TO THE HOUSE OF REPRESENTATIVES:

The Committee on Health Care to which was referred House Bill No. 866 entitled "An act relating to prescription drug manufacturer cost transparency" respectfully reports that it has considered the same and recommends that the bill be amended by striking out all after the enacting clause and inserting in lieu thereof the following:

Sec. 1. FINDINGS

The General Assembly finds that:

(1) The costs of prescription drugs have been increasing dramatically without any apparent reason.

(2) Containing health care costs requires containing prescription drug costs.

(3) In order to contain prescription drug costs, it is essential to understand the drivers of those costs, as transparency is typically the first step toward cost containment.

Sec. 2. 18 V.S.A. § 4635 is added to read:

§ 4635. PHARMACEUTICAL COST TRANSPARENCY

(a) As used in this section:

(1) "Manufacturer" shall have the same meaning as "pharmaceutical manufacturer" in section 4631a of this title.

(2) "Prescription drug" means a drug as defined in 21 U.S.C. § 321.

(b) The Green Mountain Care Board, in collaboration with the Department of Vermont Health Access, shall identify annually up to 15 prescription drugs on which the State spends significant health care dollars and for which the price has increased by 50 percent or more over the past five years or by 15 percent or more over the past 12 months, creating a substantial public interest in understanding the development of the drugs' pricing. The drugs identified shall represent different drug classes, with some of the drugs being generic drugs, some brand-name drugs, and some specialty drugs. The Board shall provide the list of prescription drugs to the Office of the Attorney General.

(c)(1) For each prescription drug identified pursuant to subsection (b) of this section, the Office of the Attorney General shall require the drug's manufacturer to report the following information by drug name, in a format that the Attorney General determines to be understandable and appropriate:

(A) the number of years the drug has been available for purchase in the United States;

(B) the year the patent for each formulation of the drug was approved and the number of years remaining, if any, on the patent for each formulation of the drug;

(C) the total research and development costs paid by the manufacturer over the preceding seven years and, separately and to the extent

the manufacturer has the information, the total research and development costs paid by any predecessor and by any third party, public or private, in the development of the drug, showing both the total amounts spent on research and development by the manufacturer, its predecessors, and third parties over time and the amounts spent by each per year as well as any amounts from federal, State, or other governmental programs and any form of subsidies, grants, tax credits, or other support;

(D) the costs of clinical trials and other regulatory costs paid by the manufacturer by year and by clinical trial phase and, separately and to the extent the manufacturer has the information, the costs of clinical trials and other regulatory costs paid by any predecessor in the development of the drug, as well as the cost of any postclinical studies mandated by the U.S. Food and Drug Administration;

(E) amounts spent per year for the preceding seven years on direct-to-consumer advertising for the drug and on physician detailing activities related to the drug, both in Vermont and nationally;

(F) a cumulative annual history of increases in the average wholesale price and wholesale acquisition cost of the drug, using the National Drug Code, over the preceding five-year period, expressed as percentages, and the month each such increase took effect;

(G) prices charged to direct purchasers in Vermont during the previous year, including pharmacies, pharmacy chains, pharmacy wholesalers, hospitals, physician practices, and other direct purchasers of prescription drugs; and

(H) prices charged to mail-order pharmacies for distribution in Vermont during the previous year.

(2) The manufacturer may provide to the Office of the Attorney General any additional information the manufacturer believes may be pertinent to the Attorney General's complete understanding of the costs related to developing and manufacturing the drug or to the drug's price, such as costs related to acquisition of the drug, and to its understanding of the reasons for the increases in the drug's price.

(3) The manufacturer shall certify, subject to the penalties of perjury, that the information provided is truthful, accurate, and complete.

(4) The manufacturer may indicate that a component of the required information is not available in the format requested if the manufacturer provides the information in an alternative format acceptable to the Attorney General as in keeping with the purposes of this section and the manufacturer includes a detailed explanation of the reasons the manufacturer is unable to provide the information in the requested format.

(d) The Attorney General, in consultation with the Department of Vermont Health Access, shall provide a report to the General Assembly on or before December 1 of each year based on the information received from manufacturers pursuant to this section.

(1) The report shall be based on the Attorney General's review and analysis of the data. The Attorney General shall aggregate the data to determine trends in components of drug production costs and shall provide recommendations for legislative, administrative, or other policy changes that may contribute to containing growth in prescription drug prices.

(2) The Attorney General shall report aggregated data separately for generic, brand name, and specialty drugs in a manner that maximizes the utility of the data while protecting the financial, competitive, or proprietary nature of the information.

(3) The report shall include a statement of total State spending for the year for each drug identified pursuant to subsection (a) of this section paid for through the State Employees Health Benefit Plan, Medicaid, VPharm, and any other State program for the purchase of prescription drugs, as well as the number of prescriptions for each drug dispensed to individuals enrolled in these programs.

(4) The Attorney General shall also post the report on the Office of the Attorney General's website.

(e) Information provided to the Office of the Attorney General pursuant to this section is exempt from public inspection and copying under the Public Records Act and shall not be released in a manner that allows for the identification of an individual drug or manufacturer or that is likely to compromise the financial, competitive, or proprietary nature of the information.

Sec. 3. EFFECTIVE DATE

This act shall take effect on passage.

(Committee vote: _____)

_____

Representative _____

FOR THE COMMITTEE