

# Canada: The New Drugstore for America or Entering the Deep Freeze?

ISPOR 2021 – Issue Panel  
Monday May 17, 2021 11:45 – 12:45 EDT

Moderator: Jill Crich

Panellists: András Incze , John Adams, Lou Garrison

# The Issue

**US Prescription Drug Prices 256%  
Higher Than Other Countries**

**Trump Approves Final Plan to Import Drugs  
From Canada 'for a Fraction of the Price'**

**Canada blocks some bulk prescription drug  
exports to U.S. to prevent shortages**

**Colorado Advances Plan To Import  
Drugs From Canada**

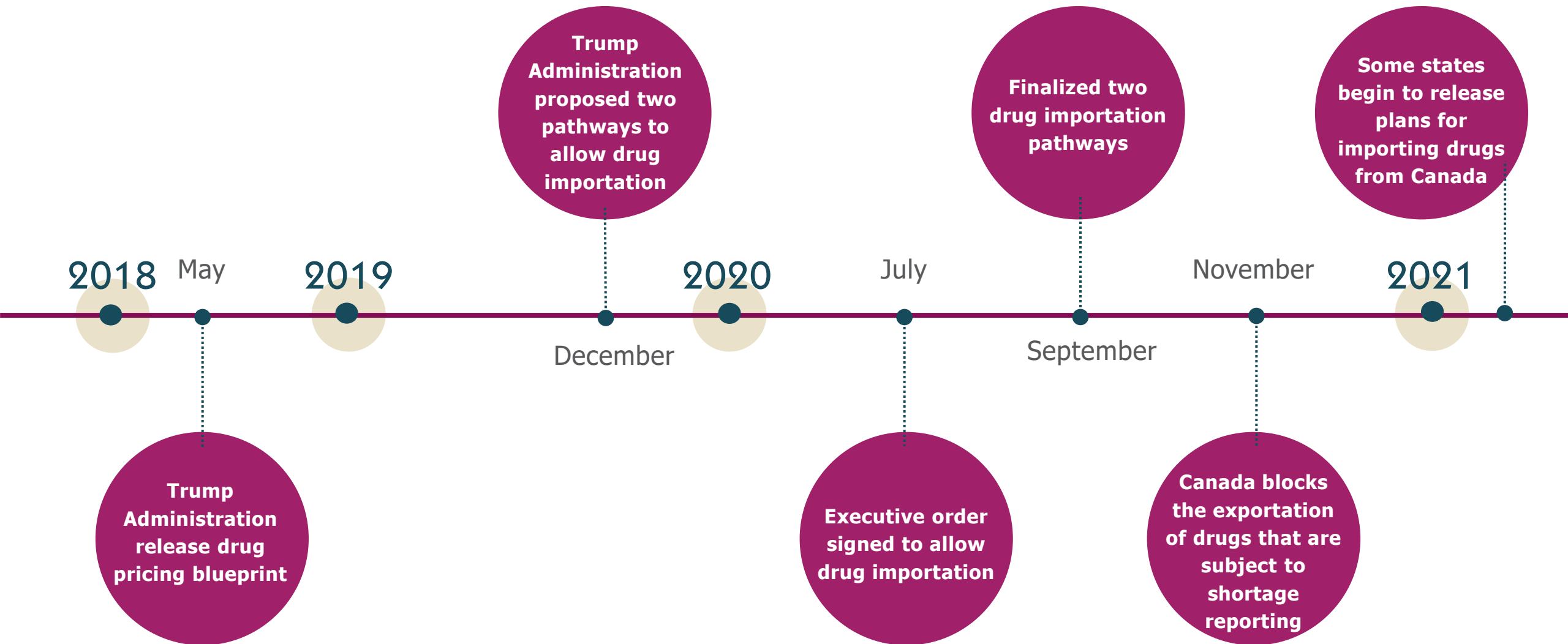
**PhRMA Files Suit to Stop Drug Importation  
from Canada**

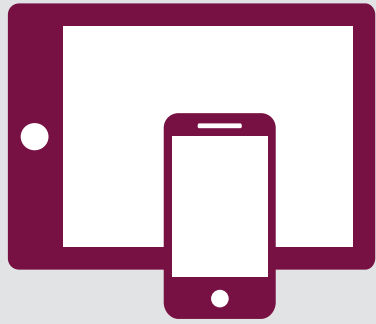
**Experts Uncertain If the President's  
Drug Import Plan Will Save  
Consumers Money**

**Why Importing Drugs From  
Canada Won't Fix High Drug Costs**

**Canadians are hopping mad about  
Trump's drug importation plan. Some of  
them are trying to stop it**

# The Issue





Do you think a US drug re-importation plan with Canada is a viable solution to reduce prescription drug costs in the United States?



Yes



No

# The Panel



**András Incze**

CEO and Founder, Akceso Advisors



**John Adams**

Board Chair Member, Best Medicines Coalition



**Lou Garrison**

Professor, University of Washington



- Each panellist will speak for ~12 minutes
- There will then be a ~15 minute discussion session



- Questions from the audience are encouraged and will be answered during the discussion session
- At the end of the issue panel the audience will vote again on the central question

# European Framework for Parallel Trade and Lessons for Canada

András Incze, Akceso Advisors (12 minutes)



Akceso Advisors AG



# CANADA: THE NEW DRUGSTORE FOR AMERICA OR ENTERING THE DEEP FREEZE? THE EUROPEAN PERSPECTIVE

**András Incze**

Akceso Advisors AG, Basel, Switzerland and Baden-Württemberg State University, Germany



Package of a parallel imported medicine  
Deutsche Apotheker Zeitung 2011, Nr. 40, S. 102

VIRTUAL ISPOR 2021 – IP1

17<sup>th</sup> May, 2021

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# **No conflict of interest to report for the current topic of Parallel Trade, US / Canada.**

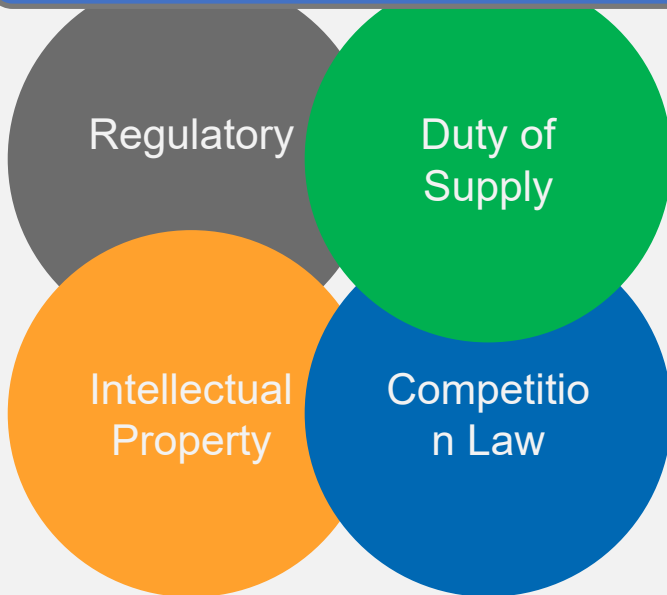
Akceso Advisors has received unrestricted research funding from PhRMA on International Reference Pricing research, not applied for the underlying research of this presentation.



# European & Country Framework for Parallel Trade (PT) is complex

A DYNAMIC ACROSS MANY PLAYERS: BRAND OWNERS, PARALLEL TRADERS, REGULATORS AND PATIENTS

Parallel Trade: the distribution of a medicinal product from one EU Member State to another by a company independent of the marketing-authorization holder



## Key areas of the Framework

### Regulatory – Opportunities for parallel importers

- What activities are A) required B) allowed ?

### Intellectual Property Rights – Limitations for brand owners

- What Rights exist ?
- When are Rights exhausted ?

### Competition Law – Opportunities for brand owners

- What unilateral company practices are allowed ?
- What is an Agreement, and what can be agreed ?
- What is a Dominant Position & what is an Abuse of it?

### Duty-of-Supply country laws – Opportunities for patients

- How do exporting countries protect supply?
- How do brand owners react?

# PT is a business opportunity for Importers

## CAPTURING LARGE SHARE OF ARBITRAGE PROCEEDS

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- Free movement of goods within EU allows parallel import of medicines from other EU
- Limited adaptation required/allowed – e.g. relabelling via a sticker, local package insert
- Payers may mandate or offer preferred treatment to prescribing and dispensing PT meds
- Parallel Traders yearly turnover est. \$6 billion
- Represents about 3% of the overall EU market. BUT can be 100% of a brand in a market.
- Ca. 100 companies engaged in parallel trade in EU employing up to 15,000 people
- Impacts the majority of patent protected Rx, with very few exceptions
- Typically larger share of the arbitrage is kept by parallel importer, only smaller share passed on to the payer in the importing country

# PT is a challenge for brand owners – pharma manufacturers

LIMITATIONS STEM FROM IP RIGHTS, OPPORTUNITIES FROM APPLICATION OF COMPETITION LAW

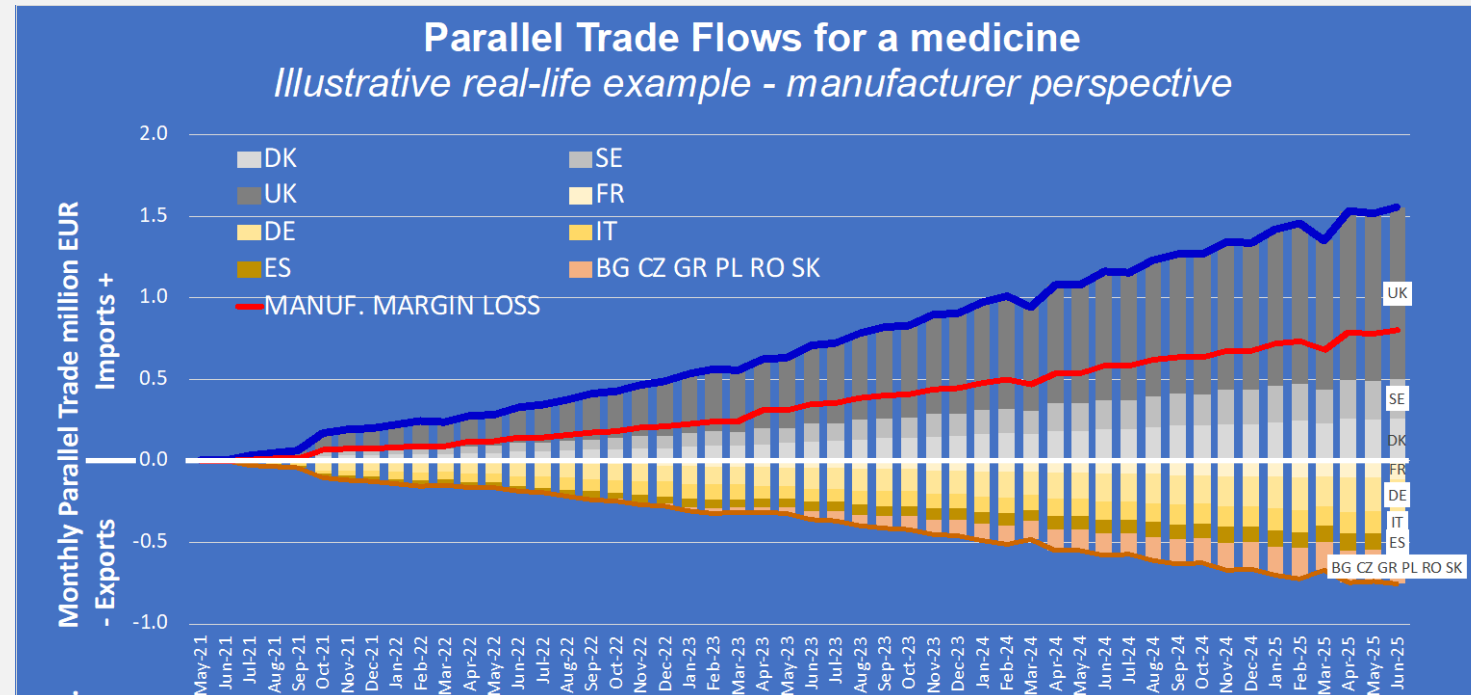
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- Brand owners – manufacturers – cannot “stop” parallel trade
- Due to parallel trade of their drugs however they face :
  - Patient access disruptions
  - Margin loss
  - Manufacturing challenges
  - Supply challenges
  - Company Management Incentive Bonus Scheme challenges
- Brand owners may unilaterally implement ‘distribution management’ practices to address their challenges.

# Brand owners may successfully address their challenges while adhering to local and international laws and regulations

MEDICINE BRAND OWNERS MAY MANAGE SUPPLY TO ENSURE LOCAL PATIENTS ARE BEING SERVED

- Brand owners – pharma manufacturers – applying **distribution management** can limit the shortages for patients stemming from parallel export.
- As result of appropriate measures, the operational challenges may be eased and supply will flow (mainly) towards satisfying local patient demand

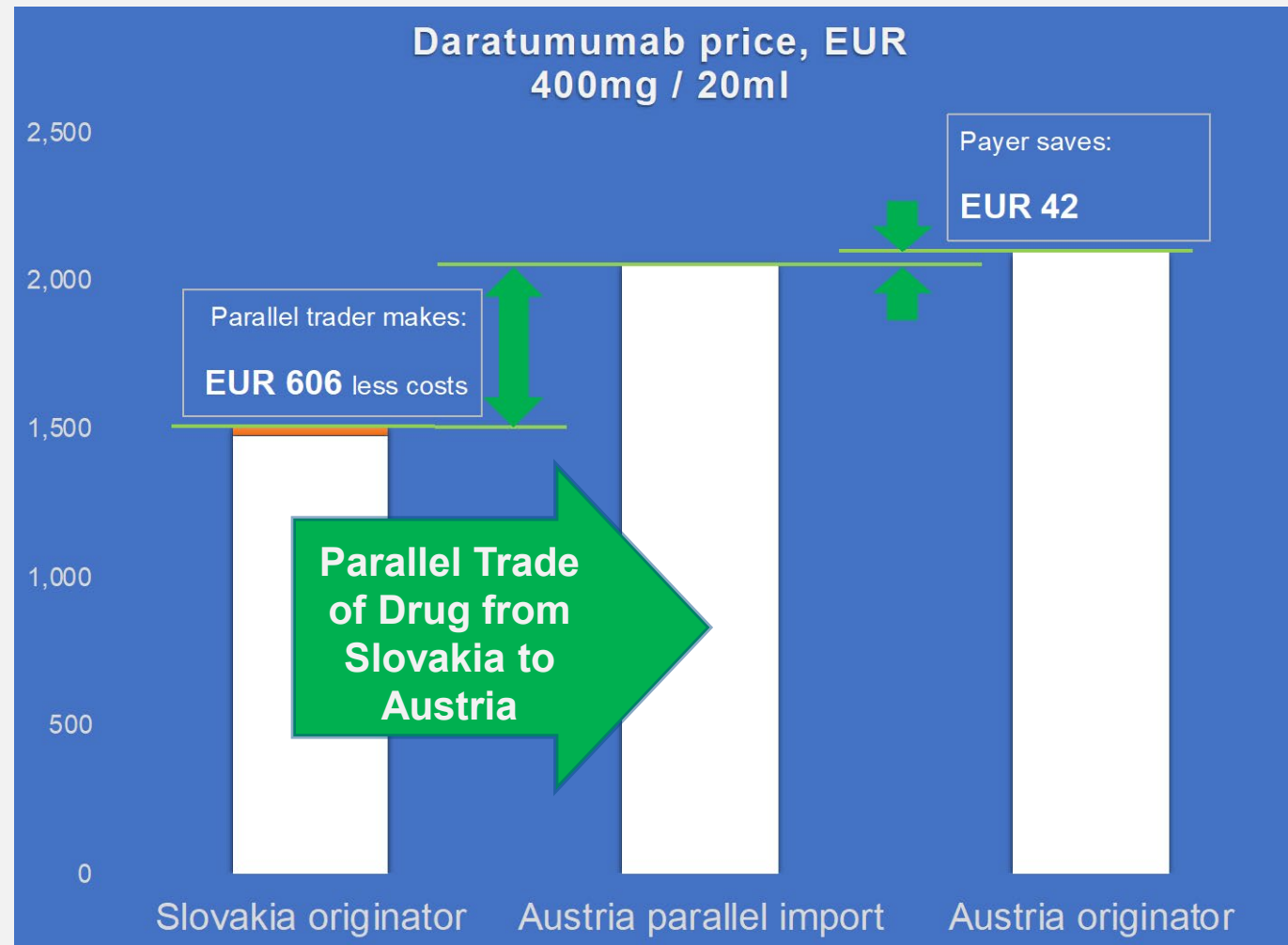


**As a side effect of appropriate distribution management: manufacturer's margin loss would be reduced, by 31%**

Source: Akceso Advisors, Jan 2021

# Payers capture only a limited share of the pie

THE LION'S SHARE OF THE ARBITRAGE GOES TO THE PARALLEL TRADER



**Typical example of parallel traded drug arbitrage sharing:**

**94% to PT company,  
6% to Payer**

Source: Akceso Advisors, May 2021

# PT's unintended consequence: lack of availability to local patients

IN THE LOWER-PRICED "EXPORT" COUNTRIES

Shortages in **47 countries** covered in 2019's newsletters, including all EU Top 5 and USA



### What caused the shortages?

- ▲ (E-)Procurement & tendering
- ▲ Distribution disruption
- ▲ Manufacturing interruptions
- ▲ Foreign exchange impacts
- ▲ Cost containment measures
- ▲ Parallel imports
- ▲ Reaction to hospital debt
- ▲ Fraud
- ▲ Poor planning
- ▲ Sanctions
- ▲ Strikes



### Range across countries

80	760
Meds	Meds

### Most common therapeutic areas

1. Hypertension
2. Analgesic/pain
3. Cancer
4. Central Nervous System
5. Vaccines
6. 'Hospital

© Akceso 2019

## Patients in countless countries face shortages

All types of drugs impacted:

- specialist and GP
- acute and chronic
- hospital and retail
- most therapy areas

A major underlying cause is inefficient

## Parallel Trade

Canada itself faced shortages for **23% of the drugs, 5 months each\***

\*CTV News, September 1, 2020



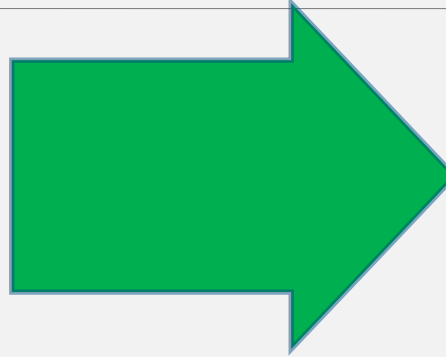
## Slovakia – a small EU country

### Case study for attempting to ensure patient supply

#### OPPORTUNITIES AND LIMITATIONS FOR DUTY-OF-SUPPLY LAWS



- Small EU country, 5.5M inhabitants
- IRP price referencing at the lowest price
- In effect: List prices = Net prices



Slovakia is a favored export market for parallel traders

- Severe stock-outs of hard-to-substitute medicines by 2016
- In their EU Presidency role in 2016: **“Elaboration of appropriate monitoring instruments relating to medicines shortages due to parallel export and to measure the access to valuable innovative medicines in the context of resilient and sustainable healthcare systems in Europe.”**
- Law put in place to fine companies up to 1m€ if unable to supply
- Stock-outs temporarily were reduced
- Companies found workaround to avoid fine when stock-out threat
- New legislation under discussion in 2021 to eliminate workaround option



# Some learnings for Canada and US

PARALLEL IMPORTER COUNTRY PATIENTS SELDOM BENEFIT, EXPORTERS OFTEN SUFFER



## Canada

To avoid unavailability to local patients, several levers may need to be pulled on national and provincial level and by private drug manufacturers:

- Regulatory “Dos” to ensure local supply – “Company Carrots”
- Regulatory “Don’ts” to avoid export causing patient access shortages – “Company Sticks”
- Private Company incentive bonus schemes should reward fulfilment of local demand and discourage export push if it leads to shortage – “Company Executive Carrots and Sticks”

If an appropriate policy and legal framework is designed and implemented in Canada – and by companies – **Canada may not need to go to supply-deep-freeze her patients**, irrespectively of what other countries are legislating.



## US

EU experience shows that import country Payers **reap only a minor share of the benefit** of parallel imports, at the cost of higher admin burden and complexity



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**Thank you for joining!**

**Andras Incze**  
[aincze@akceso.ch](mailto:aincze@akceso.ch)

# Canada is Not Equipped to Participate in a Drug Re-importation Plan with the US

John Adams, Best Medicines Coalition (12 minutes)



**BEST  
MEDICINES COALITION**

***Canada: The New Drugstore for America or  
Entering the Deep Freeze?***

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**ISPOR Issue Panel  
May 17, 2021**

# Best Medicines Coalition: Who We Are

Alliance for Access to  
Psychiatric Medications

Arthritis Consumer Experts  
JointHealth

Asthma.ca  
Asthma Society of Canada

braintumour  
foundation  
OF CANADA

CAPA  
Canadian Arthritis  
Patient Alliance

CAPP+ACPP  
Canadian Association of Psoriasis Patients  
Association canadienne des patients atteints de psoriasis

CBCN  
RCCS

CANADIAN CANCER  
SURVIVOR NETWORK

CANADIAN COUNCIL  
OF THE BLIND

LE CONSEIL CANADIEN  
DES AVEUGLES

Canadian  
Cystic Fibrosis  
Treatment Society

Canadian  
epilepsy  
Alliance

Alliance  
canadienne de  
l'épilepsie

Canadian Hemophilia Society  
Help Stop the Bleeding  
Société canadienne de l'hémophilie  
Arrêtons l'hémorragie



Canadian  
Psoriasis  
Network  
Réseau  
canadien  
du psoriasis

A  
CSPA  
P  
D  
Canadian Skin Patient Alliance  
Alliance canadienne des  
patients en dermatologie

Canadian  
Spondylitis  
Association

CANCERTAINTY  
EQUAL AND FAIR CANCER TREATMENT FOR ALL

Crohn's and  
Colitis Canada  
Crohn et  
Colite Canada

Cystic Fibrosis  
Canada

FIGHTING  
BLINDNESS  
CANADA  
VAINCRE  
LA CÉCITÉ  
CANADA

HEALTH COALITION  
OF ALBERTA

Huntington Society of Canada  
HUNTINGTON  
Société Huntington du Canada

Cancer  
du rein  
CANADA  
Kidney  
Cancer  
CANADA

LYMPHOMA  
CANADA

Medical Cannabis Canada  
PatientAccess.ca

Medicines Access Coalition - BC

MILLIONS MISSING CANADA

Ovarian Cancer Canada  
Cancer de l'ovaire Canada

Parkinson Canada

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# Best Medicines Coalition: Our Mission

***Ensuring all Canadians have safe and timely access to medications that have been shown, based on best available evidence, to improve outcomes for patients***

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# Disclosures: Personal & Financial

- Widower: spouse died without a diagnosis
- Father of an adult child with a rare disorder
- Co-founder & President, Canadian PKU and Allied Disorders
- Board Chair & Founding Trustee, Global Association for PKU
- Board Chair, Best Medicines Coalition (BMC)
- Co-chair, Disability Tax Fairness Alliance
- Member, Citizen Advisory Group, Ontario Health Care Professionals regulatory colleges
- Past Chair, Canadian Organization for Rare Disorders (CORD)

# Reality Check: Comparing Canada & USA

## *Size matters:*

- Canada has 1/9<sup>th</sup> the population of USA and about 1/9<sup>th</sup> the drug supply at best
- Manufacturers allot pharmaceutical supply based on market by country
- Canadian allotment can't accommodate our needs and USA demands
- Most drugs & APIs for Canadians are made abroad; Canada lacks power or authority to “ramp up” production



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# Reality Check: Critical Supply Issues

## *Canadian drug supply challenges:*

- 1:4 Canadians experienced/know someone who experienced a drug shortage in the last 3 years
- Pharmacists: inability to fill 50% of orders due to temporary or ongoing supply issues – 20% of time is spent on workarounds
- Physicians: addressing shortages an ongoing challenge
- Critical shortages in: epilepsy, hypertension, cancers, COVID ICUs



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# Current Drug Shortages in Canada

1,483 unresolved shortages (from 8,800 marketed drugs)

– Health Canada, April 1, 2021

Oversight ordered **51 escalations to top, Tier 3 shortage status**

- since start of pandemic (March, 2020)

May 2021: 16 active Tier 3 shortages, 6 are COVID-19 and/or related conditions

Canada chairs Drug Shortages Quadrilateral work group (EU, USA, Australia, Canada) to share information on shortage signals & mitigation strategies

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# Canadian Government Legal Actions

## Health Canada

Interim Orders for another year, 2021-22, to help prevent & alleviate shortages

- Exceptional import & sale of critical drugs (e.g. waive Canadian labels, doses)
- Request/require information from industry on shortages
- **Prevent diversion of drugs intended for Canadian market in case of shortages (emphasis added)**
- Amendments in Fall 2021 to allow flexibilities of Interim Orders to continue

# Pricing Realities: Critical Patient Challenges

- “Insulin prices in the United States nearly doubled to an average annual cost of \$5,705 US in 2016 from \$2,864 in 2012, according to a study in January.”
- In 2018, the average **insulin price** in the **US** was \$98.70, compared to \$6.94 in Australia, \$12.00 in **Canada**, and \$7.52 in the UK.
- In Canada, no prescription required for insulin.

## American caravan arrives in Canadian 'birthplace of insulin' for cheaper medicine



U.S. residents come to Canada to purchase life-saving type 1 diabetes medication

Thomson Reuters · Posted: Jun 29, 2019 2:58 PM ET | Last Updated: June 29



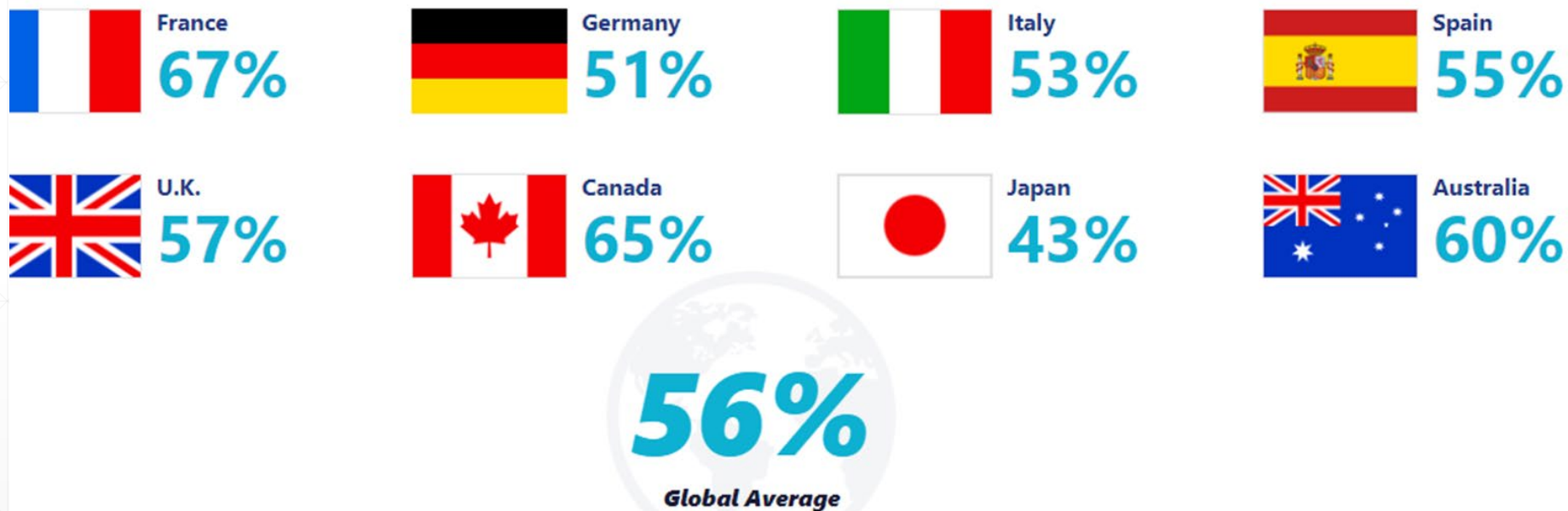
Quinn Nystrom holds insulin she purchased in Canada after travelling over the border for more affordable medication. (Lorenda Reddekopp/CBC)

# Pricing Realities: Pricing Policies Matter



# Pricing Realities: International Landscape

In other countries drugs cost an average of 56% less than in USA



Source | IHS Markit POLI

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# Safety: USA New Electronic, Interoperable Track & Trace

- Drug Supply Chain Security Act (DSCSA), 2013
- “...spur greater accountability for participants in the drug supply chain and improve our ability to trace prescription drugs at every point in the distribution chain,” FDA Commissioner Scott Gottlieb, 2019
- 10-year phase-in, to be completed 2023
- Applies to manufacturers, repackagers, wholesale distributors, dispensers & third-party logistics providers (trading partners)



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# Understanding Impact: USA Bulk Imports Not Sustainable

## *Consequences for Canadians:*

- Mass importation a **threat to Canadian drug supply and health of patients**
- Critical exacerbation of **existing shortages**
- A “**national security issue**” for Canada and Canadians

## *Consequences for USA:*

- Not sustainable; mass importation extremely short-term solution
- Jeopardizes integrity of safety tracking system
- USA patients: ongoing pricing and access challenges

# Status of Canadian Drug Importation Proposals In USA State Legislatures

Where they are	How many states
Passed a law, submitted a request to HHS, and spending state budget money right now	2: CO, FL
States who have legal frameworks in place	5: CT, ME, NH, NM, VT
Considered Canadian drug importation in legislation this year	14: CA, MT, IL, RI, WV, PA, MO, TN, WI, ND, AZ, OK, HI, MN

Data from the Partnership for Safe Medicines



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# What Are States Doing Now?

- Still introducing and debating laws to setup Canadian bulk importation
- Adjusting their laws to allow them to join multi-state purchasing groups
  - A single state would handle imports from Canada on behalf of other states
  - Lead state most likely: Colorado or Florida
- Some states expanding programs to other countries besides Canada

Data from the Partnership for Safe Medicines

# New Legislative Vehicles

- Sen. B. Sanders: “Affordable and Safe Prescription Drug Importation Act” (S. 920)
  - 21 Senate co-sponsors (all Democrats)
  - Starts with a two-year Canadian bulk importation program
  - includes intravenous drugs, biologics, and insulin
  - Authorizes consumers to purchase from online pharmacies in Canada.
  - Expands to all other OECD countries in year three
- Bills also by Sen. Amy Klobuchar (D-MN) and Rep. Chellie Pingree (D-ME).

Data from the Partnership for Safe Medicines

# Canadian Importation Regulations Are Also In US Court

NOV 24, 2020 | MORE ON PHARMACY

## PhRMA, others sue HHS and FDA for allowing import of drugs from Canada

PhRMA questions the cost savings and says the rule leaves safety considerations to state governments, rather than the required federal oversight.



Susan Morse, *Managing Editor*



**HEALTHCARE FINANCE**

# Canadian Organizations Speak Out

ASOP GLOBAL | ALLIANCE FOR SAFE ONLINE PHARMACIES

Canadian Society of Hospital Pharmacists | Société canadienne des pharmaciens d'hôpitaux

Supporting Pharmacists Committed To Patient Care

July 25, 2019

BEST MEDICINES COALITION

DIABETES CANADA

The Hon. Ginette Petitpas Taylor  
Minister of Health  
70 Columbine Driveway  
Ottawa, Ontario  
K1A 0K9

HealthCareCAN  
Leading. Innovation. Together.

cpsi icsp  
Canadian Patient Safety Institute  
Institut canadien pour la sécurité des patients

Health Charities Coalition of Canada  
Coalition canadienne des organismes de bienfaisance en santé

ASSOCIATION MÉDICALE CANADIENNE | CANADIAN MEDICAL ASSOCIATION

MCKESSON Canada

Dear Minister Petitpas Taylor,

CANADIAN NURSES ASSOCIATION

Neighbourhood Pharmacy Association of Canada  
Association canadienne des pharmacies de quartier

CORD  
Canadian Organization for Rare Disorders

OnPharm  
On your side.

CANADIAN PHARMACISTS ASSOCIATION | ASSOCIATION DES PHARMACIENS DU CANADA

Loblaws  
SHOPPERS DRUG MART

We are writing to express concern regarding the growth in legislation in the United States that permits the importation of Health Canada-approved medicines for U.S. patients. Legislation that allows the importation of medicines from Canada is popular among U.S. federal and state legislators as well as American citizens. Despite public education campaigns and statements from former and current U.S. regulatory officials to disavow importation as a strategy to reduce pharmaceutical prices, the interest in legislation has not diminished. Furthermore, U.S. President Donald Trump recently asked U.S. Health and Human Services Secretary to cooperate with Florida Governor Ron DeSantis, as the state looks to implement a new law permitting drug importation to Florida from Canada.

As a result, we request that Health Canada provide clarity and assurances to Canadians that U.S. legislation will not inadvertently disrupt Canada's pharmaceutical supply and negatively impact patient care through greater drug shortages.

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# Position of Canadian Government

## **Government of Canada technical briefing to stakeholders (August 20, 2019):**

- The Government of Canada continues to monitor the situation and is engaging U.S officials.
- All options available to the Government to respond to this issue are being considered.
- Ensuring that Canadians have access to the medicines they need is a top priority for the Government of Canada.
- The Government is committed to improving the accessibility and affordability of drugs in Canada.

# In Canada: Government Action



## Canada blocks some bulk prescription drug exports to U.S. to prevent shortages

Trump touted drug imports from Canada as a way to lower costs for Americans

November 29, 2020

- "Drug shortages remain a global challenge and COVID-19 has increased demand for certain drugs, adding to the complexity of ensuring drug supply where it is needed. The Government of Canada remains steadfast in its efforts to ensure Canadians have access to the medications they need, when they need them."

Minister of Health Patty Hadju

November 2020



# Appearance at the Michigan Legislature



December 9, 2019

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# Thank You

**John Adams**

**[john.adams@canpku.org](mailto:john.adams@canpku.org)**

**[bestmedicinescoalition.org](http://bestmedicinescoalition.org)**





# Drug Re-importation – Economic Viewpoint

Lou Garrison, University of Washington (12 minutes)

# Canada: The New Drugstore for America or Entering the Deep Freeze? -- A U.S. Health Economist's View

Lou Garrison, PhD, Professor Emeritus

The CHOICE Institute, School of Pharmacy, University of Washington Seattle WA, USA

ISPOR IP1

International Virtual ISPOR Meeting

May 17, 2021



# Disclosures

- Have received unrestricted research support from Pharmaceutical Research and Manufacturers of America on international reference pricing (not on Canadian re-importation issues).

# Basic Economics of Patent-Protected Medicines

- Patented-protected medicines are information—which has global public good properties.
- Optimal approach to achieve the optimal rate of innovation is global differential pricing.
- Patent-protected medicines have temporary monopoly (or oligopoly).
- High fixed cost of R&D: low marginal cost of production and distribution
- Country buyers can have countervailing monopsony power.
- Unlike hospital and physician prices in U.S, medicines are NOT under a price-fixing system.
- In any given year, a small percentage of (seriously ill) patients generate a large share of health spending.

By Jason D. Buxbaum, Michael E. Chernew, A. Mark Fendrick, and David M. Cutler

DOI: 10.1377/HLTH.AFFAIRS.39.09.1546-1556  
 HEALTH AFFAIRS 39, NO. 9 (2020): 1546-1556  
 ©2020 Project HOPE—The People-to-People Health Foundation, Inc.

# Contributions Of Public Health, Pharmaceuticals, And Other Medical Care To US Life Expectancy Changes, 1990-2015

**Jason D. Buxbaum** (jasonbuxbaum@g.harvard.edu) is a student in the Program in Health Policy at Harvard University, in Cambridge, Massachusetts.

**Michael E. Chernew** is the Leonard D. Schaeffer Professor of Health Care Policy and director of the Healthcare Markets and Regulation (HMR) Lab in the Department of Health Care Policy, Harvard Medical School, in Boston, Massachusetts.

**A. Mark Fendrick** is a professor in the Department of Internal Medicine and director of the Center for Value-Based Insurance Design at the University of Michigan, in Ann Arbor, Michigan.

**David M. Cutler** is the Otto Eckstein Professor of Applied Economics in the Department of Economics at Harvard University and a research associate at the National Bureau of Economic Research, in Cambridge, Massachusetts.

**ABSTRACT** Life expectancy in the US increased 3.3 years between 1990 and 2015, but the drivers of this increase are not well understood. We used vital statistics data and cause-deletion analysis to identify the conditions most responsible for changing life expectancy and quantified how public health, pharmaceuticals, other (nonpharmaceutical) medical care, and other/unknown factors contributed to the improvement. We found that twelve conditions most responsible for changing life expectancy explained 2.9 years of net improvement (85 percent of the total). Ischemic heart disease was the largest positive contributor to life expectancy, and accidental poisoning or drug overdose was the largest negative contributor. Forty-four percent of improved life expectancy was attributable to public health, 35 percent was attributable to pharmaceuticals, 13 percent was attributable to other medical care, and -7 percent was attributable to other/unknown factors. Our findings emphasize the crucial role of public health advances, as well as pharmaceutical innovation, in explaining improving life expectancy.

**G**rowth in medical spending consistently outpaces overall economic growth in the United States, prompting questions about the extent to which health care expenses somewhat less attention. One study estimated that half of all health improvements between 1960 and 2000 are due to medical care, although that estimation was extrapolated from a small number of conditions.<sup>1</sup> The difficulty is in part

Pharmaceuticals account for 35% of improved US life expectancy—of 3.3 years—from 1990-2015

**EXHIBIT 3**

Estimated impact of pharmaceuticals, other medical care, and public health on changes in US mortality, by cause of death, 1990-2015

Categories/ causes of death	Contribution to mortality reduction (%)	Contribution to mortality changes (%)			Comments
		Public health	Pharma- ceuticals	Other medical care	
<b>TOTAL</b>					
All causes	85	44	35	13	-7

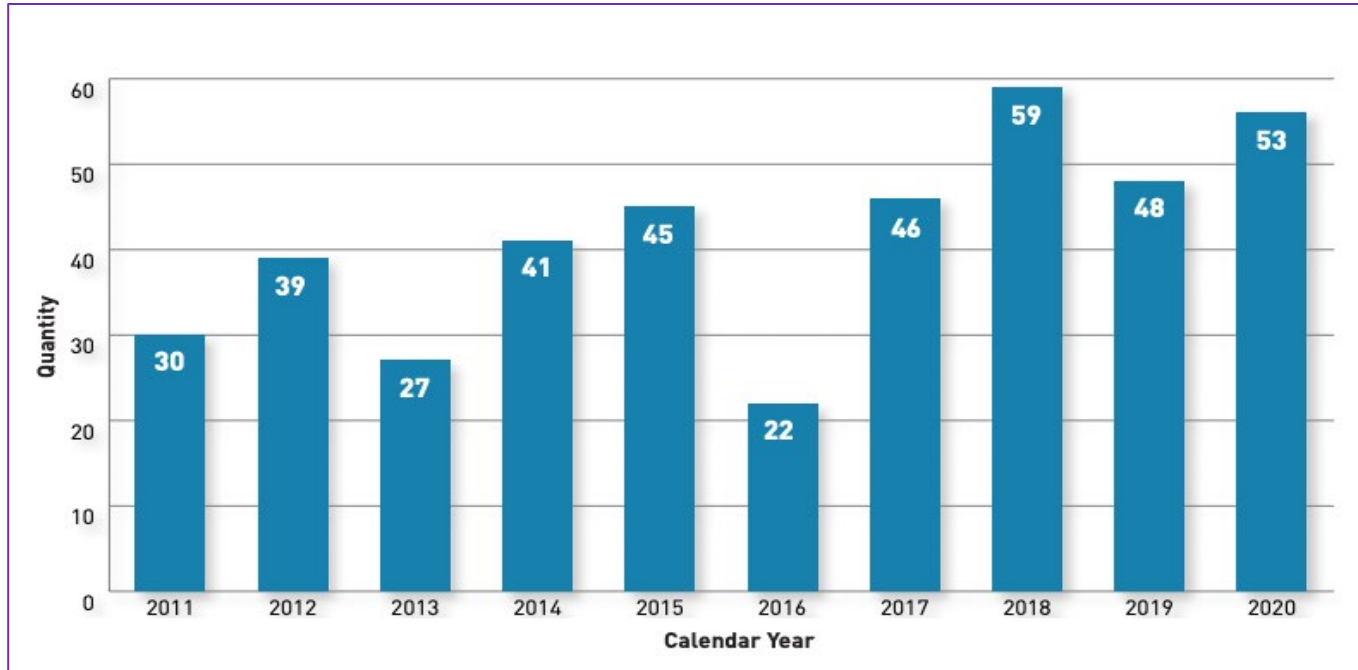
Value = 330,000,000 x 1.155 life years x \$150,000/QALY = \$57.2 Trillion!

Annual Drug R&D: \$200 Billion => \$57.2 Trillion/\$200 Billion = 286 Years!

OR

50 years of R&D at \$200B/Yr => \$57.2 T/\$10 T = 6:1 return

## CDER's Annual Novel Drug Approvals, 2011-2020



### New drugs:

- High risk/high reward
- Global public goods
- Few annually
- Productivity flat over time
- Mix constantly changing

- 21 of 54 (40%) as first-in-class
- **31 of 53 (58%) for rare or orphan diseases**
- 17 of 53 (32%) as Fast Track
- 22 of 53 (42%) as breakthrough therapies
- 30 of 53 (57%) were designated Priority Review



## Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents

PATRICIA M. DANZON

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*The Wharton School, University of Pennsylvania*

ADRIAN TOWSE

atowse@ohe.org

*Office of Health Economics*

OUTLOOK NEGLECTED DISEASES

NATURE|Vol 449|13 September 2007

### At what price?

Differential pricing could make global medicines affordable in developing countries. But drugs for diseases that have no market in the developed world will require additional subsidies, says **Patricia M. Danzon**.

For the general population in developing nations to have appropriate access to medicines, existing drugs must be affordable, and innovation is needed to develop new medicines. But this presents a potential conundrum: prices that are high enough to pay for research and development (R&D) may make medicines unaffordable in developing regions. Differential pricing\* (also known as price discrimination) can offer a solution to this dilemma, at least for drugs with considerable sales in the developed world. Prices in affluent countries — and to a lesser extent in middle-income countries — could gener-

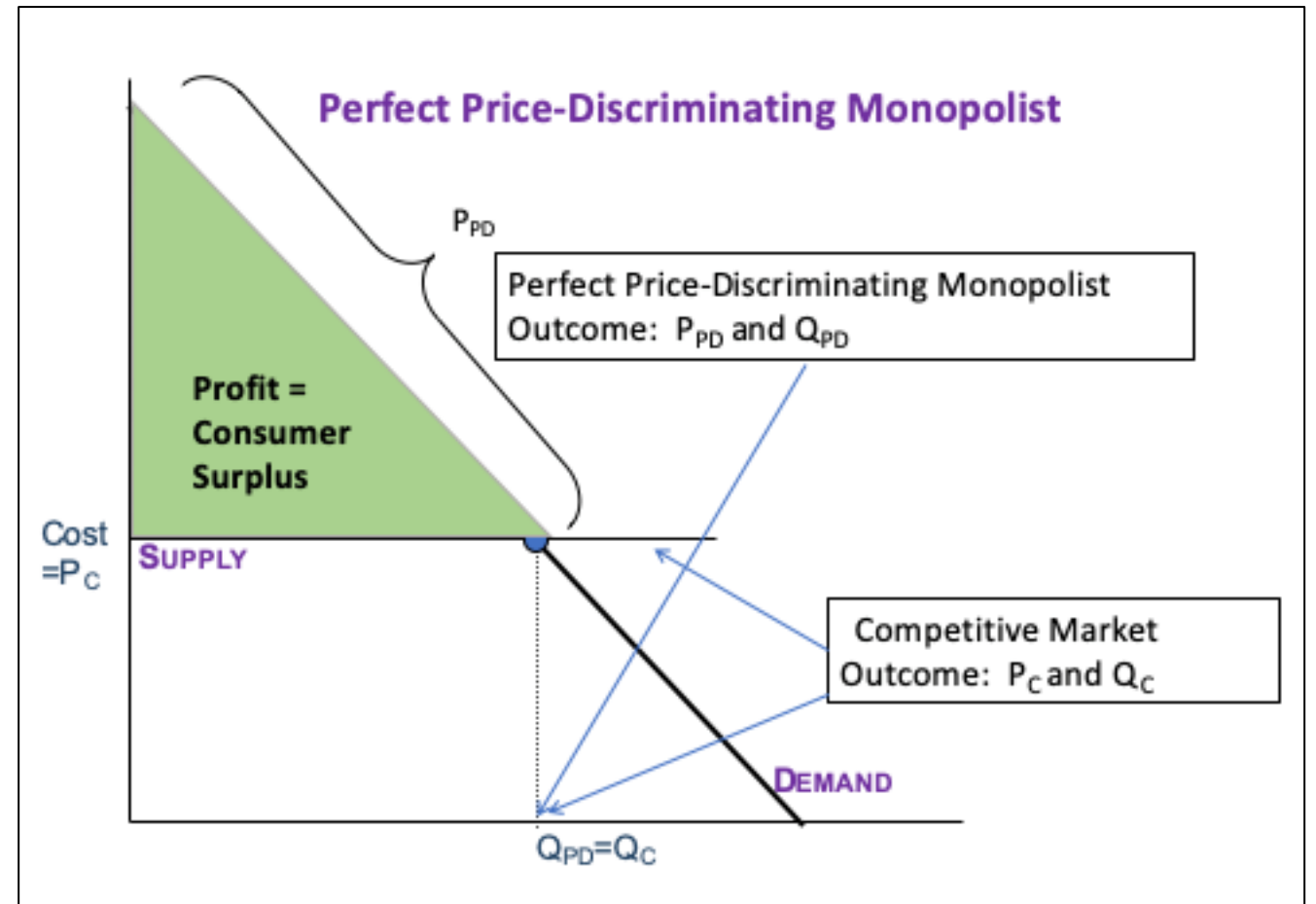


for R&D<sup>2</sup>. Pharmaceutical R&D can benefit patients globally, raising the question of how — which seems plausible for pharmaceuticals. A simulation<sup>3</sup> comparing worldwide pharma-

MAES

Economists have long argued for global differential pricing.

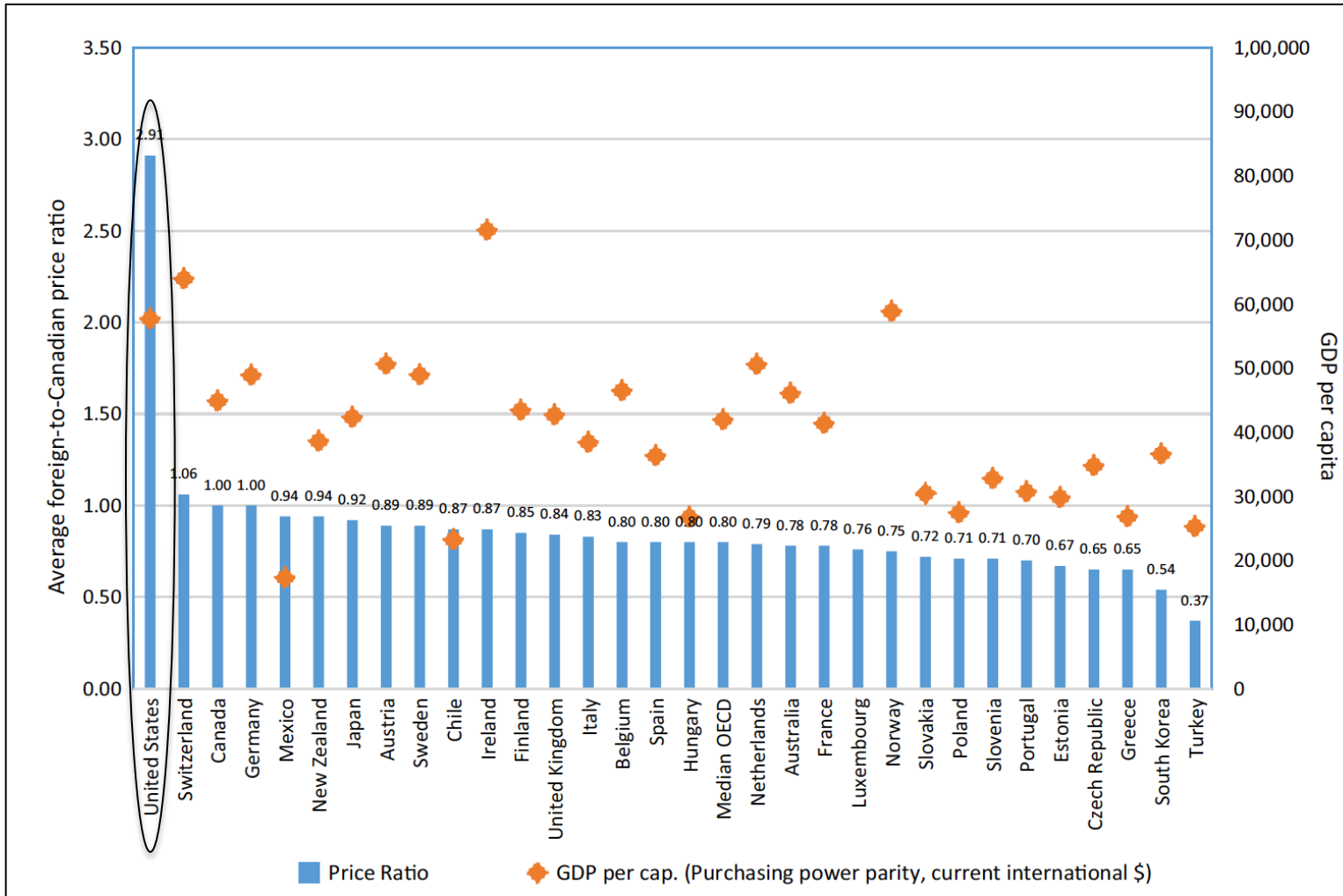
Has equity implications as well.



# Drug Prices: U.S. vs. ROW

(Average Foreign-to-Canadian Price Ratios for Patented Drugs by Country, 2016)

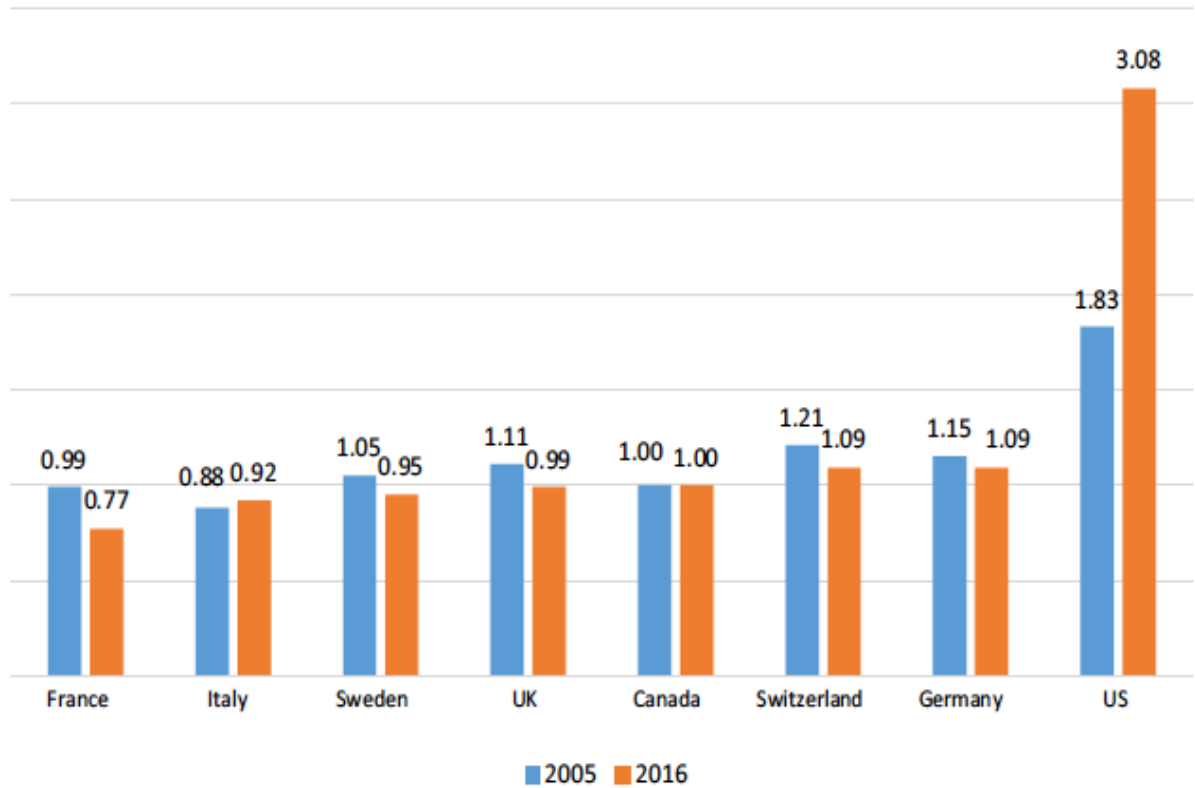
**US list price 3x higher**  
**Low correlation with GDP per capita**



Source: Danzon, *PharmacoEconomics*, 2018



# Drug Price Changes: 2005 vs. 2016—8 Countries



U.S. prices rising—  
and faster over time

**Fig. 2** Average foreign-to-Canadian price ratios, 2005, 2016. The Patented Medicine Prices Review Board requires patentees to report publicly available ex-factory prices in seven comparator countries. The US price incorporates prices from the Federal Supply Schedule

(FSS), which reflects some mandatory and negotiated rebates. Price indexes are Canadian sales-weighted arithmetic means of price ratios for individual drug products. Currency conversion at market exchange rates [36]

Source: *Danzon, PharmacoEconomics, 2018*

# U.S. Citizens Want Lower Drug Prices

## Majority of the Public Favors Allowing Americans to Buy Prescription Drugs Imported from Canada

*Percent who favor allowing Americans to buy prescription drugs imported from licensed Canadian pharmacies:*



SOURCE: KFF Health Tracking Poll (conducted October 3-8, 2019). See topline for full question wording and response options.

## PhRMA Position

- Foreign governments can't ensure safety and efficacy of imports.
- Counterfeiting is a growing problem.
- It won't reduce drug costs significantly.
  - CBO estimate (2017) was \$6.8 billion over 10 years. (Current annual spending is \$370 billion.)

Learn more at [PhRMA.org/Importation](https://www.phrma.org/importation)



# Dynamic Efficiency and Revenue Elasticity of Innovation

- We know that U.S. citizens finance about 40% of global drug R&D.
- We don't know what would be "dynamically efficient"—i.e., producing optimal amount and types of innovation
- Evidence on revenue of elasticity of innovation is very limited and dated:
  - **Acemoglu and Linn (2004)—0.4-0.6**—"a 1 percent increase in expected market size is associated with a 4 percent to 6 percent increase in the number of new molecular entities"
  - **Blume-Khout and Sood (2014)—0.28**—"Medicare Part D. ... was associated with significant increases ... for those drug classes most likely to be affected by Medicare Part D."
  - **Dubois et al. (2015)—0.23**—"on average, \$2.5 billion is required in additional revenue to support the invention of one new chemical entity."
  - **Axelsen and Jayasuriya (2021)**—"forecasting the impact on innovation of a policy change of unprecedented magnitude, in the world's biggest market for medicines is impossible, as there are no relevant analogues for change on this scale. "

# U.S. Considering International Reference Pricing (“Nash Bargaining”)

Working Paper Series  
Congressional Budget Office  
Washington, D.C.

## CBO’s Model of Drug Price Negotiations Under the Elijah E. Cummings Lower Drug Costs Now Act

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Working Paper 2021-01  
February 2021

**H.R. 3**—U.S. House of Representatives passed the “Elijah E. Cummings Lower Drug Costs Now Act” Dec. 2019.

1. Lower patient out-of-pocket costs
2. Adjust prices for recent inflation
3. Sec. of HHS negotiates drug prices based on **“International Price Index.” Not exceed 120% of average price among six countries.**
4. Negotiations would reduce prices by **57 percent to 75 percent**, relative to current prices
5. **CBO projects \$456 billion in savings over 10 years. And 8 fewer drugs in 2020-2029.**

***In contrast:*** Dubois et al. (2019; NBER Working Paper): “such a policy results in a slight decrease in US prices and a substantial increase in Canadian prices.”



## H.R. 3 and Reference Pricing

Total Market Impact

March 22, 2021

Prepared in collaboration with



**“ ... we find that implementation of international reference pricing in the United States would:**

- Reduce earnings by 62% on average for impacted companies, with one third (32%) of affected companies having reductions larger than 95% of earnings (using conservative assumptions about the impacts on prices) ...
- Reduce by 90%+ the number of medicines developed by small and emerging biotechs -- **61 fewer medicines over 10 years. ...**
- Eliminate nearly 200,000 biopharmaceutical industry jobs, and nearly 1 million jobs across the economy.”

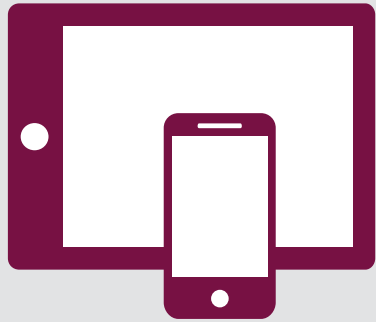
# Key Take-Away Messages

1. Re-importation (i.e., “parallel trade”) would likely result in manufacturers trying to control supply to Canada, which could adversely affect access there both through shortages and higher prices.
2. Combined with IRP, it could drastically reduce supply and access to innovative medicines in Canada.
3. This could have a serious adverse impact on global R&D and global health.

**Thanks for your interest and attention!**

**lgarrisn@uw.edu**





CBO projects that H.R. 3 International Reference Pricing would reduce the number of New Molecular Entities by **8** over the decade of 2020–29, assuming 30 per year otherwise. This would lead to a reduction of approximately 2.7%.

What number would you predict?

a)

<8

b)

8

c)

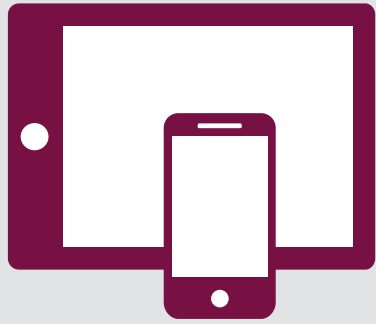
9–16

d)

17–24

e)

25+



Do you think a US drug re-importation plan with Canada is a viable solution to reduce prescription drug costs in the United States?



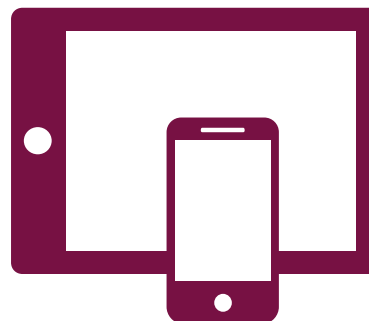
Yes



No

# Discussion

15 minutes



# Thank You

Moderator: Jill Crich ([jill.crich@costellomedical.com](mailto:jill.crich@costellomedical.com))

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