SIXTEENTH CONGRESS OF THE REPUBLIC)
OF THE PHILIPPINES)
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Senate
Office of the Secretary

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SENATE
S. No. **2451**

RECEIVED BY:

Introduced by Senator Miriam Defensor Santiago

EXPLANATORY NOTE

AN ACT
TO PROTECT THE PUBLIC HEALTH BY REQUIRING TOBACCO MANUFACTURERS TO DISCLOSE INFORMATION ON INGREDIENTS AND CONSTITUENTS IN TOBACCO PRODUCTS

The Constitution, Article 2, provides:

> Sec. 15. The State shall protect and promote the right to health of the people and instill health consciousness among them.

A consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects. In fact, the World Health Organization (WHO) has declared that the tobacco epidemic is one of the biggest public health threats the world has ever faced, killing nearly six million people a year. Here are some of the harmful effects of smoking and tobacco (from the WHO Fact sheet):

- More than five million of those deaths are the result of direct tobacco use while more than 600 000 are the result of non-smokers being exposed to second-hand smoke.
- Approximately one person dies every six seconds due to tobacco, accounting for one in 10 adult deaths.
- Up to half of current users will eventually die of a tobacco-related disease.

Over the past decades, medical and scientific reports have discovered some of the harmful chemicals in cigarettes and how they affect our health. These include the following:

1. Carcinogens- A carcinogen is defined as any substance that can cause or aggravate cancer. Approximately 70 of the chemicals in cigarettes are known to cause cancer.
2. Benzene -Benzene can be found in pesticides and gasoline. It is present in high levels in cigarette smoke and accounts for half of all human exposure to this hazardous chemical.
3. Formaldehyde- Formaldehyde is a chemical used to preserve dead bodies, and is responsible for some of the nose, throat and eye irritation smokers experience when breathing in cigarette smoke.
4. Vinyl Chloride - Vinyl Chloride is a man-made chemical that is used in making plastics and is in cigarette filters.
5. Ammonia - Ammonia compounds are commonly used in cleaning products and fertilizers. Ammonia is also used to boost the impact of nicotine in manufactured cigarettes.
6. Carbon Monoxide - Carbon monoxide is present in car exhaust and is lethal in very large amounts. Cigarette smoke can contain high levels of carbon monoxide.
7. Nicotine - Nicotine is a poison used in pesticides and is the addictive element in cigarettes.

Due to the severe effects of smoking on the health of smokers and the general public, and the use of tobacco by young people, public health officials and the public at large, recognize that the tobacco industry should be subject to ongoing oversight. For instance, in the United States, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) became law on June 22, 2009. The law gives the Food and Drug Administration (FDA) the authority to regulate the manufacture, distribution, and marketing of tobacco products to protect public health. Some of the avowed purposes of this Act are to authorize the Food and Drug Administration to set national standards controlling the manufacture of tobacco products and to require tobacco product manufacturers to disclose the identity and amount of ingredients used in such products.

The purposes of this bill are similar to those of the US Tobacco Control Act. This bill seeks to inform the public of the health risks associated with cigarette smoking and tobacco use by requiring the tobacco industry to disclose to the FDA, all information on ingredients in tobacco products and to disclose research on the health, toxicological, behavioral, or physiologic effects of tobacco use. The FDA shall, in turn, be mandated to

establish a list of harmful and potentially harmful ingredients and constituents in tobacco products, including smoke constituents, by brand and subbrand and make this available to the general public.

In the Philippines, we also have a Food and Drug Administration, which is a regulatory agency under the Department of Health, mandated to ensure the safety, efficacy or quality of consumer products that may have an effect on health. As provided by existing laws the FDA shall perform several functions, including:

- Establish safety or efficacy standards and quality measures for foods, drugs and devices and cosmetics and other health product;
- Order the ban, recall, and/or withdrawal of any health product, after due process, found to have caused the death, serious illness or serious injury to a consumer or patient, or is found to be imminently injurious, unsafe, dangerous, or grossly deceptive;
- Prescribe standards, guidelines, and regulations with respect to information, advertisements and other marketing instruments about the health products.

The FDA is also mandated to enforce the provisions of certain laws including RA 9211, or The Tobacco Regulation Act of 2003.

It is hoped that with correct and complete information, children may be deterred from taking up the habit of smoking and regular adult users may be better equipped to make healthy choices.

MIRIAM DEFENSOR SANTIAGO

SIXTEENTH CONGRESS OF THE REPUBLIC)
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SENATE
S. No. 2451

RECEIVED BY:

Introduced by Senator Miriam Defensor Santiago

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

AN ACT
TO PROTECT THE PUBLIC HEALTH BY REQUIRING TOBACCO MANUFACTURERS TO DISCLOSE INFORMATION ON INGREDIENTS AND CONSTITUENTS IN TOBACCO PRODUCTS

SECTION 1. *Short Title.* - This Act shall be known as the, "Family Smoking Prevention and Tobacco Disclosure Act."

SECTION 2. *Declaration of Policy.* – It is hereby declared the policy of the State to:

A. Promote a healthful environment;

B. Inform the public of the health risks associated with cigarette smoking and tobacco use;

SECTION 3. *Definitions.* – For purposes of this Act, the term:

A. "Cigarette" - refers to any roll or tubular construction, which contains tobacco or its derivatives and is intended to be burned or heated under ordinary conditions of use;

B. "Distributor" - refers to any person to whom a tobacco product is delivered or sold for purposes of distribution in commerce, except that such terms does not include a manufacturer or retailer or common carrier of such product;

C. "FDA" – refers to Food and Drug Administration

D. "Package" - refers to pack, boxes, cartons or containers of any kind in which any tobacco product is offered for sale to consumers;

E. "Tobacco" - refers to agricultural components derived from the tobacco plant, which are processed for use in the manufacturing of cigarettes and other tobacco products;

F. "Tobacco Products" - refers to any product that consists of loose tobacco that contains nicotine and is intended for use in a cigarette, including any product containing tobacco and intended smoking or oral or nasal use. Unless stated otherwise, the requirements of this Act pertaining to cigarettes shall apply to other tobacco products;

G. "Additive".—refers to any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical.

H. "Brand"- refers to a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name, identifiable pattern of colors, or any combination of such attributes.

I. "Distributor"- The term 'distributor' as regards a tobacco product means any person who furthers the distribution of a tobacco product, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal

consumption. Common carriers are not considered distributors for purposes of this chapter.

J. "Nicotine" - refers to the chemical substance named 3-(1-Methyl-2-pyrrolidinyl) pyridine or C[10]H[14]N[2], including any salt or complex of nicotine.

K. "Retailer" - The term 'retailer' means any person, government, or entity who sells tobacco products to individuals for personal consumption, or who operates a facility where self-service displays of tobacco products are permitted.

L. "Tobacco product manufacturer" – Refers to any person, including any repacker or relabeler, who--

(1) manufactures, fabricates, assembles, processes, or labels a tobacco product; or

(2) imports a finished tobacco product for sale or distribution in the Philippines.

SECTION 4. *Tobacco manufacturers and importers to submit list of ingredients and other information to the FDA.* – Each tobacco product manufacturer or importer, or agents thereof, shall submit to the Food and Drug Administration the following information:

A. Not later than 6 months after the date of enactment of the Family Smoking Prevention and Tobacco Disclosure Act, a listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand.

B. A description of the content, delivery, and form of nicotine in each tobacco product measured in milligrams of nicotine in accordance with regulations promulgated by the FDA.

C. Disclosure of additive.-- If at any time a tobacco product manufacturer adds to its tobacco products a new tobacco additive or increases the quantity of an existing tobacco additive, or eliminates or decreases an existing additive, the manufacturer shall, at least 90 days prior to such action so advise the FDA in writing.

D. Beginning 6 months after the date of enactment of the Family Smoking Prevention and Tobacco Disclosure Act, all documents developed after such date of enactment that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives.

E. Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) on the health, toxicological, behavioral, or physiologic effects of tobacco products and their constituents (including smoke constituents), ingredients, components, and additives.

F. Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) that relate to the issue of whether a reduction in risk to health from tobacco products can occur upon the employment of technology available or known to the manufacturer.

G. Any or all documents (including underlying scientific or financial information) relating to marketing research involving the use of tobacco

products or marketing practices and the effectiveness of such practices used by tobacco manufacturers and distributors.

SECTION 5. *List of harmful and potentially harmful ingredients contained in tobacco products.* – The FDA shall establish a list of harmful and potentially harmful ingredients and constituents in tobacco products, including smoke constituents, by brand and subbrand and make this available to the general public.

A. Not later than 24 months after the date of enactment of the Family Smoking Prevention and Tobacco Disclosure Act, the FDA shall establish, and periodically revise as appropriate, a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand.

B. Not later than 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Disclosure Act, and annually thereafter, the FDA shall publish in a format that is understandable and not misleading to a lay person, and place on public display the list established under subsection (A).

C. The FDA shall publish a public notice requesting the submission by interested persons of scientific and other information concerning the harmful and potentially harmful constituents in tobacco products and tobacco smoke.

D. The FDA shall make available to the public all documents in their possession that relate to health, toxicological, behavioral or psychological effects of tobacco products and their constituents, including smoke constituents, ingredients, components, and additives.

SECTION 6. - *Registration and inspection of tobacco companies* –

A. *Registration by Owners and Operators.*- On or before December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product

or tobacco products shall register with the FDA the name, places of business, and all such establishments of that person.

B. *Registration by New Owners and Operators.* - Every person upon first engaging in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products in any establishment owned or operated by that person shall immediately register with the FDA that person's name, place of business, and such establishment.

C. *Registration of Added Establishments.*- Every person required to register under subsection (A) or (B) shall immediately register with the FDA any additional establishment which that person owns or operates in which that person begins the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products.

D. *Registration by Foreign Establishments.*- Any establishment within any foreign country engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products which are imported or offered for import into the Philippines shall register under this section under regulations promulgated by the Secretary of the Department of Health.

E. *Public Access to Registration Information.*-The FDA shall make available for inspection, to any person so requesting, any registration filed under this section.

F. *Registration of Product List.*- Every person who registers with the FDA under subsection (A), (B), (C), or (D), shall, at the time of registration under any such subsection, file with the Secretary a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution and which have not been included in any list of tobacco products filed by that person with the DFA before such time of registration.

G. *Biennial Inspection of Registered Establishments.* - Every establishment registered with the FDA under this section shall be subject to inspection, and every such establishment engaged in the manufacture, compounding, or processing of a tobacco product or tobacco products shall be so inspected by 1 or more officers or employees duly designated by the FDA at least once in the 2-year period beginning with the date of registration of such establishment under this section and at least once in every successive 2-year period thereafter.

SECTION 7. *Authorization of Appropriations.* –

To carry out the provisions of this Act, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

SECTION 8. *Separability Clause.* - If any provision or part hereof, is held invalid or unconstitutional, the reminder of the law of the provision not otherwise affected shall remain valid and subsisting.

SECTION 9. *Repealing Clause.* - Any law, presidential decree or issuance, executive order, letter of instruction, administrative order, rule or regulation contrary to, or inconsistent with, the provisions of this Act is hereby repealed, modified or amended accordingly.

SECTION 10. *Effectivity Clause.* - This Act shall take effect fifteen (15) days after its publication in at least two (2) newspapers of general circulation.

Approved.

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