UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

DURK PEARSON, ET AL.,	)	
	)	
Plaintiffs	)	
	)	
v.	)	**Civil Action No. 95-1865(GK)**
	)	
DONNA E. SHALALA, SECRETARY, UNITED STATES DEP'T OF HEALTH AND HUMAN SERV., ET AL.,	)	
	)	
Defendants.	)	

REPLY AND MEMORANDUM IN SUPPORT OF REPLY TO GOVERNMENT'S OPPOSITION TO PLAINTIFFS' APPLICATION FOR PRELIMINARY INJUNCTION AND REQUEST FOR EXPEDITION

Durk Pearson, Sandy Shaw, and the American Preventive Medical Association, by counsel and pursuant to LCvR 7.1(d), hereby submit their Reply to the Government's Opposition to Plaintiffs' Application for Preliminary Injunction and Request for Expedition.[1]

THE REQUESTED INJUNCTION IS A FIRST AMENDMENT IMPERATIVE

At the time of the *Pearson* remand, and to the present, the state of the law has been that FDA has no constitutional basis for suppressing the four health claims. The Court left it to FDA to conduct rulemakings to explore the empirical evidence but unless and until that evidence is demonstrated to prove disclaimers ineffectual, the Government's prohibitions on the claims remain constitutionally invalid. *Pearson v. Shalala*, 164 F.3d 650, 661 (holding the FDA's prohibitions on the claims "invalid").

[1] Consistent with Plaintiffs' Request for Expedition, they file this reply within one business day of the Defendants' submission of their Opposition pleading and in advance of the hearing scheduled for April 11, 2000.

The Government misreads *Pearson* by presuming that the Court's holding of invalidity and allowance of further rulemaking gave FDA authority to maintain its speech ban until it completed its empirical evidence review. Were that the case, the Court of Appeals would not have held the prohibitions on Plaintiffs' health claims invalid. Instead, the Court would have simply remanded the case to FDA for further rulemaking consistent with its opinion. The fact that the Court held FDA's prohibitions invalid on the basis that FDA failed to meet its burden of proof under the First Amendment is the determining factor in this preliminary injunction proceeding. FDA may not enforce a ban on the health claims – regardless of its purported source of statutory authority – because the Supreme law of the First Amendment commercial speech standard prohibits FDA from suppressing the claims without empirical evidence to justify that suppression. *Ibanez v. Florida Dep't of Business and Prof'l Regulation*, 512 U.S. 136, 146 (1994) (Government may not suppress commercial speech unless it proves "that the harms it recites are real and that its restriction will in fact alleviate [those harms] to a material degree") quoted in *Pearson*, 164 F.3d at 659.

FDA claims it will have its empirical evidence by October 10, 2000, but wishes to suppress the claims before then, during the six months between now and October 10th. That it may not do because, as the *Pearson* Court found, it has not satisfied its First Amendment burden of proof to justify the suppression. Ergo, the requested injunction is a First Amendment imperative.

SUMMARY

In its Opposition, the Government does not contest:

(1) that the Court of Appeals held the Government's suppression of the Plaintiffs' health claims unconstitutional under the First Amendment based on a

thorough review of the record (i.e., all scientific and legal submissions, including those of the Government's amici), *Pearson v. Shalala*, 164 F.3d 650, 657-659 (D.C. Cir. 1999);

(2) that under the First Amendment commercial speech standard the Government -- not the Plaintiffs -- has the "heavy burden" of proof to justify its continuing suppression of Plaintiffs' health claims, *Peel v. Attorney Registration and Disciplinary Comm'n of Illinois*, 496 U.S. 91, 109 (1990) (the Government carries a "heavy burden of justifying a categorical prohibition" on commercial speech); *In re R.M.J.*, 455 U.S. 191, 203 (1982); *Pearson*, 164 F.3d at 659 (the Government "must . . . meet its burden of justifying a restriction on speech . . ."");

(3) that under the First Amendment the Government may not justify suppression of commercial speech based on speculative harm but only upon empiricial evidence "that the harms it recites are real and that its restriction will in fact alleviate [those harms] to a material degree," *Ibanez v. Florida Dep't of Business and Prof'l Regulation*, 512 U.S. 136, 146 (1994) (citing *Edenfield v. Fane*, 507 U.S. 761, 771 (1993)); *Pearson*, 164 F.3d at 659;

(4) that the Government has not completed its review of the empirical evidence and, thus, has not presented to this Court any evidence that Plaintiffs' claims, when accompanied by the disclaimers recommended by the *Pearson* Court, fail to correct for misleadingness;

(5) that the Government may only constitutionally suppress inherently misleading commercial speech but must permit potentially misleading commercial speech with disclaimers designed to correct for misleadingness, *In re R.M.J.*, 455 U.S. at 203 ("States may not place an absolute prohibition on . . . potentially misleading information . . . if the information also may be presented in a way that is not deceptive"); *Ibanez*, 512 U.S. at 144-46; *Peel*, 496 U.S. at 99-111; *Shapero v. Kentucky Bar Ass'n*, 486 U.S. 466, 478 (1988); *Pearson*, 164 F.3d at 655, 657 ("the Court has reaffirmed this principle, repeatedly pointing to disclaimers as constitutionally preferable to outright suppression"); and

(6) that the canons of statutory construction preclude FDA and this Court from construing the agency's governing statute to effect a First Amendment violation when an alternative construction can avoid that result, *De Bartolo Corp. v. Florida Guild Coast Building & Construction Trades Council*, 485 U.S. 568, 573 (1988).

In addition, the Government does not contest that it has suppressed Plaintiffs' health claims continuously since 1993 (in the case of the antioxidant vitamins, omega-3 fatty acids, and fiber claims) and since 1996 (in the case of the folic acid claim); has

suppressed Plaintiffs' health claims for an additional year after the April 20, 1999 *Pearson* mandate, and plans to continue suppressing them all for *at least* an additional six months until October 10, 2000 if not indefinitely thereafter. Moreover, the Government does not contest that it first began its deliberations on disclaimers on April 4, 2000, almost one year after the *Pearson* mandate issued, and following Plaintiffs' filing of its Application for Preliminary Injunction, and will not complete those deliberations until October 10, 2000, fully a year and six months after the mandate issued. Furthermore, the Government does not contest that it refused to set any deadline for completion of its deliberations -- despite repeated requests from Plaintiffs' counsel (Exhibits B, D, H, J, and L to Plaintiffs' Memorandum in Support of Application) -- until *after* this Court scheduled its April 11, 2000 hearing on Plaintiffs' Application for Preliminary Injunction, and that it refuses to allow Plaintiffs to use any of their health claims with the disclaimers recommended by the Court of Appeals between now and its October 10, 2000 decision date (and perhaps forever thereafter). What is more, the Government does not contest that the Court of Appeals found no evidence that Plaintiffs' dietary supplements "in any fashion threaten consumer's health and safety," *Pearson*, 164 F.3d at 656.

The Government submits that it has no obligation under the First Amendment or under *Pearson* to cease enforcement of its prohibition on Plaintiffs' health claims. The Government argues that its continued suppression of Plaintiffs' protected commercial speech is justified on the following grounds: (1) FDA prohibits Plaintiffs' health claims not based on the agency rules that prohibit the claims that the *Pearson* Court invalidated but, rather, based on the Federal Food Drug and Cosmetic Act's health claims petition pre-screening requirement and pre-screening time limits in 21 U.S.C. § 343(r)(4)(A)(i);

(2) FDA's planned October 10, 2000 decision date on re-evaluation of the Plaintiffs' health claims is within the Federal Food Drug and Cosmetic Act's (FFDCA's) time limits; (3) FDA is not obliged to allow Plaintiffs' claims with disclaimers but only to re-evaluate the claims in light of the *Pearson* Court's decision; (4) that at least two studies cited in an amicus brief filed with the Court of Appeals *before Pearson* was decided raise safety concerns about one of Plaintiffs' proposed claims; (5) that the *Pearson* Plaintiffs are participating in FDA's remand proceedings; and (6) that the cases cited by Plaintiffs holding First Amendment violations to constitute irreparable injury are inapposite.

For the following reasons, none of the Government's arguments satisfies its burden of proof under the First Amendment to justify continued suppression of the Plaintiffs' protected commercial speech. Indeed, the arguments do not even address that burden or the standard of empirical evidence that the Court of Appeals held (and the Supreme Court has repeatedly held) the Government must meet to justify continuing suppression of commercial speech. Furthermore, the Government's central argument – that its proceedings are governed by the FFDCA provisions concerning the filing of new health claim petitions – is misplaced: The health claims here in issue arose in nutrient-disease rulemakings that were required by separate Nutrition Labeling and Education Act statutory provisions, Pub. L. No. 101-535, 104 Stat. 2353 (1990) (cited in 56 Fed. Reg. 12,932 (March 28, 1991)(wherein FDA writes: "The Food and Drug Administration (FDA) is requesting scientific data and information on ten specific [nutrient-disease relationships], as required by the Nutrition Labeling and Education Act of 1990 . . . These are: (1) calcium and osteoporosis; (2) sodium and hypertension; (3) lipids and cardiovascular disease; (4) lipids and cancer; (5) dietary fiber and cancer; (6) dietary fiber

and cardiovascular disease; (7) folic acid and neural tube defects; (8) antioxidant vitamins and cancer; (9) zinc and immune function in the elderly; and (1) omega-3 fatty acids and heart disease"), and are not subject to the petition process time limits created by the FDA Modernization Act of 1997 fully seven years after three of Plaintiffs' four health claims, and fully four years after one of Plaintiffs' four health claims, were submitted in comments to FDA.[2] Finally, even if those provisions could be said to apply to the Plaintiffs' health claims, they cannot be viewed as a bar to Plaintiffs' health claims because FDA's governing statute may not be construed to effect an unconstitutional outcome consistent with the canons of statutory construction when an alternative construction can cause the Constitution and statute to be read in harmony. *De Bartolo Corp. v. Florida Guild Coast Building & Construction Trades Council*, 485 U.S. 568, 573 (1988).

Based on the pleadings there can be no doubt that FDA has presented to this Court no empirical evidence of any kind that satisfies its heavy First Amendment burden of proof to justify continued suppression of the Plaintiffs' health claims. FDA has not demonstrated to this Court that consumers are in fact misled by Plaintiffs' health claims. FDA has not demonstrated to this Court that the disclaimers recommended by the Court of Appeals actually fail to cure misleadingness. In short, FDA has not demonstrated to this Court (as it must) "that the harms it recites are real and that its restriction will in fact alleviate them to a material degree," *Ibanez*, 512 U.S. at 146. Rather, it has presented the Court with no proof that the Plaintiffs health claims (held to be protected commercial speech by the *Pearson* Court) when accompanied by the disclaimers recommended by the

[2]Plaintiffs' health claims were submitted in response to (5); (7);(8); and (10) in the NLEA list.

Court, are insufficient to cure any potential misleadingness. Accordingly, under the First Amendment, the Plaintiffs' health claims may not continue to be suppressed by this Government for a moment longer and must be allowed, bearing the *Pearson* Court's recommended disclaimers, until such time -- if ever -- that the Government in fact demonstrates with empirical evidence that the Court's recommended disclaimers and *all* others will not suffice to cure actual, proven misleadingness.

Accordingly, the Plaintiffs have shown (1) that they possess a substantial likelihood of success on the merits; (2) that they are suffering First Amendment injuries which, because they are constitutional rights violations, are palpable; (3) that entry of the injunction would prevent the Government from violating the First Amendment and the *Pearson* Court's decision; (4) that the public interest is best served by ensuring that Government fulfills its First Amendment obligations and protects, rather than transgresses, First Amendment rights; and (5) that First Amendment rights may not be violated for any period of time to suit agency convenience. Based on the evidence, this Court should promptly grant the injunctive relief the Plaintiffs seek.

ARGUMENT

I. THE GOVERNMENT MISCONSTRUES *PEARSON* AND THE FIRST AMENDMENT PRECEDENT ON WHICH *PEARSON* IS BASED

FDA HAS NOT MET ITS FIRST AMENDMENT BURDEN OF PROOF TO JUSTIFY CONTINUING SUPPRESSION OF PLAINTIFFS' HEALTH CLAIMS

Pearson held that FDA violated the First Amendment (1) by suppressing all four of Plaintiffs' health claims which the Court held to be protected commercial speech and (2) by refusing to allow the claims with disclaimers that cure potential misleadingness. *Pearson* 650 F.3d at 656-660. The *Pearson* Court based its decision on an unbroken line

of commercial speech cases from *In re R.M.J.*, 455 U.S. 191 (1982) to *Ibanez v. Florida Dep't of Business and Prof'l Regulation*, 512 U.S. 136 (1994). Those cases have held that Government may not suppress commercial speech that is potentially, but not inherently, misleading but must rely on disclaimers to permit the information to be "presented in a way that is not deceptive." *In re R.M.J.*, 455 U.S. at 203; *Pearson*, 164 F.3d at 657 ("the [Supreme] Court has reaffirmed this principle, repeatedly pointing to disclaimers as constitutionally preferable to outright suppression"). Those cases have also held that Government has the burden of proof to justify suppression of commercial speech. *Peel v. Attorney Registration and Disciplinary Comm'n of Illinois*, 496 U.S. 91, 109 (1990) (the Government carries a "heavy burden of justifying a categorical prohibition" on commercial speech); *In re R.M.J.*, 455 U.S. 191, 203 (1982); *Pearson*, 164 F.3d at 659 (the Government "must . . . meet its burden of justifying a restriction on speech . . ."). To satisfy its burden, Government must prove, *inter alia*, that "the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Ibanez v. Florida Dep't of Business and Prof'l Regulation*, 512 U.S. 136, 146 (1994) (citing *Edenfield v. Fane*, 507 U.S. 761, 771 (1993)); *Pearson*, 164 F.3d at 659.

The *Pearson* Court "reject[ed]" FDA's justification for suppressing the Plaintiffs' health claims on the basis that the justification was "almost frivolous." *Pearson*, 164 F.3d at 655. In particular, the Court found that FDA could not prove the claims lacking support in scientific evidence; rather, FDA had only argued that the evidence had not been proven to a conclusive degree. The Court wrote:

> 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 . . .

164 F.3d at 653.

The Court thus held the claims not "inherently misleading" and, thus, not unprotected by the First Amendment, but, instead, at worst only "potentially misleading," and -- as such -- protected by the First Amendment. See *In re R.M.J.*, 455 U.S. at 203; quoted in *Pearson*, 164 F.3d at 654.

As commercial speech that is, at worst, only potentially misleading, Plaintiffs' health claims may not be suppressed outright. Rather, they could only be suppressed upon proof (1) that the FDA's unsupported allegations that consumers would be misled was proven empirically to be true and (2) that no disclaimer would suffice to eliminate misleadingness.

In the first instance, the Court recommended precise disclaimers it believed sufficient to cure the misleading connotations alleged (but not proven) by the FDA. *Pearson*, 164 F.3d at 658-659 ("But certainly this concern could be accommodated, in the first claim for example, by adding a prominent disclaimer to the label along the following lines . . . A similar disclaimer would be equally effective for the latter two claims . . . . and we suspect that a clarifying disclaimer could be added to the effect that . . ."). The Court stated that it was "skeptical" that FDA could adduce empirical evidence sufficient to prove that the Court-recommended disclaimers would not suffice. *Pearson*, 164 F.3d at 659-660 ("while we are skeptical that the government could demonstrate with empirical evidence that disclaimers similar to the ones we have suggested above would bewilder consumers and fail to correct for deceptiveness, we do not rule out that possibility"). The Court did not rule out the possibility that upon a record of empirical evidence FDA might meet its burden of proof and show that the Court's disclaimers (and,

possibly, all others) would not suffice to cure misleadingness. The Court's action comports fully with the controlling First Amendment precedent it cited (*Ibanez*; *Edenfield*; *Peel*; *In re R.M.J.*; and *Shapero*), wherein the Supreme Court makes clear that suppression cannot be justified based on speculation about harm (here, misleadinginess) but only upon empirical evidence (proving the harms recited to be "real" and the restriction to alleviate the harms to a "material degree").

On the record before it, the Court received no empirical evidence from FDA (none existed then and none exists now) to prove that FDA's allegations of consumer misperception of the claims was "real" or that its absolute ban was necessary to alleviate the misperceptions to a "material degree." The *Pearson* Court wrote:

> The government disputes that consumers would be able to comprehend appellants' proposed health claims in conjunction with the disclaimers we have suggested -- this mix of information would, in the government's view, create confusion among consumers. But all the government offers in support is FDA's pronouncement that "consumers would be considerably confused by a multitude of claims with differing degrees of reliability." 59 Fed. Reg. at 405. Although the government may have more leeway in choosing suppression over disclosure as a response to the problems of consumer confusion where the product affects health, **it must still meet its burden of justifying a restriction on speech – here the FDA's conclusory assertion falls far short**. *See Ibanez*, 512 U.S., at 146 ("If the protections afforded commercial speech are to retain their force, we cannot allow rote invocation of the words 'potentially misleading' to supplant the [government's] burden to demonstrate that the harms it recites are real and that its restriction will alleviate them to a material degree") . . .

Pearson, 164 F.3d at 659 (emphasis added).

In fashioning a remedy consistent with its holding, the Court of Appeals could not allow FDA's prohibition on the four claims to stand. No, indeed, to do so would countenance a continuing First Amendment violation because the suppression was not justified by empirical proof of misleadingness or empirical proof that disclaimers were insufficient to cure misleadingness. The Court thus did not allow the four FDA rules

prohibiting the claims to stand while FDA conducted rulemakings to assess the empirical evidence. No, the Court invalidated the agency's prohibitions on Plaintiffs' claims, rendering them of no further legal force or effect. It did so leaving it to the agency to proceed with rulemakings to determine whether the Court's recommended disclaimers would suffice to cure misleadingness or, if not, whether other disclaimers would suffice. It did so "skeptical" that FDA could adduce empirical evidence that would prove its disclaimers insufficient. 164 F.3d at 659.

Thus, at the time of remand, and to the present, the state of the law has been that FDA has no constitutional basis for suppressing the four health claims. The Court left it to FDA to conduct rulemakings to explore the empirical evidence but unless and until that evidence is demonstrated to prove disclaimers ineffectual, the Government's prohibitions on the claims remain constitutionally invalid.

The Government misreads the *Pearson* case by presuming that the Court's holding of invalidity and allowance of further rulemaking gave FDA authority to maintain its speech ban until it completed its empirical evidence review. Were that the case, the Court of Appeals would not have held the prohibitions on Plaintiffs' claims invalid. Instead, the Court would have simply remanded the case to FDA for further rulemaking consistent with its opinion. The fact that the Court held FDA's prohibitions <u>invalid</u> on the basis that FDA failed to meet its burden of proof under the First Amendment is the determining factor in this preliminary injunction proceeding. FDA may not enforce a ban on the health claims – regardless of its purported source of statutory authority – because the Supreme law of the First Amendment commercial speech standard prohibits FDA from suppressing the claims without empirical evidence

to justify that suppression. See *Peel*, 496 U.S. at 106 (Given the complete absence of any evidence of deception, the "Court rejects the State's contention that the attorney's advertising was actually misleading"); *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 648-49 (1985) (striking down restrictions on attorney advertising when the State's arguments amount to little more than unsupported assertions); and *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 71 (1983) ("The party seeking to uphold a restriction on commercial speech carries the burden of justifying it").

FDA claims it will have its empirical evidence by October 10, 2000, but wishes to suppress the claims for six months between now and October 10th. That it may not do because, as the *Pearson* Court found, it has not satisfied its First Amendment burden of proof to justify the suppression. Ergo, the requested injunction is a First Amendment imperative.

II. THE GOVERNMENT'S STATUTORY CONSTRUCTION ARGUMENT IS DISINGENUOUS AND MISPLACED

On July 19, 1999, when Plaintiffs' counsel wrote to FDA CFSAN Director Levitt asking whether FDA "will refrain from taking action against plaintiffs if they commence use of the four . . . claims on labels and in labeling with the disclaimers specified by the Court" (Exhibit B to the Memorandum in Support of Plaintiffs' Application), Levitt responded not by stating that FDA was not enforcing those rules held invalid by the *Pearson* Court but by stating that "use of any of the four claims, with or without disclaimers, would violate the Federal Food, Drug and Cosmetic Act and would subject products bearing such claims to enforcement action" (Exhibit C to the Memorandum in Support of Plaintiffs' Application). Indeed, the Government never wrote, except in its Opposition pleading in this case, that it was not enforcing the four invalidated rules. That

is further confirmed by the fact that FDA has not -- for approximately a year after the *Pearson* mandate issued -- revoked the invalid rules. They are still on the books and no notice to the contrary has appeared in the Federal Register. By contrast, when the Supreme Court held FDA's tobacco rules invalid on statutory grounds, *FDA, et al., v. Brown & Williamson Tobacco Corporation, et al.*, 2000 U.S. LEXIS 2195 (2000), FDA published notice in the Federal Register revoking the invalidated rules within ten days of the Court's decision. See 65 Fed. Reg. 17135 (March 31, 2000).

Recognizing that it has no legal leg to stand on by arguing that the rules prohibiting Plaintiffs' health claims are valid when the Court of Appeals has held them invalid, the Government argues for the first time, disingenuously, that it is not enforcing a health claim prohibition based on the four rules, but, rather, is doing so based on the FFDCA's health claims pre-screening and pre-screening timetable rules in 21 U.S.C. § 343(r)(4)(A)(i).

That argument elevates form over substance when it is the substance of the health claim prohibition that is the *Pearson* Court's concern. Moreover, that argument is misplaced. The four *Pearson* claims were not the subjects of health claims petitions filed under the statutory rule on which FDA now relies. The rule FDA cites concerns "petitions for health claims." Plaintiffs' health claims were presented to FDA in rulemaking comments, not in petitions. Plaintiffs' comments were filed in response to FDA notices of proposed rulemaking which, in turn, were specifically mandated by separate NLEA provisions that compelled FDA to evaluate whether health claims could be allowed for 10 specific nutrient-disease relationship claims. See Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990).

Indeed, the statutory timetable provision the Government relies on did not even exist when the *Pearson* health claims were filed (1993 in the case of the antioxidant vitamins, omega-3 fatty acids, and fiber claims and 1996 in the case of the folic acid claim). The timetable provision the Government relies on now was enacted as part of the FDA Modernization Act of 1997 (enacted fully four years after the first three *Pearson* claims were submitted in comments and one year after the fourth *Pearson* claim was submitted in comments).

Therefore, the Government's central argument is grossly misplaced. Assuming *arguendo*, however, that the provisions the Government cites were applicable, they could not justify continued suppression of the *Pearson* claims after the *Pearson* decision invalidated agency construction of the statute. That is because the Court held FDA's health claims interpretation of its statutory review standard trumped by the First Amendment. *Pearson* in effect created a second, and superior, constitutional system of review that accompanies the dietary supplement health claims review standard FDA has adopted under the statute. The statute in 21 U.S.C. § 343(r)(5)(D) delegates to FDA the authority to adopt a "procedure and standard" for dietary supplement health claims review and *Pearson* prevents FDA from interpreting that standard to prevent dissemination of health claims that are, at worst, only potentially misleading. *Pearson* compels potentially misleading health claims capable of being rendered non-misleading through the addition of a disclaimer to be allowed with such a disclaimer. CFSAN Director Levitt has admitted as much, writing on two occasions to counsel for Plaintiffs that "even if [FDA's statutory] standard is not met," FDA "will authorize the claim" if

"the addition of a disclaimer to the claim could render it non-misleading." See Exhibits E and I to the Memorandum in Support of Plaintiffs' Application.

Consistent with well-settled rules of statutory construction, the *Pearson* Court accepted that the Nutrition Labeling and Education Act provisions for FDA to define a procedure and standard for claims it approves, 21 U.S.C. § 343(r), could not be construed to prohibit allowance of claims the First Amendment requires be permitted with disclaimers. In short, FDA's primary argument, its statutory construction basis for suppression, is in fact a red herring: It begs a question that is *res judicata*. The *Pearson* Court has already held constitutionally invalid FDA's prohibition on Plaintiffs' health claims -- a prohibition based on FDA's erroneous interpretation of its statutory duties. FDA cannot now claim in law and good conscience that a reiteration of this interpretation, regardless of its statutory basis, somehow trumps the Constitution; the Supremacy Clause, U.S. Const. Art. VI, cl. 2, forbids that construct.

III. THE GOVERNMENT'S ALLEGATION OF SAFETY RISK LACKS EVIDENTIARY SUPPORT AND HAS ALREADY BEEN CONSIDERED BY THE *PEARSON* COURT

Without presenting this Court with any empirical evidence, the Government hints at two points in its Opposition that at least two studies cited in an amicus brief filed with the Court of Appeals *before Pearson* was decided raise safety concerns about one of Plaintiffs' health claims. That bald, unsubstantiated charge lacks evidentiary support and, thus, cannot form the basis for decision on an application for preliminary injunction. See LCvR 65.1(c). Moreover, the *Pearson* Court reviewed the amicus brief, queried the Government's counsel at oral argument about the safety issue, and the Government's counsel presented no evidence to support a safety concern. See Transcript of Proceedings

(FDA, Appellee, v. Pearson, Appellants, Nos. 98-5043 and 98-5084) at 57 wherein the following colloquy appears: "THE COURT: So there was no indication it [the Plaintiffs' supplements] was dangerous, not a-- MS. KOHL [Counsel for the Government]: No, that wasn't the reason in that case why the health claim wasn't-- THE COURT: Well, that makes a big difference, doesn't it?". That admission is reflected in the following *Pearson* Court finding:

> It is important to recognize that the government does not assert that appellants' dietary supplements in any fashion threaten consumers health and safety.

Pearson, 164 F.3d at 656.

Finally, as explained in *Pearson*, all of the dietary supplements here in issue are comprised of common ingredients found in foods in common form for which FDA has already approved health claims. 164 F.3d at 658 ("FDA has approved similar health claims on foods containing these components"). Thus, antioxidant vitamins are in fruits and vegetables; omega-3 fatty acids are in fish; fiber is in fruits, vegetables, and grains; and folic acid is in green leafy vegetables and certain fruits. For FDA to claim a safety hazard associated with these ingredients, it would have to invalidate its food health claims—something it has not done and cannot reasonably do. In sum, the Government's argument on this point is also a red herring.

IV. THE *PEARSON* PLAINTIFFS' PARTICIPATION IN THE REMAND PROCEEDINGS HAS NO RELEVANCE TO THE CONSTITUTIONAL ISSUE OF FDA'S CONTINUING ENFORCEMENT OF THE UNCONSTITUTIONAL PROHIBITION ON THE CLAIMS

On remand, after a year of no substantive action of any kind, FDA has finally begun, after this Court scheduled the April 11 hearing, to commence proceedings concerning the *Pearson* remand issues. However, despite the *Pearson* Court's holding

that FDA's rules prohibiting the claims (the outward manifestation of its erroneous statutory interpretation) are invalid, FDA has continued to enforce its prohibition. Since July 1999, the Plaintiffs have consistently and repeatedly objected to FDA's unlawful enforcement of the prohibition and have objected to FDA's failure to allow the four health claims with the disclaimers recommended by the Court. Because the agency's recently commenced proceedings directly concern Plaintiffs' claims and affect their rights fundamentally, they have filed comments in response to each of them. But at no point have they either waived or discontinued their pointed objection to FDA's unconstitutional maintenance of the prohibition on their health claims between the date of *Pearson* remand to the present. In every case, in addition to supplying evidence to protect their interests, the Plaintiffs have told the Government that *Pearson*'s invalidation of FDA's prohibition on their claims requires *immediate* cessation of enforcement action to block the claims, provided the Court's recommended disclaimers are used. In every instance FDA has unequivocally refused to halt its ban. Thus, FDA's proceedings offer Plaintiffs no relief from the unconstitutional prohibition on their health claims that FDA vows to continue at least until October 10, 2000 and possibly forever thereafter. As explained above, FDA has failed to meet its First Amendment burden of proof to justify continuation of the speech ban.

V. *ELROD* AND *RILEY*'S IRREPARABLE INJURY HOLDINGS APPLY TO ALL FIRST AMENDMENT VIOLATIONS

In *Elrod v. Burns*, 427 U.S. 347, 373 (1976) (plurality opinion), and in *Riley v. National Federation for the Blind*, 784 U.S. 781, 793-94 (1998), the Supreme Court held that violations of First Amendment rights are of such gravity that sustaining them even for minimal periods of time creates irreparable injury. The Government argues that

because the two cases do not arise in the context of commercial speech they do not apply. The argument ignores the fact that the cases' holdings on irreparable injury speak in broad terms of First Amendment violation. Moreover, the Supreme Court has never held laws invalidated for violation of the First Amendment commercial speech standard any less of a threat to protected freedoms than First Amendment violations generally. Indeed, in *Rubin v. Coors Brewing Co.,* 514 U.S. 476, 482 (1995), the Supreme Court reiterated the fundamental importance of commercial speech in our society:

> [In *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 763, 765 (1976)] we noted that the free flow of commercial information is "indispensable to the proper allocation of resources in a free enterprise system" because it informs the numerous private decisions that drive the system . . . Indeed, we observed that a "particular consumer's interest in the free flow of commercial information . . . may be as keen, if not keener by far, than his interest in the day's most urgent political debate."

Accordingly, FDA's failure to cease enforcement of its ban on Plaintiffs' protected commercial speech constitutes irreparable, and intolerable, injury.

VI. CONCLUSION

For the foregoing reasons, and those explained in Plaintiffs' Application for Preliminary Injunction and in the supplement thereto, this Court should immediately enjoin FDA from continued enforcement of its prohibition on Plaintiffs' health claims provided that Plaintiffs accompany those claims with the disclaimers recommended by the *Pearson* Court. The injunction should remain in place until such time as FDA adopts final rules authorizing the four health claims with the disclaimers specified by the

Pearson Court or with such other disclaimers as are reasonably necessary to eliminate potential misleadingness.

Respectfully submitted,

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