Negative Brief: Insulin Imports

By “Coach Vance” Trefethen

The AFF plan allows / encourages US pharmacies and drug wholesalers, as well as individuals going online, to order insulin from France, Denmark and Germany.

Negative: Insulin Imports 3

TOPICALITY 3

1. No change in policy. Imported insulin is already increasing in the US today 3

Imports of insulin into the US doubled between 2004 - 2016. 3

Violation: No reform of policy 3

Impact: Negative ballot 3

INHERENCY 3

1. Sanofi. Sanofi solved the price competition problem in June 2022 3

$35/month. Sanofi pharmaceutical company lowered insulin price to $35/month 3

2. Eli Lily. Eli Lily on March 1, 2023, completely solved 3

Eli Lilly announced price reductions with maximum cost of $35 or less per month for all patients using insulin 3

No need for the Affirmative plan: Eli Lilly price reduction takes effect immediately (March 1, 2023) 4

3. Affordable Care Act. The ACA (also known as "Obamacare") solves for the poor 4

ACA insurance for low-income Americans means the poor are unlikely to spend more than $35/month on insulin 4

Anyone can get ACA health insurance and the government gives financial assistance so anyone can afford it 4

HARMS / SIGNIFICANCE 4

1. A/T "Spending $1000/month" 4

Response #1: Sanofi solves - cross apply INH-1 4

Response #2: Even before Sanofi, a 2020 study found only 5% of patients spending more than $200/month 5

SOLVENCY 5

1. Misdiagnosing the root cause. AFF blames "lack of imports" for "lack of competition" but that's not it 5

Response #1: Not in their evidence. 5

Response #2: Patents on delivery devices are blocking new insulin suppliers from entering the market 5

Response #3: Competitors are blocked because alternative insulins aren't being approved for sale 5

FDA is blocking competition by not approving alternatives 6

Response #4: We're already importing, so the problem should have been solved by now 6

2. No increased export capacity in AFF's 3 export countries 6

Affirmative burden: Must prove the 3 countries can meet the need 6

France: Nope. They import most of their insulin and are the largest importer of Insulin in the world 6

Germany: Already done. USA is the number 1 destination for German insulin exports ($1.18 billion/year) 7

Denmark: Nope. Their exports are declining 7

3. Can't avoid the oligopoly 7

The US insulin market is an "oligopoly" - a market with only 3 suppliers who can avoid competition and function almost like a monopoly. But they control the global market too - so any imports would come from those same companies 7

Barriers to entry block other companies. "Big Three" manufacturers will still control the market 7

Impact: No solvency 7

4. Non-approved suppliers wouldn't solve 8

Even if all the other suppliers (outside the current 3) had their products approved by the FDA (which they currently aren't), it still wouldn't solve for supply and affordability of insulin in the USA without several other (extra-topical) policy changes 8

THESE ARGUMENTS BELOW (Solvency 5,6, and 7) APPLY IF AFF SAYS IMPORT OF "RETAIL" INSULIN IS DIFFERENT FROM WHOLESALE 8

5. Won’t solve for drug prices 8

Cost of government regulatory apparatus would erase any possible savings 8

6. Lack of enforcement 9

FDA wouldn't be able to enforce safety standards on imported drugs 9

Not easy to enforce US laws and regulations on foreign vendors. Example: Canada Drugs in 2014 9

7. Already tried and failed 9

Illinois: 2006 study found costs of administration outweighed savings 9

DISADVANTAGES 10

1. Global shortages outweigh the benefits 10

Importing insulin would create big global disruptions with devastating effects 10

2. Dangerous drugs 10

Link: No safety regulations in the AFF plan 10

Link: Without safety standards, insulin imports would be dangerous 10

Link: Importation = more counterfeit drugs 10

Example: Maine tried drug imports from Canada in 2013 and got counterfeits and hazardous drugs 10

Impact: Sickness and death 11

3. Loss of pharmaceutical R&D 11

Artificially reducing drug prices means reduction in future research that could have made new drug discoveries 11

OECD Study finds almost 1:1 (actually 1 to 0.97) relationship between R&D spending and drug company revenues 11

Drug company revenues aren't just "free money" - It's reinvested for future drug discovery efforts 12

Impact: Negative net benefits. Lost opportunity of new drugs outweighs present benefit of lower prices 12

Impact: Net benefits. Long-term benefit justifies higher prices 12

Negative: Insulin Imports

TOPICALITY

1. No change in policy. Imported insulin is already increasing in the US today

Imports of insulin into the US doubled between 2004 - 2016.

Warren Kaplan, Abhishek Sharma, Prof. Eric Kolaczyk, and Heather Shappell 2016. (Kaplan and Sharma are with Boston University School of Public Health. Kolaczyk - Department of Mathematics and Statistics at Boston Univ. Shappell - Dept of Biostatistics Boston Univ.) INSULIN TRADE PROFILE, Apr 2016 (accessed 1 Mar 2023) https://www.researchgate.net/publication/299883692\_Insulin\_Trade\_Profile/link/58057e6108aef87fbf3bbfcf/download

Similarly, the global trade in imported insulins is dominated by high-income countries. Approximately 50 percent of the global imports of retail insulin between 2004 and 2013 were from the US, United Kingdom(UK), Germany, and Japan, with the US being the predominant importer. The imports of retail insulin (by value) into the US have doubled since 2004.

Violation: No reform of policy

Endorsing the Status Quo is not a significant reform of anything. The Affirmative team isn't affirming the resolution.

Impact: Negative ballot

If the Affirmative won't affirm, then the only choice is a Negative ballot.

INHERENCY

1. Sanofi. Sanofi solved the price competition problem in June 2022

$35/month. Sanofi pharmaceutical company lowered insulin price to $35/month

Kevin Dunleavy 2022 (journalist) 29 June 2022 "With Congress weighing insulin cost cap, Sanofi slashes price for uninsured in US" (accessed 23 Feb 2023) https://www.fiercepharma.com/pharma/us-close-capping-insulin-costs-some-sanofi-slashes-price-uninsured-us

With Congress weighing a cap on out-of-pocket costs for insulin for certain individuals, Sanofi has beaten the government to the punch. The Paris-based company [says](https://www.news.sanofi.us/2022-06-29-Sanofi-to-lower-out-of-pocket-cost-of-insulin-for-uninsured-patients-and-expand-access-in-underserved-communities) it will slash the price of its fleet of insulin products to uninsured residents of the U.S. from $99 per month to $35.

2. Eli Lily. Eli Lily on March 1, 2023, completely solved

Eli Lilly announced price reductions with maximum cost of $35 or less per month for all patients using insulin

Eli Lilly & Co. press release 2023. (manufacturer of Insulin) 1 March 2023 "Lilly Cuts Insulin Prices by 70% and Caps Patient Insulin Out-of-Pocket Costs at $35 Per Month" (accessed 2 Mar 2023) https://investor.lilly.com/news-releases/news-release-details/lilly-cuts-insulin-prices-70-and-caps-patient-insulin-out-pocket

Eli Lilly and Company (NYSE: LLY) today announced price reductions of 70% for its most commonly prescribed insulins and an expansion of its Insulin Value Program that caps patient out-of-pocket costs at $35 or less per month. Lilly is taking these actions to make it easier to access Lilly insulin and help Americans who may have difficulty navigating a complex healthcare system that may keep them from getting affordable insulin.

No need for the Affirmative plan: Eli Lilly price reduction takes effect immediately (March 1, 2023)

NBC News 2023. (journalist Berkeley Lovelace Jr.) 1 Mar 2023 "Drugmaker Eli Lilly caps the cost of insulin at $35 a month, bringing relief for millions" (accessed 2 Mar 2023) https://www.nbcnews.com/health/health-news/eli-lilly-caps-cost-insulin-35-month-rcna72713

Eli Lilly will cap the out-of-pocket cost ofits insulin at $35 a month, the drugmaker said Wednesday. The move, experts say, could prompt other insulin makers in the U.S. to follow suit. The change, which Eli Lilly said takes effect immediately, puts the drugmaker in line with a [provision in the Inflation Reduction Act](https://www.nbcnews.com/health/health-news/republicans-block-insulin-price-cap-really-gone-rcna42177), which in January imposed a $35 monthly cap on the out-of-pocket cost of insulin for seniors enrolled in Medicare.

3. Affordable Care Act. The ACA (also known as "Obamacare") solves for the poor

People in the Affirmative's evidence who are spending "too much" on insulin are people who have chosen to go without health insurance. It's their choice to do that, but they can't complain about the consequences.

ACA insurance for low-income Americans means the poor are unlikely to spend more than $35/month on insulin

Krutika Amin, Gary Claxton, Matthew Rae and Cynthia Cox 2022 (Amin - Associate Director at Kaiser Family Foundation for the Program on the Affordable Care Act. ) 24 Mar 2022 "Out-of-pocket spending on insulin among people with private insurance" (accessed 23 Feb 2023) https://www.healthsystemtracker.org/brief/out-of-pocket-spending-on-insulin-among-people-with-private-insurance/

We find that among enrollees in the individual and small group markets taking insulin, over 1 in 4 (26% and 31%, respectively) paid more than an average of $35 per month out-of-pocket for insulin in 2018. Low-income ACA Marketplace enrollees receiving significant cost-sharing assistance were less likely to have out-of-pocket insulin costs averaging over $35 per month.

Anyone can get ACA health insurance and the government gives financial assistance so anyone can afford it

Prof. Timothy Stoltzfus Jost 2018 (emeritus professor at the Washington and Lee University College of Law) "Health Care in the United States and the Affordable Care Act" (accessed 25 Feb 2023) (ethical disclosure about the date: Article is undated but references events in 2018 in the past and events in 2019 in the future) <https://www.americanbar.org/groups/crsj/publications/human_rights_magazine_home/the-state-of-healthcare-in-the-united-states/healthcare-in-us-aca/>

The ACA also established health insurance consumer protections to ensure that private insurance coverage would be available to all applicants, regardless of their medical conditions. Insurers were prohibited from refusing coverage or increasing premiums based on health status or for excluding preexisting conditions from coverage. To ensure that private markets would be sustainable while covering individuals with high health care needs, the ACA included an individual responsibility requirement to encourage healthy as well as unhealthy people to purchase coverage. The ACA also included an employer responsibility mandate to encourage large employers to continue to provide health coverage. Importantly, the ACA also offered premium tax credits to assist low- and moderate-income individuals and families in paying for coverage. The premium tax credits are available for individuals with incomes up to 400 percent of the federal poverty level, although the amount of assistance phases down as income increases. The tax credits ensure that health insurance remains affordable because the tax credits increase as premiums increase.

HARMS / SIGNIFICANCE

1. A/T "Spending $1000/month"

Response #1: Sanofi solves - cross apply INH-1

With the Sanofi reductions, nobody will spend more than $35/month.

Response #2: Even before Sanofi, a 2020 study found only 5% of patients spending more than $200/month

[Berkeley Lovelace Jr.](https://www.nbcnews.com/author/berkeley-lovelace-jr-ncpn1284341), Reynolds Lewis and Gadi Schwartz 2022 (journalists for NBC News) 29 Dec 2022 "Insulin costs will be capped in 2023, but most people with diabetes won't benefit" (accessed 23 Feb 2023) https://www.nbcnews.com/health/health-news/insulin-cost-cap-people-diabetes-no-benefit-rcna58165

A report published in 2020 in [JAMA Network Open](https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2766587) found that in 2017, the average monthly out-of-pocket cost for insulin for people with a high-deductible insurance plan was $141. High-deductible plans usually have lower monthly premiums, but require the insured to pay much more out-of-pocket before coverage kicks in. More than 50% of insulin users with employer-based insurance spent over $35 out-of-pocket on average for a 30-day supply of insulin in 2019 and 2020, according [to the Health Care Cost Institute](https://healthcostinstitute.org/diabetes-and-insulin/price-of-insulin-prescription-doubled-between-2012-and-2016), a nonprofit group that tracks drug prices. About 5% of them spent more than $200.

SOLVENCY

1. Misdiagnosing the root cause. AFF blames "lack of imports" for "lack of competition" but that's not it

Response #1: Not in their evidence.

None of their evidence says "lack of imports" is the cause for why there's not enough competition in the US insulin market. The impact is that they can't solve because they're not addressing the actual problem.

Response #2: Patents on delivery devices are blocking new insulin suppliers from entering the market

Ryan Knox 2020 (Solomon Center for Health Law and Policy, Yale Law School) 9 Oct 2020 JOURNAL OF LAW & THE BIOSCIENCES "Insulin insulated: barriers to competition and affordability in the United States insulin market" (accessed 27 Feb 2023) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8249113/

Even though there are very few insulin products that have patent protection on the compound itself, the vast majority of insulin products still have patent protection on the pens and other devices that deliver the dose of insulin. Novo Nordisk has patents for Novolog, Novolin, and FIASP products; Sanofi has patents on the devices for all of its products; and Eli Lilly still has patents on some devices that deliver Humulin and Humalog. The patent protection on the devices is significant. Because the pens and other insulin delivery devices can only be used on with one brand of insulin, competition on those products is effectively delayed. While a prospective competitor could develop a follow-on biologic or biosimilar of the insulin, it would have to develop its own delivery device. This may only be a partial barrier, but with the popularity of pens and pumps and the inability for interoperable devices, the device patent protection serves as a notable obstacle to competitor entry—the focus of the next part.

Response #3: Competitors are blocked because alternative insulins aren't being approved for sale

Ryan Knox 2020 (Solomon Center for Health Law and Policy, Yale Law School) 9 Oct 2020 JOURNAL OF LAW & THE BIOSCIENCES "Insulin insulated: barriers to competition and affordability in the United States insulin market" (accessed 27 Feb 2023) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8249113/

Introducing competitor insulin products in the United States—including biosimilar insulins—could improve affordability and accessibility of insulin. The current regulatory environment, however, is in a state of transition and does not promote the approval of biosimilar insulins.

FDA is blocking competition by not approving alternatives

Ryan Knox 2020 (Solomon Center for Health Law and Policy, Yale Law School) 9 Oct 2020 JOURNAL OF LAW & THE BIOSCIENCES "Insulin insulated: barriers to competition and affordability in the United States insulin market" (accessed 27 Feb 2023) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8249113/

A further regulatory barrier to biosimilar insulin competition is interchangeability. Unlike generics, biosimilars are not automatically substitutable with the biologic. To be interchangeable, a manufacturer must demonstrate that the product (1) is ‘biosimilar’ to the reference product, (2) ‘can be expected to produce the same clinical result as the reference product’, and (3) does not pose a greater risk ‘in terms of safety or diminished efficacy’ compared to the reference product if a patient were to switch or alternate use.  The FDA to date has only approved 19 biosimilar products of any kind,  and no biosimilar has yet received interchangeability status.  This outlook is not supportive of seeking approval of an interchangeable biologic, which may be necessary for effective market entry and competition.

Response #4: We're already importing, so the problem should have been solved by now

Warren Kaplan, Abhishek Sharma, Prof. Eric Kolaczyk, and Heather Shappell 2016. (Kaplan and Sharma are with Boston University School of Public Health. Kolaczyk - Department of Mathematics and Statistics at Boston Univ. Shappell - Dept of Biostatistics Boston Univ.) INSULIN TRADE PROFILE, Apr 2016 (accessed 1 Mar 2023) https://www.researchgate.net/publication/299883692\_Insulin\_Trade\_Profile/link/58057e6108aef87fbf3bbfcf/download

Approximately 50 percent of the global imports of retail insulin between 2004 and 2013 are due solely to the US, UK, Germany, and Japan, with the US being the predominant importer (Figure 8). Among these four countries, their imports (as percentage of global value) are fairly constant over time, except for the US, whose imports of retail insulin have doubled since 2004.

2. No increased export capacity in AFF's 3 export countries

**Note that all of this evidence updates their 2004 solvency card from Dr. Miron at Cato (which they cite "accessed date" from 2023 because they don't want to read the actual date it was published). And Miron's card doesn't even specifically mention insulin.**

Affirmative burden: Must prove the 3 countries can meet the need

Warren Kaplan, Abhishek Sharma, Prof. Eric Kolaczyk, and Heather Shappell 2016. (Kaplan and Sharma are with Boston University School of Public Health. Kolaczyk - Department of Mathematics and Statistics at Boston Univ. Shappell - Dept of Biostatistics Boston Univ.) INSULIN TRADE PROFILE, Apr 2016 (accessed 1 Mar 2023) https://www.researchgate.net/publication/299883692\_Insulin\_Trade\_Profile/link/58057e6108aef87fbf3bbfcf/download

In developing a response to the issue of access to insulin, it is crucial to understand its global need. Only a few companies dominate the market so the question, without large scale manufacturing/export from India or China or any other emerging economy, is whether the three main multinational companies can meet the global demand for insulin.

France: Nope. They import most of their insulin and are the largest importer of Insulin in the world

Volza Grow Global 2022. (international import/export research firm) Insulin import data of France from India - 108 import shipments 29 Apr 2022 (accessed 27 Feb 2023) https://www.volza.com/p/insulin/import/import-in-france/coo-india/

As per Volza’s France Import data, Insulin import shipments from India stood at 108, imported by 12 [France Importers](https://www.volza.com/p/insulin/buyers/buyers-in-france/) from 8 [India Suppliers](https://www.volza.com/p/insulin/manufacturers/manufacturers-in-india/). France imports most of its Insulin from [India](https://www.volza.com/p/insulin/import/coo-india/) and is the largest importer of Insulin in the World.

Germany: Already done. USA is the number 1 destination for German insulin exports ($1.18 billion/year)

Observatory of Economic Complexity 2020 (online data visualization and distribution platform focused on the geography and dynamics of economic activities. The OEC integrates and distributes data from a variety of sources to empower analysts in the private sector, public sector, and academia. The OEC is currently designed and developed by Datawheel, but it began as a research project at MIT's Collective Learning group) "Insulin, in dosage in Germany" (accessed 27 Feb 2023) https://oec.world/en/profile/bilateral-product/insulin-in-dosage/reporter/deu?redirect=true (brackets added)

In 2020, [Germany](https://oec.world/en/profile/country/deu) exported $2.81B[illion] in [Insulin, in dosage](https://oec.world/en/profile/hs92/insulin-in-dosage), making it the 1st largest exporter of [Insulin, in dosage](https://oec.world/en/profile/hs92/insulin-in-dosage) in the world. At the same year, [Insulin, in dosage](https://oec.world/en/profile/hs92/insulin-in-dosage) was the 65th most exported product in [Germany](https://oec.world/en/profile/country/deu). The main destination of [Insulin, in dosage](https://oec.world/en/profile/hs92/insulin-in-dosage) exports from [Germany](https://oec.world/en/profile/country/deu) are: [United States](https://oec.world/en/profile/country/usa)($1.18B), [Hungary](https://oec.world/en/profile/country/hun)($122M[illion]), [Algeria](https://oec.world/en/profile/country/dza)($120M), [Spain](https://oec.world/en/profile/country/esp)($107M), and [Saudi Arabia](https://oec.world/en/profile/country/sau)($88.3M).

Denmark: Nope. Their exports are declining

Warren Kaplan, Abhishek Sharma, Prof. Eric Kolaczyk, and Heather Shappell 2016. (Kaplan and Sharma are with Boston University School of Public Health. Kolaczyk - Department of Mathematics and Statistics at Boston Univ. Shappell - Dept of Biostatistics Boston Univ.) INSULIN TRADE PROFILE, Apr 2016 (accessed 1 Mar 2023) https://www.researchgate.net/publication/299883692\_Insulin\_Trade\_Profile/link/58057e6108aef87fbf3bbfcf/download

In 2004, Denmark exported the vast majority of the world’s bulk insulin by value (Figure 12). Danish exports have diminished over time and are being replaced by exports of bulk insulin from Germany, as clearly shown in Figure 12. The US and France exported a trivial fraction in 2004 and continue not to export much insulin in bulk form.

3. Can't avoid the oligopoly

The US insulin market is an "oligopoly" - a market with only 3 suppliers who can avoid competition and function almost like a monopoly. But they control the global market too - so any imports would come from those same companies

Ryan Knox 2020 (Solomon Center for Health Law and Policy, Yale Law School) 9 Oct 2020 JOURNAL OF LAW & THE BIOSCIENCES "Insulin insulated: barriers to competition and affordability in the United States insulin market" (accessed 27 Feb 2023) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8249113/

The insulin market in the United States is highly concentrated. Only three companies—Novo Nordisk, Sanofi, and Eli Lilly—supply insulin to patients in the United States. These three companies are commonly called the ‘Big Three’ because they control over 90 per cent of the global insulin market. The remaining share of the global insulin market is split among approximately seven insulin manufacturers.

Barriers to entry block other companies. "Big Three" manufacturers will still control the market

Ryan Knox 2020 (Solomon Center for Health Law and Policy, Yale Law School) 9 Oct 2020 JOURNAL OF LAW & THE BIOSCIENCES "Insulin insulated: barriers to competition and affordability in the United States insulin market" (accessed 27 Feb 2023) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8249113/

Policies to prevent these anticompetitive pricing strategies and lower the entry barriers should be contemplated alongside these competition-promoting strategies. Further antitrust enforcement in the insulin market could deter anticompetitive conduct on the part of the Big Three. Even so, the barriers to entry are so significant and the market control of the Big Three so complete that they deter competition in the first place. Without substantial reforms, the insulin market will likely remain insulated from competition.

Impact: No solvency

Importing more from the same three companies we're already buying from today doesn't solve anything.

4. Non-approved suppliers wouldn't solve

Even if all the other suppliers (outside the current 3) had their products approved by the FDA (which they currently aren't), it still wouldn't solve for supply and affordability of insulin in the USA without several other (extra-topical) policy changes

Ryan Knox 2020 (Solomon Center for Health Law and Policy, Yale Law School) 9 Oct 2020 JOURNAL OF LAW & THE BIOSCIENCES "Insulin insulated: barriers to competition and affordability in the United States insulin market" (accessed 27 Feb 2023) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8249113/

Outside of the United States, there are a few biosimilar human insulin and analog insulin products available. For example, in addition to the Big Three products discussed above, there are several other insulin products manufactured for the Indian market by other large manufacturers, including Biocon and Wockhardt.  Wockhardt, an Indian manufacturer, launched the first insulin analog in Asia in 2003.  Biocon, an Indian manufacturer, received approval for an insulin glargine biosimilar in Japan in 2016 and in Mexico in 2015, in cooperation with its local partner Pisa Pharmaceuticals. Studies have demonstrated that reciprocal approval policies would greatly increase the number of generic products available in the United States, reaching four or more approved manufacturers for 39 per cent of the products studied if reciprocal approval applied to seven non-United States regulators. This would have a lesser impact on complex drugs like biologics, although the study did not single out insulin.  Due to the complexity of biologics, the study suggested first permitting reciprocal generic drug approval for small molecule drugs and excluding complex drugs (like insulins). If interchangeability could be achieved and the system were effective and trusted, this could eventually be a means to increase competition in the insulin market. Even so, other local reforms would need to be instituted to increase supply and affordability as well as address the failures in the biosimilar market and approval process.

THESE ARGUMENTS BELOW (Solvency 5,6, and 7) APPLY IF AFF SAYS IMPORT OF "RETAIL" INSULIN IS DIFFERENT FROM WHOLESALE

…which their plan doesn't specify. To gain their advantages, they would probably have to import retail insulin and import the European price controls that go with it, which their plan also doesn't mention (no price controls).

5. Won’t solve for drug prices

Cost of government regulatory apparatus would erase any possible savings

Liam Sigaud 2019 (*works on economic policy and research for the American Consumer Institute, a nonprofit educational and research organization*) 9 Sept 2019 " Drug Importation: High Risk, Low Reward" <https://www.realclearhealth.com/articles/2019/09/09/drug_importation_high_risk_low_reward_110943.html> (accessed 29 May 2022)

Constructing an oversight apparatus capable of closely monitoring drug imports from abroad would be so costly as to erase any economic benefits from importation. Even if we ignore safety concerns over poorly regulated imported drugs, the cost savings from importation would likely be negligible. When the nonpartisan Congressional Budget Office (CBO) [examined](https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/04-29-prescriptiondrugs.pdf) a similar proposal in 2005, it found that “permitting the importation of foreign-distributed prescription drugs would produce at most a modest reduction in prescription drug spending in the United States” -- on the order of 1 percent of total spending.

6. Lack of enforcement

FDA wouldn't be able to enforce safety standards on imported drugs

Dr. Nigel S.B. Rawson and Louise Binder 2017 (Rawson - PhD in pharmacoepidemiology;   pharmaceutical policy researcher in Saskatoon, Saskatchewan, Canada. Binder - LLD; attorney; co-founder of the Canadian Treatment Action Council, an HIV advocacy organization) "Importation of drugs into the United States from Canada" CANADIAN MEDICAL ASSOCIATION JOURNAL 19 June 2017 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5478407/> (accessed 5 June 2022)

Third, the FDA lacks the resources needed to oversee a major importation program, as recently stated by four former FDA commissioners in a March 2017 letter to Congress.  Without a large increase in resources, the FDA would not be able to certify each seller’s credentials under the act, which implies that the program would rely on self-certification. Adequate certification of sellers is crucial because, as the former commissioners highlighted, ineffective accreditation may lead to “substandard, unsafe, adulterated or false” drugs being purchased by Americans.

Not easy to enforce US laws and regulations on foreign vendors. Example: Canada Drugs in 2014

Shabbir Imber Safdar 2021 (Executive Director, Partnership for Safe Medicines, a not-for-profit that accepts no corporate members or donations; members are other nonprofits and trade associations that represent manufacturers, wholesalers, pharmacists, and patients) 18 Jan 2021 Executive Director, Partnership for Safe Medicines, <https://www.ndlegis.gov/assembly/67-2021/testimony/HIBL-1250-20210118-972-A-SAFDAR_SHABBIR.pdf> (accessed 29 May 2022)

If a serious violation does occur, holding a Canadian vendor responsible will not be easy. Even if the case warrants the involvement of the U.S. Department of Justice, that does not mean that justice will be easy to achieve. For example, CanadaDrugs.com was indicted in November 2014 for selling $78 million worth of unapproved, mislabeled, and counterfeit cancer drugs to doctors across the U.S. including North Dakota. The Canadian defendants spent years objecting to the case until a deal was brokered. In April 2018, the CEO of CanadaDrugs.com finally stood in a U.S. courtroom and admitted to the widespread illegal sale of misbranded and counterfeit drugs. No one involved received even a one-day jail sentence. The fines and forfeiture came to just over $34 million.

7. Already tried and failed

Illinois: 2006 study found costs of administration outweighed savings

Shabbir Imber Safdar 2021 (Executive Director, Partnership for Safe Medicines, a not-for-profit that accepts no corporate members or donations; members are other nonprofits and trade associations that represent manufacturers, wholesalers, pharmacists, and patients) 18 Jan 2021 Executive Director, Partnership for Safe Medicines, <https://www.ndlegis.gov/assembly/67-2021/testimony/HIBL-1250-20210118-972-A-SAFDAR_SHABBIR.pdf> (accessed 29 May 2022)

The theory that importing drugs from Canada will allow patients to see significant savings is just that: a theory. Many states looking into drug importation have applied a blanket 45% increase to the Canadian, but no state actually knows if this number is accurate. While no state has yet to operate an HHS-approved drug importation program, some have tried and there are lessons to be learned from them. Illinois operated a program called i-SaveRx in the mid-2000s. The Office of the Auditor General released a report in 2006 that showed the program was expensive for the state to run:
● Twenty-eight agencies reported that 521 employees provided almost 5,600 hours of assistance at an estimated payroll cost of $488,000.
● Illinois had significant expenditures on the program, including travel, contractual services, marketing, and legal services. Additionally, no state discussion importation to date has actually addressed the cost of testing outlined above. Testing alone is sufficient to make most every importation program financially unworkable.

DISADVANTAGES

 1. Global shortages outweigh the benefits

Importing insulin would create big global disruptions with devastating effects

Ryan Knox 2020 (Solomon Center for Health Law and Policy, Yale Law School) 9 Oct 2020 JOURNAL OF LAW & THE BIOSCIENCES "Insulin insulated: barriers to competition and affordability in the United States insulin market" (accessed 27 Feb 2023) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8249113/

By expanding the United States insulin market to include other countries, companies could be incentivized to raise the prices at a global scale, aggravating the global problem of access to medicines. Legalized importation would likely also influence the trade routes, which could negatively impact the global supply. Other countries could suffer decreased sales, disruptions to supply, higher prices, and delayed access to new prescription drugs.

2. Dangerous drugs

Link: No safety regulations in the AFF plan

Check the mandates, there aren't any.

Link: Without safety standards, insulin imports would be dangerous

Ryan Knox 2020 (Solomon Center for Health Law and Policy, Yale Law School) 9 Oct 2020 JOURNAL OF LAW & THE BIOSCIENCES "Insulin insulated: barriers to competition and affordability in the United States insulin market" (accessed 27 Feb 2023) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8249113/ (brackets in original)

Limitations on importation would be needed to make it a safe, viable option. First, there would likely need to be guidelines on where individuals can import insulin from. The FDA is considered the gold standard for drug approval, and removing limitations on which regulatory approvals are adequate could incentivize a ‘race to the bottom’. A study by Gupta et al. recommends only allowing importation of prescriptions from ‘manufacturers approved by non-[United States] peer regulators with strong safety records under a baseline set of requirements for approval’.

Link: Importation = more counterfeit drugs

Liam Sigaud 2019 (*works on economic policy and research for the American Consumer Institute, a nonprofit educational and research organization*) 9 Sept 2019 " Drug Importation: High Risk, Low Reward" <https://www.realclearhealth.com/articles/2019/09/09/drug_importation_high_risk_low_reward_110943.html> (accessed 29 May 2022)

And foreign countries like Canada have [made it clear](https://www.safemedicines.org/2019/03/drug-importation-claim-vs-fact-at-florida-senate-subcommittee-hearing.html) that Americans shouldn’t expect them to monitor the safety of drugs being shipped to the U.S. “There’s no question that a drug importation scheme will increase the flow of counterfeits in the U.S. supply chain,” [wrote](https://www.forbes.com/sites/scottgottlieb/2016/03/04/why-trump-is-wrong-on-drug-prices/#4decbe892e74) former FDA Commissioner Scott Gottlieb in 2016.

Example: Maine tried drug imports from Canada in 2013 and got counterfeits and hazardous drugs

Shabbir Imber Safdar 2021 (Executive Director, Partnership for Safe Medicines, a not-for-profit that accepts no corporate members or donations; members are other nonprofits and trade associations that represent manufacturers, wholesalers, pharmacists, and patients) 18 Jan 2021 Executive Director, Partnership for Safe Medicines, <https://www.ndlegis.gov/assembly/67-2021/testimony/HIBL-1250-20210118-972-A-SAFDAR_SHABBIR.pdf> (accessed 29 May 2022)

While Maine is currently attempting to run a state-sponsored drug importation program, the state did allow a personal drug importation program beginning in 2013. Long before a federal judge ruled that the law was in violation of federal law, counterfeit and substandard medicine was being illegally shipped into the state. The former head of the Maine Pharmacy Association filed a lawsuit after testing of drugs he purchased showed that all of the drugs did not have enough active pharmaceutical ingredients and one of them had an unknown, potentially hazardous contaminate. While Maine’s law required the medications to be sourced from a limited set of countries, the medications received came from unapproved countries anyway (India, Mauritius, and Turkey.)

Impact: Sickness and death

Liam Sigaud 2019 (*works on economic policy and research for the American Consumer Institute, a nonprofit educational and research organization*) 9 Sept 2019 " Drug Importation: High Risk, Low Reward" <https://www.realclearhealth.com/articles/2019/09/09/drug_importation_high_risk_low_reward_110943.html> (accessed 29 May 2022)

Opening the door to counterfeit drugs from abroad would not only endanger the health of those who took the drugs but also anyone taking a similar drug. Just a few unsafe capsules could trigger massive nationwide recalls, creating shortages and discontinuities of care for millions of patients. In 1982, for example, 31 million bottles of Tylenol were [removed](https://www.pbs.org/newshour/health/tylenol-murders-1982) from circulation after seven people died from pills laced with potassium cyanide. Imagine the effects of a similar recall of insulin or other life-saving medicine triggered by a tainted shipment of foreign products.

3. Loss of pharmaceutical R&D

Artificially reducing drug prices means reduction in future research that could have made new drug discoveries

Dr. Joe Kennedy 2019 (law degree and a master’s degree in agricultural and applied economics from the University of Minnesota and a Ph.D. in economics) 9 Sept 2019 " The Link Between Drug Prices and Research on the Next Generation of Cures" <https://itif.org/publications/2019/09/09/link-between-drug-prices-and-research-next-generation-cures> (accessed 5 June 2022)

For the issue of pharmaceutical drugs, an overwhelming body of academic research shows that price controls will significantly restrict the number of new drugs in the future. The pharmaceutical industry is the epitome of a dynamic high-tech industry, wherein the profits from one generation of products go to pay the high development costs for the next generation. Artificially reducing drug revenues today will not only cause companies to cut back on their future research—meaning the next generation will benefit less from new drug discoveries—it will jeopardize U.S. leadership in an industry that punches above its weight in funding research and employing scientists.

OECD Study finds almost 1:1 (actually 1 to 0.97) relationship between R&D spending and drug company revenues

**[This means if revenues go up 1%, R&D research spending goes up almost 1%, or 0.97%]**

Dr. Joe Kennedy 2019 (law degree and a master’s degree in agricultural and applied economics from the University of Minnesota and a Ph.D. in economics) 9 Sept 2019 " The Link Between Drug Prices and Research on the Next Generation of Cures" <https://itif.org/publications/2019/09/09/link-between-drug-prices-and-research-next-generation-cures> (accessed 5 June 2022)

The Organization for Economic Cooperation and Development (OECD) conducted a detailed study of this issue in the pharmaceutical industry. It found that “[p]harmaceutical pricing and reimbursement policies stand to affect innovation through multiple channels, influencing both the incentives to invest in private R&D and the costs of investment. The main channel of prospective influence is the impact of pricing and reimbursement policies on the expected return on investment in R&D.” In fact the generation of large revenues is closely related to the amount of research an individual company does. Figure 9 shows R&D expenditures and sales of the 151 largest pharmaceutical firms in the world in 2006. There was clearly a very strong correlation (0.97).

Drug company revenues aren't just "free money" - It's reinvested for future drug discovery efforts

Dr. Joe Kennedy 2019 (law degree and a master’s degree in agricultural and applied economics from the University of Minnesota and a Ph.D. in economics) 9 Sept 2019 " The Link Between Drug Prices and Research on the Next Generation of Cures" <https://itif.org/publications/2019/09/09/link-between-drug-prices-and-research-next-generation-cures> (accessed 5 June 2022)

In order to maximize social welfare with limited resources, policymakers need to appreciate the costs and benefits of each decision they make. In the context of drug prices, they need to clearly understand the strong link between current revenues (which may or may not be the same as consumer prices) and the generation of future drugs. Put simply, drug companies must make significant profits on their best-selling drugs in one generation in order to reinvest in the next generation. A large portion of these “profits” goes to three sources before they are available for distribution to shareholders. First, the revenues must cover the costs of the high number of failed research efforts, most of which generate no revenues. Second, they must pay for the long delays between initial research and product sales. These capital expenditures account for roughly half of the total costs of developing new drugs. Finally, a large portion of the remainder goes into new research on the next generation of drugs.

Impact: Negative net benefits. Lost opportunity of new drugs outweighs present benefit of lower prices

Dr. Joe Kennedy 2019 (law degree and a master’s degree in agricultural and applied economics from the University of Minnesota and a Ph.D. in economics) 9 Sept 2019 " The Link Between Drug Prices and Research on the Next Generation of Cures" <https://itif.org/publications/2019/09/09/link-between-drug-prices-and-research-next-generation-cures> (accessed 5 June 2022)

The creation of net benefits also extends to future drugs. Reduced biomedical innovation would increase future health care costs and slow improvements in health and longevity. The Alzheimer’s Association recently evaluated the current cost of treating the disease.  By 2050, 16 percent of Americans 65 or older will suffer from some stage of Alzheimer’s, with 6.5 million individuals in the severe stage of needing round-the-clock care. The cost of treating Alzheimer’s that year will be $1.2 trillion in 2019 dollars. The report estimates that discovering a drug in 2025 that would delay the onset of Alzheimer’s by 5 years would reduce the cost of treatment in 2050 by one-third. Savings in the first 10 years alone would total $935 billion.

Impact: Net benefits. Long-term benefit justifies higher prices

Dr. Joe Kennedy 2019 (law degree and a master’s degree in agricultural and applied economics from the University of Minnesota and a Ph.D. in economics) 9 Sept 2019 " The Link Between Drug Prices and Research on the Next Generation of Cures" <https://itif.org/publications/2019/09/09/link-between-drug-prices-and-research-next-generation-cures> (accessed 5 June 2022)

The granting of a monopoly through patents and other intellectual property protection has a positive effect on product development—which in the case of drug companies, is on research, development, and testing. While market power from intellectual property protection may reduce short-term welfare, it increases long-term welfare by encouraging more investment and innovation. This is why the Founding Fathers included patent protection in the Constitution.