Recent Developments In U.S. Pharmaceutical Pricing: The Case Example Of The Proposed Medicare Part B Experiment

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This Presentation at a Glance

- Trump Administration's policies on drug pricing now coming into focus
- Multiple steps across many areas in recent weeks and months; more to come
- Case example: Medicare Part B pricing proposal
- Entering new and uncertain terrain in linking domestic payment under Medicare to international prices and regulatory policies
- Questions abound: How far will these moves go? What will be impact on both pricing and innovation?
- Bottom line: In drug pricing, nothing is easy -- or noncontroversial

Administration's Drug Pricing Focus

- High and rising list prices for many drugs
- Overpayment in government programs due to lack of negotiation
- High out-of-pocket costs for consumers and patients
- "Foreign governments' free-riding off of American investment in innovation"

American Patients First

The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

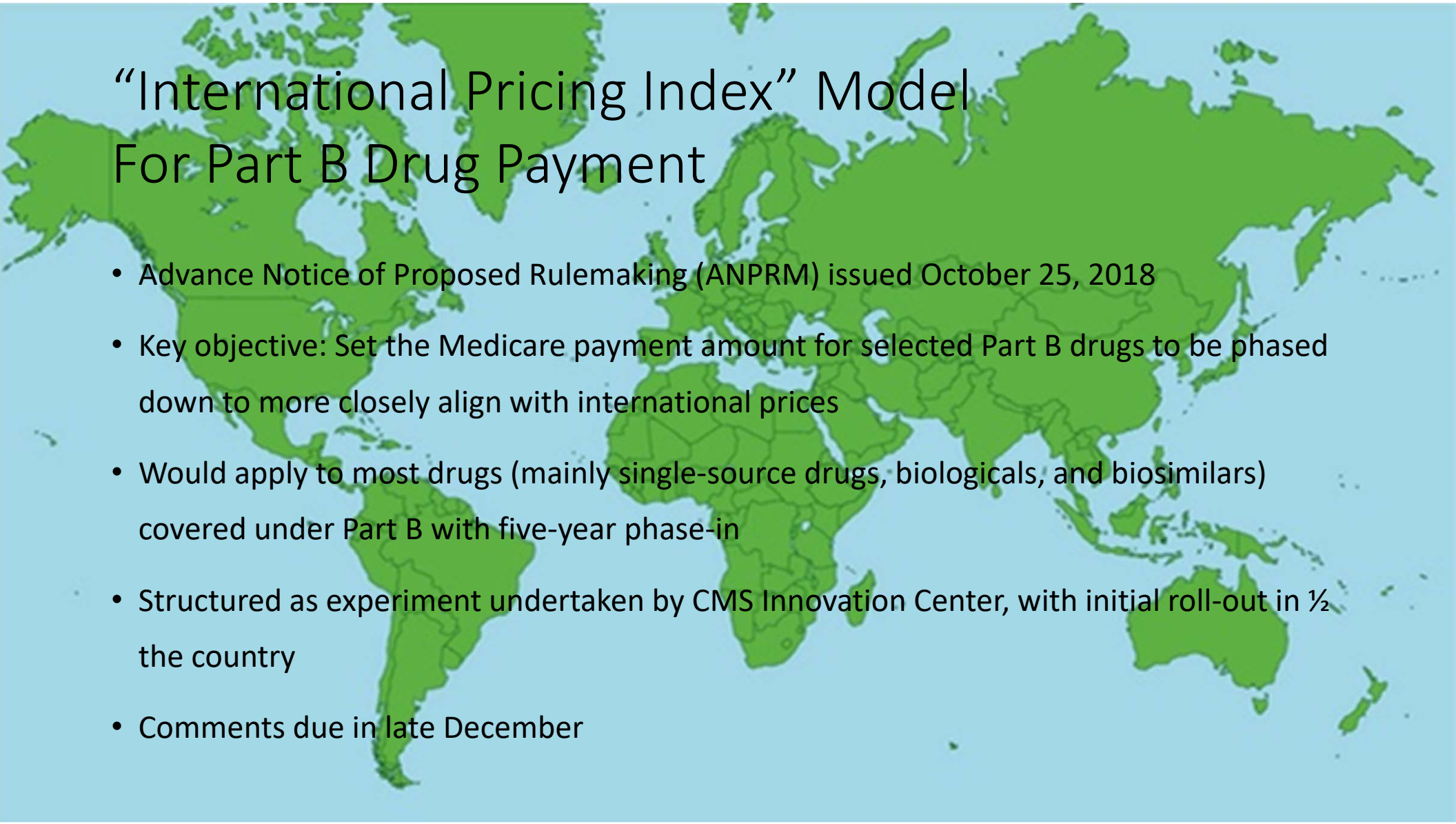
MAY 2018

Key Blueprint Features And Follow-Through

- Bring down out-of-pocket (OOP) costs
  - ➢E.g., cut in Medicare Part B reimbursement for drugs purchased under 340B program; estimated to save enrollees $320 million in OOP costs
- Boost competition
  - ➢E.g., step up approvals of generics; records in FDA approvals set in FY 2017 and 2018; investigate potential to import sole-source drugs with big price spikes

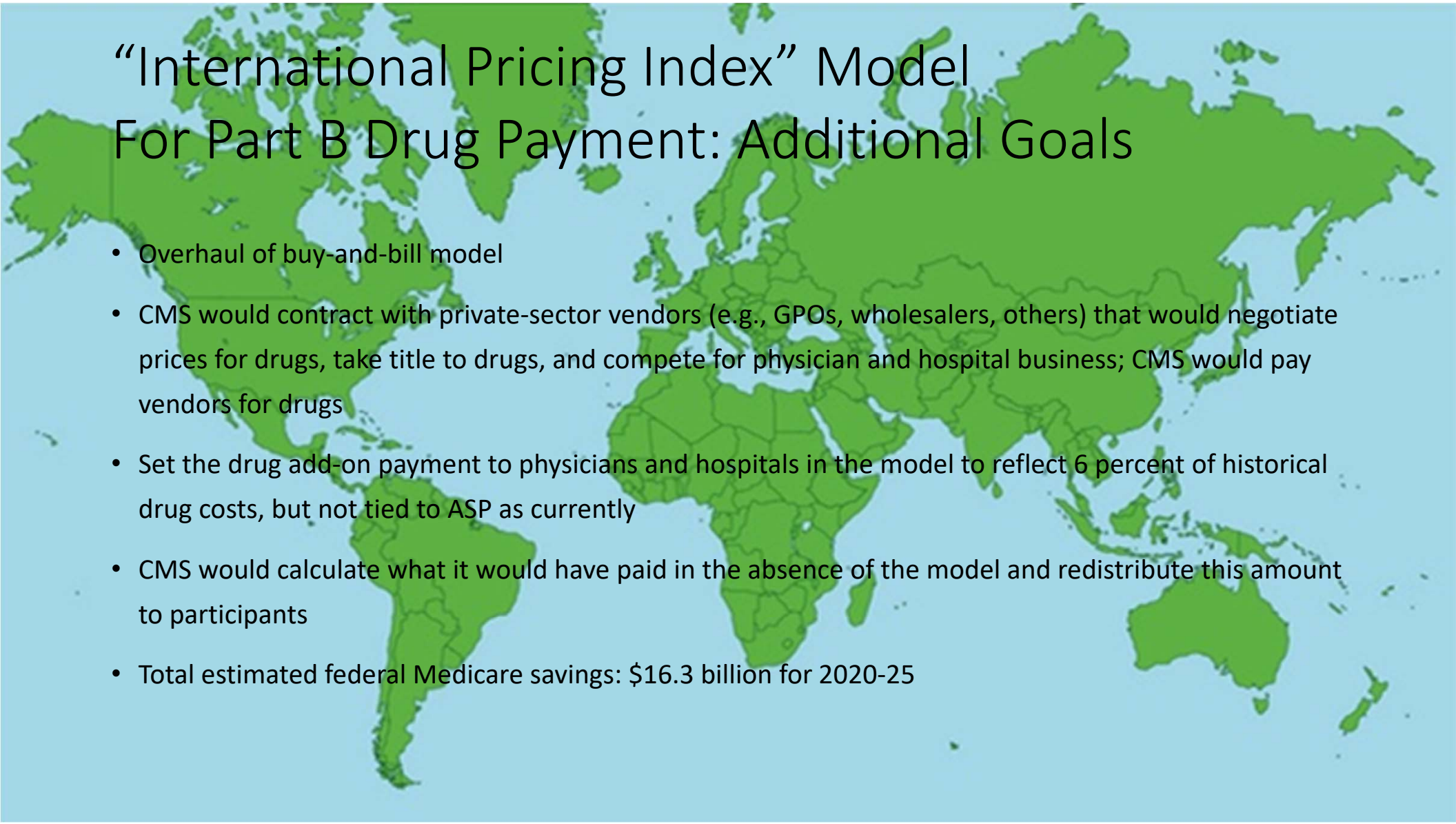
Key Blueprint Features And Follow-Through

- Strengthen negotiation
  - ➢E.g., Medicare Advantage plans can use step therapy; consolidate management of Part B and D drugs
- Create incentives for lower list prices
  - ➢E.g., CMS's drug pricing dashboard; proposal to include list prices in direct-to consumer television advertising



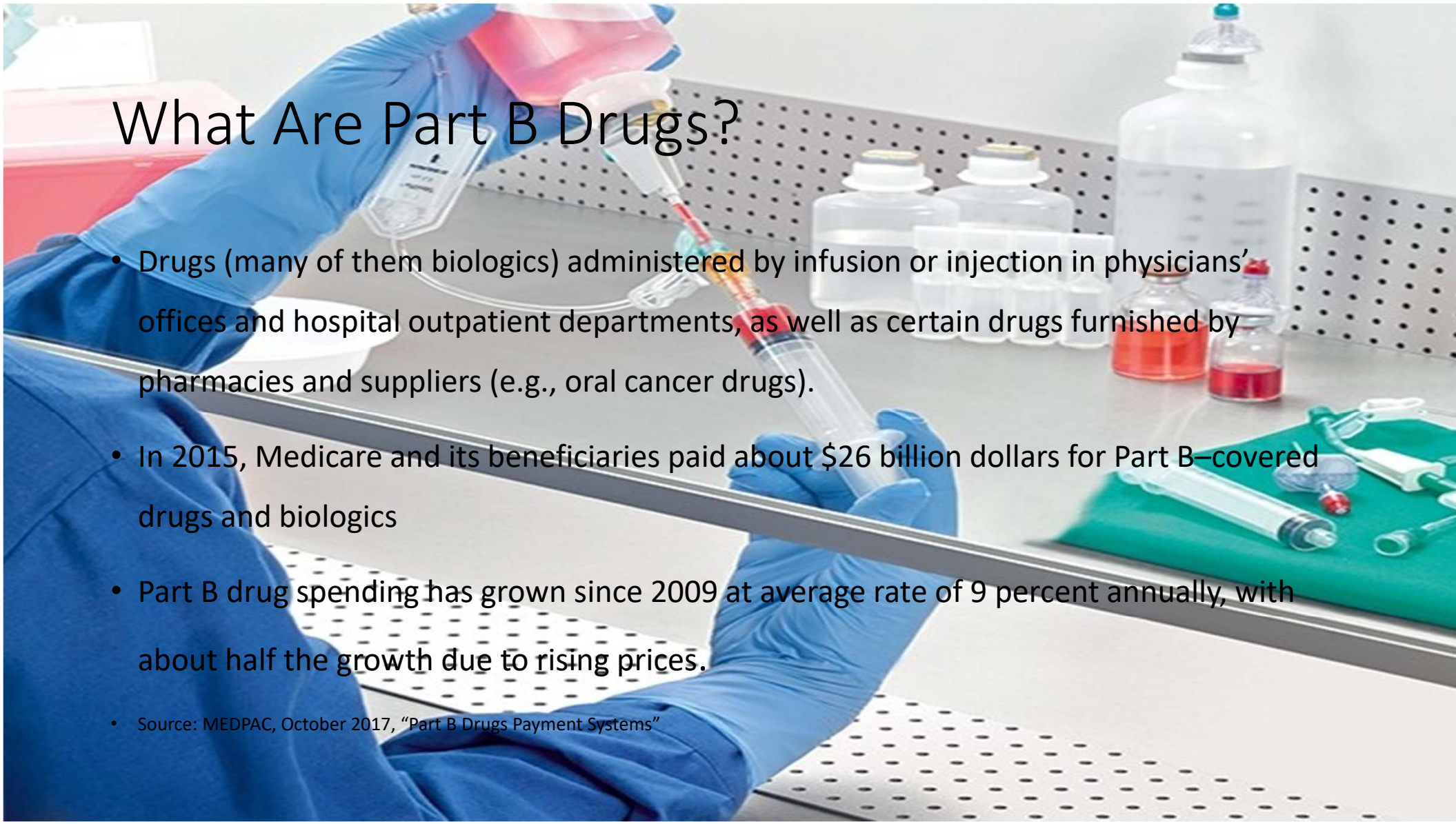
"International Pricing Index" Model For Part B Drug Payment

- Advance Notice of Proposed Rulemaking (ANPRM) issued October 25, 2018
- Key objective: Set the Medicare payment amount for selected Part B drugs to be phased down to more closely align with international prices
- Would apply to most drugs (mainly single-source drugs, biologicals, and biosimilars) covered under Part B with five-year phase-in
- Structured as experiment undertaken by CMS Innovation Center, with initial roll-out in ½ the country
- Comments due in late December



"International Pricing Index" Model For Part B Drug Payment: Additional Goals

- Overhaul of buy-and-bill model
- CMS would contract with private-sector vendors (e.g., GPOs, wholesalers, others) that would negotiate prices for drugs, take title to drugs, and compete for physician and hospital business; CMS would pay vendors for drugs
- Set the drug add-on payment to physicians and hospitals in the model to reflect 6 percent of historical drug costs, but not tied to ASP as currently
- CMS would calculate what it would have paid in the absence of the model and redistribute this amount to participants
- Total estimated federal Medicare savings: $16.3 billion for 2020-25



What Are Part B Drugs?

- Drugs (many of them biologics) administered by infusion or injection in physicians' offices and hospital outpatient departments, as well as certain drugs furnished by pharmacies and suppliers (e.g., oral cancer drugs).
- In 2015, Medicare and its beneficiaries paid about $26 billion dollars for Part B–covered drugs and biologics
- Part B drug spending has grown since 2009 at average rate of 9 percent annually, with about half the growth due to rising prices.
- Source: MEDPAC, October 2017, "Part B Drugs Payment Systems"

How Are Part B Drugs Paid For Today?

- Most are paid based on the average sales price, or ASP
- ASP = average of manufacturers' sales prices to all purchasers net of discounts, rebates, and price concessions (although not all manufacturers have to report data and data is lagged)
- Under "buy and bill" system, providers purchase the drugs, and then Medicare pays providers the ASP plus 6 percent for drugs furnished in physicians' offices; home infusion drugs; and clotting factor, as well as for Part B drugs furnished in hospital outpatient departments
- In some settings, Part B drug payment is bundled into payment for other services (e.g., prospective payment for dialysis for end-stage renal disease patients)
- Medicare makes an additional, separate payment to physician or hospital for administering the drug based on the Medicare physician fee schedule or the outpatient prospective payment system

Perverse Incentives

- Since Part B payment is linked to ASP, it will rise as drug prices rise, with no overall check on system
- If providers always receive 106 percent of ASP, they have no incentive to choose the lowest-priced among drugs with similar health effects
- Unlike in other aspects of Medicare (e.g, Part D), there is no formulary management, such as step therapy, to achieve better value
- Since beneficiaries cost-sharing equals 20 percent of the total payment, they are not protected against rising drug costs or providers' perverse decisions

TABLE

Top 10 Part B–covered drugs paid based on ASP by total expenditures and by number of beneficiaries who used the drug, 2015

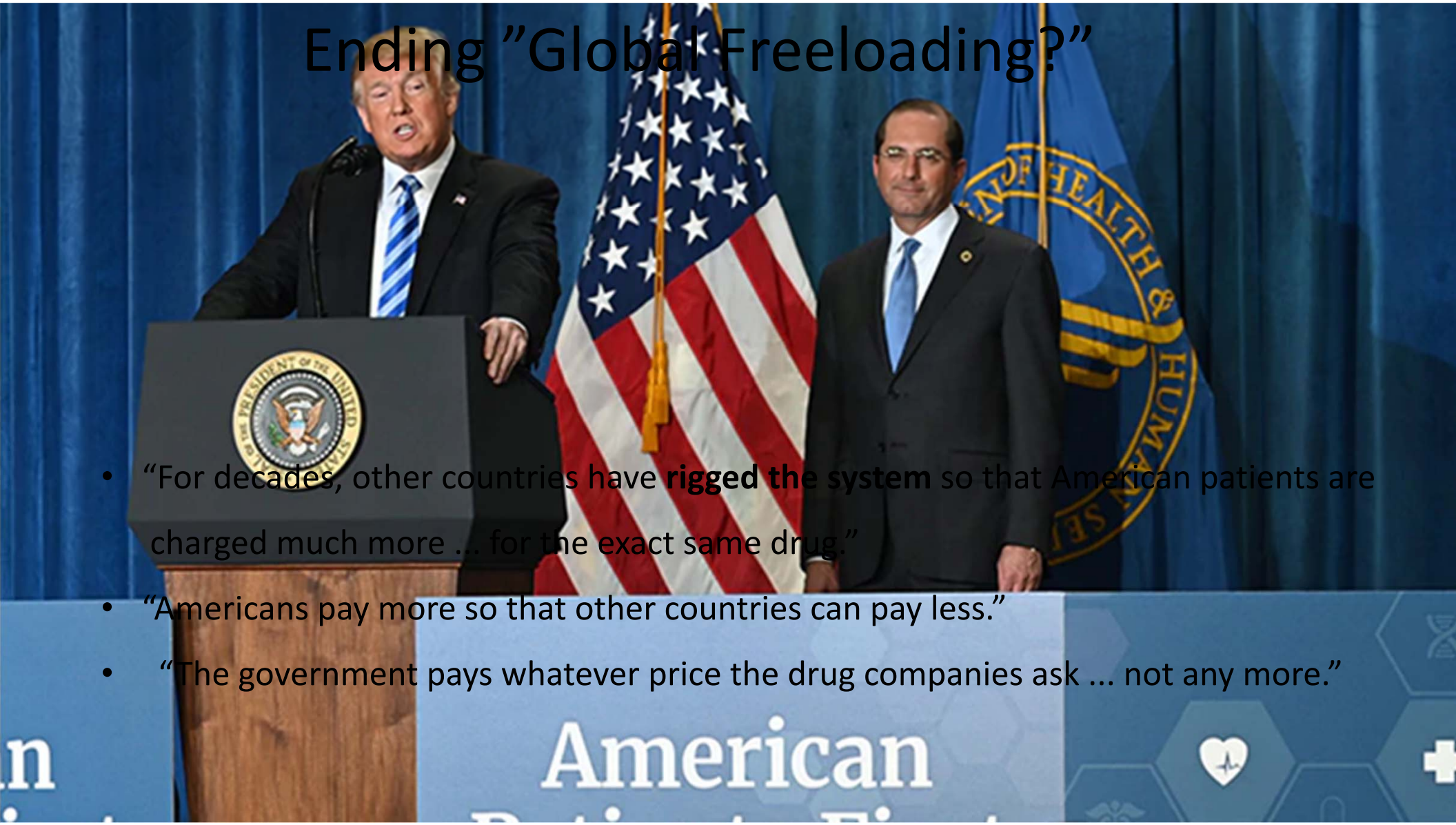
HCPCS code	Drug name	Common indication or type of drug	Total Medicare payments (in billions)	Number of beneficiaries who used drug (in thousands)	Average ASP + 6 percent payment	
					Per administration	Per beneficiary
J0178	Aflibercept	Macular degeneration	$1.8	180	$2,100	$10,000
J9310	Rituximab	Cancer, RA				22,800
J2505	Pegfilgrastim	Cancer supportive	1.3	97	3,600	12,800
J1745	Infliximab					21,200
J2778	Ranibizumab	Macular degeneration	1.2	120	2,000	9,500
J9035	Bevacizumab	Cancer, [illegible]				4,100
J0897	Denosumab	Osteoporosis, cancer supportive	0.9	354	1,200	2,400
J9355	Trastuzumab	Cancer	0.6	20	3,200	32,400
J9305	Pemetrexed	Cancer	0.5	22	5,500	24,900
J9041	Bortezomib	Cancer	0.5	21	1,500	24,000

Bevacizumab (Avastin) – even lower costs and most favorable cost-effectiveness of 3 drugs for AMD

[illegible] are calculated at the drug billing-code level and do not include the effect of the [illegible] are calculated after [illegible] for the HCPCS code). Critical access hospitals and other hospitals not paid under the outpatient prospective payment system are excluded from the analysis. Data for beneficiaries with Medicare as a secondary payer are excluded from the analysis. Vaccines paid 95 percent of the average wholesale price are also excluded (e.g., Prevnar 13, a pneumococcal vaccine, for which Medicare paid about $0.9 billion in 2015).

Source: MedPAC analysis of Medicare claims data for physicians, outpatient hospitals, and suppliers.

Ending ”Global Freeloading?”

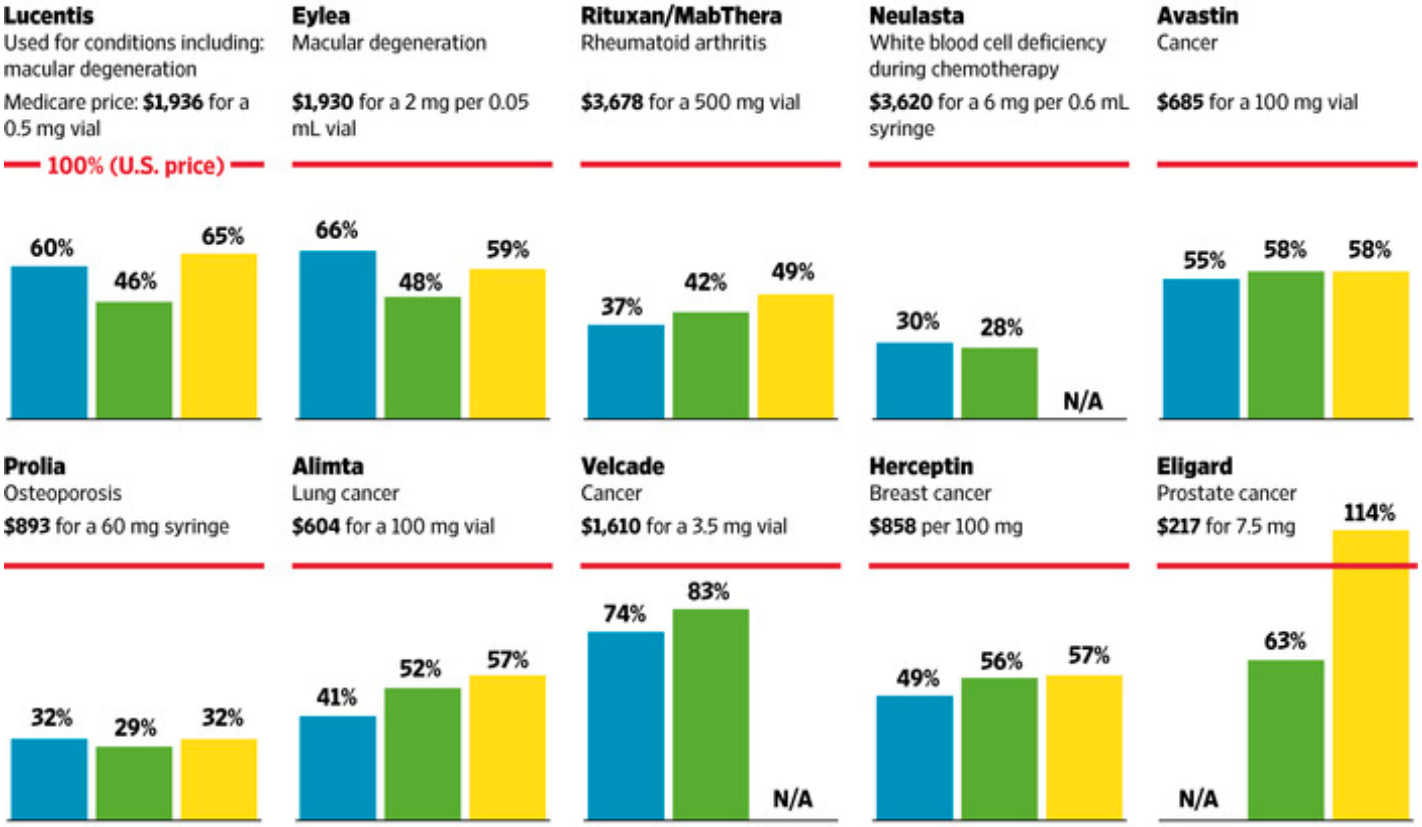


- “For decades, other countries have **rigged the system** so that American patients are charged much more … for the exact same drug.”
- “Americans pay more so that other countries can pay less.”
- “The government pays whatever price the drug companies ask … not any more.”

Same Drug, Higher Price

Here are prices the government health systems of England, Norway and Ontario, Canada, paid for some of the biggest brand-name drugs by Medicare Part B expenditure, for which pricing was available in multiple countries.

Price as a percentage of U.S. Medicare price in: England Norway Ontario



Note: Medicare beneficiaries are responsible for paying 20% of prices listed here. Medicare itself covers 80%. Prices listed reflect a temporary 2% discount imposed by federal spending cuts known as budget sequestration. All prices are for third quarter of 2015; foreign prices were converted to U.S. dollars at July 1, 2015, exchange rates. Top drugs were determined by Medicare Part B payments to doctors' offices and medical practices in 2013, the latest year for which data were available. Norwegian prices include 25% Value Added Tax levied on pharmaceuticals. England's National Health Service says prices listed here are 'indicative' and may vary in some circumstances.

Sources: WSJ analysis of data from the Centers for Medicare & Medicaid Services; the Norwegian Medicines Agency and the Norwegian Drug Procurement Cooperation; the NHS Business Services Authority; and Ontario's Ministry of Health and Long-Term Care

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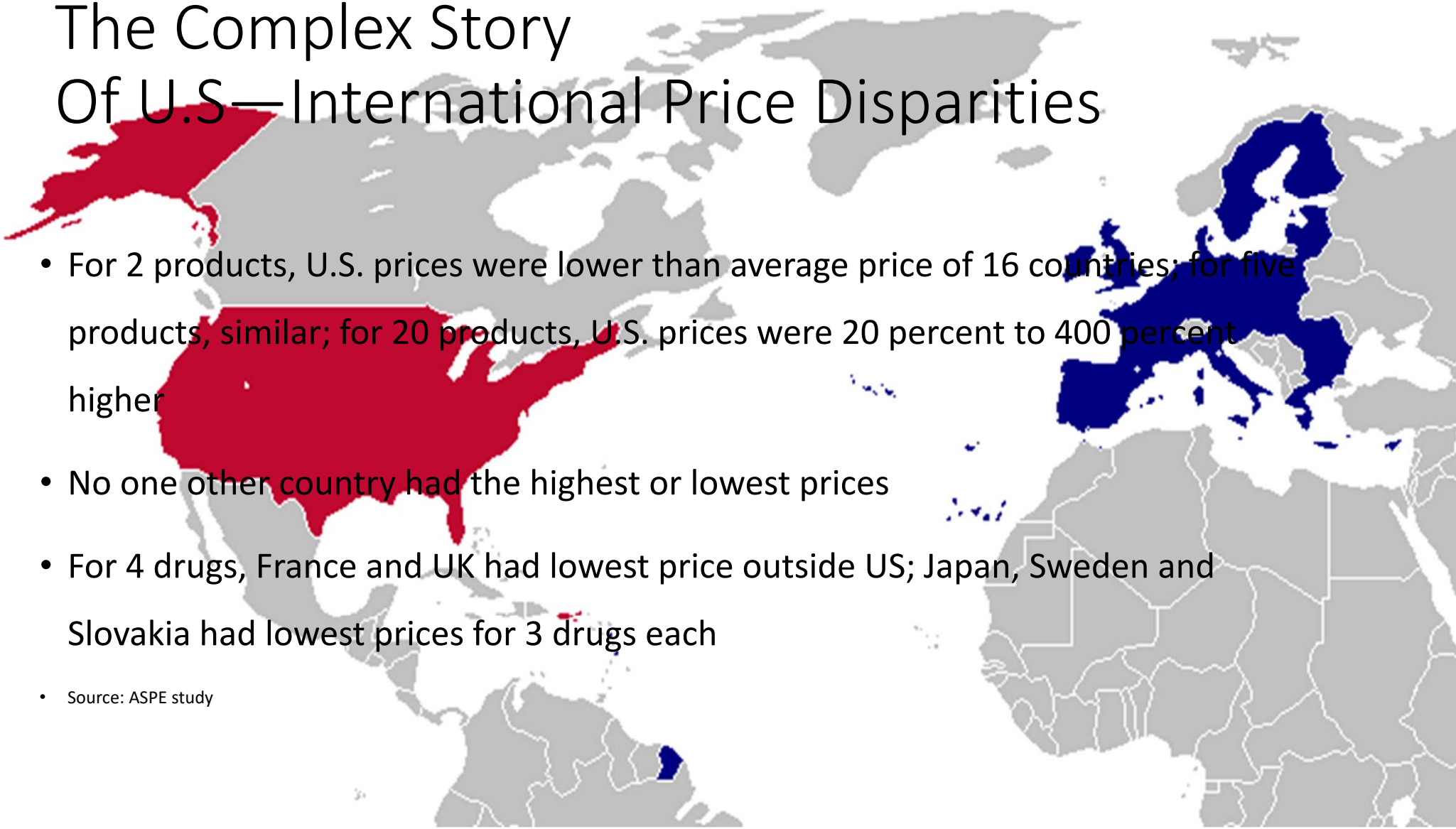
The Complex Story Of U.S—International Price Disparities

- ASPE study of drugs paid for under Part B in United States and 15 European countries and Japan
- Across 27 drugs, “ex-manufacturer prices” (before wholesaler markups) are 1.8 times that of the average international prices in 2018
- But: The U.S. **actually had the highest prices for just 13 (1/2) of these drugs**
- Germany and Canada had the highest prices for 6 drugs; Japan for 5 drugs
- Source: “Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures,” U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Oct. 25, 2018

The Complex Story Of U.S—International Price Disparities

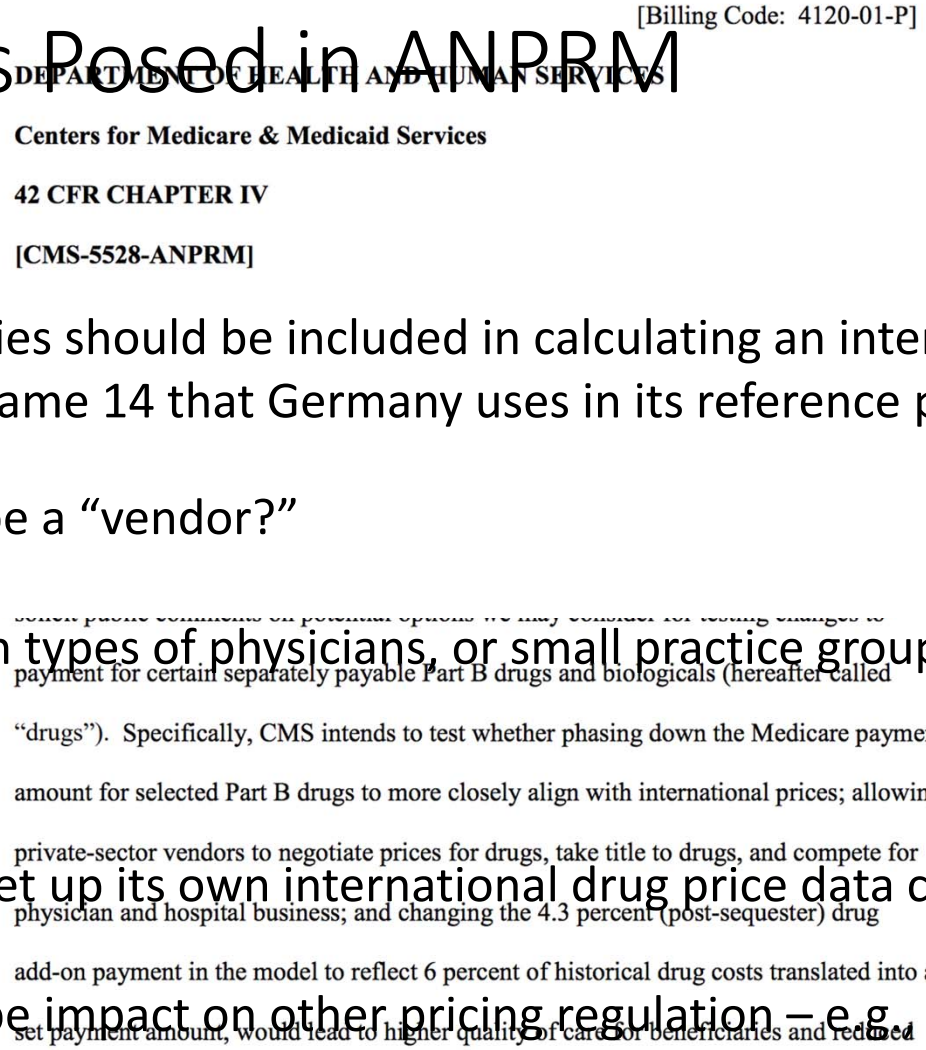


- For 2 products, U.S. prices were lower than average price of 16 countries; for five products, similar; for 20 products, U.S. prices were 20 percent to 400 percent higher
- No one other country had the highest or lowest prices
- For 4 drugs, France and UK had lowest price outside US; Japan, Sweden and Slovakia had lowest prices for 3 drugs each
- Source: ASPE study

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.					

Key Issues Posed in ANPRM



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DEPARTMENT OF HEALTH AND HUMAN SERVICES

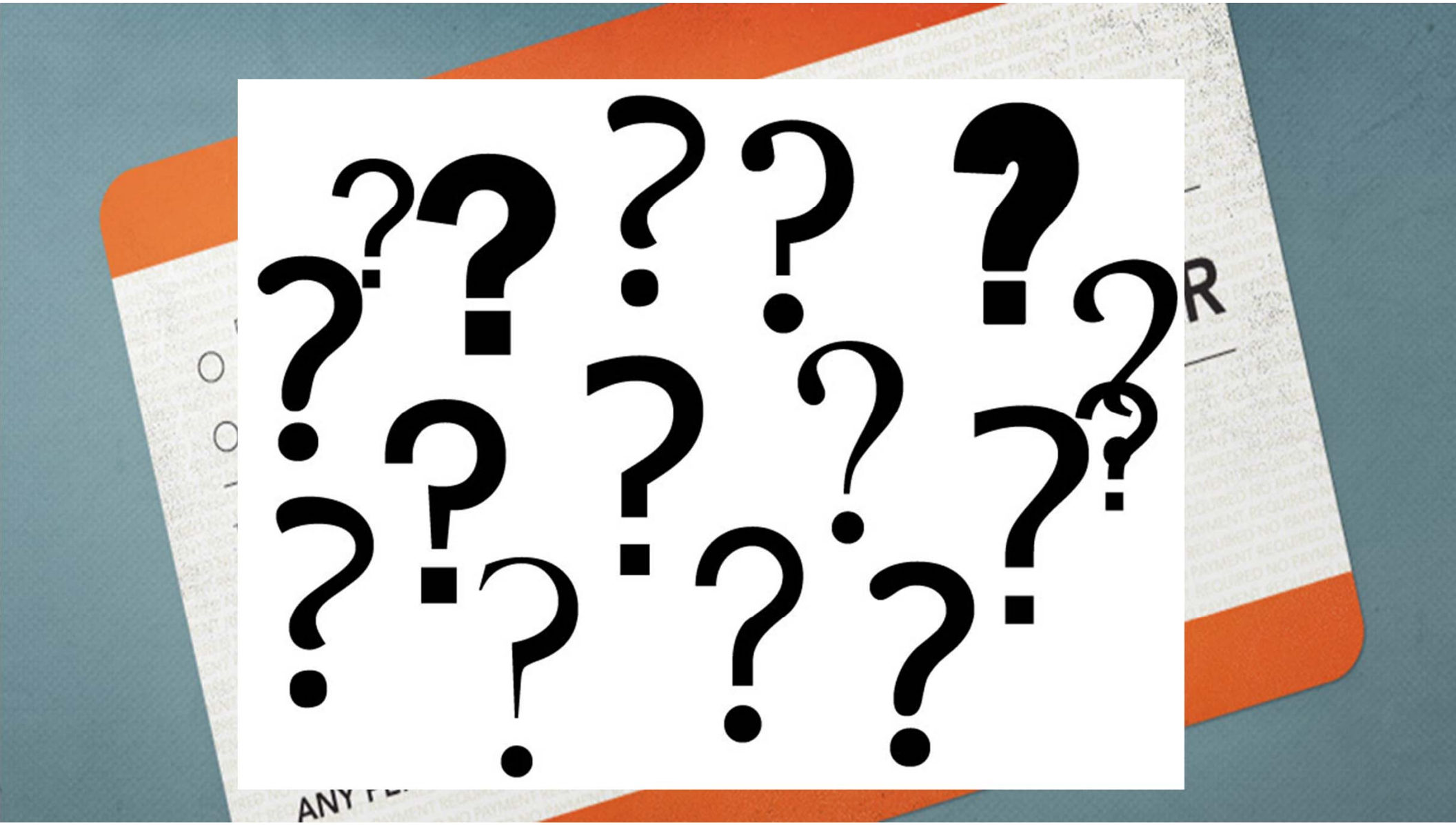
Centers for Medicare & Medicaid Services

42 CFR CHAPTER IV

[CMS-5528-ANPRM]

solicit public comments on potential options we may consider for testing changes to payment for certain separately payable Part B drugs and biologicals (hereafter called "drugs"). Specifically, CMS intends to test whether phasing down the Medicare payment amount for selected Part B drugs to more closely align with international prices; allowing private-sector vendors to negotiate prices for drugs, take title to drugs, and compete for physician and hospital business; and changing the 4.3 percent (post-sequester) drug add-on payment in the model to reflect 6 percent of historical drug costs translated into a set payment amount, would lead to higher quality of care for beneficiaries and reduced

- Which countries should be included in calculating an international pricing index? (The same 14 that Germany uses in its reference pricing system, e.g.?)
- Who gets to be a "vendor?"
- Should certain types of physicians, or small practice groups, be excluded from model?
- Should CMS set up its own international drug price data collection system?
- What would be impact on other pricing regulation – e.g., Medicaid Best Price?

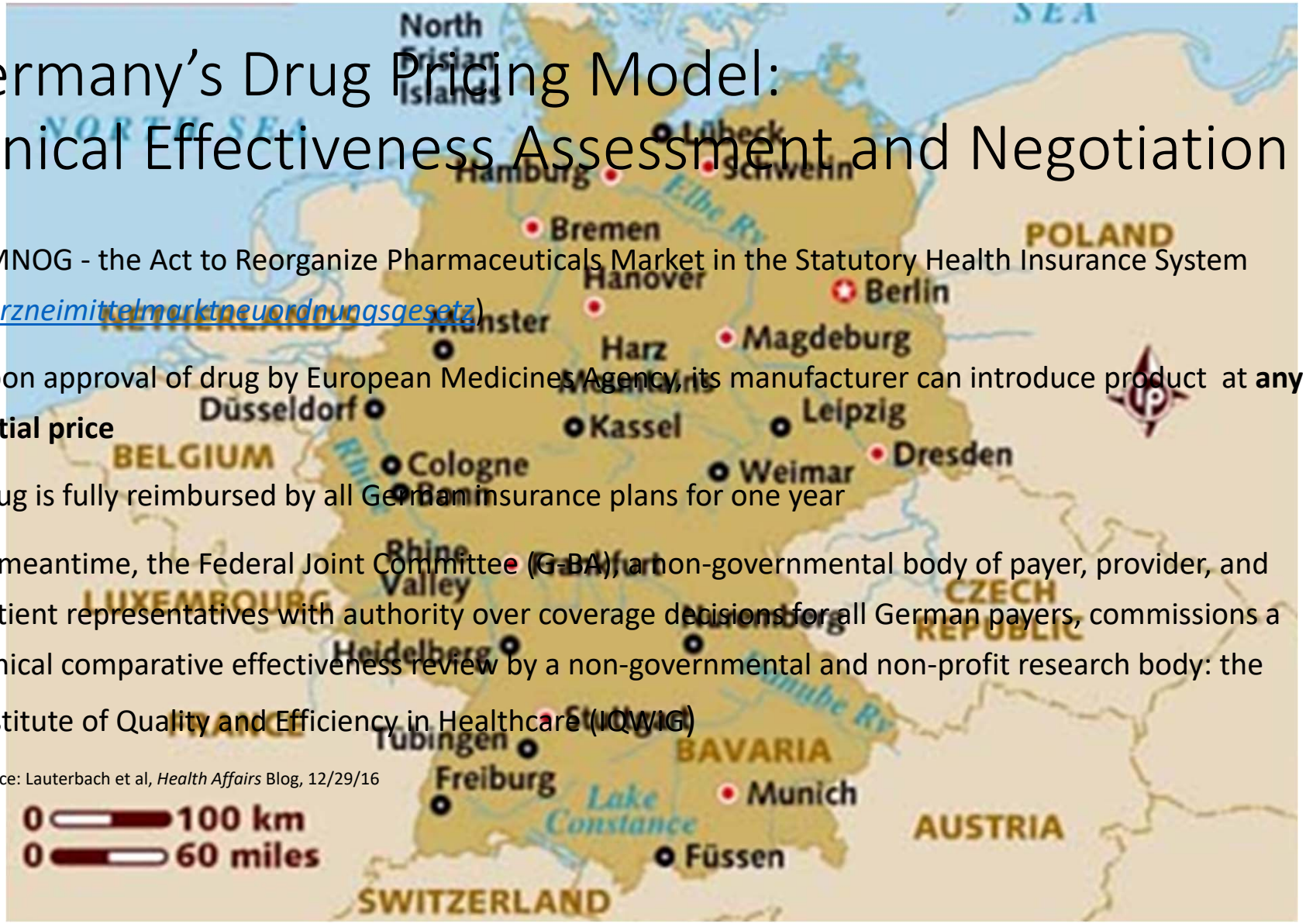


"The administration is imposing foreign price controls from countries with socialized health care systems that deny their citizens access and discourage innovation."

-Stephen Ubl, CEO, PhRMA, statement on 10/25/18

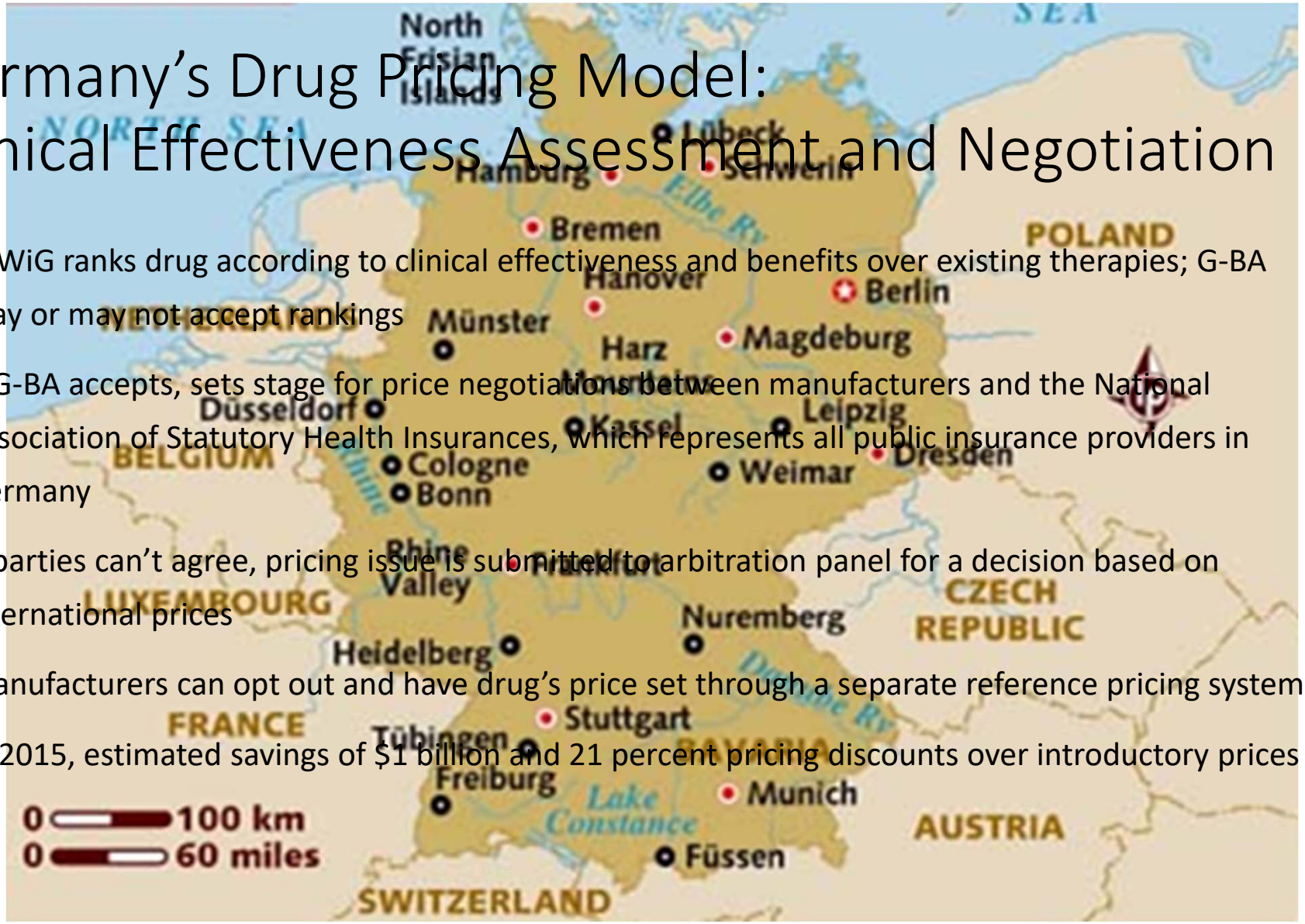
Germany's Drug Pricing Model: Clinical Effectiveness Assessment and Negotiation

- AMNOG - the Act to Reorganize Pharmaceuticals Market in the Statutory Health Insurance System (*Arzneimittelmarktneuordnungsgesetz*)
- Upon approval of drug by European Medicines Agency, its manufacturer can introduce product at **any initial price**
- Drug is fully reimbursed by all German insurance plans for one year
- In meantime, the Federal Joint Committee (G-BA), a non-governmental body of payer, provider, and patient representatives with authority over coverage decisions for all German payers, commissions a clinical comparative effectiveness review by a non-governmental and non-profit research body: the Institute of Quality and Efficiency in Healthcare (IQWiG)
- Source: Lauterbach et al, *Health Affairs* Blog, 12/29/16



Germany's Drug Pricing Model: Clinical Effectiveness Assessment and Negotiation

- IQWiG ranks drug according to clinical effectiveness and benefits over existing therapies; G-BA may or may not accept rankings
- If G-BA accepts, sets stage for price negotiations between manufacturers and the National Association of Statutory Health Insurances, which represents all public insurance providers in Germany
- If parties can't agree, pricing issue is submitted to arbitration panel for a decision based on international prices
- Manufacturers can opt out and have drug's price set through a separate reference pricing system
- In 2015, estimated savings of $1 billion and 21 percent pricing discounts over introductory prices



More questions

- Isn't administration just proposing to piggyback on other nation's pharmaceutical pricing approaches?
- "A little socialism to avoid more socialism"
- What about direct negotiation between CMS and manufacturers?

More questions

- In paying higher prices for biopharmaceuticals generally, is the U.S. subsidizing more global innovation, more global industry profitability, or both?


The End