Electronic Nicotine Delivery System (ENDS), commonly known as electronic cigarettes, are new products that are becoming popular in the country. ENDS may deliver nicotine, which is an addictive substance, and other chemicals to the body. Nicotine can have adverse effects during pregnancy and may contribute to cardiovascular disease. The evidence is sufficient to caution children and adolescents, pregnant women, and women of reproductive age about use of ENDS because of the potential for fetal and adolescent nicotine exposure to have long-term consequences for brain development. There is also risk through nicotine overdose through ingestion or dermal contact. Furthermore, inhalation of second hand aerosol exhaled by ENDS users poses health risks to the public.

Regulation of ENDS is necessary, especially considering that there is lack of scientific research and long-term studies on its effect and potential harms to users and to the public. Claims by the industry about its utility as a smoking cessation aid must be well-established, and must have regulatory approval before it is used and marketed as such. Promotion of health is paramount concern and the public must have current and reliable information and protected from products that may cause harm. There is a legitimate State interest in strictly regulating ENDS by the proper agencies to ensure protection of public health.

In view of the foregoing, the immediate passage of this bill is most earnestly sought.

Precious Hipolito Castelo

AN ACT
REGULATING THE MANUFACTURE, DISTRIBUTION, SALE, IMPORTATION, USE, AND
ADVERTISEMENT OF ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS) AND FOR
OTHER PURPOSES

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

SECTION 1. Short Title. - This Act shall be known as the “Electronic Cigarettes Regulation
Act”.

SEC. 2. Declaration of Policy. - It is State policy to protect and promote the right to health of
the people and instill health consciousness in them. It is hereby declared a policy of the
State to protect the people from hazardous products. Use of electronic nicotine delivery
systems (ENDS) or more commonly known as electronic cigarettes poses risks that can
cause addictiveness to nicotine, as well as exposure to toxic particles that may be in the
product that can be harmful to the user and the people around him. Hence, State interest in
regulating the product and ensuring that the public is protected is well-justified.

SEC. 3. Definition of Terms.
   a) Electronic Nicotine Delivery Systems (ENDS) - are devices that vaporizes liquid, typically
      comprising nicotine, propylene glycol, glycerine, and flavourings. It is commonly known
      as electronic cigarettes or e-cigarettes. For the purpose of this law, ENDS shall include
      e-cigarettes, electronic cigar, electronic pipe or any similar product or device.
   b) E-liquid - is the liquid that is often heated in an electronic cigarette to create a vapor that
      the user inhales. It usually contains nicotine, propylene glycol, glycerine, and flavorings.
   c) Persons-in-charge - refers to any person who has control or responsibility over public
      places, workplace, public transport, public transport terminals, accommodation and
      entertainment establishments, or any agent or designee of such person, including the
      proprietor, possessor, manager, or administrator.
   d) Vaping - the act of inhaling and exhaling the vapor produced by an ENDS.
SEC. 4. Ban of Sale to and Purchase by or Possession by Minors. Sale of ENDS to persons under eighteen (18) years old is prohibited. Purchase or possession of ENDS by persons under eighteen (18) years old is prohibited.

SEC. 5. Ban of Use of ENDS in Public Places. The use of ENDS is prohibited in places that are accessible and open to the public, such as but not limited to, schools, parks, playgrounds, facilities where minors are present, hospitals, public transportation vehicles, public transportation terminals, elevators, staircases, workplace, malls, restaurants, waiting sheds, sidewalks, and any other places where people usually congregate.

It shall be the responsibility of person-in-charge to undertake all reasonable steps to ensure the strict implementation of the ban of use of ENDS in public places, and to inform individuals about the ban, and restrict them from vaping.

SEC. 6. Health Warnings in ENDS packaging. The manufacturers are required to put health warnings in the packaging of their products. Within sixty (60) days from effectivity of this Act, the Department of Health shall prescribe the necessary health warnings, including the standard for the size, content, and other details.

Prescribed warnings on ENDS may contain the following:
  a) Warning on the harmful effects and addictive nature of nicotine
  b) Warning to keep the product away from children
  c) Statement that vaping is illegal for minors
  d) Disclosure of the amount of nicotine

SEC. 7. Manufacturers shall ensure that all liquid nicotine containers shall be packaged in accordance with standards to make it child-resistant.

SEC. 8. Ban on Advertising, Promotions, and Sponsorships of ENDS. Advertisement and promotion of ENDS are prohibited, except for one signage inside the point of sale establishment, with a maximum size of 8 x 11 inches. The signage shall contain a statement that ENDS are sold in the establishment.

Any form of sponsorship by manufacturers, retailers, distributors, or importers of ENDS is prohibited.

SEC. 9. Registration of Manufacturers, Distributors, Importers, and Retailers. Manufacturers, distributors, importers, and retailers of ENDS shall register with the Food and Drugs Administration before the products can be manufactured, distributed, imported, or sold in the Philippines.

No person may engage in or conduct business as a manufacturer, distributor, importer, or retailer of ENDS without a valid permit issued by the Food and Drug Administration.
SEC. 10. **Prohibiting Unproven Health Claims.** - Manufacturers, importers, distributors, or retailers are prohibited from making health claims about ENDS, including that their product are smoking cessation aids, until they provide convincing supporting scientific evidence and obtain the approval of the Food and Drug Administration to make such health claims.

SEC. 11. **Regulation of Nicotine Content, Chemicals, and Flavorings.** The Food and Drugs Administration may regulate ends to reduce the ill-effects of vaping and nicotine addiction. Such regulation may include, but are not limited to the following:

a) Minimizing content and emission of toxicants;
b) Ensuring the use of nicotine of pharmacological quality, when nicotine use is intended;
c) Standardizing nicotine delivery at levels known to the consumers;
d) Minimizing acute nicotine toxicity;
e) Impeding product alteration to use of other drugs;
f) Banning ENDS solutions with fruit, candy-like and alcohol-drinks flavors until empirical evidence shows that they are not attractive to minors;
g) Requiring manufacturers and importers to disclose to governmental authorities information about the contents and emissions of ENDS;

SEC. 12. **Penalties.** -

a) The following penalties shall be imposed on violators for violations of Sections 4 and 5.
   i. First Offense: Fine of Ten Thousand Pesos (Php 10,000.00) or 1 month imprisonment, or both, at the discretion of the court;
   ii. Second Offense: Fine of Twenty Thousand Pesos (Php 20,000.00) or 2 months imprisonment, or both, at the discretion of the court;
   iii. Third and Subsequent Offenses: Fine of Fifty Thousand Pesos (Php 50,000.00), or 3 months imprisonment, or both, at the discretion of the court;

b) The following penalties shall be imposed on violators for violation of Sections 6 to 10 of this Act:
   i. First Offense: Fine of One Hundred Thousand Pesos (Php 100,000.00) or 1 month imprisonment, or both, at the discretion of the court;
   ii. Second Offense: Fine of Two Hundred Thousand Pesos (Php 200,000.00) or 2 months imprisonment, or both, at the discretion of the court;
   iii. Third and Subsequent Offenses: Fine of Five Hundred Thousand Pesos (Php 500,000.00), or 3 months imprisonment, or both, at the discretion of the court;

c) If the violation is by a business entity, the owner, president, manager, or most senior officers shall be liable for the offense.

   In addition, the license or registration of manufacturer, importer, distributor, or retailer may be cancelled or revoked, upon showing of any violation of this Act.

d) Minors who have been found to have violated this Act shall be properly dealt with in accordance with the provisions of the Child and Youth Welfare Code and Juvenile Justice and Welfare Act of 2006;

SEC. 12. **Implementing Rules and Regulations.** The Food and Drugs Administration shall promulgate the Implementing Rules and Regulation IRR to carry out the provisions of this
Act within three (3) months from effectivity of this Act. The IRR shall take effect upon its publication in two (2) newspapers of general circulation.

SEC. 13. Appropriations. - The amount necessary to carry out the provisions of this Act shall be included in the budget of concerned government agencies in the General Appropriations Act of the year following its enactment into law and thereafter.

SEC. 14. Separability Clause. – If any provision or section of this Act is held invalid or unconstitutional, the other provisions and sections not affected thereby shall remain in full force and effect.

SEC. 15. Repealing Clause. – All laws, presidential decrees, executive orders, or issuances, or any part thereof which are inconsistent with the provisions of this Act are hereby repealed, amended, or modified accordingly.

SEC. 16. Effectivity. – This Act shall take effect fifteen (15) days after its publication in the Official Gazette or two (2) newspapers of general circulation.

Approved,