Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City, Metro Manila

SEVENTEETH CONGRESS
First Regular Session

House Bill No. 1300

Introduced by Honorable Florida P. Robes

AN ACT REGULATING THE MANUFACTURE, DISTRIBUTION AND SALE OF SUPPLEMENTARY COMPLEMENTARY ALTERNATIVE MEDICINES AND FOR OTHER PURPOSES

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

SECTION 1. Short Title. This Act shall be known as the "Supplementary Complementary and Alternative Medicine Regulation Act (SCAMRA)".

SEC. 2. Declaration of Policy. It is hereby declared the policy of the State to enhance and safeguard the health of the Filipino people by ensuring that medicines work, are acceptably safe, properly prescribed by licensed health and medical professionals, and efficiently administered.

SEC. 3. Objective. The main objective of this Act is to safeguard public health and safety by establishing and maintaining a scheme consistent with best practice for the regulation of the quality, safety, and efficacy of complementary medicine and supplements, and of their manufacture, sale and promotion.

SEC. 4. Definition of Terms. – As used in this Act, the following terms shall mean:

a. "Supplementary Medicine" – refers to biologically-based therapies which includes herbs, minerals, teas, vitamins, amino acids, animal tissue extracts and essential oils.

b. "Complementary Medicine" – refers to medical products that are not part of standard medical care which includes herbal remedies and medicines and dietary supplements.

c. "Alternative Medicine" – is any medical treatment that is not part of conventional evidence-based medicine

d. "Fraudulent" – refers to a failure to disclose all information that the person knows or ought reasonably to know, which is materially relevant.

e. "Regulation" – relates to the circumstances and manner in which, and the conditions on which, a member of a prescribed class of health professional may administer, possess, prescribe, supply or use a medicine.

f. "Herbal Medicines" – finished, labeled medicinal products that contain as active ingredient/s aerial or underground part/s of plant or other materials or combination

thereof, whether in the crude state or as plant preparations. Plant material includes juices, gums, fatty oils, essential oils, and other substances of this nature. They, however, may contain plant material(s) combined with chemically-defined active substances, including chemically-define, isolated constituents of plants, are not considered to be herbal medicines.

g. "Manufacture" – refers to any and all operations involved in the production, including preparation, propagation, processing, formulating, filling, packing, repacking, altering, ormenting, finishing, or otherwise changing the container, wrapper, or labeling of a consumer product in the furtherance of the distribution of the same from the original place of manufacture to the person who makes the final delivery or sale to the ultimate consumer.

h. "Advertising" - means the business of conceptualizing, presenting or making available to the public, through any form of mass media, fact, data or information about the attributes, features, quality or availability of consumer products, services or credit.

i. "Consumer" – means a natural person who is a purchaser, lessee, recipient or prospective purchaser, lessor or recipient of consumer products, services or credit.

SEC. 4. Prohibited Acts – The following fraudulent and deceptive marketing practices shall be deemed prohibited under this Act:

a. Marketing Fraud – This refers to any illegal practice/s employed in the promotion of a product or services which centers on making false claims and exaggerating the qualities of a product or service, selling imitations, or hiding negative aspects or side effects.

b. Misleading Advertising – This refers to any deceptive representations for the purpose of promoting a product or a business interest and encouraging the provision of sufficient information to allow consumers to make informed choices.

c. Deceptive Packaging and Labelling – This refers to the making of false or misleading representations as products are required to bear accurate and meaningful labelling information to help consumers make informed purchasing decisions, clearly indicating that the product has "No Approved Therapeutic Claims" written in English, Filipino and Visayan languages or other languages used by target consumers.

d. Pyramid or Ponzi Scheme – Otherwise known as chain referral schemes, this involves a marketing strategy in which an individual is offered a distributorship or franchise to market a particular product and that real profit is earned, not by the sale of the product, but by the sale of new distributorships.

e. Bait and Switch Tactic – This refers to an illegal business tactic in which the seller advertises a product with the intention of persuading customers to purchase a more expensive product.

f. Other offences punishable under this Act are:

a. Manufacture of complementary medicines not in accordance with an appropriate license or professional authority or violated provisions of Republic Act No.8423;

b. Prescriptions of complementary medicines by a person without a license or professional authority;

c. Supply and referral of complementary medicines to patients believing that such would be appropriate for therapeutic purposes, in spite of the label indicate therein; and

d. Sale of complementary medicines without the seal of approval of the Food and Drug Administration and certification by the Philippine Institute of Traditional and Alternative Health Care.

e. Medical Practice, punishable under the Revised Penal Code and other special laws.

SEC. 5. Penalties.

a. Any person, natural or juridical, who shall violate any of the acts enumerated in Section 4 of this Act shall upon conviction, be subject to a fine of five hundred thousand pesos (PhP500,000.00) but not more than one million pesos (Php1,000,000.00) or imprisonment of not less than six months but not more than six (6) years, or both upon the discretion of the court. If the offender is an alien, he shall be deported after service of sentence and payment of fine without further deportation proceedings.

b. In case the offender is a naturalized citizen, he shall, in addition to the penalty prescribed herein, suffer the penalty of cancellation of his naturalization certificate and its registration in the civil registrar and immediate deportation after service of sentence and payment of fine.

c. Any director, officer or agent of a corporation who shall authorize, order or perform any of the acts or practices constituting in whole or in part a violation of Section 6, and who has knowledge or notice of noncompliance received by the corporation from the concerned department, shall be subject to penalties to which that corporation may be subject.

d. For medical malpractice, the punishments provided by the Revised Penal Code and other special laws shall be prescribed.

In case the violation is committed by, or in the interest of a foreign juridical person duly licensed to engage in business in the Philippines shall immediately be revoked, suspended or cancelled.

SEC. 7. Government Agency Support and Coordination. – The Department of Health, Food and Drugs Administration, the Nutrition Council of the Philippines, Department of Trade and Industry, in coordination with the Philippine Institute of Traditional and Alternative Health Care and Philippine Medical Association shall ensure the strict compliance of quality and safety standards by manufacturers, distributors and sellers of complementary medicines. It shall create a joint committee whose composition shall come from these agencies including affected industries and shall implement the policies and guidelines for the compliance of this Act.

SEC. 8. Professionalization of Alternative Medical Practitioners.- The Department of Health and the Professional Regulations Commission, in coordination with Philippine Medical Association, are hereby mandated to formulate policies on the professionalization of alternative medical practitioners.

SEC. 9. Appropriations. – The sum necessary for the effective implementation of this Act shall be charged against the appropriations for the Department of health under the current General Appropriations Act. Thereafter, such amount as may be necessary for the continued operation of the Center shall be included in the Annual General Appropriations Act.

SEC. 10. Implementing Rules and Regulations. – The DOH, FDA, NCP, DTI and PITAHC and other concerned stakeholders shall promulgate within sixty (60) days the Implementing Rules and Regulations necessary to implement the provisions of this Act.

SEC. 11. Repealing Clause. – All laws, ordinances, rules and regulations, and other issuances or parts thereof which are inconsistent with this Act are hereby repealed or modified.

SEC. 12. Separability Clause. – If for any reason any section or provision of this Act is declared unconstitutional or invalid, the other sections or provisions thereof, shall not be repealed or modified.

SEC. 13. Effectivity. – This Act shall take effect fifteen (15) days from its publication in the Official Gazette or in any two newspapers of general circulation.

Approved,

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EXPLANATORY NOTE

It is a declared mandate of the State to protect consumers against deceptive, unfair and unconscionable sales acts and practices, especially if it pertains to medicines that affect their health and total well-being.

Nowadays, nearly half of our population use some supplementary complementary alternative medicine (SCAM), including dietary supplements. As such, their popularity has surpassed conventional medicines. More so, there is an increase of their commercialization that it seems anyone can produce and manufacture them and claim them to cure different illnesses without sufficient evidenced-based information about their efficacy, safety, and drug interaction.

Inasmuch as the State recognizes the development and enhancement of traditional or alternative medicine, as clearly enunciated in Republic Act. No. 8423 or otherwise known as the "Traditional and Alternative Medicine Act of 1997", the State should be wary of incidents where the patients, instead of getting treated of their illnesses, end up in a hospital, or worse, in a coma because alternative medicines were taken instead of pharmaceutical products which take years and thorough research to produce. The Author does not claim that herbal medicine such as that extracted from malunggay, ginger, guyabano leaves, turmeric, etc. are inferior. There have been studies on the efficacy and medicinal value of these herbals. However, it seems that there is no proper regulation to that effect. In fact, it is being prescribed by people, who sometimes are not medical doctors, negligently. Many people are unaware of the potential health risks since most products have not undergone quality control and without FDA Approval.

Although they purport to be just supplementary as they do not have approved therapeutic claims, complementary medicines are being sold in the market in such a manner that people are convinced that they do have healing elements. Albeit the fact that they have not presented persuasive evidence to support claims that they can treat, cure or relieve specific conditions or

symptoms, they are selling like pancakes. Advertisements of these products are misleading, false, unfair or exaggerated. This is further aggravated by the marketing scheme employed by manufacturers, which is known as pyramid as well as their prescriptions by non-medical doctors or health professionals. With this in mind, the focus is on the marketing side and not on the product itself.

For the interest and well-being of the citizens, the passage of this Bill is earnestly sought.

FLORIDA P. ROBES