



*Producers of Quality
Nonprescription Medicines and
Dietary Supplements for Self-Care*

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

Formerly Nonprescription Drug Manufacturers Association

April 19, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Docket No 00N-0598 Food Labeling;
Dietary Supplement Health Claims; Public Meeting
Regarding Pearson Health Claims

Dear Sir or Madam:

Enclosed are comments submitted by the Consumer Healthcare Products Association in response to a Federal Register notice published on March 16, 2000 announcing a public meeting and opportunity for written comments regarding *Food Labeling; Dietary Supplement Health Claims; Public Meeting Concerning Implementation of Pearson Court Decision and Whether Claims of Effects on Existing Diseases May Be Made as Health Claims*.

Three comments have been submitted to dockets and desk copies have been sent to Dr. Christine Lewis, Ms. Jeanne Latham, Mr. Michael Landa, Ms. Margret Dotzel, and Dr. Rachel Behrman.

Thank you for your consideration of these comments.

Sincerely,

Patrice B. Wright, Ph.D.
Director, Pharmacology & Toxicology

00N-0598

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Regarding *Pearson* Health Claims

To Whom It May Concern:

On April 4, 2000, FDA held a meeting to obtain input on changes to the agency's general health claim regulations for dietary supplements that may be warranted in light of the Court decision in *Pearson v. Shalala*. FDA stated that its intention to accept written comments to providing additional information in relation to the questions posed in the March 16, 2000 *Federal Register* announcement of the meeting. A member of CHPA staff was an invited panelist during the third Panel of the April 4th meeting. The Consumer Healthcare Products Association (CHPA) submits these comments as additional information to that presented orally and in writing at the meeting.

CHPA is the 119-year-old trade organization with over 200 members involved in the manufacturing, distribution, supply, research testing and advertising of dietary supplements and nonprescription medicines. CHPA members have a direct interest in assuring that the Dietary Supplement Health Education Act (DSHEA) continues to provide for broad access to dietary supplements for consumers and that there is a rational regulatory framework that provides FDA authority to pre-approve accurate health claims on dietary supplements.

CHPA's comments are organized below as direct answers to questions posed in the Federal Register announcing the April 4th meeting and calling for input on FDA's plans to

implement the *Pearson* decision in the context of the current health claims approval mechanism and for input on health claims related to disease states.

FDA's Pearson Question 1: *What is the best regulatory approach for protecting and promoting the public health? Specifically, what approach to regulating health claims will: (a) protect consumers from fraudulent and misleading claims; and (b) provide reliable, understandable information that will allow consumers to evaluate claims intelligently and identify products that will in fact reduce the incidence of diseases? By what criteria should implementation options be judged?*

CHPA Response:

The principles that should be used to approve health claims are:

- The law stating that dietary supplement claims must be truthful and not misleading. This encompasses the ability to make claims about emerging disease-substance relationships and does not mean that truthfulness is defined only when the disease-substance relationship has been determined to be so strong as to be unlikely to be reversed;
- The First Amendment rights of commercial free speech as maintained by the *Pearson* decision;
- The essentiality of information as the basis for labeling; and
- The safety of the dietary ingredient subject of the claim. FDA may determine under the law that there is inadequate information to provide reasonable assurance that the ingredient will not present a significant or unreasonable risk of illness or injury.

The regulatory approach for health claims should be maintained as the now in place pre-approval process for health claims based on a determination of significant scientific agreement defined by the truthfulness of the claim, not the validity of the substance-disease relationship. Health claims should not be approved based upon the current

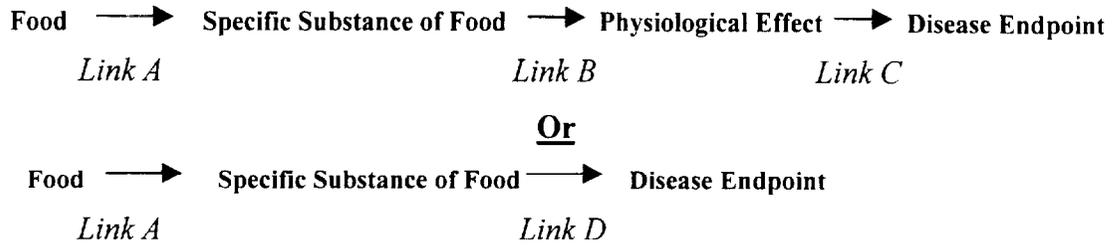
guidance on significant scientific agreement that focuses only on the validity of the substance-disease relationship.

Section 101.14(a)(1) as the Basis for Defining the Approach to Approving Health Claims in the Context of *Pearson* Decision

According to regulation, a health claim characterizes disease/substance relationship, and it is this characterization that should be used to judge the truthfulness of the health claim, not the validity of the substance-disease relationship. Health claims are defined in 101.14 (a) (1):

“Health claim means **any claim** made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including “third party” references, written statements (e.g., a brand name including a term such as “heart”), symbols (e.g., a heart symbol), or vignettes, **characterizes the relationship of any substance to a disease or health-related condition**. Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition (emphasis added).”

To insure that consumers are being provided with reliable, understandable information that will allow them to evaluate claims intelligently and identify products that reduce the incidence of disease, FDA will need to evaluate the totality of the scientific evidence supporting each relationship in the claim submitted by the petitioner. When evaluating the truthfulness of a health claim in the context of the totality of the evidence, it is useful to conceptually breakdown the potential relationships in a given health claim. A health claim may contain statements regarding the relationship of four possible links between a substance and a disease (i.e., Links A-D below).



Relationships and links that do not have the scientific support as stand alone statements should have qualifying language accompanying the claim. If the substance-disease link (Link D) is not proven, the claim should state such. If the disease-biomarker link (Link C) is not proven, the claim should state such. The expression of the nature of the links, in the context of the available evidence supporting those links, through the use of qualifiers or disclaimers is consistent with the *Pearson* decision and presents a workable regulatory framework to implement the decision.

Truthfulness of the Claim that Characterizes a Disease-Substance Relationship as the Basis for Significant Scientific Agreement

Health claims should be based on a standard that is consistent with the statutory provisions of the Food Drug Cosmetic Act (FDCA), the Nutrition Labeling and Education Act (NLEA), and the *Pearson* decision. FDA's current definition of significant scientific agreement¹ is inconsistent with the *Pearson* decision and NLEA. FDA's guidance definition focuses on the validity of the food-disease relationship, when in fact the focus should be on the truthfulness of the claim that characterizes the relationship.

Specifically, the basis for the significant scientific standard for health claims should be consistent with the statutory provisions that food claims must be neither false nor misleading. Health claims are intended by Congress to characterize the relationship of a substance to a disease or health-related condition. They are not mandated by NLEA to represent whether the relationship is so secure as to be unlikely to be overturned by future

¹ FDA: Guidance for industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements. December 22, 1999.

research. Such a standard would be unreasonably high, given the nature of the evolving nature of scientific understanding. Rather, health claims “characterize the relationship,” meaning such characterization may be made in the context of qualifier or disclaimer as discussed in the *Pearson* decision.

Pearson maintains that both qualifiers and disclaimers may be considered as a means to characterize a health claim. The *Pearson* decision upholds the following:

- “Truthful” promotion that is “related to lawful activities” is “entitled to the protections of the First Amendment;”
- FDA “may not place an absolute prohibition on . . . potentially misleading information . . . if the information also may be presented in a way that is not deceptive;”
- The “preferred remedy” for a potentially-misleading statement “is more disclosure, rather than less;”
- The use of promotional information with “disclaimers” is “constitutionally preferable to outright suppression.”

Hence, health claims must be allowed on the basis of significant scientific agreement that address truthful representation in labeling of the available scientific evidence concerning a food-disease relationship.

FDA’s Guidance to Industry Misses the Mark

On December 22, 1999, FDA issued a guidance with a request for comments on its definition of significant scientific agreement. In that guidance FDA sets forth “the standard of scientific validity” based on (1) “the totality of the publicly available evidence support[ing] the substance/disease relationship that is the subject of the claim; and (2) existence of significant scientific agreement among qualified experts that the relationship is valid.” FDA states that “the standard of scientific validity” is a “strong standard that

provides a high level of confidence” that “the relationship is not likely to be reversed by new and evolving science.”

FDA’s creation of “the standard of scientific validity” as an approach of responding to the *Pearson* decision to define significant scientific standard indicates that the agency does not understand the intent of the Court. If the standard for a health claim must be so high as to be forever after not be able to be reversed by evolving science, why then would the Court permit the use of qualifier?² FDA’s definition of “the standard of scientific validity” to replace statutory requirement of “significant scientific agreement” is not better than word-smithing FDA’s original position before the Court.

CHPA therefore formally requests that FDA retract its guidance on significant scientific agreement and adopt one that is statutorily based and expresses the intent of *Pearson* decision.

Essentiality of Labeling Information

An important additional principle in the determination of what information needs to be on the label of a dietary supplement making an approved health claim consistent with the *Pearson* decision is the concept of essentiality of labeling information. This concept is one of “paring” of information to only that which is important for the safe and beneficial intended use of the product, and has been used repeatedly by FDA in the development of OTC drug labeling [e.g., 48 F.R. 6830 (2/15/83); 58 F.R. 28216, 28230 (5/12/93); 57 F.R. 58369 (12/9/92); 53 F.R. 2455 (1/27/88)]. Essentiality of information applies to the nature of qualifiers and disclaimers and speaks to the need for concise, precise, truthful statements that accurately convey the character of the substance-disease relationship.

² The Supreme Court has permitted the government to ban *inherently* misleading, but not *potentially* misleading speech. FDA argued that claims made without “significant scientific agreement” regarding their basis would *inherently* mislead consumers. Emphasizing the ability of consumers to exercise judgment when buying a product regardless of FDA’s evaluation of the claims, the D.C. Circuit rejected FDA’s argument. Rather, the Court conceded that these health claims could be *potentially* misleading because consumers would have difficulty independently verifying the claims and because consumers might also believe the FDA approved the claims. Despite these possibilities, the Court believed FDA should have considered disclaimers, rather than an outright ban, to cure potentially misleading claims. Arent Fox: *Pearson v. Shalala*; Invalidating Four FDA Dietary Supplement Health Claim Regulations.

Preapproval

As a point of emphasis, FDA has pre-approval authority for health claims (both *Pearson* claims & traditional health claims) and, therefore, FDA is in a position to decide if a claim is fraudulent or misleading based on the totality of the evidence supporting it. If the claim is not truthful, if it is misleading, or if it would pose a safety concern to the public, FDA has authority to deny the claim. The *Pearson* case emphasizes this authority:

- “Nor do we rule out the possibility that where the 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”
- “Similarly, we see no problem with the FDA imposing an outright ban on a claim where evidence in support of the claim is qualitatively weaker than evidence against the claim – for example, where the claim rests on only one or two old studies.”
- “Finally, we are skeptical that the government could demonstrate with empirical evidence that disclaimers similar to the ones suggested above would bewilder consumers and fail to correct for deceptiveness, we do not rule out that possibility.”

Summary for FDA’s *Pearson* Question 1

In summary, by withdrawing its guidance on significant scientific agreement, and re-issuing a proposed guidance that would define significant scientific agreement in the context of the truthfulness of the health claim that characterizes the given disease-substance relationship, FDA will be implementing the health claim regulation in a manner consistent with *Pearson* decision. In addition, the report of the Foods Advisory Committee³ on “Interpretation of Significant Scientific Agreement in the Review of Health Claims” is a suitable a basis for the first step of evaluating the quality of individual

³ Foods Advisory Committee: Report of the Foods Advisory Committee Working Group of Significant Scientific Agreement for Health Claims, June 24, 1999.

studies and the weight of the body of evidence in the context of a possible health claim. The concept of essentiality of labeling information is important to maintain as a criterion for defining the character of the disease-substance relationship.

FDA Pearson Question 2: *Can qualifying language (including disclaimers) be effective in preventing consumers from being misled by health claims based on preliminary or conflicting evidence? If so, what are the characteristics of effective qualifying language? How should the agency determine what constitutes an appropriately qualified claim? If the available information is not sufficient to answer these questions, what research needs to be done, and who should be responsible for doing it? The agency encourages those commenting to submit empirical data on the effectiveness of qualifying language.*

CHPA Response:

FDA's use of the word "prevent" implies that the agency is seeking to ensure that no consumer would be misled by a qualified health claim. This standard is too high and is not consistent with the Court's decision in the *Pearson* case. The Court maintained, FDA "may not place an absolute prohibition on . . . potentially misleading information . . . if the information also may be presented in a way that is not deceptive."

Effective qualifying language therefore must provide a reasonable expectation that the average consumer would not be deceived by the claim. This would be determined on a case-by-case basis in the context of the totality of the available evidence. There is a certain common sense logic that the agency will inevitably have to apply, and it is important that the agency not attempt to over-drive the development of specific criteria that would limit the needed flexibility to approve health claims individually. The basic intent of a qualifying phrase related to a claim on emergent scientific information that characterizes a disease/substance relationship would be to inform the consumer that the relationship has not been established to the point that it is unlikely to be reversed. Proximity of the disclaimer to the claim is an important criterion in this regard. An example of a health claim is given below to illustrate our point.

Specifically, qualifying language must characterize the strength of the relationship between the substance and the disease. Using the example of omega-3 fatty acids and heart disease cited in the *Pearson* case, the following claim should be approved:

Consumption of long chain omega-3 fatty acids (EPA and DHA) may reduce your risk of heart disease by lowering your triglycerides, promoting a regular heartbeat, and helping to prevent unnecessary blood clotting. The role of these mechanisms in lowering your overall risk of heart disease has not been fully resolved.

Since FDA's last evaluation of the relationship between omega-3 fatty acids (EPA and DHA) and heart disease in 1993, six additional observational studies in conjunction with information previously reviewed by the Agency confirms that the relationship between omega-3 fatty acids (EPA and DHA) and heart disease is consistent. Two recent intervention trials support the strength of the association between heart disease and omega-3 fatty acids (EPA and DHA). Studies published since FDA's review in 1993 have been examined by CHPA, and no new information has become available to invalidate FDA's previous conclusions regarding safety of omega-3 fatty acids (EPA and DHA) up to 3g/day as stated in the GRAS affirmation of the menhaden oil petition. This claim is truthful and adequately characterizes the relationship of the substance and the disease. (See CHPA submission to FDA dated April 3, 2000.)

In sum, an appropriately qualified claim does not pose public health risks and clarifies the relationship of a biomarkers, a disease and a substance.

FDA's Pearson Question 3: *Is there a way to preserve the existing regulatory framework for health claims consistent with the First Amendment?*

CHPA Response:

Yes, through interpretation of the existing regulatory definition of health claims in the context of the *Pearson* decision. Under section 101.14 (a) (1), health claims are defined:

“Health claim means **any claim** made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including “third party” references, written statements (e.g., a brand name including a term such as “heart”), symbols (e.g., a heart symbol), or vignettes, **characterizes the relationship of any substance to a disease or health-related condition**. Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition (emphasis added).”

This definition should not be changed. However, to be consistent with the first amendment and the *Pearson* decision, FDA’s guidance definition of significant scientific agreement will need to be modified. FDA’s guidance definition of significant scientific agreement focuses on the validity of the substance-disease relationship as the decision point, when in fact based on the *Pearson* decision and NLEA the focus should be the claim that characterizes the relationship of a substance and a disease. CHPA’s position on this point is explained in the Association’s response to FDA’s question #1.

FDA’s Pearson Question 4: *If health claims are permitted based on a standard less rigorous than significant scientific agreement, what is the best way to distinguish among claims supported by different levels of evidence so that consumers are not misled? Does the word “may” in existing health claims accurately communicate the strength of the evidence supporting claims that meet the significant scientific agreement standard, or should other language be used?*

CHPA Response:

CHPA's Proposed Framework for Health Claims Consistent with *Pearson* Is Not Less Rigorous than FDA's Proposed Standard Under Its Guidance for Significant Scientific Agreement.

The implication of FDA's question is that nothing other than its definition of significant scientific agreement is a rigorous approach to the pre-approval of health claims in the context of the *Pearson* decision. This suggests that FDA is resistant to the conceptual framework imposed by the *Pearson* decision, when in fact it is FDA's mission to fulfill the law as written and interpreted. CHPA's recommended alternative approach to the pre-approval of health claims by FDA envisions a process that is rigorous. It is only the conceptual framework that is different from FDA's approach, that must change if *Pearson* is to be faithfully implemented, and the one proposed by CHPA. Indeed, the rigor that would need to be applied to ensure that health claims are truthful based on the totality of the scientific evidence would be expected to be a genuine, reasonable, and defensible standard.

A "Truth-in-Labeling" Standard as the Criterion of the Scientific Soundness of the Claim, Similar to the Federal Trade Commission's Truth-in-Advertising Standard

When health claims are approved, there should be significant scientific agreement (as explained by CHPA above) that the claim as stated is truthful and not misleading. The approval decision on an allowable health claim should be based on the claim as stated, and not on the validity of the disease-substance relationship.

The criterion for the scientific soundness of the claim is a determination that the label claim must not be false or misleading – in essence a "truth-in-labeling-standard," not unlike FTC's truth-in-advertising standard. To distinguish among claims supported by different levels of evidence, there should be three levels of claims according to *Pearson*, an unqualified health claim, a qualified health claim, and a health claim with a disclaimer. The *Pearson* decision clarifies that FDA should consider both qualifiers and disclaimers as approaches to allowing health claims. While *Pearson* does not define a qualifier or a disclaimer, it is clear that the Court understood that they are different, since the summary decision provided a distinct and very different example for each.

- A **qualifier** modifies a particular statement in a way that ensures its limitations are understood, as for example, a statement might qualify that the substance is effective in disease risk reduction for a subset of the general population. The example provided in *Pearson*: “The evidence is inconclusive because existing studies have been performed with foods containing antioxidant vitamins, and the effect of those foods on reducing the risks of cancer may result from other components of foods.”
- A **disclaimer** does more than modify a statement, since it is also a denial or disavowal of ownership of a statement, such as the statutory disclaimer for structure/function claims. The example provided in *Pearson* is: “FDA does not approve this claim.”

The Federal Trade Commission has already addressed this issue of the characteristics of disclaimers and qualifiers to assess the truthfulness of a dietary supplement claim and these elements can should be included in FDA’s evaluation of disclaimer:

- The substantiating evidence should provide a reasonable basis for making the claim. A “reasonable basis,” per FTC’s guide, “depends greatly on what claims are being made, how they are presented in the context of the entire ad, and how they are qualified,” yet it should be “flexible to ensure that consumers have access to information about emerging areas of science ...[and]... sufficiently rigorous to ensure that consumers can have confidence in the accuracy of information presented...”
- If a qualifier or disclaimer is to be used, it should be:
 - Clear, simple, and prominent;
 - Able to be understood in terms of the extent of the scientific support and the existence of any significant contrary evidence; and
 - Based on studies and other support that is a stronger body of evidence any contrary information.

CHPA requests that FDA adopt an approval health claim standard that is statutorily based and expresses the intent of *Pearson* decision, such as outlined in the FTC's "Dietary Supplements: An Advertising Guide for Industry."

FDA's *Pearson* Question 5: *If health claims are permitted based on a less rigorous standard, what actions can be taken to provide incentives to manufacturers to conduct further research on emerging substance-disease relationships?*

CHPA Response:

Again, CHPA objects to the implications of the phrase, "less rigorous." See CHPA's response to FDA's question # 4 for details.

The action that CHPA proposes FDA take – i.e., redefining significant scientific agreement in the context of the claim vs. the validity of the disease-substance relationship (see CHPA response to FDA's question #1 above) – would provide incentive to industry to undertake research. This is because FDA has shown its willingness and intent to faithfully implement *Pearson*. In the absence of that type of assurance, industry would be facing the daunting task of extensive epidemiologic research involving many millions of dollars over many years to provide beyond the shadow of a doubt that the disease-substance relationship could not be reversed – all for a claim for which there is no market exclusivity.

The intent of DSHEA was to provide information to consumers about the potential health benefits of dietary supplements, and the *Pearson* decision clearly intends that FDA permit claims about emerging science related to those benefits. Therefore, FDA's adoption of a more flexible claims construct should, in our view, stimulate research in many areas that may not currently have active programs.

FDA's *Pearson* Question 6: *The *Pearson* opinion mentions circumstances in which FDA might be justified in banning certain health claims outright (e.g., where the evidence in support of the claim is outweighed by evidence against the claim, or where the evidence*

supporting it is qualitatively weaker than the evidence against it) (Pearson, 164 F.3d at 659 and n.10).

- a. *How should FDA determine when evidence supporting a health claim is outweighed by evidence against the claim?*
- b. *How should FDA determine when evidence supporting a health claim is qualitatively weaker than the evidence against the claim?*
- c. *Are there other circumstances in which health claims are inevitably misleading and cannot be made nondeceptive by qualifying language?*

CHPA Response:

Each health claim should be judged on its own merit on a case-by-case basis through an examination of the totality of the scientific evidence. To judge the science supporting the claim, FDA's Food Advisory Committee has set forth a framework for evaluating individual studies. Weighing the strengths and limitations of the of individual studies to derive a weight-of-the-evidence judgement, in the context of the truthfulness of the submitted health claim, is the scientific approach FDA should use to create its regulatory decision to approve or not approve the claim.

FDA's questions over-drive an attempted solution to the current issue. It is virtually impossible to standardize a process that by its nature is case-specific. Each situation is likely to be different and the collective scientific and medical expertise of the agency will need to be utilized. Hence, CHPA recommends that FDA use the document created by the Foods Advisory Committee for the evaluation of individual studies, and then make an overall judgement based on the collective evidence.

FDA's Pearson Question 7: *What safety information is necessary to prevent a health claim from being misleading? For example, such information might include side effects, drug and food interactions, and segments of the population who should not use the product or should consult a physician before doing so. When a product may have adverse effects unrelated to the subject of a scientifically valid health claim, is the claim misleading? Under what circumstances, if any, should the product be allowed to bear the claim?*

CHPA Response:

Safety of dietary supplements should be a paramount concern to both the agency and the manufacturer. If there are safety concerns about a claim that can be addressed through labeling, the claim should be approved. If safety concerns about a claim cannot be addressed through labeling, the claim should not be approved. However, FDA should not take a narrow view of the types of information that consumers can utilize and understand in labeling to safely use the product making the claim.

FDA's Disease-State Question 1: *Does the language and structure of the act restrict the permissible types of substance-disease relationships that can be described in a health claim? How should FDA interpret the health claim and drug provisions of the act and the medical food provision of the Orphan Drug Amendments in relationship to each other?*

CHPA Response:

The language and structure of NLEA does not restrict the permissible types of substance disease relationships that can be described in a health claim. The act states a "health claim characterizes the relationship of any nutrient . . . to a disease or health-related condition". Such language does not limit claims to only disease risk-reduction claims. FDA should consider all petitions for health claims whether they are disease risk reduction claims or claims for disease management. For disease management claims, FDA will need to review the claims in the context of current treatment options and if there are safety concerns, these should be addressed in labeling.

FDA's Disease-State Question 2: *If FDA were to permit at least some claims about effects on an existing disease as health claims, what criteria should be used to determine when a claim is a permissible health claim and when it is a drug claim under section 201(g)(1)(B) of the act?*

CHPA Response:

Health claims relating to disease treatment is an issue with potentially great public health benefits and FDA should consider their approval. Importantly, it bears a clear relation to the *Pearson* decision which concludes that “truthful” promotion that is “related to lawful activities” is “entitled to the protections of the First Amendment”, notwithstanding the fact that *Pearson* did not address “treatment health claims.”

To date, health claims authorized by FDA have been for reducing the risk of disease. An example of such a claim is that published by FDA in FDA Consumer:

“Sample Claim: Regular exercise and a healthy diet with enough calcium helps teen and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life.”

However, treatment of osteoporosis, while requiring a diagnosis, includes calcium supplementation. Hence, truthful and not misleading information on the label of calcium supplements about the treatment of osteoporosis, in addition to its prevention, would be an important public health outreach to a vulnerable population. Indeed, such a treatment claim for calcium for the treatment of osteoporosis could be qualified to recommend a physician visit to determine whether the potential product user was suffering from the disease. Note that in the OTC arena, FDA permits self care products with labeling recommending physician diagnosis before use (e.g., bronchodilators for use in asthma; antifungals for use in vaginal candidiasis), and such labeling was undertaken at the discretion of the agency, entirely within existing laws and regulations.

Furthermore, calcium has recognized nutritive value. Hence, the potential conundrum that FDA describes in the Federal Register announcing the April 4th meeting on *Pearson* and health claims [i.e., that pertaining to FDA’s requirement that for a product to bear a health claim, it must establish that it is a food by demonstrating nutritive value; 21 CFR 101.14(b)(3)], is self-resolvable in this instance. As other dietary supplements with known nutritive value have scientific support gathered to support treatment of disease (e.g., vitamin D and calcium in conjunction with prescription drug therapy for osteoporosis; Omega-3 fatty acids, folic acid, B-complex and possibly others for heart disease), it would make sense to have a mechanism available to provide consumer access

to FDA authorized information on important health and diet-related issues. If the agency is concerned that patients may forego prescription drug treatment for dietary supplements, then as needed such a concern could be the basis for a qualifier on the treatment-health claim.

As logical as this sounds, the issue of nutritive value becomes a stumbling stone when considering health claims for dietary supplements which do not have a documented nutritive value. As defined by FDA in the final rule: “Nutritive value means a value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients, or providing energy.”(6) At the time of that proposed rule, the agency received many comments expressing concern that the definition of nutritive value was potentially too narrow. However, the agency in answering these concerns stated:

“As FDA explained in the health claims final rule (58 FR 2478 at 2488), the definition of ‘nutritive value’ is intended to be very flexible. The agency incorporated this flexibility in the definition because FDA recognizes that certain substances can play a major role in reducing the risk of certain chronic diseases and may confer their benefits through a number of processes. FDA believes that the agency should evaluate the nutritive value claimed for a substance that is proposed as the subject of a health claim, as described in a health claim petition, on a case-by-case basis. This approach will best ensure that the definition retains its intended flexibility and does not become an unintentional barrier to authorization for legitimate health claims.”

The agency also stated the following, which creates the current apparent conundrum when considering a dietary supplement such as saw palmetto for treatment of benign prostatic hypertrophy as one having a documented nutritive value:

“In general, the agency will look for evidence that the claimed effect on disease is associated with the normal maintenance of human existence. If the substance is used to correct an abnormal physiological function caused by a disease or health-related condition, the action of the substance is clearly beyond a normal maintenance function, and the health benefit

would therefore not derive from the substance's nutritive value." (FR 59: 407, 1994)

FDA's Disease-State Question 3: *If FDA were to permit at least some disease treatment or mitigation claims as health claims, what about claims that are covered by an existing over-the-counter (OTC) drug monograph? For example, if there is an existing drug monograph on the use of a dietary ingredient in an OTC drug product to treat or mitigate disease, and the monograph concludes that the substance is not safe and effective for the intended use, should FDA still consider authorizing a health claim for the substance-disease relationship?*

Diet/disease relationships can be a logical health-based extension of dietary supplement function. FDA's recognition of this issue carries First Amendment implications. Therefore, it would be sound public policy to permit such claims. In so doing, FDA should redefine nutritive value, so as to recognize that the processes by which a nutrient promotes health, maintains proper bodily functioning, and protects the body from the development of chronic disease or other health-related conditions are, in and of themselves, characteristic of "nutritive value," thereby creating a more logically flexible approach to health claims.

Further, FDA could stipulate specific criteria that might be considered as part of a "disease treatment-related health claim," including documentation of safe use for treatment of the specific disease under consideration, consideration of how labeling addresses informing consumers of adequate diagnosis to optimize treatment, among other things. In effect, because of the authorization procedure for health claims, FDA maintains control of the claims environment to ensure the claims are truthful and not misleading, and if necessary appropriately accompanied by a qualifier or disclaimer.

Finally, by allowing health claims for disease treatment for dietary supplements, FDA would create a regulatory mechanism that would provide a means to create a generic authorized (or approved) claim for a dietary supplement or food that might have been tested for disease treatment in an NIH trial (i.e., not company sponsored), as may be the case for St. John's wort which is under study by NIH for depression.

Conclusion

In conclusion, FDA has a distinct opportunity through CHPA's proposal to create a claims framework based on the truthfulness of the claim that will meet both the intent of NLEA and that of the *Pearson* decision. The regulatory framework will provide truthful information to consumers about emerging science of the benefits of dietary supplements and foods.

Sincerely yours,


R. William Soller, Ph.D.
Senior Vice President and
Director of Science and Technology


Patrice Wright, Ph.D.
Director of Pharmacology & Toxicology

cc: Dr. Christine Lewis
Mr. Michael Landa
Ms. Margret Dotzel
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