Bristol Myers Squibb™

State Senator Virginia Lyons
241 White Birch Lane
Williston, VT 05495
Email: vlyons@leg.state.vt.us

RE: Senate Bill 243, An Act Relating to Implementation of an Unused Prescription Drug Repository Program

Dear Senator Lyons,

My name is Joni Arvai, Director of State Government Affairs covering Vermont for Bristol Myers Squibb. I am writing on behalf of Bristol Myers Squibb to express concern regarding Senate Bill 243, An Act Relating to Implementation of an Unused Prescription Drug Repository Program. SB 243 directs the Board of Pharmacy, the Board of Medical Practice, and Human Services to evaluate how feasible it is to implement a drug repository program for donated prescription drugs. Bristol Myers Squibb respectfully submits exemption language that would ensure patient safety.

Bristol Myers Squibb (BMS) specializes in the discovery, development, and delivery of medicines for cancer, inflammatory, and immunological conditions. A select few of our Food and Drug Administration (FDA) approved cancer medications have the potential for severe side effects to patients if they are prescribed, dispensed, or taken inappropriately. Specifically, those side effects may include birth defects or death to an unborn child should there be fetal exposure.

Due to the potential for severe side effects from fetal-embryo product exposure and in an effort to prevent any such exposure, these medications are conditionally approved by the FDA only with Risk Evaluation Mitigation Strategies (REMS) in place. REMS programs are FDA mandated management plans that use risk minimization strategies to ensure that the benefits of certain prescription drugs outweigh their risks[1]. REMS may include medication safety guides (patient package inserts), communications plans, and/or Elements To Assure Safe Use (ETASU), like restricted distribution[2].

To avoid embryo-fetal exposure in individuals prescribed of the above-referenced BMS' drugs, the drugs are available only under tightly controlled restricted distribution REMS programs. Only certified prescribers can prescribe and only certified pharmacies can dispense these REMS medications. In addition, in order to receive one of these select medications subject to BMS' REMS program, all patients must be enrolled with Bristol Myers Squibb and agree to comply with the requirements of the REMS program. The highest risk patients, females with reproductive potential, must formally agree to take two forms of birth control throughout the duration of therapy and must agree to take pregnancy tests before each prescription.

Before receiving the BMS REMS medication to dispense, all pharmacies must be trained and subsequently classified as certified pharmacies. Each pharmacy must also ensure that they only accept prescriptions from certified prescribers, dispense medications within a certain timeframe,

[1] 21 U.S.C. § 355-1
[2] https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/whats-rems

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communicate with the REMS program to obtain the appropriate documentation in order to dispense each prescription, conduct and document the required patient counseling session before every dispense, and be audited for REMS compliance annually. All of these actions are done through multiple communications with Bristol Myers Squibb to help ensure that patients are receiving these medications under the required safe-use conditions.

In relation to drug repository programs referenced in SB 243, if unused amounts of these medications are collected and re-dispensed by non-REMS-certified pharmacies or health care facilities, without any knowledge of the REMS requirements or communication with Bristol Myers Squibb, the potential for fetal-embryo exposure may increase and patient safety could be undermined. Re-distribution of a REMS product without compliance with the REMS program also would be a direct violation of the conditions under which these products were approved by the FDA.

We suggest the following language be added to SB 234: Sec. 1(a)(4).

"Drugs that can only be dispensed to a patient registered with the drug's manufacturer in accordance with federal Food and Drug Administration requirements may not be accepted or distributed under the provisions of the program."

Other states which have passed similar legislation to create drug repository/reuse programs have incorporated this model language in order to help ensure patient safety as well as to maintain compliance with the Food and Drug Administration Amendments Act of 2007.

Thank you for your consideration and assistance. Please feel free to contact me at (860) 888-1750 or joni.arvai@bms.com with any questions or to discuss this issue in more detail.

Sincerely,

Joni Arvai

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