AN ACT relating to prescription drugs.

Be it enacted by the General Assembly of the Commonwealth of Kentucky:

➔SECTION 1. A NEW SECTION OF KRS CHAPTER 367 IS CREATED TO READ AS FOLLOWS:

For the purpose of Sections 1 to 3 of this Act, unless context otherwise requires:

(1) (a) "Essential off-patent or generic drug" means any prescription drug that meets all of the following criteria:

1. All exclusive marketing rights for the drug, if any, granted pursuant to the federal Food, Drug, and Cosmetics Act, Section 351 of the federal Public Health Service Act, or federal patent law have expired;

2. The drug appears on the model list of essential medicines most recently adopted by the World Health Organization or has been designated by the secretary as an essential medicine due to its efficacy in treating a life-threatening health condition or a chronic health condition that substantially impairs an individual's ability to engage in activities of daily living;

3. The drug is actively manufactured and marketed for sale in the United States by three (3) or fewer manufacturers; and

4. The drug is made available for sale in the Commonwealth.

(b) "Essential off-patent or generic drug" includes any drug-device combination product used for the delivery of a drug for which all exclusive marketing rights, if any, granted pursuant to the federal Food, Drug, and Cosmetics Act, Section 351 of the federal Public Health Service Act, or federal patent law have expired;

(2) "Manufacturer" has the same meaning as in KRS 315.010;

(3) "Medical assistance program" means the state medical assistance program established in KRS Chapter 205;

(4) "Secretary" means the secretary of the Cabinet for Health and Family Services;

(5) "Wholesale acquisition cost" means the manufacturer's list price for a prescription drug to wholesalers or direct purchasers in the United States, not including any discounts, rebates, or other reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug pricing data; and

(6) "Wholesaler" has the same meaning as in KRS 315.010.

➔SECTION 2. A NEW SECTION OF KRS CHAPTER 367 IS CREATED TO READ AS FOLLOWS:

(1) A manufacturer or wholesaler of an essential off-patent or generic drug is prohibited from engaging in unfair and unconscionable price increases in the sale of the drug.

(2) It shall not be a violation of subsection (1) of this section for a wholesaler to increase the price of an essential off-patent or generic drug if the price increase is directly attributable to additional costs for the drug imposed on the wholesaler by the manufacturer of the drug.

➔SECTION 3. A NEW SECTION OF KRS CHAPTER 367 IS CREATED TO READ AS FOLLOWS:

(1) The secretary shall notify the Attorney General of any increase in the price of an essential off-patent or generic drug if the price increase, by itself or in combination with other price increases:

(a) 1. Would result in an increase of fifty percent (50%) or more in the wholesale acquisition cost of the drug within the preceding one (1) year period; or

2. Would result in an increase of fifty percent (50%) or more in the price paid by the medical assistance program for the drug within the preceding one (1) year period; and

(b) Meets at least one (1) of the following criteria:

1. A thirty (30) day supply of the maximum recommended dosage of the drug for any indication, according to the label for the drug approved under the federal Food, Drug, and Cosmetic Act, would cost more than eighty dollars ($80) at the drug's wholesale acquisition cost;

2. A full course of treatment with the drug, according to the label for the drug approved under the federal Food, Drug, and Cosmetic Act, would cost more than eighty dollars ($80) at the drug's wholesale acquisition cost; or

3. If the drug is made available to consumers only in quantities that do not correspond to a thirty (30) day supply, a full course of treatment, or a single dose, it would cost more than eighty dollars ($80) at the drug's wholesale acquisition cost to obtain a thirty (30) day supply or a full course of treatment.

(2) The Attorney General's receipt of notification pursuant to subsection (1) of this section shall constitute notice of a potential violation of Section 2 of this Act or KRS 367.170.

(3) Any investigative demand issued by the Attorney General to a manufacturer or wholesaler shall include a request for all of the following:

(a) An itemization of the components of the cost of producing the drug;

(b) An identification of the circumstances and timing of any increase in materials or manufacturing costs that cause any increase in the price of the drug within the one (1) year period immediately preceding the date of the price increase;

(c) 1. An identification of the circumstances and timing of any expenditures made by the manufacturer or wholesaler to expand access to the drug; and

2. An explanation of any improvement in the public health associated with those expenditures; and

(d) Any other information that the manufacturer or wholesaler believes to be relevant to a determination of whether a violation of Section 2 of this Act or KRS 367.170 has occurred.

(4) If a court determines that a violation of Section 2 of this Act or KRS 367.170 has occurred, in addition to the remedies provided for in KRS 367.110 to 367.300, a court may:

(a) Issue an order requiring a manufacturer or wholesaler that has engaged in unrestrained price increases in the sale of an essential off-patent or generic drug to make the drug available to residents of the Commonwealth for a period of up to one (1) year at the price at which the drug was made available to residents of the Commonwealth immediately prior to the manufacturer's violation of Section 2 of this Act or KRS 367.170; and

(b) Impose a civil penalty of up to ten thousand dollars ($10,000) for each violation of Section 2 of this Act or KRS 367.170.

(5) The Attorney General shall not bring an action for a remedy pursuant to this section unless the Attorney General has provided the manufacturer or wholesaler with an opportunity to meet with the Attorney General or his or her staff to offer justification for the increase in the price of the essential off-patent or generic drug.

(6) Any information provided by a manufacturer or wholesaler to the Attorney General pursuant to this section shall be considered confidential commercial information not subject to disclosure pursuant to KRS 61.870 to 61.884.

(7) In any action brought by the Attorney General pursuant to this section, a person who is alleged to have violated Section 2 of this Act or KRS 367.170 shall not assert as a defense that the person did not deal directly with a consumer residing

in the Commonwealth.