does not have the requirement of § 343-2(a)(5) (restricting the appended information by sticker or other method)." (Pls.' Surreply at 5.) Moreover, Plaintiffs concede that "[o]therwise the summary and the final law are identical." (*id.*) Thus, there in no evidence that § 343-2(a)(2-5) defies the true congressional intent behind the statute's inception. To the contrary, there is every indication that the statute and each of its subsection provisions patently meet Congress' expressed intent. *Compare* 21 U.S.C. § 343-2(a) *with* S. Rep. No 103-410 at 25, 36, 47.

While § 343-2(a)(5) is not specifically mentioned in the Senate Report summary, its relevance and importance to the other subsections as well as the overriding purpose of the statute cannot be doubted. Section 343-2(a)(5) requires that the qualified publication cannot have any additional information appended to it by sticker or any other method. 21 U.S.C. § 343-2(a)(5). Thus, a manufacturer cannot backdoor the other subsection requirements by adding new information via sticker or attachment to the otherwise content-neutral scientific literature. For instance, without § 343-2(a)(5), a manufacturer could simply place a sticker on the publication stating the manufacturer's name, address, ordering information, or product listings in an effort to get around § 343-2(a)(2)'s requirement that the literature itself not promote a particular brand of dietary supplement. Furthermore, adding a sticker or other attachment to the publication may render it misleading in that, in many circumstances, the reader would not know whether the third party author, the manufacturer, or the distributor added the additional information by sticker. *See* 21 U.S.C. § 343-2(a)(1). In this way, § 343-2(a)(5) ensures compliance with the other subsection requirements and serves the overall legislative purpose of exempting only truthful, non-misleading, and non-promotional publications. Thus, it materially advances the government's interest here.

***12** Overall, § 343-2(a), in its entirety, directly advances the government's interest in promoting public safety and protecting the public from fraud. *See Pearson,* 164 F.3d at 656 ("We also recognize that the government's interest in preventing consumer fraud/confusion may well take on added importance in the context of a product, such as dietary supplements, that can affect the public's health.") On its face, § 343-2(a)(2-5) ensures that the labeling exemption only applies to publications that are non-promotional and not misleading. This directly advances the government interest because § 343-2(a) exempted publications may contain health/disease claims or even drug claims regarding the underlying supplement.

Importantly, if § 343-2(a)'s labeling exemption does in fact provide a shelter from the FDA's intended use enforcement policy and drug definition, the government has an even greater interest in proscribing and regulating the qualifications necessary for the labeling exemption. Moreover, § 343-2(a) would then allow manufacturers to distribute scientific publications with drug claims regarding their underlying supplements without fear that those publications could render their supplements drugs under the intended use definition. In this light, §

343-2(a) must positively ensure that a publication is non-promotional in order to provide the intended use exception in the first place. Thus, § 343-2(a)(2-5) directly advances the government's special interest as well as the statute's intended purpose.

d. *REASONABLE FIT BETWEEN GOVERNMENT'S INTEREST AND CHOSEN MEANS*

The First Amendment mandates that speech restrictions be "narrowly drawn." *In re Primus,* 436 U.S. 412, 438, 98 S.Ct. 1893, 56 L.Ed.2d 417 (1978). "The regulatory technique may extend only as far as the interest it serves. The State cannot regulate speech that poses no danger to the asserted state interest ...." *Central Hudson,* 447 U.S. at 565 (citation omitted). Furthermore, the government cannot "completely suppress information when narrower restrictions on expression would serve its interest as well." *Id.* For example, in *Bates* the Supreme Court did not "foreclose the possibility that some limited supplementation, by way of warning or disclaimer or the like, might be required" in promotional materials. 433 U.S. at 384.

However, the regulation need not be the least restrictive measure that could effectively protect the government interest. *Board of Trustees of the State University of New York v. Fox,* 492 U.S. 469, 480, 109 S.Ct. 3028, 106 L.Ed.2d 388 (1989). In *Fox,* the Supreme Court explained that *Central Hudson* does not impose a least restrictive means requirement. *Id.* (the Court does not require that the "manner of restriction is absolutely the least severe that will achieve the desired end"). Rather, *Fox* made clear that the Supreme Court only requires a " 'fit between the legislature's ends and the means chosen to accomplish those ends,' ... that is *not necessarily perfect, but reasonable* ...." *Id.* (quoting *Posadas de Puerto Rico Associates v. Tourism Company of Puerto Rico,* 478 U.S. 328, 341, 106 S.Ct. 2968, 92 L.Ed.2d 266 (1986)) (emphasis added).

***13** Plaintiffs argue that § 343-2(a)(2-5) fails this requirement because the subsection provisions suppress far more speech than necessary to serve the government's substantial interest. Moreover, Plaintiffs contend that because a disclaimer regime would be a far less restrictive and more precise means of serving the government interest, § 343-2(a)'s subsection requirements (2) through (5) are necessarily overbroad and unconstitutional. Again, Defendants' counter-argument incorrectly centers on the FDA's drug approval requirement and not on § 343-2(a). However, Defendants do stress that a disclaimer regime is simply inadequate to protect the government interest.

It is important to note that § 343-2(a)(2-5) does not ban truthful commercial speech outright. These provisions only act as requirements to qualify for the labeling exemption. If the publication does not meet all the subsection criteria, the manufacturer's speech is not foreclosed; rather, the speech simply does not qualify for a labeling exemption and will consequently trigger other FDCA statutes that may expose the manufacturer to heightened FDA regulation.

Section 343-2(a)(2-5) does not restrict more speech than necessary and constitutes a "reasonable fit" between the means and end. Significantly, subsection requirements (2) through (5) do not prevent, let alone restrict, the dissemination of truthful, non-misleading scientific publications as Plaintiffs suggest. Section 343-2(a)(2-5) is designed to restrict additional advertising and promotional statements attached to or woven into the truthful scientific literature itself. As explained earlier, the subsection requirements ensure that a § 343-2(a) labeling exemption only applies to truthful publications that are non-promotional, not misleading and manufacturer-neutral. The subsection requirements-(2) that the publication not promote a particular manufacturer or brand, (3) present a "balanced view" of the available scientific data, (4) is "physically separate" form the dietary supplements displayed in a store, and (5) not have any additional information appended to it by sticker or other means-are all "narrowly tailored" to achieve this end. Moreover, they comply with Congress' intent behind § 343-2(a).

Furthermore, Plaintiffs do not contest the validity of § 343-2(a) (1) that the publication not be "false or misleading." Indeed, Plaintiffs suggest that this is the overall thrust of the § 343-2(a) exemption. Assuming this is correct, Plaintiffs' argument nevertheless fails because § 343-2(a)(2-5) still constitutes a *reasonable fit* to ensure that the publication is not false or misleading. From any angle, § 343-2(a)(2-5) does not restrict more speech than necessary. The fact that Plaintiffs are now willing to place a disclaimer on the Magnesium Package does not change this. A disclaimer regime simply cannot provide the same protection that Congress envisioned and provided for in § 343-2(a)(2-5). Moreover, a disclaimer regime will not ensure that a § 343-2(a) labeling exemption only covers non-promotional publications.

***14** Accordingly, § 343-2(a)(2)-(5) are constitutional restrictions on commercial speech that comply with the legislative intent driving the labeling exemption. As such, the Court will not alter § 343-2(a) in its present form by striking four out of its five subsection requirements.[FN15] Plaintiffs' motion for summary judgment is **DENIED** and Defendants' cross motion for summary judgement is **GRANTED.**

FN15. Because the Court does not find § 343-2(a)(2-5) unconstitutional, it need not reach the issue of severability.

IV. *CONCLUSION AND ORDER*

The Court hereby **GRANTS** Defendants' motion to dismiss Plaintiffs' second claim pursuant to Fed.R.Civ.P. 12(b)(1) for lack of standing. The Court **GRANTS** Defendants' cross motion for summary judgment on Plaintiffs' first claim. Accordingly, the Court **DENIES** Plaintiffs' summary judgement motion in its entirety. The Clerk shall enter a final judgment in accordance with this Order.

IT IS SO ORDERED.

S.D.Cal.,2005.

Westlaw

--- F.Supp.2d ----, 2011 WL 667950 (D.D.C.)
(Cite as: 2011 WL 667950 (D.D.C.))

Only the Westlaw citation is currently available.

United States District Court,
District of Columbia.
Tonia EDWARDS, et al., Plaintiffs,
v.
DISTRICT OF COLUMBIA, Defendant.

Civil Action No. 10–1557 (PLF).
Feb. 25, 2011.

Background: Owners and operators of tour company brought action against District of Columbia, bringing First Amendment challenge to statute and regulations defining tour guide profession and specifying requirements for obtaining tour guide license, and seeking declaratory and injunctive relief. Company moved for preliminary injunction and District of Columbia moved to dismiss.

Holdings: The District Court, Paul L. Friedman, J., held that:
(1) company engaged in more than mere commercial speech, which would have been entitled to lesser First Amendment protection;
(2) statute was content–neutral, and thus subject to intermediate scrutiny;
(3) regulations were content–neutral, and thus subject to intermediate scrutiny; and
(4) licensing scheme was not overly–broad delegation of authority, was narrowly tailored, and left open ample alternatives for communication.

Motions denied.

West Headnotes

[1] District of Columbia 132 ⇐19

132 District of Columbia
132k18 Police Power and Regulations
132k19 k. In general. Most Cited Cases
Congress has generally delegated to the District of Columbia the police power to regulate businesses and occupations.

[2] Injunction 212 ⇐132

212 Injunction
212IV Preliminary and Interlocutory Injunctions
212IV(A) Grounds and Proceedings to Procure
212IV(A)1 In General
212k132 k. Nature and scope of provisional remedy. Most Cited Cases

Injunction 212 ⇐147

212 Injunction
212IV Preliminary and Interlocutory Injunctions
212IV(A) Grounds and Proceedings to Procure
212IV(A)4 Proceedings
212k147 k. Evidence and affidavits. Most Cited Cases
Preliminary injunction is an extraordinary remedy that should be granted only when the party seeking the relief, by a clear showing, carries the burden of persuasion.

[3] Injunction 212 ⇐138.1

212 Injunction
212IV Preliminary and Interlocutory Injunctions
212IV(A) Grounds and Proceedings to Procure
212IV(A)2 Grounds and Objections
212k138.1 k. In general. Most Cited Cases
To warrant preliminary injunctive relief, a moving party must show that: (1) there is a substantial likelihood that it will succeed on the merits of its claims; (2) it will suffer irreparable harm in the absence of an injunction; (3) an injunction would not substantially harm the defendant or other interested parties; and (4) the public interest would be furthered, or at least not adversely affected, by the injunction.

[4] Injunction 212 ⚿138.1

212 Injunction
212IV Preliminary and Interlocutory Injunctions
212IV(A) Grounds and Proceedings to Procure
212IV(A)2 Grounds and Objections
212k138.1 k. In general. Most Cited Cases

Four factors considered on a motion for preliminary injunctive relief must be viewed as a continuum, with more of one factor compensating for less of another.

[5] Injunction 212 ⚿138.6

212 Injunction
212IV Preliminary and Interlocutory Injunctions
212IV(A) Grounds and Proceedings to Procure
212IV(A)2 Grounds and Objections
212k138.6 k. Nature and extent of injury; irreparable injury. Most Cited Cases

Movant must demonstrate at least some injury for a preliminary injunction to issue, and a failure to show any irreparable harm constitutes grounds for denying the motion for a preliminary injunction, even if the other three factors entering the calculus merit such relief.

[6] Constitutional Law 92 ⚿1600

92 Constitutional Law
92XVIII Freedom of Speech, Expression, and Press
92XVIII(C) Trade or Business
92k1600 k. In general. Most Cited Cases

Owners and operators of tour company engaged in more than mere commercial speech, and thus company's speech was not subject to lesser First Amendment protection applicable to commercial speech, for purposes of their challenge to District of Columbia code and regulations defining tour guide profession and specifying requirements for for–hire tour guides to obtain license; speech governed by code and regulations did not simply propose commercial transaction, but actually was transaction itself. U.S.C.A. Const.Amend. 1; D.C. Official Code, 2001 Ed. § 47–2836.

[7] Constitutional Law 92 ⚿1535

92 Constitutional Law
92XVIII Freedom of Speech, Expression, and Press
92XVIII(A) In General
92XVIII(A)2 Commercial Speech in General
92k1535 k. In general. Most Cited Cases

Degree of First Amendment protection is not diminished merely because speech is sold rather than given away. U.S.C.A. Const.Amend. 1.

[8] Constitutional Law 92 ⚿1536

92 Constitutional Law
92XVIII Freedom of Speech, Expression, and Press
92XVIII(A) In General
92XVIII(A)2 Commercial Speech in General
92k1536 k. What is "commercial speech". Most Cited Cases

"Commercial speech" is speech which does no more than propose a commercial transaction, but speech carried in a form that is sold for profit. U.S.C.A. Const.Amend. 1.

[9] Constitutional Law 92 ⚿1517

92 Constitutional Law
92XVIII Freedom of Speech, Expression, and Press
92XVIII(A) In General
92XVIII(A)1 In General
92k1516 Content-Based Regulations or Restrictions
92k1517 k. In general. Most Cited Cases

Determination of whether a law is content–neutral or content–based is critical, not be-

cause it might end the inquiry, but because it will direct its path; laws that permit the government to discriminate on the basis of the content of the message are not tolerated under the First Amendment. U.S.C.A. Const.Amend. 1.

[10] Constitutional Law 92 ⚿1600

92 Constitutional Law
92XVIII Freedom of Speech, Expression, and Press
92XVIII(C) Trade or Business
92k1600 k. In general. Most Cited Cases

District of Columbia statute made no reference to speech at all, and instead required only that for–hire tour guides obtain license regardless of any message they might convey, and thus was content–neutral and subject to intermediate, rather than strict, scrutiny on tour guide company's First Amendment challenge to statute. U.S.C.A. Const.Amend. 1; D.C. Official Code, 2001 Ed. § 47–2836(a).

[11] Constitutional Law 92 ⚿1600

92 Constitutional Law
92XVIII Freedom of Speech, Expression, and Press
92XVIII(C) Trade or Business
92k1600 k. In general. Most Cited Cases

District of Columbia regulations, which defined tour guide profession and provided requirements for for–hire tour guides to obtain necessary license, was directed at tour guides' conduct, rather than their speech, and thus regulations were content–neutral and subject to intermediate, rather than strict, scrutiny on tour guide company's First Amendment challenge to regulations; tour guides guided or directed tour groups around District, which was trigger for applying regulations. U.S.C.A. Const.Amend. 1.

[12] Constitutional Law 92 ⚿1600

92 Constitutional Law
92XVIII Freedom of Speech, Expression, and Press
92XVIII(C) Trade or Business
92k1600 k. In general. Most Cited Cases

Provision of District of Columbia regulations did not turn on whether driver of sightseeing tour vehicle spoke during tour, but instead provided only very narrow exception to for–hire tour guide licensing requirement for individuals who acted only as vehicle driver and did not otherwise guide or direct people around District, and thus requirement was content–neutral and subject to intermediate, rather than strict, scrutiny on tour guide company's First Amendment challenge to regulations. U.S.C.A. Const.Amend. 1.

[13] Constitutional Law 92 ⚿1600

92 Constitutional Law
92XVIII Freedom of Speech, Expression, and Press
92XVIII(C) Trade or Business
92k1600 k. In general. Most Cited Cases

Examination requirement under District of Columbia regulations for for–hire tour guide licensing ensured minimal competence and knowledge for those guiding and directing people to points of interest around District, regardless of whether guide spoke or not, and thus requirement was content–neutral and subject to intermediate, rather than strict, scrutiny on tour guide company's First Amendment challenge to regulations. U.S.C.A. Const.Amend. 1.

[14] Constitutional Law 92 ⚿1518

92 Constitutional Law
92XVIII Freedom of Speech, Expression, and Press
92XVIII(A) In General
92XVIII(A)1 In General
92k1516 Content-Based Regulations or Restrictions
92k1518 k. Strict or exacting scrutiny; compelling interest test. Most Cited Cases

Content–based regulations of speech are constitutional only if they withstand strict scrutiny.

U.S.C.A. Const.Amend. 1.

[15] Constitutional Law 92 ⇐1514

92 Constitutional Law
92XVIII Freedom of Speech, Expression, and Press
92XVIII(A) In General
92XVIII(A)1 In General
92k1511 Content-Neutral Regulations or Restrictions
92k1514 k. Narrow tailoring requirement; relationship to governmental interest. Most Cited Cases

Content–neutral regulations are subject only to an intermediate scrutiny analysis. U.S.C.A. Const.Amend. 1.

[16] Constitutional Law 92 ⇐1514

92 Constitutional Law
92XVIII Freedom of Speech, Expression, and Press
92XVIII(A) In General
92XVIII(A)1 In General
92k1511 Content-Neutral Regulations or Restrictions
92k1514 k. Narrow tailoring requirement; relationship to governmental interest. Most Cited Cases

Constitutional Law 92 ⇐1515

92 Constitutional Law
92XVIII Freedom of Speech, Expression, and Press
92XVIII(A) In General
92XVIII(A)1 In General
92k1511 Content-Neutral Regulations or Restrictions
92k1515 k. Existence of other channels of expression. Most Cited Cases

Courts, in applying intermediate scrutiny to the examination of content–neutral regulations, utilize a multi–part test: first, the regulation may not delegate overly broad licensing discretion to a government official; second, the scheme must be narrowly tailored to serve a significant governmental interest; and third, it must leave open ample alternatives for communication. U.S.C.A. Const.Amend. 1.

[17] Constitutional Law 92 ⇐1600

92 Constitutional Law
92XVIII Freedom of Speech, Expression, and Press
92XVIII(C) Trade or Business
92k1600 k. In general. Most Cited Cases

Licenses 238 ⇐7(1)

238 Licenses
238I For Occupations and Privileges
238k7 Constitutionality and Validity of Acts and Ordinances
238k7(1) k. In general. Most Cited Cases

District of Columbia's content–neutral licensing scheme for for–hire tour guides did not constitute overly–broad delegation to District's Department of Consumer and Regulatory Affairs (DCRA), under intermediate scrutiny equal protection analysis in tour guide company's challenge to scheme; regulations simply required that applicants were at least eighteen years old and proficient in English, that applicants had not been convicted of certain specified felonies, and that applicants were capable of passing examination covering multiple topics concerning District. U.S.C.A. Const.Amend. 1; D.C. Official Code, 2001 Ed. § 47–2836.

[18] Constitutional Law 92 ⇐1600

92 Constitutional Law
92XVIII Freedom of Speech, Expression, and Press
92XVIII(C) Trade or Business
92k1600 k. In general. Most Cited Cases

Licenses 238 ⇐7(1)

238 Licenses
238I For Occupations and Privileges
238k7 Constitutionality and Validity of Acts

and Ordinances
238k7(1) k. In general. Most Cited Cases
District of Columbia's content–neutral licensing scheme for for–hire tour guides was narrowly tailored to serve significant government interests of promoting important industry and protecting general public, under intermediate scrutiny equal protection analysis in tour guide company's challenge to scheme; District was third–most popular tourist destination in country, attracting almost 15 million visitors each year, and scheme was intended to ensure those visitors that their guides were minimally competent. U.S.C.A. Const.Amend. 1; D.C. Official Code, 2001 Ed. § 47–2836.

[19] Constitutional Law 92 ⚿1514

92 Constitutional Law
92XVIII Freedom of Speech, Expression, and Press
92XVIII(A) In General
92XVIII(A)1 In General
92k1511 Content-Neutral Regulations or Restrictions
92k1514 k. Narrow tailoring requirement; relationship to governmental interest. Most Cited Cases
Content–neutral statute or regulation will meet the narrow–tailoring requirement of intermediate scrutiny equal protection analysis if a substantial portion of the burden it imposes furthers the government's significant interest, even if a less intrusive alternative might also exist. U.S.C.A. Const.Amend. 1.

[20] Constitutional Law 92 ⚿1600

92 Constitutional Law
92XVIII Freedom of Speech, Expression, and Press
92XVIII(C) Trade or Business
92k1600 k. In general. Most Cited Cases

Licenses 238 ⚿7(1)

238 Licenses
238I For Occupations and Privileges
238k7 Constitutionality and Validity of Acts and Ordinances
238k7(1) k. In general. Most Cited Cases
District of Columbia's content–neutral licensing scheme for for–hire tour guides left open ample alternatives for communication, under intermediate scrutiny analysis in tour guide company's challenge to scheme; prior to obtaining license, guides were able to engage in expressive activity, so long as they were not conducting their tours for profit. U.S.C.A. Const.Amend. 1; D.C. Official Code, 2001 Ed. § 47–2836.

Clark M. Neily, III, Robert William Gall, Robert J. McNamara, Arlington, VA, for Plaintiffs.

Andrew J. Saindon, D.C. Office of Attorney General, Washington, DC, for Defendant.

OPINION

PAUL L. FRIEDMAN, District Judge.

***1** Since 1932, the District of Columbia has required that those who conduct tours for profit in the District must obtain a license before doing so. In July 2010, the District promulgated regulations defining the tour guide profession and specifying five requirements for obtaining a tour guide license. This action presents the question whether the District's tour guide licensing scheme is in violation of the First Amendment to the United States Constitution.

Plaintiffs are owners and operators of a tour guide company in the District of Columbia. On September 16, 2010, they filed a complaint in this Court, requesting declaratory and injunctive relief from the District's tour guide licensing scheme and thereafter filed a motion for a preliminary injunction. Defendant opposed this motion and simultaneously filed a motion to dismiss. The Court heard oral argument on both motions on December 22, 2010, and took them under advisement.[FN1] Upon careful consideration of the parties' papers, the oral arguments presented by counsel, the relevant legal

authorities, and the entire record in this case, the Court will deny plaintiffs' motion for a preliminary injunction and will deny without prejudice defendant's motion to dismiss.[FN2]

I. BACKGROUND

A. Segs in the City

Plaintiffs Tonia Edwards and Bill Main "earn their living as tour guides." Compl. ¶ 4. They own and operate " 'Segs in the City,' a Segway-rental and tour business that operates in Washington, D.C., as well as in Annapolis and Baltimore." Mot. for PI at 1.[FN3] Plaintiffs' business model is the same in all three cities: they "both rent Segways to individuals for private use and provide tours to small groups of people." *Id.* During the summer months, the busiest time of the year for Segs in the City, "about half of the tours are conducted directly by either [Bill] Main or [Tonia] Edwards—the rest are conducted by independent contractors [p]laintiffs hire for the summer." *Id.* Most of plaintiffs' part-time guides "are usually college students working on their summer break." Main Decl. ¶ 9. Plaintiffs "usually hire around 15 part-time guides a summer" and consider it a "short-term job": plaintiffs "either never or almost never had any of [their part-time guides] return for a second summer." *Id.*

Plaintiffs describe their tours as follows:

> A Segs in the City tour has two basic phases. First, the tour leader spends time training the group (which never has more than 10 people) in how to ride a Segway, including instruction in how to ride safely and how to comply with relevant safety regulations like speed limits. Then, the group puts their newfound knowledge to use, riding the Segways with their guide along one of several established tour routes. Edwards Decl. ¶¶ 14–17; Main Decl. ¶¶ 14–17. Each tour lasts between one and three hours, and Segs in the City operates up to five tours a day, seven days a week. Edwards Decl. ¶¶ 7, 18; Main Decl. ¶¶ 7, 18. As the group members ride, the tour leader communicates with them via a radio earpiece (provided by Segs in the City), occasionally pointing out or describing points of interest along the route. Edwards Decl. ¶¶ 17–19; Main Decl. ¶¶ 17–19.
>
> ***2** Mot. for PI at 2.

By statute in effect since 1932, the District of Columbia has required that those who conduct tours for profit in the District must obtain a license before doing so. *See* D.C.CODE § 47–2836(a). In 2010, the District of Columbia Department of Consumer and Regulatory Affairs ("DCRA") promulgated new regulations that specifically define tour guides and that specify five requirements for a tour guide license. *See* 57 D.C. REG. 6116 (July 16, 2010); D.C. MUN. REGS. TIT. 19, § 1200 *et seq.* Any individual who violates either the statute or the regulations "shall upon conviction be fined not more than $300 or imprisoned for not more than 90 days." D.C.CODE § 47–2846; *see* D.C. MUN. REGS. TIT. 19, § 1209.2.[FN4] The regulations further provide for the possibility of both a fine and imprisonment. D.C. MUN. REGS. TIT. 19, § 1209 .2.

Plaintiffs have been leading tours in the District of Columbia for more than six years and continue to do so. *See* Segs in the City, http://www.segsinthecity.com/FAQ.htm (last visited Feb. 24, 2011); *see* PI Opp. & MTD at 15. Plaintiffs have never obtained a tour guide license, however, and they "refuse to obtain one," because they view the requirement as burdensome and in violation of their First Amendment rights. Main Decl. ¶ 21; *see id.* ¶¶ 22–25; Edwards Decl. ¶¶ 22–25.

B. Tour Guide Licensing in the District of Columbia

1. The District of Columbia Code

[1] Since nearly the establishment of the District of Columbia, Congress has delegated to the District the police power to regulate businesses and occupations. *See, e.g., District of Columbia v. John R. Thompson Co.*, 346 U.S. 100, 113 n. 9, 73 S.Ct. 1007, 97 L.Ed. 1480 (1953). The current general

business licensing scheme derives from an Act passed by Congress in 1902, making "it illegal for any person to engage in or carry on any business, trade, profession, or calling in this District for which a license tax is imposed without first obtaining a license...." *Richards v. Davison,* 45 App.D.C. 395, 399, 1916 WL 21670, at *3 (D.C.Cir.1916). In that Act, Congress imposed license-registration and fee requirements on various businesses and professions,

> including apothecaries, auctioneers, cattle dealers, proprietors of passenger vehicles for hire, real estate brokers and agents, hotels, restaurants, theaters, and owners or lessees of grounds used for horse racing, tournaments, athletic sports, baseball, football, polo, golf, and kindred games, or where feats of horsemanship are performed.

PI Opp. & MTD at 6 (internal quotations and citation omitted).

Thirty years later, in 1932, Congress specifically authorized the regulation of for-profit tour guides in the District of Columbia, providing:

> No person shall, for hire, guide or escort any person through or about the District of Columbia, or any part thereof, unless he shall have first secured a license to do so. The fee for each such license shall be $10 per annum. No license shall be issued hereunder without the approval of the major and superintendent of police. The Commissioners of the District of Columbia are hereby authorized and empowered to make reasonable regulations for the examination of all applicants for such licenses and for the government and conduct of persons licensed hereunder, including the power to require said persons to wear a badge while engaged in their calling.

***3** ACT OF JULY 1, 1932, 47 STAT. 550, 558 ¶ 38; *see* PI Opp. & MTD at 6.

In 1994, the Council of the District of Columbia created the Business Regulatory Reform Commission for the purpose of identifying " 'statutes and regulations in the District of Columbia that are obsolete, inconsistent or duplicative, especially as they relate to building and land uses, businesses, occupations and professions.' " PI Opp & MTD at 9 (quoting COUNCIL OF THE DISTRICT OF COLUMBIA, COMMITTEE ON CONSUMER & REGULATORY AFFAIRS, REPORT ON BILL 12–458 at 3, Dec. 19, 1997). Defendant explains that the ultimate result of the Commission's work was a "streamlined ... business-licensing process" that eliminated "a number of boards and commissions and outdated license categories." *Id.* at 10 (citing D.C. CODE § 47–2801 *et seq.*). The tour guide licensing statute, however, remained essentially unchanged from the 1932 statute, and is still in effect to this day, now providing:

> No person shall, for hire, guide or escort any person through or about the District of Columbia, or any part thereof, unless he shall have first secured a license to do so. The fee for each such license shall be $28 per annum. No license shall be issued hereunder without the approval of the Chief of Police. The Council of the District of Columbia is authorized and empowered to make reasonable regulations for the examination of all applicants for such licenses and for the government and conduct of persons licensed hereunder, including the power to require said persons to wear a badge while engaged in their calling.

D.C.CODE § 47–2836(a). Any violation of this statute shall subject an individual, upon conviction, to a fine of not more than $300 or imprisonment for not more than 90 days. *Id.* § 47–2846.[FN5]

2. The District of Columbia Municipal Regulations

The tour guide licensing statute empowers the Council of the District of Columbia to make "reasonable regulations for the examination of all applicants for such [tour guide] licenses and for the government and conduct of persons licensed hereunder...." D.C. CODE § 47–2836(a). Until recently, the regulations promulgated pursuant to this statutory authority had required, among other things,

> that a guide be a citizen of the United States, be "of sound physique, with good eyesight ... and hearing in both ears; not subject to epilepsy, vertigo, or heart trouble; free from any contagious or infectious disease; and not a drunkard or addicted to the use of habit-forming drugs." PI Opp. & MTD at 10 (quoting D.C. POLICE REG., ART. II, SEC. 5 (1970); COMMISSIONERS' ORDER NO. 59–1043 (Jun. 17, 1959)).

In December 2008, however, the DCRA proposed to revise those regulations. *See* 55 D.C. REG. 12284 (Dec. 5, 2008). The DCRA released a notice of proposed rulemaking that provided the opportunity for the public at large to comment. *See id.* After receiving comments, the DCRA further revised these proposed regulations, *see* 57 D.C. REG. 4434 (May 21, 2010), and then revised the proposed regulations a final time before formally promulgating them in their official, current form on July 16, 2010. *See* 57 D.C. REG. 6116 (July 16, 2010).

***4** As promulgated, these regulations first specifically define a "tour guide," as follows:

> Whenever used in this chapter, the term "tour guide" or "sightseeing tour guide" shall mean any person [1] who engages in the business of guiding or directing people to any place or point of interest in the District, or [2] who, in connection with any sightseeing trip or tour, describes, explains, or lectures concerning any place or point of interest in the District to any person.

D.C. MUN. REGS. TIT. 19, § 1200.1. These regulations then define a "sightseeing tour company" as "a business that employs a sightseeing tour guide." *Id.* § 1200.2.

The following section of the regulations, Section 1201, imposes the requirement that for-profit tour guides obtain a license. It provides:

> No person shall offer to act as a sightseeing tour guide on the roads, sidewalks, public spaces, or waterways of the District of Columbia unless the person holds a valid sightseeing tour guide license issued by the Department of Consumer and Regulatory Affairs (Department)....
>
> No business or entity shall offer, for a fee, to conduct walking tours or tours where customers operate self-balancing personal transport vehicles, mopeds, or bicycles unless the business or entity is licensed by the Department as a sightseeing tour company.

D.C. MUN. REGS. TIT. 19, §§ 1201.1, 1201.3.

The regulations also include what the parties refer to as a "holding-out" provision, which provides that "[n]o person, other than a licensed sightseeing tour company or sightseeing tour guide may use the words 'sightseeing,' 'tours,' 'guide,' or any combination of these words, to advertise the availability of sightseeing tour services." D.C. MUN. REGS. TIT. 19, § 1201.5. This latter prohibition does not apply "to the use of these words as part of the identifying lettering on vehicles coming into the District or to a tour that is not conducted for profit or compensation." *Id.*

Under the regulations, in order to obtain the required tour guide license, an applicant must satisfy five requirements. *See* D.C. MUN. REGS. TIT. 19, § 1203. An applicant must (1) be at least eighteen years old, *id.* § 1203.1(a); (2) be proficient in English, *id.* § 1203.1(b); (3) not have been convicted of certain specified felonies, *id.* § 1203.1(c); (4) make a sworn statement that all statements contained in his or her application are true and pay all required licensing fees, *id.* § 1203.2; and (5) pass an examination "covering the applicant's knowledge of buildings and points of historical and general interest in the District." *Id.* § 1203.3.

With respect to the fifth requirement, the examination, the regulations do not provide any further description or explanation and the Court has not been provided a copy of the examination for its review. The DCRA has, however, provided a "Study Reference" that explains that "[t]here are different

versions of the examination, each consisting of 100 multiple choice questions." DISTRICT OF COLUMBIA SIGHTSEEING TOUR GUIDE PROFESSIONAL LICENSING EXAMINATION STUDY REFERENCE, http://www.asisvcs.com/publications/publist.cgi?st=09&ind=TG&CPCat=TG09STATEREG (last visited Feb. 24, 2011). Applicants must obtain a minimum score of 70 to pass. *Id.* According to the DCRA,

> ***5** questions may come from any of the following categories: Architectural; Dates; Government; Historical Events; Landmark Buildings; Locations; Monuments, Memorials; Museums and Art Galleries; Parks, Gardens and Zoo Aquariums; Presidents; Sculptures and Statutes; Universities; Pictures; Regulations.
>
> *Id.* The examination fee is $200.00. *Id.*

Similar to the penalty provision in D.C.Code Section 47–2846, any individual who violates any provision of the tour guide regulations "shall, upon conviction, be fined not more than three hundred dollars ($300) or imprisoned for not more than ninety (90) days, or both." D.C. MUN. REGS. TIT. 19, § 1209.2.[FN6]

II. LEGAL STANDARD

[2][3] A preliminary injunction is " 'an extraordinary remedy that should be granted only when the party seeking the relief, by a clear showing, carries the burden of persuasion.' " *Chaplaincy of Full Gospel Churches v. England,* 454 F.3d 290, 297 (D.C.Cir.2006) (quoting *Cobell v. Norton,* 391 F.3d 251, 258 (D.C.Cir.2004)). To warrant preliminary injunctive relief, a moving party must show: (1) that there is a substantial likelihood that it will succeed on the merits of its claims; (2) that it will suffer irreparable harm in the absence of an injunction; (3) that an injunction would not substantially harm the defendant or other interested parties (balance of harms); and (4) that the public interest would be furthered, or at least not adversely affected, by the injunction. *See id.; Davis v. Pension Benefit Guar. Corp.,* 571 F.3d 1288, 1291 (D.C.Cir.2009); *Serono Labs., Inc. v. Shalala,* 158 F.3d 1313, 1317–18 (D.C.Cir.1998).

[4] These four factors must be viewed as a continuum, with more of one factor compensating for less of another. *Davis v. Pension Benefit Guar. Corp.,* 571 F.3d at 1291–92. "If the arguments for one factor are particularly strong, an injunction may issue even if the arguments in other areas are rather weak." *CityFed Fin. Corp. v. Office of Thrift Supervision,* 58 F.3d 738, 747 (D.C.Cir.1995). An injunction may be justified "where there is a particularly strong likelihood of success on the merits even if there is a relatively slight showing of irreparable injury." *Id.* Conversely, when the other three factors strongly favor interim relief, a court may grant injunctive relief when the moving party has merely made out a "substantial" case on the merits. The necessary level or degree of likelihood of success that must be shown will vary according to the Court's assessment of the other factors. *Washington Metro. Area Transit Comm'n v. Holiday Tours, Inc.,* 559 F.2d 841, 843–45 (D.C.Cir.1977). An injunction may be issued "with either a high probability of success and some injury, or *vice versa.* " *Cuomo v. U.S. Nuclear Regulatory Comm'n,* 772 F.2d 972, 974 (D.C.Cir.1985) (emphasis in original).

[5] Despite this flexibility, however, "a movant must demonstrate 'at least some injury' for a preliminary injunction to issue," and "[a] ... failure to show *any* irreparable harm" constitutes grounds for denying the motion for a preliminary injunction, "even if the other three factors entering the calculus merit such relief." *Chaplaincy of Full Gospel Churches v. England,* 454 F.3d at 297 (quoting *CityFed Fin. Corp. v. Office of Thrift Supervision,* 58 F.3d at 747, and citing *Sea Containers Ltd. v. Stena AB,* 890 F.2d 1205, 1210–11 (D.C.Cir.1989)) (emphasis added).

III. DISCUSSION

***6** Plaintiffs assert both a facial and an as-applied First Amendment challenge to D.C.Code Section 47–2836 and to the regulations recently

promulgated under it. *See* Compl. at 10. Although plaintiffs contend that each preliminary injunction factor weighs strongly in their favor, Mot. for PI at 6, their motion is essentially dependent on a favorable finding on the first factor—the likelihood of success on the merits of their First Amendment claim. Plaintiffs contend that they are substantially likely to succeed on the merits because the District's tour guide licensing scheme is a content based prior restraint on speech that cannot survive strict scrutiny review. *Id.* at 7. Plaintiffs also maintain that they will suffer irreparable harm in the absence of an injunction because of their asserted clear constitutional injury. *Id.* at 13–14.

Defendant responds that the tour guide licensing scheme implicates only commercial speech, subject to a less searching standard of review than pure speech. Opp. & MTD at 16. In the alternative, defendant contends that even if the Court were to reject its commercial speech argument, the licensing scheme is content neutral and survives intermediate scrutiny review. *Id.* at 20, 23. [FN7]

A. The Merits

1. More Than Commercial Speech

[6] Defendant argues that because the licensing scheme is triggered only when tour guides are " *for hire,* .... the challenged restrictions apply only to commercial speech, which is accorded lesser protection under the First Amendment than other speech." PI Opp. & MTD at 5 (internal quotations and citation omitted) (emphasis in original). Plaintiffs disagree with defendant's "sweeping proposition that 'commercial speech' means 'speech someone wouldn't engage in for free.' " PI Reply & MTD Opp at 7. Plaintiffs argue that the type of speech at issue in this case is well outside of the commercial speech category. *Id.* at 6–7.

[7] The Court agrees with plaintiffs. As this Court has recognized: " '[T]he degree of First Amendment protection is not diminished merely because ... speech is sold rather than given away.' " *Enten v. District of Columbia,* 675 F.Supp.2d 42, 50 (D.D.C.2009) (quoting *City of Lakewood v. Plain Dealer Publ'g Co.,* 486 U.S. 750, 756 n. 5, 108 S.Ct. 2138, 100 L.Ed.2d 771 (1988)). "[E]xpressive materials do not lose their First Amendment protection merely because they are offered for sale.... Indeed, the [Supreme] Court long ago reminded us 'that the pamphlets of Thomas Paine were not distributed free of charge.' " *ISKCON of Potomac, Inc. v. Kennedy,* 61 F.3d 949, 953–54 (D.C.Cir.1995) (quoting *Murdock v. Pennsylvania,* 319 U.S. 105, 111, 63 S.Ct. 870, 87 L.Ed. 1292 (1943)).

[8] Defendant fails to appreciate the distinction between speech-for-profit and commercial speech. Commercial speech is "speech which does no more than propose a commercial transaction," *Bolger v. Youngs Drug Prods. Corp.,* 463 U.S. 60, 66, 103 S.Ct. 2875, 77 L.Ed.2d 469 (1983) (internal quotations and citation omitted), but speech "carried in a form that is sold for profit," *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.,* 425 U.S. 748, 761, 96 S.Ct. 1817, 48 L.Ed.2d 346 (1976) (internal quotations and citation omitted), is not commercial speech. As an example, "[a]n astrological prediction, without more, is not commercial speech because the speech is the substance of the transaction. Commercial speech—like an advertisement—is incidental to an economic transaction; it proposes or encourages a transaction." *Rushman v. City of Milwaukee,* 959 F.Supp. 1040, 1043 (E.D.Wis.1997). Thus, to qualify as commercial speech subject to lesser protection under the First Amendment, the speech

> ***7** must ... be a means to another end, not an end in itself. In other words, commercial speech, statements encouraging a future economic transaction, is different than speech-for-profit, the sale of ideas and words.... Tutoring, providing legal advice, or giving medical advice is speech-for-profit, not commercial speech.... Telling fortunes or giving advice based on astrology (without more) is speech-for-profit, not commercial speech.

Id. (internal citations omitted); *see also*

Trimble v. City of New Iberia, 73 F.Supp.2d 659, 666 (W.D.La.1999) ("Just because someone may pay a fee for the plaintiffs' services, the telling of fortunes and the giving of spiritual advice does not propose a commercial transaction.").

Indeed, the Eighth Circuit, in the context of a First Amendment challenge to a law prohibiting for-profit fortune-telling, rejected the very same argument that defendant makes here:

> The speech itself, fortunetelling, is not commercial simply because someone pays for it. The speech covered by the ordinance, for the most part, does not simply propose a commercial transaction. Rather, it *is* the transaction. The speech itself is what the client is paying for.... There is a distinct difference between the offer to tell a fortune ("I'll tell your fortune for twenty dollars."), which is commercial speech, and the actual telling of the fortune ("I see your future ...."), which is not.

Argello v. City of Lincoln, 143 F.3d 1152, 1153 (8th Cir.1998) (emphasis in original) (internal quotations and citation omitted). The Court therefore rejects defendant's contention that only commercial speech is implicated in this case.[FN8]

2. Content Neutral

[9] The next question, then, is whether the tour guide licensing scheme is content neutral or content based. This determination "is critical, not because it might end the inquiry, but because it will direct its path." *Boardley v. U.S. Dep't of the Interior,* 615 F.3d 508, 516 (D.C.Cir.2010). " 'Regulations which permit the Government to discriminate on the basis of the content of the message cannot be tolerated under the First Amendment.' " *Forsyth County, Ga. v. Nationalist Movement,* 505 U.S. 123, 135, 112 S.Ct. 2395, 120 L.Ed.2d 101 (1992) (quoting *Regan v. Time, Inc.,* 468 U.S. 641, 648–49, 104 S.Ct. 3262, 82 L.Ed.2d 487 (1984)). Not surprisingly, therefore, defendant argues that the licensing scheme is content neutral, while plaintiffs contend that it is content based. The Court agrees with defendant that it is content neutral and therefore is subject to intermediate—not strict—scrutiny. As this Court has explained:

> "The principal inquiry in determining content neutrality, in speech cases generally and in time, place, or manner cases in particular, is whether the government has adopted a regulation of speech because of disagreement with the message it conveys." *Ward v. Rock Against Racism,* 491 U.S. 781, 791, 109 S.Ct. 2746, 105 L.Ed.2d 661 (1989). "Government regulation of expressive activity is content neutral so long as it is 'justified without reference to the content of the regulated speech.' " *Id.* (internal citations omitted).

***8** *A.N.S.W.E.R. Coal. v. Kempthorne,* 537 F.Supp.2d 183, 195 (D.D.C.2008).

a. The District of Columbia Statute

[10] The parties' papers generally treat the District's statute and the regulations promulgated under it as one and the same. *See, e.g.,* Compl. at 10. During oral argument, however, plaintiffs' counsel came close to conceding that, with respect to the statute, there is no basis, independent from the regulations, for concluding that it is content based. *See* Tr. at 16:12–17:19. This concession would be appropriate because D.C.Code Section 47–2836 is "indisputably content-neutral on [its] face." *Boardley v. U.S. Dep't of the Interior,* 615 F.3d at 516.

This statute, in effect and unchallenged since 1932, makes no reference to speech at all; its focus is only on conduct, providing that "[n]o person shall, for hire, *guide or escort* any person through or about the District of Columbia ... unless he shall have first secured a license to do so." D.C.CODE § 47–2836(a) (emphasis added). Clearly, this statute requires a license regardless of any message a tour guide may wish to convey. *See Boardley v. U.S. Dep't of the Interior,* 615 F.3d at 516; *A.N.S.W.E.R. Coal. v. Kempthorne,* 537 F.Supp.2d at 195. And plaintiffs have provided no basis for the Court to conclude that Congress and then the Council of the

District of Columbia were "motivated to adopt [this statute] by [their] agreement with or hostility toward any particular message or speaker." *Boardley v. U.S. Dep't of the Interior,* 615 F.3d at 516.

b. The District of Columbia Municipal Regulations

[11] Plaintiffs' "primary First Amendment argument is in the regulations." Tr. at 16:23–24. It begins with the proposition that plaintiffs "tell stories for a living." Mot. for PI at 5. Plaintiffs then assert that "[w]hat [they] do for a living is no different from what stand-up comedians do, is no different from what broadcast journalists do, is no different from what college professors do." Tr. at 27:12–15. Plaintiffs continue: the recently promulgated regulations are expressly directed at speech—and only speech—because they "apply only to people who 'describe[ ], explain[ ], or lecture[ ] concerning any place or point of interest in the District to any person' on a tour...." Mot. for PI at 8 (quoting D.C. MUN. REGS. TIT. 19, § 1200 .1); *see also* PI Reply & MTD at 3–4. By contrast, plaintiffs contend, "[p]eople who choose to talk about other things may do so freely." Mot. for PI at 8. Thus, plaintiffs conclude that the District's tour guide "licensing regulations are content based because they impose burdens (in the form of fees and a mandatory examination) on people whose speech contains particular content: information about points of interest in Washington, D.C." *Id.*

The Court disagrees. First, plaintiffs do more than speak for a living and their comparison with stand-up comedians, broadcast journalists, and college professors is inapt. As plaintiffs state in their complaint, their profession has two components: plaintiffs (1) "direct" tour groups around the District and (2) "describe" sights and buildings. Compl. ¶ 31. Indeed, as plaintiffs further specify, their tours have "two basic phases": first, after providing some training on how to ride a Segway, "the group ... *rid[es] the Segways with their guide along one of several established tour routes* "; second, "[a]s the group members ride, the tour leader communicates with them via a radio earpiece ..., *occasionally* pointing out or describing points of interest along the route." Mot. for PI at 2 (emphasis added) (internal quotations and citations omitted). Thus, plaintiffs' profession involves conduct and, by their terms, only occasional speech. *Id.*; *see* Edwards Decl. ¶ 17; Main Decl. ¶ 17.

***9** The Court concludes that the plain reading of the municipal regulations shows that they are directed at plaintiffs' conduct—not their speech. The regulations unambiguously define a tour guide to mean any person

> [1] who engages in the business of *guiding or directing* people to any place or point of interest in the District, *or*
>
> [2] who, *in connection with any sightseeing trip or tour,* describes, explains, or lectures concerning any place or point of interest in the District to any person.

D.C. MUN. REGS. TIT. 19, § 1200.1 (emphasis added). The plain language of the regulations thus makes clear that speech is not the trigger for the licensing requirement. Rather, like the statute, the regulations are triggered by conduct: the *guiding or directing* of a sightseeing trip or tour. Any individual who guides or directs people around the District for profit—regardless of whether that individual, like plaintiffs, " *occasionally* point[s] out or describ[es] points of interest along the route," Edwards Decl. ¶ 17 (emphasis added)—must first acquire a license. Therefore, like the statute, these regulations require a license regardless of any message a tour guide may wish to convey. *See Boardley v. U.S. Dep't of the Interior,* 615 F.3d at 516; *A.N.S.W.E.R. Coal. v. Kempthorne,* 537 F.Supp.2d at 195. These regulations are " 'unrelated to the content of expression' " and have, at most, " 'an incidental effect on some speakers or messages but not others.' " *Mahoney v. District of Columbia,* 662 F.Supp.2d 74, 87 (D.D.C.2009) (quoting *Ward v. Rock Against Racism,* 491 U.S. at 791–92, 109 S.Ct. 2746).

[12] Plaintiffs argue in reply that "[t]he best way to see that the guide-licensing scheme takes aim at pure speech" is to examine (1) how the regulations treat vehicles that utilize only audio recordings rather than a person who talks or conveys information, PI Reply & MTD Opp. at 4–5, and (2) the requirement that licensees pass "a history test." Tr. at 5:12–14. Turning first to the distinction between the types of vehicles that may be utilized by a sightseeing tour company, plaintiffs refer to Section 1204.3 of the municipal regulations, which provides:

> A vehicle operated by a licensed sightseeing tour company shall have at least one (1) licensed sightseeing tour guide on board the vehicle during its sightseeing tours in the District. *This requirement shall not apply to a vehicle that utilizes only audio recordings during the sightseeing tour;* provided, that a driver of such a sightseeing tour vehicle who talks, lectures, or otherwise provides sightseeing information to passengers while the vehicle is in motion must be licensed as a sightseeing guide.

D.C. MUN. REGS. TIT. 19, § 1204.3 (emphasis added). According to plaintiffs, this regulation means that "[d]rivers of tour buses, buses that drive around town while information plays on a prerecorded loop, while they're certainly escorting people around town, do not need a [tour guide] license," whereas drivers who "talk, lecture, or otherwise provide sightseeing information to passengers" do need a license. Tr. at 4:5–11. Plaintiffs thus contend that this one section of the regulations is "very strong evidence of ... the most natural reading of" this regulatory scheme, which is that it only covers and is directed at "people who are conveying sightseeing information to people on tours." *Id.* at 12:15–18. The Court disagrees.

***10** The section of the regulations on which plaintiffs rely must be read both according to its plain language and in the context of the entire regulatory scheme. It is a portion of Section 1204 of the regulations, entitled "Requirements for Sightseeing Tour Companies." It thus applies to sightseeing tour companies which must, under the regulations, first have obtained a license to operate as a sightseeing tour company, *see* D.C. MUN. REGS. TIT. 19, §§ 1201, 1202, as well as to any tour guides it employs, who also must obtain their own separate licenses. *See id.* §§ 1201, 1203. The portion of Section 1204 on which plaintiffs rely requires that a vehicle operated by a "licensed sightseeing tour company" must have a licensed sightseeing tour guide on board its vehicle while conducting a sightseeing tour in the District of Columbia. *Id.* § 1204.3. But it provides a narrow exception to this requirement: If a licensed sightseeing tour company chooses to operate a vehicle that utilizes only audio recordings during a sightseeing tour, it is not required to have a licensed sightseeing tour guide on board. *Id.* In such case, the sightseeing tour company is permitted to hire a driver only—who may insert an audio recording into a recorder as he begins the drive—rather than hiring both a driver and a separate tour guide. This exception recognizes that the business of driving a bus is different from the business of guiding or directing tours. But if a bus driver wears two hats—both driving the tour vehicle and also "provid[ing] sightseeing information to passengers" while driving—the regulations require that he or she must be licensed as a sightseeing tour guide. *Id.* Why? Because then the driver is engaging in the conduct of "guiding or directing people" to places of interest in the District, *id.* § 1200. 1, and, in connection with the activities of "guiding or directing," *id.*, the driver is explaining points of interest along the way. *Id.* § 1204.3. In other words, he or she then is both a bus driver and a tour guide, and—like everyone else who engages in the conduct of guiding or directing—the regulations require that such person be licensed.

The section of the regulations on which plaintiffs rely does not turn on whether one person speaks and the other does not but, rather, on the distinction between those who are engaged in the conduct of "guiding or directing" people to places of interest and those who engage in the very different

conduct of driving a bus. By focusing on the one narrow exception in the regulations with respect to one type of vehicle that might be used by a licensed sightseeing tour company, plaintiffs totally ignore the "guiding or directing" component of the definition of a tour guide, which is the central focus of the regulations at issue in this case. *See Gonzalez–Vera v. Townley,* 597 F.Supp.2d 98, 101 (D.D.C.2009) (" '[C]ourts must give effect, if possible, to every clause and word' " of a regulation.) (quoting *Williams v. Taylor,* 529 U.S. 362, 364, 120 S.Ct. 1495, 146 L.Ed.2d 389 (2000)).[FN9]

***11** [13] The Court also disagrees with plaintiffs' argument that the examination requirement somehow shows that "the licensing requirements are all geared toward confirming a tour guide's ability to communicate adequately," PI Reply & MTD Opp. at 4, and thus are aimed at speech. Although the Court has not reviewed an actual copy of the examination, according to the DCRA,

> questions may come from any of the following categories: Architectural; Dates; Government; Historical Events; Landmark Buildings; Locations; Monuments, Memorials; Museums and Art Galleries; Parks, Gardens and Zoo Aquariums; Presidents; Sculptures and Statutes; Universities; Pictures; Regulations.

DISTRICT OF COLUMBIA SIGHTSEEING TOUR GUIDE PROFESSIONAL LICENSING EXAMINATION STUDY REFERENCE, http://www.asisvcs.com/publications/publist.cgi?st=09&ind=TG&CPCat=TG09STATEREG (last visited Feb. 24, 2011). The Court agrees with defendant that the purpose of this examination is to ensure some minimal competence and knowledge for those who "guid[e] or direct[ ] people" around the District of Columbia—whether they choose to speak or not. The Court therefore finds that the tour guide licensing regulations are content neutral.

3. Intermediate Scrutiny

[14][15][16] Content based regulations of speech are constitutional only if they withstand strict scrutiny. *United States v. Playboy Entertainment Group, Inc.,* 529 U.S. 803, 813, 120 S.Ct. 1878, 146 L.Ed.2d 865 (2000). Content neutral regulations, by contrast, are subject only to an intermediate scrutiny analysis. *Emergency Coal. to Defend Educ. Travel v. U.S. Dep't of the Treasury,* 545 F.3d 4, 12 (D.C.Cir.2008) (citing *United States v. O'Brien,* 391 U.S. 367, 377, 388, 88 S.Ct. 1673, 20 L.Ed.2d 672 (1968)). Because the Court concludes that both the statute and the regulations at issue in this case are content neutral, they must be examined "under a familiar multipart test: First, the regulation may not delegate overly broad licensing discretion to a government official. Second, the scheme must be narrowly tailored to serve a significant governmental interest. And third, it must leave open ample alternatives for communication." *Boardley v. U.S. Dep't of the Interior,* 615 F.3d at 516; *see also Enten v. District of Columbia,* 675 F.Supp.2d at 51 (content neutral licensing requirements must be "narrowly tailored" to serve a significant governmental interest; must "leave open ample alternative channels of communication"; and must "not unduly delegate authority to a government official").

[17] First, the Court concludes that the tour guide licensing scheme does not delegate overly broad licensing discretion to the DCRA. As discussed, the regulations require that an applicant be at least eighteen years old, be proficient in English, have not been convicted of certain specified felonies, and pass an examination that, according to the DCRA, requires an applicant to answer correctly 70 out of 100 questions on multiple topics concerning the District. *See* D.C. MUN. REGS. TIT. 19, § 19–1203. These specifications are "sufficiently 'narrow, objective, and definite' that they do not constitute an undue delegation of authority to the DCRA or give it the kind of discretion that could become a 'means of suppressing a particular viewpoint.' " *Enten v. District of Columbia,* 675 F.Supp.2d at 54 (quoting *A.N.S.W.E.R. Coal. v. Kempthorne,* 537 F.Supp.2d at 197).

***12** [18] Second, the licensing scheme is narrowly tailored to serve a significant government interest. According to defendant, this scheme

> helps ensure that professional tour guides will be reliable and reputable, and enables the District to monitor the business and practice of tour guides ... to guarantee compliance with District law and continued protection of consumers from "ignorance, incapacity or imposition."

PI Opp. & MTD at 30. As defendant notes, a recent study shows that the District is the third-most popular tourist destination in America, which attracts approximately fifteen million visitors each year. *Id.* at 31. It is estimated, according to the defendant, that travel and tourism supports more than 66,000 full-time jobs in the District, generating some $2.6 billion in wages. *Id.* Thus, visitors and District residents alike "are entitled ... to have minimal competence standards for tour guides ..., who can be held responsible for their business practices." *Id.* at 35. Clearly, the promotion of a major industry and the protection of the general welfare of society are significant government interests. *See Smith v. City of Fort Lauderdale, Fl.,* 177 F.3d 954, 956 (11th Cir.1999) (upholding content neutral city regulations proscribing soliciting, begging, or panhandling in a specified area because the regulations were narrowly tailored to provide "a safe, pleasant environment" and to prevent an adverse impact on tourism); *One World One Family Now v. City of Miami Beach,* 175 F.3d 1282, 1288 (11th Cir.1999) ("There is ... no question that the city's ... interest in creating an aesthetic ambiance which will attract tourists ... is a substantial government interest ...."); *see also United States v. Mahoney,* 247 F.3d 279, 286 (D.C.Cir.2001) (stating that the government has a significant interest in " 'ensuring public safety and order' ") (quoting *Schenck v. Pro–Choice Network of W. N.Y.,* 519 U.S. 357, 376, 117 S.Ct. 855, 137 L.Ed.2d 1 (1997)); *cf. People v. Bowen,* 11 Misc.2d 462, 175 N.Y.S.2d 125, 128 (N.Y.Ct.Spec.Sess.1958) (Tour guides have "the responsibility of seeing that the strangers in our midst are properly cared for and guided. Guides must be persons of knowledge and integrity—not steerers for fly-by-night operators. It is a matter of public concern and interest that they be carefully supervised.").

[19] With respect to whether the licensing scheme is narrowly tailored, defendant maintains that the regulations "are narrowly drawn, because they do not prohibit all commercial sightseeing activity, but merely prevent unlicensed tour guides from conducting paid tours." PI Opp. at MTD at 25. Plaintiffs disagree, arguing that there are many other less-restrictive options: for example, the District of Columbia could provide city-operated educational forums or hire its own tour guides; or the District could adopt a voluntary certification program. Mot. for PI at 11–12. It is established, however, that the District is not required to adopt the least restrictive means of pursuing its interests. *See American Library Ass'n v. Reno,* 33 F.3d 78, 88 (D.C.Cir.1994) ("[A] narrowly tailored regulation need not be the least restrictive or least intrusive means of serving the government's content-neutral interests.") (internal quotations and citation omitted). A content neutral statute or regulation will meet the narrow-tailoring requirement "if a substantial portion of the burden it imposes furthers the Government's interest, even though a less intrusive alternative might also exist." *Id.*

***13** Under the regulations, individuals who wants to act as for-profit tour guides, among other things, cannot have committed certain specified felonies and must pass an examination concerning general knowledge about the District. The Court concludes that these basic requirements are narrowly tailored to substantially further (1) the purpose of providing for the general welfare of society by attempting to ensure that those with serious felonies on their records are not guiding or directing tourists and residents around the District, and (2) the purpose of promoting the tourism industry by attempting to ensure that those who guide or direct people around the District have, at least, some

minimal knowledge about what and where they are guiding or directing people to.

[20] Finally, the licensing scheme leaves open ample alternatives for communication. Prior to obtaining a license, plaintiffs "still may engage in expressive activity by doing everything [they do] now except for" conducting their tours for profit. *Enten v. District of Columbia,* 675 F.Supp.2d at 53. The Court therefore concludes that "the means of communication available to [plaintiffs] are adequate." *Id.*

Both the statute and the regulations survive intermediate scrutiny review. Therefore, plaintiffs fail to meet their burden of establishing that they have a substantial likelihood of success on the merits of their First Amendment claim.

B. Irreparable Harm

Plaintiffs' irreparable harm argument rests entirely on their First Amendment claim. Because the Court concludes that plaintiffs have not shown that the tour guide licensing scheme violates their rights under the First Amendment, it also concludes that plaintiffs are "not faced with irreparable harm absent the issuance of an injunction." *Enten v. District of Columbia,* 675 F.Supp.2d at 54. "Although having one's protected speech chilled can constitute an irreparable injury," plaintiffs have not shown that their right to freedom of speech has been restricted. *Id.* (citing *Chaplaincy of Full Gospel Churches v. England,* 454 F.3d at 301) ("[T]he loss of First Amendment freedoms, for even minimal periods of time, may constitute irreparable injury ....") (internal quotations and citation omitted).[FN10]

IV. CONCLUSION

The Court concludes that plaintiffs have not demonstrated that they are likely to prevail on the merits of their claim that the District of Columbia tour guide licensing scheme is an unconstitutional restriction on plaintiffs' First Amendment rights. Furthermore, the Court concludes that plaintiffs are not faced with irreparable harm in the absence of an injunction. Absent a showing of a likelihood of success on the merits and irreparable injury, the two remaining prongs, balance of harms and the public interest, need not be addressed. *See Enten v. District of Columbia,* 675 F.Supp.2d at 54.

For the foregoing reasons, plaintiffs' motion for a preliminary injunction [Dkt. No. 7] will be DENIED and defendant's motion to dismiss [Dkt. No. 9] will be DENIED without prejudice. An Order consistent with this Opinion shall issue this same day.

***14** SO ORDERED.

ORDER

For the reasons set forth in the Opinion issued this same day, it is hereby

ORDERED that plaintiffs' motion for a preliminary injunction [Dkt. No. 7] is DENIED; it is

FURTHER ORDERED that defendant's motion to dismiss [Dkt. No. 9] is DENIED without prejudice; and it is

FURTHER ORDERED that the parties shall file a joint statement regarding how they wish to proceed in this case by March 15, 2011.

This is an appealable order with respect to the denial of plaintiffs' motion for a preliminary injunction. *See* FED. R.APP. P. 4(a); 28 U.S.C. § 1292(a)(1).

SO ORDERED.

FN1. During oral argument, the parties noted the possibility of introducing documentation into the record, under seal, or filing a set of stipulated facts and then moving for summary judgment. *See* December 22, 2010 Motions Hearing Transcript ("Tr.") at 46–50. The Court therefore will deny defendant's motion to dismiss without prejudice and will direct the parties to file a joint statement regarding how they wish to proceed in this case.

FN2. The papers reviewed in connection with the pending motions include the following: plaintiffs' complaint ("Compl."); plaintiffs' motion in support of their motion for a preliminary injunction ("Mot. for PI"); the declaration of Tonia Edwards and the declaration of Bill Main in support of plaintiffs' motion for a preliminary injunction ("Edwards Decl.") ("Main Decl."); defendant's motion to dismiss and opposition to plaintiffs' motion for a preliminary injunction ("PI Opp & MTD"); the declaration of Harold P. Pettigrew, Jr. ("Pettigrew Decl."); plaintiffs' combined reply in support of their motion for a preliminary injunction and opposition to defendant's motion to dismiss ("PI Reply & MTD Opp."); and defendant's reply ("MTD Reply"). The Court also has reviewed the transcript of the December 22, 2010 motions hearing.

FN3. Segways are defined as "self-balancing personal transport vehicle[s]." Compl. ¶ 27.

FN4. The statute and regulations are hereinafter referred to together as the "tour guide licensing scheme," unless otherwise noted.

FN5. There are only two reported decisions that discuss the District's tour guide licensing statute. Neither involved the First Amendment. In *District of Columbia v. Landmark Servs., Inc.,* 416 F.Supp. 559 (D.D.C.1976), the District brought an action against a company providing tour guide services, seeking to enjoin the company from operating until it complied with the District's tour guide statute, among others. *Id.* at 559–60. The company "admit[ted] that ordinarily it would have to comply," *id.* at 560, but argued that it was exempted by federal law because it was providing tour guide services from Robert F. Kennedy Memorial Stadium to the Mall, pursuant to its contract with the Secretary of the Interior. *Id.* at 560–61. Judge Sirica agreed with the company, holding that it was exempted from compliance with the tour guide statute. *Id.* at 564. The court of appeals affirmed the district court's judgment with modifications. *See United States v. District of Columbia,* 571 F.2d 651, 653, 660 (D.C.Cir.1977).

FN6. At least four other cities have promulgated similar tour guide licensing regulations: Philadelphia, Pennsylvania; New York, New York; Savannah, Georgia; and Charleston, South Carolina. *See* PHILADELPHIA CODE § 9–214 *et seq.;* NEW YORK CITY ADMINISTRATIVE CODE § 20–242 *et seq.;* CITY OF SAVANNAH, GEORGIA, ORD. 2–9–78, SEC. 1, § 6–1501 *et seq.;* CITY OF CHARLESTON, SOUTH CAROLINA, ORD. NO. 1998–174, ARTICLE III, § 29–58. The National Park Service has a similar regulation, promulgated in 1959, that requires the licensing of tour guides in National Military Parks. *See* 36 C.F.R. § 25.2.

As far as the Court is aware, Philadelphia's tour guide regulations are the only other regulations to have been challenged on First Amendment grounds. *See Tait v. City of Philadelphia,* 639 F.Supp.2d 582 (E.D.Pa.2009). The district court in *Tait,* however, did not reach the merits of the First Amendment claim. *See id.* at 585. Instead, because the city indicated that it would not be able to enforce the regulations due to economic decline and scarcity of resources, the district court held that the city's inability to enforce the regulations "vitiates ripeness" and dismissed the case for lack of subject matter jurisdiction. *Id.* The Third Circuit affirmed this decision, without comment on the merits of the First

Amendment claim. *See Tait v. City of Philadelphia,* No. 09–3599, 2011 WL 359700, at *1, *4 (3d Cir. Feb. 7, 2011).

FN7. Defendant's papers suggested that plaintiffs may lack standing. *See* Opp. & MTD at 40. During oral argument, however, defendant's counsel conceded that defendant does not challenge plaintiffs' standing in this case. Tr. at 34:16–21.

The parties' papers also raise two possible threshold questions. First, defendant contends that plaintiffs' challenge can only be a facial one, given that plaintiffs have "never applied for a license, and there's no credible threat of prosecution." Tr. at 31:21–22; *see also* PI Opp. & MTD at 15. Accordingly, defendant contends that plaintiffs must satisfy a high burden to prevail in this case. PI Opp. & MTD at 15. Plaintiffs did not respond to this argument in their papers. During oral argument, plaintiffs' counsel stated that plaintiffs did in fact plead both types of challenges in their complaint but conceded that plaintiffs have not applied for a license. *See* Tr. at 18:2–19:13. Plaintiffs' counsel then asserted that *Citizens United v. Federal Election Commission,* —— U.S. ——, 130 S.Ct. 876, 893, 175 L.Ed.2d 753 (2010), now makes clear that the difference between facial and as-applied challenges "is fundamentally a question of remedy...." Tr. at 18:7.

Second, the parties' papers raise the question whether the District's tour guide licensing requirements could be considered general occupational licensing requirements subject only to rational basis review and outside of First Amendment scrutiny. *See Schware v. Bd. of Bar Exam'rs,* 353 U.S. 232, 239, 77 S.Ct. 752, 1 L.Ed.2d 796 (1957); *Taucher v. Born,* 53 F.Supp.2d 464, 476 (D.D.C.1999).

The Court need not resolve either question. Regardless of how plaintiffs characterize the nature of their challenge and assuming that the First Amendment does in fact apply, the Court concludes that the tour guide licensing scheme is content neutral and survives intermediate scrutiny review.

FN8. Plaintiffs do concede that one—but only one—regulation is directed purely at commercial speech: the holding-out provision. *See* Mot. for PI at 12–13. As discussed, Section 1201.5 of the regulations prohibits anyone other than a licensed sightseeing company or tour guide from advertising its services using the words " 'sightseeing,' 'tours,' 'guide,' or any combination of these words, to advertise the availability of sightseeing tour services." D.C. MUN. REGS. TIT. 19, § 1201.5. Plaintiffs' argument here is that this commercial speech restriction cannot stand separately from the underlying licensing requirements and that these terms are truthful and nonmisleading. Mot. for PI at 13. Given the Court's conclusion that the underlying licensing requirements are valid, plaintiffs' argument on this point becomes moot. *Cf. Nat'l Ass'n for the Advancement of Psychoanalysis v. California Bd. of Psychology,* 228 F.3d 1043, 1056 n. 10 (9th Cir.2000) ("Plaintiffs concede that, if the licensing scheme is otherwise valid, they have no viable commercial speech claim for the right to use professional titles, such as 'psychoanalyst' and 'analytical psychologist.' ").

FN9. Even apart from the distinction explained above, the Court suspects that this exception may also have been included in

the tour guide licensing scheme because drivers of such sightseeing vehicles are already regulated under another Title of the municipal regulations, which was neither discussed nor cited by the parties. Section 1000 of Title 31 of the municipal regulations provides that "[n]o person shall operate or permit to be operated any vehicle for sightseeing purposes unless a certificate permitting that use is issued by the Chairperson of the District of Columbia Taxicab Commission." D.C. MUN. REGS. TIT. 31, § 1000.3. Those who wish to obtain a "license to operate a[ ] ... sightseeing vehicle"—the bus drivers—already must meet minimum standards of good moral character and health requirements, *id.* § 1008. 1, and must take a test concerning "knowledge of the Metropolitan Area." *Id.* § 1008.4.

FN10. Plaintiffs assert that this tour guide licensing scheme would limit their ability to hire part-time guides, and, "without these part-time guides, [plaintiffs are] not sure [they] could keep the business going—at least not in its current form." Main Decl. ¶ 24. To the extent that this is an irreparable harm argument, this assertion suggests nothing more than general economic harm. Such an argument fails under the rule that " 'economic harm does not constitute irreparable injury.' " *Sterling Commercial Credit–Michigan, LLC v. Phoenix Indus. I, LLC,* Civil Action No. 10–2332, —— F.Supp.2d ——, ——, 2011 WL 263674, at *6 (D.D.C. Jan. 28, 2011) (quoting *Davis v. Pension Benefit Guar. Corp.,* 571 F.3d 1288, 1295 (D.C.Cir.2009)).

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