

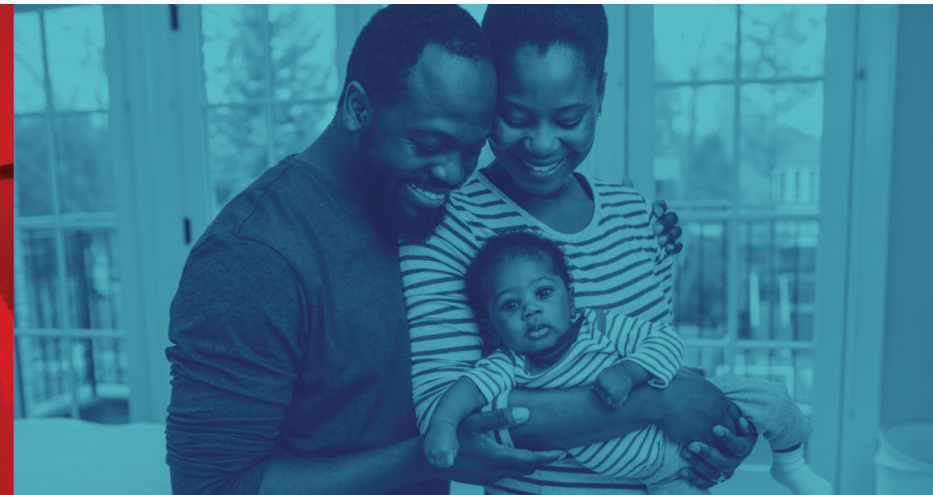
# ERIC

*Shaping benefit policies  
before they shape you.*

September 15, 2020

## ***Healthcare Policy: The Latest from Washington on Pharmacy and Opioids***

*James Gelfand, Senior Vice President, Health Policy  
The ERISA Industry Committee*



# Introduction to The ERISA Industry Committee

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- ERIC is the only national association that advocates exclusively for large employer plan sponsors on health, retirement, compensation, and paid leave public policies at the federal, state, and local levels. With member companies that are leaders in every sector of the economy and have employees in every state, The ERISA Industry Committee is promoting uniformity and flexibility for nationwide benefit plans

You are likely to engage with ERIC member companies when:

- Drive a car, fill it with gas
- Dine out or at home
- Use a cellphone
- Visit a bank, hotel
- Fly on an airplane
- Watch T.V.
- Use a computer
- Benefit from our national defense
- Receive or send a package
- Go shopping
- Use cosmetics
- Drink a beverage



# Agenda

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- Unsustainable Rx Costs
- Employers and the Opioid Crisis
- Recent Rx and Opioid Activity in Washington, DC
- Seeking Solutions: Rx Prices and Opioids



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# ***Rx Costs: Crisis brewing***

# The Cost of Prescription Drugs

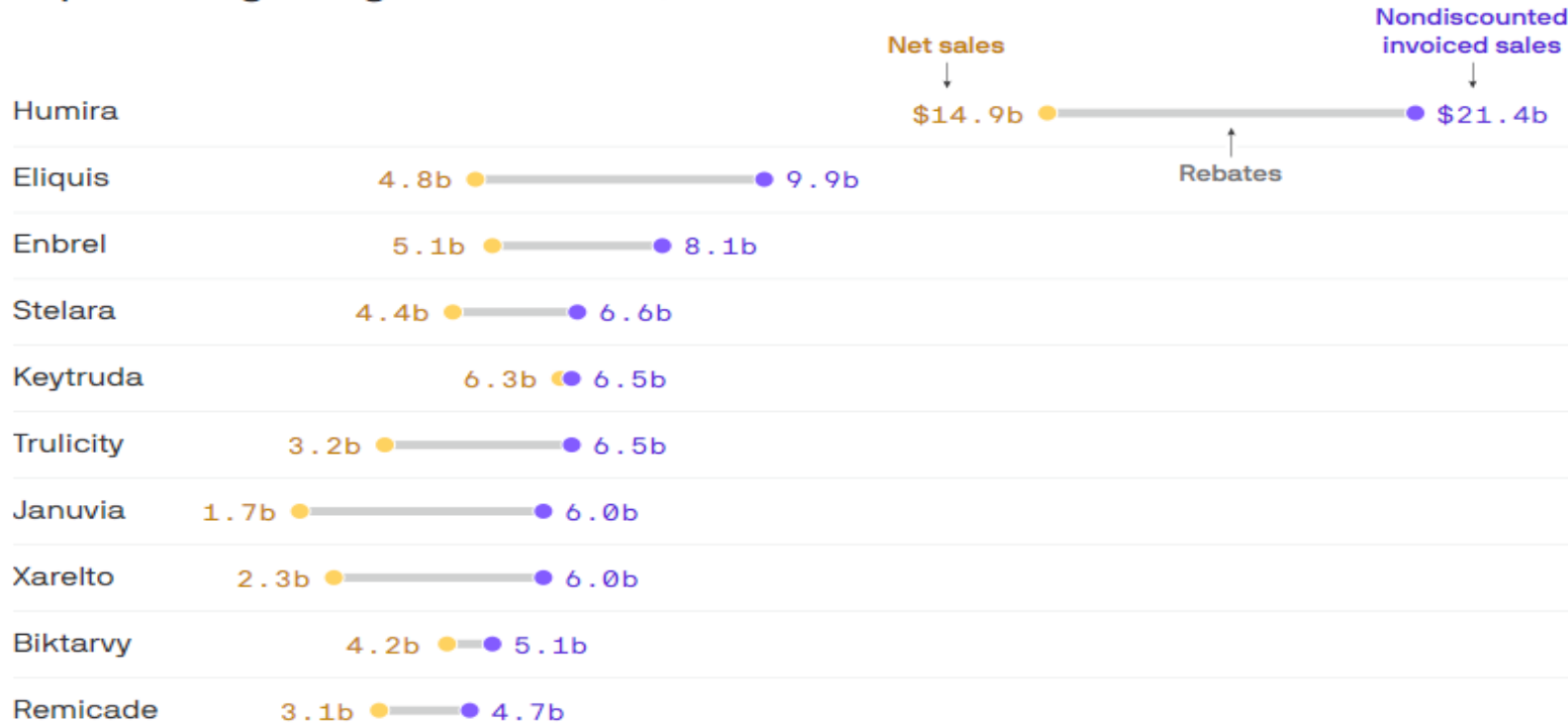
- Employers provide health coverage to 180 million people in the U.S. <sup>1</sup>
- Employers continue to struggle with the escalating cost of prescription drugs – especially biologic medicines
- Thirty percent of Americans who currently take prescription drugs say their out-of-pocket cost for a drug has increased in the past year<sup>2</sup>
- In 2018, retail prices for 267 widely used brand name prescription drugs increased by 5.8 percent, more than twice the rate of inflation<sup>3</sup>
- Misaligned incentives lead to underutilization of cheaper medications
- The Congressional Budget Office estimates that PBM reform would save the federal government \$1.7 billion over ten years<sup>4</sup>



1. U.S. Census Bureau, Health Insurance Coverage in the United States: 2018, Issued Nov. 2019. (Table 1, Page 3)
2. Lisa Gill. "The Shocking Rise of Prescription Drug Prices." Consumer Reports, November 26, 2019. Available at <https://www.consumerreports.org/drug-prices/the-shocking-rise-of-prescription-drug-prices/>.
3. Leigh Purvis and Stephen W. Schondelmeyer. "Brand Name Drug Prices Increase More Than Twice As Fast As Inflation in 2018." AARP Public Policy Institute. November 2019. At <https://www.aarp.org/content/dam/aarp/ppi/2019/11/brand-name-drug-prices-increase-more-than-twice-as-fast-asinflation.doi.10.26419-2Fppi.00073.005.pdf>.
4. CBO Cost Estimate for section 306 of the Lower Health Care Costs Act, S. 1895, at [https://www.cbo.gov/system/files/2019-07/s1895\\_0.pdf#page=13](https://www.cbo.gov/system/files/2019-07/s1895_0.pdf#page=13)

# 2019 High Grossing Rx Drugs

Gap between invoiced and net sales for top-selling drugs in the U.S., 2019



- The top ten highest-selling drugs gave \$23 billion in rebates to insurance intermediaries and netted almost \$58 billion in sales

Data: IQVIA, company financial documents; Note: Data has been corrected for Biktarvy, Enbrel, Januvia, Remicade and Stelara (more info below).  
 Chart: Andrew Witherspoon/Axios

# Drug Costs: Market Forces Being Thwarted

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The following strategies lead to higher prescription and health insurance costs for patients:

- Drug “**coupon**” arrangements steer patients to expensive drugs and hinder generic and biosimilar competition
- **Rebate and discount structures** cause drug formularies to be based on metrics other than value for patients
- Patent “**evergreening**” and other methods of extending exclusivity negate statutory limitations on market monopolies
- Patient groups that are potentially funded by interested parties are lobbying state legislatures to **eliminate medical management** techniques designed to help patients control costs
- **Pharmacy Benefit Managers** develop and maintain formularies of covered medications on behalf of health insurers, which influence what drugs individuals use and determine out-of-pocket costs



# More Market Manipulations That Keep Costs High

- “*Pay-for-delay*” agreements between generic and brand manufacturers keep generic competition off the market for a period of time
- “*Product hopping*” enables drugs to maintain exclusivity by making small changes so that the patient stays on the drug’s newly patented formulation
- “*International freeriding*” leads to much lower prices in other industrialized markets, and requires US purchasers to pay many times more
- “*Bona fide fee agreements*” between manufacturers and supply chain actors for indistinct or unperformed services may cause patients to be steered to more expensive drugs



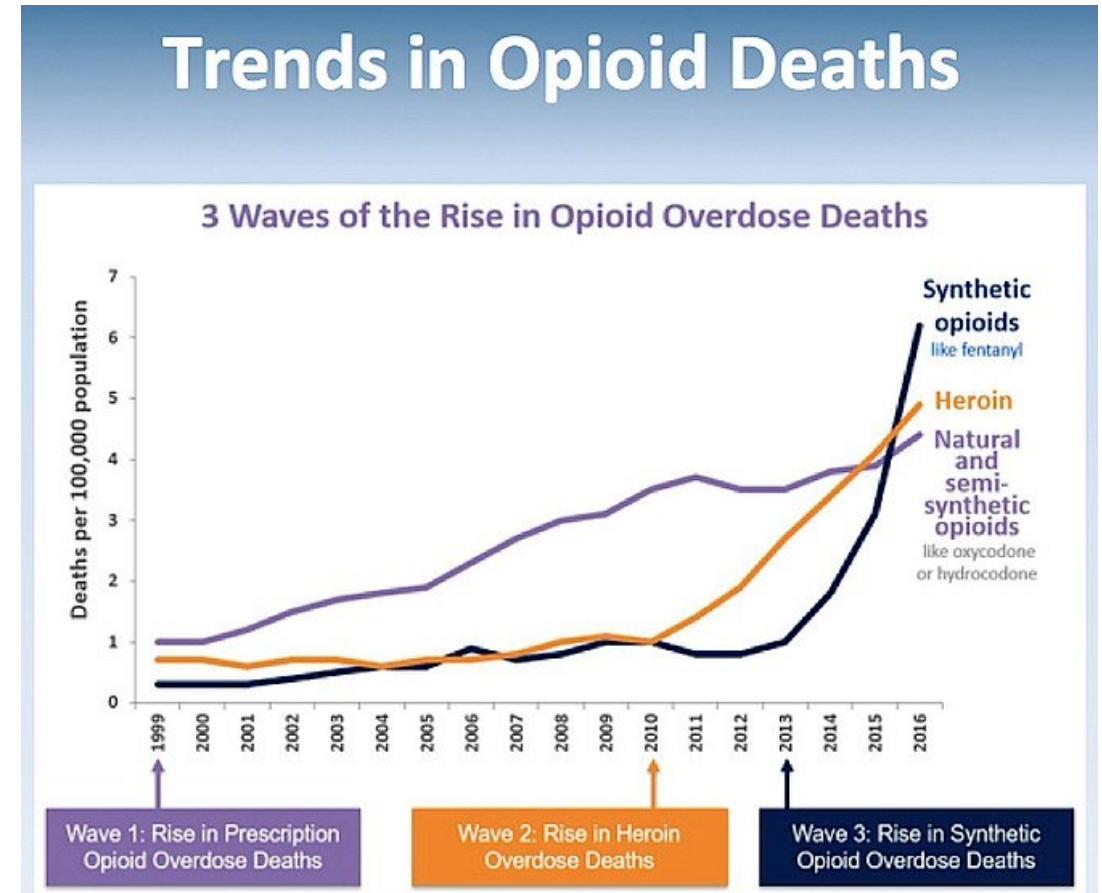


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# *Opioids Crisis: A series of waves*

# Waves of the Opioid Epidemic

- First Wave – 1990s
  - Increase of prescription drugs
- Second Wave – 2010
  - Overdose deaths involving heroin
- Third Wave – 2013
  - Synthetic opioids and heroin
- Fourth Wave – 2020
  - Methamphetamines



# Opioid Epidemic Investigation – Rural America

- In 2017, the House Energy and Commerce Committee opened an investigation into the distribution of prescription opioids by wholesale drug distributors, with a specific focus on distribution practices in West Virginia, and enforcement practices by the DEA
- In Clay County, Kentucky, 21,000 residents filled prescriptions for 2.2 million doses of hydrocodone and about 617,000 doses of oxycodone in the 12-month period in 2017
  - That's about 150 doses for every man, woman and child
- In Williamson, West Virginia, a town with 3,200 residents, received 20.8 million hydrocodone and oxycodone pills in 2018
  - That's more than 6,500 pills per person



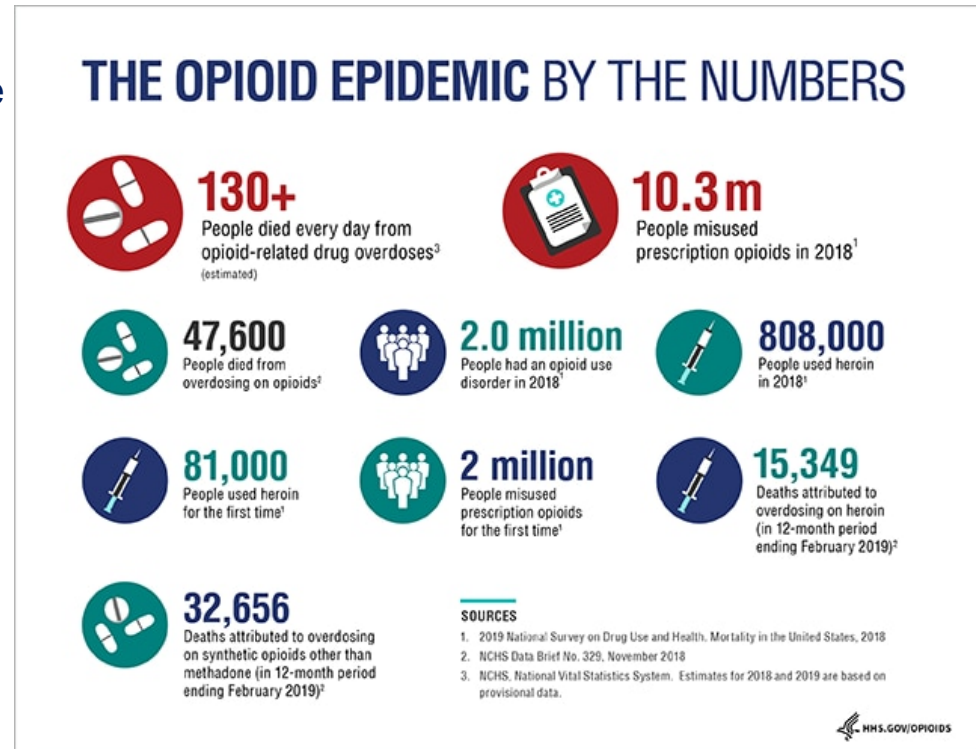
# Opioid Epidemic Investigation – Rural America (Cont.)

- McKesson Corp., Cardinal Health Inc., AmerisoruceBergen Drug Corp., Miami-Luken Inc., and H.D. Smith Wholesale Drug Company testified May 8, 2018 to the House Energy and Commerce Subcommittee on Oversight and Investigations
  - Miami-Luken was the only company that believed his company's actions had played a role in the opioid crisis
- December 2018, House report was released
  - Distributors lacked follow through in their due diligence evaluations of prospective pharmacy customers
  - Distributors failed to monitor the volume of controlled substances sold to customers and failed to address suspicious orders
  - Distributors turned a blind eye to red flags of possible drug diversion



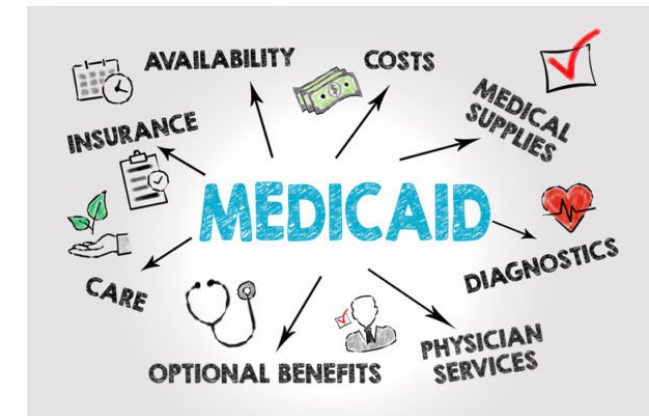
# Opioid Hard Facts

- In 2017, more than 47,000 Americans died as a result of an opioid overdose
- An estimated 1.7 million people in the United States suffered from substance use disorders related to prescription opioid pain relievers
- Roughly 21 to 29 percent of patients prescribed opioids for chronic pain misuse them
- Between 8 and 12 percent develop an opioid use disorder
- An estimated 4 to 6 percent who misuse prescription opioids transition to heroin
- Among 38 states with prescription opioid overdose death data, 17 states saw a decline between 2017-2018; none experienced a significant increase



# Opioid Hard Facts (Cont.)

- Copays and other additional costs, especially if a patient has a high deductible health plan (HDHP), makes it hard for patients to get the treatment they need
- 40 percent of Medicaid funding goes towards addiction treatment. 40 percent of Medicaid patients seek this treatment
  - More than 60 million people are enrolled in Medicaid



# Employers on the Front Line vs. Opioids

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- Out of necessity, many employers have taken an active role in opioids mitigation
- At the same time, many have done benefit redesigns in order to improve access to treatment, remove barriers, and steer patients away from opioids
- Progress has been unsteady. Some areas of the country are much more significantly affected
- Employers are doing a good job-sharing best practices, working with groups like the National Alliance to implement strategies that work



## Opioids and the Workplace

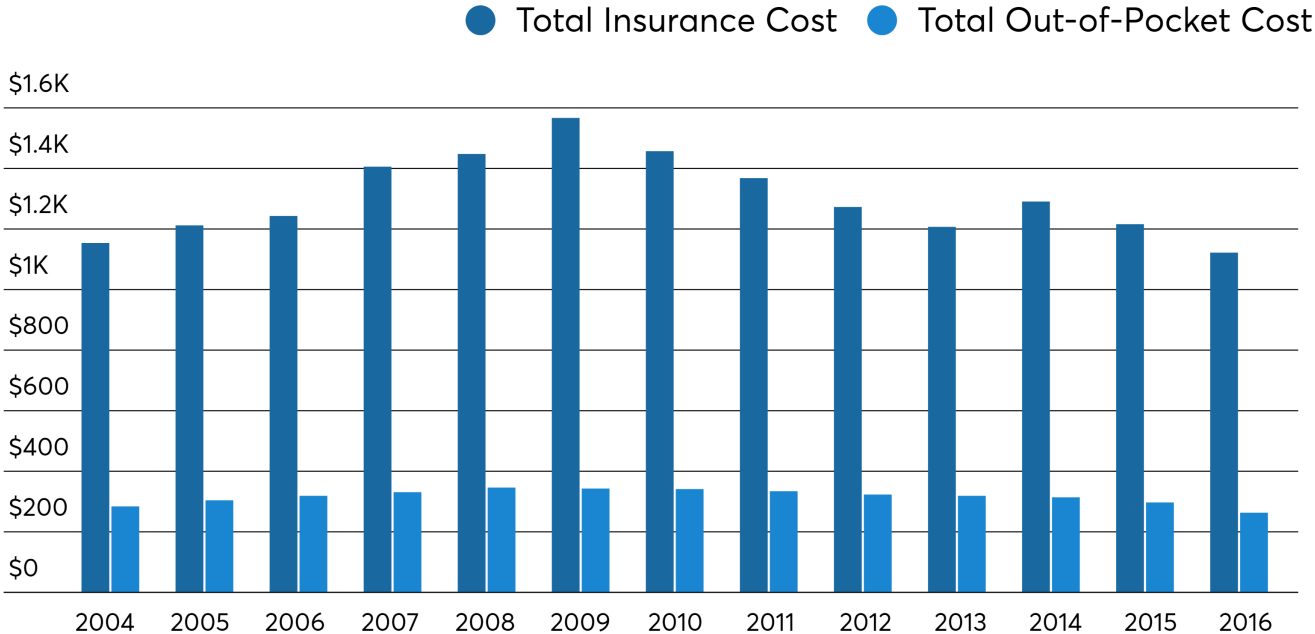
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An Employer Toolkit for  
Supporting Prevention,  
Treatment, and Recovery

# Rx Costs and Opioids Collide

## Spending on opioid prescriptions

Total cost of opioid prescriptions among enrollees in a large employer plan, in millions



Source: Kaiser Family Foundation



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# *Recent Rx and Opioid Activity in Washington, DC*

# Rx Cost Legislation Fizzles Out in Congress

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- “*The Prescription Drug Pricing Reduction Act*” (S. 2543) was the best chance for bipartisan, comprehensive reform this Congress
- Senator Grassley’s June 29 WSJ Op-Ed
  - D’s won’t negotiate, R’s won’t act
  - President Trump says drugs costs are still priority
- Widely believed the bill is now dead
- Potentially a top issue for 2021 – House Ds may use Rx cost savings to pay for coverage expansion legislation



# Administration Boomerangs on Copay Accumulators

- Administration had proposed a rule banning copay accumulators, unless the drug had a generic competitor
- Administration published the 2021 Notice of Benefit and Payment Parameters (NBPP), you are now free again to implement and use accumulators without restriction
- ERIC lobbied the Administration not to *\*require\** that coupons be counted toward deductible/MOOP
- 50+ LGBTQ advocacy organizations sent a letter to CMS Administrator Verma pushing back against the decision, saying that it will limit the affordability of a daily medication to prevent HIV. PhRMA's patient groups are livid



# CMS Medicare Part D “Senior Savings Model

- Caps insulin costs at \$35 a month for beneficiaries who opt-in
  - 3.3 million beneficiaries rely on insulin
  - May save \$446 in annual out-of-pocket costs
  - Saves the government \$250 million over 5 years
- Participation
  - More than 1,750 prescription drug plans applied for the model
  - 3 participating drug manufacturers



# Presidential Executive Orders – Rx Drugs

- Lowering Prices for Patients by Eliminating Kickbacks to Middlemen
  - Revival of the “rebate rule”
- Increasing Drug Importation to Lower Prices for American Patients
  - Allows states to import certain drugs from Canada safely
- Access to Affordable Life-saving Medications
  - Directs Federally Qualified Health Centers (FQHCs) to pass along massive discounts on insulin (reforming the notorious 340B program)
- Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States



EOs are expected to be followed with proposed rules

# Executive Order – “Most Favored Nation”

- The “Most-favored-nation” proposal
  - Ensures the United States pays the lowest price available in economically comparable countries for Medicare Part B drugs
  - This is seen as a way to end “international freeriding”
  - Language has currently not been released
- PhRMA counter-proposal to White House – 2 voluntary demonstrations
  - The first demonstration would test a voluntary Part B model in which manufacturers would provide a “market-based” discount for covered drugs that translates to a roughly 10 percent reduction in the average sales price for Medicare
  - The second demonstration would put a cap of 5 percent on patient cost-sharing in the catastrophic phase of the Medicare Part D outpatient prescription drug program

***THIS JUST IN: PhRMA’s offer rejected.  
Most-favored-nation rule moving forward!***



Rulemaking process will still have to be completed

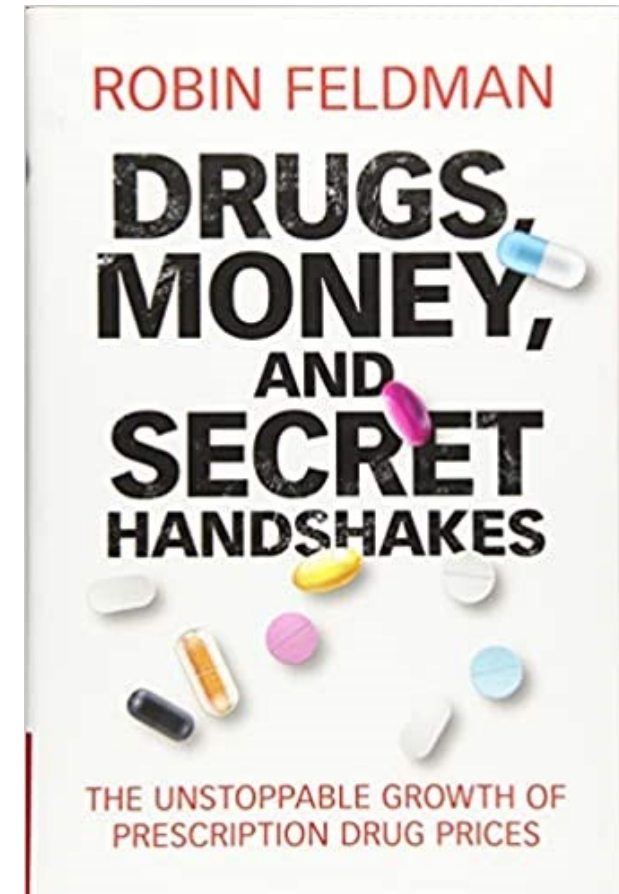
# Drug Price Transparency in Advertising Rule

- HHS issued a rule, if a medicine's list price was more than \$35 a month, it would have to be stated during commercials
- This enraged pharma, as patients rarely pay the full list price
- They sued prior to rule being finalized, stating:
  - (1) This violates their freedom of speech
  - (2) This rule exceeds HHS' statutory authority



# Drug Price Transparency Defeated in Court

- The rule was thrown out in District Court, due to a lack of statutory authority.
- Judge Amit Mehta: "*That policy very well could be an effective tool in halting the rising cost of prescription drugs. But no matter how vexing the problem of spiraling drug costs may be, HHS cannot do more than what Congress has authorized.*"
- The D.C. Circuit Court of Appeals upheld the ruling





# Price Fixing in the Generics Industry

- DOJ has charged seven companies with price fixing in the generics industry
- Five cases were resolved with pharmaceutical companies paying more than \$426 million in penalties
- Does it ever seem like generic prices suddenly jolt up, and certain products just disappear?



# COVID-19: Substance Use Disorder Treatment

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- **Coronavirus Aid, Relief, and Economic Security (CARES) Act (H.R. 748)**
- Section 3221: Confidentiality and disclosure of records relating to substance use disorder (42 CFR Part 2 fix)
  - Employers must obtain consent from employees before their protected health information is shared with other entities
- The provision will help to improve the coordination of care, and empower plan sponsors and their vendors to do more to help beneficiaries
- Rule is finalized. Removes barriers



# COVID, Opioids and Telehealth

- Federal policy has relaxed restrictions on the remote prescription of controlled substances during the pandemic
  - Will it be rolled back once the public health emergency period ends?
- Pros and cons to telehealth visits for OUD treatment
- Studies are still in progress, looking at whether telehealth services provided in the home for the treatment of OUD are effective
- Many pharmacies and PBMs had taken actions to limit fills...



# Opioid Litigation

- AmerisourceBergen, McKesson, and Cardinal Health offered an \$18 billion settlement with 21 states for their role in the opioid epidemic...
  - Rejected by 21 state attorney generals
- These states want a larger settlement amount: \$26.4 billion over less than 18 years
- The issue most likely won't be settled until the COVID-19 pandemic calms down and will involve a larger sum than some anticipated



# Opioid Litigation (Cont.)

- Nearly all states are seeking an aggregate of \$2.156 trillion from the maker of the opioid painkiller OxyContin, Purdue Pharma
  - Purdue filed for Chapter 11 bankruptcy in 2019
- A 2006 Department of Justice memo found evidence that executives at the drugs giant Purdue Pharma may have committed multiple crimes, including wire fraud and money laundering
  - However the \$654 million settlement over deceptive marketing claims in 2007 fell short of what prosecutors actually sought



*Will Purdue Pharma be held accountable?*

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# *Seeking Solutions: Rx Prices, and Opioids*

# Employer-Backed Federal Rx Cost Legislation

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- S. 1416, “Affordable Prescriptions for Patients Act” [**Patent thickets**]
  - S. 658, “ADAPT Act” [**Fast-track approvals for EU/etc. approved products**]
  - S. 61, “Safe and Affordable Drugs from Canada Act” [**Limited reimportation**]
  - S. 64, “Preserve Access to Affordable Generics and Biosimilars Act” [**Pay-for-delay**]
  - H.R. 938, “Bringing Low-cost Options and Competition while Keeping Incentives for New Generics (**BLOCKING**)”
  - H.R. 1520, “**Purple Book** Continuity,” and H.R. 1503, “**Orange Book** Transparency”
  - H.R. 2113, “Prescription Drug STAR Act” [**Limited transparency**]
  - S. 440, “PACED Act” [**Sovereign immunity schemes**]
  - S. 474, “Stopping the Pharmaceutical Industry from Keeping Drugs Expensive (**SPIKE**)”
  - S. 476, “Creating Transparency to Have Drug Rebates Unlocked (**C-THRU**)”
  - H.R. 5204, “PBM Transparency in Prescription Drugs Costs Act” [**PBM reform**]
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# “Comprehensive” Prescription Drug Legislation

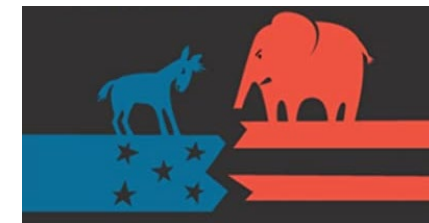
- *Prescription Drug Pricing Reduction Act, S. 2543*  
(Grassley/Wyden Bill)
  - The bill leverages competition, transparency, and inflation limits to lower drug prices, redesigns the financing of the Medicare Part D prescription drug benefit, and makes other changes to improve drug markets. The bill includes less controversial transparency provisions, bans spread pricing in Medicaid, etc.
- *The Lower Drug Costs Act, H.R. 3*  
(House Speaker Pelosi Bill)
  - The bill requires Centers for Medicare & Medicaid Services (CMS) to negotiate prices for insulin products 125 drugs that account for the greatest national spending
- *The Lower Costs, More Cures Act, H.R.19*  
(House Republican Alternative)
  - The bill is a is an amalgamation of smaller bills, familiar material





# The Future of Rx Price Legislation

- Cannot pass without at least SOME bipartisan support
- So far, Democrats and Republicans have not engaged enough. There was limited agreement during the Senate Finance Committee markup last year, but that's over now.
- Momentum has stopped with COVID. And next year, no more Chairman Grassley...



# The Future of Addressing Opioids

- States will continue to utilize opioid grants from HHS as long as plans are evidenced based
- Next year, there will be a significant legislative push on mental health
  - Tighten mental health parity (MHP) requirements
  - Require more disclosure from plan sponsors
  - Implement a strong penalty regime for perceived bad actors – both insurance carriers and self-insured plan sponsors
- Public health stakeholders will push for better integration between medication-assisted treatment (MAT) and behavioral/mental health



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INDUSTRY COMMITTEE

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