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. 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 shall **~~develop~~ identify annually, in collaboration with the Department of Vermont Health Access, ~~a list of specific~~ 15** prescription drugs on which the State spends significant health care dollars, creating a substantial public interest in understanding the development of the drugs' pricing. **The drugs identified shall represent different drug classes, with five of the drugs being generic drugs, five brand-name drugs, and five specialty drugs.**

(c)(1) For each prescription drug **~~that the Green Mountain Care Board places on the list developed~~ identified** pursuant to subsection (b) of this

section, the Board shall require the drug's manufacturer to report the following information **by drug name**:

(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 **over the preceding seven years 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) other costs to acquire the drug, including costs for the purchase of patents, licensing, property rights, or acquisition of a corporate entity owning rights to the drug while in development;

~~**(F) any other information the manufacturer believes to be pertinent to the Board's complete understanding of the costs related to developing and manufacturing the drug or to the drug's price;**~~

(F) 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;

(G) 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;

(H) prices for the drug charged to ~~**purchasers outside the United States, by country, for a representative set of five countries to be selected annually by the Green Mountain Care Board**~~ **the U.S. Veterans Administration and to 340B covered entities, using the National Drug Code**;

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

(J) typical prices charged to ~~**pharmacy benefit managers**~~ **mail-order pharmacies** for distribution in Vermont during the previous year~~**, net of rebates and of other payments from the manufacturer to the pharmacy benefit manager and the pharmacy benefit manager to the manufacturer**~~.

(2) The manufacturer may provide to the Board any additional information the manufacturer believes may be pertinent to the Board'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.

~~**(3) The reported information shall be audited by an independent, third-party auditor prior to filing**~~ **The manufacturer shall certify, subject to the penalties of perjury, that the information provided is truthful, accurate, and complete**.

(d) The Green Mountain Care Board shall provide a report to the General Assembly on or before December 1 of each year ~~**describing**~~ **based on** the information received from manufacturers pursuant to this section.

(1) The ~~**Board shall review and analyze**~~ **report shall be based on the Board's review and analysis of** the data**. The Board shall** aggregate the data to determine trends in components of drug production costs~~,~~ and ~~**determine whether the data suggest the need for**~~ **shall provide recommendations for** legislative, administrative, or other policy changes.

(2) The Board shall report aggregated data by drug class 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 ~~**the total cost to the State of Vermont**~~ **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 Board shall also post the report on the Board's website.

(e) Information ~~**and reports**~~ provided to the Green Mountain Care Board pursuant to this section ~~**are**~~ **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**~~**. Any public reporting of the information shall be**~~

~~aggregated in order to protect the financial, competitive, or proprietary nature of the information.~~

Sec. 2. EFFECTIVE DATE

This act shall take effect on passage.

(Committee vote: _____)

_____

Representative _____

FOR THE COMMITTEE