

The potential impact of the 2020 US presidential election on global health care pricing

November 24th, 2020

Dr. Stefan Walzer^{1,2,3}

&

Karen Sandman, Anna Forsythe⁴

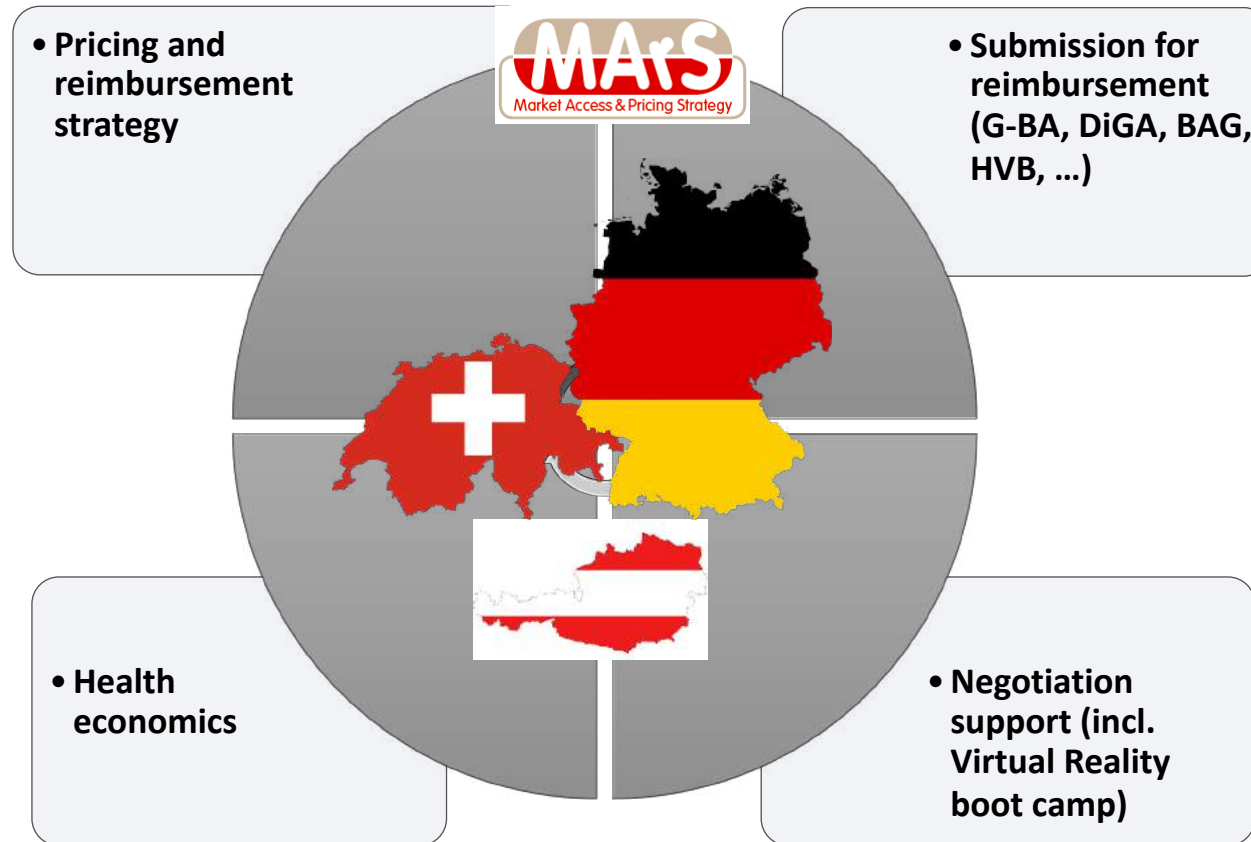
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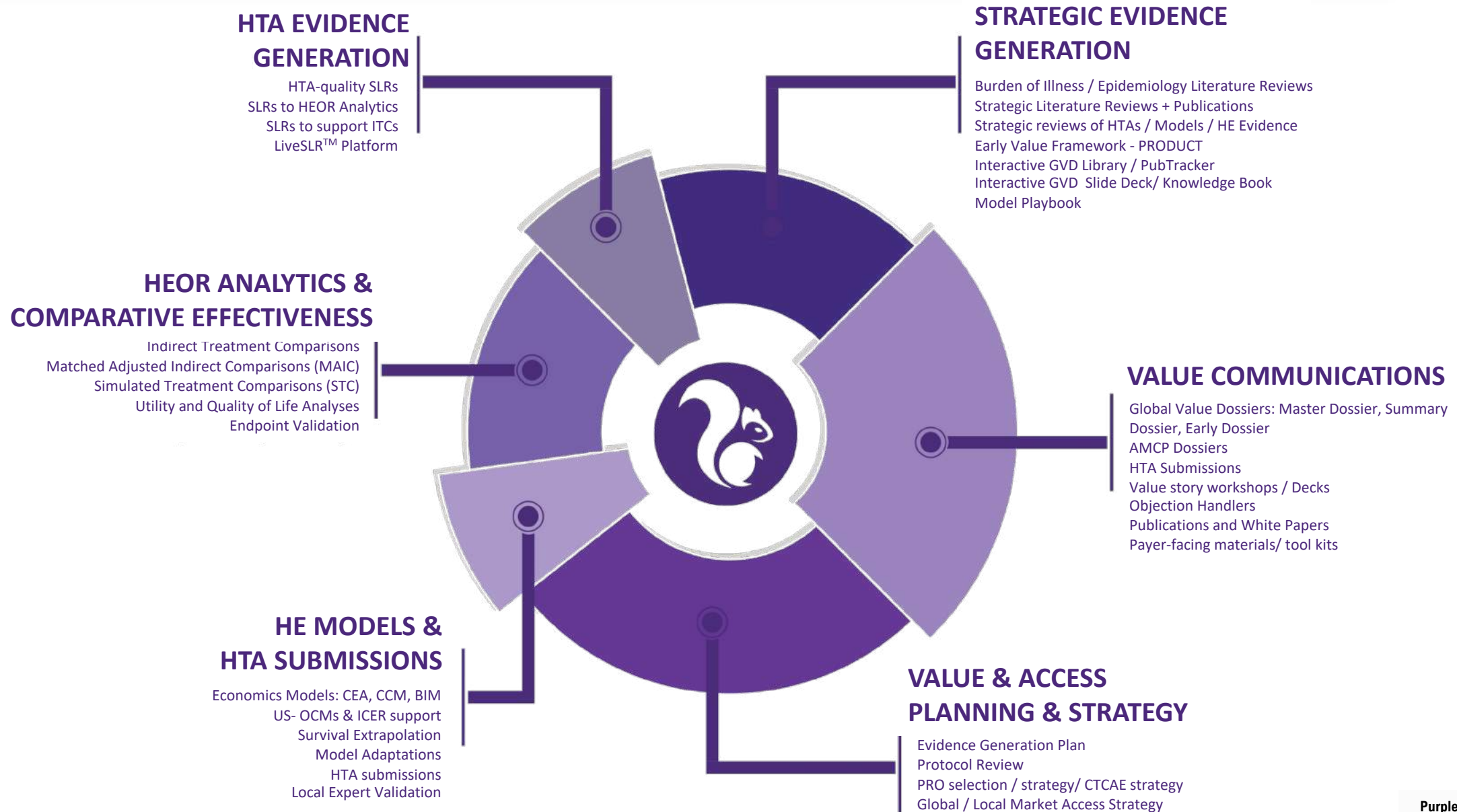


Virtual Reality Negotiation Training Increases Negotiation Knowledge and Skill

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Broekens J., et al. (2012) Virtual Reality Negotiation Training Increases Negotiation Knowledge and Skill. In: Nakano Y., et al. (eds) Intelligent Virtual Agents. IVA 2012. Lecture Notes in Computer Science, vol 7502. Springer, Berlin, Heidelberg



Questions welcome!

- Feel free to ask questions. After the presentation, we will have time for your questions.
- Use either the Zoom chat function or the Q&A function to raise your questions or comments.
- As always, slides will be provided afterwards, and the video will be published on our website.



Webinar

The potential impact of the **2020 US presidential election** on global health care pricing



Dr. Stefan Walzer
Speaker



Karen Sandman
Purple Squirrel Economics (PSE)



Lutz Vollmer
Moderator



Gabriel Trembley
PSE



Anna Forsythe
PSE



Market Access &
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24.11.2020
9pm CET /
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<https://youtu.be/3qUg72Henzs>

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[A possible second wave of Covid-19 in Germany \(25.06.2020\)](#)

[Covid-19 pushes digitalization in health care \(26.05.2020\)](#)

[The economic impact of Covid-19 in Germany \(23.04.2020\)](#)



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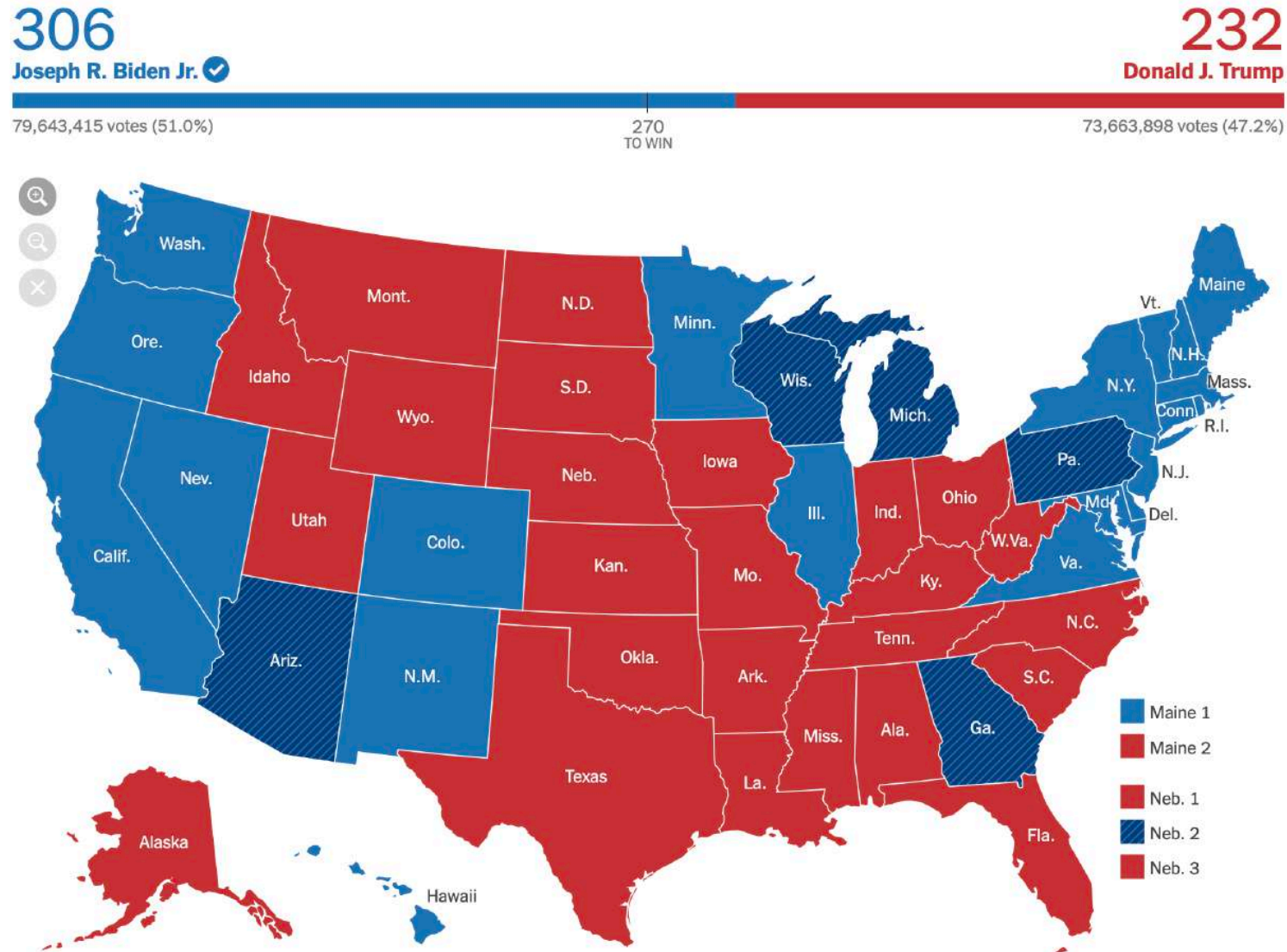
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US elections... the winner is Joe Biden!?



Joe Biden's Vision...





PURPLE SQUIRREL
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**The potential impact of the US 2020
presidential election on global
healthcare pricing**

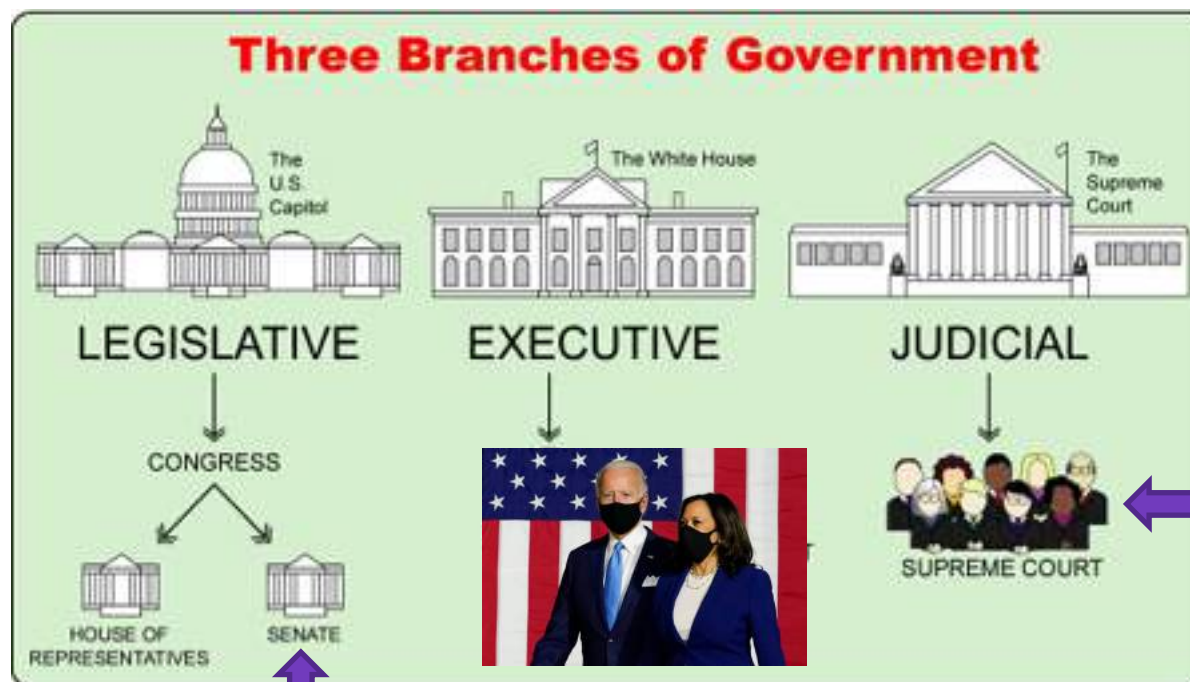


We have a president- and vice president-elect

Inauguration date: January 20, 2021

- Legal wrangling is unlikely to change the outcome, but may make the transition chaotic

How much can the president do alone?



Democratic majority
Likely to work with
Biden-Harris

? majority: depends on January Georgia
election; if Republican, unlikely to
cooperate with Biden-Harris

Conservative majority

**Could overturn laws if they are
challenged in court**
**Republicans are trying to overturn
Obamacare; there are several vocal
opponents on the court**

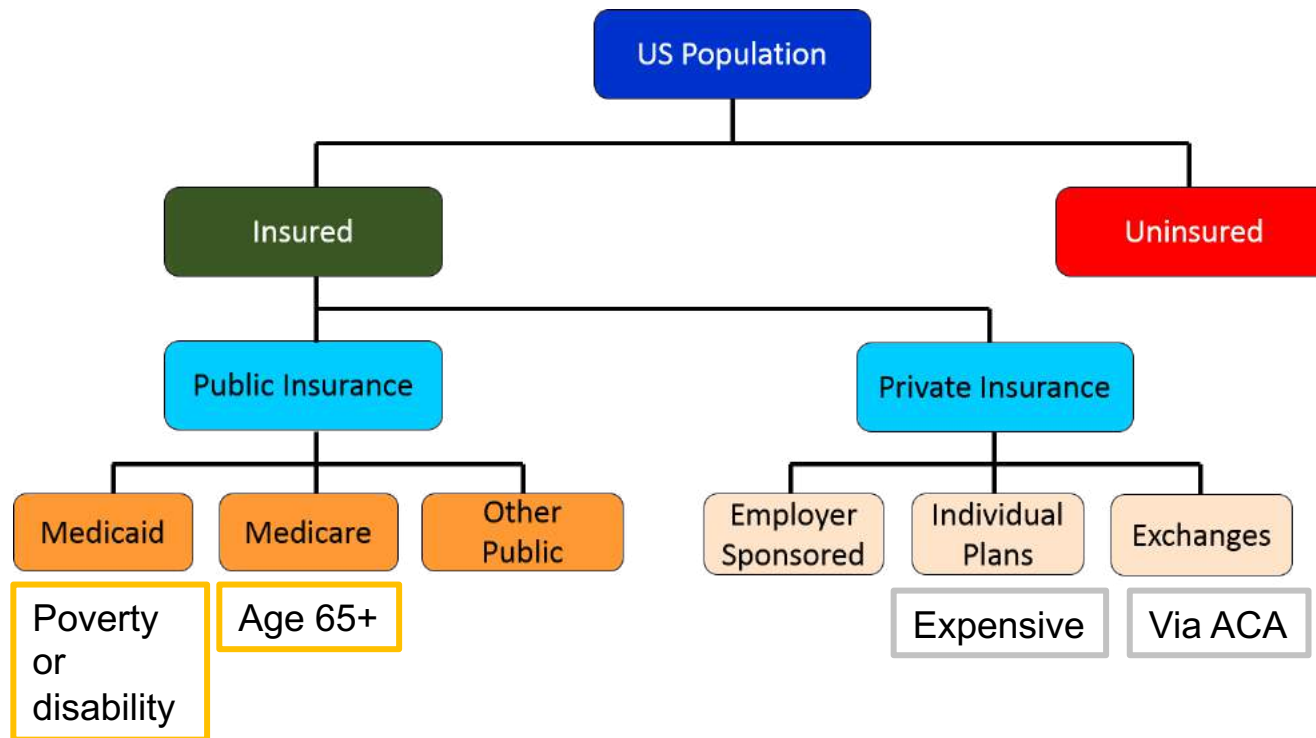


Key elements of the Biden-Harris healthcare proposal

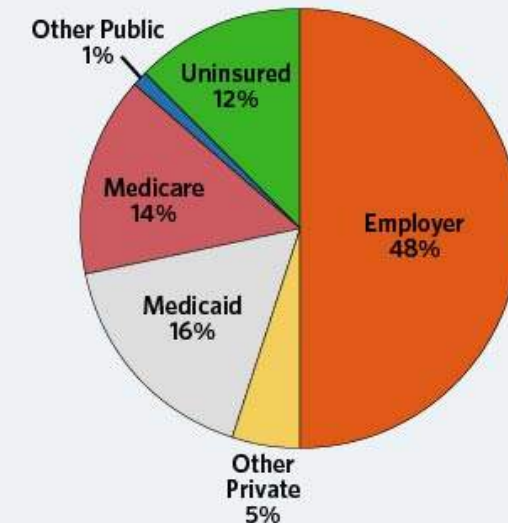
- “Protect and build on the ACA”
- “Affordable, quality healthcare in a less complex healthcare system”
 - “Ensure healthcare is for all, not privileged few”
- “Stand up to abuse of power by prescription drug corporations”



What are the insurance options for Americans?



Health Insurance Coverage of the Total United States Population, 2012



SOURCES: Urban Institute and Kaiser Commission on Medicaid and the Uninsured estimates based on the Census Bureau's March 2012 and 2013 Current Population Survey (CPS: Annual Social and Economic Supplements)

“Protect and build on the ACA”



Affordable Care Act (2010): “Obamacare”

- **3 main goals:**
- Increase availability of affordable health insurance
 - Provides consumers with subsidies (“premium tax credits”) lowering costs for households with incomes between 100% and 400% of the federal poverty level
- Expand Medicaid to cover all adults with income <138% of the federal poverty level
 - Not all states have complied
- Support innovative medical care delivery methods designed to lower the costs of health care generally



Biden-Harris proposal

- **How Biden plan builds on ACA:**
- Access to affordable health insurance for all Americans through a public option
 - Increase tax credits to reduce amount people pay for health insurance
- Ensure a cap of 8.5% of income spent on a “gold” health plan
 - Cap is currently 9.86% for a “silver” plan
 - “Gold” plan has lower deductibles and lower out-of-pocket costs
- Expand Medicaid coverage for low-income people in states that have limited access to Medicaid



More on healthcare access under Biden plan

“Affordable, quality healthcare in a less complex healthcare system”

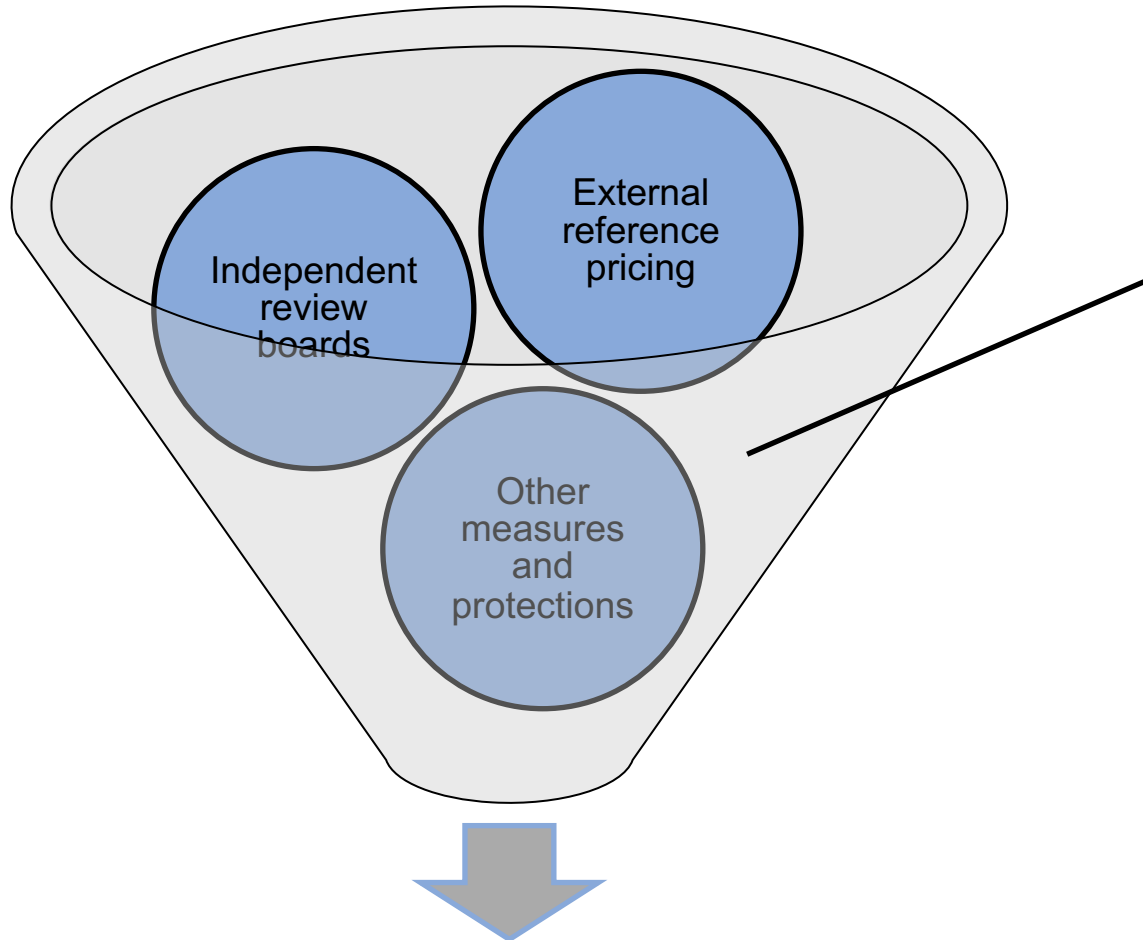
- Public option will negotiate prices with providers
- Stop “surprise billing” in which providers charge out-of-network rates for patients who can’t access in-network providers
- Use antitrust laws to increase competition within healthcare system
- Partner with HCPs to drive innovation and quality improvements and improve working conditions

“Ensure healthcare is for all, not privileged few”

- Expand access to contraception; protect abortion rights
- Reduce high maternal mortality rate, especially among Black women
- Ban healthcare discrimination on basis of gender, sexual orientation, gender identity, HIV status, etc.
- Invest in community health centers
- Mental health parity and expanded mental healthcare access



“Stand up to...prescription drug corporations”

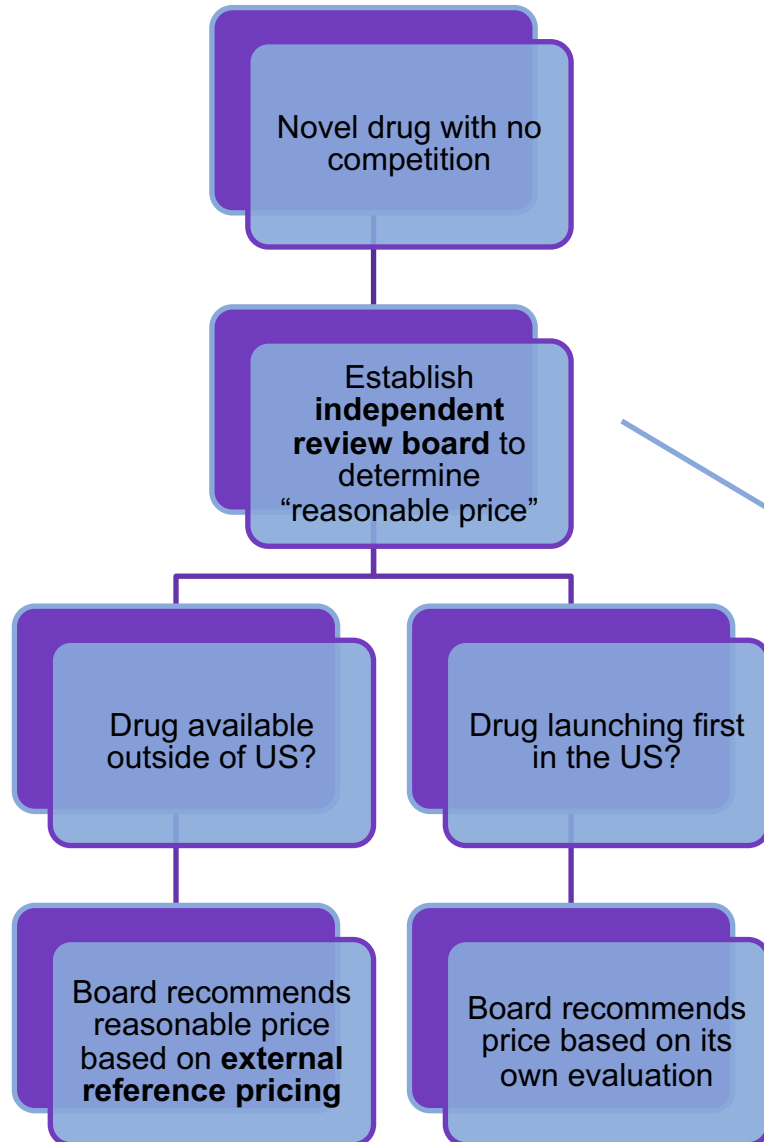


Decreased drug prices

- Limit price increases to inflation for branded, biotech, and “abusively priced generic drugs”
 - To participate in Medicare/public option, drugs may not increase prices beyond the general inflation rate
 - Tax penalty on manufacturers that increase prices beyond inflation
- Allow consumers to import safe Rx from other countries
- Stop allowing pharma companies to tax-deduct the costs of advertising
- Improve the supply of quality generics
 - Accelerate development of safe generics



Drug price negotiation in the Biden plan



- Manufacturers historically have relatively few controls applied to US pricing
- Biden plan introduces several mechanisms for price controls:
 - Repeal existing law that bars Medicare from negotiating lower prices with drug companies

Reasonable price = price that Medicare and public option will pay

Private plans can access a similar price IF they participate in the individual marketplace (“exchanges”)



External reference pricing

- External reference pricing has not historically been used in the US
 - Trump (Sept 2020 executive order), Biden (proposed plan) favor ERP
- US often is the first launch site
- US drug prices are about 3 to 4 times higher than in the UK, Japan, and Canada, after rebates are accounted for, with some drugs up to 70 times more expensive
- If Medicare alone adopted external reference pricing, could save an estimated >\$70 billion



On international price indexing: Another component of Biden's plan would establish an independent review board to assess the value of new specialty drugs that lack competition. The board will use that analysis — along with the prices charged in other countries, when available — to recommend a price for the drug that is paid by Medicare, Obamacare plans and Biden's public option health plan.

Sanders would also use international reference pricing — but for more medicines and for the entire U.S. drug market, not just a segment of American patients. Sanders says he would push the Prescription Drug Price Relief Act, S. 102 (116), which would incentivize companies to **charge prices in the U.S. that are comparable to those paid in countries** like Canada, the United Kingdom, Germany, France and Japan. If the companies don't cooperate, the federal government could intervene to allow generic companies to produce cheaper copycats. Sanders' campaign website says the plan would cut drug prices in half.



Independent review board: expanding role of ICER?

- Biden proposal includes independent review board for Medicare drug pricing negotiations
- US payer experts consider ICER to be well-positioned to take on such a role

Is ICER ready to serve to review all technologies?

Capacity?

Process?

Authority?

Budget?

Expertise?

Influence?

Are ICER methods appropriate?

German vs. UK Model?

Value-based or QALY?

Transparency?

Methods?

Consistency?

- Outside US, perception is that ICER is independent and trying to follow UK—bring into perspective that ICER isn't quite there yet



Other legislation to watch

- 21st Century CURES 2.0
 - PDUFA VII



CURES 2.0 updates

21st century CURES Act: Dec 2016

- Accelerate product development with faster, more efficient innovation
- Authorized \$500 million over 9 years to help FDA to implement the law
- Includes patient experience data, patient-focused drug development guidance, novel clinical trial designs and RWE

CURES 2.0: currently up for discussion

- Public health and pandemic preparedness
- Caregiver integration
- Patient engagement in health care decision-making
- Diversity in clinical trials
- FDA modernization
- Medicare & Medicaid modernization



Food and Drug Administration Reauthorization Act (FDARA) (August 2017)

- Reauthorization of the Prescription Drug User Fee Act (PDUFA)
 - Provides FDA with the necessary resources to maintain a predictable and efficient review process for human drug and biologic products
- Ensures that FDA will continue to receive a source of stable and consistent funding during fiscal years 2018-2022
 - Will allow FDA to fulfill its mission to protect and promote public health by helping to bring to market critical new medicines for patients

PDUFA VII, which is currently under discussion, will cover 2023 through 2027

- Stakeholder discussions are ongoing
 - Needs to be passed by Q3 2022
- Pharma industry has requested **more predictable and timely engagement and better communication during drug development**
- **Greater support on incorporating RWE in FDA decisions**
- COVID-19 experience is shaping the discussion:
 - Greater flexibility and consideration of decentralized trials, digital engagement

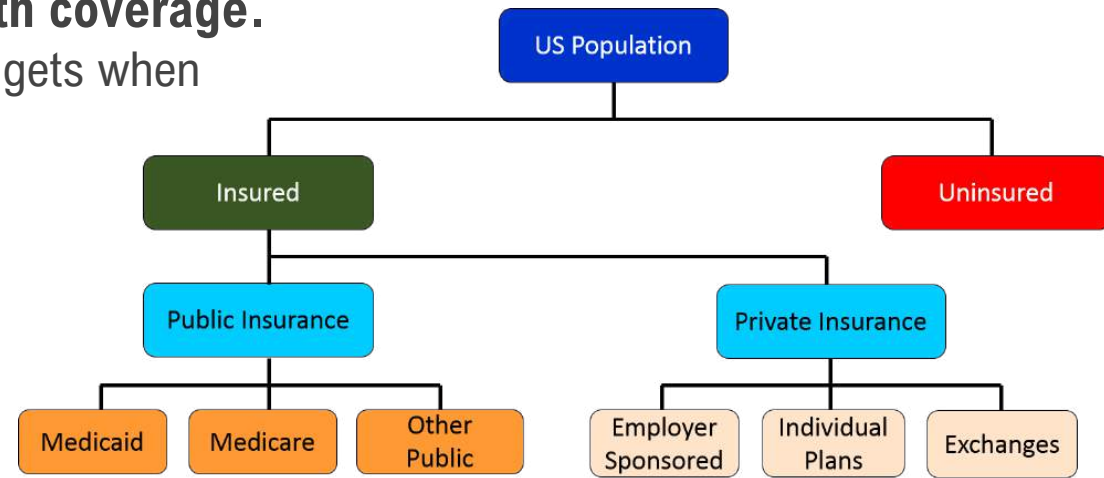


Impact of COVID-19 on US healthcare



COVID-19 (regardless of legislation)

- **US unemployment rates are at 6.9 as of October 2020. The rise in unemployment is leading to:**
 - Increase in Medicaid enrolment
 - Decline in private payer enrolment
- **Medicaid enrollment is increasing in 2020 due to COVID-19, with 4.3 million or 6.1% increase just between Feb and July 2020¹**
 - 2021 will bring additional strain on Medicaid budgets and may offer Medicaid an ability to negotiate pricing – definite pressure for high-priced branded launches
- **As a heavily private insurance country, an economic shock due to COVID not only destroyed jobs, but also destroyed access to health coverage.**
 - Private payers will have smaller budgets when they are evaluating expensive drugs (PMPM just got larger)



1. CMS, Medicaid & CHIP: Monthly Application and Eligibility Reports, last updated October 30, 2020.



How might US changes impact the situation in EU?

Discussion on reference basket in the US

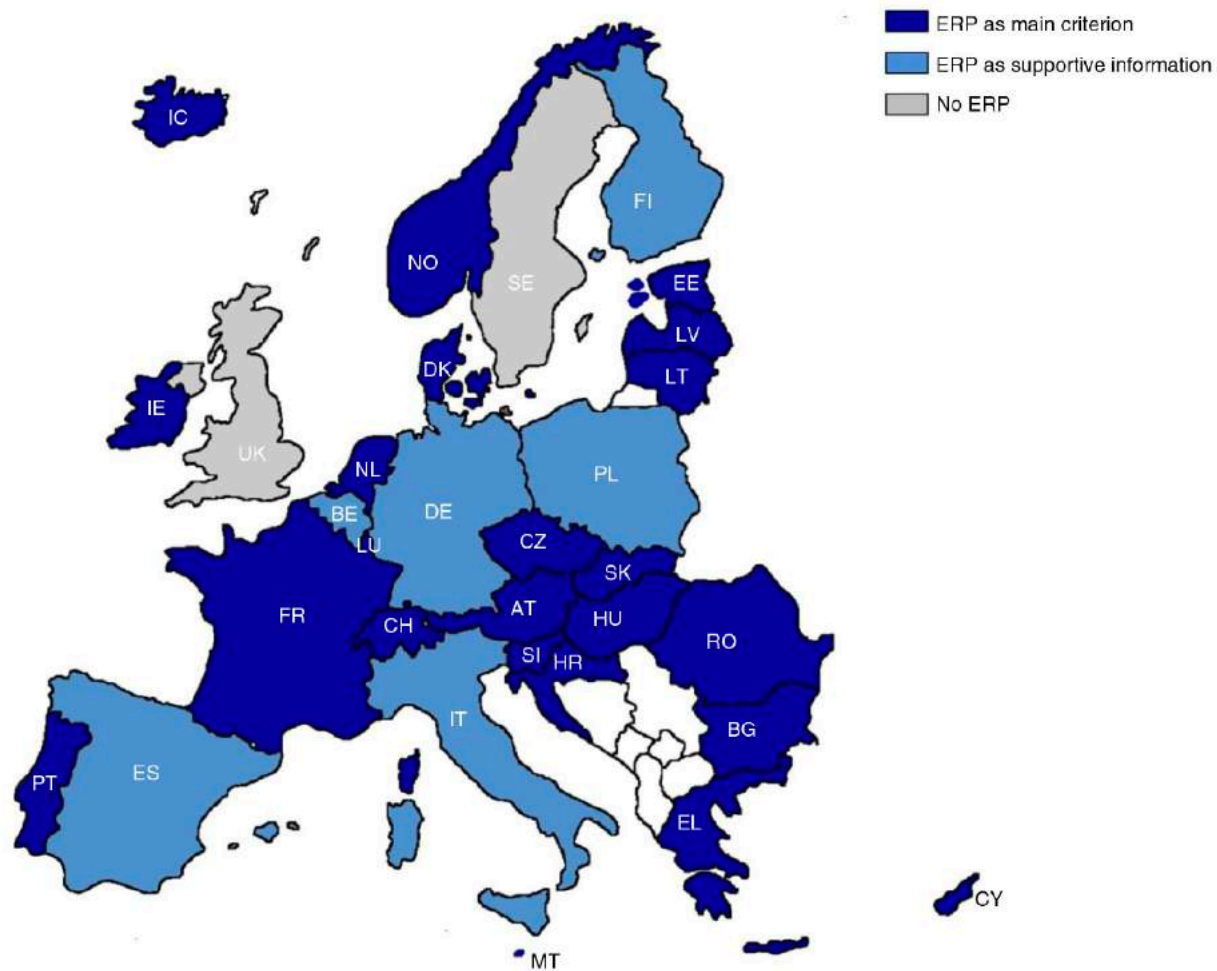
IPI vs. MBII on International Drug Price Benchmarks

TRUMP IPI	FREOPP MBII
Canada	
Denmark	Denmark
Finland	Netherlands
Greece	Singapore
Italy	Switzerland
Austria	Austria
Belgium	Belgium
Czech Republic	Czech Republic
France	France
Germany	Germany
Ireland	Ireland
Japan	Japan
Portugal	Portugal
Slovakia	Slovakia
Spain	
Sweden	
United Kingdom	

- Trump's International Pricing Index (IPI) includes 7 single-payer countries that use price controls
- FREOPP's Market-Based International Index (MBII) excludes all single-payer countries except Denmark
- MBII Tier 1 countries (Denmark, Netherlands, Singapore, Switzerland) represent 60% of index



Potential impact on Europe?



Why should the US be important? No country uses the US as a reference

	AT	BE	BU	CH	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE	IS	IT	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	UK	Add. countries	N. of countries	
AT																																	24	
BE																																	Or Country of origin	26
BU																																	12	
CH																																	6	
CY																																	4	
CZ																																	19	
DE																																	15	
DK																																	9	
EE																																	Country of origin	4
EL																																	22	
ES																																	Eurozone but not regulated	16
FI																																	Liechtenstein	29
FR																																	4	
HR																																	3	
HU																																	Liechtenstein	31
IE																																	9	
IS																																	4	
IT																																	27	
LT																																	8	
LU																																	Country of origin	1
LV																																	7	
MT																																	Public sector*	11
NL																																	4	
NO																																	9	
PL																																	Liechtenstein	31
PT																																	3	
RO																																	12	
SE																																	n/a	
SI																																	3	
SK																																	27	
UK																																	n/a	
Reference frequency	16	15	9	2	10	13	17	15	12	13	16	15	19	5	13	13	3	15	14	9	11	8	15	6	10	13	10	13	13	16	17			

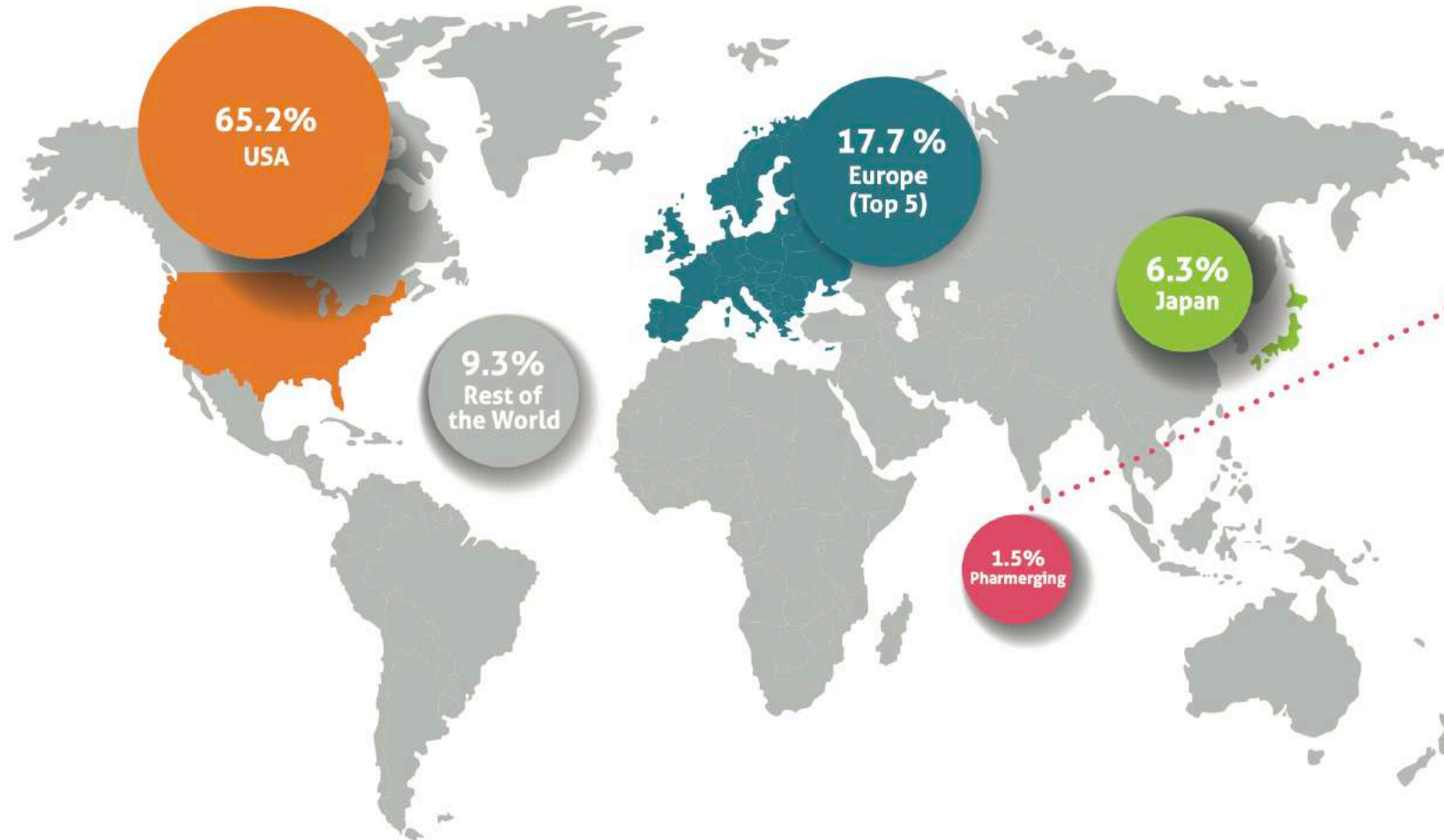
*For private sector in Malta, data from 12 European reference countries, classified in a three-tier system, are used for ERP: low-priced tier: ES; UK; PT; FR/medium-priced tier: BE; IS; CY; IT/high-priced tier: DK; DE; IE; NO.

Add., additional; AT, Austria; BE, Belgium; BG, Bulgaria; CH, Switzerland; CY, Cyprus; CZ, Czech Republic; DE, Germany; DK, Denmark; EE, Estonia; EL, Greece; ES, Spain; FI, Finland; FR, France; HR, Croatia; HU, Hungary; IE, Ireland; IS, Iceland; IT, Italy; LT, Lithuania; LU, Luxembourg; LV, Latvia; MT, Malta; NL, the Netherlands; NO, Norway; PL, Poland; PT, Portugal; RO, Romania; SE, Sweden; SI, Slovenia; SK, Slovakia; UK, United Kingdom.

America first – still true for launch sequence?



US trumps Europe



... but prices in few countries still high

Table 2. Comparisons of Price per Gram, U.S. and International Ex-Manufacturer Prices, Q1 2018.

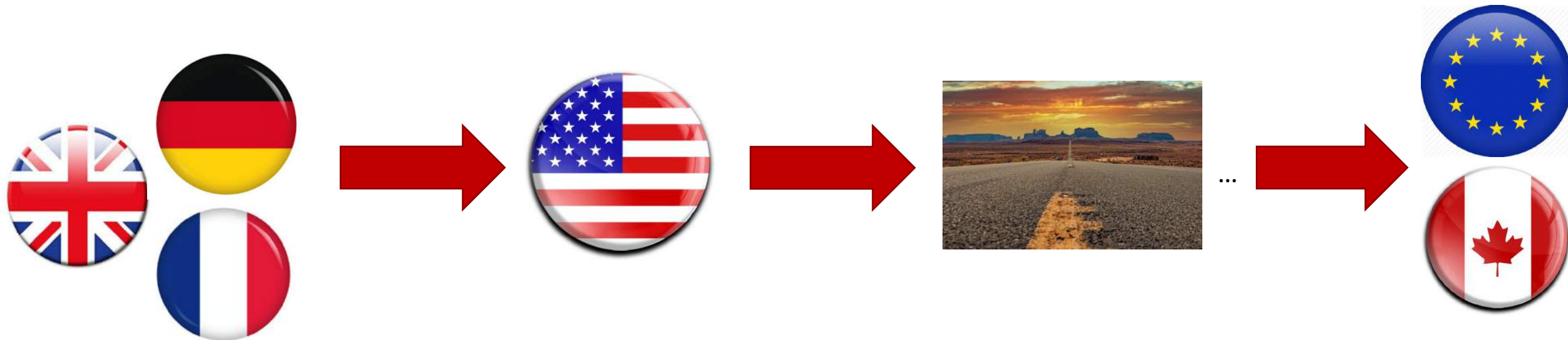
Product	U.S. Price per Gram	U.S. Price Divided by Average International Price (U.S. = 1)	Country with Lowest Price	Country with Median Price	Country with Highest Price
Alimta (pemetrexed sodium)	\$4,690	2.0	39.7 (Canada)	1.8 (Japan)	1.3 (Austria)
Aranesp (darboepoetin alfa)	\$3,517,653	2.1	3.4 (Portugal)	2.4 (France)	1.3 (Belgium)
Avastin (bevacizumab)	\$6,504	2.0	2.4 (France)	2.2 (Japan)	1.5(Belgium)
Cimzia (certolizumab pegol)	\$8,197	3.0	4.2 (France)	3.3 (Sweden)	2.2 (Germany)
Eligard/ Lupron (leuprolide acetate)	\$37,814	1.3	5.8 (Greece)	1.4 (Sweden)	0.95 (Japan)
Eylea (aflibercept)	\$775,994	1.7	3.1 (Belgium)	1.6 (UK)	1.4 (Canada)
Gammagard (IVIG)	\$68	0.95	1.8 (Japan)	1.0 (France)	0.69 (Spain)
Gamunex-c/ Gammaked (IVIG)	\$67	1.1	1.8 (Sweden)	1.1 (Italy)	1.0 (Finland)
Herceptin (trastuzumab)	\$7,688	2.2	2.7 (Japan)	2.4 (Portugal)	1.5 (Germany)
Kadcyla (ado-trastuzumab emtansine)	\$26,249	1.3	1.6 (Canada)	1.2 (France)	1.0 (Spain)
Keytruda (pembrolizumab)	\$40,036	1.2	1.5 (Slovakia)	1.3 (UK)	0.91 (Spain)
Lucentis (ranibizumab)	\$3,270,469	5.4	9.8 (Greece)	6.9 (France)	1.4 (Japan)
Neulasta (pegfilgrastim)	\$588,937	3.2	4.7 (Portugal)	3.3 (France)	1.8 (Canada)
Opdivo (nivolumab)	\$22,856	1.4	1.9 (Germany)	1.5 (Sweden)	0.86 (Japan)
Orencia (abatacept)	\$4,381	2.3	3.2 (Slovakia)	2.5 (France)	1.6 (Germany)
Privigen (IVIG)	\$65	1.2	1.8 (Sweden)	1.3 (Belgium)	0.91 (Finland)
Prolia/Xgeva (denosumab)	\$15,575	4.6	5.9 (France)	4.8 (Japan)	3.4 (Canada)
Remicade (infliximab)	\$7,108	1.2	1.9 (Slovakia)	1.2 (Japan)	0.84 (Sweden)
Rituxan (rituximab)	\$6,597	2.7	4.3 (UK)	2.8 (Spain)	2.1 (Japan)
Sandostatin LAR (octreotide acetate)	\$111,548	2.7	6.1 (Spain)	3.1 (UK)	1.5 (Germany)
Soliris (eculizumab)	\$16,720	0.99	1.3 (UK)	1.0 (Italy)	0.86 (Germany)
Treanda (bendamustine)	\$24,138	6.9	34.2 (Sweden)	10.8 (France)	2.5 (Canada)
Tysabri (natalizumab)	\$18,674	2.9	4.1 (UK)	2.8 (France)	2.1 (Canada)
Velcade (bortezomib)	\$359,040	1.1	5.9 (Czech Republic)	1.0 (Italy)	0.82 (Germany)
Xolair (omalizumab)	\$6,128	2.2	2.9 (UK)	2.2 (Italy)	1.8(Canada)
Yervoy (ipilimumab)	\$121,862	1.5	1.7 (Japan)	1.6 (Germany)	1.2 (Belgium)
Zaltrap (ziv-aflibercept)	\$7,413	1.7	2.1 (France)	1.6 (Italy)	1.3 (Japan)
All Products Total	N=27	1.8			

Source: IQVIA MIDAS. Analysis based on data released August 17, 2018.

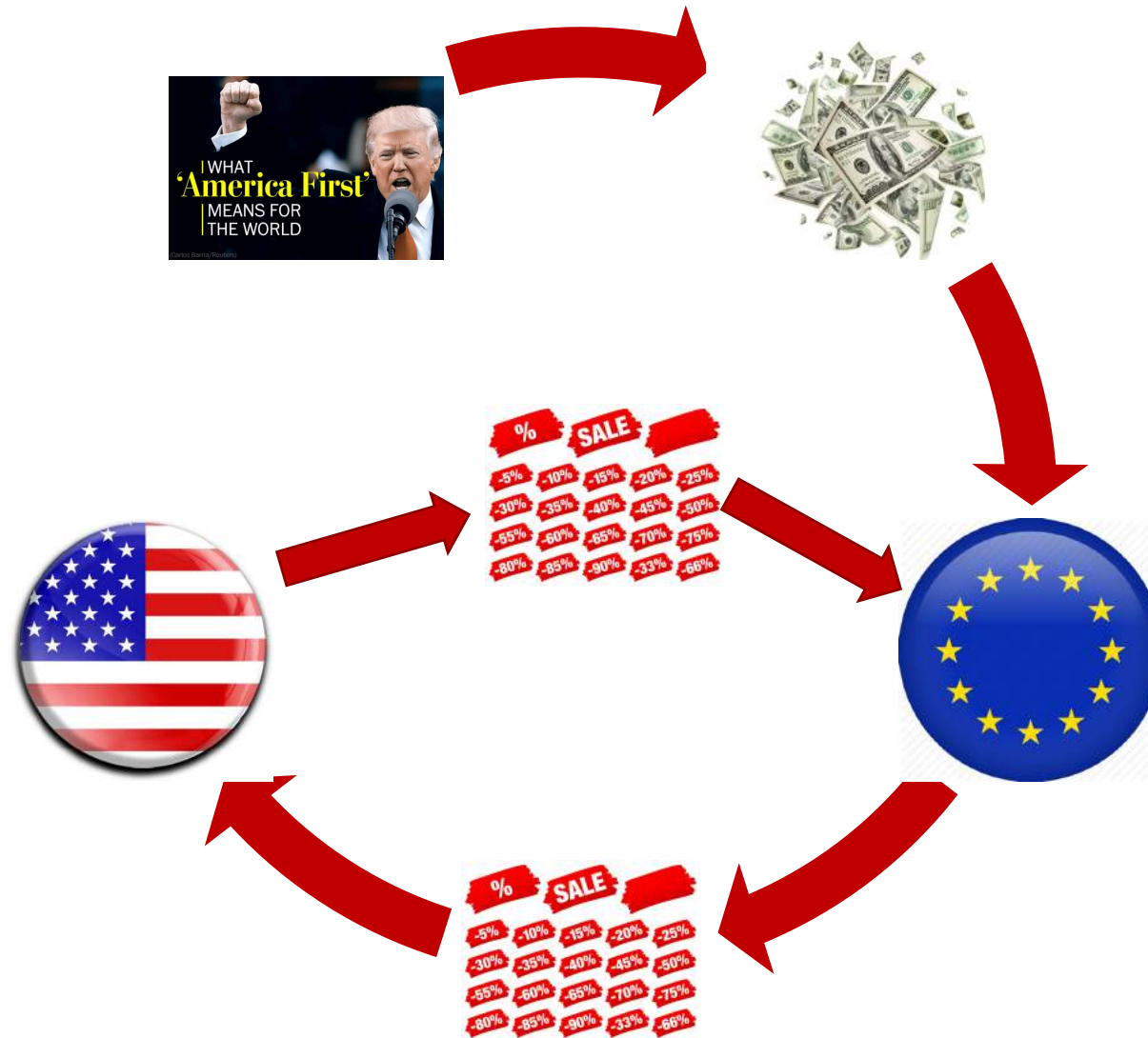
Scenario thinking... What if...



Or maybe...



Downward spiral upcoming?!



Questions?