



SIXTEENTH CONGRESS OF THE REPUBLIC)
OF THE PHILIPPINES)
First Regular Session)

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SENATE
S. No. **1764**

RECEIVED BY: *js*

Introduced by Senator Miriam Defensor Santiago

EXPLANATORY NOTE

The Constitution, Article 2, Section 15 provides:

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

It is absolutely imperative that consumers be made aware of the effects of pharmaceutical products, prescribed or bought over the counter. With greater importance are pharmaceutical products that cause impairment of certain cognitive functions of those who take them and affect their abilities to perform certain activities.

This bill seeks to require pharmaceutical companies to properly label drugs that cause impairment of certain cognitive functions.*

Miriam Defensor Santiago
MIRIAM DEFENSOR SANTIAGO
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* This bill was originally filed in the Thirteenth Congress, Third Regular Session.



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1 AN ACT
2 PRESCRIBING THE PROPER LABELING OF PHARMACEUTICAL PRODUCTS
3 WHICH ACT ON THE BRAIN AND CENTRAL NERVOUS SYSTEM

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

4 SECTION 1. *Short Title.* - This Act shall be known as the "Pharmaceutical Labeling
5 Act."

6 SECTION 2. *Definition of Terms.* - In this Act, the term:

7 (A) "Consumer" means a person who takes a psychoactive pharmaceutical whether in
8 the recommended or prescribed dose or otherwise;

9 (B) "Over-the-counter" means available without prescription from a pharmacy or
10 other retail outlet;

11 (C) "Packaging" means such of the external packaging as is clearly on view on
12 purchase or receipt of the product;

13 (D) "Prescription only" means available only by a prescription from a registered
14 medical practitioner;

15 (E) "Psychoactive pharmaceutical" means a pharmaceutical product which has a
16 clinical effect on the brain and central nervous system, and it is immaterial whether the
17 psychoactive pharmaceutical is available through prescription only or over the counter;

18 (F) "Specified psychoactive pharmaceutical" means a psychoactive pharmaceutical
19 specified by the Secretary of Health by order under Section 3; and

20 (G) "Warning symbol" means a prominent symbol the size, color and design of which
21 shall be prescribed by the Secretary of Health by regulations.

1 SECTION 3. *Pharmaceuticals with Psychoactive Side Effects.* - The Secretary of Health
2 shall make a determination of which psychoactive pharmaceuticals can lead to impairment of the
3 consumer's ability to drive a motor vehicle or operate machinery such that the consumer is a
4 danger to himself or others. The Secretary of Health shall promulgate this order within twelve
5 (12) months from the effectivity of this Act.

6 SECTION 4. *Regulations.* - Not later than twelve (12) months from the effectivity of this
7 Act, the Secretary of Health shall promulgate final regulations to carry out the provisions of this
8 Act.

9 SECTION 5. *Warning Label.* - Drugs containing specified psychoactive pharmaceuticals,
10 as determined by the Secretary of Health, shall include on their packaging a warning stating the
11 following: "Warning: This drug may cause cognitive function impairment"

12 SECTION 6. *Penalty Clause.* - Any person who shall violate the provisions of this Act
13 shall, upon conviction, be subject to a fine of not less than Ten Thousand Pesos (P10,000.00) but
14 not more than One Hundred Thousand Pesos (P100,000.00), or imprisonment of not less than
15 two (2) months but not more than one (1) year, or both, upon the discretion of the court.

16 SECTION 7. *Separability Clause.* - If any provision or part of this Act is declared invalid
17 or unconstitutional, the same shall not affect the validity and effectivity of the other provisions
18 not affected thereby.

19 SECTION 8. *Repealing Clause.* - All laws, decrees, executive orders, rules and
20 regulations, and other issuances or parts thereof which are inconsistent with this Act are hereby
21 repealed, amended, or modified accordingly.

22 SECTION 9. *Effectivity Clause.* - This Act shall take effect fifteen (15) days following its
23 publication in at least two (2) national newspapers of general circulation.

Approved,