Written Testimony of
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Vermont General Assembly

Regarding H. 309 - An act relating to substitution of epinephrine auto-injector devices

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Chairman Lippert, Vice Chair Donahue, Ranking Member Briglin, members of the Committee, thank you for the opportunity to provide comments on H 309. On behalf of Mylan Specialty L.P., the distributor of EpiPen® and EpiPen Jr® Auto-Injectors (collectively, "EpiPen") and the authorized generic versions of those products, we believe H 309, while possibly well-intentioned, poses significant patient safety risks and respectfully urge the Committee to reject H 309.

Vermont's existing generic substitution laws carefully balance providing broader access and safeguarding patient health. This is accomplished by making available less expensive, generic drugs for substitution while limiting substitution to those generic drugs that the FDA has determined are therapeutically equivalent to the prescribed product. H. 309 would upend this balance by requiring a pharmacist to substitute an epinephrine auto-injector that has not been shown to be therapeutically equivalent. This would put patients at risk, and because anaphylaxis can quickly be fatal, that risk is unacceptable. For that reason, we oppose H 309.

We cannot overstate the risk. Epinephrine auto-injectors are prescribed for patients who may be at risk of anaphylaxis from any number of triggers, notably including certain foods, insect stings, and medications. Anaphylaxis, which is an extreme allergic reaction, can proceed to life-threatening effects in a matter of minutes. Moreover, the vast majority of epinephrine auto-injectors are used by patients – including children – or caregivers, not medical professionals, in extremely high-stress situations.

For that reason, epinephrine auto-injectors must be easy to use, and patients and caregivers must be trained in their use. This is reflected in how the EpiPen® and EpiPen Jr® Auto-Injectors and our authorized generic versions of them are made available to consumers. The FDA-approved labeling instructs healthcare providers to train patients and caregivers when prescribing the drug, and the product is packaged with a free trainer device for repetitive practicing. The goal is for the user, which may include the patient and many others in his or her daily network, to be so familiar and comfortable with the product that he or she can use it in an emergency quickly, safely and effectively.

These imperatives are also relevant to how generic epinephrine products are approved and substituted. As a general proposition, generic drugs are approved upon demonstrating to FDA's satisfaction that they are therapeutically equivalent to the reference product for which they will be substituted. Therapeutic equivalence means that the generic product can be expected to have the same safety and effectiveness as the reference product when used under the same conditions. FDA has recognized that, with products like epinephrine auto-injectors that are a combination of a drug and a medical device by which the drug is delivered, the therapeutic equivalence analysis must take into account the design and operation of the proposed generic

auto-injector, how similar or different it is to the already-approved delivery device, and the potential implications of any differences.

As FDA has explained, the key consideration is whether, despite the differences between the two devices, patients and caregivers who are trained on and familiar with the reference product auto-injector will, without any additional training or instruction on the new device, be able to safely and effectively use the proposed generic injector in an emergency. A "yes" answer to that question is necessary before FDA will approve a generic version of an epinephrine auto-injector. Accordingly, approval of a generic epinephrine auto-injector – and the associated Orange Book "A" rating of therapeutic equivalence that goes with it – reflects FDA's view that the generic product, if substituted for the reference product, will have the same safety and effectiveness profile. This finding, in turn, is the basis for substitution under any number of state pharmacy laws, including Vermont's.

This framework for interchangeability, which is incorporated into Vermont law and applicable to epinephrine auto-injectors, ensures that making less expensive generic drugs available – an important public health goal – does not come at the price of patient safety. H. 309 would undermine that balance by removing considerations of patient safety. The bill would require substitution of one epinephrine auto-injector for another, regardless of whether the products are therapeutically equivalent – that is, regardless of whether FDA has found that the generic product can be substituted without risk to patient safety.

In essence, the legislation assumes that all epinephrine auto-injectors are interchangeable, and that's a faulty assumption. There are three approved epinephrine auto-injectors currently marketed – EpiPen®, Auvi-Q®, and Adrenaclick®. Not only are these products not A-rated to each other; they are listed in the Orange Book with a "BX" therapeutic equivalence code, which

according to the FDA means the products are "presumed to be therapeutically *in*equivalent" to each other. Yet these are precisely the products that H. 309 would require a pharmacist to substitute. These are three products that do not look the same, do not feel the same, and do not work the same way. And because this is a product that a patient or caregiver has to be able to successfully deploy immediately and while under great stress, in a life-threatening situation, there is little room for error.

Here is just one example of a difference that can matter. With the EpiPen® Auto-Injector, when the patient or caregiver has administered the injection and removes the auto-injector from the thigh, the auto-injector automatically sheaths the needle and the product can be disposed of. Adrenaclick®, on the other hand, has an exposed needle when the auto-injector is removed from the thigh. In fact, Adrenaclick® users are told to look for the exposed needle, and if they do not see it, attempt another injection with the same auto-injector. A patient or caregiver trained on the EpiPen® device would not know to look for an exposed needle, would not be surprised with an Adrenaclick® that has no exposed needle (because that is what patients expect from using the EpiPen®), and therefore would not know that the lack of an exposed needle means the patient has received no injection. Such an error can potentially be fatal. Moreover, such an error is easily imaginable, when one recognizes – as FDA explicitly does in its analysis of proposed generic epinephrine auto-injectors – that a patient being dispensed a different product in substitution for his/her prescribed product is not likely to receive instruction or training with the new product.

Mylan well understands the concerns that have been raised about the cost of epinephrine auto-injectors, and we have taken significant steps to ensure wide access to this life-saving product. Among other things, Mylan has brought to market an authorized generic version of the EpiPen® Auto-Injector that is priced at half the cost of the branded EpiPen® product. . Mylan

has a coupon program and a patient assistance program that make the product available to many patients at a significantly reduced cost, and at no cost to uninsured or underinsured patients earning less than 400% of the federal poverty level. For example, a family of four earning less than $97,200 a year can receive EpiPen® Auto-Injectors for free. And finally, Mylan offers a savings card for eligible patients with commercial health insurance, providing up to $300 off the out-of-pocket cost for EpiPen® Auto-Injector and up to $25 off the out-of-pocket cost for the authorized generic. In January 2017, approximately 87% of consumers who received EpiPen® Auto-Injector or its authorized generic had an out-of-pocket cost of less than $50 and the vast majority paid less than $100. Mylan has also provided EpiPen® Auto-Injectors free of charge to more than 70,000 schools across the country, including 382 schools or 70% of schools in Vermont

Broadening patient access to epinephrine auto-injectors is a goal Mylan supports. Recent research suggests that only 50% of patients who need an epinephrine auto-injector have one – there is still work to be done on that front. The vast majority of patients who are prescribed an epinephrine auto-injector in Vermont are familiar with EpiPen® Auto-Injector. A switch in the device that patients receive without proper training and instruction would put a significant number of severe allergy patients in the state at risk during a life-threatening situation. To that end, Mylan would welcome the opportunity to work with the Committee in further developing ways to achieve that goal, because in our view, H. 309 is not the right way to do it.

Thank you for your time and consideration.