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

PANEL III:

"SHOULD HEALTH CLAIMS GO BEYOND CLAIMS ABOUT REDUCING THE RISK OF A DISEASE TO INCLUDE CLAIMS ABOUT MITIGATION OR TREATMENT OF AN EXISTING DISEASE, OR ARE SUCH CLAIMS DRUG CLAIMS? WHERE IS THE BOUNDARY, IF ANY, BETWEEN THESE CLAIMS?"

PREPARED REMARKS OF CLAUDIA A. LEWIS-ENG, ESQ[1]

On December 1, 1999, FDA summarily denied a health claim filed by my firm's clients associating saw palmetto (an herbal dietary supplement) with a reduction in the symptoms of mild benign prostatic hyperplasia.[2] It did so without following the procedure for dietary supplement health claims review specified in the Nutrition Labeling and Education Act and without following the First Amendment requirements of *Pearson v. Shalala*.

FDA based its refusal to follow the governing law on the view that the claim "goes beyond risk reduction to claim an effect on an existing disease" which FDA surmises may only be made if the dietary supplement is granted new drug approval under the Act's drug approval provisions, 21 U.S.C. § 355(d). See Attachment. Based on FDA's refusal to process the health claim under the Act's health claims provision and under the *Pearson* standard, my firm filed suit against FDA seeking declaratory and injunctive relief.

The questions posed to the panel arise out of FDA's summary denial of the Saw Palmetto claim. The questions suggest that FDA wants the scope of the NLEA health claims provision to be construed narrowly, reaching not all nutrient-disease relationship claims but only those that concern disease risk reduction. But the plain language of the NLEA health claims provision and its underlying history make it undeniable that

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[2] The claim reads: "Consumption of 320 mg daily of Saw Palmetto extract may improve urine flow, reduce nocturia and reduce voiding urgency associated with mild benign prostatic hyperplasia (BPH)."

Congress meant for all dietary supplement claims that associate a nutrient with a disease to be subject to the NLEA health claims provision. FDA's attempt to restrict the scope of the health claims definition, causing dietary supplement health claims to be redefined as drug claims, is a rather obvious attempt to hinder, rather than foster, the dissemination of dietary supplement nutrient-disease information. It is also an anti-competitive move designed to protect the drug approval process from competition arising from full implementation of the NLEA health claims provision. That attempt violates the NLEA. It violates Congress's intent. It violates the First Amendment, and it violates the Administrative Procedure Act's prohibition on arbitrary and capricious agency action.

In 1994, Congress reviewed FDA's implementation of the health claims provision of NLEA. S. Rep. No. 103-410. Congress concluded that FDA has "a long history of bias against dietary supplements." S.Rep. No. 103-410, at 14. Congress faulted FDA for "hindering, rather than fostering, the dissemination of truthful and nonmisleading information about the nutrient/disease relationship." S.Rep. No. 103-410, at 23. Congress concluded that FDA "has . . . acted to restrict the information that the public may receive about dietary supplements." S.Rep.No. 103-410. The United States Court of Appeals for the D.C. Circuit similarly found in *Pearson v. Shalala,* 164 F.3d 650, 654 (1999), that "[i]n general, the FDA appears quite reluctant to approve health claims on dietary supplements . . ."

FDA's current attempt to say that health claims do not include disease treatment and mitigation claims is yet another effort to block full implementation of the NLEA health claims provision. If FDA redefines health claims to exclude disease mitigation and treatment claims, it would defeat the essential purpose of the NLEA health claims provision. In 1990, the President signed the NLEA into law. Prior to its adoption, FDA treated as drugs all food and dietary supplements that included disease treatment claims. See H.R. Rep. 101-538 (1990). NLEA was designed to make it possible for dietary supplements to carry disease claims without having to become approved drugs, without having to satisfy the "substantial evidence," near conclusive proof, pre-market drug approval standard in 21 U.S.C. § 355. See S.Rep. No. 103-410, at 24. Congress expressly rejected the "drug certainty" standard as a legal condition for dietary supplement health claim approval. S. Rep. No. 103-410, at 24.

If FDA redefines health claims to exclude disease mitigation and treatment claims, it will effectively prohibit those claims all together. Under 21 U.S.C. § 379h(b)(1), those who wish to file a new drug application must pay the FDA the hefty and anti-competitive sum of $256,338 per application (in 2000). In addition, proof of drug efficacy is required, i.e., proof to a near certain degree under the "substantial evidence" drug standard. 21 U.S.C. § 255(d). In adopting the NLEA health claims provision, Congress intended to avoid this heavy burden for dietary supplements. Congress wanted disease claims to be possible on dietary supplements without having to obtain drug approval for them.

FDA has no statutory authority to define health claims in a manner contrary to the NLEA. NLEA defines dietary supplement health claims broadly to include "[ones which] characterize[] the relationship of any nutrient . . . to a disease or health-related condition . . ." 21 U.S.C. § 343(r)(1)(B). Note well that Congress has used the broadest possible language: any "*relationship*" between a nutrient and a disease or health-related condition. The term "relationship" in its ordinary sense and meaning refers

to a "connection" of one thing to another, without restriction. WEBSTER'S NEW UNIVERSAL UNABRIDGED DICTIONARY, p. 1525 (2d ed. 1983). Disease treatment and disease mitigation are plainly within the universe of nutrient-disease relationships. To prove that Congress intended something other than the plain meaning of the statutory language requires proof in legislative history that the plain language was not intended. You will look in vain, however, to find any basis in the legislative history to support FDA's position. Congress never stated any intention to define nutrient-disease relationships to exclude statements that associate nutrients with disease treatment or mitigation.

In the 1990 committee report from the House Committee on Energy and Commerce, Congress emphasized that the NLEA health claims provision applied to "any disease claim" and never once stated that the provision was meant to apply only to those claims that refer to disease risk reduction as opposed to disease treatment or disease mitigation. Congress stated with respect to the NLEA:

> **Section 403(r)(3) regulates disease claims. It prohibits any disease claim . . . unless the claim meets the requirements of regulations promulgated by the Secretary. The requirement applies to any disease claim that is made with respect to required nutrients and other nutrients in food.**

H.Rep. 101-538 at 20.

Reflecting upon the NLEA health claims provision, Congress in 1994 again made clear that Congress intended the NLEA to permit authorization of all manner of nutrient-disease relationship claims, not just disease risk reduction claims. Moreover, it made clear that dietary supplements were expressly intended to bear health claims without having to be separately approved as drugs:

> **One of the salutary purposes of the Nutrition Labeling and Education Act was to allow claims for nutrient/disease relationships to reflect current science, without bringing food within the drug definition of the Federal Food, Drug, and Cosmetic Act. A clear purpose of the NLEA was to assure that the public would be provided with clear information about the relationship of nutrient to disease, and to ascertain that that information would be accurate and not misleading.**

S.Rep. No. 103-410, at 23.

Congress was thus concerned that the nutrient-disease "relationship" be accurately characterized, not that the relationship be limited to exclude disease treatment and disease mitigation. Were it concerned that the naturally all-encompassing term "relationship" be interpreted in a less than all-encompassing way, we should expect to find evidence of that intent in the legislative history. There is none. Contrary to the position FDA tries to maintain, Congress sought to ensure that claims were accurately stated. If claims were artificially limited to exclude treatment and mitigation and include only risk reduction, the result would necessarily be a mass suppression of accurately stated nutrient-disease claims, ones that accurately reflect the disease treatment or disease mitigation effect of certain nutrients.

Following FDA's position would also produce the unconstitutional result of causing the NLEA health claims provision to conflict with the First Amendment by denying consumers access to scientifically accurate information that dietary supplements treat or mitigate disease symptoms. Consistent with the rules of statutory construction, FDA must not construe the NLEA to conflict with the First Amendment but must construe the two to be in harmony with one another. See *De Bartolo Corp. v. Florida Gulf Coast Building & Construction Trades Council, et al.*, 485 U.S. 490, 499-501 (1979).

Repeatedly in the legislative history Congress has emphasized that the NLEA health claims provision was designed to be flexible and was to embrace all manner of disease claims. The Congress wrote:

> **In implementing the significant scientific agreement standard, FDA will be expected to take full advantage of the flexibility of the standard to maximize the availability on food and dietary supplement labels and labeling of disease-related information consumers can prudently use to affect their risk of disease.**
>
> **This includes recognizing that there will nearly always be some remaining scientific uncertainty about the validity of any diet-related health claims; that some individual consuming or avoiding a nutrient in response to a health claim may benefit, while others may not; and that the benefit for any individual may consist not of absolutely avoiding a disease, but rather of reducing her or his risk of a disease.**

S. Rep. No. 103-410, at 24.

FDA's denial and suppression of the Saw Palmetto/BPH claim not only violates the NLEA health claims provision but also the First Amendment. Under *Pearson v. Shalala*, the health claim is protected commercial speech that may not be suppressed outright but must be authorized with such disclaimer or such disclaimers as FDA deems reasonably necessary to avoid a misleading connotation. Consistent with its commitment to the Court, FDA should reverse its position and evaluate the Saw Palmetto claim under the NLEA health claims provision and under the First Amendment standard established in *Pearson*. It should stop trying to do an end-run around the NLEA health claims provision and once and for all implement fully and faithfully consistent with the intent of Congress and with the First Amendment.