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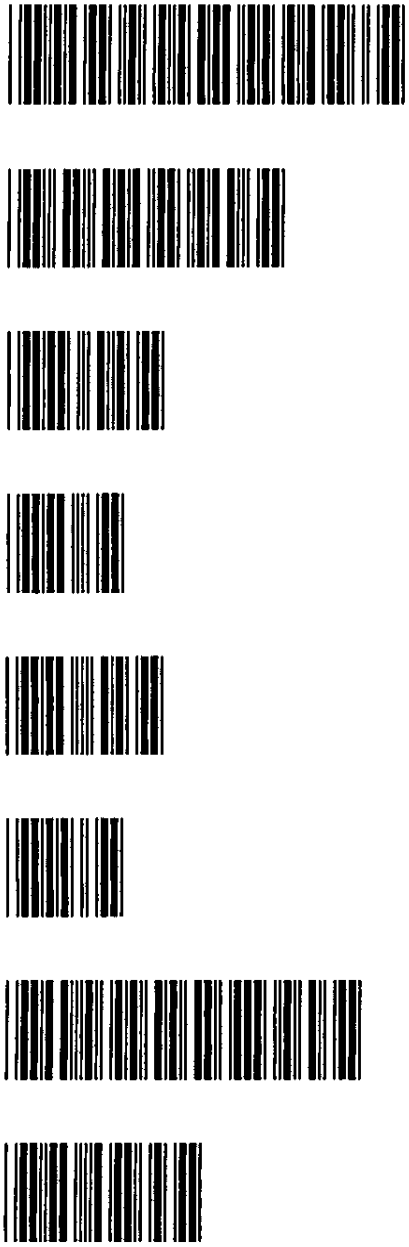

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3:04-CV-00216 WALLACH V. FDA

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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

JOEL D. WALLACH, D.V.M., N.D., an individual, and AMERICAN LONGEVITY, INC., a California Corporation,

Plaintiffs,

vs.

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.

CASE NO. 04CV216 BTM (WMC)

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

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.

34

§ 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 affixed 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.[1] 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.

II. STATUTORY BACKGROUND

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

[1]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.)

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

Article III of the United States Constitution requires that a party have standing to bring an action in federal court. Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (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) if displayed in an establishment, is physically 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.[2]

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[2] Cf., e.g., National Park Hospitality Ass'n v. Department of Interior, 538 U.S. 803, 810 (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 (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 (1948). The Court in Kordel held that promotional pamphlets and circulars distributed by the drug manufacturer to its vendors, though *separate* from the drug product, nevertheless constituted "labeling" thereby rendering the product misbranded.[3] Id. at 346-49.

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) articles (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.[4]

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

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[3]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.

[4]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).

claim, established by regulation of the Secretary." 21 U.S.C. § 343(r)(5)(D).[5] 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).[6]

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

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

[6]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.

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.

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 (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 Lujan, 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.[7]

The Magnesium Package, as presented to this Court, patently fails to meet § 343-2(a)(2), (3), and (5).[8] 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, – F.3d –, 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 (1975) (Article III requires that "the plaintiff . . . must allege a distinct and palpable injury to himself"). At best, Plaintiffs'

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[7]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).

[8]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.

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(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 (1962)); Whitmore v. Arkansas, 495 U.S. 149, 155-156 (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.[9]

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 (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).[10]

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[9]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).

[10]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

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 (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 (2002) (citing Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 770 (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

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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).

burden of justifying it." Bolger, 463 U.S. at 71, n. 20. See also Edenfield v. Fane, 507 U.S. 761, 770 (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.[11] Defendants, on the other hand, argue that the Magnesium Package is misleading because the PDR chapter contains drug related claims. Furthermore, Defendants argue that the 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.

The government may ban *inherently* misleading speech outright. See In re R. M. J., 455 U.S. 191, 203 (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-

[11]The First Amendment protects scientific speech and expression. See Miller v. California, 413 U.S. 15, 34 (1973); Keyishian v. Board of Regents, 385 U.S. 589, 603 (1967); Board of Trustees of Leland Stanford Jr. Univ. v. Sullivan, 773 F.Supp. 472 (D.D.C. 1991).

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" under the 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.[12] 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.").

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

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[12]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.

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 (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

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 (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."); California 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.[13] Rubin v. U. S., 449 U.S. 424, 430 (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).

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 (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 (1992) (citations omitted).

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

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[13]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) itself.

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.[14] However, Congress expressly cautioned that:

> 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.

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[14]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).

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.

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 (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 (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 (1986)) (emphasis added).

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.

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.[15] Plaintiffs' motion for summary judgment is **DENIED** and Defendants' cross motion for summary judgement is **GRANTED**.

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.

Dated: 3/29/05

HONORABLE BARRY TED MOSKOWITZ
United States District Judge

cc: All parties and counsel of record

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