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FDA PUBLIC MEETING ON IMPLEMENTING THE *PEARSON* COURT DECISION AND OTHER HEALTH CLAIM ISSUES

PANEL I:
"SHOULD HEALTH CLAIMS BE ALLOWED ON DIETARY SUPPLEMENTS ON A BASIS OTHER THAN SIGNIFICANT SCIENTIFIC AGREEMENT? IF SO, WHAT SHOULD THAT BASIS BE AND WHAT ARE APPROPRIATE CRITERIA FOR MAKING DECISIONS ABOUT SUCH CLAIMS?"

PREPARED REMARKS OF JONATHAN W. EMORD, ESQ.[1]

The questions posed to the panel are in fact legal issues that have already been resolved in a final and binding order of an authority higher than this agency, the United States Court of Appeals for the D.C. Circuit in the case of *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), *reh'g denied en banc*, 172 F.3d 72 (D.C. Cir. 1999). The questions are thus *res judicata*: they have been judicially acted upon and decided; they are settled by the judgment of the court. It is thus not the time to ask these questions. It is, rather, long past the time for this agency to comply with the Court's order.

In *Pearson v. Shalala*, the United States Court of Appeals held unconstitutional under the First Amendment four FDA rules that suppressed four separate health claims my clients wish to make.[2] The Court's decision invalidated the agency's rules. As a matter of law the rules are of no further legal force or effect, yet FDA continues to enforce them.

The Court's mandate to implement its decision issued to this agency on April 20, 1999. Upon receipt of the mandate, FDA's duty was clear. It had to discontinue enforcement of the invalidated rules immediately, and it had to allow my clients' claims to be made with dispatch. In flagrant defiance of the Court's order, this agency, over eleven months later, still enforces all four of the constitutionally invalid rules. Moreover,

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[2] The four claims are:

(1) "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers."
(2) "Consumption of fiber may reduce the risk of colorectal cancer."
(3) "Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease."
(4) ".8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form."

it has adopted a cumbersome, extensive, and protracted series of regulatory steps that it intends to take before finally addressing the Court's constitutional mandate. Those steps appear calculated to postpone FDA compliance with the Court's order for years. FDA is thus engaged in a pattern of delay and denial of its constitutional duties. This past Friday, my firm filed an application for preliminary injunction with the United States Court of Appeals to stop this agency from continuing to enforce the four invalid rules.

FDA's continued enforcement of those rules is an act of contempt in the face of a final and binding order. It is an act that challenges the Supremacy of the Constitution over contrary agency laws. It is an act taken by officers of this agency who have sworn oaths to support and defend the Constitution. It violates those oaths.

To be sure, FDA is not above the law. It is certainly not above the Constitution. The Constitution is the Supreme law, and FDA must obey it.

FDA should take heed and immediately, this very day, discontinue enforcement of the invalidated rules. It should authorize all four of the Plaintiffs' health claims with the disclaimers specified by the Court. It may thereafter proceed with its rulemaking to determine precisely how, if it all, it should tailor those disclaimers. But it may not, consistent with the First Amendment, continue to suppress my clients' protected speech, their health claims, for a moment longer.

The Supreme Court has held violation of a First Amendment right, *even for a very short period of time*, an irreparable injury. See *Elrod v. Burns*, 427 U.S. 347, 373 (1976) (plurality opinion) ("The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury"). When First Amendment rights are violated, the Supreme Court expects Government to eliminate the violation without delay. It considers delay intolerable. See *Riley v. National Federation of the Blind*, 784 U.S. 781, 793-94 (1988) (internal quotes omitted) ("Speakers . . . cannot be made to wait for years before being able to speak with a measure of security").

So, then, what are the Court of Appeals' legally binding answers to the questions you pose? The *Pearson* Court held that FDA may not suppress health claims on the basis that they do not satisfy its "significant scientific agreement" standard regardless of how FDA defines that standard. 164 F.3d at 654. In letters to me of October 5, 1999, and February 17, 2000, Director Levitt accepts this legal requirement. Thus, separate from FDA's health claims review standard, by which FDA officially *authorizes and approves* claims under 21 U.S.C. § 343(r), is the First Amendment, by which it must *allow* even claims it does not authorize and approve if those claims can be rendered non-misleading through the addition of a disclaimer. FDA may not substitute a new scientific validity test for the First Amendment standard articulated in the Court's decision. The Constitution is Supreme law, and the agency must ensure protection for all lawful commercial speech, not just a subset of that universe. The FDA must do so in strict accordance with the standards articulated in the *Pearson* decision itself.

Consistent with rules of statutory construction, FDA may not construe its statutory obligation under 21 U.S.C. § 343(r) (to establish a procedure and standard for the *authorization* of dietary supplement health claims) as in conflict with the First Amendment. *See generally DeBartolo Corp. v. Florida Guild Coast Building & Construction Trades Council*, 485 U.S. 568, 573 (1988). Rather, as the *Pearson* Court

explained, 164 F.3d at 652; 659, under the statute FDA must define a procedure and standard for *authorization and approval* of health claims but under the First Amendment, even if a claim is not *authorized and approved* by the agency, it must nevertheless be *allowed* to be made so long as the addition of a disclaimer can render the claim non-misleading. The purpose of the disclaimer is to inform consumers of the lack of conclusive evidence for a claim and of such other information as is necessary, on a case by case basis, to avoid consumer misperception. In light of the infinite variety of potential nutrient-disease claims, case by case evaluation is unavoidable.

The *Pearson* Court held that *inconclusive* health claims may not be suppressed by FDA unless they convey *no* scientific information or unless they otherwise cannot be rendered nonmisleading through the addition of a disclaimer. 164 F.3d at 659. Rather, FDA's remedy for inconclusive claims is the addition of a disclaimer, making the inconclusiveness clear to consumers.

The *Pearson* Court squarely placed the burden upon FDA to favor disclosure over suppression in every instance where a disclaimer can eliminate a misleading connotation. Thus, for example, if a claim accurately conveys a nutrient-disease association, FDA must allow it even if the agency believes the evidence preliminary unless FDA also reasonably finds no disclaimer capable of eliminating a misleading connotation. The First Amendment makes FDA, like every other government agency that censors speech, meet a high threshold burden of proof to justify claim suppression: proof that a claim cannot be rendered nonmisleading through use of a disclaimer. The general rule is disclosure of information. That is the constitutionally preferred means for overcoming misperceptions in the market.

Turning to the four claims at issue in *Pearson*, this agency should note well that the Court found all of the claims, at worst, only *potentially* misleading. The Court wrote specific disclaimers for each of the claims to cure that potential. The Court explained that FDA could avoid the erroneous public view that the agency had authorized the claims by including an additional disclaimer, to wit: "The FDA does not approve this claim." 164 F.3d at 659.

Given the *Pearson* Court's constitutional order to this agency, FDA must immediately discontinue enforcement of the four invalidated rules and must, until it ultimately decides the precise language it prefers for the disclaimers, authorize on an interim basis all four *Pearson* claims with the disclaimers the Court has recommended.

Pearson tells this agency that its legacy of suppression must come to an end; that it must henceforth favor disclosure over suppression as the rule, not the exception; that it may not use its health claims review standard as a barrier to the communication of any claim that can be rendered non-misleading through the addition of a disclaimer; and that the Court will view as dubious any agency justification for suppression that is based on alleged "benefits" of public ignorance.

Consumers can make choices they perceive in their own best interests if well enough informed. It is the constitutional duty of this agency to ensure that they are so informed and to favor disclosure over suppression as its standard practice. Thank you.