FOURTEENTH CONGRESS OF THE)
REPUBLIC OF THE PHILIPPINES)
Third Regular Session)

9 AUG 11 P4 :47

SENATE
S. No. 3385

RECEIVED BY

Introduced by **Senator Richard J. Gordon**

EXPLANATORY NOTE

Our Constitution, under Article XIII, Section 12, provides that the State shall establish and maintain an effective food and drug regulatory system and undertake appropriate health manpower development and research, responsive to the country's health needs and problems.

Adverse events arising from consumption of herbal medicines may be due to any one of a number of factors. These include the use of the wrong species of plant by mistake, adulteration of herbal products with other, undeclared medicines, contamination with toxic or hazardous substances, over dosage, misuse of herbal medicines by either health care providers or consumers and use of herbal medicines concomitantly with other medicines. Furthermore, herbal medicines are often used for self care; thus, there is a great need to educate consumers and public in their proper use. However, herbal medicines and food or dietary supplements marketed and distributed in our country are currently not being required to undergo testing by the Bureau of Food and Drugs.

Analysis of adverse events related to the use of herbal medicines is more complicated than in the case of conventional pharmaceuticals. The general lack of knowledge about herbal medicines within national drug authorities and the lack of appropriate evaluation methods are factors that further delay the creation or updating of national policies, laws and regulations for traditional medicines, contemporary/alternative medicines and herbal medicines.

This bill seeks to establish standards for and adopt measures to regulate the manufacture, importation, marketing/promotion, and distribution of herbal medicines and food or dietary supplements to protect the consuming public against unscrupulous manufacturers, importers and distributors of the same. In view of the foregoing, the passage of this bill is earnestly sought.

RICHARD J. GORDON
Senator

FOURTEENTH CONGRESS OF THE)
REPUBLIC OF THE PHILIPPINES)
Third Regular Session)

OFFICE OF THE SECRETARY

9 AUG 11 P4 :47

SENATE
S. No. 3385

RECEIVED BY

Introduced by **Senator Richard J. Gordon**

AN ACT REGULATING THE MANUFACTURE, IMPORTATION, MARKETING/ PROMOTION, AND DISTRIBUTION OF HERBAL MEDICINES, FOOD SUPPLEMENTS AND SIMILAR PREPARATIONS AND ESTABLISHING STANDARDS WITH RESPECT THERETO FOR CONSUMER HEALTH PROTECTION

Be it enacted by the Senate and the House of Representatives of the Philippines in Congress assembled:

Section 1. ***Title.*** - This Act shall be known as the ***"Herbal Medicine and Food Supplement Act."***

Section 2. ***Declaration of Policy.*** - It is hereby declared the policy of the State to ensure safe and good quality of herbal medicines, food supplements, and nutriceuticals as this term is defined herein, in whatever form and to regulate the production, sale, marketing and promotion, and distribution of the same to protect the health of the people.

Section 3. ***Objectives.*** - In the implementation of the foregoing policy, the Government shall:

(a) Establish standards and quality measures for herbal medicines and food dietary supplements to protect the consuming public against unscrupulous manufacturers, importers and distributors; and,

(b) Adopt measures to regulate and prevent unsubstantiated claims from manufacturers and advertisers that tend to suggest that their products intend to cure certain diseases or to improve or positively alter physical condition thus, misleading the consuming public.

Section 4. ***Definition of Terms.*** -For the purpose of this Act, the term:

(a) *"Herbal medicine"* refers to the preparation and/or combination of any plant seeds, berries, roots, leaves, bank, or flowers for medicinal purposes. It includes traditionally used herbal products;

(b) *"Food or dietary supplement"* means a product, other than tobacco, intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, the metabolite, constituent, extract or combination of any ingredient heretofore mentioned, the term also includes nutriceuticals;

(c) *"Nutriceuticals"* refer to common food products that have been modified potentially by genetic engineering to have enhanced nutritional characteristics and/or pharmaceutical application;

(d) *"Traditionally used herbal products"* refer to preparations from plant materials whose claimed application(s) is/are based only on traditional experience of long usage over time, which should be at least five (5) years or more as documented in medical, historical and technological literature;

(e) *"Label"* means a display of written, printed, or graphic matter upon the immediate container of any article and a requirement made by or under the authority of this Act, that any word, statement, or other information appearing on the label shall not be considered to be complied with unless such word or statement, if there be any, of the retail package of such article, are easily legible through the outside container or wrapper;

(f) *"Drugs"* mean -

(1) Articles recognized in the official United States Pharmacopoeia, official Momeopathic Pharmacopoeia of the United States, official national Formulary or any supplement to any of them;

(2) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of diseases in man or other animals;

(3) Articles, other than food, intended to affect the structure or any function of the body of man or animals; and

(4) Articles intended for use as component of any articles specified under numbers (1), (2) or (3) of this section but does not include devices or their components, parts or accessories.

(g) *"Adulterated/Substandard herbal medicines or food/dietary supplements"* refer to those supplements manufactured or packed under the following conditions:

(1) If the methods used in, or the facilities or controls used for its manufacture do not conform to or are not operated or administered in conformity with current good manufacturing practices to assure that it meets the requirements of this Act, as to safety, quality and efficacy, and has the identity and strength and meets the quality and purity characteristics which it purports or is represented to possess;

(2) If it has been mixed or packed with any substance or any substance of which has been partially or wholly substituted, so as to reduce its safety, efficacy, strength or purity;

(3) If its strength differs from, or its efficacy, quality or purity falls below the standards as prescribed by the Department of Health or that which it purports or is represented to possess;

(4) If it contains filthy, putrid or decomposed substance which may affect its safety, efficacy, or good quality or is manufactured, prepared or held under unsanitary conditions whereby it may have been contaminated with dirt or filth or if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(h) *"Manufacturer"* refers to any person who manufactures, assembles and processes herbal medicines, food/dietary supplements and similar preparations, except that if they are manufactured, assembled or processed for another person who attaches his own brand name to the consumer products, the latter shall be deemed the manufacturer;

(i) *"Importer"* refers to any person who shall import or bring into the Philippines herbal medicines, food/dietary supplements and similar preparations manufactured from another country;

(j) *"Distributor"* refers to any person to whom herbal medicines, food/dietary supplements and similar preparations are delivered to or sold to for purposes of distribution in commerce;

(k) *"Special dietary uses"*, as applied to food for man, means particular, as distinguished from general, uses of food as follows:

(1) Uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not

limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, being underweight or overweight;

(2) Uses for supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood;

(3) Uses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral or other dietary property. Any such particular use of food is a special dietary use, regardless of whether such food also purports to be or is represented for general use.

(l) *"Marketing/promotion"* refers to the dissemination of information about a product, product line, brand or company. It includes promotion in media i.e., television, newspapers, internet, mobile phones, and all other kinds of promotion such as sales promotion, sponsorship, product placement, endorsements, merchandising, direct mail, trade shows and the like.

Section 5. ***Prohibited Acts***. - The following acts and the causing thereof are hereby prohibited:

(a) The manufacture, sale, offering for sale, or transfer of any herbal medicine or food dietary supplement, and the like that are misbranded or adulterated or substandard;

(b) Falsely representing in its marketing/promotion that a herbal medicine or food/ dietary supplement can improve or positively alter physical conditions or sure illnesses regardless of any disclaimer such as "No approved therapeutic claim" and the like through print, TV or radio and any other forms of mass media;

(c) Forging, counterfeiting, simulating or falsely representing or without proper authority, using any mark, stamp, tag label or other identification device, authorized or required by regulations promulgated under the provisions of this Act;

(d) The alteration, mutilation, destruction, obliteration or removal of the whole or any part of the labeling of, or the doing of any act with respect to herbal medicine or food/ dietary supplement which results in such article being adulterated or misbranded;

(e) The unsubstantiated statement in the labeling of any herbal medicine or food/ dietary supplement or in any advertising or sales promotion relating to such drug

that the use or application of such drug is effective or has a tendency to be effective as a cure for a certain illness or disease.

Section 6. ***Penalties.*** –

(a) Any person who violates any of the provisions of this Act shall, upon conviction, be subject to imprisonment of not less than six (6) months and one (1) day, but not more than five (5) years, and/or a fine of not less than One Thousand Pesos (P1,000), upon discretion of the Court. ",

(b) Any herbal medicine or food/dietary supplement that is adulterated or misbranded when introduced into the domestic commerce may be seized and held in custody pending proceedings, without hearing or court order, when the Secretary of Health has probable cause to believe from facts found by him or any officer or employee of the Bureau of Food and Drug (BFAD) that the misbranded article is fraudulent or would be in a material respect misleading, thus causing injury or damage to purchasers or consumers.

Section 7. ***Standards for Herbal Medicine or Food/Dietary Supplements.*** –

(a) All manufacturers or distributors of herbal medicines or food/dietary supplements, prior to marketing, sale, and/or distribution of their products to the public, shall submit said products for registration with the BFAD in accordance with AO no. 23-C s.2000 for over-the-counter medicine and other pertinent rules and regulations.

(b) Whenever, in the judgment of the Secretary of Health, such action will promote honesty and fair dealing in the interest of the consumers, he shall, upon recommendation of the BFAD Director, promulgate regulations for any herbal medicine or food/dietary supplement, fixing and establishing a reasonable standard(s) of quality.

Section 8. ***Adulterated herbal medicine or food/dietary supplement.*** - An herbal medicine or food/dietary supplement shall be deemed to be adulterated:

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health;

(b) If any substance has been added or mixed thereto or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it really is;

(c) If it is a confectionary and it contains any alcohol or non-nutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glass not in excess of four-tenths of one per centum, natural glum and pectin: Provided, that this paragraph shall not apply to any confectionary by reason of its containing less than one half of one centum by volume of alcohol derived solely from the use of flavoring extracts;

Section 9. ***Misbranded herbal medicine or food/dietary supplement.*** - An herbal medicine or food/dietary supplement shall be deemed misbranded:

(a) If its label is false or misleading in any particular manner subject further to the requirement in Section 7 hereof;

(b) If its label does not contain the mandatory warning in both the English and Filipino language: "THIS IS NOT A DRUG AND HAS NO APPROVED THERAPEUTIC CLAIM/S. ANG PRODUKTONG ITO AY HINDI GAMOT AT HINDI NAPATUNAYANG NAKAGAGALING NG ANUMANG KARAMDAMAN."

(c) If any word, statement or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such consciousness and in such terms as to render it likely to be read and understood by an ordinary individual under customary conditions of purchase and use;

(d) If it purports to be or is represented, in its literature or in print, radio or TV advertisements, as a drug that can improve or positively alter physical conditions, or cure an illness but is labeled as a food or dietary supplement with no approved therapeutic claim and does not provide the mandatory warning provided under paragraph (b) of this section.

(e) If it purports to be or is presented for special dietary uses, unless its label bears such information concerning its vitamins, minerals and other dietary properties as the Secretary of Health determines to be, and by regulations, prescribes as necessary in order to fully inform the purchasers as to its value for such uses;

(f) If it bears or contains any artificial flavoring, artificial coloring or chemical preservatives, unless it bears labeling stating the fact: Provided, that to the extent that the compliance with the requirements of this paragraph is impracticable,

exemptions shall be established by regulations promulgated by the Secretary of Health.

Section 10. ***Registration License.*** - The BFAD shall prescribe rules, regulations for registration, testing and issuance of licenses of herbal medicines or food/dietary supplements using the same standards required of other pharmaceutical products.

Section 11. ***Suspension/Revocation of Permit.*** - Whenever the Secretary of Health finds in domestic commerce, after investigation, that a class of herbal medicine or food/dietary supplement may be injurious to health, he shall promulgate regulations, in accordance with the recommendations of the Food and Drug Administrator, for the suspension of the permit issued to manufacturers, processors or packers of such herbal medicine or food/dietary supplement, after notice, if it is found that any of the conditions of the permit have been violated.

Section 12. ***Repealing Clause.*** - All provisions of laws, rules and regulations which are in conflict with this Act are hereby repealed or modified accordingly.

Section 13. ***Separability Clause.*** -If any of the provisions of this Act is declared invalid, the other provisions not affected thereby shall remain in full force and effect.

Section 14. ***Effectivity.*** - This Act shall take effect fifteen (15) days after its publication in the Official Gazette or in a newspaper of general circulation

Approved,