DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC

MAY 26 2000

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Dear Mr. Emord:

This letter concerns your health claim petition (Docket Number 99P-3030) submitted to the Food and Drug Administration (FDA) on May 25, 1999, on behalf of Julian Whitaker, M.D., Durk Pearson and Sandy Shaw, American Preventive Medical Association, and Pure Encapsulations, Inc. The petition requests that FDA authorize a health claim concerning the relationship between dietary supplements containing saw palmetto (specifically, the *n*-hexane lipidosterolic extract of the pulp and seed (fruit) of the dwarf American palm, *Serenoa repens*) and benign prostatic hyperplasia (BPH). The model claim set forth in the petition is: "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)."

I. Background

In accordance with the procedures in 21 C.F.R. § 101.70(j)(2), the agency filed your petition for comprehensive review on September 1, 1999. The petition was denied by operation of law on December 1, 1999, under section 403(r)(4)(A)(i) of the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. § 343(r)(4)(A)(i)) and 21 C.F.R. § 101.70(j)(3)(iii), which provide that if FDA does not propose a regulation to take the action proposed in a health claim petition within 90 days after the agency has filed the petition, the petition is deemed to be denied. On December 1, we forwarded a letter to you explaining that we were not proposing a rule because we were unable to resolve, within the statutorily prescribed timeframe, the threshold issue presented by the petition: whether a claim about an effect on an existing disease is within the scope of the food[1] labeling health claims provisions of the FFDCA.

All of the health claims that FDA has authorized since the passage of the Nutrition Labeling and Education Act of 1990 (NLEA) have been claims about reducing the risk of contracting a particular chronic disease. In contrast, the saw palmetto extract claim for which you have requested authorization represents a claim about an effect on an existing disease – namely, a claim to relieve symptoms of BPH. The claim would therefore be directed at men who have

[1]When the term "food" is used in this letter, it encompasses both conventional foods and dietary supplements. Except for purposes of the drug definition in 21 U.S.C. § 321(g)(1), dietary supplements are deemed to be foods under the FFDCA. 21 U.S.C. § 321(ff).

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already contracted BPH. To date, authorized health claims have been targeted to the general population or to a population subgroup whose members are at risk for a particular disease, but not to those who already have the disease.

FDA held a public meeting on April 4, 2000, to solicit public comment on, among other issues, whether claims about effects on an existing disease may qualify as health claims. The agency also created a docket (Docket No. 00N-0598) to receive written comments. The docket was open for more than 30 days, from March 16, 2000, through April 19, 2000. Eighty-nine written comments and prepared statements were received and filed in the docket; thirty-four of these comments expressed an opinion on whether claims about effects on an existing disease may qualify as health claims.[2] Fourteen people spoke on this issue at the meeting, including five panelists specifically invited to discuss it.

Written comments in the docket and oral comments at the meeting show basically two opposing opinions on this issue. One group of comments pointed to the broad language of 21 U.S.C. § 343(r)(1)(B), which defines a health claim as a claim that "characterizes the relationship of any nutrient . . . to a disease or health-related condition." These comments argued that this language shows that Congress intended to permit any truthful claim about disease as a health claim on foods. The other main view expressed in the comments was that Congress enacted the NLEA health claim provisions in response to manufacturers' desire to use information about diet and long-term health to promote food products and that Congress did not intend to undermine the established premarket drug approval procedures for products bearing claims about mitigation or treatment of disease. Some of the comments adopting the latter view raised public health concerns about allowing foods to make health claims for effects on existing diseases, both generally and in the context of saw palmetto dietary supplements and BPH.

II. Scope of Issue and Explanation of Terminology

This letter states FDA's position on whether certain types of disease claims for foods fall within the scope of the health claim provisions in 21 U.S.C. § 343(r).

Your proposed claim for saw palmetto extract is a claim to relieve the symptoms of an existing disease. Such a claim could be characterized as a claim to treat disease, a claim to mitigate disease, or both. In the absence of health claim authorization, both types of claims subject a food to regulation as a drug under 21 U.S.C. § 321(g)(1)(B), which encompasses articles "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." FDA believes that claims to treat, mitigate, and cure disease are closely related, in that all are claims to have an effect on an existing disease. Because of this close relationship and because the statute and legislative history support treating them the same way for purposes of the issue your petition presents, this letter states FDA's position on that issue with

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[2]The relevant comments and prepared statements from the public meeting docket and the transcript of the public meeting have been included in the docket of this proceeding.

respect to all three types of claims. Although FDA has not defined the exact meaning of these three terms or the extent to which they may overlap, the agency believes that there is no meaningful distinction between them with respect to the scope of the health claims provisions in 21 U.S.C. § 343(r). For simplicity, the term "treat" will be used as a synonym for "treat, mitigate, or cure" throughout the remainder of the letter.

III. Agency Decision

After thoroughly reviewing the relevant statutory provisions and legislative history, FDA's past statements on this issue, and the comments we have received on it, we have concluded that claims about effects on existing diseases do not fall within the scope of the health claim provisions in 21 U.S.C. § 343(r) and therefore may not be the subject of an authorized health claim. We have come to this conclusion after carefully considering the language and structure of the NLEA and the FFDCA as well as the public health importance of ensuring that claims to treat disease be substantiated by the appropriate level of evidentiary support to provide protection for patients who are already sick and, therefore, especially vulnerable.

A. Pre-NLEA FDA Proposals and the Enactment of the Medical Foods Definition

Drugs have always been permitted to claim an effect on disease. The term "drug" is defined, in part, as an article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." 21 U.S.C. § 321(g)(1)(B). Thus, foods that claim an effect on disease generally have been subject to regulation as drugs.

FDA first proposed to allow a limited *subset* of such claims in food labeling in 1987. FDA based its original 1987 proposal on health claims for foods, and subsequent reproposal in 1990, on the increasingly prevalent scientific view that good nutrition and diet are essential components of health protection and promotion efforts. See 52 Fed. Reg. 28843 (1987); 55 Fed. Reg. 5176 (1990). This view, and the related view that making information about diet and health available to consumers in food labeling would assist such efforts, had been embraced by a broad spectrum of society, including industry, consumer advocacy groups, and professional societies. See 52 Fed. Reg. at 28844. Both proposed rules, as well as the scientific publications cited to support them, focused on diet as a means of reducing the risk,[3] or forestalling the premature onset, of chronic diseases, such as cancer and coronary heart disease. The preamble to the 1987 proposed rule stated that health claims "should not imply that a particular food be used as part of a drug-like treatment or therapy oriented approach to health care." 52 Fed. Reg. at 28845. The regulatory text of the 1990 proposed rule would have explicitly limited acceptable health claims to claims about "the value that ingestion (or reduced ingestion) of a dietary component may have in either lowering the risk, or forestalling the premature onset, of a particular chronic disease condition." 55 Fed. Reg. at 5192.

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[3]Throughout this letter, the phrase "reducing the risk" of a disease refers to reducing the risk of contracting the disease.

Several citizen petitions requesting that FDA permit health claims similarly limited the scope of health claims for foods. A petition from a dietary supplement trade association (Docket No. 85N-0061/CP3) included recommended criteria that specifically excluded "therapeutic" statements. The criteria were designed to differentiate "therapeutic" statements from "nutritional" statements. Another petition from a conventional food trade association (Docket No. 85N-0061/CP1) requested FDA to permit claims about "the relationship between the presence or absence of a particular dietary property provided by [a] food as part of a well-balanced diet and the *maintenance of health or wellness*, including the *incidence* of specific diseases, symptoms, or disorders" (emphasis added). A petition from a consumer group (Docket No. 85N-0061/CP5) would have limited health claims to claims about reducing the risk of a disease.

Hence, before the passage of NLEA, health claims were envisioned as being intended to assist the general population in maintaining good health (or avoiding poor health), and not to treat existing disease.

In 1988, Congress enacted legislation that, among other things, provided for another type of disease-related claim for a limited subset of foods. The Orphan Drug Amendments established a new statutory product category called "medical foods." A "medical food" is defined as "a food which is formulated to be consumed or administered enterally (i.e., via the digestive system) under the supervision of a physician and which is intended for the specific *dietary management* of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." 21 U.S.C. 360ee(b)(3) (emphasis added).[4] Thus, medical foods are foods that are intended to affect an existing disease through a nutritional mechanism.

B. The Statute and the Legislative History

In the NLEA, Congress authorized foods to carry health claims without becoming drugs, prescribing conditions under which a food may bear a health claim without being misbranded and creating a partial exemption from the drug definition for foods that meet those conditions. The health claim provisions of the NLEA are similar in many ways to the 1990 FDA health claims proposal, although the NLEA establishes more elaborate procedural requirements for health claims. Both emphasize dietary context, requiring that health claims for conventional foods explain the role of the food in the context of the total diet and that such claims be consistent with generally accepted nutritional principles regarding healthy eating. Compare 21 U.S.C. § 343(r)(3)(B)(iii), 343(r)(3)(A)(ii) with 55 Fed. Reg. at 5192. In addition, Congress expressly adopted the same scientific standard of scientific validity for conventional food health claims that FDA had proposed. Compare 21 U.S.C. § 343(r)(3)(B)(i) with 55 Fed. Reg. at 5192. See also H. R. Rep. No. 101-538, at 21 (1990) ("House Report"),

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[4]For example, products formulated to deliver a specified level of glutamine to patients recovering from burns or wounds are medical foods. Burns and other injuries create an increased nutritional need for glutamine, an amino acid.

reprinted in 1990 U.S.C.C.A.N. 3336, 3351. Finally, Congress directed FDA to consider authorizing ten nutrient-disease relationships as health claim topics; six of these had been identified in FDA's 1990 proposal as the health claim topics that the agency intended to first consider authorizing and had been characterized in the proposal as relationships between a nutrient and reduction of the risk of a chronic disease. Compare Pub. L. No. 101-535, § 3(b)(1)(A)(vi), (x), 104 Stat. 2353, 2361 (1990) with 55 Fed. Reg. at 5184. See also House Report at 22, reprinted in 1990 U.S.C.C.A.N. at 3352.

The purpose of NLEA was to "clarify and strengthen" FDA's legal authority to permit health claims and require nutrition information in food labeling. House Report at 7, reprinted in 1990 U.S.C.C.A.N. at 3337. The legislative history of the NLEA evidences no Congressional intent to expand the scope of health claims beyond what FDA had envisioned in its 1990 proposal. On the contrary, the legislative history reflects concern that FDA had been too permissive and that health claims in the marketplace needed more control. See House Report at 9, reprinted in 1990 U.S.C.C.A.N. at 3338-39.

The legislative history characterizes the health claims that NLEA provides for as claims about preventing or helping to prevent disease. Where examples of health claims are given, they invariably refer to the role of a food substance in preventing or helping to prevent a chronic disease, not to any role in treating an existing disease. See House Report at 8, reprinted in 1990 U.S.C.C.A.N. at 3337 ("fiber prevents cancer"); House Report at 20, reprinted in 1990 U.S.C.C.A.N. at 3350 ("fiber helps to prevent cancer"); 136 Cong. Rec. H5841 (statement of intent of changes since bill was reported out of committee) ("fiber prevents cancer"); 136 Cong. Rec. H5841 (statement of Rep. Waxman) ("bran prevents cancer"); 136 Cong. Rec. S16,609 (Statement of Sen. Mitchell) ("reduces the risk of cancer"); 136 Cong. Rec. H12,953 (statement of House floor managers) ("fiber in cereal prevents cancer"); 136 Cong. Rec. H12,954 (statement of Rep. Madigan) ("bran prevents cancer").

The legislative history further indicates that the common purpose behind all three main parts of the NLEA – the nutrition labeling, nutrient content claims, and health claims provisions – was to promote long-term health maintenance and prevention of disease by providing truthful, scientifically valid information to consumers on the food label. See 136 Cong. Rec. H5843 (statement of Rep. Moakley) (legislation responds to Americans' increasing concern about their diets and reducing the risk of disease); 136 Cong. Rec. H5843 (statement of Rep. Madigan) (question under consideration is how to most effectively inform consumers about health risks related to diet); 136 Cong. Rec. S16,609 (statement of Sen. Metzenbaum) (many Americans use dietary supplements to help prevent chronic disease; rapid scientific advances link nutritional substances to maintenance of long-term health and prevention of long-term disease); 136 Cong. Rec. S16,610-11 (statement of Sen. Hatch) (vitamins and minerals are important in helping to prevent certain serious illnesses and health problems; because of rapid scientific advances linking the prevention of long-term disease to improved nutritional supplementation, important to allow dietary supplements to be marketed so that consumers are informed of the health or disease-prevention benefits they may confer); 136 Cong. Rec. H12,954 (statement of Rep. Moakley) (healthy eating can lower risk for certain illnesses, such

as heart disease and cancer). Nowhere in the legislative history are there any statements of Congressional intent to promote the *treatment* of disease with foods.

This general theme that the diet has an important role in reducing the risk, or forestalling the premature onset, of certain chronic disease conditions also was the thrust of the National Research Council's 1989 report entitled "Diet and Health Implications for Reducing Chronic Disease Risk," which provided much of the scientific rationale for health claims, as referenced in FDA's 1990 pre-NLEA proposed rule. See 55 Fed. Reg. at 5178. That report clearly focuses on dietary reduction of risk rather than treatment of an existing disease or condition. Similarly, the 1988 Surgeon General's Report on Nutrition and Health focuses on how dietary factors contribute to the development of disease and how dietary changes can reduce the risk of common chronic diseases, not on how diet can treat disease. That report also was cited in FDA's 1990 proposed rule. See 55 Fed. Reg. at 5178. Both reports were cited in the NLEA legislative history, and Congress relied on them in constructing the list of nutrients that must be included in nutrition information on the food label. See House Report at 13-14, reprinted in 1990 U.S.C.C.A.N. at 3343. Consequently, there is a significant body of evidence that the 1990 legislation permitting health claims in food labeling was founded on the premise of reducing risk of potential disease, not treatment of existing disease.

We also have considered that the health claim provisions of the NLEA were enacted as part of a statutory scheme that already included extensive, longstanding regulatory requirements for drugs. Before the NLEA, the drug provisions of the FFDCA had been applied to foods, including dietary supplements, that made claims about effects on disease. As discussed in the preceding paragraphs, nothing in the legislative history indicates an intent to abrogate the FFDCA's drug requirements for foods that make disease treatment claims. Moreover, when the Dietary Supplement Health and Education Act of 1994 (DSHEA) was enacted, Congress did not provide that dietary supplements are deemed to be foods in all circumstances; rather, it provided that dietary supplements are deemed to be foods "except for purposes of section 201(g)" of the FFDCA (21 U.S.C. 321(g)), the drug definition. Congress' decision to proceed in this manner, rather than by providing unconditionally that dietary supplements are not drugs, suggests that it wanted the drug provisions to continue to apply to dietary supplements in certain circumstances, such as when the dietary supplement makes a claim about treatment of disease.

We also note that the NLEA specifically exempted medical foods from, among other things, the health claims provisions that were added to the FFDCA. Pub. L. No. 101-535, § 3(a), 104 Stat. 2353, 2360 (1990) (codified at 21 U.S.C. § 343(r)(5)(A)). See also House Report at 22, *reprinted in* 1990 U.S.C.C.A.N. at 3351-52 (noting the exemption). The NLEA was passed just two years after Congress had established medical foods as a new statutory product category for the dietary management of diseases with distinctive nutritional requirements. The exemption from the NLEA health claim provisions for medical foods shows that Congress was aware of the existence of the medical foods category and did not intend an overlap between medical foods and foods bearing health claims. Thus, the statute provides not only clear statutory evidence that claims for dietary management of disease are addressed under the provisions for medical foods, but also clear evidence that Congress intended dietary

management claims for foods and health claims for foods to occupy separate regulatory spheres.

C. Agency Interpretation and Application to the Petitioned Claim for Saw Palmetto

FDA has consistently taken the position, in notice and comment rulemaking, that claims to treat disease cannot be made as health claims for foods under the NLEA. As FDA prepared to implement the NLEA, the agency considered the nature of the science supporting dietary effects on disease and Congress' expressed intent to allow conventional foods and dietary supplements to make disease-specific health claims without ceasing to be foods. The agency came to the conclusion that the relationship of a food or food component to a disease is different from that of a drug because of genetic, environmental, dietary and behavioral factors in addition to diet that affect the development of disease, and because of the complexity of foods themselves. 58 Fed. Reg. 2478, 2501-02 (1993). FDA concluded that most types of disease claims that appear on drugs would not be appropriate as health claims on foods because they "imply a degree of association between the substance and the disease that is not supportable for any food." 56 Fed. Reg. 60537, 60552 (1991). FDA did conclude, however, that science supports some claims that foods can reduce the risk of disease, and that claims of this type are consistent with the statutory differences between foods and drugs.

In preambles to the NLEA health claim regulations, FDA maintained the distinction not only between a health claim target population consisting of the general population (or a subgroup that is at risk for a particular disease) and one consisting of a diseased population, but also between drug claims and food claims. In the January 1994 final rule on health claims for dietary supplements, the agency noted that Congress had given FDA a statutory structure within which to work and that "that structure divides the world of substances that have a relationship to disease into foods and drugs. Congress placed the health claims provisions on the food side of the ledger." 59 Fed. Reg. 395, 411 (1994). In the health claim preambles, we consistently distinguished between nutritional effects of food substances, which we said would be an appropriate subject for a health claim, and effects that are pharmacological, therapeutic, or medicinal, which would not. See, e.g., 56 Fed. Reg. at 60545-46; 58 Fed. Reg. at 2501; 59 Fed. Reg. at 408. To the extent the effect of saw palmetto is documented and understood, it is clear that its effect is pharmacological. It is thought to have multiple mechanisms of action on BPH. According to your petition, (page 11; Appendix 2, page 24) the mechanisms most likely involved include inhibition of 5-alpha-reductase, inhibition of binding of dihydrotestosterone to cytosolic androgen receptors in prostate cells, and alpha-one-adrenergic blocking activity.

In the 1994 final rule, FDA said that claims to "correct an abnormal physiological function caused by a disease or health-related condition" would be drug claims rather than health claims. 59 Fed. Reg. 395 at 407-08. Your proposed claim for saw palmetto is clearly aimed at correcting an existing abnormal physiological function--namely, urinary abnormalities caused by BPH. With respect to claims about effects on symptoms of disease, the agency said:

> [T]here is no provision in the act for the agency to exempt statements about symptoms of disease from causing products to be regulated as drugs. Although such statements may not be claims that the product will treat the disease that causes the symptoms, the statements clearly pertain to the mitigation of disease by addressing the symptoms caused by the disease. Section 201(g)(1)(B) of the act provides, in part, that articles intended for use in the mitigation of disease are drugs.

59 Fed. Reg. 395 at 413. Your petition clearly identifies the intended use of saw palmetto extract products bearing the proposed claim as the treatment of the urinary symptoms of BPH. The proposed model claim, "*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)*," explicitly describes the mitigation of disease by treating its symptoms and establishes the intended use of products bearing the claim as drugs.

With respect to botanicals like saw palmetto, FDA said in a 1993 preamble:

> [T]here is no basis under the act for FDA to permit health claims for herbs whose only known use is for medicinal effects. Health benefits of such herbs may appear in the labeling only in accordance with the drug provisions of the act. . . . Where herbs have a history of use both as foods and drugs, the context of all of the available information on the intended use of the product will determine whether FDA will regulate the herbs as foods, as drugs, or as both foods and drugs.

58 FR at 2501.[5] The history of saw palmetto extract use, as summarized in documents such as the Commission E monograph on saw palmetto berry, the Physicians' Desk Reference for Herbal Medicines, and The Lawrence Review of Natural Products, is solely for medicinal effects in the treatment of urinary symptoms of BPH. The petition includes no information documenting that there is a food use of saw palmetto berries.

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[5]FDA has continued to emphasize the limited scope of health claims in later rulemakings. For example, in 1995, the agency explained, "In contrast to a drug claim, a health claim provides information about how diet can help reduce a person's risk of developing certain diet-related diseases." 60 Fed. Reg. 37502, 37505 (1995). More recently, FDA responded to comments expressing concern that a proposed health claim about oats and coronary heart disease would portray oat products as "magic bullets." The comments argued that the claim would mislead consumers by creating the false impression that consumption of oat bran and oatmeal alone would protect against heart disease. The agency responded that limiting the claim to describing the relationship of a total diet low in saturated fat and cholesterol that includes whole oats to the risk of coronary heart disease would prevent the foods eligible to bear the claim from being perceived as "magic bullets." 62 Fed. Reg. 3584, 3589-90 (1997).

D. Further Considerations

Claims about products targeted to persons with a disease invoke a higher level of safety and public health consideration than do claims for products intended for people who, while they may be at risk for a disease, have not yet contracted it. The clear separation of medical foods, and hence intended use for dietary management of disease, from the ordinary food supply with its claims targeted to non-diseased people recognizes that the diseased populations targeted for dietary management are particularly vulnerable by virtue of having the disease. For example, because of this increased vulnerability, the medical foods provision of the Orphan Drug Amendments contemplates supervision by a physician to ensure that the medical food is appropriate for the patient and is being used correctly. See 21 U.S.C. § 360ee(b)(3); 61 Fed. Reg. 60661, 60668 (1996). It should also be noted that, consistent with the distinction between foods and drugs articulated by FDA in the health claim preambles, medical foods focus on *dietary* management of disease by meeting distinctive *nutritional* requirements; they do not operate by a pharmacological mechanism.

FDA has considered the use of saw palmetto to treat the symptoms of BPH in the over-the-counter (OTC) drug context. That review concluded that there are health risks associated with the use of saw palmetto to treat BPH symptoms. In a 1990 final rule, FDA concurred with a recommendation from the Advisory Review Panel on OTC Miscellaneous Internal Drug Products that saw palmetto[6] and certain other substances should not be available OTC for the relief of symptoms of BPH. See 55 Fed. Reg. 6926 (1990). The agency concluded that the clinical studies testing saw palmetto did not provide "sufficient evidence of effectiveness, i.e., adequate and meaningful clinical improvement" in treating the symptoms of BPH. 55 Fed. Reg. at 6927. Although FDA concluded that saw palmetto "probably" provides some "minimal" symptomatic relief, it expressed concern that, as long as only the symptoms of the condition are relieved, men with BPH may be lulled into a false sense of security and postpone reexamination by a physician, resulting in delay in treatment of the disease. Such delay could result in delayed diagnosis of secondary complications such as stagnation of residual urine, urinary tract infection, and potential renal damage. 55 Fed. Reg. at 6929.

At FDA's April 4, 2000, public meeting, a physician representing the American Urological Association (AUA) expressed views consistent with those stated in the 1990 final rule. H. Logan Holtgrewe, M.D., emphasized that lower urinary tract symptoms in older men (urinary frequency, urinary urgency, slowing of the urinary stream, hesitation on initiation of urination, getting up several times during the night to urinate) are symptoms of disease, not a normal process of natural aging. Included among the diseases that produce such symptoms are life-threatening cancers, e.g., cancer of the prostate and cancer of the urinary bladder. Dr. Holtgrewe expressed the AUA's concern that men experiencing lower urinary tract symptoms may self-medicate with dietary supplements marketed for such symptoms and thus delay the

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[6]The final rule refers to saw palmetto as "sabal." Both saw palmetto and sabal are English names for the plant whose Latin binomial name is *Serenoa repens*. See 55 Fed. Reg. at 6927.

timely and accurate diagnosis of their cancers. These cancers can rarely be cured once they have spread beyond the confines of the bladder and prostate; a cure is possible only when the disease remains confined to the primary organ. Thus, early diagnosis is essential. Therefore, Dr. Holtgrewe emphasized that dietary supplements marketed for symptoms of BPH may cause "irreparable harm" when men with cancer lose precious time by self-medicating under the illusion that they are treating a benign, non-life-threatening condition. Transcript of Proceedings, "Public Meeting on Implementing the Pearson Court Decision and Other Health Claim Issues," pp. 158-163, 185-205.

E. Consequences of a Contrary Interpretation

Many pharmacologically active substances with possible uses in disease treatment could qualify as dietary ingredients for use in dietary supplements because they are botanicals or otherwise meet the definition of "dietary ingredient" in 21 U.S.C. 321(ff)(1). Likewise, there are a number of substances found in conventional foods that are pharmacologically active. Therefore, if health claims for treatment of disease were permitted, there would be a serious danger that dietary supplements and food components would undermine the public health protections of the statutory and regulatory requirements for drugs. Approximately 94% of prescription drugs (memorandum from Behrman, May 24, 2000) and almost all OTC drugs for disease uses[7], (memorandum from DeLap, May 26, 2000) are for treatment of disease, rather than disease prevention. Both prescription and OTC drugs are subject to stringent safety and efficacy standards. See 21 U.S.C. 321(p), 355(a), (d); 21 C.F.R. Parts 314 and 330. Given the time and expense necessary to bring a new drug to market, it is unlikely that manufacturers would seek drug approval from FDA for any product containing a substance that could be characterized as a dietary supplement or conventional food component, but rather would take the health claim route. For that reason, the protections of the drug approval system and other regulatory requirements applicable to drugs would be lost for a large number of products used to treat disease. Moreover, incentives to perform research would be diminished, since less research is necessary to obtain authorization of a health claim than to meet the new drug approval standard.[8]

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[7]Some OTC drugs are intended for use in affecting the structure or function of the body rather than for use in affecting disease.

[8]Indeed, industry representatives have argued that, under Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), they need only present sufficient evidence to establish that the claim itself is truthful and non-misleading and need not demonstrate that the substance-disease relationship that is the subject of the claim exists. Under this approach, research incentives would be drastically lessened, as a claim could be worded to require minimal research support.

IV. Conclusion

For the reasons discussed above, we are denying your petition.

Sincerely,

Joseph A. Levitt

Joseph A. Levitt
Director
Center for Food Safety
and Applied Nutrition

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