To: Vermont Senate Health and Welfare Committee

From: Ashlie Van Meter, Senior Director State Government Affairs,
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Re: S.B. 175

Chairwoman Ayer and Members of the Senate Health and Welfare Committee:

The Association for Accessible Medicines (AAM), previously the Generic Pharmaceutical Association, is the trade association that represents generic and biosimilar manufacturers. AAM thanks you for allowing stakeholders to provide comment on S.B. 175. AAM contends that generics, not uncontrolled foreign drugs, are the solution to the rising costs of healthcare. AAM opposes the importation of pharmaceuticals that have not been under the continuous regulatory oversight of FDA. Foreign imports, because of their uncertain safety and efficacy, unregulated nature, are not a viable solution. Rather, AAM believes that the solution to this important issue starts with regulated, FDA-approved generic pharmaceuticals. Federal and state governments could immediately and substantially lower prescription drug costs for all Americans by taking steps to increase the timely introduction and utilization of FDA-approved generic medicines.

Generics account for 89% of prescriptions dispensed in the United States but only 26% of total drug spending. Last year, generics saved Vermont $405 million dollars, and that could be increased through increased generic utilization. Increased generic utilization is the answer to concerns about high priced drugs, not the importation of "lower-priced" drugs.

In response to concerns about the high prices of brand drugs, S.B. 175 proposes to allow the importation of "lower-priced" drugs from Canada. Importation proposals such as S.B. 175 are misguided. S.B. 175 ignores and would undermine the availability of quality, FDA approved generic drugs and would expose American consumers to significant safety risks.

Generic Drugs Already Provide Access to Quality, Lower Cost Treatments

Multiple, independent sources, such as AARP, Express Scripts and the U.S. Department of Health and Human Services[1], have made it clear that generic drugs continue to drive savings. Generics are 88% of prescriptions dispensed but only 28% of overall drug costs, according to the annual Generic Drug Savings in the U.S. report compiled by IMS Health on behalf of GPhA[2]. In 2015 alone, the use of generic drugs saved $227 billion. The 2014 Express Scripts Drug Trend Report shows that since 2008, the price of brand drugs has almost doubled, while generic drug prices have fallen almost in half[3].

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[1] https://aspe.hhs.gov/sites/default/files/pdf/175071/GenericsDrugpaperr.pdf
[2] Generic Drug Savings in the U.S. Eighth Annual Edition: 2015. Generic Pharmaceutical Association, October 2016. http://www.gphaonline.org/media/generic-drug-savings-2016/index.html
[3] htpp://lab.express-scripts.com/lab/drug-trend-report

According to AARP[4], brand name and specialty drugs experienced substantial price increases of 12.9 percent and 10.6 percent in 2013. By contrast, generic drugs prices decreased 4.0 percent. AARP has also reported that between January 2006 and December 2013, retail prices for 103 chronic-use generic drugs decreased cumulatively over 8 years by an average of 22.7 percent[5].

Price Controls Will Result in Low Generic Utilization, Which Will Increase Costs

With the unregulated importation of prescription drugs as proposed, S.B. 175 abandons the free market principles that have been so instrumental in allowing the generic industry to provide cost-effective prescription drugs. Today, FDA-approved generics account for nearly 90% of all prescriptions filled in the United States. Yet, generics represent less than eight cents of every dollar consumers spend on prescription drugs. These savings are in no small part the result of our Nation's commitment to free market principles. These free market principles have been the major force in creating today's robust and competitive U.S. generic pharmaceutical industry. Other nations often have lower generic utilization rates, and higher generic costs due to regulatory environments that do not allow for as robust competition.

Consumer Safety Must Be Paramount

Importation without adequate safeguards could shred the fabric of FDA's safety net that has protected consumers from the importation of unregulated drugs of questionable safety, potency and quality for more than 70 years. Allowing importation into Vermont without a comprehensive system of FDA oversight and enforcement likely will allow counterfeit, adulterated, misbranded and unapproved drugs into this Vermont's secure drug supply and ultimately into consumer medicine cabinets. The Canadian regulatory system exempts from its health and safety standards, drugs manufactured for "export only." As a result, there can be no assurance of the actual origin of the drugs that are imported from Canada unless there is FDA supervision.

Imported Drugs Present Unique Safety Risks

FDA has stated on multiple occasions that lowering safety requirements would pose serious potential risk to consumers, whether they obtain imported prescription products from on-line "pharmacies" or other sources; receive products by mail or consignment carrier; or personally bring drugs into the U.S. Under Federal law, all drugs marketed in the United States must be approved by FDA based on demonstrated safety and efficacy. This "closed" regulatory system has been largely successful in safeguarding the American pharmaceutical supply. Congress further strengthened this system in 2013 through the bipartisan Drug Quality and Security Act (DQSA). The Act created a national system to track drug products from the manufacturer to the pharmacy and protect patients from compromised or counterfeit drug products. Importation would undermine the ability to accurately track drug products, weakening the important protections put into place by Congress.

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[4] Trends in Retail Prices of Prescription Drugs Widely Used by Older Americans, 2006 to 2013

[5] AARP Public Policy Institute. Trends in Retail Prices of Generic Prescription Drugs Widely Used by Older Americans, 2006 to 2014. May 2015.

In 2010, then-Commissioner Hamburg noted "in some parts of the world, somewhere between 30 and 50 percent of drugs to treat serious diseases were, in fact, counterfeit…Counterfeits, diversions and cargo theft are all part of a growing criminal enterprise, which also includes the deliberate adulteration of drugs and consumer products to maximize profits and unknown threats that have yet to surface.[6]" FDA enforcement demonstrates the reality of this threat. On June 18, 2015, FDA and international authorities, took action against more than 1,000 websites illegally selling potentially dangerous and unapproved prescription drug[7]. FDA and other public health authorities have warned providers and consumers about a range of counterfeit products including Harvoni[8], Botox[9], Cialis[10], Avastin[11], Tamiflu[12], and Vicodin[13].

According to FDA, such counterfeits and unapproved drugs pose significant risks to American consumers. "Patients may experience unexpected side effects, allergic reactions, or a worsening of their medical condition. A number of counterfeit products do not contain any active ingredients, and instead contain inert substances, which do not provide the patient any treatment benefit. Counterfeit drugs may also contain incorrect ingredients, improper dosages of the correct ingredients, or they may contain hazardous ingredients.[14]

Cost Savings Through Importation is Uncertain at Best

Reports suggest that, on average, U.S. generic drugs are more affordable than Canadian generics. (Palmer D'Angelo Consulting Inc. Report Series, "Generic Drug Prices: A Canada-US Comparison," August 2002. John R. Graham and Beverly A. Robson, The Fraser Institute, "Prescription Drug Prices in Canada and the United States – Part I: A Comparative Survey," Public Policy Sources, No. 42 (2000). If S.B. 175 is enacted, a new, and likely expensive regulatory program will become necessary. Given the necessity of the development of a costly regulatory program to govern importation so that FDA can ensure consumer safety, the purported cost savings of importation may never be realized. Without adequate resources and the time to train the requisite number of specialists to oversee such a critical program, the agency will be hard pressed to implement the necessary safeguards, provide the requisite oversight, and take appropriate enforcement actions to ensure that this Nation's drug supply system remains secure. Importation of unregulated imports should be banned if there is a less expensive generic already available to consumers here at home.

At a minimum, unregulated prescription drug importers should be required to establish that the proposed imported product has no lower cost generic equivalent approved in the United States. Cost savings from importation should be required to be passed along to the consumer.

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[6] 2010 PSM speech. Remarks as Delivered of Margaret A. Hamburg, M.D., Commissioner of Food and Drugs.

[7] http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/UCM235240.pdf.

[8] https://www.swissmedic.ch/aktuell/00673/03287/index.html?lang=en.

[9] http://www.fda.gov/Drugs/DrugSafety/ucm443217.htm.

[10] http://www.fda.gov/Drugs/DrugSafety/ucm431071.htm.

[11] http://www.fda.gov/Drugs/DrugSafety/ucm291960.htm.

[12] http://blogs.fda.gov/fdavoice/index.php/tag/fake-tamiflu/

[13] https://www.nabp.net/news/counterfeit-vicodin-es-sold-via-rogue-internet-drug-outlet-abbott-reports

[14] http://www.fda.gov/Drugs/DrugSafety/ucm169898.htm

Importation ignores the potential costs associated with medical treatment for consumers who have obtained poor quality drugs that do not work. Further, S.B. 175 ignores the costs associated with treating consumers of unregulated drugs that are contaminated or contain harmful ingredients. S.B. 175 also fails to account for the cost of treating consumers taking unregulated imported drugs that are improperly labeled.

Business Implications for U.S. Generic Manufacturers

Who should assume the risk under importation? (i.e., should liability be placed on the importer or end-user rather than the original manufacturer or the manufacturer believed to have produced the drug). We cannot predict how the cost of an importation oversight program will impact the future availability of FDA-approved generic drugs or the generic drug industry in the United States, possibly impacting the ability of manufacturers maintain U.S. facilities. Allowing for importation from Canadian, sellers will directly undermine the existing generic markets in the United States, effectively destroying generic manufacturers' ability to negotiate effectively with wholesalers in the United States. Importation from Canada will fundamentally alter the demand for those products, thereby shifting market dynamics there and preventing any real savings for US patients.

Immediate and Available Solutions for Lowering Prescription Drug Costs

There are tools available that help would immediately increase generic drug utilization and thereby savings: (1) educating consumers, physicians and states about the generic availability; 2) encouraging generic substitution; (3) employing benefit designs that incentivize the use of generics; and (4) ensuring their timely market entry. Every 1% increase in generic utilization will result in nearly a 1% increase in savings for prescription drug payers. AAM believes one answer to lowering prescription drug costs will be found in removing obstacles to improve access to generic medicines that already have FDA scrutiny, and already save consumers more than $10 billion each year.

Examples of US Generics Offering Savings that would not be realized through Importation:

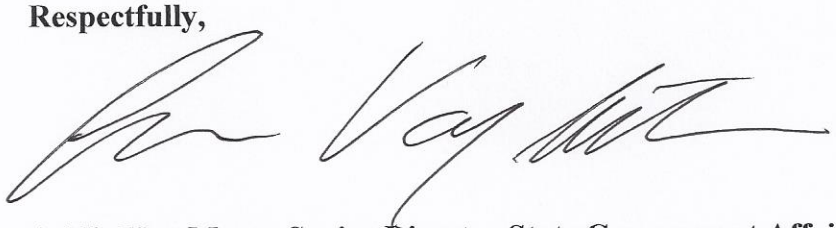
Generic Name	US as of December 2016	Canada List Prices as of March 2017
METFORMIN	0.19	0.07
GABAPENTIN	0.06	0.29
METOPROLOL	0.11	0.13
FLUTICASONE	0.04	6.00
LEVOTHYROXINE SODIUM	0.28	3.57
LISINOPRIL	0.02	0.22
ATORVASTATIN	0.12	0.41
AMLODIPINE	0.02	0.29

OMEPRAZOLE	0.08	0.49
TRAMADOL	0.04	1.58
ALPRAZOLAM	0.02	0.12
SIMVASTATIN	0.03	0.51
	0.28	0.14
CARVEDILOL	0.03	0.42
OXYCODONE	0.30	0.87
HYDROCHLOROTHIAZIDE	0.02	0.03
FUROSEMIDE	0.05	0.19
SALBUTAMOL	0.22	3.60

Conclusion

For the reasons cited herein, AAM respectfully opposes S.B 175. As such, AAM urges Members of the Committee to not support S.B. 175, and instead agree to work with AAM to increase generic utilization to realize cost savings.

Respectfully,



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