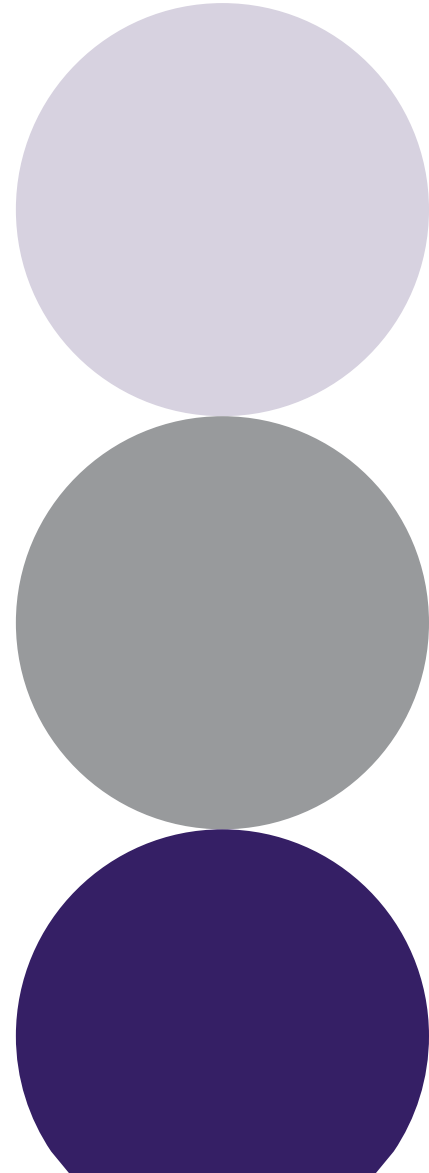


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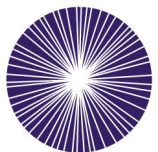
# The Continuing Saga of Part B Drugs

George A. Williams, M.D.



# Financial Disclosure

- None



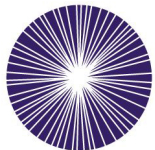
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# Financial Disclosure

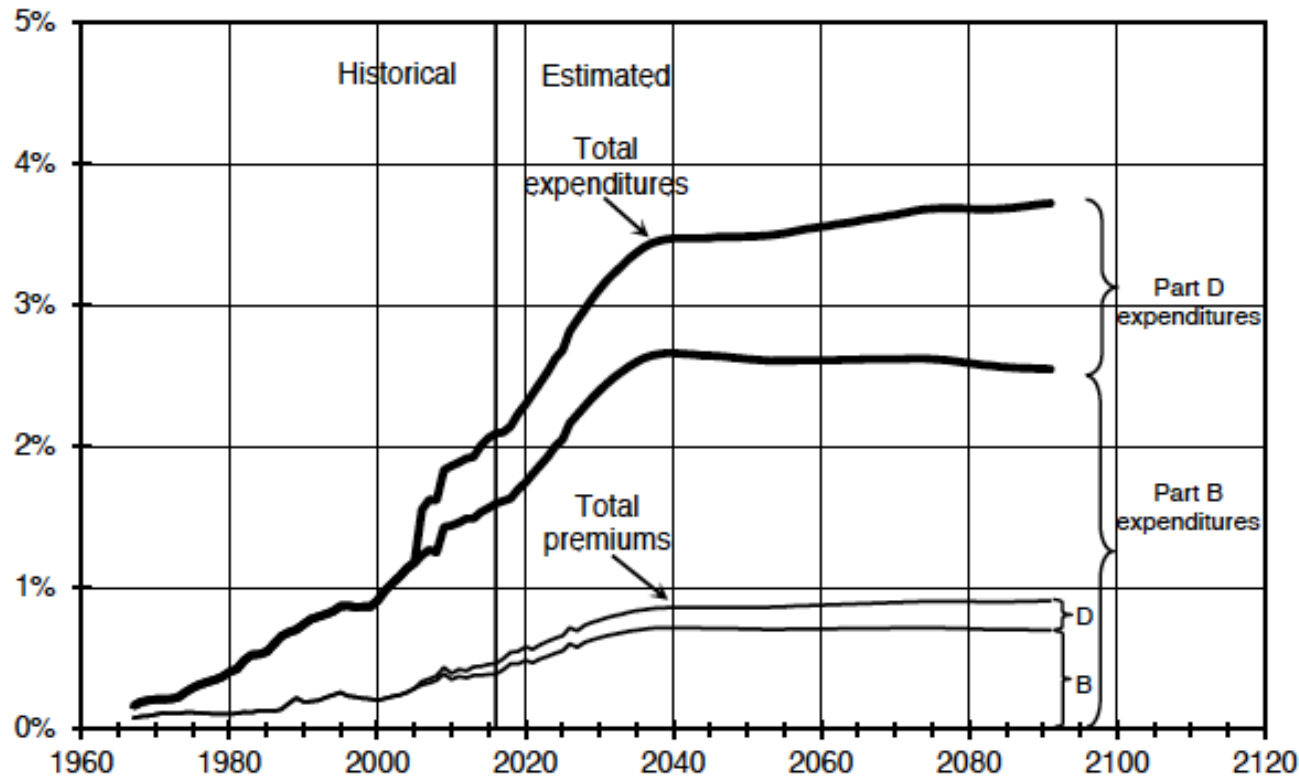
- I use drugs, lots of drugs



# The Problem



Figure II.F1.—SMI Expenditures and Premiums as a Percentage of the Gross Domestic Product

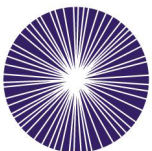


Medicare Trustees Report, 2017

HealthAffairs

The Washington Post

- Drug spending will increase faster than any other major medical good or service over the next decade.
- Prescription drug spending expected to grow at 6.3% per year, on average, between 2017 and 2026.



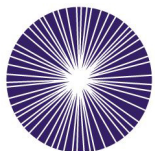
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Cuckler GA. Health Affairs 2018;37(3)

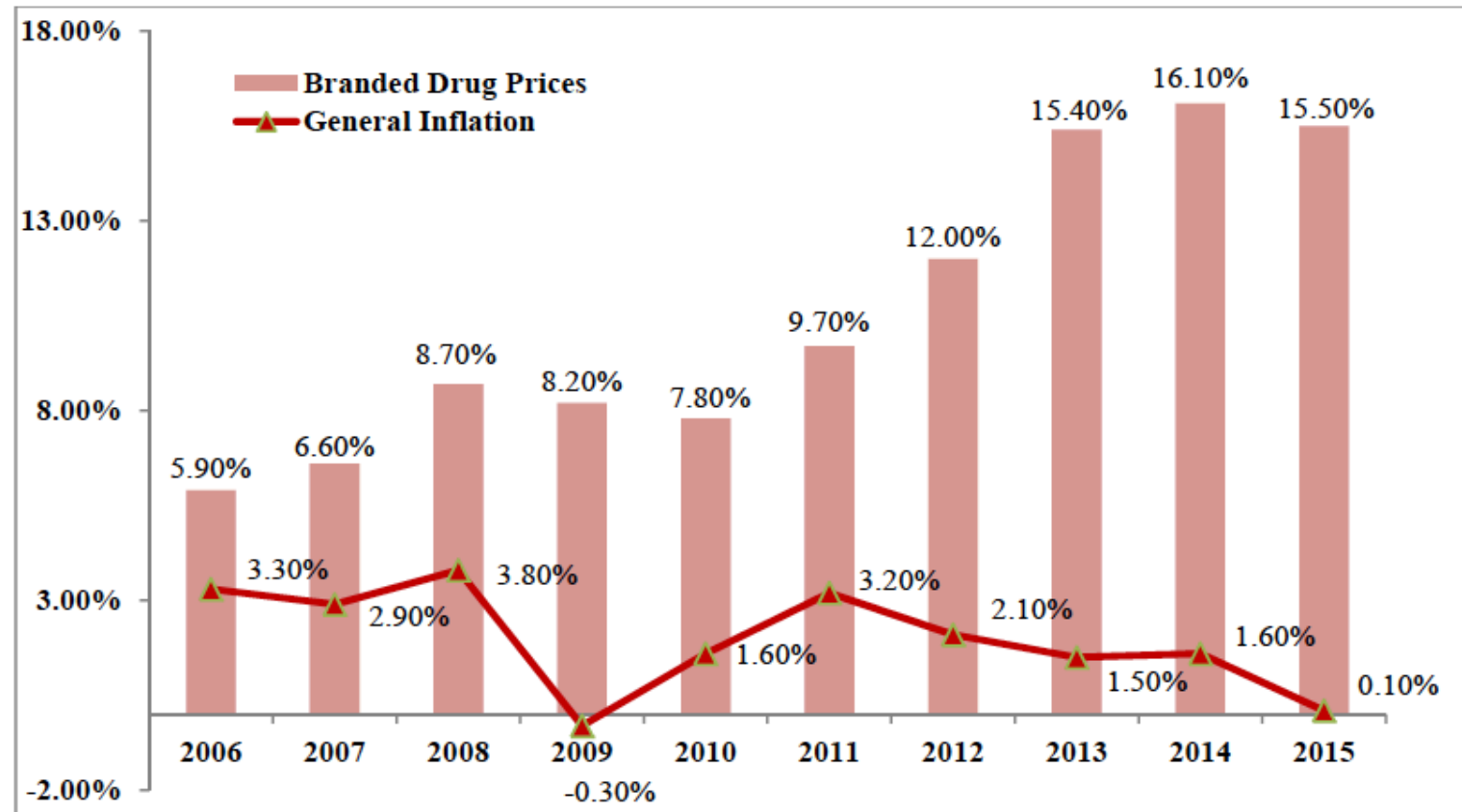
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# Trump vs PhRMA

- In 2017, President-Elect Donald Trump called out pharmaceutical companies for “getting away with murder” and driving up the costs of their drugs.
- “Pharma has a lot of lobbies, a lot of lobbyists and a lot of power. And there’s very little bidding on drugs. We’re the largest buyer of drugs in the world, and yet we don’t bid properly. And we’re going to start bidding and we’re going to save billions of dollars over a period of time.”



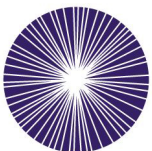
# Brand-Name Drug Price Increases vs. Inflation



**FIGURE 3-1** Average annual brand-name drug prices (a composite of 268 top drug products) compared with general inflation from 2006 to 2015.

SOURCE: Schondelmeyer and Purvis, 2016.

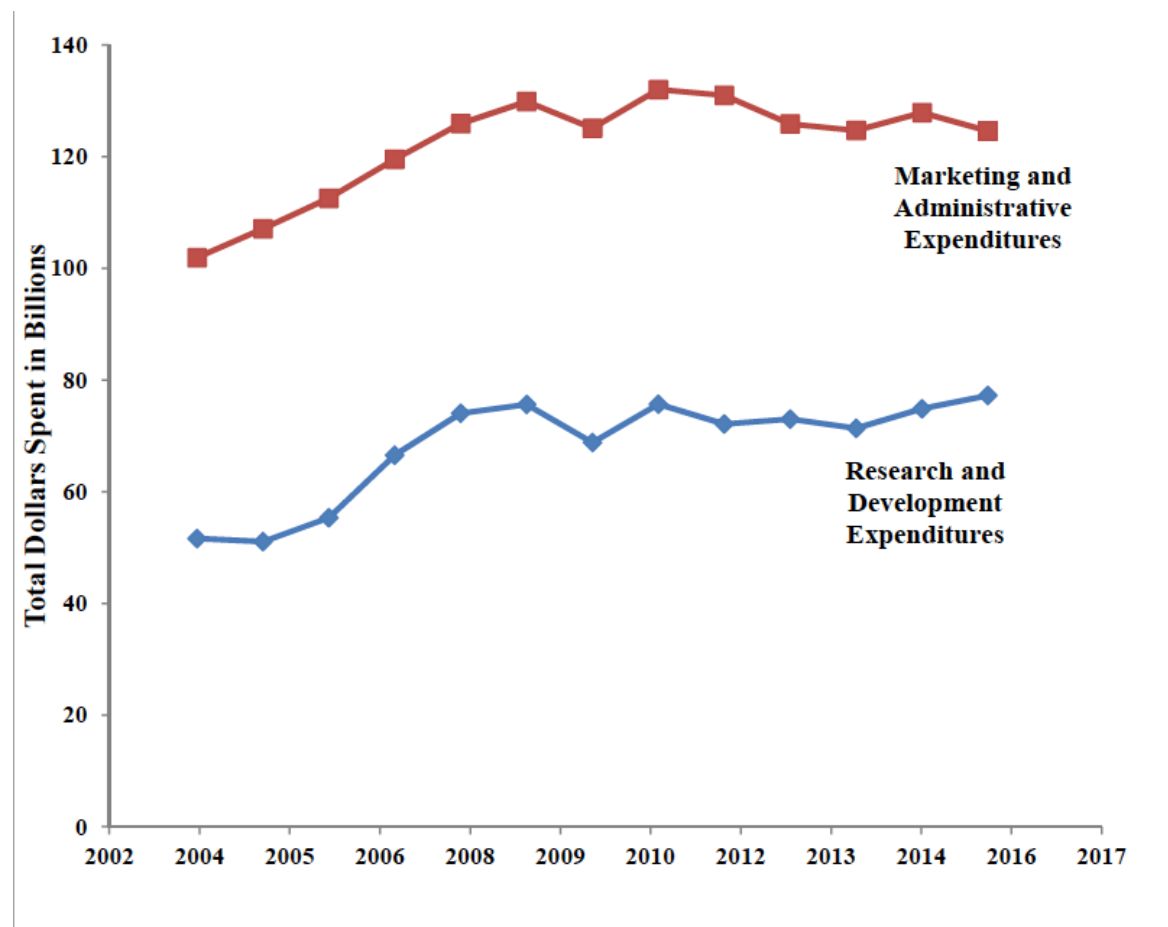
NASEM, Making Medicines Affordable, 2018



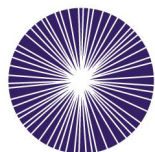
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# Marketing/Administrative vs. R&D Expenditures



**FIGURE 3-3** Comparison of total aggregate research-and-development and marketing-plus-administrative (including executive compensation) expenditures by 12 large pharmaceutical companies from 2003 to 2015.



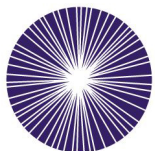
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NASEM, Making Medicines Affordable, 2018

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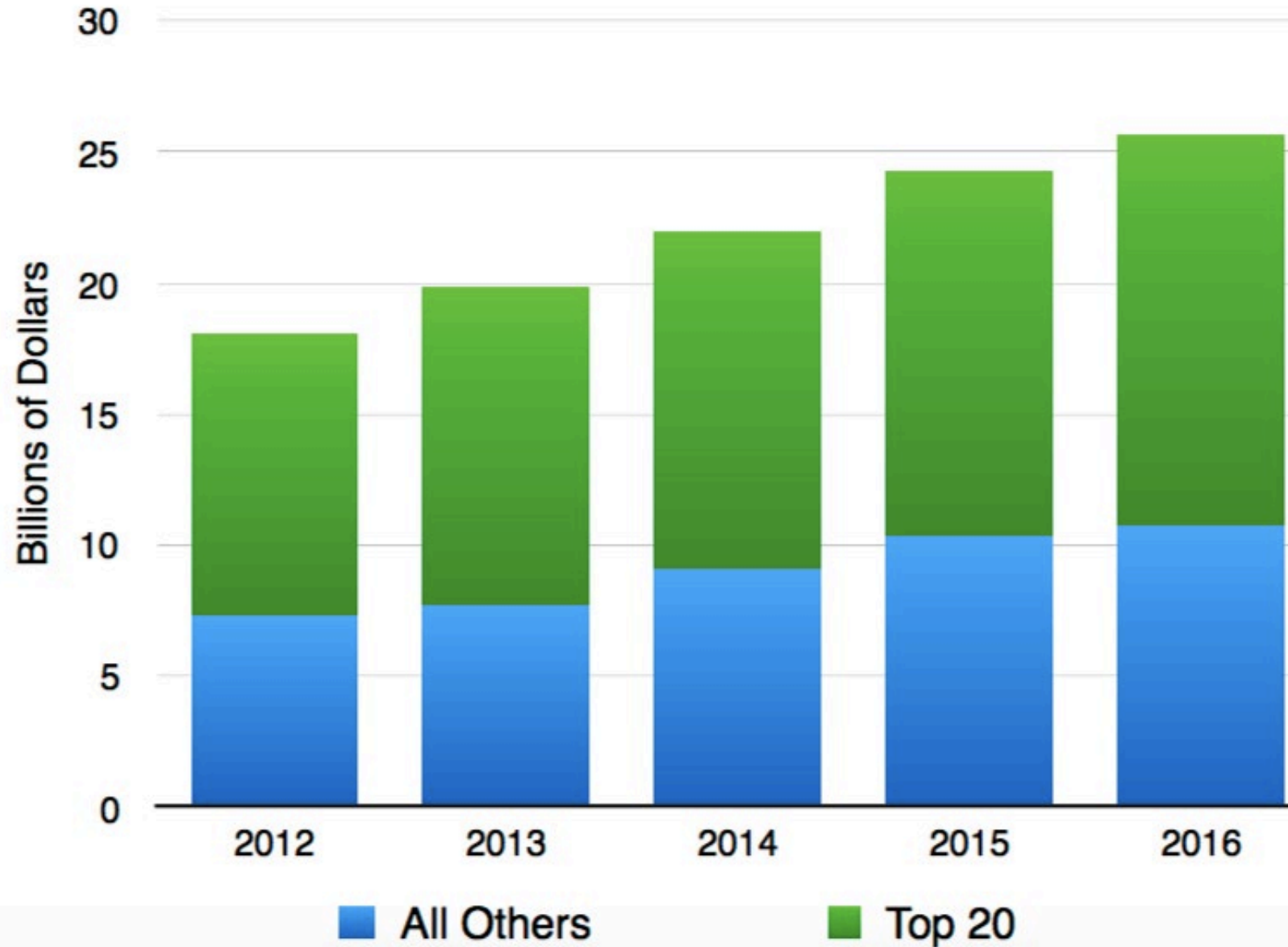
# Part B Growth

Medicare Part B drug expenditures have increased significantly over time. From 2011 to 2016, Medicare FFS drug spending increased from \$17.6 billion to \$28 billion under Medicare Part B, representing a compound annual growth rate (CAGR) of 9.8 percent, with per capita spending increasing 54 percent, from \$532 to \$818.[\[1\]](#) Medicare





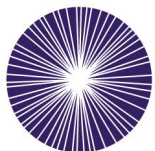
## Medicare Part B Medication Expenditures



# Injection Bubble

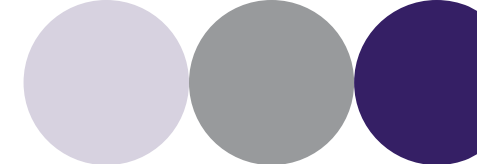


Richard Heeks / Barcroft Media

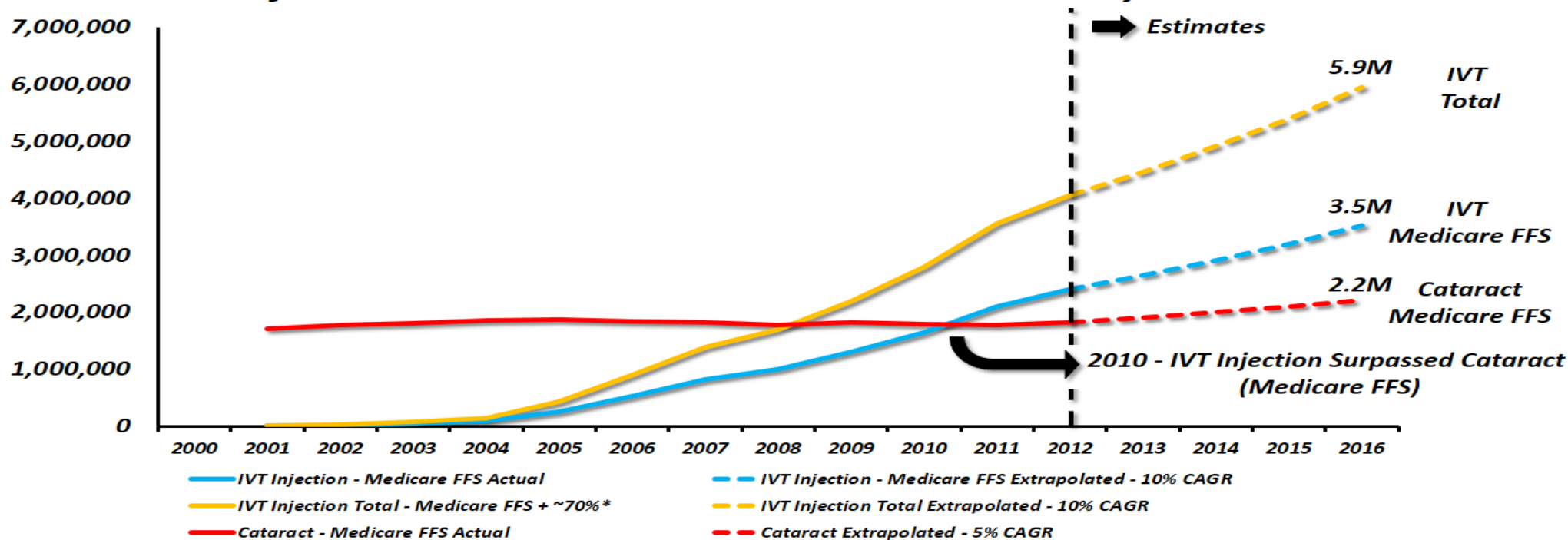


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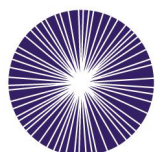


## IVT Injection and Cataract Procedures in the USA by Year<sup>†</sup>



<sup>†</sup>IVT Injection CPT code 67028; Cataract CPT codes 66984 and 66982

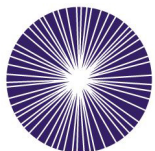
\*~70% includes Medicare Advantage (~30%) and Private (~30%) multiplier estimates



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# Injection Bubble



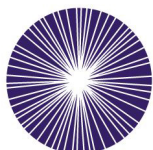
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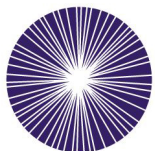
Medication	Primary Indication	Total Spent From 2013-2016
<b>Eylea</b>	Wet Macular Degeneration	\$6.4 Billion
<b>Rituxan</b>	Cancer Chemotherapy	\$6.2 Billion
<b>Neulasta</b>	Low White Blood Cell Count	\$4.9 Billion
<b>Lucentis</b>	Wet Macular Degeneration	\$4.9 Billion
<b>Remicade</b>	Connective Tissue Disease	\$4.9 Billion
<b>Avastin</b>	Cancer Chemotherapy	\$4.3 Billion
<b>Prolia*</b>	Oseoporosis	\$3.4 Billion
<b>Totals for all Seven Medications</b>		\$35 Billion
<b>Total Part B Spent on All Medications</b>		\$92 Billion





# The Solutions

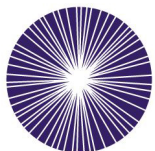
- Pre-authorization
- Step therapy
- Competitive Acquisition Program (CAP)
- International Pricing Index
- Move Part B drugs to Part D
- Medicare Formulary
- Import drugs from Canada



# Pre-authorization



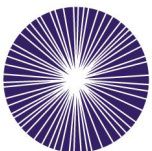
- Drugs
- Devices
- Surgery
- More than 90% of PA requests are granted
- Impedes patient access



# Step Therapy



- 2019 CMS policy on step therapy in MA for “new” patients
- Includes off label compounded drugs
- Many questions: what constitutes a trial, treatment failure, treatment duration?
- Patient access issues
- Potential game changer





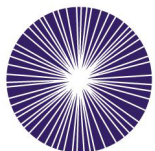
# Step Therapy in Commercial Insurance Specialty Drug Evidence and Coverage Database at Tufts

PHARMACEUTICALS & MEDICAL TECHNOLOGY

By James D. Chambers, David D. Kim, Elle F. Pope, Jennifer S. Graff, Colby L. Wilkinson, and  
Peter J. Neumann

## Specialty Drug Coverage Varies Across Commercial Health Plans In The US

- 1 in 4 coverage decisions involve step therapy
- Wide variation in coverage
- Only 16% of drug-indication pairs covered by all plans
- Less than half covered by 75%
- Protocols c/w FDA label 52%, more restrictive 33%, no coverage 5%



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# Step Therapy

Mrs. Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-4180-P  
P.O. Box 8013  
Baltimore, MD 21244-8013

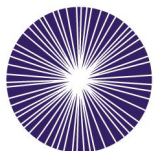
**RE: Modernizing Part D and Medicare Advantage to Lower Out-of-Pocket Expenses**

Dear Administrator Verma:

The undersigned organizations greatly appreciate the opportunity to comment on the Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses Proposed Rule (CMS-4180-P) (hereinafter the “Proposed Rule”).

Together, we oppose CMS’s proposal to permit Medicare Advantage plans to implement step therapy for Part B drugs. **Step therapy is a coverage tool that, if used by Medicare Advantage (“MA”) Plans, will inappropriately deny Medicare beneficiaries access to Part B items and services that they would receive under Original Medicare, it will delay access to necessary care, and will interfere in physician decisionmaking.** Importantly, the Medicare

- AAO, RS, ASRS, AGS, ASCRS recently filed comments pointing out the dubious legal standing and potential adverse clinical consequences
- If it stands, provided many suggestions for improvement



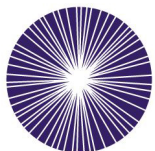
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# OIG Report on Medicare Advantage Plans

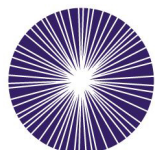
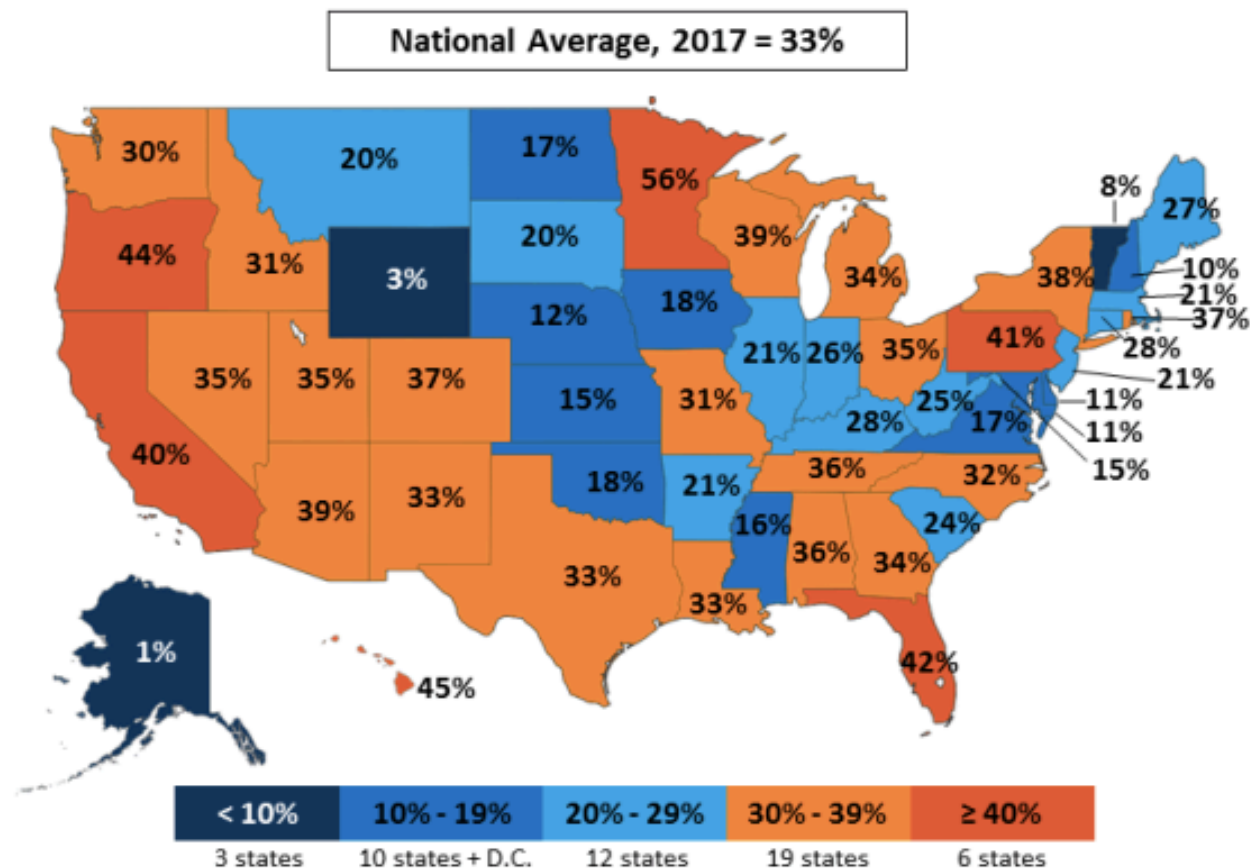


- Incentives to deny access to services and payment to increase their profit
- 75% of of denials reversed
- Only 1% of denials appealed
- “Especially burdensome for beneficiaries with urgent health conditions”



# Continued shift to Medicare Advantage

## Share of Medicare Beneficiaries Enrolled in Medicare Private Plans, by State, 2017

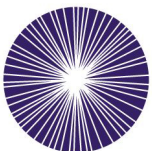


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# *Trump Proposes to Lower Drug Prices by Basing Them on Other Countries' Costs*



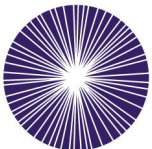
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**1<sup>ST</sup> QUARTER, 2018**

# Comparisons of Price per Gram, U.S. and International Ex-Manufacturer Prices

Product	Ratio of International Volume Weighted Prices to U.S. (U.S.=1)
Alimta (pemetrexed sodium)	2.0
Aranesp (darboepoetin alfa)	2.1
Avastin (bevacizumab)	2.0
Cimzia (certolizumab pegol)	3.0
Eligard/ Lupron (leuprolide acetate)	1.3
Eylea (aflibercept)	1.7
Gammagard (IVIG)	0.95
Gamunex-c/ Gammaked (IVIG)	1.1
Herceptin (trastuzumab)	2.2
Kadcyla (ado-trastuzumab emtansine)	1.3
Keytruda (pembrolizumab)	1.2
Lucentis (ranibizumab)	5.4
Neulasta (pegfilgrastim)	3.2
Opdivo (nivolumab)	1.4
Orencia (abatacept)	2.3
Privigen (IVIG)	1.2
Prolia/Xgeva (denosumab)	4.6
Remicade (infliximab)	1.2
Rituxan (rituximab)	2.7



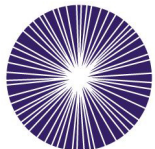
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Neulasta (pegfilgrastim)	3.2
Opdivo (nivolumab)	1.4
Orencia (abatacept)	2.3
Privigen (IVIG)	1.2
Prolia/Xgeva (denosumab)	4.6
Remicade (infliximab)	1.2
Rituxan (rituximab)	2.7



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# InsideHealthPolicy

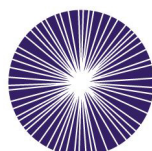
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Wednesday, January 30, 2019

## Grassley: Azar Should Use IPI Model As Leverage Against Pharma

January 29, 2019



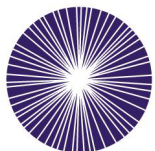
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# Moving Part B Drugs to Part D

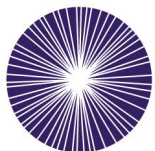
Idea is to take advantage of Part D negotiating power





FDA Commissioner Scott Gottlieb then seemed to say there is a chance for drug makers to avoid the foreign price controls if they present the administration with better to move Part B drugs into Part D.

"We have long wanted to move the injectable drugs under Part B into some kind of competitively bid system," Gottlieb said. "And there's still the opportunity to do that. I think as we go forward with this proposal perhaps that's going to drive greater interest on the part of the industry and other stakeholders to try to move that into a competitively bid model."





# InsideHealthPolicy

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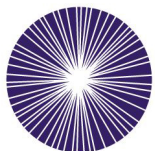
Wednesday, January 30, 2019

## Lobbyists Say PhRMA Considering Self Imposing Price Hike Caps

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January 28, 2019

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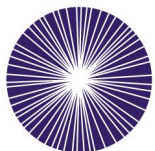
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# Moving Part B Drugs to Part D

January 2019 | Issue Brief

## The Out-of-Pocket Cost Burden for Specialty Drugs in Medicare Part D in 2019

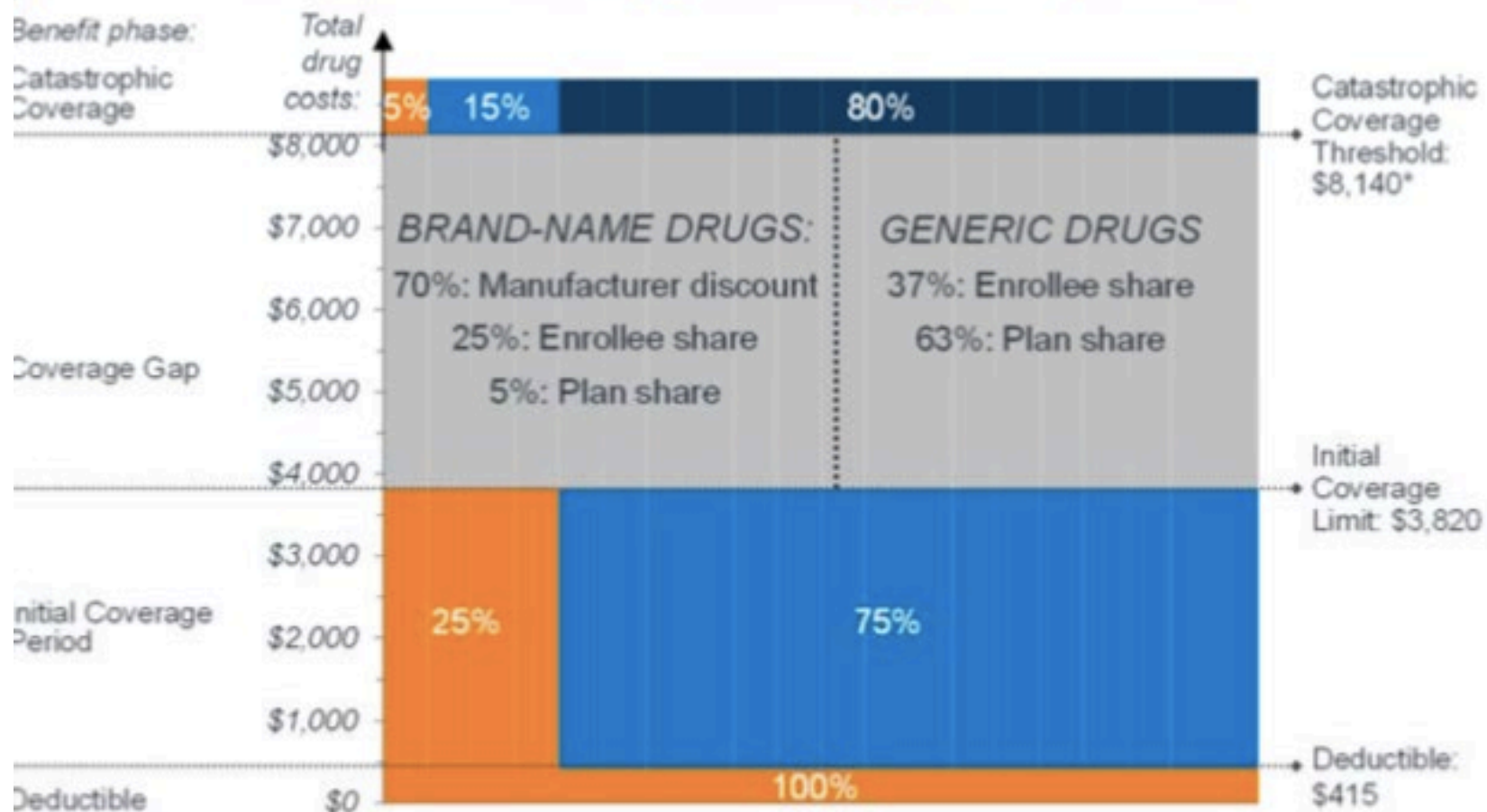


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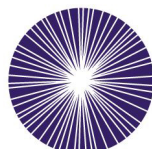
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# Medicare Part D Standard Benefit Design in 2019

Share of costs paid by: ■ Enrollees ■ Plans ■ Medicare



NOTE: Some amounts rounded to nearest dollar. \*The estimate of \$8,140 in total drug costs corresponds to a \$5,100 out-of-pocket threshold for catastrophic coverage in 2019.  
SOURCE: KFF, based on 2019 Part D benefit parameters.



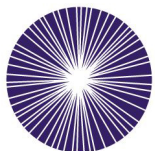
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# Moving Part B Drugs to Part D

- Actually worse than current 20% co-pay unless it results in massive price reductions
- Logistical nightmare
- DOA





# Competitive Acquisition Program

- Been there, done that, didn't work for multiple reasons
- This time will be different
- Multiple vendors, new types of vendors, competitive pricing, timely delivery and inventory management
- Financial logistics of co-payments a potential disaster and defeats the goal of getting docs out of the buy and bill model
- So far, little interest from vendors or docs



# Medicare Formulary

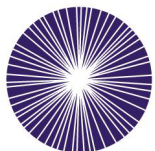
- Currently illegal
- Increasing bipartisan Congressional support to allow Medicare to negotiate drug prices
- Medicaid models a first step





# Oh, Canada!

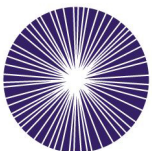
- Importation of identical but cheaper drugs from Canada
- Sounds great
- Not a chance it moves the needle

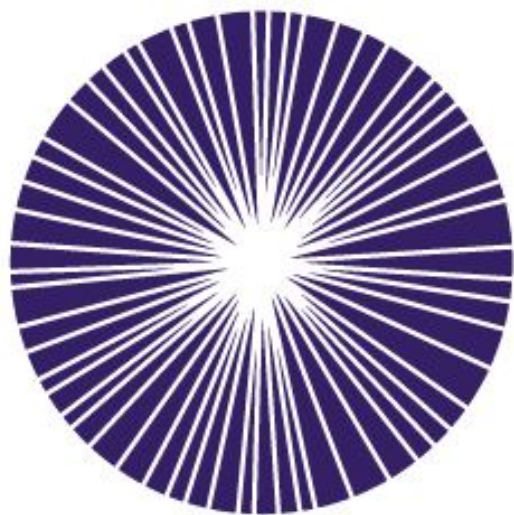


# Part B Drugs



- More to come
- Lots to do





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