



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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The Honorable Ron Paul
House of Representatives
Washington, D.C. 20515-4314

JAN 15 2004

Dear Mr. Paul:

Thank you for your July 16, 2003, letter co-signed by Representative Frank Pallone, Jr., in support of the Food and Drug Administration's (FDA or the Agency) December 18, 2002, Guidance, "Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements."

As you know, the Agency issued an advance notice of proposed rulemaking on November 25, 2003, soliciting comments on ways to manage qualified health claims, including the First Amendment concerns raised in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) and subsequent decisions. FDA is seeking comments in three broad areas:

- Alternatives for regulating health claims that do not meet the significant scientific agreement standard,
- Other issues related to health claims, and
- Dietary guidance statements on conventional food and dietary supplement labels.

We are forwarding your correspondence to the public docket so that your comments will be considered during our review of this issue.

Thank you again for contacting us about this matter. If you have further concerns or questions, please let us know. An identical copy of the letter is being sent to Representative Pallone.

Sincerely,

Amit K. Sachdev
Associate Commissioner
for Legislation

2003N-0496

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Congress of the United States
House of Representatives
Washington, DC 20515

July 16, 2003

Mark B. McClellan, M.D., Ph.D.
Commissioner of Food and Drugs
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. McClellan:

We are submitting this comment in support of the December 18, 2002 Guidance, "Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements," and to express our respectful disagreement with the comment of our colleagues Representatives Henry A. Waxman, Barbara Boxer, Edward J. Markey, Jeff Bingaman, and David E. Price. We believe that were the Food and Drug Administration (FDA) to adopt the policy suggestions contained in our colleagues' comments, the agency would be contradicting the constitutional mandate of the United States Court of Appeals for the D.C. Circuit in Pearson v. Shalala, 164 F.3d 650 (D.C.Cir. 1998).

Pearson held that the FDA was prohibited by the First Amendment from suppressing potentially misleading health claims that did not satisfy the Significant Scientific Agreement (SSA) standard if those claims could be rendered nonmisleading through the addition of a disclaimer. The Pearson Court faulted the FDA for refusing to use the disclaimer approach. Pearson thus appears to demand that the FDA allow qualified health claims as a less speech restrictive alternative to suppression.

The FDA's exercise of enforcement discretion to avoid a First Amendment violation is not an "illegal assertion of authority," it is a constitutional imperative. Nor is the Guidance a "unilateral attempt...to permanently change a statutory standard." The statutory standard for FDA-authorized health claims remains unchanged. Indeed, were there a conflict between permitting qualified claims and the statutory health claim provisions, in such a circumstance, the First Amendment would trump the statute, and allowance of qualified claims would have been required nonetheless. Under the avoidance doctrine, the statute must not be read to conflict with the Constitution if at all possible. U.S. ex rel. Atty. Gen. v. Del. & Hudson Co., 213 U.S. 366, 408 (1909); Edward J. DeBartolo Corp. v. FL Gulf Coast Bldg. & Const. Trades Council, 485 U.S. 568, 575 (1988)(It is beyond

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debate that a court will construe a statute to avoid constitutional problems unless such construction is plainly contrary to the intent of Congress). The Pearson decision did just that. In light of Pearson, section 343(r) must be read as requiring notice and comment rulemaking only for those health claims authorized by the agency. The FDA thus lacks statutory authority to authorize claims not supported by SSA. However, if those claims are, at worst, only potentially misleading, the FDA cannot prohibit those claims without running afoul of the Constitution. Therefore, the FDA must allow the claim to be made through the exercise of enforcement discretion (electing to take no action to prevent the claim), precisely the mechanism described in the Guidance. The Constitution is an authority superior to, and independent of, the statute and must be obeyed – as the federal courts have told the agency on four occasions (Pearson, 164 F.3d 650; Pearson v. Shalala, 130 F. Supp. 2d 105 (D.D.C. 2001); Pearson v. Thompson, 141 F.Supp.2d 105 (D.D.C. 2001); Whitaker v. Thompson, 248 F.Supp.2d 1 (D.D.C. 2002)). Therefore, far from being an unlawful exertion of power, the Guidance is an essential and responsible legal policy that fulfills the constitutional mandates in each of the aforementioned court decisions.

Our colleagues object to the qualified health claim process, calling it “an unprecedented assertion of authority on the part of the executive branch to ignore a specific congressional mandate.” However, the December 18, 2002 Guidance implements the Pearson decision. Federal courts have held that a policy statement concerning the law determined by a federal court, such as the Guidance, is not required to be the subject of notice and comment rulemaking. 5 U.S.C. § 553(b)(3)(A); see also, Syncor In’tl Corp v. Shalala, 127 F.3d 90, 94-95 (D.C.Cir. 1997). We believe that the December 18, 2002 Guidance does not impose any new rights or obligations. See, American Bus Assoc. v. U.S.A., 627 F.2d 525, 529 (D.C.Cir. 1980) citing Texaco v. FPC, 412 F.2d 740, 744 (3d Cir. 1969). It recognizes First Amendment rights defined by the federal courts and it properly prevents use of agency power to violate those rights. The Guidance explains the agency’s position, updates the industry on its implementation of Pearson, and describes a process that the agency will follow to ensure that the FDA does not violate the First Amendment by suppressing a claim that is, at worse, only potentially misleading. The Guidance is not a binding norm, nor does it finally determine the issues or rights of future petitioners. See American Bus Assoc. v. U.S.A., 627 F.2d 525, 529 (D.C.Cir. 1980) citing Pacific Gas & Electric Co. v. FPC, 506 F.2d 33, 38 (D.C.Cir. 1974). In this circumstance, we believe the FDA is under no legal obligation whatsoever to rely on rulemaking. Indeed, since First Amendment jurisprudence defines delays in the ability to speak as an unconstitutional infringement on the right of free speech, we would be concerned that relaying on a long comment period could be considered unconstitutional. 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”) (citing New York Times Co. v. U.S., 403 U.S. 713 (1971)); see also, Lakewood v. Plain Dealer Publ’g Co., 486, U.S. 750, 758 (1988)(noting that “opportunities for speech,” if suppressed, “are irretrievably lost”); Pearson v. Shalala, 130 F.Supp.2d 105, 119(“the case law makes it very clear that Plaintiffs are harmed by the FDA’s suppression of the Folic Acid Claim”).

We also believe that our colleagues mischaracterize the qualified health claim process as a “lower ... scientific standard for approving ‘health claims.’” The qualified health claim process is not an approval process at all (nor is it a “scientific” standard) but, rather, it fulfills a constitutional requirement that the FDA allows claims to be made without the agency’s authorization or imprimatur. The FDA does not approve qualified health claims; it exercises enforcement discretion to allow them. Indeed, when the FDA suggested in Pearson that consumers might assume that a qualified health claim was FDA-approved, the court identified an “obvious answer: the agency could require the label to state that ‘The FDA does not approve this claim.’” Id. at 659. Implicit in that statement is the court’s recognition that claims not approved under SSA must nevertheless be allowed if the First Amendment requires it. Id. at 654 (“[E]ven if ‘significant scientific agreement’ were given a more concrete meaning, appellants might be entitled to make health claims that do not meet that standard – with proper disclaimers”).

Similarly, our colleagues argue that qualified claims in the marketplace with varying degrees of reliability will confuse consumers. The Pearson court rejected that speculative reasoning, stating that it was “skeptical that the government could demonstrate with empirical evidence that disclaimers similar to the ones [the court suggested] would bewilder consumers and fail to correct for deceptiveness.” Id. at 659-660. Such a paternalistic argument, which assumes consumers unable to exercise judgment at the point of sale, was judged “almost frivolous” by the Pearson court. Id. at 655. In short, our colleagues’ arguments were considered by the Pearson court and rejected in favor of disclosure of information to consumers. Indeed, the federal courts have found that disclosure over suppression is generally required by the First Amendment rule, while suppression is rarely justified. Whitaker, 248 F.Supp.2d at 27 (“While the Court did not ‘rule out the possibility that where evidence in support of a claim is outweighed by evidence against the claim, the FDA could deem it incurable by a disclaimer and ban it outright,’ it is clear that the Court was alluding to a very narrow set of circumstances in which suppression would be permissible under the First Amendment”), citing Pearson 164 F.3d. at 659.

Finally, our colleagues accuse the FDA of exceeding its statutory authority, stating that the Guidance suggests that the FDA has decided that the NLEA standard for health claims on foods violates the First Amendment. Neither the FDA nor the courts have so held because the statute and the First Amendment can be interpreted as consistent with one another (and, thus, must be). However, federal courts would likely find that Pearson applies equally well in the food claim context. Thus, the prohibition on claim suppression is a constitutional requirement, not a matter of statutory interpretation. While under the statute, the FDA may only authorize a food claim if SSA is met, under the First Amendment it must use enforcement discretion to avoid suppressing a food claim that fails SSA but is nevertheless at worst only potentially misleading. It is axiomatic that the First Amendment, applicable to all scientific and commercial speech, applies to FDA speech regulation – regardless whether the speech in issue is a supplement or a food claim.

In its December 18, 2002 Guidance, the FDA does not unilaterally change a statutory standard. It dutifully follows constitutional mandates to the agency as defined by the U.S. Court of Appeals in Pearson and its progeny. The FDA's December 18, 2002 Guidance implements the federal court's rulings permitting health claims separate and apart from the statutory SSA standard. The December 18, 2002 Guidance is not contrary to the SSA standard and should not be rescinded. Rather, it complies with the federal courts' orders as it must and should. Indeed, if the FDA did not adopt the Guidance, it would be derelict in its duty to comply with the constitutional mandates of four federal courts and that truly would be an "illegal" act.

For the foregoing reasons, we strongly urge the FDA to reject the contrary comments of our colleagues and move forward with implementation of its policy to comply with Pearson and its progeny.

Sincerely,


Ron Paul
Ron Paul


Frank Pallone
Frank Pallone