I. INTRODUCTION

Second verse, same as the first. Plaintiff's First Amended Complaint (Dkt. #27) charges Defendants with violating Sections 5(a) and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45(a) and 52, in connection with the marketing of products that purportedly treat or prevent diabetes. Defendants have moved to dismiss the First Amended Complaint on grounds different from those asserted in their first motion to dismiss. Motion to Dismiss First Amended Complaint (Dkt. #30, "2d Mot. Dismiss"). Defendants' motion is ill-founded. It misapprehends the standard for a Rule 12(b)(6) motion; ignores decades of relevant case law interpreting the statutes at issue here; brazenly asserts a constitutional right to deceptive advertising; and rests on the irrelevant premise that Defendants' products qualify as "medical foods" under a statutory scheme not applicable here. The Federal Trade Commission ("FTC" or "Commission") respectfully requests that the Court deny Defendants' attack on the First Amended Complaint in its entirety.

II. STATEMENT OF ISSUES PURSUANT TO LOCAL RULE 7-4

A. For purposes of analyzing a Rule 12(b)(6) motion, Plaintiff's factual allegations must be taken as true.

B. The FTC Act applies to Defendants' deceptive advertising.

C. Deceptive advertising is not a constitutional right.

D. The Administrative Procedure Act does not bar the FTC from challenging Defendants' deceptive advertising.

III. ARGUMENT

A. For purposes of analyzing a Rule 12(b)(6) motion, Plaintiff's factual allegations must be taken as true.

The Court has previously set forth in this matter the standards that apply to a Rule 12(b)(6) motion:

> A complaint may be dismissed for failure to state a claim for which relief can be granted under Rule 12(b)(6) of the Federal Rules of Civil Procedure. Fed. R. Civ. P. 12(b)(6). "The purpose of a motion to dismiss under Rule 12(b)(6) is to test the legal sufficiency of the complaint." N. Star Int'l v. Ariz. Corp. Comm'n, 720 F.2d 578, 581 (9th Cir. 1983).***
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> In ruling on a motion to dismiss under Rule 12, the court analyzes the complaint and takes "all allegations of material fact as true and construe(s) them in the light[] most favorable to the nonmoving party." Parks Sch. of Bus. v. Symington, 51 F.3d 1480, 1484 (9th Cir. 1995). Dismissal may be based on a lack of a cognizable legal theory or on the absence of facts that would support a valid theory. Balistreri v. Pacifica Police Dep't, 901 F.2d 696, 699 (9th Cir. 1990).

Order Granting in Part and Denying in Part Motion to Dismiss ("Order on Mot. Dismiss"), p. 9 (emphasis added).[1] Analyzing the FTC's original Complaint,

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[1] The FTC set forth the facts and legal theories underpinning its original Complaint in its Opposition to Defendants' Motion to Dismiss Complaint (Dkt. #18, "Opp. to Mot. Dismiss"), pp. 3-6. The facts contained in

this Court found that it properly alleged an action against corporate defendant Wellness Support Network and individual defendant Robert Held under Sections 5(a) and 12 of the FTC Act. Id. at 14-15.[2]

Motions to dismiss thus test the sufficiency of the complaint; they are not

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the First Amended Complaint are not materially different, and the legal theories are unchanged, so they are not further detailed here.

[2] The Court dismissed the FTC's allegations as to individual defendant Robyn Held with leave to amend. The FTC's First Amended Complaintadds additional detail on Robyn Held's involvement in Wellness Support Network and its deceptive practices. See First Amended Complaint, ¶¶ 7-8, p. 3.

the purposes of this motion, the Court should accept

[3] FTC v. Pantron I Corp., 33 F.3d 1088 (9th Cir. 1994) (holding that claims that are false or that lack adequate substantiation are deceptive and violate Sections 5(a) and 12 of the FTC Act).

[4] Despite Defendants' assertions to the contrary, see 2d Mot. Dismiss, p. 10, Pantron I remains good law. The Ninth Circuit continues to use its formulations for what constitutes a violation of Sections 5(a) and 12 of the FTC Act and how liability is created thereby. See, e.g., FTC v. Cyberspace.com, LLC, 453 F.3d 1196, 1199-1200, 1201-02 (9th Cir. 2006); FTC v. Stefanchik, 559 F.3d 924, 931 (9th Cir. 2009).

Defendants' citation to FDA v. Brown & Williamson, 529 U.S. 120,

§ 45(a). Order on Mot. Dismiss, p. 10. The FTC's jurisdiction under Section 5 of the FTC Act is very broad, covering nearly all products and services. There are only a handful of exceptions, which are stated in the statute. None of these exceptions applies to Defendants' products, nor have defendants cited to any. Neither do Defendants cite to any FTC case law that suggests that medical foods should be treated any differently under Section 5 than any other product.

In addition to Section 5, this action is brought under Section 12 of the FTC Act, 15 U.S.C. § 52. Section 12 prohibits dissemination of false advertisements in or affecting commerce for the purposes of inducing, or which

[6] Available at: http://business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry.pdf

[7] Discussed in more detail infra.

[8] For the widespread use of the reasonable basis or substantiation standard see, e.g., Daniel Chapter One v. FTC, 2010 U.S. App. LEXIS 25496, at *2-3 (D.C. Cir. 2010), cert. denied, 2011 U.S. LEXIS 3931 (U.S. 2011); Pantron I, 33 F. 3d at 1096; FTC v. Medlab, Inc., 615 F. Supp. 2d 1068,1079 (N.D. Cal. 2009); FTC v. Nat'l Urological Group, Inc., 645 F. Supp. 2d 1167, 1190 (N.D. Georgia 2008); FTC v. Natural Solution, Inc., 2007 U.S. Dist. LEXIS 60783 (C.D. Cal. 2007), *10-12 (relying on FTC v. QT, Inc., 448 F. Supp. 2d 908, 961 (N.D. Ill. 2006); FTC v. Sabal, 32 F. Supp. 2d 1004,1007 (N.D. III. 1998).

For the widespread use of the deception standard see, e.g., FTC v. Stefanchik, 559 F.3d 924, 928 (9th Cir. 2009); Nat'l Urological Group, Inc., 645 F. Supp. 2d at 1188-89; FTC v. Cyberspace.com

[10] Defendants' reliance on Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999) is misplaced. See 2d Mot. Dismiss, pp. 5-6. That case involved a challenge to an FDA regulation that imposed a blanket prohibition on making health claims for dietary supplements unless there was significant scientific agreement among experts regarding the accuracy of the claim. Id. at 651. The principal issue in Pearson was whether a claim lacking scientific agreement could be barred on the ground that it was "potentially misleading." Id. at 655. That is, the FDA argued that its rule should be free from First Amendment scrutiny because some of the health claims to which the regulation applied might be deceptive, even though others would not be. The Court rejected that argument and therefore conducted a First Amendment analysis of the rule's restrictions under the three-part test set forth in Central Hudson. Id. at 655-56. The situation here is different. The Commission has alleged that defendants' advertisements were actually (not potentially) deceptive. If these allegations are established, then the advertising is entitled to no First Amendment protection at all.

Amended Complaint, ¶¶ 24-27, pp. 9-10. Both statements that are false and those that lack adequate substantiation constitute deceptive acts or practices under the FTC Act in the Ninth Circuit. See Pantron I, 33 F.3d at 1095-96. This Court will ultimately decide whether the challenged representations are deceptive, but for purposes of a motion to dismiss, the Court must assume the representations are false or lack substantiation, as alleged. As false and unsubstantiated claims are considered deceptive under relevant Ninth Circuit law, see id., Defendants' representations are entitled to no constitutional protection and the First Amended Complaint must stand.

Defendants' commercial speech rights are not infringed by this proceeding. If the Court finds that the Defendants' advertising claims are false or unsubstantiated, then there is no constitutional violation because the First Amendment does not protect false or misleading commercial speech, and an order prohibiting such speech is an appropriate remedy. See Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 638 (1985) ("The States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading."); In re R. M. J., 455 U.S. 191, 203 (1982) ("Misleading advertising may be prohibited entirely."); Central Hudson, 447 U.S. at 563-64 ("The government may ban forms of communication more likely to deceive the public than to inform it."); Bristol-Myers Co. v. FTC, 738 F.2d 554, 562 (2d Cir. 1984) ("deceptive advertising enjoys no constitutional protection") (citation omitted).[11]

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[11] Defendants also claim that the First Amended Complaint "fails to even consider the disclaimers" made in their advertising and that this "amounts to a constitutional violation." 2d Mot. Dismiss, p. 6. This is perplexing, as Defendants themselves note that the First Amended Complaint attaches examples of their disclaimers. See 2d Mot. Dismiss, p. 6. Furthermore, it is well (continued...)

D. The Administrative Procedure Act does not prevent the FTC from challenging Defendants' deceptive advertising.

By basing part of their second Motion to Dismiss on the Administrative Procedure Act, 5 U.S.C. § 553 et seq. ("APA"), Defendants are essentially arguing that the APA serves as an absolute bar to this enforcement action. See 2d Mot. Dismiss, pp. 6-8. To make this argument, however, Defendants must take the position that the legal standards which apply here, requiring that Defendants' advertising claims be truthful and adequately substantiated, are new. Id. at 7-8. This borders on the frivolous. The FTC is in no way seeking to extend the law in this case, only to enforce the law which has always applied to Defendants' advertising. Furthermore, even if the FTC were attempting to change the law or adopt "new rules of widespread application," the agency could clearly do so, as the FTC's action here is not an attempt to circumvent a pending r 4.6800 0.0000 TD (s4000 0.00000 0.00000 1.00000 .0000 TD (not)T 21.2400

[11](...continued)
established that "a disclaimer does not automatically exonerate deceptive activities." FTC v. Gill, 71 F. Supp. 2d 1030, 1044 (C.D. Cal. 1999), aff'd, 265 F.3d 944 (9th Cir. 2001). The mere existence of disclaimers in Defendants' advertising here does not insulate that advertising from challenge under the FTC Act.

[12] See 2d Mot. Dismiss, pp. 9-10.

Defendants have misled consumers in violation of Sections 5 and 12 of the FTC Act. Pantron I, 33 F.3d at 1096. First, the FTC can use a "falsity" theory, under which the Commission must prove that the express or implied messages conveyed by the advertisements are false. The FTC can also use a "reasonable basis" theory, under which the FTC must show that Defendants lacked a "reasonable basis" also known as "substantiation" for their claims. See id.

Under the "reasonable basis" theory, advertising claims must be substantiated by competent and reliable evidence. Id. Health claims, however, must be substantiated by competent and reliable scientific evidence. See, e.g., FTC v. Natural Solution, Inc., 2007 U.S. Dist. LEXIS 60783 (C.D. Cal. Aug. 7, 2007), *10-12 (quoting FTC v. QT, Inc., 448 F. Supp. 2d 908, 961 (N.D. Ill. 2006), aff'd 512 F. 3d 858 (7th Cir. 2008)); FTC v. Nat'l Urological Group, 645 F. Supp. 2d 1167, 1190 (N.D. Georgia 2008); FTC v. Direct Marketing Concepts, 569 F. Supp. 2d 285, 299 (D. Mass. 2008). This standard has been applied in numerous cases finding that advertisements making health claims without a reasonable basis substantiating those claims were deceptive. See, e.g., Natural Solution, 2007 U.S. Dist. LEXIS 60783 at *16-17; FTC v. Sabal, 32 F. Supp. 2d 1004, 1007 (N.D. III. 1998); QT, 448 F. Supp. 2d at 961.

As noted above, the First Amended Complaint properly alleges that Defendants' products are "foods" or "drugs" for purposes of Section 12 of the FTC Act, and that violations of Section 12 are also violations of Section 5. The FTC has also properly alleged that Defendants' advertising claims for their products were false or unsubstantiated at the time they were made. The requirement that substantiation include competent and reliable scientific evidence applies not only to "dietary supplements," but to health claims generally. It does not matter whether those health claims are about dietary

supplements,[13] drugs,[14] metal bracelets with purported healing powers,[15] or, as in this case, about a combination of pills touted as a "diabetes breakthrough."[16] Regardless of the product, the standard for health claims is the same, and the application of this standard to Defendants' advertising is neither new nor elusive.

Defendants make much of the fact that the FTC referred to "guidance documents" in its opposition to Defendants' First Motion to Dismiss. See Mot. Opp., pp. 2, 4, 8-9. From this reference, Defendants argue that the Commission is trying to improperly give its guidance documents the force of law. The Defendants are simply wrong. The Commission never suggested that guidance documents, in and of themselves, have the force of law. See FTC Opposition to Motion to Dismiss (Dkt. #18), pp. 8-9. The relevant law here is, and always has been, those Ninth Circuit decisions applying the FTC Act.[17] The FTC's guidance documents, including those cited in this case, describe the state of FTC law as it currently exists – something Defendants previously claimed they did not understand. See Defendants' Motion to Dismiss (Dkt. #9), p. 6, n.1.

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[13] Natural Solution, Inc., 2007 U.S. Dist. LEXIS 60783.

[14] Pantron I Corp., 33 F.3d at 1105.

[15] QT, Inc., 448 F. Supp. 2d at 961 (N.D. Ill. 2006).

[16] First Amended Complaint, ¶ 20.

[17] Defendants also argue that Commission policy statements that were not promulgated under the APA do not warrant "Chevron deference," citing Christensen v. Harris County, 529 U.S. 576 (2000). 2d Mot. Dismiss, p. 8. Chevron deference, which refers to the level of deference a court will show an agency's interpretation of its own statute, is a red herring. The FTC has not asked for Chevron deference here. This and the FTC's prior pleadings cite to cases in which courts have taken up the FTC's recommended deception and substantiation standards and made them their own.

agency cannot articulate new principles through adjudication: (1) if doing so would amount to an abuse of discretion; or (2) if doing so would circumvent APA requirements. Union Flights, Inc. v. Administrator, Federal Aviation Admin., 957 F.2d 685,688 (9th Cir. 1992)(citing Bell, 416 U.S. at 294). As noted above, the Commission is not announcing new principles in this case. Even if it were, however, it is neither abusing its discretion nor circumventing the APA. We now address the applicability of these exceptions to this case.

a. The FTC is not abusing its discretion.

The first exception, where announcing new principles through adjudication constitutes an abuse of discretion, applies when the agency suddenly changes its direction and that change also results in a unique hardship for those who relied on past policy. Union Flights, 957 F.2d at 688. This is obviously not the case here, as the Commission has consistently filed enforcement actions against companies who make false or unsubstantiated health claims. In fact, the courts' willingness over the year..0000 0.0000 TD0.0000 Tc 1.00000 0.0000 0.0000 cm 0.

part on other grounds, 47 F. 3d 990 (9th Cir. 1994) (rejecting a Ford-based challenge by individual weight loss providers to the Commission's case-by-case approach to an industry-wide problem, even though the remedy requested by the FTC was new; "[s]ubsequent Ninth Circuit law ... has limited the holding of Ford.").

In this case, not only is there no new principle of law being advanced, even if there were, the limited Ford exception would not apply. Defendants' reliance on Ford is unavailing.

IV. CONCLUSION

This laws