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Dietary Supplement Health and Education Act of 1994 P.L. 103-417

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DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994: P.L. 103-417

SUMMARY

Since passage of the 1990 Nutrition Labeling and Education Act (NLEA, P.L. 101-535), there has been considerable controversy about the regulation of dietary supplements under that Act. Concerns focus primarily on nutrition labeling, nutrient content and health claims regulations. The Food and Drug Administration (FDA) has taken the position that the supplement industry should follow the same rules as those established for conventional foods under NLEA. The health food and supplement industries believe their products are unique and should be regulated under a different and less restrictive framework.

Contributing to the debate are questions concerning the safety of these products. In 1989 FDA banned the amino acid L-tryptophan from the market following the determination that a contaminated batch of this product had contributed to thousands of consumers becoming ill and three dozen deaths. It has yet to be clearly determined whether the amino acid, the contaminates, or a combination caused the public health problem. In addition, while some believe that most supplement ingredients are relatively benign from a safety standpoint, others are concerned that some manufacturers make health claims for their products which are unsupported by extant scientific evidence.

During the last two Congresses, numerous bills were introduced, but not enacted, on the regulation of dietary supplements with hearings held to examine the options for future regulation of these products. On August 13, 1994 the Senate passed a substitute for S. 784 (the Dietary Supplement Health and Education Act), with several changes from the bill reported out of the Committee on Labor and Human Resources on May 11, 1994. Following considerable debate and additional compromises, the House passed the bill on October 7, the Senate passed the House version on October 8, and the Act was signed into law on October 25, 1994 as P.L. 103-417.

The Act defines supplements, places the burden of proof for safety on FDA, sets standards for the distribution of third party literature, allows statements of nutritional support under certain conditions, specifies the supplement ingredient and nutrition labeling information, and requires good manufacturing practices to be established. It also creates a commission to make nonbinding recommendations on the standards and procedures for setting supplement health claims, and sets up an NIH supplements office to oversee research and provide advice on these products to other Federal agencies. While the new law provides new authority for some aspects of supplement regulation to the agency, it places further limits on FDA's regulation of the safety and labeling of these products.

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The following report outlines the language and implications of the provisions of the Dietary Supplement Health and Education Act of 1994, which was enacted by Congress to address the regulation of dietary supplement labeling and health claims. On October 7, 1994 the House passed the bill by unanimous consent as an amendment to the earlier passed Senate version of S.784; the Senate agreed to the final version the following day. By unanimous consent, the chief sponsors of the legislation agreed that a "statement of agreement" would stand as the law's only legislative history. A summary of each section of the law followed by comments on the implications of its provisions is presented below. Where the term supplements is used, it refers to dietary supplements. Analysis of other supplement bills introduced in the 103d Congress and a background report on the regulation of supplements are also available in CRS reports 103-101 SPR and 103-208 SPR, respectively.

Sec. 1 Short Title, Reference and Table of Contents

Summary: The title of the law is the "Dietary Supplement Health and Education Act of 1994." The reference to amendment or repeal of any section or provision throughout the Act is to the Federal Food, Drug, and Cosmetic Act (FDCA).

Comment: The title of this Act is the same as the Senate bill, S. 784, which became P.L. 103-417.

Sec. 2 Findings

Summary: The Act lists 15 findings and the rationale for its enactment.

Comment: Many of the findings affirm a positive relationship between sound dietary practices and good health. Some imply that there is a scientifically confirmed link between the use of dietary supplements, reduced health care expenditures, and disease prevention.. However, many of the "findings" suggest correlations that still await further scientific confirmation. For example, one finding is that "the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies." While there is an ever-increasing body of evidence that nutrition in general and specific nutrients in particular are important to health promotion and disease prevention, no such evidence has been provided for the use of dietary supplements per se. Although the findings allude to supplement safety, only a few supplement ingredients have been subjected to extensive scientific evaluation to determine their safety or the validity of their role in disease prevention or treatment.

Sec. 3 Definitions

Summary: The Act defines the term "dietary supplement" to include a product (other than tobacco) added to the total diet that contains at least one of the following ingredients: a vitamin, mineral, herb or botanical, amino acid, another dietary substance for use to supplement the diet, or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above. These products can be ingested in any form (tablet, capsule, powder, softgel, gelcap, or liquid), must be labeled as a dietary supplement, and cannot be represented for use as a conventional food or sole item of a meal or diet.

In addition, the term dietary supplement includes a product such as a new drug, antibiotic, or biologic that was marketed as a supplement or food before approval was sought to market it as a prescription drug. This provision is conditional on the Secretary of Health and Human Services having not issued a regulation finding that the product, when used as a supplement, is unlawful for safety reasons. However, the definition of dietary supplement does not include a product that is approved as a new drug, antibiotic, or biologic (or a product authorized for investigational use in clinical trials) that was not previously marketed as a supplement or a food. This provision could be waived should the Secretary decide to issue a regulation finding that this product would be lawful under this Act. Dietary supplements, including any ingredient used, are generally considered to be foods, but are excluded from the definition of a food additive under FDCA.

Comment: The Act allows the ingredients in a supplement to be excluded from regulation as a food additive or drug, which both require premarket approval, regardless of the form or composition of the supplement. The general food regulations would still apply to these products. Food additive approval requires FDA premarket review of a petition submitted by the manufacturer that provides evidence of the safety of the additive and its application in a given product (amount to be used for a specific function). The language in the new Act appears to be intended to refer to the supplement components that are active ingredients (which have some effect on the product's action), although this is not specifically stated. Otherwise, the language under this provision might be construed as applicable to any supplement ingredient ("another dietary substance for use to supplement the diet"), including binders, fillers, excipients, stabilizers, emulsifiers and flavors, which would then all be exempt from premarket regulation. Since these components are inactive, but play a functional role in supplements as well as in other products, it would be inconsistent for them to be exempt from premarket regulation when they provide that function in a supplement, but not exempt from regulation when used in other foods and drugs.

The inclusion of the phrase "another dietary substance for use to supplement the diet" would seem to suggest that there is no limit on the substances that could be considered to be supplementing the diet and therefore exempted from regulation as food additives or drugs. Given the agency's resource constraints, the exemption from the food additive provisions of FDCA

may make it considerably more difficult for FDA to challenge products for which there is a health or safety question. The burden of proof will be placed on the agency, not on the manufacturer as in the premarket approval required for food additives. Under the food additive provisions of FDCA, FDA had challenged some supplement ingredients as unapproved food additives. A food additive can be declared unsafe based the standard of "may be injurious to health", meaning that some subgroup of the population would have an adverse reaction from consumption of the ingredient. Under the provisions of this Act, the agency will have to use the general food safety provision which requires it to show that an ingredient is "ordinarily injurious to health", meaning it would be expected to harm most individuals who consume it. This latter standard is much more difficult to meet. Exemption from the food additives amendment would also apply to the provisions of the Delaney clause, which prohibit the use of any additive, regardless of the amount, shown to cause cancer in humans or animals.

For drugs, premarket approval for use under FDCA is only granted after their safety and efficacy has been demonstrated by adequate and well-controlled clinical investigations. In some cases, a substance that is properly included in a supplement may also function as an active ingredient in a drug product. Examples include L-carnitine and caffeine which are dietary substances, but are also approved as drug ingredients. The supplement definition in this Act establishes that should a supplement ingredient (e.g., vitamin C) some day be approved for marketing as a prescription drug, the decision to make it a prescription drug will not in any way affect its continuing regulatory status as a dietary supplement. In general, it is the intended use (i.e therapeutic claim) of a particular finished product that determines whether that product and its ingredients are subject to food or drug regulations, which contributes to blurring the distinction between foods and drugs. Absent the issuance of clarifying regulations by FDA, some are concerned that manufacturers may choose to market their products as supplements in order to avoid needing to meet the requirements of the drug approval process (e.g., antacids of calcium carbonate being marketed as dietary supplements for digestion).

The provisions also prevent any restrictions based on the form of a product, so that if a product contains a higher dose of a substance with increased potency, the agency would be unable to regulate it on that basis alone. FDA and the health profession in general has long held the view that many substances, while not hazardous at low doses, may become a health problem at higher concentration levels.

Sec. 4 Safety of Dietary Supplements and Burden of Proof on FDA

Summary: FDCA is amended by adding the provision that a supplement is adulterated (unsafe) if it, or an ingredient, presents a significant or unreasonable risk of illness or injury under conditions of use stated, or under ordinary conditions of use, if none are stated, on the label. The agency can also declare the supplement is unsafe if it contains a dietary ingredient for which there is inadequate information to provide a reasonable assurance that it does not present a significant or unreasonable risk of illness or injury. A supplement

can also be unsafe if the Secretary himself declares it to pose an imminent hazard to public health or safety and promptly initiates a proceeding for proper adjudication and hearings to affirm or withdraw the adulteration declaration. In such a situation the U.S. Government bears the burden of proof to show that a supplement is adulterated. The court is charged with deciding any issue of the safety of a supplement or its ingredient on a *de novo* basis. Before the Secretary may report a violation of safety to a U.S. attorney, the individual accused of such violation is to be given appropriate notice and opportunity to present views at least 10 days prior to any such proceeding.

Comment: This provision shifts the burden of proof for demonstrating that a supplement or its ingredient is unsafe to FDA. This change represents a significant policy shift from the present procedures applied to food additives and drugs, where the burden of proof is on manufacturers to demonstrate that their products are safe prior to marketing. Since manufacturers are not required to provide evidence of a product's safety prior to marketing or when the agency challenges a product already on the market, there will be increased demands placed on FDA resources to address perceived safety problems of a supplement or its ingredients when they arise. The difficulty of demonstrating a potential safety problem might be mitigated, if regulations clearly define the terms "substantial and unreasonable risk" of illness or injury. (The term "imminent hazard" is all ready defined in FDCA regulation and well understood by the affected industry.) However, FDA's interpretation of these terms may result in the same type of protracted public and legal debate that has ensued from the interpretation of the "significant scientific agreement" standard for the authorization of health claims for foods under the Nutrition Labeling and Education Act (NLEA). While these two terms might seem to clarify the anticipated level of safety desired before a supplement is challenged, those terms arguably may be viewed as synonyms for the standard "ordinarily injurious to health" (sec. 3). Furthermore, there has never been a comprehensive safety review of supplement products and their ingredients. While such a review would, no doubt, demonstrate that most products are relatively safe, there may be some products whose long-term use might lead to toxic effects. Such products might warrant the need for public notification and/or limiting access.

Consumers seem to believe that any product that appears in pill form has been reviewed for safety by FDA, which is not true for supplements. This perception was demonstrated by the L-tryptophan contamination case, in which victims believed their physicians would not prescribe a substance whose safety had not been assured by the agency[1]. (It has yet to be determined whether the L-tryptophan-related illnesses and deaths were caused by the amino acid itself, the contaminants, or a combination of both.)

The Act seems to suggest that a supplement label would be required to state the conditions for use, unless the ordinary conditions of use would be

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[1]U.S. Congress. House. Committee on Governmental Operations. Subcommittee on Human Resources and Interogovernmental Relations. Hearing on FDA's Regulation of the Dietary Supplement L-Tryptophan. July 18, 1991. 102d Cong., 1st. Sess. 336 p.

understood by consumers. However, it is unclear where consumers would obtain this information, if it is not on the label. Nor is it clear whether conditions of use on the label includes the type of information that appears on an over-the-counter (OTC) drug which, by regulation, must provide consumers with information such as warnings, precautions, and adequate directions for use. For OTC drugs, a monograph system was developed which provides all data and information publicly available that supports safe use of a product in a given therapeutic category. The monograph contains information on general provisions, active ingredients, labeling and testing procedures. While this type of monograph system is not envisioned under the provisions of this Act, the availability of such information would likely be useful to manufacturers and would facilitate regulation of these products. The Handbook of Nonprescription Drugs devotes a chapter to nutritional products containing vitamins and minerals, and provides the type of extensive information that would be used in a monograph-type document on these substances.[2] No comparable, objective source is currently available for amino acid and herbal products.

The courts are charged with being the final arbitrator in determining the safety of supplements as if they had not been previously reviewed by the agency. This provision puts the final decision on a scientific matter in the hands of the legal system.

Sec. 5 Dietary Supplement Claims

Summary: This section is concerned with supplement labeling exemptions which allow information in the form of an article, other publication, book chapter, or official abstract of a peer-reviewed scientific publication to be exempted from the definition of labeling, when it is used in connection with the sale of supplements to consumers. These materials must not be false or misleading; cannot promote a particular brand of supplement; must be displayed with other such materials on the subject so as to present a balanced view of the available scientific information; must be displayed physically separate from the supplements; and may not have any information appended to it by any method. This section does not apply to the sale of books or other publications as part of normal business. In any proceeding to establish any such material as false or misleading, the burden of proof is on the U.S. Government.

Comment: This provision allows for the availability of nonmisleading informational materials that promote the therapeutic use of various substances for certain diseases. Exempting this information from the definition of labeling means that these materials will not be subject to the preclearance provisions and scientific standards that other health claims must meet. The term "misleading" is not defined in the Act but may be clarified in the regulations. There is concern among some health professionals that these informational materials may play on the fears and desperation of individuals with serious health conditions, if the information promoting the use of certain substances is

[2]American Pharmaceutical Association. The Handbook of Nonprescription Drugs. 10th Edition. Chapter 17 Nutritional Products, by L. V. Allen, Jr. Washington, D.C. 1993. p. 283-311.

not balanced. (Concern has been raised by some health professionals that the use of supplements to treat these conditions may at the very least be a waste of money, and at the worst delay individuals with serious medical complications from seeking a qualified health professional until their condition worsens or becomes life-threatening.) While there are, undoubtably, supplement ingredients that have beneficial health effects for certain conditions, few, if any, of these ingredients have been subjected to systematic randomized clinical trials in the United States.

The provision requires that the materials be placed with information that presents a balanced view of the state of knowledge on the subject, but there is no provision to enforce this requirement. This provision assumes that information that balances the presentation, e.g., that a substance will not do what it purports in some materials, will be publically available, when such information may not be available. Further, it places the burden of proof on FDA to demonstrate that the materials are false and misleading, a responsibility the agency may find difficult to implement due to limited enforcement resources.

Sec. 6 Statements of Nutritional Support

Summary: The law states that a nutritional benefit statement is not considered a disease-related claim, if it does not profess to diagnose, prevent, mitigate, treat, or cure a specific disease. It specifically allows statements to be made that address classical nutrient deficiency diseases as long as these statements disclose the prevalence of disease incidence in the United States, describe the role or characterize the documented mechanism of the nutrient intended to affect the structure or function in humans, or describe the general well-being from consumption of a nutrient without such statements being considered to be a disease-prevention claim. The manufacturer must have substantiation that any such statement is truthful and not misleading. Where such statements are made, the following statement must appear prominently displayed and in boldface type: "**This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.**" A manufacturer who makes a nutritional support statement must notify the Secretary within 30 days after the first marketing of the supplement with such a statement.

Comment: This provision allows statements of nutrient function to be made. While these claims may have been allowed in the past, the situation has needed to be clarified. These statements are not now nor would they be considered to be health claims as long as they do not profess to diagnose, prevent, mitigate, treat or cure a disease or condition. Such statements would need to be made in a very factual and straightforward manner to prevent them from being misleading to consumers. Such statements are neither characterized nor defined in the Act, but may be clarified in regulations. These structure and function statements will need to be monitored to assure that manufacturers limit their claims to either structure or functional roles.

FDCA defines a drug to be "... article intended to affect the structure and function of the body of man..." Delineation between "dietary supplement" and "drug related " structure and function statements may become problematic for FDA. Terms like structure and function may be confusing when used interchangeably to define drugs and nutritional support claims. For vitamins and minerals, this type of information is readily available in textbooks, which describe their biological function or role as established through nutrition and health research. However, this type of information on "function in the body" is not currently available through peer reviewed scientific sources for supplement ingredients that are not by definition nutrients (i.e., herbs, botanicals and other dietary ingredients).

The materials that will be used to document the function of these non-nutrient ingredients in the body may be controversial. The requirement for the FDA disclaimer statement, i.e., "not evaluated by FDA", will inform consumers that the agency has not evaluated the validity of such statements. While the manufacturer is required to have substantiation, there is no indication in the law as to what this constitutes and it may be addressed in regulations. This ambiguity may well open the same type of debate that has faced policymakers over what constitutes "significant scientific agreement," the current standard for authorizing health claims under NLEA. Furthermore, the manufacturer is not required to provide its substantiation to FDA. The 30-day time period for FDA notification after the appearance of such statements does not allow for agency oversight and enforcement of such statements before they appear on product labels. Even if a statement is challenged by the agency, it will likely have been read by consumers, and used to sell products before it could be removed either voluntarily or involuntarily by the manufacturer.

Sec. 7 Dietary Supplement Ingredient and Nutrition Information Labeling

Summary: The Act requires a supplement label to state the name and the quantity of each ingredient in the product, or the total quantity of ingredients in a proprietary blend. The label, which must identify the product as a "dietary supplement," also may be modified with the name of the characterizing ingredient, e.g., a vitamin C dietary supplement. In the case of an herbal product, the part of the plant from which the ingredient is derived must be stated. The supplement must be covered by and represented to conform to the specifications or standards of an official compendium, or if it does not, list the identity, strength, quantity, purity or compositional specifications that the supplement contains. The nutrition information on a supplement must first list the dietary ingredients present in the product in significant amounts and for which there is an established recommendation for daily consumption. Ingredients not present in significant amounts are not required to be listed. A listing of nonessential dietary ingredients would also be required on the nutrition label and identified as not having an established daily consumption recommendation.

Supplement labels would be required to list the amount of each ingredient per serving, could identify the source of the ingredient, must list the nutrition

information preceding the ingredient information, and would not be required to list an ingredient a second time. The language allows a statement of the percentage level of an ingredient in a product for which there is not a recommended daily intake value, without requiring it to meet the labeling statement requirements for ingredients for which there is currently an established level. The Act substitutes the term "dietary supplement ingredients" for "vitamins and minerals" and provides new labeling language for the existing provisions of Section 411 in FDCA. The labeling provisions are effective and may be used after the date of enactment, with the final implementation date set for December 31, 1996.

Comment: The provisions require a supplement to state that it is a dietary supplement and provide the name and amount of each ingredient used in the products. For an herbal product, the labeling must identify the part of the plant from which the ingredients are derived. This language is a step forward in the labeling of these products. Tying products to the specifications in an official compendium (presumably the U.S. Pharmacopeia (USP) or its equivalent) would require that monograph standards of identity, strength, quantity, purity or compositional specifications be met for the first time for many of these products that contain vitamins and minerals. Since there is no existing official compendium on herbals, botanicals, or amino acids, it is unclear how the standards will be established for these substances. There is no requirement to verify that the portion of the herbal product stated to be present in the supplement is that portion which is actually present. The lack of verification arguably creates the potential for fraud, abuse and health problems as there are certain portions of some herbs that are hazardous to health.

While the listing of the product's nonessential substances on the nutrition label may be desirable, it may detract from the recent attempt in food labeling reform to attain consistency among all food labels for the sake of clarity. Listing nonessential dietary ingredients on the nutrition facts panel may suggest to consumers that these ingredients have some nutritional role, which they do not. Furthermore, if supplements are allowed to list any ingredient on the nutrition panel, it may be contrary to other labeling reform limiting the focus of nutrition panel information to those nutrients for which there is public health significance.

There is no requirement that the Secretary promulgate regulations for this section of the Act. In the absense of such rules, manufacturers can adopt the language of the provisions into their labeling according to their own interpretations as soon as they choose.

Sec. 8 New Dietary Ingredients

Summary: The Act includes a section which allows new dietary ingredients to be used in supplements only if they have been present in the food supply in a form in which the food has not been chemically altered, or have a history of use or other evidence of safety establishing that the dietary ingredient, when consumed, can reasonably be expected to be safe. In addition, 75 days before

introduction into interstate commerce, a supplement manufacturer must provide the Secretary with information, including citations to any published articles, which is the basis on which the manufacturer has concluded that a supplement ingredient will be expected to be safe. The information is to be kept confidential for 90 days after which it is to be put on display, except for materials that are trade secrets or otherwise confidential commercial information. Any individual may file a petition proposing the issuance of an order prescribing the conditions under which a dietary ingredient will be expected to be safe. The Secretary must make a decision in 180 days on such a petition, and that decision will be considered the agency's final action. A "new dietary ingredient" means a substance that was not marketed in the United States before October 15, 1994.

Comment: New dietary ingredients will be allowed to be used in supplements, if they are unaltered from their natural form in the food supply, or there is other evidence of their safety. The law allows "a history of use or other evidence of safety" to be the basis for judging whether a new ingredient is considered safe. A "history of safe use" is not defined, and it is not clear what documentation will be required to demonstrate evidence of long term effects.

In the case of some herbal products already used for decades, the history of use standard has been shown to be a flawed premise on which to base safety alone. The Act grandfathers many substances that have previously been on the market which have never undergone any thorough safety review. Use of some dietary ingredients (e.g., herbal ingredients comfrey and chaparral) have recently raised safety concerns. Laboratory analysis of some imported chinese herbs--used for centuries--has identified the presence of steroids. Manufacturers are required to provide citations to published articles that provide evidence that a new dietary ingredient is safe. However, there is no requirement that the articles be from scientific journals, which have undergone any degree of peer review. Furthermore, "dietary ingredient" is not defined in the Act, leaving open the question of whether there is any limit on the type of products that can be marketed under these provisions, as outlined above in section 3.

Sec. 9 Good Manufacturing Practices

Summary: Supplements are to be prepared, packed or held under good manufacturing practices (GMPs) established specifically for these products (including expiration date labeling) through regulations promulgated by the Secretary. GMPs are to be modeled after those practices for conventional foods and may not impose standards for which there is not current and generally available analytical methodology. No standard of current GMP can be imposed, unless it is included in a regulation promulgated after notice and comment in accordance with current Administrative Procedures (Chpt. 5, Title 5, U.S. Code).

Comment: Currently, there are no GMP regulations specifically for supplements. Instead supplements have been subject to the same GMPs used for foods. Manufacturers of supplements who also produce drugs generally follow the GMPs for drug products which, by comparison, are relatively strict standards. However, the unique nature of supplements would suggest that

there needs to be a separate set of these standards established for their unique properties. Included in GMPs for foods are requirements for the quality of raw materials, processing and quality control methods, equipment, environmental conditions in the plant, sanitary practices of employees, recordkeeping, and qualifications for certain key employees. These provisions in the food GMP regulation would need to be modified for supplement products, which contain food ingredients compounded in pill form. Current U.S. Pharmacopeia (USP) monograph standards for vitamin and mineral supplements include assays, reference standards packaging and storage information, labeling requirements, identification, disintegration rates, weight variation, and microbial limit tests. The new law provides no specific directive for establishing USP standards for supplements, but does address the use of an official compendium for setting product specifications (sec. 7). USP monograph standards have been developed for vitamins and minerals and could be adopted into supplement GMPs, after proper regulatory review. Similar USP standards have not been established for herbals and botanicals, which are frequently combined with vitamins and minerals. These standards are arguably needed to assure product consistency and provide some degree of consumer protection. Although the Act does not allow the imposition of standards for which there is no current and generally available analytical methodology, such methods will need to be developed in the future, should such standards be established for herbals and botanicals.

Sec. 10 Conforming Amendments

Summary: A supplement for which a disease-prevention claim is made in compliance with the established regulations is not a drug solely because the label contains such a claim or other truthful, nonmisleading statement. The Act prohibits the introduction of a supplement into interstate commerce that is unsafe because it contains a new dietary ingredient that has not been determined to be safe. A supplement is not deemed to be misbranded solely because its labeling contains directions or conditions of use or warnings.

Comment: This provision is a conforming amendment that restates language outlined elsewhere in the Act.

Sec. 11 Withdrawal of the Regulations and Notice

Summary: This provision states that the advance notice of proposed rulemaking (ANPR) on supplement safety published in the Federal Register of June 18, 1993 (58 FR 33690-33700) is null and void, and has no force or effect on these products. The Secretary is directed to publish a Federal Register notice to revoke this document.

Comments: In 1991 FDA decided to reexamine its approach to the regulation of the safety of supplements. This review followed the case of the contaminated amino acid, L-tryptophan, in which thousands of consumers became ill and about three dozen died. The Task Force on Dietary Supplements was established to examine current procedures and make recommendations for future regulation of these products. Once the Task Force report was completed,

the agency was under considerable pressure from the supplement industry to publish it. The agency published an ANPR that appeared in the Federal Register on June 18, 1993 which contained some information from the Task Force report[8] and outlined the issues that the agency believed warranted further discussion before it decided whether to propose new regulations on supplement safety. Since publication of the ANPR, however, the agency has been criticized about its content and the supplement industry has demanded that the notice be withdrawn. The language in the ANPR suggested that FDA was considering a stricter approach to future regulation of supplement products, particularly for safety testing. The controversy that this stricter approach generated, based in part on the Task Force report, was why the agency had resisted publishing the document for such a long time.

Since an ANPR seeks the input of interested parties before the agency decides whether to proceed with rulemaking on a particular subject, a withdrawal notice is not formally required to be published, which is why FDA has not withdrawn the June 1993 notice on supplements. The decision to publish an advance notice of proposed rulemaking is generally done by an agency when it is deciding whether and what to do concerning an issue, not when it has a clear mandate to promulgate regulations such as the provisions of this Act would require. Given the controversy created by the publication of this ANPR, FDA to date has shown no intention of proceeding with rulemaking on this issue.

Sec. 12 Commission on Dietary Supplement Labels

Summary: The Act establishes an independent executive branch agency to be called the Commission on Dietary Supplement Labels. Its seven members, appointed by the President, are to include individuals with experience in the manufacture, regulation, distribution and use of supplements. At least three members are to be qualified by scientific training and experience to evaluate the benefits of supplements, with one member experienced in pharmacognosy, medical botany, traditional herbal medicine or other related sciences. Members and staff of the Commission are to be without bias on the use of supplements.

The Commission is instructed to conduct a study and provide recommendations for the regulation of label claims and statements for supplements, including the use of literature in connection with the sale of these products and procedures for the evaluation of such claims. The Commission is to evaluate how best to provide truthful, scientifically valid, and nonmisleading information to consumers so that they can make informed and appropriate health care choices. The Commission may obtain information through hearings and receive any evidence it considers necessary, including from Federal agencies. Funds are authorized to be appropriated as needed to carry out the Commission's work. A final report is to be prepared and submitted to the

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[8]U.S. Dept. of Health and Human Services. Food and Drug Admin. Dietary Supplements Task Force Final Report. May 1992. 98 p.

President and Congress within 24 months containing recommendations, including any legislation the Commission deems necessary.

Within 90 days of the issuance of the report, the Secretary is directed to publish a notice of the Commission's recommendations for change in the regulations for supplements and include a notice of proposed rulemaking of such changes with an opportunity for comment on the views on such changes. Rulemaking is to be completed within 2 years after the date of the issuance of the Commission report. If the rulemaking is not completed within that 2-year period, the final regulations on supplement health claims published January 4, 1994 would no longer be in effect.

Comment: The bill creates a two-year commission to recommend the procedures and standards to be used in the approval of health claims for supplement products. The members of the Commission would be appointed by the President, and are required to meet certain criteria as to their knowledge, experience and personal views on the use of dietary supplements. It appears from the debate on this issue that the supplement industry anticipates that the Commission will be composed of individuals who promote supplement use and the unlimited use of health claims. The supplement industry favors a weaker standard than significant scientific agreement (or its current interpretation in the existing regulations under NLEA) for the authorization of health claims for their products. Balanced representation on the Commission will be important to the weight given its recommendations by policymakers.

There is concern among health professionals and conventional food industry that the Commission might recommend a different procedure and interpretation of the significant scientific agreement standard than that currently applied to conventional foods under NLEA. With a separate standard for supplement claims, manufacturers of a nutrient or other supplement ingredient contained in these products might be able to make a claim that others using the same ingredient in a conventional food or over-the-counter drug would not be allowed to make. They fear a separate standard might result in unfair marketing advantage between the different segments of the market, conventional foods versus supplements. (The conventional food industry has filed a petition with FDA requesting an easing of the existing regulations for health claims on its products.)

The recommendations of the Commission are advisory in nature and do not carry a requirement for implementation by the Administration. The 90-day time frame to propose new regulations for supplement health claims is short and may impose a difficulty for a policy issue of this complexity and scope. Until two years after the Commission reports, the supplement health claims will be subject to and must be authorized under the significant scientific agreement standard for conventional foods as established by NLEA. If the Commission's recommendations are not adopted, it is unclear how supplement health claims will be regulated after the four year period, because supplements will no longer be subject to the NLEA regulations.

Sec. 13 Office of Dietary Supplements

Summary: The Secretary is to establish an Office of Dietary Supplements at NIH which is to explore the potential role of supplements to improve health care and promote scientific study of their benefits in maintaining health and preventing chronic diseases. The Director of this Office is (1) to conduct and coordinate scientific research within NIH related to supplements on the extent to which their use can limit or reduce the risk of disease; (2) collect and compile the results of scientific research relating to supplements, including scientific data from foreign sources or the Office of Alternative Medicine; (3) serve as principal scientific advisor to officials in DHHS and FDA on issues related to supplement regulation, safety claims, disease prevention claims, and scientific issues in connection with labeling and composition; (4) compile a database of scientific research on supplements and individual nutrients; and (5) coordinate funding related to supplements. The substances to be addressed by this Office are vitamins, minerals, amino acids, herbs and botanicals, any dietary substance used to increase total dietary intake, any concentrate, metabolite, constituent, extract, or combination of these substances. To establish and maintain this Office, five million dollars are authorized for appropriation for fiscal year 1994 and such funds as are necessary in future years are added on to the NIH budget.

Comment: This provision amends Section 485 B of the Public Health Service Act to create a new NIH Office of Dietary Supplements for the purpose of coordinating and conducting research on supplements and serving as a primary advisor on the regulation and promotion of these products to other governmental agencies. This Office appears to be primarily designed to advise FDA on the regulation of these products on such issues as their intake, safety, claims, labeling and composition, while at the same time overseeing the Federal research on the benefits of these products. To some observers, the separation of research and regulation might be desirable for the sake of independence and credibility. The amount of money authorized for research appears to be small in terms of supporting a comprehensive program to undertake the numerous tasks anticipated by the bill.

In addition, no language in the bill suggests the location of this office within NIH, or the relationship between this Office and (a) the Division of Nutrition Research Coordination or the Office of Alternative Medicine (OAM), both of which already exist at NIH and deal, in part, with research on certain dietary substances, or (b) the Office of Special Nutritionals at FDA created to address these issues in the 1992 reorganization plan at the Center for Food Safety and Applied Nutrition. Generally offices, such as the one created by this Act, are attached to the Office of the Director of NIH.

Recently, proponents of alternative medical therapies have criticized what they perceive to be the slow rate of output from OAM in supporting such practices[4]. However, receiving results from any NIH funded research program

[4]Marshall, E. The Politics of Alternative Medicine. *Science*, v. 265. Sept. 30 1994. p. 2000-2002.

is a time-consuming process. Grant proposal review and funding takes at least a year, followed by an average four-year period during which the research is conducted, and then additional months are needed to prepare the research results for publication. The pursuit of objective science proceeds at a relatively slow pace, sometimes taking decades to generate the evidence to support a particular therapy.