Drug Prices in the United States

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Faculty Disclosure

• I do not have a vested interest in or affiliation with any corporate organization offering financial support or grant monies for this continuing education activity, or any affiliation with an organization whose philosophy could potentially bias my presentation.

• I do not speak for or consult with any pharmaceutical manufacturer.
Questions?

• Who gets blamed when a patient gets to the pharmacy and finds out how much the prescription will cost?
• Who determines what the patient pays?
• Who determines what the pharmacy gets paid for the prescription?
• Who negotiates the contracts with the manufacturers and the pharmacy networks?
Branded Drug Prices Increased An Average Of Almost 13 Percent in 2016

• Fierce Pharma (5/10) reports that “branded drug prices increased an average of 12.92% last year, with an industrywide rise of 8.77% – both numbers several times the rate of overall increases in consumer costs,” according to Truveris’ National Drug Index. The report adds that “sticker prices have risen an average of 9.98% annually over the last three years.”

• In 2017 we expect to see price increases of 12 plus% again.
2017 Pfizer Price Increases

- 6/2/17 The Financial Times reports the Pfizer (PFE -0.5%) has raised the price of almost 100 drugs by an average of 20% this year, a move that may solicit criticism from a range of interested groups, including lawmakers. The company raised prices of 91 medicines by 5 - 13%, including Viagra and Lyrica, on June 1, following a similar hike in January.

- Most drug firms used a "raise twice" approach to pricing until enduring intense criticism from patients, polititions and advocacy groups. Some, including AbbVie, Sanofi and Allergan, have pledged to constrain annual hikes to less than 10%.
### Table 1. Prescription Drug Expenditures and Growth by Sector

<table>
<thead>
<tr>
<th>Sector</th>
<th>2016 Expenditures (Millions)</th>
<th>Percent of Total Expenditures</th>
<th>Percent Change From 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retail pharmacies</td>
<td>217,428</td>
<td>48.5</td>
<td>4.7</td>
</tr>
<tr>
<td>Mail-order pharmacies</td>
<td>103,171</td>
<td>23.0</td>
<td>6.7</td>
</tr>
<tr>
<td>Clinics</td>
<td>63,693</td>
<td>14.2</td>
<td>11.9</td>
</tr>
<tr>
<td>Nonfederal hospitals</td>
<td>34,461</td>
<td>7.7</td>
<td>3.3</td>
</tr>
<tr>
<td>Long-term care</td>
<td>16,541</td>
<td>3.7</td>
<td>0.3</td>
</tr>
<tr>
<td>Staff-model HMOs</td>
<td>5,084</td>
<td>1.1</td>
<td>6.5</td>
</tr>
<tr>
<td>Home healthcare</td>
<td>3,672</td>
<td>0.8</td>
<td>2.0</td>
</tr>
<tr>
<td>Federal facilities</td>
<td>2,890</td>
<td>0.6</td>
<td>7.9</td>
</tr>
<tr>
<td>Other</td>
<td>1,232</td>
<td>0.3</td>
<td>8.4</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>448,173</strong></td>
<td><strong>5.8</strong></td>
<td></td>
</tr>
</tbody>
</table>
Facts to know about US drug spending:

• Specialty medications remain a key contributor to drug spending for payers, accounting for more than 37% of drug spend in 2015, and forecast to reach 50% by 2018. Spending on specialty medications jumped 17.8% in 2015.
  – Among drivers of specialty pharmacy spend were unit cost increases greater than 17% for Enbrel (etanercept) and Humira Pen (adalimumab), which contributed significantly to the 25% spending increase for the inflammatory conditions medication class.
  – Formulary Watch 4-2016
Facts to know about US drug spending:

• The average patient out of pocket cost exposure for brand prescriptions filled through a commercial plan has increased more than 25% since 2010, reaching $44 per prescription last year. The increased prevalence of health plans with pharmacy deductibles, copayments and coinsurance is contributing to the rise. **In response, brand manufacturers are steadily increasing their use of mechanisms like coupons or vouchers to help patients offset the expenses.**

• Total prescriptions dispensed in 2015 reached 4.4 billion, up 1% year over year. Demand was higher in some therapy areas, such as antidepressants and anti-diabetes, each of which increased about 10% in 2015. Among those therapy areas that declined, narcotic drugs saw a 16.6% drop in the number of prescriptions dispensed.
  
  – Formulary Watch 4-2016
The Mission of the Campaign for Sustainable Rx Pricing (CSRxP) aims to foster a national dialogue focused on the issue of drug pricing that strikes a balance between innovation and affordability. We believe in market-based reforms that address the underlying causes of high drug prices in the U.S. through increased transparency, competition, and value.

CSRxP is a non partisan coalition of organizations informing the debate on drug pricing and finding bipartisan, market-based solutions to lower drug prices in the U.S. Members represent hospitals, physicians, nurses, consumers, health plans, pharmacists, and employers.
The Campaign for Sustainable Rx Pricing

• Prescription spending is growing faster than any other part of the health care dollar

• In 2015 the prices of prescription drugs had the largest increases in 24 years. In fact, prescription drug prices rose more than 7% since last year, the largest one-year hike since 1992.

• May 2017, The Campaign for Sustainable Rx Pricing launched a national TV and digital advertising campaign, featuring a commercial for the mock drug "Price Gougi$ol," that delivers a harsh rebuke of direct-to-consumer advertising of prescription drugs.
  – https://www.youtube.com/watch?v=175rbyp3C80
Direct To Consumer Advertising

• In 2008, the House Commerce Committee reported that every $1,000 spent on drug ads produces 24 new patients, and a 2003 research report found the prescriptions derived for drugs promoted with DTC ads were nearly seven times greater in number than those without such promotions.

• Prior to 1997, drug ads could only be run along with lengthy consumer information warning of risks and side effects, therefore, few companies used them. In 1997, the U.S. Food and Drug Administration (FDA) revised the rule so that rather than providing a full disclosure, companies only needed to meet an "adequate standard" when it came to describing risks to consumers.

• The US and New Zealand are the only two countries where direct to consumer advertising of prescription medications is allowed.
Direct To Consumer Advertising

- November 17, 2017 the American Medical Association (AMA) called to ban all DTC advertising for drugs and medical devices. Billions of dollars are being spent promoting prescription only products driving demand and expensive treatment at the expense of less costly alternatives. DTC demonstrates the anticompetitive behavior of the consolidated pharmaceutical marketplace.

- June 29, 2016 the American Society of Health Care Pharmacists ASHP) called to ban all DTC of prescription drugs and medication containing devices. DTC has been shown to influence consumers to pursue medication treatment without knowing all the risks, costs and side effects. DTC has increased drug spending more than drug spending on research and development.
Direct To Consumer Advertising

• Avanir Pharmaceuticals’ advertising campaign to support its Nuedexta (quinidine sulfate/ dextromethorphan) by providing consumers with information about pseudobulbar affect. According to the article, “the strategic marketing of Nuedexta is part of a trend in which even small pharmaceutical firms turn to the airwaves to encourage use of their products.”
  – Nuedexta (quinidine sulfate/dextromethorphan) 20/10 mg x 60 caps $810.00/ month

• Since 2012, spending by the pharmaceutical industry on TV ads has increased 62%, according to Kantar Media.

• 2017 is already a record-breaking year for pharma advertising. TV ad spending totaled $3.2 billion through the end of November
Economic Outlook Survey of US Healthcare Leaders

- Premier, Inc.’s spring Economic Outlook Survey polled 91 people representing a variety of roles in U.S. health systems, including physicians, C-suite members and supply chain management professionals.

- Almost every respondent agreed that increasing pharmaceutical prices pose a significant challenge to their operations. In addition, more than 90% said they would likely experience continued drug shortages over the next three years.

- Drug prices and shortages have consistently ranked among the biggest issues facing health systems over the past two years of surveys, according to an announcement from Premier. Part of the problem is a lack of generic drug options, so a solution to this is increased competition, the organization concluded.

- “In our view, one of the best ways to ensure fair pricing is by driving increased competition and greater use of generics and biosimilars,” Michael J. Alkire, Premier’s chief operating officer, said in the announcement.

- “At the same time, we also need to provide prescribers with apples-to-apples mechanisms they can use to compare products in a therapeutic category, evidence-based facts around which products deliver optimal quality at the best value and aligned financial incentives.”

- FierceHealthcare 4/25/2017
Public Opinions on Healthcare Priorities

• When asked what the next healthcare priority should be for the White House and Congress, 76% of Americans said "making sure that high-cost drugs for chronic conditions ... are affordable to those who need them," according to a Kaiser Family Foundation poll released earlier this week. In addition, 60% of those surveyed said they support government action to lower drug prices.

  — Formulary Watch 4-2016
**Figure 3**

**Lowering Out-of-Pocket Costs Tops Health Care Priorities Among Partisans, Other Priorities Vary by Party**

Percent who say each of the following things should be a “top priority” for Donald Trump and the next Congress when it comes to health care:

<table>
<thead>
<tr>
<th>Priority</th>
<th>Democrats</th>
<th>Independents</th>
<th>Republicans</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lowering the amount individuals pay for health care</td>
<td>64%</td>
<td>65%</td>
<td>70%</td>
</tr>
<tr>
<td>Lowering the cost of prescription drugs</td>
<td>55%</td>
<td>61%</td>
<td>67%</td>
</tr>
<tr>
<td>Dealing with the prescription painkiller addiction epidemic</td>
<td>39%</td>
<td>46%</td>
<td>51%</td>
</tr>
<tr>
<td>Repealing the 2010 health care law</td>
<td>21%</td>
<td>32%</td>
<td>63%</td>
</tr>
<tr>
<td>Decreasing the role of the federal government in health care</td>
<td>26%</td>
<td>34%</td>
<td>50%</td>
</tr>
<tr>
<td>Decreasing how much the federal government spends on health care over time</td>
<td>31%</td>
<td>35%</td>
<td>43%</td>
</tr>
</tbody>
</table>

*NOTE: Question wording abbreviated. See topline for full question wording. Items asked of half samples.*

*SOURCE: Kaiser Family Foundation Health Tracking Poll (conducted December 13-19, 2016)*
**Most of the Public Favors Actions to Keep Drug Costs Down**

Please tell me whether you would favor or oppose the following actions to help keep prescription drug costs down...

<table>
<thead>
<tr>
<th>Action</th>
<th>Oppose</th>
<th>Favor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allowing the federal government to negotiate with drug companies to get a lower price on medications for people on Medicare</td>
<td>6%</td>
<td>92%</td>
</tr>
<tr>
<td>Making it easier for generic drugs to come to market in order to increase competition and reduce costs</td>
<td>11%</td>
<td>87%</td>
</tr>
<tr>
<td>Requiring drug companies to release information to the public on how they set their drug prices</td>
<td>13%</td>
<td>86%</td>
</tr>
<tr>
<td>Limiting the amount drug companies can charge for high-cost drugs for illnesses like hepatitis or cancer</td>
<td>20%</td>
<td>78%</td>
</tr>
<tr>
<td>Allowing Americans to buy prescription drugs imported from Canada</td>
<td>25%</td>
<td>72%</td>
</tr>
<tr>
<td>Creating an independent group that oversees the pricing of prescription drugs</td>
<td>26%</td>
<td>72%</td>
</tr>
<tr>
<td>Allowing Americans to buy prescription drugs from online pharmacies based in Canada</td>
<td>32%</td>
<td>64%</td>
</tr>
<tr>
<td>Eliminating prescription drug advertisements</td>
<td>38%</td>
<td>56%</td>
</tr>
<tr>
<td>Encouraging people to buy lower-cost drugs by requiring them to pay a higher share if they choose a similar, higher-cost drug</td>
<td>41%</td>
<td>52%</td>
</tr>
</tbody>
</table>

**NOTE:** Items asked of separate half samples.
**SOURCE:** Kaiser Family Foundation Health Tracking Poll (conducted April 17-23, 2017)
A Large Majority Agree Importing Canadian Prescription Drugs Would Make Medicines More Affordable

Percent who agree with each of the following statements:

- Allowing Americans to buy prescription drugs imported from Canada...
  - 76%
- Allowing Americans to buy prescription drugs from online pharmacies based in Canada...
  - 68%
- ...will make medicines more affordable without sacrificing safety or quality
  - 35%
- ...will expose Americans to unsafe medicines from other countries
  - 39%
- ...will lead U.S. drug companies to do less research and development
  - 33%

NOTE: Questions asked of separate half samples.
SOURCE: Kaiser Family Foundation Health Tracking Poll (conducted April 17-23, 2017)
Counterfeit Meds and Internet Pharmacies

• In 2016 there are an estimated 30-35,000 illicit internet pharmacies. Of these, 96% globally as well as in the US, fail to adhere to legal requirements, and 92% of them are operating in a blatantly illicit manner including the sale of prescription drugs without a prescription. 9% are selling controlled substances without a prescription with a focus on anabolic steroids to athletes.

• The U.S. is far and away the primary focus of the illegal on-line prescription drug industry, with 82% on internet pharmacies in English and roughly 85% offering to ship drugs to the U.S.
  – There has been a shift from the illicit sale of controlled substances online to the sale of “psychoactive highs” such as synthetic cannabinoids, which have been linked to significant user harm.

• The Internet Pharmacy Market in 2016: Prepared by LegitScript.com for The Center for Safe Internet Pharmacies
Counterfeit Meds and Internet Pharmacies

- A Google and Bing search of 20 common medications identified about 33% of the 29,000 “hits” led to illicit internet pharmacies including “web-spam” and “hacked” web-sites, that is otherwise legitimate web-sites such as an .edu domain registered to a University that lined to an illicit internet pharmacy.

- 29 test buys from the illicit internet pharmacies were made, the majority came from India (none of the pharmacies was licensed even in India), other countries included Germany, Singapore, US, Canada and the UK
  - Private carries including UPS, DHL and FedEx were not used for any of the shipments but 100% used the US Postal Service for US delivery.
  - None of the shipments was seized by US Customs

- The Internet Pharmacy Market in 2016: Prepared by LegitScript.com for The Center for Safe Internet Pharmacies
Some illicit internet pharmacies have hijacked web-sites previously operated by legitimate pharmacies, such as Reynolds Drug.

Years ago EVApharmacy hijacked the pharmacies domain name: while reynoldsdrug.com retains the pharmacies address and branding, orders placed on the web-site are filled by EVApharmacy with drugs being shipped from Pakistan and China. When you click on buy now it takes you to a site called Canadian Online Pharmacy

The site advertises Viagra 25mg - $1.85; 50 mg - $2.17; 75 mg - $1.89; 100 mg - $2.55; 120 mg - $4.88; 130 mg - $4.89; 150 mg - $5.45; 200 mg - $7.50

Brand Viagra only comes as 25, 50 and 100 mg tabs and costs $50.00 per tablet

The Internet Pharmacy Market in 2016: Prepared by LegitScript.com for The Center for Safe Internet Pharmacies
Counterfeit Meds and Internet Pharmacies

• Many Internet pharmacies give the impression that they are located in Canada and are selling legitimate brand-name drugs that have been manufactured in Canada, but many of these legitimacy claims are blatantly false. In these cases, the drugs are not approved by the FDA and they are not safe or effective. They are often not even approved by the Canadian government.

• Medicines that are not used in Canada are not subject to the scrutiny of Canada’s safety laws. Therefore, drugs from Canadian Internet pharmacies can come from anywhere in the world. The fact is that many so-called Canadian Internet pharmacies are not Canadian at all, but are actually based in places such as Belize, Russia, and Vietnam, to name a few.

• A 2005 study found that only 214 of 11,000 online pharmacies claiming to be Canadian were actually registered in Canada. This has made “Canadian” Internet pharmacies the primary supplier of counterfeit drugs to the United States.
  • Am Health Drug Benefits 2014;7(4):216-224
This counterfeit drug manufacturing site in China produced fake Viagra and other drugs that were sold to customers in the European Union and the U.S.
Analysis of purity and active pharmaceutical ingredient concentration (using high-performance liquid chromatography) of 55 samples labelled 'Viagra 100 mg' ordered via the Internet (Data on File. New York, NY: Pfizer Inc.)
Prescriptions Purchased on the Internet

• A credit card (MasterCard) was obtained and medicines were ordered to a central location in the UK. Over 36 prescription-only medicines were ordered, comprising two packets each of 18 medicines commonly purchased via the internet.

• These included medicines indicated to treat neurological disorders, cardiovascular disease, mental health, obesity and erectile dysfunction – The Counterfeiting Superhighway, 2008 European Alliance for Access to Safe Medicines
# Prescriptions Purchased on the Internet

## Table 1. Medicines ordered online as part of the Counterfeiting Superhighway research

<table>
<thead>
<tr>
<th>Men’s health</th>
<th>Cardiovascular and respiratory</th>
<th>Mental Health</th>
<th>Alzheimer’s disease</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cialis (Lilly)</td>
<td>Lipitor (Pfizer)</td>
<td>Zyprexa (Lilly)</td>
<td>Aricept (Pfizer)</td>
<td>Zoton (Wyeth)</td>
</tr>
<tr>
<td>Levitra (Bayer-Schering)</td>
<td>Plavix (sanofi-aventis)</td>
<td>Efexor (Wyeth)</td>
<td>Reminyl (Shire)</td>
<td>Reductil (Abbott)</td>
</tr>
<tr>
<td>Viagra (Pfizer)</td>
<td>Seretide (GSK)</td>
<td>Risperdal (J&amp;J)</td>
<td></td>
<td>Mirapex (Boehringer-Ingelheim)</td>
</tr>
<tr>
<td>Propecia (MSD)</td>
<td>Coversyl (Servier)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Micardis (Boehringer-Ingelheim)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Spiriva (Boehringer-Ingelheim)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The Counterfeiting Superhighway, 2008 European Alliance for Access to Safe Medicines
Prescriptions Purchased on the Internet

• Results of the laboratory analysis indicated that an alarming 62% of the products received were counterfeit, substandard or unapproved generic medicines. This figure closely reflects the findings of the expert panel during their visual analysis of the medicines.

• While 38% of the medicines received were found to be genuine branded medicines, 16% of these were illegal non-EU imports (genuine products, imported into the EU illegally from a non-EU country).

  — The Counterfeiting Superhighway, 2008 European Alliance for Access to Safe Medicines
CAUTION Buyer Be Ware!

The Counterfeiting Superhighway landmark research by the European Alliance for Access to Safe Medicines in 2008 found that:

• 96% of online pharmacies researched were operating illegally
• 94% of websites did not have a named, verifiable pharmacist
• over 90% of websites did not require a prescription to sell prescription only medications
• More than eight in 10 internet pharmacies do not ‘physically exist’ – in order to comply with the law all online pharmacies must be traceable to a verifiable bricks and mortar address.
• Fewer than five in 100 internet pharmacies are licensed by a board of pharmacy or appropriate pharmacy listing.
• 86% of internet pharmacies link to a bogus ‘approval’ web page ‘stamp of approval’ from a recognized society or association
FDA Campaign: BeSafeRx – Know Your Online Pharmacy

- Patients should only buy prescription medicine through online pharmacies that:
  - require a valid prescription from a doctor or other health care professional;
  - are located in the United States and provides a physical address and telephone number
  - have a licensed pharmacist available for consultation; and
  - are licensed by the patient’s state board of pharmacy.
- Are Verified Internet Pharmacy Practice Sites (VIPPS) by National Association of Boards of Pharmacy
- http://www.nabp.net/programs/accreditation/vipps/find-a-vipps-online-pharmacy/
Verified Internet Pharmacy Practice Sites (VIPPS) by National Association of Boards of Pharmacy

• The VIPPS accreditation program (Verified Internet Pharmacy Practice Sites), is a strong indicator of an Internet pharmacy’s compliance with state and federal laws and regulations and NABP's criteria.

• To date, NABP has reviewed over 9,600 sites – only 3% of those online sites appear to be in compliance with pharmacy laws and practice standards

• To date there are 51 VIPPS Accredited Internet Pharmacies. The complete list can be found at:
  • http://www.nabp.net/programs/accreditation/vipps/find-a-vipps-online-pharmacy/
Total prescription sales in the United States for the 2016 calendar year were $448.2 billion, 5.8% higher than in 2015.

Table 3. Top 25 Drugs by Expenditures Overall in 2016

<table>
<thead>
<tr>
<th>Drug</th>
<th>2016 Expenditures ($ Thousands)</th>
<th>Percent Change From 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adalimumab</td>
<td>13,590,435</td>
<td>27.6</td>
</tr>
<tr>
<td>Insulin glargine</td>
<td>10,063,158</td>
<td>2.6</td>
</tr>
<tr>
<td>Ledipasvir-sofosbuvir</td>
<td>9,959,780</td>
<td>-30.1</td>
</tr>
<tr>
<td>Etanercept</td>
<td>7,362,086</td>
<td>11.2</td>
</tr>
<tr>
<td>Infliximab</td>
<td>5,309,916</td>
<td>6.0</td>
</tr>
<tr>
<td>Fluticasone salmeterol</td>
<td>5,227,908</td>
<td>0.4</td>
</tr>
<tr>
<td>Insulin lispro</td>
<td>5,108,684</td>
<td>28.3</td>
</tr>
<tr>
<td>Insulin aspart</td>
<td>4,964,540</td>
<td>10.2</td>
</tr>
<tr>
<td>Rosuvastatin</td>
<td>4,943,624</td>
<td>-20.9</td>
</tr>
<tr>
<td>Sitagliptin</td>
<td>4,787,767</td>
<td>15.1</td>
</tr>
<tr>
<td>Pregabalin</td>
<td>4,395,804</td>
<td>15.0</td>
</tr>
<tr>
<td>Olirameri</td>
<td>4,274,347</td>
<td>-4.6</td>
</tr>
<tr>
<td>Pegfilgrastim</td>
<td>4,237,673</td>
<td>3.2</td>
</tr>
<tr>
<td>Rituximab</td>
<td>3,913,944</td>
<td>8.6</td>
</tr>
<tr>
<td>Insulin detemir</td>
<td>3,730,934</td>
<td>0.4</td>
</tr>
<tr>
<td>Dimethyl fumarate</td>
<td>3,668,714</td>
<td>8.0</td>
</tr>
<tr>
<td>Rivaroxaban</td>
<td>3,589,899</td>
<td>27.2</td>
</tr>
<tr>
<td>Emtricitabine-tenofovir disopropil</td>
<td>3,400,820</td>
<td>23.0</td>
</tr>
<tr>
<td>Tiotroplum bromide</td>
<td>3,368,359</td>
<td>-5.7</td>
</tr>
<tr>
<td>Apixaban</td>
<td>3,167,756</td>
<td>98.0</td>
</tr>
<tr>
<td>Lisderamfetamine</td>
<td>3,111,569</td>
<td>18.2</td>
</tr>
<tr>
<td>Bevacizumab</td>
<td>3,082,273</td>
<td>-1.8</td>
</tr>
<tr>
<td>Budesonide formoterol</td>
<td>3,035,857</td>
<td>13.2</td>
</tr>
<tr>
<td>Trastuzumab</td>
<td>2,655,434</td>
<td>5.5</td>
</tr>
<tr>
<td>Nivolumab</td>
<td>2,649,364</td>
<td>246.2</td>
</tr>
</tbody>
</table>

*For each drug listed, the expenditures shown are the total for brand and generic products and for various dosage forms.

Am J Health-Syst Pharm. 2017; 74:e339-59
# Top 10 U.S. Drugs, 2012 vs. 2018E

<table>
<thead>
<tr>
<th>Product</th>
<th>Company</th>
<th>Sales ($B)</th>
<th>2018E</th>
</tr>
</thead>
<tbody>
<tr>
<td>Humira</td>
<td>Abbvie</td>
<td>$4.4</td>
<td>$5.6</td>
</tr>
<tr>
<td>Abilify</td>
<td>Otsuka Holdings</td>
<td>4.1</td>
<td>5.3</td>
</tr>
<tr>
<td>Seretide/Advair</td>
<td>GlaxoSmithKline</td>
<td>4.0</td>
<td>4.5</td>
</tr>
<tr>
<td>Lantus</td>
<td>Sanofi</td>
<td>4.0</td>
<td></td>
</tr>
<tr>
<td>Enbrel</td>
<td>Amgen</td>
<td>4.0</td>
<td>4.2</td>
</tr>
<tr>
<td>Cymbalta</td>
<td>Eli Lilly</td>
<td>3.9</td>
<td>3.6</td>
</tr>
<tr>
<td>Remicade</td>
<td>Johnson &amp; Johnson</td>
<td>3.6</td>
<td>4.1</td>
</tr>
<tr>
<td>Rituxan</td>
<td>Roche</td>
<td>3.3</td>
<td>3.6</td>
</tr>
<tr>
<td>Neulasta</td>
<td>Amgen</td>
<td>3.2</td>
<td></td>
</tr>
<tr>
<td>Crestor</td>
<td>AstraZeneca</td>
<td>3.2</td>
<td>2.9</td>
</tr>
<tr>
<td><strong>Top 10 Total</strong></td>
<td><strong>$37.6</strong></td>
<td></td>
<td><strong>$39.7</strong></td>
</tr>
</tbody>
</table>

Totals may not sum due to rounding.

The Association for Accessible Medicines

• On Feb 14, 2017 The Generic Pharmaceutical Association (GPhA) unveiled a new national effort to contain the cost of prescription medicines. To assist in accomplishing this goal the group will now be called The Association for Accessible Medicines (AAM).

• Along with the name change the group is also launching a new campaign called “Keeping Medicines in Reach” which shares stories of patients whose health and lives are improved by access to generic medications.

• According to Jeff Watson, President of Global Generics, Apotex the new Chairman of AAM – “Our evolution to the Association for Accessible Medicine reflects an industrywide recognition that it is time to amplify the critical cost savings and access that generics and biosimilars make possible.”
Generic Medication Use

• In 2014 ~88% of all medications dispensed in the US were for generic medications but only accounted for 28% of total drug costs
  – Harris Poll (1/26/09) Found that between Oct 2006 and Dec 2008 the proportion of adults who would choose generic drugs over branded drugs increased from 68% to 81%

• Commercial insurance helped pay for 63% of prescriptions, down from 66% five years ago.

• Federal government spending through Medicare Part D covered 22% of prescriptions
Top drugmakers by 2016 generics revenue in USD billions

- Teva Pharmaceutical Industries 9.85
- Mylan 9.43
- Novartis 9
- Pfizer 4.57
- Allergan 4.5
- Sun Pharmaceutical Industries 3.61
- Fresenius 2.8
- Endo International 2.57
- Lupin 2.49
- Sanofi 2.05
- Aspen Pharmacare 2
- Aurobindo Pharma 1.86
- Dr. Reddy's Laboratories 1.78
- Cipla 1.61
- Apotex 1.6
What Drives Generic Drug Prices?

• **Competition is the primary cost driver**
  – The generic drug market operates like a commodities market, and manufacturers are asked to submit a proposal offering their best possible price to their customers—for example, companies that operate pharmacies, wholesalers or PBM’s. If another manufacturer offers a lower price to a customer, manufacturers we interviewed indicated that they are usually asked to match it or risk losing market share to the other manufacturer. Additionally, manufacturers said that if a company is bringing a generic drug into an established drug market, it typically offers a price that is lower than the current market price in order to build its customer base. **Manufacturers also said that as each new manufacturer enters an established generic drug market the price of that generic will fall, with one manufacturer noting that it is typically a 20 percent price decline per entrant. As long as manufacturers continue to enter the market, generic drug prices continue the general downward trend.**

• GAO-16-706  Generic Drugs under Medicare Part D
What Drives Generic Drug Prices?

Access to active pharmaceutical ingredients (API):

- Stakeholders indicated that reliable and affordable access to APIs which are used to manufacture a drug is critical to ensuring ongoing production of a drug. Any issues obtaining necessary APIs, which could affect multiple manufacturers, could impact the ability of these manufacturers to produce the drug. If the manufacturers cannot produce the drug, demand is not being met, and prices can increase.

— GAO-16-706 Generic Drugs under Medicare Part D
What Drives Generic Drug Prices?

Supplier Consolidation:

• Dr. Kesselheim from the Harvard School of Public Health said that “generic drug increases often come about when there is a lack of intense competition in the marketplace. He pointed to studies showing that when three or fewer manufacturers sell a generic drug, prices are far higher than when four or five makers compete.”

• A recent study done by Dr. Kesselheim and four other academics found that one third of generic drugs had three or fewer manufacturers.

• “People expect a generic to be inexpensive, but the reason it is inexpensive is that there is reasonable competition,” Dr. Kesselheim said. “When you take that away, there is nothing to stop generic companies from trying to extract the maximum they can.”

  – From the NY Times 4-14-2017 Defiant, Generic Drug Maker Continues to Raise Prices
Generic Drug Pricing?

• A recent analysis of 4,421 generic drug groups from November 13, 2013 to November 13, 2014, using the pricing solution, Predictive Acquisition Cost (PAC), and found:
  – 222 drug groups increased in price by more than 100%
  – 90 drug groups increased in price by more than 200%
  – 25 drug groups increased in price by more than 500%
  – 17 drug groups increased in price by more than 1,000%

• Tetracycline HCl 250 mg cap from $0.04 to $2.36/dose or an increase of 6500% (now 30 caps $40.00-217.00)

• Niacin ER 1000 mg tab from $0.09 to $4.54/dose or an increase of 5300% (now 30 tabs generic $75.00-105.00)

• Amitriptyline 100 mg tab from $0.05 to $0.92/dose or an increase of 1900% (now 30 tabs generic $ 4.00-40.00)
  – WHITE PAPER: Generic Drug Price Increases 2015 by Elsevier Clinical Solutions
Metformin Pricing?

- Glucophage AB 500 mg/60: $68.00; 850 mg $115.00; 1000 mg $136.00
- Generic Glucophage AB 500 mg/60 $0.00-12.00; 850 mg and 1000 mg $0.00-12.00
- Glucophage XR 500 mg/60 $70.00; 750 mg $100.00
- Generic Glucophage XR 500 mg/60 $4-12.00; 750 mg $10-20.00
- Glumetza AB 500 mg/60 $3,250.00; 1000 mg/60 $6,800-7,200.00 (Santarus)
- Generic Glumetza AB 500 mg/60 $1,000-2,500.00; 1000 mg/60 $1,500.00-5,512.00
- Fortamet AB 500 and 1000 mg/60 $2,100.00 (Andrx)
- Generic Fortamet AB 1000 mg/60 $400.00-$775.00

– GoodRx.com 1-4-2018
Price Gouging

• When a drug shortage happens or one is anticipated, a “gray market” may spring up, with the potential for price gouging. The practice of price gouging by secondary wholesalers, which largely comprise the “gray market,” is unacceptable and presents serious concerns for patient safety, as it cannot be assured that the products have been handled in a way that maintains their integrity. The manufacturer of a drug has no influence or control over the prices charged by a secondary wholesaler to a hospital or pharmacy.

— Pharmaceutical Research and Manufacturers of America®
Drug Shortages

- Drug shortages are an increasing problem: the FDA listed 154 drugs in short supply back in 2007 and in April of 2016 the list has grown to more than 300 and most of them are for generic medications and many are injectables used in acute care situations.

- The FDA has a significant backlog of generic drug applications (~4,000) with a wait time of ~42 months. (Managed Healthcare Executive 5-31-2016)
  - The shortages increased significantly after the 81 deaths from contaminated heparin produced in China in 2008 (FDA has inspectors in the plants)
Drug Shortages

• The reason(s) for the recent spike in medication shortages are multiple but include:
  – A lack of competition with generic manufacturer mergers (many of these medications have only 1 or 2 manufacturers)
  – A lack of the raw materials to manufacture the medication or its containers
  – Production and manufacturing quality issues forcing shutdowns (not up to FDA GMP’s)
  – Low reimbursement rates (IE Medicare Part B)

• Patient care is in potential jeopardy and it is estimated that hospitals spend ~$216 million in labor costs to manage medication shortages each year.
<table>
<thead>
<tr>
<th>Drug</th>
<th>2016 Expenditures ($ Thousands)</th>
<th>Percent Change From 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pyrimethamine</td>
<td>10,103</td>
<td>552.7</td>
</tr>
<tr>
<td>Thiotepa</td>
<td>39,570</td>
<td>394.3</td>
</tr>
<tr>
<td>Zinc sulfate</td>
<td>1,774</td>
<td>327.0</td>
</tr>
<tr>
<td>Tetrabenazine</td>
<td>2,849</td>
<td>303.6</td>
</tr>
<tr>
<td>Physostigmine salicylate</td>
<td>1,801</td>
<td>240.2</td>
</tr>
<tr>
<td>Chlordiazepoxide</td>
<td>2,529</td>
<td>168.5</td>
</tr>
<tr>
<td>Sodium bicarbonate</td>
<td>27,310</td>
<td>143.9</td>
</tr>
<tr>
<td>Phentolamine</td>
<td>9,034</td>
<td>109.4</td>
</tr>
<tr>
<td>Fluphenazine</td>
<td>8,656</td>
<td>107.5</td>
</tr>
<tr>
<td>Vasopressin</td>
<td>319,113</td>
<td>102.9</td>
</tr>
<tr>
<td>Indocyanine green</td>
<td>5,923</td>
<td>63.8</td>
</tr>
<tr>
<td>Lidocaine viscous</td>
<td>3,690</td>
<td>60.3</td>
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<tr>
<td>Calcitonin salmon</td>
<td>114,880</td>
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<tr>
<td>Penicillamine</td>
<td>5,741</td>
<td>56.0</td>
</tr>
<tr>
<td>Albendazole</td>
<td>11,721</td>
<td>50.0</td>
</tr>
</tbody>
</table>

*For each drug listed, the expenditures shown are the total for brand and generic products and for various dosage forms.*
What does it Cost to Develop a New Drug???

• In 2003 Tufts Univ. estimated the cost to bring a new drug to the US market was ~$800 million
• In 2014 Tufts updated their estimate which is now at ~$2.6 billion
• In 2011, the London School of Economics and Political Science (LSEPS) came up with quite a different - much lower! - estimate of $59 million
• In 2013 the Office of Health Economics (OHE) at the University College London estimated the cost to be $1.5 billion
• In 2015 Forbes said it is now about $5 billion to develop one new drug.
"There is actually a lot of evidence about drug development costs from the orphan drug tax credit," notes Love (a critic of the Tufts data). "Since 2005, 57 percent of new cancer drugs have been registered first for orphan indications, and 78 percent have benefited from the Orphan designation. Yet in the press conference, DiMasi from Tufts acted as if these drugs were not important. Through 2010, the amount of money claimed for the Orphan Drug tax credit, which covers 50 percent of the costs of clinical testing, was less than $650 million --- for all drugs being tested in that year! Hard to get from $650 million for 14 approvals to $2.6 billion for one approval." May not reflect normal drug development as much smaller patient numbers?

Jamie Love of Knowledge Ecology International, said “The study is long on propaganda and short of details. The drug companies that fund the CSDD are hoping people will just take the number and quote it for several years until a new one is needed"
U.S. Drug Pricing?

• A broken U.S. drug pricing system is leading to spiraling chemotherapy and other drug costs—and hurting patients—argued Peter B. Bach, MD, the director of the Center for Health Policy and Outcomes at Memorial Sloan Kettering Cancer Center in New York City, during the 2016 annual Hematology/Oncology Pharmacy Association (HOPA) Oncology Pharmacy Practice Management Program.
Oncology Medications?

Cancer Drug Price Surge

• Median monthly costs for new cancer drugs in the United States:
  – $129 in 1975-1979 (Five new drugs introduced)
  – $10,059 in 2010-2014 (34 new drugs introduced)
    • Source: Peter Bach and Geoffrey Schnorr, Memorial Sloan Kettering Cancer Center.
  – Note: Costs are based on monthly Medicare prices for drug approvals the year they were introduced, adjusted for inflation; drugs approved through early 2014 are included.
• The average launch price of anticancer drugs, adjusted for inflation and health benefits, increased by 10 percent annually—or an average of $8,500 per year—from 1995 to 2013.

• Medicare is the most prominent US payer for anticancer drugs, followed by commercial insurers and then state Medicaid programs. Medicare pays for physician-administered intravenous drugs through the medical “Part B” benefit. By law, Medicare does not directly negotiate with drug manufacturers over prices for prescription drugs covered under the Part B benefit or the oral anticancer drugs covered under Medicare’s pharmacy “Part D” benefit. Section 1861 of the Social Security Act, which requires that the Medicare program cover “reasonable and necessary” medical services, precludes consideration of cost or cost-effectiveness in coverage decisions (Neumann 2005). Consequently, Medicare covers all newly approved anticancer drugs for indications approved by the FDA.

• The private insurance plans that provide prescription drug coverage under Medicare “Part D” are required to cover all drugs in six protected classes, one of which is anticancer drugs (Center for Medicare and Medicaid Services 2014).
Medicare Part D Coverage?

• A part D plan is required to cover all or substantially all drugs in the following six therapeutic classes: anti-retrovirals; immunosuppressants when used for organ rejection; anti-depressants; anti-psychotics; anti-convulsant agents; and anti-neoplastics.

• By law the Sec of DHHS can not negotiate discounts including volume discounts with the manufacturer!

• Who wrote the Medicare part D legislation? Pharma!

• Who in the world does not negotiate with the manufacturers about price based upon the value provided? US Government! Note almost every country in the world negotiates based upon value provided and price is set by the regulatory body (I.E. UK-NICE)
Medicaid and VA Pricing

• However, Medicaid, the program for low-income people that is administered by the CMS and the Department of Veterans Affairs (VA), both are able to negotiate with drug companies for lower prices. In fact, under federal law, drug makers must provide a discount or rebate equal to at least 15% of the average manufacturer price for most brand-name drugs covered by Medicaid. Federal law also guarantees discounts for the Department of Veterans Affairs, which can negotiate with drug makers to secure discounts on top of those guaranteed by law. Generally, they are able to negotiate prices that are 25% to 50% lower than Medicare.

• A report by Families USA, which compared VA prices with those in Part D of Medicare, found a median price difference of 58%, suggesting that market forces are not bringing prices down, as was hoped.
US Pharmaceutical Data

• Although PhRMA argues that high prices are necessary to recoup its large investment in R&D, profit margins among the top 10 drug makers ranged from 10 percent to 43 percent in 2013, with five of these companies racking up profit margins of 20 percent or higher.

• On average, the pharmaceutical sector has significantly higher annual net profit margins than almost any other industry—more than double the average net profit margin for Standard & Poor’s, or S&P, 500 companies.

  — Enough Is Enough: The Time Has Come to Address Sky-High Drug Prices Center for American Progress September 2015
2013 revenue, R&D, and marketing budgets for major pharmaceutical companies, in billions

<table>
<thead>
<tr>
<th>Company</th>
<th>Total Revenue</th>
<th>R&amp;D Spending</th>
<th>R&amp;D to Revenue</th>
<th>Marketing Spend</th>
<th>Marketing to Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Novartis</td>
<td>$58.8</td>
<td>$9.9</td>
<td>16.8%</td>
<td>$14.6</td>
<td>24.8%</td>
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<tr>
<td>Pfizer</td>
<td>$51.6</td>
<td>$6.6</td>
<td>12.8%</td>
<td>$11.4</td>
<td>22.1%</td>
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<td>Roche</td>
<td>$50.3</td>
<td>$9.3</td>
<td>18.5%</td>
<td>$9.0</td>
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</tr>
<tr>
<td>Sanofi</td>
<td>$44.4</td>
<td>$6.3</td>
<td>14.2%</td>
<td>$9.1</td>
<td>20.5%</td>
</tr>
<tr>
<td>Merck &amp; Co.</td>
<td>$44.0</td>
<td>$7.5</td>
<td>17.0%</td>
<td>$9.5</td>
<td>21.6%</td>
</tr>
<tr>
<td>GSK</td>
<td>$41.4</td>
<td>$5.3</td>
<td>12.8%</td>
<td>$9.9</td>
<td>23.9%</td>
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<tr>
<td>AstraZeneca</td>
<td>$25.7</td>
<td>$4.3</td>
<td>16.7%</td>
<td>$7.3</td>
<td>28.4%</td>
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<tr>
<td>Eli Lilly</td>
<td>$23.1</td>
<td>$5.5</td>
<td>23.8%</td>
<td>$5.7</td>
<td>24.7%</td>
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<tr>
<td>AbbVie</td>
<td>$18.8</td>
<td>$2.9</td>
<td>15.4%</td>
<td>$4.3</td>
<td>22.9%</td>
</tr>
</tbody>
</table>
Pharma Lobby

Even as Washington politicians are busy on a range of proposals that might impact the drug industry, new data show that pharmaceutical lobbying groups and drugmakers including Pfizer, Amgen and Mylan have been busy as well, boosting their spending in hopes of influencing the way legislation gets written.

Compared to 2016’s first quarter, the industry’s top lobby group, PhRMA, increased lobby spending by 34% to $7.98 million in the first three months of this year, according to info from media group Axios. But that paled on a first-quarter percent basis compared to Mylan and Teva, which topped all other pharma players with Q1 increases of 138% and 115%, respectively.

Novartis, Pfizer, Amgen, Teva and AbbVie ranked one through five for drugmakers spending the most on lobbying in the first quarter, collectively spending $15.9 million. At the top, Novartis spent $4 million, a 29% jump over last year.
Total for Pharmaceuticals/Health Products: $209,395,967
Total Number of **Clients** Reported: 365
Total Number of **Lobbyists** Reported: 1,403
Total Number of Revolvers: 926 (66.0%)
### 2017 Lobbing Spending (1st Quarter)

<table>
<thead>
<tr>
<th>Industry</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceuticals/Health Products</td>
<td>$78,142,678</td>
</tr>
<tr>
<td>Insurance</td>
<td>$40,155,621</td>
</tr>
<tr>
<td>Oil &amp; Gas</td>
<td>$36,143,101</td>
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<tr>
<td>Business Associations</td>
<td>$33,525,293</td>
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<tr>
<td>Electronics Mfg &amp; Equip</td>
<td>$32,022,119</td>
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<tr>
<td>Electric Utilities</td>
<td>$31,807,178</td>
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<tr>
<td>Hospitals/Nursing Homes</td>
<td>$25,168,245</td>
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<tr>
<td>Securities &amp; Investment</td>
<td>$23,858,638</td>
</tr>
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<td>Air Transport</td>
<td>$23,004,356</td>
</tr>
<tr>
<td>Health Professionals</td>
<td>$22,702,226</td>
</tr>
<tr>
<td>Misc Manufacturing &amp; Distributing</td>
<td>$22,418,664</td>
</tr>
<tr>
<td>Health Services/HMOs</td>
<td>$21,179,452</td>
</tr>
</tbody>
</table>

[https://www.opensecrets.org/lobby/top.php?showYear=2017&indexType=i](https://www.opensecrets.org/lobby/top.php?showYear=2017&indexType=i)

Center for Responsive Politics accessed 5-30-2017
# 2017 Health Related Lobbying

Total for Health: **$417,834,140**  
Total Number of **Clients** Reported: **1,269**  
Total Number of **Lobbyists** Reported: **2,742**  
Total Number of **Revolvers**: **1,495 (54.5%)**

*Campaign Contributions from this sector*

<table>
<thead>
<tr>
<th>Industry</th>
<th>Total spending</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceuticals/Health Products</td>
<td><strong>$209,395,967</strong></td>
</tr>
<tr>
<td>Hospitals/Nursing Homes</td>
<td><strong>$74,557,301</strong></td>
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<tr>
<td>Health Professionals</td>
<td><strong>$68,341,274</strong></td>
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<tr>
<td>Health Services/HMOs</td>
<td><strong>$60,034,040</strong></td>
</tr>
<tr>
<td>Misc Health</td>
<td><strong>$5,505,558</strong></td>
</tr>
</tbody>
</table>
Pharma Lobby

- The Pharmaceutical Research and Manufacturers of America, or PhRMA, was so concerned about its vulnerability this year that it increased its annual dues by 50 percent — generating an extra $100 million to flood social media, television stations, as well as newspapers and magazines with advertising that reminds consumers of the industry’s role in helping to save lives.

- A second set of PhRMA ads point blame for price increases elsewhere, like benefit managers and health insurers.
  
  — New York Times May 29, 2017
Pharma Lobby

• “Nearly every week that Congress is in session, the industry holds fund-raisers at private clubs and restaurants to help bankroll the re-election campaigns of its allies. One former lobbyist for PhRMA recently boasted that he had once organized six fund-raising events in a two-day period. (He asked that he not be named because the fund-raising efforts are supposed to be confidential.)”

   – New York Times May 29, 2017
Congress Hampers the DEA

• In April 2016, at the height of the deadliest drug epidemic in U.S. history (Opioid Overdoses), Congress effectively stripped the Drug Enforcement Administration of its most potent weapon against large drug companies suspected of spilling prescription narcotics onto the nation's streets.

• The new law makes it virtually impossible for the DEA to freeze suspicious narcotic shipments from the companies, according to internal agency and Justice Department documents and an independent assessment by the DEA's chief administrative law judge. That powerful tool had allowed the agency to immediately prevent drugs from reaching the street.
The chief advocate of the law that hobbled the DEA was Rep. Tom Marino, a Pennsylvania Republican who is now President Trump's nominee to become the nation's next drug czar. Marino spent years trying to move the law through Congress. It passed after Sen. Orrin G. Hatch (R-Utah) negotiated a final version with the DEA.

Political action committees representing the industry contributed at least $1.5 million to the 23 lawmakers who sponsored or co-sponsored four versions of the bill, including nearly $100,000 to Marino and $177,000 to Hatch. Overall, the drug industry spent $106 million lobbying Congress on the bill and other legislation between 2014 and 2016.

Since the DEA started to crack down on the opioid industry a decade ago, pharmaceutical companies and the law firms that represent them have hired at least 46 DEA officials - 32 of them directly from the division.
Congress Hampers the DEA

• "The drug industry, the manufacturers, wholesalers, distributors and chain drugstores, have an influence over Congress that has never been seen before," said Joseph T. Rannazzisi, who ran the DEA's division responsible for regulating the drug industry and led a decade-long campaign of aggressive enforcement until he was forced out of the agency in 2015. "I mean, to get Congress to pass a bill to protect their interests in the height of an opioid epidemic just shows me how much influence they have."

• The bill sailed through Congress and was passed by unanimous consent, a parliamentary procedure reserved for bills considered to be noncontroversial and was signed by President Obama without objection.

— 60 Minutes 10-15-2017
Congress Hampers the DEA

• 2016: 197,713 deaths from prescription opioid overdoses since 2000.

• John Mulrooney, the chief DEA administrative law judge, has been documenting the falling number of immediate suspension orders against doctors, pharmacies and drug companies. That number has dropped from 65 in fiscal year 2011 to six so far this fiscal year, according to the DEA. Not a single order has targeted a distributor or manufacturer since late 2015.
DEA Actions Prior to the New Law

• In the most egregious cases, the DEA employed an "immediate suspension order," allowing the agency to lock up a distributor's drugs. The orders instantly halted all commerce in controlled substances on the grounds that the drugs constituted an "imminent danger" to the community.

• Under Rannazzisi in the mid-2000s, the DEA repeatedly warned the companies that they were shipping unusually large volumes of opioids to customers around the country. Despite the warnings, some companies continued the shipments.
  – The DEA soon began bringing enforcement actions against distributors. In 2007, the agency moved against McKesson, the nation's largest drug distributor and the fifth-largest corporation in the nation, for failing to report hundreds of suspicious orders placed by Internet pharmacies. McKesson settled the case, paying a $13.2 million fine.
  – In 2008, Rannazzisi and Barber targeted Cardinal Health, another large drug distributor, for filling "blatantly suspicious" orders from online drugstores. Cardinal paid a $34 million fine.
Congress Hampers the DEA

• A pharmacy in Kermit, WV population 392 a small rural town in the state with the highest rate of opioid deaths in the US. According to the DEA this one pharmacy dispensed 9 million doses of hydrocodone over 2 years.

• In the past DEA would take action against the wholesaler like McKesson, Cardinal Health and Amerisource-Bergan and prevent them from selling controlled substances and fine them but since this new legislation the DEA has not brought a case against any of the distributors.

• As of Oct 15, 2017 Congress is considering repealing the law and many Congressmen are concerned that they were deceived into passing the law in 2016. President Trump is also reconsidering nominating Congressman Tom Marino (R-PA) who sponsored the bill approved last year.
New State Laws Regulating Drug Pricing Transparency

• Vermont recently passed a law requiring drug manufacturers to justify their price increases.
• A new law in New York caps Medicaid prescription drug spending.
• Nevada has passed a new pricing transparency law focused on insulin for diabetes patients.
• The Maryland attorney general, is now authorized to take action against certain increases in generic drug prices.
• Many other states are also working on legislation that would regulate drug pricing transparency.
California Drug Pricing Transparency Law

- On October 9, 2017, California Governor Jerry Brown (D) signed into law what may be the most comprehensive prescription drug pricing transparency bill in the country. Effective date 1/1/2019

- The new California law requires a drug manufacturer to provide 60 days’ notice to certain purchasers of any planned increase in a drug’s wholesale acquisition cost (“WAC”) of 16 percent or more over a two-year period, if the drug has a WAC of over $40. The purchasers to be notified pursuant to this requirement include state agencies, health care service plans, health insurers and pharmacy benefit managers. The notice must include the date and amount of the increase, and a statement as to whether the price increase is necessitated by a change or improvement in the drug.
“Evergreening”

• “Evergreening” also drives up costs. In this practice, pharmaceutical companies faced with expiring patents will make slight, cosmetic tweaks to an existing product. The tweaked drug then receives a new period of market exclusivity, delaying generic competition—despite the fact that there is no real clinical difference between the tweaked drug and the older version.

• For example, Abbott Laboratories managed to get three separate patent extensions for its cholesterol-reducing drug Tricor-1, which it renamed Tricor-2, Tricor-3, and Trilipix. None of these subsequent versions improved the clinical efficacy of the drug; rather, Abbott merely tweaked the dosage of the drug and switched it first from capsules to tablets and then to delayed-release capsules. By delaying generic competition, this single case of evergreening drives up overall U.S. health care spending by an estimated $700 million every year.

  – Enough Is Enough: The Time Has Come to Address Sky-High Drug Prices Center for American Progress September 2015
US Prescription Drug Spending

- The pharmaceutical industry has downplayed these costs by noting that retail prescription drugs have consistently accounted for about 10 percent of total health spending in the United States. This figure comes from the official National Health Expenditures, or NHE, estimates, which in 2013 found retail prescription drugs to represent 9.3 percent of total spending. However, the NHE figure does not include drugs administered by physicians, hospitals, and nursing homes rather than sold through retail outlets. Many expensive drugs, such as those used to treat cancer, fall under these categories and thus are not accounted for in the 10 percent figure. For example, drug spending under Medicare Part B, which covers physician administered drugs, totaled $19 billion in 2013, without even accounting for private insurance spending on these drugs. Consequently, the 10 percent figure understates the true amount of prescription drug spending in the U.S. health system.

   - Enough Is Enough: The Time Has Come to Address Sky-High Drug Prices Center for American Progress September 2015
Medicare Part-B

• Traditional Medicare pays for certain categories of prescription drugs—including drugs administered in doctors’ offices or hospital outpatient departments—based on the drug’s average sales price plus 6 percent of that price, or ASP plus 6. The ASP is essentially an average of the prices—net of rebates, discounts, and other price concessions—charged by the manufacturer in the commercial market, and when a drug is administered to a patient, the provider receives the Medicare payment directly, regardless of how much the provider paid for the drug.

• In 2013, Medicare and beneficiaries paid more than $19 billion for Part B-covered drugs paid for under ASP plus 6.
  – Enough Is Enough: The Time Has Come to Address Sky-High Drug Prices Center for American Progress September 2015
Companies are also increasing prices for existing products far in excess of inflation. A recent AARP Public Policy Institute study found that retail prices for brand-name prescription drugs increased by nearly 13 percent in 2013, which is more than eight times the general inflation rate.

For example, the prices for certain forms of some brand-name insulins—such as Humulin and Lantus—rose by up to 160 percent between 2007 and 2014, compared with a 12 percent increase in the Consumer Price Index over the same time period.

– Enough Is Enough: The Time Has Come to Address Sky-High Drug Prices
  Center for American Progress  September 2015
What is a Pharmacy Benefit Manager (PBM)

- Entity that administers managed pharmacy programs
- Controls costs associated with the delivery of pharmaceutical care:
  - Improve prescribing and dispensing process
    - Through online and real-time claims adjudication
  - Retail network of pharmacies (Contracts)
  - Drug utilization review (DUR)
    - Online at the point of sale
    - Prior Authorizations
    - Step - Protocols
    - Drug safety monitoring
  - Data and Reporting
    - In regards to drug usage
  - Formulary development and rebate contracting
PBM Compensation

- Administrative fees
  - Charging payers an administrative fee for adjudicating a claim, evaluating a P/A and developing the plan formulary

- Rebates*
  - Retaining all or a part of rebates negotiated with manufacturers

- Securing discounts from pharmacies* or in-house (PBM) mail-order & specialty pharmacies

- Direct and indirect remuneration fees (DIR Fees)?*

- Retaining pharmacy spread or the difference between the amount a PBM collects from the payer and the amount a PBM pays to the pharmacy
  
  Example: The PBM collects $50 from the payer for Drug A and pays the pharmacy $20. The pharmacy spread is $30 and is typically retained by the PBM.

* Often not disclosed to the client (lack of transparency)
PBM Market Share, by Total Prescription Claims, 2015

- **Express Scripts**: 26%
- **CVS Health¹ (Caremark)**: 25%
- **OptumRx² (UnitedHealth)**: 22%
- **Humana Pharmacy Solutions**: 10%
- **Prime Therapeutics**: 8%
- **Medimpact Healthcare Systems**: 6%
- **All Others**: 4%

Total prescription claims includes claims at a PBM’s network pharmacies plus prescriptions filled by a PBM’s mail and specialty pharmacies. Excludes cash-pay prescriptions. Total may not sum due to rounding.
1. Includes Aetna prescription claims volume.
2. Includes pro forma combination of OptumRx with Catamaran. Includes Cigna prescription claims volume.
Source: Pembroke Consulting estimates

Pharmacy Benefit Managers (PBM’s)

• PBMs regularly face a variety of allegations about their business model, especially the lack of transparency about rebates from drug companies. For example, lawsuits have alleged that PBMs pocket rebates from manufacturers that should be passed along to plan sponsors.

• The Affordable Care Act, or ACA, increased transparency for PBMs who administer Medicare Part D benefits and in the new marketplaces, but other arrangements between PBMs, pharmacies, and pharmaceutical manufacturers continue to be secret.

  – Enough Is Enough: The Time Has Come to Address Sky-High Drug Prices Center for American Progress  September 2015
US Pharmaceutical Market

• Without government control over drug prices, stickers for meds are higher in the U.S. than they are in other parts of the world. But just how much higher?
• On average, three times as high as they are in Britain, Reuters reports, citing a new University of Liverpool analysis of the world's 20 top-selling drugs.
• U.S. prices came in at 6 times those in Brazil and 16 times higher than average in the lowest-price country—usually India.
Undermining Value-Based Purchasing — Lessons from the Pharmaceutical Industry

- For years, insurers and pharmacy benefits managers have steered consumers toward generic and other high-value drugs by categorizing drugs into “tiers” and requiring lower copayments for preferred drugs.

- Tiering not only encourages consumers to use high-value drugs, it also gives insurers leverage during price negotiations with manufacturers. Under tiering, insurers offer manufacturers favorable tier placement in exchange for better discounts.

- Placement on a preferred brand tier, with a typical copayment of about $30, will yield higher sales than placement on a nonpreferred-brand tier, with a typical copayment of more than $50.

In recent years, drug manufacturers have counterattacked by offering “copayment coupons.” These coupons or discount cards — distributed by physicians’ offices, through the mail, and online — enable the manufacturer to pay some or all of a consumer’s copayment for a prescription.

By severing the link between cost sharing and the value generated by a drug, copayment coupons can undo the beneficial effects of tiering.

Coupons shift spending toward these higher-priced drugs, the net effect will be higher pharmaceutical spending and, ultimately, higher health insurance premiums.

• Coupons greatly reduce the incentive for drug manufacturers to offer price concessions in exchange for preferred tier placement. In fact, the opposite strategy becomes profitable: charge insurers the highest price possible while remaining on the formulary, and then use a copayment coupon to promote use.

• It has been estimated that coupons increase the percentage of prescriptions filled with brand-name formulations by more than 60%.

• The only recourse insurers have is to exclude a drug from their formulary entirely, and that may be much worse for patients than placing it in a high tier.

US Prescription Drug Spending

- Some price spikes are the result of a new company buying the rights to the drug. For example, when Horizon Pharma acquired the pain medication Vimovo, it increased the price by 597 percent on the first day. As a result, Horizon earned more than eight times as much for the drug in 2014 as the drug had earned in the year before the price increase, despite the fact that fewer patients actually received it. In 2015, Horizon increased the price again by another 75 percent, bringing the cumulative price markup under Horizon’s ownership to more than 1,000 percent of the original price—despite the fact that no clinical improvements to the drug had been made.
  - Current cost for 60 tablets of Vimovo 500mg/20mg is now ~$2,400.00 (naproxen 500 mg and esomeprazole 20 mg) both are available as a generic for $4.00 and ~$100-200.00 respectively (NOTE Nexium 24 Hr OTC 22.3mg caps ~ $40.00/42 caps)
  - Enough Is Enough: The Time Has Come to Address Sky-High Drug Prices Center for American Progress September 2015
Vimovo Co-pay Card by Horizon

Both CVS Caremark and Express-Scripts have excluded Vimovo from coverage which means 100% co-pay for patients!
California Restricts Coupons and Discounts for Branded Drugs

• Oct. 16, 2017
• California Gov. Jerry Brown signed a law that limits drugmakers from offering a coupon or other discount for a branded product if a cheaper generic is available.
• The law applies to coupons, vouchers or refunds applicable to patient copayments, deductibles and other expenses. Exceptions include prior authorization of the branded drug from an insurer.
• The drug industry opposed the bill
Formulary Exclusions for 2017

• CVS/Caremark 154 medications
  – Including the following diabetes meds: Byetta, Bydureon, Glumetza, Humalog, Humalin 70/30, Humalin N and R, Lantus, Invokana and Toujeo
  – Also includes: Abilify, Crestor, Lipito, Livalo, Macrodantin, Beconase AQ, Veramyst, Proventil HFA, Ventolin HFA, Xopenex HFA, Incruz Ellipta, Symbicort, Nexium, Zegerid

• Express Scripts 85 medications
  – Including the following diabetes meds: Victoza, Tanzeum, Novalog, Apidra, and Glumetza
  – Also includes: Beconase AQ, Veramyst, doxycycline 40 mg caps, levalbuterol HFA, Xopenex HFA, Proventil HFA

• Optum Rx (United Healthcare) 89 medications
  – Including the following diabetes meds: Tanzeum, Novolin, Novolog, Apidra, Levemir, Tresiba, Farxiga, Xigduo XR, Alogliptin, alogliptin with metformin, alogliptin with pioglitazone, Kazano, Nesina, Oseni, Kombiglyze XR, Onglyza
  – Also includes: Duexis, Dulara, Vimovo, Xopenex HFA and Proventil HFS

(Patients will be required to pay 100% out of pocket)

What does this mean to you and your patients?
For the first time ever, in 2018, brand drug manufacturers must provide significant savings to be included on the NPF if there are clinically equivalent, lower cost options available. For the 2018 NPF, we focused on high-spend multi-source brand drugs and excluded 46.
Drug Pricing

• Discount: A reduction in the amount that an insurer or other entity is charged for a medicine at the time of sale.

• Rebate: A reduction from the price of a medicine, paid to an insurer or other entity retroactively, after the medicine is dispensed. This rebate is typically paid at the end of some defined period of time typically months after the claim is paid.
### Lilly Drug Pricing Transparency

**COMPARISON OF LILLY LIST AND NET PRICE CHANGES FOR U.S. PRODUCT PORTFOLIO**

(% CHANGE VERSUS THE PRIOR YEAR)

<table>
<thead>
<tr>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LIST PRICE</strong> ³</td>
<td>12.8</td>
<td>15.0</td>
<td>11.8</td>
<td>16.3</td>
<td>14.0</td>
</tr>
<tr>
<td><strong>NET PRICE</strong> ⁴</td>
<td>7.8</td>
<td>11.9</td>
<td>1.6</td>
<td>9.4</td>
<td>2.4</td>
</tr>
</tbody>
</table>

Net Price represents weighted average year-over-year change in net price, which is WAC minus rebates, discounts, and channel costs.
Lilly Drug Pricing Transparency

AVERAGE DISCOUNTS TO LIST PRICE ACROSS THE U.S. PRODUCT PORTFOLIO

- 2012: 28%
- 2013: 30%
- 2014: 41%
- 2015: 45%
- 2016: 50%

1 Total Average Discount

1 Source: Lilly Annual Report

2 Data from IMS Health
Lilly Drug Pricing Transparency

• What’s causing that increase? Lilly says more competition among drugmakers to win coverage, a change in its product portfolio, and hardball “rebate” negotiations with PBMs. Mandatory government discounts that have grown “significantly” since the Affordable Care Act went into law in 2010 are also playing a role, according to the company.
J&J, Merck drug prices outpace inflation

The drugmakers’ prices increase at a much faster rate than core CPI, even after discounts.

AVerage Drug Price Change, Year-on-Year*

Johnson & Johnson: List price  Net price  Merck: List price  Net price
Average core CPI**

* List price is average wholesale acquisition cost (WAC); net price is WAC less rebates, discounts and returns.
** Seasonally-adjusted consumer price index, excluding food and energy
Sources: Merck; U.S. Bureau of Labor Statistics

Staff, 27/02/2016
Who is driving up drug prices?

- The blame game of who is responsible for jacking up drug prices is at the cusp of turning into a full-blown war. A leaked e-mail, from Mark Merritt, president and CEO of the trade group Pharmaceutical Care Management Association (PCMA), to the organization’s board, lays out a plan to develop an aggressive campaign to convince the new administration that the fault rests with pharmaceutical manufacturers.
<table>
<thead>
<tr>
<th>Company (stock symbol)</th>
<th>Revenues ($B)</th>
<th>Revenues, % vs. 2015</th>
<th>2016 Fortune 500 Rank</th>
<th>Revenue per Employee ($M)</th>
<th>Profit as % of Revenues</th>
<th>Profit as % of Assets</th>
<th>Annualized Return to Investors (2005-2015)</th>
<th>Total Return to Investors (2015)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Johnson &amp; Johnson (JNJ)</td>
<td>$70.1</td>
<td>-5.7%</td>
<td>39</td>
<td>$0.6</td>
<td>22.0%</td>
<td>11.6%</td>
<td>8.8%</td>
<td>1.2%</td>
</tr>
<tr>
<td>Pfizer (PFE)</td>
<td>$48.9</td>
<td>-1.5%</td>
<td>55</td>
<td>$0.5</td>
<td>14.2%</td>
<td>4.2%</td>
<td>7.8%</td>
<td>7.1%</td>
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<tr>
<td>Merck &amp; Co. (MRK)</td>
<td>$29.5</td>
<td>-6.5%</td>
<td>72</td>
<td>$0.4</td>
<td>11.2%</td>
<td>4.4%</td>
<td>9.4%</td>
<td>-4.0%</td>
</tr>
<tr>
<td>Gilead Sciences (GILD)</td>
<td>$32.6</td>
<td>31.1%</td>
<td>86</td>
<td>$4.1</td>
<td>55.5%</td>
<td>34.9%</td>
<td>22.8%</td>
<td>8.7%</td>
</tr>
<tr>
<td>Amgen (AMGN)</td>
<td>$21.7</td>
<td>8.0%</td>
<td>130</td>
<td>$1.2</td>
<td>32.0%</td>
<td>9.7%</td>
<td>8.4%</td>
<td>4.0%</td>
</tr>
<tr>
<td>AbbVie (ABBV)</td>
<td>$22.9</td>
<td>14.5%</td>
<td>123</td>
<td>$0.8</td>
<td>22.5%</td>
<td>9.7%</td>
<td>-6.5%</td>
<td></td>
</tr>
<tr>
<td>Eli Lilly and Company (LLY)</td>
<td>$20.0</td>
<td>1.7%</td>
<td>141</td>
<td>$0.5</td>
<td>12.1%</td>
<td>6.8%</td>
<td>8.4%</td>
<td>25.3%</td>
</tr>
<tr>
<td>Bristol-Myers Squibb Company (BMY)</td>
<td>$16.6</td>
<td>4.3%</td>
<td>168</td>
<td>$0.7</td>
<td>9.5%</td>
<td>4.9%</td>
<td>16.4%</td>
<td>19.3%</td>
</tr>
<tr>
<td>Biogen Idec (BIIB)</td>
<td>$10.8</td>
<td>10.9%</td>
<td>263</td>
<td>$1.5</td>
<td>33.0%</td>
<td>18.2%</td>
<td>21.1%</td>
<td>-9.8%</td>
</tr>
<tr>
<td>Celgene (CELG)</td>
<td>$9.3</td>
<td>20.7%</td>
<td>305</td>
<td>$1.3</td>
<td>17.3%</td>
<td>5.9%</td>
<td>22.1%</td>
<td>7.1%</td>
</tr>
<tr>
<td>Baxalta</td>
<td>$6.1</td>
<td>n.a.</td>
<td>420</td>
<td>$0.4</td>
<td>15.5%</td>
<td>7.8%</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
<tr>
<td><strong>Average</strong></td>
<td><strong>$26.2</strong></td>
<td><strong>7.8%</strong></td>
<td><strong>164</strong></td>
<td><strong>$1.1</strong></td>
<td><strong>22.3%</strong></td>
<td><strong>10.7%</strong></td>
<td><strong>13.9%</strong></td>
<td><strong>5.2%</strong></td>
</tr>
<tr>
<td><strong>Median</strong></td>
<td><strong>$21.7</strong></td>
<td><strong>6.2%</strong></td>
<td><strong>130</strong></td>
<td><strong>$0.7</strong></td>
<td><strong>17.3%</strong></td>
<td><strong>7.8%</strong></td>
<td><strong>9.4%</strong></td>
<td><strong>5.6%</strong></td>
</tr>
</tbody>
</table>

Source: Pembroke Consulting analysis of 2016 Fortune 500 list
Published on Drug Channels (http://www.DrugChannels.net) on June 21, 2016.
# Drug Channels Companies in the 2016 *Fortune* 500 List

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<th>Total Return to Investors (2015)</th>
</tr>
</thead>
<tbody>
<tr>
<td>McKesson (MCK)</td>
<td>$181.2</td>
<td>31.3%</td>
<td>5</td>
<td>$2.6</td>
<td>0.8%</td>
<td>2.7%</td>
<td>15%</td>
<td>-5%</td>
</tr>
<tr>
<td>CVS Health (CVS)</td>
<td>$153.3</td>
<td>10.0%</td>
<td>7</td>
<td>$0.8</td>
<td>3.4%</td>
<td>5.6%</td>
<td>15%</td>
<td>3%</td>
</tr>
<tr>
<td>AmerisourceBergen (ABC)</td>
<td>$136.0</td>
<td>13.7%</td>
<td>12</td>
<td>$8.0</td>
<td>-0.1%</td>
<td>-0.5%</td>
<td>19%</td>
<td>16%</td>
</tr>
<tr>
<td>Walgreens Boots Alliance (WBA)</td>
<td>$103.4</td>
<td>35.4%</td>
<td>19</td>
<td>$0.3</td>
<td>4.1%</td>
<td>6.1%</td>
<td>8.6%</td>
<td>13.6%</td>
</tr>
<tr>
<td>Cardinal Health (CAH)</td>
<td>$102.5</td>
<td>12.6%</td>
<td>21</td>
<td>$3.0</td>
<td>1.2%</td>
<td>4.0%</td>
<td>7.8%</td>
<td>12.6%</td>
</tr>
<tr>
<td>Express Scripts Holding (ESRX)</td>
<td>$101.8</td>
<td>0.9%</td>
<td>22</td>
<td>$3.9</td>
<td>2.4%</td>
<td>4.7%</td>
<td>15.4%</td>
<td>3.2%</td>
</tr>
<tr>
<td>Rite Aid (RAD)</td>
<td>$26.5</td>
<td>3.9%</td>
<td>107</td>
<td>$0.4</td>
<td>8.0%</td>
<td>23.8%</td>
<td>8.5%</td>
<td>4.3%</td>
</tr>
<tr>
<td><strong>Average</strong></td>
<td><strong>$115.0</strong></td>
<td><strong>15.4%</strong></td>
<td><strong>28</strong></td>
<td><strong>$2.7</strong></td>
<td><strong>2.8%</strong></td>
<td><strong>6.6%</strong></td>
<td><strong>12.8%</strong></td>
<td><strong>6.9%</strong></td>
</tr>
<tr>
<td><strong>Median</strong></td>
<td><strong>$103.4</strong></td>
<td><strong>12.6%</strong></td>
<td><strong>19</strong></td>
<td><strong>$2.6</strong></td>
<td><strong>2.4%</strong></td>
<td><strong>4.7%</strong></td>
<td><strong>15.2%</strong></td>
<td><strong>4.3%</strong></td>
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Published on Drug Channels ([http://www.DrugChannels.net](http://www.DrugChannels.net)) on June 21, 2016.
Who or What is driving up drug prices?

- Pharmaceutical Manufacturers?
- Pharmacy Benefit Managers (PBM’s)?
- Both?
- Specialty Pharmacy
- Aging Population with Increased Utilization
- Employee and Employer Demands
PBM's view of Pharmaceutical Manufacturers
PBM’s Blame Pharma

- America’s Health Insurance Plans, the insurance industry’s main lobbying group, answered Pharma with a strong push back: “Enough with the distractions. We need drugmakers to be more transparent in their pricing, so people know what they are paying for.”

- “Prescription drug costs continue to skyrocket, with consumers paying the price with their health, as well as their wallets,” Kristine Grow, an AHIP spokeswoman, said by email. “The truth is, no one knows how drug prices are determined, and what makes them go up by double-digit percentages year after year.”

- The Pharmaceutical Care Management Association, which lobbies on behalf of pharmacy benefit managers, said drug company efforts to shift blame are a “losing strategy.”

- “Manufacturers in reality by and large understand that rebates and discounts do go to reduce premiums and cost sharing,” Mark Merritt, PCMA’s CEO, said by phone. “The problem is high-priced drugs.”
Pharmaceutical Manufacturers view of PBMs
PhRMA Blames PBM’s

• April 6, 2017 -- The Pharmaceutical Research and Manufacturers of America (PhRMA) today unveiled "Share the Savings," a new campaign to educate the public about the lack of rebate pass-through for commercially insured patients with high deductibles and coinsurance.

• Robust negotiations between biopharmaceutical companies and health plans result in significant rebates and discounts. According to a recent study from the Berkeley Research Group, more than a third of the list price for brand medicines is rebated back to payers and the supply chain.
Pharma Ad to raise public awareness of the fact that the PBM’s/Insurer’s do not pay list prices for the medications when they get discounts and rebates from the manufacturer and more often than not these lower prices are not shared with the patient.
PhRMA Blames PBM’s

According to Stephen J. Ubl, president and chief executive officer of PhRMA. "It is a problem that more and more Americans are being asked by their insurers to pay cost sharing based on undiscounted list prices, even though insurers may be receiving significant rebates. Providing access to discounted prices at the point-of-sale could dramatically lower patients' out-of-pocket costs."
PhRMA Reorganizes to Help Image?

• On Tuesday May 9, 2017 PhRMA said under its new criteria, which is “effective immediately,” members must invest at least 10% of their budgets on research and development and spend at least $200 million a year on average over three years on R&D. It also eliminated the lower tier of associate members.

• “By putting in place new membership criteria, the board is sending a clear message that being a member of PhRMA means being committed to doing the time-intensive, scientifically sound research it takes to bring bold new advances in treatments and cures to patients,” Joaquin Duato, PhRMA board chairman and worldwide chairman, pharmaceuticals for Johnson & Johnson, said in a statement.

• Of the 22 companies ousted, 15 were in the associates member tier that was dropped, and seven were full members but didn’t meet the organization’s new R&D threshold. PhRMA said that those who we eliminated could reapply when they met the new criteria.

  • The 7 full members ousted include: Mallinckrodt, Horizon, AMAG Pharmaceuticals, Leading Biosciences, Orexigen Therapeutics, The Medicines Co. and Jazz Pharmaceuticals.
PhRMA Associate Members who are no longer members of PhRMA as of May 9, 2017

- ACADIA Pharmaceuticals Inc.
- Aerie Pharmaceuticals, Inc.
- Avanir Pharmaceuticals, Inc.
- BioMarin Pharmaceutical Inc.
- CSL Behring, LLC
- Esperion Therapeutics, Inc.
- Ferring Pharmaceuticals Inc.
- Grifols USA, LLC
- Ipsen Biopharmaceuticals, Inc.
- Marathon Pharmaceuticals, LLC
- Shionogi Inc.
- Sucampo Pharmaceuticals, Inc.
- Theravance Biopharma
- Vifor Pharma
- VIVUS, Inc.
New Performance-Based Guaranteed Pricing?

• In March, when cardiovascular outcomes (FOURIER Trial) results were presented for evolocumab (Repatha) at the 66th Scientific Sessions of the American College of Cardiology (ACC), manufacturer Amgen announced a first-of-its-kind offer: the company would pay a refund for all eligible patients who had a heart attack or stroke while taking the cholesterol-fighting injection.

• This week (5-8-2017), Amgen announced that that health services company Harvard Pilgrim has taken the deal. The company, which covers 2.7 million people centered in New England, has signed an outcomes-based contract that some call groundbreaking and others say don’t address the high price of the drug, which lists for more than $14,000 a year but reduces low-density lipoprotein (LDL) cholesterol by 60%.

• At ACC, the results of the FOURIER trial showed that evolocumab reduced the combined risk of heart attack, stroke, and cardiovascular death 15% to 20%, and 25% beyond the first year. No early death reduction in overall deaths were seen.
  • AJMC.com In Focus Blog 5-7-2017
Making Medicines Affordable: A National Imperative

• An ad hoc committee under the auspices of the National Academies of Sciences, Engineering, and Medicine issued a report with findings and recommendations for policy actions that could address drug price trends, improve patient access to affordable and effective treatments, and encourage innovations that address significant needs in health care.

• So, will the committee’s recommendations spur action? Kaiser Health News (12/12/2017) takes the political temperature, talks to experts and rates their chances on a 1(least likely) to 10 (most likely) scale.

• Recommendation A: Accelerate the market entry and use of safe and effective generics as well as biosimilars, and foster competition to ensure the continued affordability and availability of these products. (4/10)
  – Vigorously deter manufacturers from pay for delay and reduce “evergreening”.

Making Medicines Affordable: A National Imperative

- Recommendation B: Consolidate and apply governmental purchasing power, strengthen formulary design, and improve drug valuation methods. (9/10)
  - Allow federal negotiation of drug prices, including on behalf of state agencies that wish to be represented.
  - Test and further refine methods for determining the “value” of drugs and identify approaches to support value-based payments, formulary design, and price negotiation.
  - Amend the Medicaid Drug Rebate Program to allow for exclusion of certain drugs from coverage under the rebate provisions.
Making Medicines Affordable: A National Imperative

• Recommendation C: Assure greater transparency of financial flows and profit margins in the biopharmaceutical supply chain. (3/10)
  – Require biopharmaceutical companies and insurance plans to disclose net prices received and paid, including all discounts and rebates, at a National Drug Code level on a quarterly basis.
• Recommendation D: Promote the adoption of industry codes of conduct, and discourage direct-to-consumer advertising of prescription drugs as well as direct financial incentives for patients. (1/10)
  – Terminate the tax deductibility of direct-to-consumer advertising expenses.
  – Adopt industry codes of conduct that reduce or eliminate direct-to-consumer advertising of prescription drugs and support efforts to enhance public awareness of disease prevention and management.
  – Prohibit patient coupon programs, in which pharmaceutical companies give payments or discounts to consumers who fill prescriptions for the company’s drug, except in cases where no competing drug is available in the market.

Making Medicines Affordable: A National Imperative

• Recommendation E: Modify insurance benefits designs to mitigate prescription drug cost burdens for patients. (7/10)
  – Establish limits on the total annual out-of-pocket costs paid by enrollees in Medicare Part D plans that cover prescription drugs by removing the cost-sharing requirement for patients who reach the catastrophic coverage limit.
  – Calculate patient deductibles and copayments in all insurance policies as a fraction of net prices, not list prices.
Making Medicines Affordable: A National Imperative

• Recommendation F: Eliminate misapplication of funds and inefficiencies in federal discount programs that are intended to aid vulnerable populations. (9/10)
  – Increase oversight and regulation of the 340B program to assure that participation by covered entities, contract pharmacies, and drug manufacturers is consistent with the intent of the original legislation.

• Recommendation G: Ensure that financial incentives for the prevention and treatment of rare diseases are not extended to widely sold drugs. (6/10)
  – Promote agreements that enable concessions on launch price, annual price changes, or assistance in satisfying important public health goals.
  – Ensure that drugs with orphan designation receive program benefits under the act only for the target rare disease, not for ancillary non-orphan indications.
  – Limit the market exclusivity awarded to orphan drugs to one 7-year extension.

Recommendation H: Increase available information and implement reimbursement incentives to more closely align prescribing practices of clinicians with treatment value. (4/10)

- Establish payment policies for drugs administered by clinicians in medical practices and hospitals that do not differentiate for the site of care (site neutral payment).
- Ensure that clinicians have readily accessible and routinely updated information regarding drug cost and efficacy to support sound prescribing decisions at the point of care.
- Substantially tighten restrictions on pharmaceutical detailing visits, the acceptance and use of free drug samples, special payments, and other inducements paid by biopharmaceutical companies to clinicians, medical practices and hospitals.