TO THE HONORABLE SENATE:

The Committee on Health and Welfare to which was referred House Bill No. 350 entitled "An act relating to the posting of medical unprofessional conduct decisions and to investigators of alleged unprofessional conduct" respectfully reports that it has considered the same and recommends that the Senate propose to the House that the bill be amended as follows:

First: By adding a new section to be Sec. 5a to read:

Sec. 5a. 18 V.S.A. § 4631a is amended to read:

§ 4631a. EXPENDITURES BY MANUFACTURERS OF PRESCRIBED PRODUCTS

(a) As used in this section:

(1) "Allowable expenditures" means:

* * *

(H) Sponsorship of an educational program offered by a medical device manufacturer at a national or regional professional society meeting at which programs accredited by the Accreditation Council for Continuing Medical Education, or a comparable professional accrediting entity, are also offered, provided:

(i) no payment is made directly to a health care professional or pharmacist; and

(ii) the funding is used solely for bona fide educational purposes, except that the manufacturer may provide meals and other food for program participants.

(I) Other reasonable fees, payments, subsidies, or other economic benefits provided by a manufacturer of prescribed products at fair market value.

* * *

(7)(C) "Regularly practices" means to practice at least periodically under contract with, as an employee of, or as the owner of, a medical practice, health care facility, nursing home, hospital, or university located in Vermont.

* * *

(12) "Prescribed product" means a drug ~~or device~~ as defined in section 201 of the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321, a compound drug or drugs, a medical device as defined in this subsection, a biological product as defined in section 351 of the Public Health Service Act, 42 U.S.C. § 262, for human use, or a combination product as defined in 21 C.F.R. § 3.2(e), but shall not include prescription eyeglasses, prescription sunglasses, or other prescription eyewear.

* * *

(15) "Medical device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is:

(A) recognized in the official National Formulary or the United States Pharmacopeia, or any supplement to them;

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals; or

(C) intended to affect the structure or any function of the body of humans or other animals, and which does not achieve its primary intended purposes through chemical action within or on such body and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Second: By adding a new section to be Sec. 5b to read:

Sec. 5b. DATA ANALYSIS AND REPORT REGARDING THE EFFICACY OF THE VERMONT DISCLOSURES AND GIFT BAN LEGISLATION

The Department of Vermont Health Access, in consultation with the Office of the Attorney General, shall examine the data available for relevant expenditures and gifts and determine whether and to what extent prescribing patterns by health care providers of prescribed products reimbursed by

Medicaid, Dr. Dynasaur, VPharm, and private insurers may reflect manufacturer influence and the impact of 2007 Acts and Resolves No. 80 and 2009 Acts and Resolves No. 59 on the State of Vermont's spending on pharmaceuticals, biologics, and medical devices. The Department may select the data most relevant to its analysis. The Department shall report its analysis to the House Committee on Health Care and the Senate Committees on Health and Welfare and on Finance on or before January 15, 2015.

Third: In Sec. 6, effective dates, by striking out Sec. 6 in its entirety and inserting in lieu thereof a new Sec. 6 to read:

Sec. 6. EFFECTIVE DATES

This act shall take effect on passage, except:

(1) Secs. 1 (amending 26 V.S.A. § 1318), 3 (amending 26 V.S.A. § 1351), and 5a (amending 18 V.S.A. § 4631a) shall take effect on July 1, 2014; and

(2) Sec. 2 (amending 26 V.S.A. § 1368) shall take effect on July 1, 2015.

(Committee vote: _____)

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Senator _____

FOR THE COMMITTEE