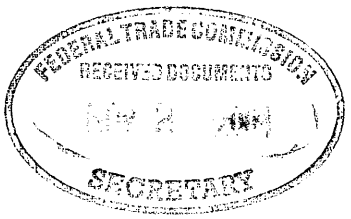
IN THE UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION



In the Matter of	:	
DYNAMIC HEALTH OF FLORIDA, LLC, **CHHABRA GROUP, LLC,** **DBS LABORATORIES, LLC,** **Limited liability companies,**	:	
VINCENT K. CHHABRA, **Individually and as an officer of** **Dynamic Health of Florida, LLC,** **And Chhabra Group, LLC, and**	:	**DOCKET NO. 9317**
JONATHAN BARASH, **Individually and as an officer of** **DBS Laboratories, LLC.**	:	

RESPONDENTS' REPLY TO THE FEDERAL TRADE COMMISSION'S MOTION TO STRIKE RESPONDENTS' AFFIRMATIVE DEFENSES

The Federal Trade Commission has moved to strike the affirmative defenses raised by Respondents in their answer. For the reasons which follow, Respondents respectfully submit that the motion to strike should be denied.

I. Federal Rule of Civil Procedure 12(f).

The FTC correctly notes that Rule 12(f) permits an affirmative defense to be stricken if it is "redundant, immaterial, impertinent or scandalous." Mot. Str. at 2. However, "Courts disfavor motions to strike." *Nwachukwu v. Karl,* 216 F.R.D. 176, 178 (D.D.C. 2003) (citations omitted). In considering a motion to strike, all reasonable inferences are drawn in favor of the pleader and all doubts are resolved in favor of denying the motion to strike. *Id.* (citations omitted). "Consequently, the burden lies with the movant." *Id.* (citations omitted).

A matter should not be stricken from a pleading "unless it is clear that it can have no possible bearing upon the subject matter of the litigation." *North Carolina Shellfish Growers v. Holly Ridge Associates,* 200 F.Supp.2d 551 (E.D.N.C. 2001). A party seeking to strike an affirmative defense must demonstrate "that the allegations being challenged are so unrelated to the plaintiff's claims as to be unworthy of any consideration as a defense and that the moving party is prejudiced by the presence of the allegations in the pleading." *FTC v. Commonwealth Marketing,* 72 F.Supp.2d 530, 545 (W.D.Pa. 1999) (citations and internal quotations omitted).

Courts should be careful to ensure that federal agencies do not utilize motions to strike for improper purposes. *See generally Cobell v. Norton,* 224 F.R.D. 1 (D.D.C. 2004). For example, if a federal administrative agency, such as the Federal Trade Commission, were to develop an established practice of routinely moving to strike affirmative defenses which are obviously relevant and pertinent to the proceedings at issue, such a practice would clearly be improper and it should not be tolerated.

A. Respondents' First Amendment defense is obviously relevant and pertinent to this proceeding.

The FTC concedes that this is a case about commercial speech. Mot. Strike at 3. The FTC acknowledges that commercial speech is protected by the First Amendment. *Id.* at 3-4. The FTC nevertheless claims that the First Amendment is wholly inapplicable to these proceedings. *Id.* The FTC contends:

> If the Court finds that the Respondents' advertising claims are false or misleading, there is no First Amendment violation because the First Amendment does not protect false or misleading commercial speech and an order prohibiting such speech is an appropriate remedy. If the Court finds that the Respondents' advertising claims are not false or misleading, then there is still no First Amendment violation because no restrictions will be imposed on the Respondents' future marketing statements.
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> Mot. Strike at 4.

As the FTC implicitly acknowledges, the relevant issue is whether the statements in question were "false and misleading" within the meaning of the First Amendment. The FTC cannot seriously argue that the First Amendment is inapplicable to these proceedings while simultaneously recognizing that any standard of review which is utilized must comport with the First Amendment as a matter of federal constitutional law. Moreover, it is beyond dispute that the First Amendment is applicable to administrative proceedings in which commercial speech is at issue. *See, e.g., Pearson v. Shalala,* 164 F.3d 650 (D.C. Cir. 1999). The assertions of the FTC to the contrary have no basis in law and must accordingly be rejected.

B. *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002) is controlling authority in these proceedings and is clearly relevant and pertinent to the issues in this case.

The FTC contends that the binding authority of the Supreme Court of the United States is "insufficient as a matter of law" to provide Respondents with a defense in this case. Mot. Strike at 4-5. Because the decision of the Supreme Court in *Western States* is fully applicable to these proceedings, the claims of the FTC to the contrary must be rejected.

The FTC's interest in excluding *Western States* from the jurisprudential framework of this case is obvious: the decision of the Supreme Court in *Western States* reaffirmed that in the context of commercial speech regulation, the government bears the burden of proving that the manner of regulation it seeks to utilize constitutes the least restrictive means available. *Western States, supra,* 535 U.S. at 371-74; *see also Thompson v. Whitaker I,* 248 F.Supp.2d 1, 9 (D.D.C. 2002), citing *Western States.* The FTC cannot satisfy this burden because the District of Columbia Circuit has previously held that health claims relating dietary supplements will qualify as protected commercial speech so long as the claims are supported by some credible evidence

and are accompanied by an appropriate disclaimer. *See Whitaker I, supra,* 248 F.Supp.2d at 10, applying *Pearson.*

As Respondents have asserted in their Answer to the complaint filed by the FTC in this case, the advertising at issue in this case is supported by a reasonable degree of credible evidence. The use of an appropriate disclaimer accordingly brings the advertisements at issue within the boundaries of constitutionally protected commercial speech. *See, e.g., Whitaker I, supra.* If the FTC wishes to achieve a different result it has the burden of demonstrating that any additional measures it wishes to impose are necessary and the least restrictive means available. *See, e.g., Whitaker I, supra.* The inability of the FTC to meet the burden in question does not constitute a valid basis for striking a defense guaranteed to Respondents by the Federal Constitution. The protestations of the FTC to the contrary are unavailing and must accordingly be rejected.

C. The FTCA obviously does not apply to statements which qualify as entirely permissible structure/function claims under the DSHEA.

In enacting the Dietary Supplement Health and Education Act of 1994, Congress reaffirmed[1] that it wished to permit the utilization of structure/function health claims in conjunction with the marketing of dietary supplements. *Whitaker v. Thompson II,* 239 F.Supp.2d 43, 46 (D.D.C. 2003). The scope of permissible structure/function claims is well-established under the precedent of both the District of Columbia Circuit and the District Court for the District of Columbia, and it is clear that the structure/function claims utilized by Respondents are permissible under the relevant framework. *See, e.g. Pearson, supra; Whitaker I & II, supra.*

[1] The DSHEA was preceded by the Nutritional Labeling and Education Act of 1990; the NLEA had established the original legal framework permitting the utilization of health claims in the marketing of dietary supplements. *See Pearson, supra,* 164 F.3d at 653.

It is patently obvious that Congress did not intend to release supplement marketers from the labyrinth of pharmacological strictures imposed by the FDA only to have the FTC move in and seek liability on exactly the same grounds that the DSHEA is supposed to eliminate. If the FTC mistakenly believes that it can demonstrate that the structure/function claims utilized by Respondents are not protected by the DSHEA, it is by all means free to attempt to do so. The FTC has every right to raise such arguments when this case has progressed to the merits stage of litigation. However, the FTC's arguments in this regard have absolutely no place in a pretrial motion to strike.

The FTC contends that "Whether or not Respondents' claims are consistent with the DSHEA has no bearing on the legality of Respondents' claims under Section 5 of the FTC Act." Mot. Strike at 7. The government's argument is squarely refuted by the decision of the Supreme Court in *Food and Drug Administration v. Brown & Williamson Tobacco,* 529 U.S. 120 (2000):

> In determining whether Congress has specifically addressed the question at issue, a reviewing court should not confine itself to examining a particular statutory provision in isolation. The meaning--or ambiguity--of certain words or phrases may only become evident when placed in context. *See Brown v. Gardner*, 513 U. S. 115, 118 (1994) ("Ambiguity is a creature not of definitional possibilities but of statutory context"). It is a "fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Davis v. Michigan Dept. of Treasury*, 489 U. S. 803, 809 (1989). A court must therefore interpret the statute "as a symmetrical and coherent regulatory scheme," *Gustafson v. Alloyd Co.*, 513 U. S. 561, 569 (1995), and "fit, if possible, all parts into an harmonious whole," *FTC v. Mandel Brothers, Inc.*, 359 U. S. 385, 389 (1959). Similarly, the meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand. *See United States v. Estate of Romani*, 523 U. S. 517, 530-531 (1998); *United States v. Fausto*, 484 U. S. 439, 453 (1988). In addition, we must be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of such economic and political magnitude to an administrative agency. *Cf. MCI Telecommunications Corp. v. American Telephone & Telegraph Co.*, 512 U. S. 218, 231 (1994).
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> 529 U.S. at 132-33.

As in *Brown & Williamson*, in the present case the proper application of the relevant statutes cannot be discerned unless the statutes in question are considered in conjunction with one another. *Id.* The protestations of the FTC to the contrary cannot be reconciled with the Supreme Court's unambiguous instruction that "one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand." *Id.* at 133. In this case, it is beyond dispute that Congress has enacted legislation permitting the utilization of structure/function health claims in the marketing of dietary supplements. *See, e.g., Pearson, supra.* The FTC nevertheless contends that it has the authority to disregard this unambiguous Congressional objective and institute proceedings based on structure/function claims, whether or not such claims are lawful under the DSHEA. Mot. Strike at 7. The FTC's argument has no basis in law and directly contradicts the guidance provided by the Supreme Court in *Brown & Williamson.* As a result, the FTC's motion to strike should be denied.

D. It is settled law that the defense of entrapment by estoppel may be raised against the government, and the defense is clearly relevant to this case.

The FTC contends that the affirmative defense of entrapment by estoppel should be stricken from Respondents' Answer. Mot. Strike at 9. The availability of entrapment by estoppel as a defense against the United States is not subject to debate. *See, e.g., United States v. Batterjee,* 361 F.3d 1210 (9th Cir. 2004); *United States v. Abcasis,* 45 F.3d 39 (2d Cir. 1995); *United States v. Thompson,* 25 F.3d 1558, 1563-65 (11th Cir. 1994); *United States v. Lewin,* 973 F.2d 463, 468 (6th Cir. 1992).*United States v. Hedges,* 912 F.2d 1397, 1403-06 (11th Cir. 1990).

Entrapment by estoppel is properly raised as a defense where a defendant has reasonably relied on an official government statement in concluding that his conduct did not violate the statute at issue. *United States v. Rosenthal,* 266 F.Supp. 2d 1068, 1081 (N.D. Cal. 2003), citing

United States v. Penn. Indust. Chem. Corp., 411 U.S. 655, 670-74 (1973). Where an individual has relied on an official government pronouncement delineating the meaning of the law, "the traditional notions of fairness in our system of criminal justice prevent the government from proceeding with the prosecution." *Penn. Indust. Chem., supra,* 411 U.S. at 674.

Furthermore, as recognized in *Zwak v. United States,* 848 F.2d 1179 (11th Cir. 1998), in appropriate circumstances the principles of entrapment should be applied against the United States in civil proceedings where the interests of justice so require. 848 F.2d at 1183-84. *See also Morrison v. U.S. Department of Labor et al.,* 713 F.Supp. 664, 674-76 (S.D.N.Y. 1989) (explaining that the justifications which make reasonable reliance upon an official statement of law a valid defense to a criminal charge are equally applicable in the context of civil proceedings). This Court should accordingly hold that the defense of entrapment by estoppel is available in the context of administrative proceedings, such as the present case.

The Federal Register statement at issue in this case clearly constituted an official statement by the Food and Drug Administration providing guidance on the requirements of the law:

> (33.) Some comments argued that the types of claims permitted under the proposal may discourage serious approaches to substantiation because the terms used are not scientifically verifiable. Stating that the preferred method of substantiation is an adequate and well-controlled trial, one comment contended that the claims permitted under the rule are not amenable to such proof. According to this comment, this rule may preclude companies from meeting the substantiation rules of the Federal Trade Commission (FTC). A few comments said that manufacturers cannot substantiate claims that a product maintains healthy status. One of these comments stated that it was impossible to show by adequate studies that "cranberry extract supports healthy urinary tract functioning," and that companies should instead be able to show that cranberry extract reduces frequency of urinary tract infections in susceptible people. Similarly, because it is "impossible" to test whether St. John's Wort "supports mood" in the general population, companies need to be able to test its effect on depressed people.

> FDA agrees that some structure/function claims that are acceptable under DSHEA may be difficult to substantiate. For example, some structure/function claims currently in the marketplace use terms that do not have clear scientific meaning. Other claims concern health maintenance in the general population and therefore could require studies in a large population for substantiation. FDA believes, however, that such claims are within the intended scope of section 403(r)(6) of the act. Difficulty in substantiating them does not alter the terms of the statute. Manufacturers are responsible for determining whether claims for their products can be appropriately substantiated, and to use only those claims for which they have substantiation. FDA does not agree that difficulty in substantiating a particular claim justifies the use of express or implied disease claims for which methods of substantiation may be more straightforward. Such an approach would turn section 403(r)(6) of the act on its head.
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> FDA also does not agree that it is impossible to substantiate the claims described in the comments. For example, to substantiate the claim "supports mood," it is not necessary to study the effects of a substance on clinical depression. Instead, it is quite possible to assess the effects of a substance on mood changes that do not constitute clinical depression.
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> 65 FR 1000 at 1012.

"[S]ection 403(r)(6) of the act" in the foregoing Federal Register notice refers to 21 U.S.C. § 343(r)(6), which is the statute permitting the use structure/function health claims. *See* 68 FR 59189 at 59189. While the FDA declined to adopt a fixed formula for the substantiation of structure/function claims, *see* 65 FR 1032, the foregoing statements of the FDA clearly indicate that the structure/function claims utilized by Respondents in this case were permissible under the DSHEA.

The notice quoted above also clearly indicates that controlled clinical studies on a specific product are not a prerequisite to a lawful structure/function claim, so long as the claim in question is supported by adequate substantiation. The FDA subsequently explained:

> There is no specific statutory requirement that the studies substantiating the statement be performed using the actual marketed formulation. However, many ingredients and factors influencing the formulation can affect the safety and effectiveness of the dietary supplement. These variations from the marketed product should be considered before using a study to substantiate a statement made for a particular product.

65 FR at 1032.

The foregoing statement unambiguously indicates that structure/function claims relating to a dietary supplement can be adequately substantiated by evidence relating to the ingredients in the supplement, rather than the specific formulation utilized in the supplement itself. Respondents had adequate substantiation for all of the statements cited in the FTC's Complaint based on the ingredients contained in Pedia Loss and Fabulously Feminine. As a result, the statements of the FDA in the Federal Register notice clearly indicated that such evidence would constitute substantiation within the meaning of the FTCA. *See* 65 FR at 1012. Furthermore, comments submitted by the FTC which related to the substantiation requirement were addressed by the FDA in the Federal Register notice at issue. *See* 65 FR at 1032. Under such circumstances, the defense of entrapment by estoppel should clearly be available to Respondents. The arguments of the FTC to the contrary must be rejected.

E. Respondents are obviously entitled to challenge the merits of the FTC's case.

The FTC contends that Respondents are not entitled to challenge the merits of the FTC's complaint. Mot. Strike at 10. The FTC claims that "Respondents' bald and conclusory assertion that the complaint 'fails on the merits' provides absolutely no hint as to the nature of the alleged deficiencies in the Commission's complaint." *Id.*

The entire purpose of this hearing is to provide Respondents with an opportunity to challenge the merits of the allegations made by the FTC. The FTC has read Respondents' Answer. Respondents' Answer specifically denies several of the allegations set out in the Complaint. The merits of the Complaint are accordingly at issue. As a result, the FTC cannot seriously claim that it has "absolutely no hint as to the nature of the alleged deficiencies in the Commission's Complaint." The motion to strike should accordingly be denied.

CONCLUSION

All of the affirmative defenses raised by Respondent have an adequate basis in law and fact. The FTC's motion to strike should accordingly be denied.

Respectfully Submitted,

/s/ Max Kravitz

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CERTIFICATE OF SERVICE

This is to certify that on November 1, 2004, I caused a copy of the attached Respondent's Reply to the Federal Trade Commission's Motion to Strike Respondent's Affirmative Defenses to be served upon the following persons by facsimile, email or U.S. First Class Mail:

(1) the original and one (1) paper copy filed by Federal Express, and one electronic copy via email to:

Donald S. Clark, Secretary
Federal Trade Commission, Room 159
600 Pennsylvania Avenue, NW
Washington, DC 20580
E-mail: secretary@ftc.gov

(2) two (2) paper copies served by Federal Express and one electronic copy via email to:

The Honorable Stephen J. McGuire
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580
E-mail: dgross@ftc.gov

(3) one (1) electronic copy via email and one (1) paper copy via U.S. mail to:

Janet Evans
Syd Knight
Federal Trade Commission
600 Pennsylvania Avenue, NW
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E-mail: jevans@ftc.gov

I further certify that the electronic copy sent ot the Secretary of the Commisssion is a true and correct copy of the paper original, and that a paper copy with an original signature is being filed with the Secretary of the Commission by being sent by U.S. mail.

Dated: Columbus, Ohio
November 1, 2004

/s/ Max Kravitz
Max Kravitz