to be factored into legislative efforts to block the work. Good policy requires that we confront these choices, not redefine reality or scientific method to avoid them.

Reasonable people may disagree about how to interpret data, but they do not ignore scientific method by giving credence to flawed, fraudulent, or misrepresented studies. They may disagree about the moral significance of fertilization, but they do not delete implantation from the stages of pregnancy and do not confuse the public debate by conflating opposition to abortion with opposition to contraception. They may disagree about the morality of using cadaveric fetal tissue for research, but they do not claim that it is useless. Ignoring, denying, or reimagining reality has real consequences for public policy and human health. Whether in the debates regarding climate change, evolutionary theory, or human reproduction, alternative facts are just fiction, and alternative science is just bad policy.

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The Price of Crossing the Border for Medications

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Canadians are used to paying more for identical products sold south of the border. Hockey equipment, perhaps paradoxically, can sometimes cost up to 18% more up north; and there are similar price differences for toiletries, books, and electronics. There are many reasons why goods cost more in Canada than in the United States, regardless of the value of the Canadian dollar, including higher costs of doing business (Canada has a higher minimum wage), lower purchasing power, and tariffs, among others.

Prescription medications, however, don't usually follow this pattern. According to a 2015 report from the Organization for Economic Cooperation and Development (OECD), in 2013 per capita prescription-drug spending in the United States (approximately $1,026 [U.S.]) exceeded that in all other countries, including Canada (approximately $713 [U.S.]) and was nearly twice the OECD average (approximately $515 [U.S.]). The high spending is related to two factors: market exclusivity and negotiating power.[1] In the United States, new drugs receive about 12 to 15 years of market exclusivity, on average, after being approved by the Food and Drug Administration (FDA), and biologic drugs can be free of direct competition for even longer. During the market-exclusivity period, the brand-name medication is protected against competition from generics, the manufacturer sets prices at whatever level the market will bear, and there is no limit on how much the price can increase each year. U.S. government payers are restricted in negotiating drug prices by various rules, such as those requiring coverage for many FDA-approved drugs (nearly all of them, in the case of Medicaid, and all in certain categories, in the case of Medicare Part D).

In Canada, as in other countries with a national health insurance system, government agencies or independent organizations negotiate drug prices with manufacturers and can recommend that coverage be rejected on the basis of a drug's cost, cost-effectiveness, or comparative effectiveness. The price of brand-name medications is also not allowed to increase more than the Consumer Price Index. Countries with a national drug-coverage system like those

found in the United Kingdom, Australia, and Sweden achieve even greater price concessions. Negotiation and price control in Canada partially explain why some of the most common brand-name medications have cash prices (the costs paid by people with no health insurance) that are a fraction of those in the United States.

A recent poll showed that about 8% of U.S. citizens purchase prescription drugs from Canada or other countries in order to obtain lower purchase prices,[2] and policymakers periodically propose institutionalizing that solution. The Food, Drug, and Cosmetic Act officially prohibits such importation, although the FDA has not generally enforced this prohibition for individuals importing products for their personal use. The agency has also occasionally overseen importation of drugs on an emergency basis to respond to shortages of key products.

Legislative attempts to authorize broader importation of Canadian drugs have never gained traction at the state or federal level and have been actively opposed by the brand-name pharmaceutical industry. In 2013, the Maine Pharmacy Act was passed to allow residents of that state to directly import their medications from registered pharmacies in Canada, the United Kingdom, New Zealand, or Australia. In 2015, however, a federal district court invalidated the law, holding that drug importation falls under the purview of the federal government.

On the national level, the 2003 Medicare Modernization Act, which established Medicare Part D, included a provision that would allow importation of medications if they are safe and provide cost savings. But that provision has never been implemented. More recent federal legislation has mostly stalled. In January 2017, in the face of widening public concern about the high cost of prescription drugs, Senators Bernie Sanders (I-VT) and Amy Klobuchar (D-MN) introduced a proposal to allow U.S. citizens to purchase prescription medications from an approved Canadian pharmacy; it was voted down 52 to 46. Some senators who voted against the measure said they worried that Canadian drugs were not safe.

Concerns about safety were also raised in a recent open letter to Congress from four past FDA commissioners. They argued, "drugs purchased from foreign countries might be substandard, unsafe, adulterated, or fake."[3] Though we certainly need to be vigilant about the quality of the prescription-drug supply, we know of no evidence of greater safety problems with medications sold in Canada; a bipartisan report from the Senate Special Committee on Aging in 2016 found that drug-safety standards are quite similar in Canada and the United States. Health Canada, the country's FDA equivalent, follows rigorous standards to ensure the safety of pharmaceuticals, including inspections and application of the World Health Organization's standards for Good Manufacturing Practices (GMPs).[4] In 2014 to 2015, a total of 97% of Canadian drug manufacturing sites were deemed GMP-compliant.[4] Of the nondomestic manufacturing sites for Canadian drugs, approximately one quarter are actually in the United States. Most medications sold in the United States — whether brand-name or generic drugs — are manufactured outside the country and, in that sense, are already being imported. The FDA has well-established procedures for ensuring the safety of these "foreign" products.

Sanders and other senators have also drafted the Affordable and Safe Prescription Drug Importation Act to address the issue of the safety of Canadian drugs.[2] The proposal includes development of a regulatory system that would allow Canadian pharmacies and wholesale distributors to become "certified foreign" sellers.[2] To earn the designation, the seller must be in Canada, be a distributor of prescription drugs offered for importation, be established for 5 years or more, provide medications only if there is a valid prescription, comply with applicable Canadian laws and regulations, conduct regular quality assurance, allow regular laboratory testing, notify all parties of product recalls, have a process for resolving rule violations, not sell products that are illegal in Canada, and meet any additional criteria implemented by the secretary of health and human services.[2] Canadian pharmacies would also have to pay a user fee for additional FDA monitoring. The proposal requires that within 18 months after its implementation, the Government Accountability Office evaluate the drug safety, consumer savings, and regulatory expenses of the importation process. The bill would expand to include importation from other OECD countries after 2 years, to help protect Canada's drug supply for Canadians.

Although the proposed law provides clear safeguards for medication importation, there are other

U.S. and Canadian Prices of Some Generic Drugs with U.S. Prices That Have Recently Increased by 1000% or More.*

Drug	United States		Canada	
	GoodRx	NADAC	Saskatchewan	Ontario
	U.S. $/30 pills			
Tetracycline, 500-mg capsule	892.33	255.90	3.00	3.00
Captopril, 50-mg tablet	55.00	48.00	6.26	12.51
Clomipramine, 25-mg capsule	568.75	212.70	8.90	3.93
Doxycycline, 100-mg tablet	146.00	19.20	13.11	13.11
Hydroxychloroquine, 200-mg tablet	108.33	22.86	6.76	3.53
Amitriptyline, 100-mg tablet	14.00	28.86	10.51	6.89
Enalapril, 20-mg tablet	20.80	10.86	10.31	7.15
Carbamazepine, 200-mg tablet	37.00	18.00	5.30	3.45
Ursodiol, 250-mg capsule	97.00	99.00	22.83	17.09

* The GoodRx cost represents the cash price and does not include rebates or coupons. NADAC denotes National Average Drug Acquisition Cost (from the Centers for Medicare and Medicaid Services). The Saskatchewan and Ontario prices listed are provincial formulary prices.

hurdles to be considered. Manufacturers holding patents on brand-name medications could limit the supply of drugs to Canadian pharmacies that sell drugs to Americans. (The Sanders bill makes this practice illegal, but it's unclear how such a rule could be enforced.) This possibility represents an important barrier for brand-name drugs, but it wouldn't apply to generic medications made by multiple manufacturers.

One report showed that the U.S. prices of at least 50 older generic medications increased by 400% or more between 2012 and 2015.[5] Prices increased by 3516% for albuterol sulfate, 1649% for enalapril, and 1309% for fluoxetine.[5] For some generic drugs for which the U.S. prices have recently increased by 1000% or more, Canadians pay a fraction of what Americans do (see table).

Importing medications from Canada or elsewhere may help address the cost of essential medicines — particularly generic drugs — by allowing competition when it's currently lacking. Several proposals have been put forward to address U.S. drug pricing, but many entail fundamental changes to the marketplace or long-term time horizons. The high costs of medications for chronic conditions (e.g., inhalers for asthma, antihypertensives, and antidepressants) and lifesaving drugs (e.g., epinephrine autoinjectors, insulin) are currently preventing millions of Americans from purchasing them, with worrisome clinical consequences. The health and safety risks faced by the many Americans who cannot afford medications necessitate consideration of alternative strategies to provide less expensive medications. Importing safe and effective medications from countries with more patient-friendly drug pricing, including our neighbors to the north, represents one potential solution.

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