

THIRTEENTH CONGRESS OF THE REPUBLIC)  
OF THE PHILIPPINES )  
Third Regular Session )

SENATE  
S.B. No. 2669

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  
gldt

THIRTEENTH CONGRESS OF THE REPUBLIC)  
OF THE PHILIPPINES )  
Third Regular Session )

SENATE  
S.B. No. 10009

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Introduced by Senator Miriam Defensor Santiago

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AN ACT  
PRESCRIBING THE PROPER LABELING OF PHARMACEUTICAL PRODUCTS  
WHICH ACT ON THE BRAIN AND CENTRAL NERVOUS SYSTEM SO AS TO IMPAIR  
DANGEROUSLY THE CONSUMER'S ABILITY TO CARRY OUT CERTAIN ACTIVITIES  
AND PROVIDING PENALTIES FOR VIOLATION THEREFOR

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

SECTION 1. *Short Title.* – This Act shall be known as the “Pharmaceutical Labeling (Warning of Cognitive Function Impairment) Act of 2007”.

SECTION 2. *Definition of Terms.* – In this Act, the term

(1) “consumer” means a person who takes a psychoactive pharmaceutical whether in the recommended or prescribed dose or otherwise;

(2) “over the counter” means available without prescription from a pharmacy or other retail outlet;

(3) “packaging” means such of the external packaging as is clearly on view on purchase or receipt of the product;

(4) “prescription only” means available only by a prescription from a registered medical practitioner;

(5) “psychoactive pharmaceutical” means a pharmaceutical product which has a clinical effect on the brain and central nervous system, and it is immaterial whether the psychoactive pharmaceutical is available through prescription only or over the counter;

(6) “specified psychoactive pharmaceutical” means a psychoactive pharmaceutical specified by the Secretary of Health by order under Section 3;

(7) “warning symbol” means a prominent symbol the size, color and design of which shall be prescribed by the Secretary of Health by regulation.

SECTION 3. *Pharmaceuticals with psychoactive side effects.* – The Secretary of Health shall make a determination of which psychoactive pharmaceuticals can lead to impairment of the consumer’s ability to drive a motor vehicle or operate machinery such that the consumer is a danger to himself or others. The Secretary of Health shall promulgate this order within 12 months from the effectivity of this Act.

SECTION 4. *Regulations.* – Not later than 12 months from the effectivity of this Act, the Secretary of Health shall promulgate final regulations to carry out the provisions of this Act.

SECTION 5. *Warning label.* – Drugs containing specified psychoactive pharmaceuticals, as determined by the Secretary of Health, shall include on their packaging a warning stating the following:

“Warning: This drug may cause cognitive function impairment”

SECTION 6. *Penalty Clause.* – Any person who shall violate the provisions of this Act shall, upon conviction, be subject to a fine of not less than Ten Thousand Pesos (Php 10,000.00) but not more than One Hundred Thousand Pesos (Php 100,000.00), or imprisonment of not less than two months but not more than one year, 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 need for further deportation proceedings.

SECTION 7. *Separability Clause.* – If any portion or provision of this Act is declared unconstitutional, the same shall not affect the validity and effectivity of the other provisions not affected thereby.

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

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

Approved.