

HOUSE BILL 885

By Dixie

AN ACT to amend Tennessee Code Annotated, Title 47,
Chapter 18, relative to prescription drugs.

WHEREAS, pharmaceutical drugs are necessary to maintain the health and welfare of the American people; and

WHEREAS, America currently faces a chronic shortage of drugs necessary for surgery, treating cancer, and fighting life-threatening illnesses; and

WHEREAS, in order to prevent any party in the distribution chain of any vital drugs from taking unfair advantage of consumers during market shortages, the public interest requires that such conduct be prohibited and made subject to criminal penalties; now, therefore,

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 47, Chapter 18, is amended by adding the following as a new part:

47-18-3001.

As used in this part:

(1) "Biologic" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component, or derivative allergenic product or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound) applicable to the prevention, treatment, or cure of a disease or condition of human beings;

(2) "Drug" means a drug intended for use by human beings, that:

(A) Because of its toxicity or other potential for harmful effects, the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a licensed practitioner; or

(B) Is limited by an approved application pursuant to § 505 of the Federal Food, Drug, and Cosmetic Act to use under the supervision of a licensed practitioner;

(3) "Market emergency" means a declaration of a state of emergency by the governor or the president;

(4) "Market shortage" means a situation in which the total supply of all clinically interchangeable versions of a drug regulated by the food and drug administration is inadequate to meet current or projected user demand;

(5) "Price gouging" means charging a consumer an unreasonably high price for any drug during a declared market emergency;

(6) "Unreasonably excessive drug pricing" means the amount charged represents a gross disparity between the average prices at which the same or similar commodity was readily available, sold, or offered for sale within the local area in the normal course of business during the thirty (30) days immediately before the declaration of a market emergency and the additional charges are not substantially attributable to increased costs to retailers imposed by their suppliers, including replacement costs imposed by a vendors' source. The average price calculation during the thirty (30) day period does not include discounted prices set and offered as a result of bona fide limited discounts or rebates by manufacturers or suppliers; and

(7) "Vital drug" means any drug or biologic used to prevent or treat a serious or life-threatening disease or medical condition for which there is no other available source with sufficient supply.

47-18-3002.

(a) The governor may issue an executive order or rely on an executive order of the president of the United States declaring a market shortage or market emergency for

a period of six (6) months with regard to one (1) or more vital drugs due to a market shortage.

(b) It is an offense to sell vital drugs at an unreasonably excessive price if the governor or the president of the United States issues an executive order under subsection (a).

(c) The attorney general may enforce penalties under this part.

47-18-3003.

(a)

(1) It is an offense to sell any vital drug during a declared market shortage with the knowledge or with the intent to charge a price that is unreasonably excessive under the circumstances.

(2) A violation of subdivision (a)(1) is a Class C felony.

(b) Each day of a continuing violation is considered a separate violation.

(c) The attorney general may bring an action in a court of competent jurisdiction to enjoin such acts or practices and upon a proper showing a permanent or temporary injunction or restraining order may be granted.

47-18-3004.

(a) The attorney general, in determining whether a price was unreasonably excessive, shall consider whether:

(1) The price reasonably reflected additional costs not within the control of a person or company that were paid, incurred, or reasonably anticipated;

(2) The price reasonably reflected additional risks taken by a person or company to produce, distribute, obtain, or sell such product under the circumstances;

(3) There is a gross disparity between the challenged price and the price at which the same or similar goods were readily available in this state prior to the declared market shortage;

(4) The marginal benefit received by a wholesaler or distributor differs significantly compared to marginal earnings in the year before the market shortage;

(5) The price charged was comparable to the price at which the goods were generally available in the region if the wholesaler or distributor did not sell or offer to sell the prescription drug in question prior to the declared market shortage; and

(6) The price was substantially attributable to local, regional, national, or international market conditions.

(b) Not later than one (1) year after the date of enactment of this part and annually thereafter, the attorney general or designee shall consult with representatives of the National Association of Wholesalers, or their successor organization, group, purchasing organizations, pharmaceutical distributors, hospitals, manufacturers, patients, and other interested community organizations to reassess the criteria set forth in subsection (a) and report to the general assembly on the results of the reassessment.

47-18-3005.

(a) Any market shortage declared by the governor or president of the United States in accordance with this part must not exceed six (6) months from the date on which the governor or president of the United States issues an executive order.

(b) Any market shortage declared by the governor or president in accordance with this part terminates if:

(1) There is enacted a law terminating the market shortage, which must be passed by the general assembly; or

(2) The governor or president of the United States issues a proclamation terminating the market shortage.

(c) A state of market shortage may be established under subsection (a) if a severe shortage continues to affect the health and well-being of citizens beyond the initial six-month period.

SECTION 2. This act shall take effect upon becoming a law, the public welfare requiring it.