

# Spotlight on 2018 State Drug Legislation: Part 1 - Drug Importation: The Next Frontier for State-action to Control Prescription Drug Costs

*\*Update: This post was written before the end of the 2018 legislative session. For the most recent count of states that passed these legislation, see the [Spotlight on 2018 State Drug Legislation Summary: The Year in Review](#) or download our [Summary Chart](#).*

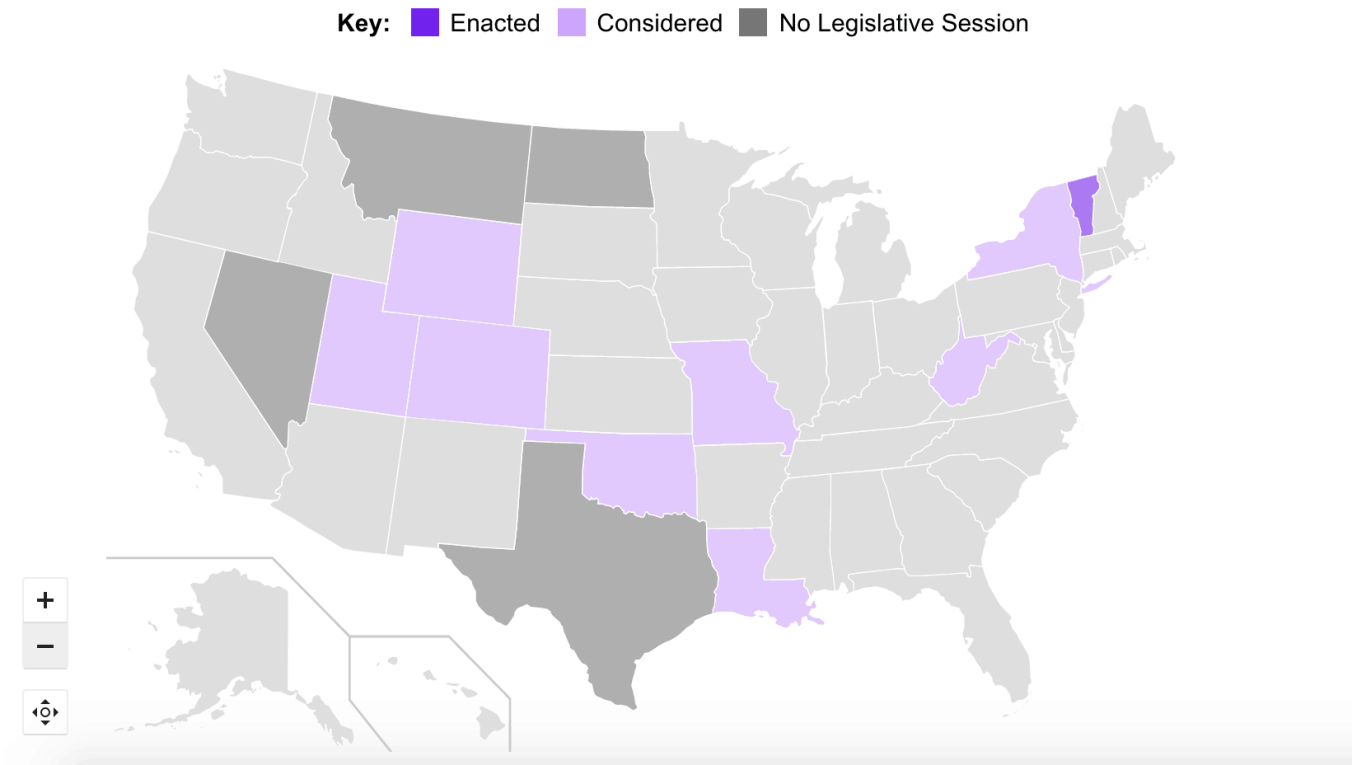
In the most recent legislative sessions, states have demonstrated they are increasingly willing to use their power to target prescription drug prices. In 2018, only two states with active legislative sessions, North Carolina and Alabama, did *not* consider legislation with the aim of reducing prescription drug costs. Of the forty-four states<sup>[1]</sup> that introduced bills, twenty-nine states passed legislation to address rising drug costs (see [2018 Legislation Map](#)). While the states were united in the objective of making prescriptions more affordable, the methods the laws employed varied substantially. For example, many states prohibited gag clauses in contracts between pharmacists and pharmacy benefit managers (PBMs) or prohibited pharmacies from collecting more money from insured patients for a prescription than they would pay if they did not have insurance (see [Pharmacy Gag Clause Regulation Map](#)). Other states prohibited price gouging by asking the attorney general to step in if a manufacturer doubles the list price for a generic drug in a given period. The Source will cover both of these types of laws and other state legislative efforts to control drug prices in future blog posts.

Nine states<sup>[2]</sup> however, considered a more drastic option in 2018 and proposed to import drugs from Canada for sale to their residents (see map below). In May 2018, Vermont Governor Phil Scott signed [S 175](#) into law, making Vermont the first state to begin development of a wholesale importation program for prescription drugs.

This post will discuss these state efforts to import drugs, examine how they fit into a nationwide effort to address drug prices, determine whether states can legally import drugs, and finally, analyze whether these efforts are likely to have the intended outcome of lowering drug prices for state residents.

## Drug Importation Legislation

Click on highlighted states to see drug importation legislation considered or enacted in the 2018 session. For more information, see the [Source Blog post](#) on state drug importation programs, with a specific analysis of Vermont's law passed in 2018.



## Drug Importation: the Federal Landscape

In 1987, Congress passed the Prescription Drug Marketing Act,[\[3\]](#) to establish legal guidelines to ensure safe distribution of pharmaceutical drugs and, as a result, restricted reimportation of drugs from other countries. Congress repeatedly considered, but never passed, legislation to amend this act and permit drug importation. For example, the Affordable and Safe Prescription Drug Importation Act of 2017[\[4\]](#) and the [Dorgan amendment](#) to the Affordable Care Act[\[5\]](#) would have

allowed patients and wholesalers to purchase drugs from other countries. In theory, Congress relaxed the Food and Drug Administration (FDA) regulation on drug importation through the Medicine Equity and Drug Safety Act, enacted in 2000,[\[6\]](#) and the Medicare Prescription Drug Improvement and Modernization Act of 2003.[\[7\]](#) Both laws allow prescription drugs manufactured in the United States and exported to certain foreign markets to be re-imported for sale in this country. Both pieces of legislation, however, include a provision stipulating that re-importation may occur only after the Secretary of the Department of Health and Human Services (HHS) determines that an adequate level of safety can be ensured for U.S. consumers. No HHS Secretary has ever certified that level of safety could be met, including former HHS Secretaries Donna Shalala and Tommy Thompson, who both concluded and publically announced that that these safety conditions could not be met.[\[8\]](#)

Most recently, on July 19, 2018, HHS [announced](#) that it is forming a working group to examine how the U.S. could import drugs from other countries. The HHS proposes to assess how importation could fit into a broader effort of legislative proposals and regulatory reforms that are part of President Trump's American Patients First Blueprint that targets prescription drug costs. HHS's plan will only consider drugs that are unprotected by patents or exclusivities (e.g. generic drugs) and "will be limited to cases where drugs can be imported with adequate assurances of safety and effectiveness."[\[9\]](#)

## **Drug Importation: the State Landscape**

Despite recent announcements by HHS, the federal government has historically been unwilling to allow importation of drugs from other countries. In response, many states considered implementing their own programs. [Vermont's law](#), for example, tasks the Agency of Human Services to create a state agency that will act as a licensed drug wholesaler to import drugs from Canada for sale to Vermont residents. The wholesaler will only import drugs "expected to generate substantial savings for Vermont consumers" and must "ensure that only prescription drugs meeting the U.S. Food and Drug Administration's safety, effectiveness, and other standards shall be imported".[\[10\]](#)

While Vermont's law reflects a new wave of state-based reimportation efforts, it is not the first. In 2013, Maine passed the Act to Facilitate the Personal Importation of Prescription Drugs from International Mail-Order Pharmacies<sup>[11]</sup> that would have allowed Maine residents to import prescription drugs from licensed pharmacies in Australia, Canada, New Zealand, and the United Kingdom. Pharmacists and pharmacy trade organizations, however, challenged the law and the U.S. District Court in Maine held that the law was preempted by the Federal Food, Drug, and Cosmetic Act (FDCA).<sup>[12]</sup> In light of the unconstitutionality of Maine's law, how could Vermont's law possibly survive legal challenges?

Vermont's law requires compliance with "the applicable requirements of [21 U.S.C. § 384](#), including the requirements regarding safety and cost savings".<sup>[13]</sup> This federal statute, also known as Section 804 of the Federal Food, Drug, and Cosmetic Act (FDCA),<sup>[14]</sup> is the code section added by the [Medicare Prescription Drug, Improvement, and Modernization Act of 2003](#), which Congress enacted to relax regulation on drug importation as discussed above. It gives the secretary of HHS the ability to approve drugs for reimportation and promulgate any regulations that he determines "appropriate as a safeguard to protect the public health or as a means to facilitate the importation of prescription drugs".<sup>[15]</sup> Because Vermont made its law subject to federal law 21 U.S.C. §384, the law is likely to survive constitutional challenges. That provision, however, also makes Vermont's importation program subject to approval by HHS. Until recently, most experts were skeptical that HHS would ever give such approval, but the announcement that HHS was creating a task force to explore drug importation should give supporters of the Vermont law some hope.

## **Can Drug Importation Work to Reduce Drug Prices?**

Assuming that HHS allows Vermont to implement an importation program, or the task force that it created allows drug importation, are those programs likely to reduce prices for American patients? In 2004, the Congressional Budget Office (CBO) [analyzed](#) the effects of importing drugs from other countries and found that importation of foreign-distributed prescription drugs would save only about \$40

billion over a period of 10 years, or *a mere 1% of drug spending* and, if importation were limited to drugs from Canada, the savings would be negligible.[\[16\]](#) The CBO noted that importation programs would likely eliminate international price differences because it would become difficult for manufacturers to charge different prices in different markets. Because the volume of drug sales in the U.S. is so high, manufacturers are likely to raise prices internationally in response to higher demand, rather than lower the prices charged in the United States.[\[17\]](#) While the exact savings calculated in the report are dated, many experts, including four former FDA Commissioners[\[18\]](#) and HHS Secretary Azar in his [prepared remarks](#) made in May 2018, agree that a widespread program of importing drugs from Canada would produce little savings and risks exposing Americans to counterfeit drugs and destabilizing the Canadian drug market.[\[19\]](#)

Upon further consideration, however, there may be reason for optimism. The CBO calculations showing lack of significant savings were based on drug importation programs that applied to all FDA-approved drugs. Instead of considering a program to allow importation of all FDA approved drugs, however, the HHS announcement in July 2018 suggests the department is considering a much more focused importation program that only allows importation for a limited type of drugs. Specifically, HHS announced that its working group “will examine the potential to promote competition for drugs that are off-patent or off-exclusivity and produced by one manufacturer. This stands in contrast to proposals to import a broader range of drugs, which raise additional questions about how to protect American patients.”[\[20\]](#)

While such single-source generic medications targeted by the HHS represent a small fraction of prescriptions dispensed, they have been the subject of public outcry and severely harmed patients who rely on these medications. Most famously, the “Pharma bro” and former CEO of Turing Pharmaceuticals, Martin Shkreli, raised the price of Daraprim, a drug that treats rare toxoplasmosis and cystoisosporiasis infections, from \$13.50 to \$750 per pill overnight.[\[21\]](#) Shkreli was able to impose an excessive price increase because he implemented a closed distribution system and thereby prevented generic competition from entering the market.[\[22\]](#) The threat of importation of drugs from Canada or other countries may deter drug companies from such anticompetitive practices.

Currently, if a drug manufacturer chose to increase the price of a drug by 5500% overnight (like Turing did for Daraprim), American patients must pay that price. Other countries, however, employ measures to negotiate prices for drugs directly, often based on cost-effectiveness (for a detailed discussion see The Source's issue brief on [international drug pricing](#)). Prices in other countries, therefore, would likely rise only slowly. If a drug importation program allowed American patients or government-approved wholesalers to purchase drugs from overseas following such a massive price increase, the effect of such drastic measures would be muted, because patients could import the drug at a lower price. Furthermore, as price for the generic drug increases, other generic manufacturers would consider entering the market, thereby increasing competition for that specific drug. As a result, an importation program would be most effective when used with other policies to increase competition, such as recent changes at the FDA to expedite review of applications for drugs where competition is limited.[\[23\]](#)

In summary, a targeted importation program as suggested in the HHS announcement serves primarily as a deterrent for anticompetitive behavior. It threatens competition in response to a manufacturer's gaming of inefficiencies in the pharmaceutical market, like the ability to eliminate competitors and charge excessively high prices in the period before other manufacturers get approval from the FDA to sell their products. Finally, limiting drug importation to only drugs that are not protected by patents, as the HHS announcement proposes, avoids the complicating issue of variation in patent laws between countries.[\[24\]](#)

While widespread drug importation programs may be unfeasible and economically ineffective, targeted programs that seek to address specific inefficiencies in the pharmaceutical market that limit competition may be more effective. It may be difficult to adequately measure the cost-effectiveness of such programs because they may serve as a deterrent to anticompetitive behavior rather than a method of obtaining cheaper prescriptions. Nonetheless, they remain a compelling new tool in the toolbox for addressing anticompetitive behavior in the pharmaceutical market. Additionally, while a federal program will provide the most pressure in preventing such behavior, HHS should consider allowing Vermont to act as an experimental

model for developing the best regulations to implement a state-run wholesale importation business.

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[1] Alabama, Montana, North Dakota, and Texas did not have a 2018 regular legislative session and therefore did not consider bills to address rising drug costs.

[2] The nine states are: Colorado, Louisiana, Missouri, New York, Oklahoma, Utah, Vermont, West Virginia, and Wyoming.

[3] P.L. 100-293, 102 Stat. 95

[4] The bill, S. 469 – 115<sup>th</sup> Congress (2017-2018), died in Committee.

[5] The proposed amendment, S.Amdt 2793 to H.R. 3590 – 111<sup>th</sup> Congress (2009-2010) Patient Protection and Affordable Care Act, failed to get the necessary 60 votes in the Senate, so it was withdrawn.

[6] P.L. 106-387, Oct. 28, 2000 (incorporating by reference H.R. 5426, containing the MEDS Act, § 745).

[7] Public Law 108-173- 108th Congress (2003-2004).

[8] **Imported Drugs Raise Safety Concerns.** U.S. Food and Drug Administration. <https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143561.htm>.

[9] **HHS Secretary Azar Directs FDA to Establish Working Group on Drug Importation to Address Price Spikes.** *HHS.gov*. July 19, 2018. <https://www.hhs.gov/about/news/2018/07/19/hhs-secretary-azar-directs-fda-establish-working-group-drug-importation-address-price-spikes.html>.

[10] 18 V.S.A. §4651. Wholesale Prescription Drug Importation Program.

[11] T S.P. 60, L.D. 171 126th Leg., 1st Reg. Sess. (Me. 2013), <http://www.mainelegislature.org/legis/bills/getPDF.asp?paper=SP0060&item=2&sn>



[um=126](#).

[12] *Ouellette v. Mills*, 91 F. Supp. 3d 1 (D. Me. 2015).

[13] 18 V.S.A. § 4651 (a). Wholesale Prescription Importation Program for Prescription Drugs.

[14] FDCA Act § 804 codified at [21 U.S.C. § 384](#).

[15] 21 U.S.C. §384 (c)(3).

[16] **Would Prescription Drug Importation Reduce U.S. Drug Spending?** *CBO Economic and Budget Issue Brief*. April 29, 2004.

[17] *Id.*

[18] McGinley, Laurie. **Four former FDA commissioners denounce drug importation, citing dangers to consumers.** *Washington Post*. March 17, 2017. [https://www.washingtonpost.com/news/to-your-health/wp/2017/03/17/four-former-fda-commissioners-denounce-drug-importation-citing-dangers-to-consumers/?noredirect=on&utm\\_term=.8b01528660eb](https://www.washingtonpost.com/news/to-your-health/wp/2017/03/17/four-former-fda-commissioners-denounce-drug-importation-citing-dangers-to-consumers/?noredirect=on&utm_term=.8b01528660eb)

[19]

<https://www.drugchannels.net/2018/05/the-trump-drug-plan-short-term-relieve.html>

[20] **HHS Secretary Azar Directs FDA to Establish Working Group on Drug Importation to Address Price Spikes.** *HHS.gov*. July 19, 2018. <https://www.hhs.gov/about/news/2018/07/19/hhs-secretary-azar-directs-fda-establish-working-group-drug-importation-address-price-spikes.html>.

[21] Pollack A. **Drug Goes From \$13.50 a Tablet to \$750, Overnight.** *The New York Times*. Published September 20, 2015. [https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html?\\_r=0](https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html?_r=0).

[22] Susan M. Collins and Claire McCaskill. **Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients,**



**Taxpayers, and the U.S. Health Care System.** *Special Committee on Aging*

*United States Senate.* December 2016. Available from:  
<https://www.collins.senate.gov/sites/default/files/Drug%20Pricing%20Report%20Unlocked.pdf>.

[\[23\]](#) **FDA Tackles Drug Competition to Improve Patient Access.** *U.S. FDA. New Release.* June 27, 2017.  
<https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm564725.htm>.

[\[24\]](#) For a detailed discussion of how the difference in patent laws complicates drug importation legislation, see: John R. Thomas **Patents and Prescription Drug Importation.** *Congressional Research Services.* October 4, 2016. Available from:  
<https://fas.org/sqp/crs/misc/R44640.pdf>.