(No. 92-2015)

(Approved June 19, 2015)

AN ACT

To amend Sections 2 and 3 of Act No. 62 of August 5, 1993, as amended, known as the "Act to Regulate the Publicity and Promotion of Every Product Manufactured with Tobacco", in order to include electronic cigarettes or e-cigarettes.

STATEMENT OF MOTIVES

The World Health Organization establishes that Electronic Nicotine Delivery Systems (ENDS), known as electronic cigarettes or e-cigarettes, are battery-powered devices that supply inhalable doses of nicotine by releasing a vaporized mixture of the substance and propylene glycol. Likewise, electronic cigarettes that can supply inhalable doses of nicotine, but which contain no nicotine, also exist and the vials that are added to e-cigarettes are sold separately and with a variety of nicotine levels so consumers can choose their nicotine dose.

The Epidemiology Bureau on Tabaco Control of the Center for Disease Control [sic] in Atlanta describes the electronic cigarette or e-cigarette, created in China in 2002, as a system that contains an atomizer and a fluid, which is almost always nicotine, that when heated creates a vapor that helps simulate smoking a cigarette. According to the Bureau, there are over two-hundred and fifty (250) brands of these types of cigarettes with a variety of flavors and fragrances such as vanilla and chocolate. Many electronic cigarettes come with cartridges that can be refilled, thus users are exposed to potentially toxic nicotine levels. These cartridges can also be refilled with substances other than nicotine, so there is a possibility that they may serve as a new way to administer other drugs. They are sold in attractive packaging and are very easy to acquire since they are distributed in stores, kiosks, gas stations, and, especially, over the Internet. The Bureau believes that young people who begin with electronic cigarettes may be condemned to a lifelong battle against nicotine and conventional cigarette addiction.

Marketing for the use of this type of cigarette began in 2009 with Njoy and Blue being the most popular brands. At present, no studies have been conducted in Puerto Rico on the use of these types of electronic cigarettes or e-cigarettes, which are marketed as "green smoke," smoke-free, or as an alternative to quit smoking. In the United States, however, it has been determined that the use of these types of cigarettes among high school students doubled from 2011 to 2012 and that 1.8 million middle school and high school students have used such cigarettes. For such reason, forty-one (41) Attorney Generals in the United States wrote a letter to the FDA on September 13, 2013, requesting that it regulate e-cigarettes to protect minors from nicotine addiction and any other effects such cigarettes may cause.

During the Tobacco Control Summit organized by the Department of Health and the Coalition for a Tobacco Free Puerto Rico, held on November 14, 2013, it was stated that an electronic cigarette may contain a nicotine dose equal to twenty (20) or thirty (30) conventional cigarettes. Paper is slowly being burned in a conventional cigarette; however, electronic cigarettes have no paper so a person may smoke until all the nicotine in the device has been consumed.

There is enough information which proves that these electronic cigarettes or e-cigarettes pose a health risk due to their nicotine content and other substances such as aluminum, arsenic, copper, and lead, among others, as well as carcinogenic compounds. To illustrate the foregoing, the following table compares the metal concentrations in electronic cigarettes or e-cigarettes with those of conventional cigarettes:

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Aluminum Iron Nickel Sodium Chromium Copper Magnesium Manganese Lead Potassium Zinc

After the year 2002, the Food and Drug Administration (FDA) established regulations for conventional cigarettes, chewing tobacco, smokeless tobacco, and roll-your-own tobacco. The Administration shall soon regulate electronic cigarettes or e-cigarettes. The FDA found carcinogenic substances in half of the eighteen (18) samples it took from two leading brands. Furthermore, it found inconsistencies such as variations in the levels of nicotine per puff even though the cartridge label stated it was consistent. Diethylene glycol, a toxic liquid which is used as antifreeze, was detected in one of the cartridges. Despite the technical complexity of these cigarettes, the FDA has affirmed that the analyses conducted have found carcinogens and toxic chemicals.

At present, there are approximately twenty-five (25) states in the United States of America that have enacted legislation to regulate these electronic cigarettes under the provisions of the Family Smoking Prevention and Control Act, which allows state and local governments to regulate the sale and use of tobacco products, including electronic cigarettes or e-cigarettes. Among such states are: Colorado, Minnesota, New Hampshire, New Jersey, Tennessee, Alabama, Alaska, Arizona, Arkansas, and California, among others. In other countries, such as Uruguay, the sale thereof has been banned since 2009; Turkey has suspended the sale and advertisement of such cigarettes; Norway has banned the import and sale thereof; Brazil banned their import, sale, and advertisement since 2009; and Australia banned the import and sale thereof. The state of California shall implement a tax on the product since it has been proven that people smoke less the more expensive cigarette packs become.

The World Health Organization has declared that electronic cigarettes or e-cigarettes have not been scientifically proven to be safe; therefore, consumers must be advised against their use; the levels of nicotine and other substances vary; and the alleged efficiency of this product in helping individuals quit smoking has not been proven. The Pan American Health Organization criticized how the tobacco industry uses media such as film to advertise these types of products. In social media, there are videos in multiple languages on how to use electronic cigarettes or e-cigarettes. Tobacco advertisements were eliminated from television forty-two (42) years ago, but there are no restrictions for these types of cigarettes. Furthermore, these cigarettes cannot be advertised as products that aid in smoking cessation because it has not been proven by any study, and they are not yet regulated by the FDA and FTC. It is worth noting that these cigarettes have no wording on their packaging stating that they are products to aid smoking cessation such as with nicotine patches and chewables.

The European Union issued a new directive to its member states to regulate electronic cigarettes or e-cigarettes, and to classify them as tobacco products. In summary, the sale thereof shall not be banned, but they shall be regulated like any other tobacco product. In Spain, health authorities shall regulate this product, giving special attention to the protection of minors and applying the same regulations applied to tobacco consumption. It is estimated that between six hundred thousand (600,000) and eight hundred thousand (800,000) individuals use electronic cigarettes or e-cigarettes in Spain which represents twenty (20) million euros in revenue annually since an e-cigarette with an e-liquid dose for a month costs between fifty (50) and sixty (60) euros. The sale of these cigarettes in Europe generates five

hundred (500) million euros and up to two (2) billion dollars worldwide according to data published by the United Kingdom. In 2013, the sale thereof generated two (2) billion dollars in sales in the United States which is equal to two percent (2%) of the tobacco market. It is expected that electronic cigarettes shall generate \$10 billion in revenue by 2017 if the necessary measures are not taken.

The WHO Study Group on Tobacco Product Regulation, which is attached to the United Nations, in its final report on the Fifth Session of the Conference of the Parties to the World Health Organization Framework Convention on Tobacco Control, held at Seoul, Korea, drafted in preparation for the Sixth Session of the Conference of the Parties to the World Health Organization Framework Convention on Tobacco Control to be held at Moscow, Russia, recommended that member states prohibit claims that these products reduce harm, or can be used to aid smoking cessation. It also suggested that they be regulated as nicotine delivery devices, and that they be subject to regulation of contents and labeling, prohibitions against use in public places, and restrictions on advertising, promotion, and sponsorship.

It is important to stress that there are no studies which scientifically prove that these types of cigarettes aid smoking cessation. Firstly, nicotine addiction risks are not reduced by replacing conventional cigarettes with electronic cigarettes because they both contain nicotine. Secondly, it does not prevent the psychological component of this habit since electronic cigarettes simulate the act of smoking. Thirdly, when smoking electronic cigarettes the nicotine is absorbed through the lungs and the brain quickly feels the pleasurable sensation which is similar to the effect of a conventional cigarette.

Therefore, this Legislative Assembly deems it necessary to prohibit the advertising and promotion of ENDS, better known as electronic cigarettes or e-cigarettes.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF PUERTO RICO:

Section 1.- Section 2 of Act No. 62 of August 5, 1993, as amended, is hereby amended to read as follows:

"Definitions

(a) .

(f) Electronic cigarette or e-cigarette - Means any product designed to provide the user with a nicotine dose, in combination with other substances, in the form of vapor as defined by the Department of Health through regulations and in coordination and consultation with the Department of the Treasury. For the purposes of this definition, any established provision on electronic cigarettes that is inconsistent with or pertains to a matter regulated by any law, federal regulation, or an administrative order issued by the U.S. Food and Drug Administration with regards to electronic cigarettes, which is applicable to Puerto Rico, shall be deemed to be amended so it is consistent with such law or regulation.

(g) Alternative Nicotine Products - Means any product that contains nicotine and is destined for human consumption whether it is chewed, absorbed, dissolved or ingested in any other manner. 'Alternative Nicotine Product' does not include any tobacco product, vapor product, or any other product regulated by the U.S. Food and Drug Administration as a drug or device under Chapter V of the Food, Drug, and Cosmetic Act.

(h) Vapor Products - Any type of product that contains nicotine and uses a heating element, energy source, electronic circuit, or any electronic, chemical, or mechanical means, regardless of size and shape that can be used to produce nicotine vapor as a solution or in any other form. 'Vapor Product' includes any electronic cigarette, electronic cigar, electronic pipe, or any similar product or device and any vape cartridge or any other container for nicotine as a solution, or in any other form, which is destined to be used with or within an electronic cigarette, electronic cigar,

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electronic pipe, or any similar product or device. 'Vapor Product' does not include any product regulated as a drug or device by the U.S. Food and Drug Administration (FDA) under Chapter V of the Food, Drug, and Cosmetic Act."

Section 2.- Section 3 of Act No. 62 of August 5, 1993, as amended, is hereby amended to read as follows:

"For the purposes of this Act, the following prohibitions are established:

(a) No person may place or allow the placement of advertisements, signs or commercial propaganda for cigarettes, electronic cigarettes or e-cigarettes, or for any other product manufactured with tobacco or with any kind of material, regardless of what it is made of, that may be used to roll any kind of shredded tobacco for the preparation of cigarettes, cigars, or flavored cigarettes, as these are defined in this Act, at a distance of less than five hundred (500) feet from a public or private school. This distance shall be measured from the point closest to the outer boundary of the school grounds to the point where the advertisement, sign or commercial propaganda is located.

(b) No person may promote or advertise, in local media, cigarettes or products manufactured with tobacco or any kind of material, regardless of what it is made of, that may be used to roll any kind of shredded tobacco for the preparation of cigarettes, cigars, electronic cigarettes or e-cigarettes, or flavored cigarettes, as these are defined by this Act, in cinemas, television, theaters, and parks.

(c) No person may distribute free samples of cigarettes or products manufactured with tobacco or any kind of material, regardless of what it is made of, that may be used to roll any kind of shredded tobacco for the preparation of cigarettes, cigars, electronic cigarettes or e-cigarettes, or flavored cigarettes, as these are defined by this Act:

(1) To minors under eighteen (18) years of age.

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(2) In places where, due to the activity being carried out, the presence of minors under eighteen (18) years of age is allowed.

(3) Within a distance of less than five hundred (500) feet from a public or private school, it being understood that this distance shall be measured from the point closest to the outer boundary of the grounds occupied by the school."

Section 3.- This Act shall take effect immediately after its approval.

CERTIFICATION

I hereby certify to the Secretary of State that the following Act No. 92-2015 (S. B. 923) of

the 5th Regular Session of the 17th Legislative Assembly of Puerto Rico:

AN ACT to amend Sections 2 and 3 of Act No. 62 of August 5, 1993, as amended, known as the "Act to Regulate the Publicity and Promotion of Every Product Manufactured with Tobacco", in order to include electronic cigarettes or e-cigarettes.

has been translated from Spanish to English and that the English version is correct.

In San Juan, Puerto Rico, on this 4th day of December, 2019.

Orlando Pagán-Ramírez Director