

1 H.866 - Rep. Donahue proposal

2 **Sec. 1. FINDINGS**

3 **The General Assembly finds that:**

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

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

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

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

12 § 4635. PHARMACEUTICAL COST TRANSPARENCY

13 (a) As used in this section:

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

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

17 (b) The Green Mountain Care Board, in collaboration with the Department
18 of Vermont Health Access, shall identify annually **up to 15** prescription drugs
19 on which the State spends significant health care dollars **and for which the**
20 **price has increased by 50 percent or more over the past five years or by 15**
21 **percent or more over the past 12 months,** creating a substantial public

1 interest in understanding the development of the drugs' pricing. The drugs
2 identified shall represent different drug classes, with **five some** of the drugs
3 being generic drugs, **five some** brand-name drugs, and **five some** specialty
4 drugs. **The Board shall provide the list of prescription drugs to the Office**
5 **of the Attorney General.**

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

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

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

16 (C) the total research and development costs paid by the
17 manufacturer over the preceding seven years and, separately and to the extent
18 the manufacturer has the information, the total research and development costs
19 paid by any predecessor and by any third party, public or private, in the
20 development of the drug, showing both the total amounts spent on research and
21 development by the manufacturer, its predecessors, and third parties over time

1 and the amounts spent by each per year as well as any amounts from federal,
2 State, or other governmental programs and any form of subsidies, grants, tax
3 credits, or other support;

4 (D) the costs of clinical trials and other regulatory costs paid by the
5 manufacturer **over the preceding seven years** by year and by clinical trial
6 phase and, separately and to the extent the manufacturer has the information,
7 the costs of clinical trials and other regulatory costs paid by any predecessor in
8 the development of the drug, as well as the cost of any postclinical studies
9 mandated by the U.S. Food and Drug Administration;

10 ~~(E) other costs to acquire the drug, including costs for the~~
11 ~~purchase of patents, licensing, property rights, or acquisition of a~~
12 ~~corporate entity owning rights to the drug while in development;~~

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

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

1 (H) prices for the drug charged to the U.S. Veterans
2 Administration and to 340B covered entities, using the National Drug
3 Code:

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

8 (J) typical prices charged to mail-order pharmacies for distribution in
9 Vermont during the previous year.

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

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

18 (4) The manufacturer may indicate that a component of the
19 required information is not available in the format requested if the
20 manufacturer provides the information in an alternative format
21 acceptable to the Attorney General as in keeping with the purposes of this

1 section and the manufacturer includes a detailed explanation of the
2 reasons the manufacturer is unable to provide the information in the
3 requested format.

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

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

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

18 (3) The report shall include a statement of total State spending for the
19 year for each drug identified pursuant to subsection (a) of this section paid for
20 through the State Employees Health Benefit Plan, Medicaid, VPharm, and any
21 other State program for the purchase of prescription drugs, as well as the

1 number of prescriptions for each drug dispensed to individuals enrolled in
2 these programs.

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

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

11 Sec. 3. EFFECTIVE DATE

12 This act shall take effect on passage.