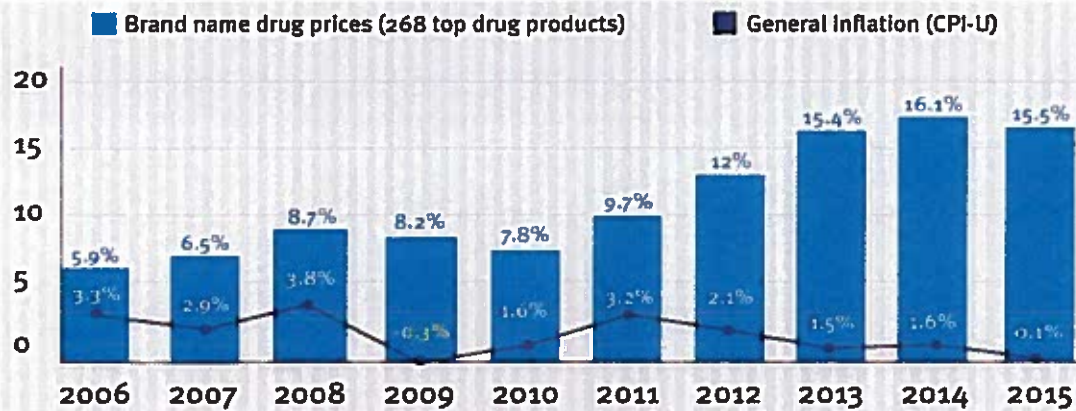


# Prescription Price Transparency Legislation – HB 5223

MARCH 14-2018



## Prescription Drug Pricing Inflation Outpaces CPI by 150% Over Last Decade



<https://www.aarp.org/content/dam/aarp/ppi/2016-12/trends-in-retail-prices-dec-2016.pdf>

## Growth in Prescription Drug Expenditures Far Outpace Other Categories in Health Care

Prescription drugs  
were 5.6% of  
U.S. Health Care  
expenditures in 1990

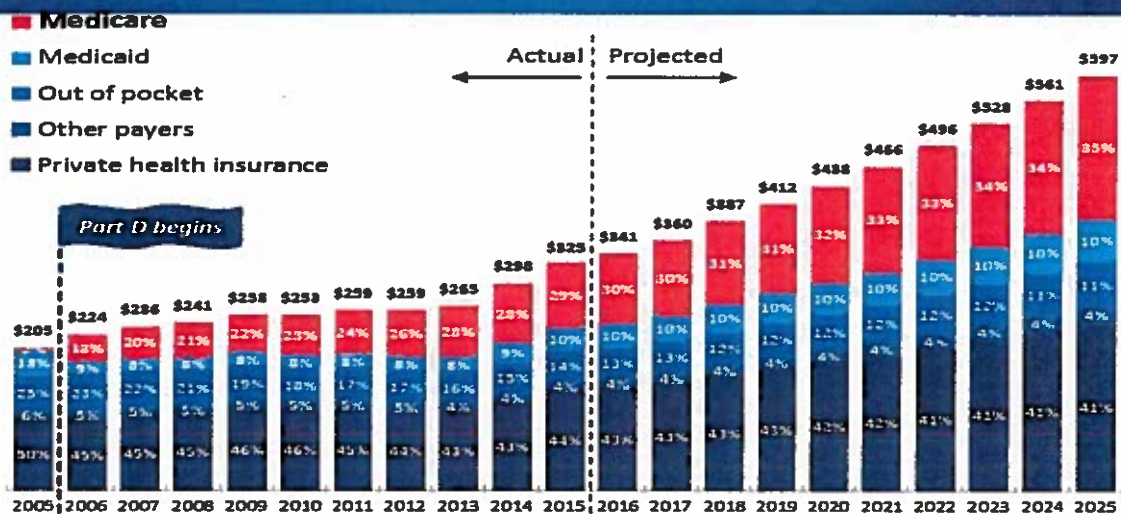


Today, drugs are  
22.1% of U.S.  
Health Care  
expenditures<sup>1</sup>.



<sup>1</sup><https://healthpayerintelligence.com/news/prescription-drugs-account-for-22-of-payer-premium-spending>

## U.S. Prescription Drug Spend (in billions)

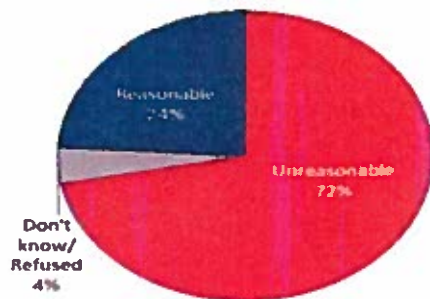


SOURCE: Kaiser Family Foundation analysis of CMS National Health Expenditure Data for Historical (CY2005-2015) and Projected (CY2016-2025) Retail Prescription Drug Expenditures.

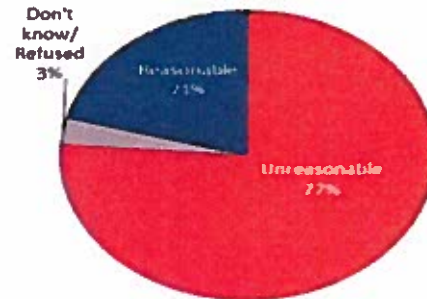
## U.S. Consumers Increasingly Say Cost of Prescription Drugs is Unreasonable

In general, do you think the cost of prescription drugs is reasonable or unreasonable?

August 2015 Tracking Poll



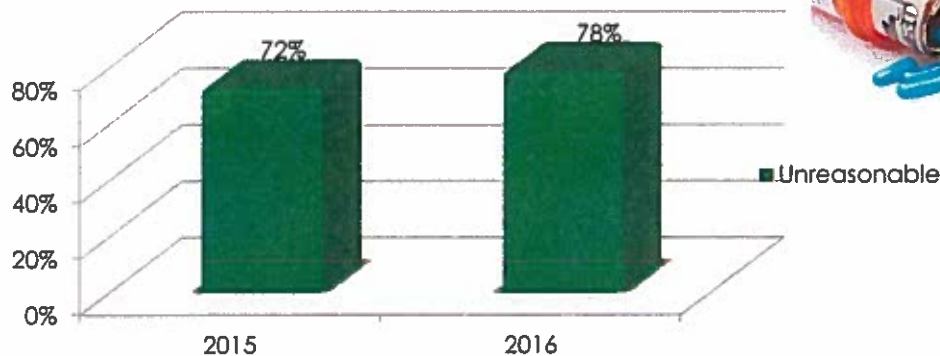
September 2016 Tracking Poll



SOURCE: Kaiser Family Foundation Health Tracking Poll (conducted 2015 & 2016)

## Michigan Viewpoint on Cost of Prescription Drugs ... If Reasonable or Unreasonable?

### Unreasonable



Mitchell Research & Communications – Michigan Statewide Poll, July 2016

## Skyrocketed Drug Prices – Examples

### Allergic Reaction Medication



EpiPen (Mylan)  
rose to **\$600** in 2017  
from **\$57** in 2007

### Cancer treatment drug



Gleevec rose to  
**\$146,000** from  
**\$26,000** in 2001

Insulin product  
Humulin R **jumped**  
to **\$15,869**  
a year in 2015  
from **\$2,487**  
per-year, a  
**\$13,373** increase



Narcotic overdose  
treatment Naloxone  
rose to **\$4,500**  
in 2017 from from  
**\$690** in 2014



## Medicaid Drug Spending – FFS (2016-2017)

Drug Name	2016 Units	2017 Units	2016 Reimbursement	2017 Reimbursement	2016 Cost Per Unit	2017 Cost Per Unit	Change in Cost per Unit (13% Avg)
TYSABRI	225	89	\$ 355,564.34	\$ 203,895.54	\$1,580.29	\$2,290.96	45%
AVONEX PEN	108	76	\$ 153,396.95	\$ 121,710.25	\$1,420.34	\$1,601.45	13%
NORDITROP	222	256.5	\$ 49,666.67	\$ 122,608.58	\$223.72	\$478.01	114%
BYETTA	91.2	100.8	\$ 20,092.93	\$ 24,235.81	\$220.32	\$240.43	9%
TUDORZA PR	44	14	\$ 8,942.43	\$ 3,169.49	\$203.24	\$226.39	11%
GILENYA	660	600	\$ 110,850.05	\$ 128,805.02	\$167.95	\$214.68	28%
RAVICTI	3900	5600	\$ 578,693.43	\$ 922,225.82	\$148.38	\$164.68	11%
TEFLARO	67	247	\$ 8,348.27	\$ 39,194.36	\$124.60	\$158.68	27%
BYDUREON P	372	528	\$ 42,792.77	\$ 72,615.65	\$115.03	\$137.53	20%
GENOTROPIN	203	94	\$ 2,126.64	\$ 8,902.70	\$10.48	\$94.71	804%
MEDROXYPRO	144,048	139,049	\$ 9,553.33	\$ 11,277.53	\$66.32	\$81.10	22%
VICTOZA 3-	1026	1002	\$ 41,158.26	\$ 49,601.58	\$40.12	\$49.50	23%
VANCOMYCIN	23.67	67.65	\$ 1,044.66	\$ 3,278.25	\$44.13	\$48.46	10%
SPIRIVA RE	212	216	\$ 7,151.11	\$ 8,121.84	\$33.73	\$37.60	11%
HUMULIN 70	495	1263	\$ 12,049.99	\$ 36,825.75	\$24.34	\$29.16	20%
TOUJEO SOL	737.5	674.5	\$ 16,408.74	\$ 19,644.09	\$22.25	\$29.12	31%
APIDRA SOL	606	1077	\$ 10,810.00	\$ 29,717.77	\$17.84	\$27.59	55%
HUMALOG MI	3189	1080	\$ 75,622.86	\$ 29,488.36	\$23.71	\$27.30	15%

Source: Data.Medicaid.Gov – 2016, 2017 State Drug Utilization Data

## Medicaid Drug Spending – MCO (2016-2017)

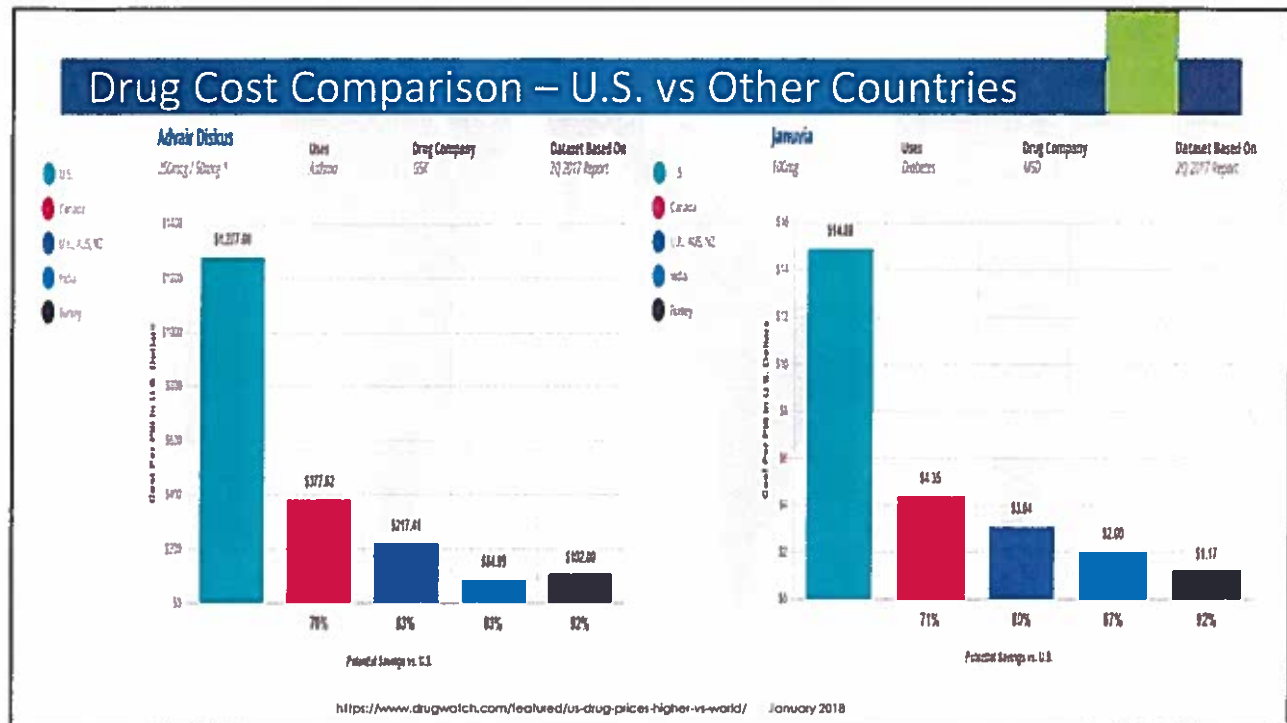
Drug Name			2016		2017		2016 Cost per	2017 Cost	Change in Cost
	2016 Units	2017 Units	Reimbursement	Reimbursement	Unit	per Unit	per Unit	per Unit	
EXTAVIA	435	525	\$ 150,349.49	\$ 204,690.29	\$345.63	\$389.89		13%	
LETAIRIS	2033	960	\$ 561,506.56	\$ 276,879.78	\$276.20	\$288.42		4%	
OPSUMIT	1335	1625	\$ 338,506.47	\$ 448,982.71	\$253.56	\$276.30		9%	
GLUCAGEN	41	39	\$ 8,432.14	\$ 10,085.97	\$205.66	\$258.61		26%	
SUMATRIPTA	97	90	\$ 12,668.71	\$ 12,871.15	\$130.61	\$143.01		10%	
EXIADE	3325	1052	\$ 413,777.52	\$ 147,838.51	\$124.44	\$140.53		13%	
EPOGEN	62.5	65.75	\$ 3,112.31	\$ 3,741.98	\$49.80	\$56.91		14%	
RELPAK	509	487	\$ 24,354.18	\$ 24,322.10	\$47.85	\$52.08		9%	
STRIVERDI	184	128	\$ 7,179.74	\$ 5,831.99	\$39.02	\$45.56		17%	
EPOGEN	217,206	37.7	\$ 7,721.88	\$ 1,499.74	\$35.55	\$39.78		12%	
TRISENOX	400	1120	\$ 12,411.93	\$ 37,968.00	\$31.03	\$33.90		9%	
BACITRACIN	381.5	483.4	\$ 6,711.98	\$ 12,260.79	\$17.59	\$25.36		44%	
NUDEXTA	7146	4560	\$ 83,410.57	\$ 57,214.73	\$11.67	\$12.55		7%	
MYRBETRIQ	3808	4644	\$ 36,436.89	\$ 49,891.44	\$9.57	\$10.74		12%	
FENTANYL	4939	1673	\$ 46,028.02	\$ 16,701.82	\$9.32	\$9.98		7%	
INCRUSE EL	287	166	\$ 2,617.64	\$ 1,658.59	\$9.12	\$9.99		10%	
VANCOMYCIN	425.5	67	\$ 3,688.78	\$ 716.11	\$8.67	\$10.69		23%	
CHANTIX	154847	249330	\$ 891,821.84	\$ 1,622,741.74	\$5.76	\$6.51		13%	
ZENPEP	27330	29290	\$ 137,746.73	\$ 161,309.52	\$5.04	\$5.51		9%	
TRETINOIN	1660	1520	\$ 6,471.10	\$ 7,897.90	\$3.90	\$5.20		33%	

Source: Data.Medicaid.Gov – 2016, 2017 State Drug Utilization Data

## High Cost Drugs Don't Always Correlate to Improved Health Outcome

Drug	Total drug acquisition costs per patient and estimated increase in survival
Cetuximab	<ul style="list-style-type: none"> <li>US\$ 80 352</li> <li>1.2 months (non-small cell lung carcinoma)</li> </ul>
Bevacizumab	<ul style="list-style-type: none"> <li>US\$ 90 816</li> <li>1.5 months (metastatic breast cancer – not statistically significant)</li> </ul>
Erlotinib	<ul style="list-style-type: none"> <li>US\$ 15 752</li> <li>10 days (pancreatic cancer)</li> </ul>
Sorafenib	<ul style="list-style-type: none"> <li>US\$ 34 373</li> <li>2.7 months (renal cell carcinoma)</li> </ul>

WHO 2015 Report <http://apps.who.int/medicinedocs/documents/s21793en/s21793en.pdf>



## Private and Public Support of Pharmaceutical R&D and Clinical Trials

- 210 new drug entities approved by FDA from 2010-2016
  - 10.6% funded by academic institutions
  - 14% funded by non-profit research organizations
  - 29% associated with funding by NIH with expenditures of >\$100 billion
- 70% of most popular non-controlled brand name drugs sold in the U.S. are manufactured outside the U.S.

March 2018 PNAS Report

## Prescription Drug Transparency Legislation

- ▶ Responding to rapidly rising drug costs, **43 states in 2017** drafted more than **130 drug price transparency bills**
- ▶ Legislation enacted in **18 states**: California, Colorado, Louisiana, Maryland, Massachusetts, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, Virginia, and Washington
- ▶ Transparency legislation on prescription drugs is also included under the European Medicines Agency (Policy 0070) which covers 33 countries



[WWW.MAHP.ORG](http://WWW.MAHP.ORG)

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KAREN A. JONAS – MAHP PHARMACY CONSULTANT

# Time for Prescription Price Transparency

## Rising drug costs push employer health care spending up



### Premiums for a Michigan Family



rose from \$5,000 annually to \$18,000 annually over the past 15 years. An increase of 300%

The cost of providing health care is the single most expensive cost to employers in Michigan today according to Michigan Chamber of Commerce. The most significant contributor to these rising costs for employers is prescription drugs.

### Top Cost Drivers of Rising Health Care Costs



#### Specialty pharmacy

High cost claimants

Specific diseases or conditions

Overall medical inflation

Hospitalization (i.e. inpatient care)

Outpatient procedures

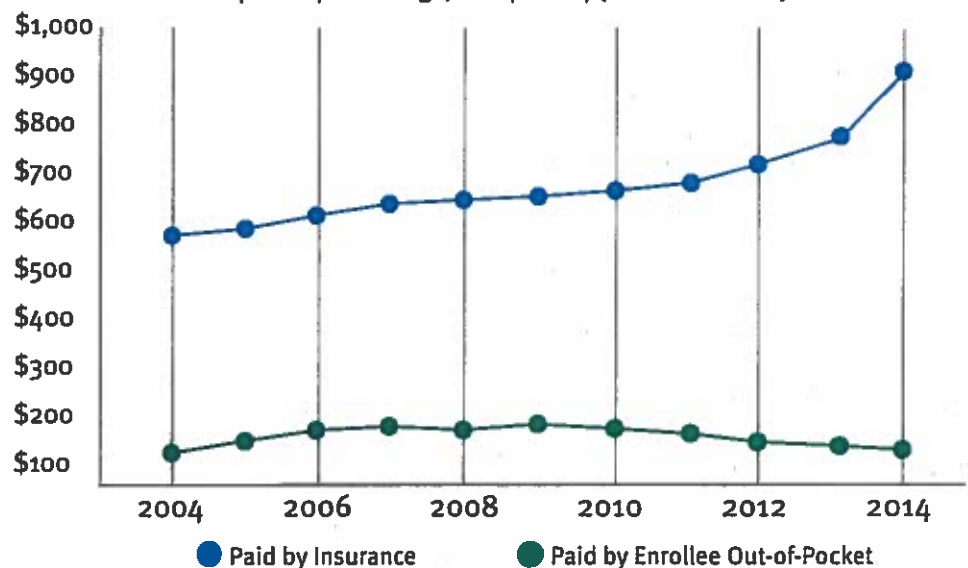
Traditional pharmacy

ACA compliance

### Trends in Out-of-pocket Prescription Drug Spending by Large Employer Groups

While the public worries about rising prescription drug costs, the Kaiser Foundation has found consumer out-of-pocket spending for prescription drugs has decreased for people with large employer coverage. That drives more of the cost burden for coverage of these drugs onto employers.

Average amount spent out-of-pocket and by insurance on retail prescription drugs, 2004 - 2014 (nominal dollars)



Source: Kaiser Family Foundation analysis of Truven Health Analytic MarketScan Commercial Claims and Encounters Database, 2004-2014

Spending on health care in America will take \$1 of every \$5 of gross domestic product in 2025, with prescription drug spending increasing 79.6%<sup>1</sup>.



2016 – Prescription drug spend  
\$342.1 trillion

2025 – Prescription drug spend  
\$614.5 trillion



This represents a percent change of 79.6% compared to the comparative spending change in hospitals of 68.7% and physician and other professional services change 64.1%.



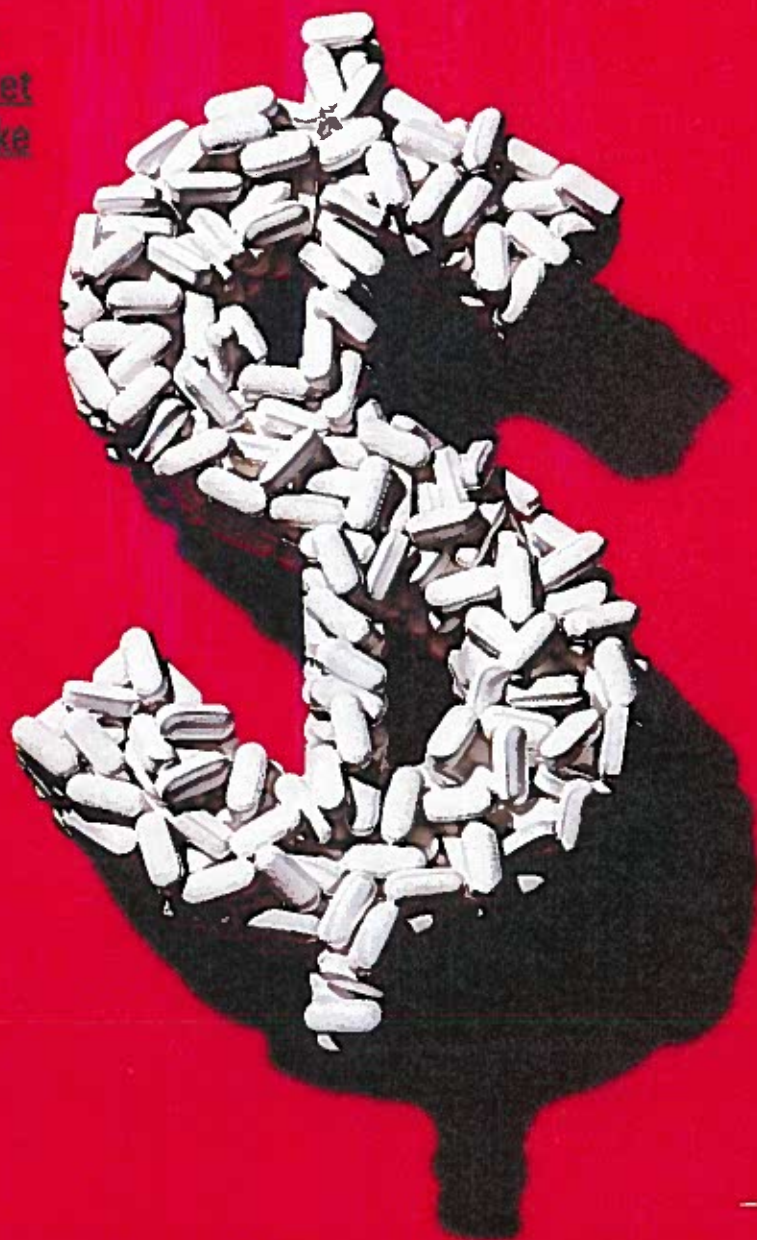
<sup>1</sup><https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2016.0459>

# WHY DRUGS COST SO MUCH

Nothing stops drug companies from charging the highest price the market will bear. The result: prices that make little sense, but lots of profit

**P**rescription drug prices in America are among the highest in the world. On the campaign trail, President Trump said drug companies were “getting away with murder.” Is that true? Or are these firms the beneficiaries of a system that turns a blind eye to excessive profit-making at the expense of society? In this report, we explain in simple, clear terms why drugs cost what they do. We also examine the drug-price debate in Washington, explain how the complicated business of medicine works and give you ways to save money at the pharmacy. AARP stands by your side to help lower drug costs and make sure all Americans over 50 have affordable access to the medicine they need to live their fullest lives.

—Robert Love, editor in chief



# [THE ISSUE]

## An insider's guide to why drug prices keep rising, despite widespread complaints

BY THE EDITORS OF AARP

**F**or Susan Goodreds, Repatha has been as close as you can get to a miracle drug. The 74-year-old resident of Delray Beach, Fla., has a hereditary disorder that causes dangerously high cholesterol levels. Without medicine, her "bad" cholesterol count was in the 300s; statin drugs brought the count to about 220. With Repatha, it has fallen to 35.

The catch is, simply, cost. Repatha, a new medicine that made headlines in March when a large-scale study confirmed some of its beneficial effects, costs \$14,000 annually, or nearly \$1,200 for each month's injection. Even with insurance, Goodreds pays \$4,650 a year for it. Add in other prescription drugs and medical costs, and her yearly health bill is \$13,500—equal to most of her fixed income. "I'm faced with some hard decisions about whether to stay on the drug," Goodreds says. "I still have a lot of things I want to do with my life."

Confusion, anxiety and anger over the high cost of medicine has been on the rise for more than a decade. But even as the chorus of criticism has grown louder, the price of pharmaceutical products in the U.S. continues to skyrocket. Consider:

► The cost of Bavencio, a new cancer drug that was approved in March, is about \$156,000 a year per patient.

► A new muscular dystrophy drug came on the market late last year for an eye-popping price of \$300,000 annually.

► In 2016, the FDA approved Tecentriq, a new bladder cancer treatment that costs \$12,500 a month, or \$150,000 a year.

► Even older drugs that have long been

on the market are not immune: The cost of insulin tripled between 2002 and 2013, despite no notable changes in the formulation or manufacturing process. And the four-decade-old EpiPen, a lifesaving allergy medication, has seen a price hike of 500 percent since 2007. Public outrage this past winter over its price tag (\$609 for a package of two injectors) helped to speed up the arrival of lower-cost generic variations to the market.

The issue of high drug prices came up frequently in the recent election cycle, and in a speech in Kentucky in March, President Trump called drug prices "outrageous." Increasingly, Americans are asking the same question of pharmaceutical companies: Why?

### THE WAYS OF DRUG PRICING

"The simple answer is because there's nothing stopping them," says Leigh Purvis, director of health services research for the AARP Public Policy Institute. Other countries drive a much harder bargain with drug companies. In contrast, the U.S. allows drug companies to pretty much set their own prices.

And as we all know, when demand is high for a product, companies often raise prices. That's exactly the case for many prescription drugs. Tens of millions of Americans suffer from conditions like high cholesterol, high

blood pressure and diabetes, all of which can be treated successfully with prescription medications. More recently, drugmakers have developed game-changing therapies for a host of serious illnesses, including multiple sclerosis, hepatitis C and several cancers. That means people are living longer lives.

**How can drugmakers charge so much? "Because there's nothing stopping them."**

—Leigh Purvis, director of health services research for the AARP Public Policy Institute

### THE DRUG COST DEBATE AT A GLANCE

**\$457 BILLION**

The amount Americans spent on prescription drugs in 2015, up by about 8 percent over the previous year

**208%**

The rise in prices for the most popular brand-name drugs from 2008 to 2016

**\$14.5 MILLION**

Median salary of a pharmaceutical firm CEO in 2015, more than any other industry

**\$6.4 BILLION**

Amount drug companies spend advertising directly to consumers in the U.S. annually

**\$24 BILLION**

Amount drug companies spend per year marketing to doctors

The supply of a newer medicine, however, is controlled entirely by the drug manufacturer that holds the patent rights. That gives the manufacturer a monopoly on the drug for the 20-year life of the patent. During that time, it is free to raise the price as frequently and as much as the market will bear. An example: Last February, the price of Evzio, an auto-injected drug that is used to treat opioid overdose, jumped to over \$4,000—from just \$690 in 2014—just as demand for the medicine was quickly rising.

You may not realize the high cost of medicine if you're relatively healthy and have insurance to cover those occasional needs for, say, a week's course of antibiotics. But if you or someone in your family develops a chronic or serious condition, prepare for sticker shock—even if you have insurance.

When Janet Huston was diagnosed with a rare stomach cancer in 2009, surgery seemed to offer a cure. But a year later the cancer—called gastrointestinal stromal tumor or GIST—returned with a vengeance. The 66-year-old retired lawyer is now taking an arsenal of drugs, including Gleevec, to contain her tumor and control its symptoms. But the medicines that allow her to lead “a somewhat normal life” cost her more than \$17,000 a year, including about \$12,000 for Gleevec.

“That’s about 30 percent of my total income,” says Huston, who lives in Des Moines, Iowa, on Social Security and a modest pension from her years as an attorney. “I don’t always take my medication as I should, especially in the months when income taxes and property taxes come due,” she admits.

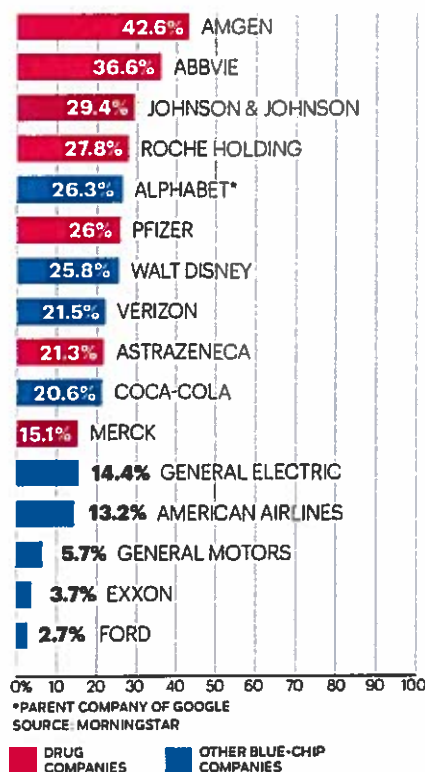
It’s not just people like Huston who suffer financially. “High prescription drug prices affect everyone,” Purvis says. “Even if patients are fortunate enough to have good health care coverage, higher prices translate into higher out-of-pocket costs, premiums and deductibles. And greater spending by taxpayer-funded programs like Medicare and Medicaid are eventually passed along to all Americans in the form of higher taxes, cuts to public programs or both.”

Put even more simply: One reason that your health insurance rates are high is because you are subsidizing other people’s high-cost medicines. For example, imag-

## THE PROFITS

### How pharmaceutical earnings compare

Operating profit margins of some prominent drug manufacturers, compared with other successful and well-known American companies, for 2016. The average for S&P 500 companies that year was 10.4 percent.



ine the euphoria if a company developed a breakthrough treatment for Alzheimer’s disease. Let’s say it costs \$60,000 a year per patient, and it gets prescribed to every American with the disease. To pay for the medicine, insurance premiums for each privately insured person in the U.S. would increase by more than \$140 per month, based on a new calculator developed by the Biotechnology Innovation Organization.

## A CONTORTED MARKETPLACE

If you needed a new TV, you would do some research, shop around and pick the

best model at the price you can afford. That creates competition that pushes prices down. The market for prescription drugs doesn’t work that way. For example, you don’t make the product choice—your health care provider does. And doctors and nurse practitioners often do so in the dark: There’s little information available to compare one drug to another. The Food and Drug Administration (FDA) does not require drug companies to prove that their new products are better than existing products. So many physicians write prescriptions for the drugs they’re most familiar with—and that information often comes from manufacturers themselves. Drug companies spend \$24 billion a year marketing to health care professionals.

Other factors that cause the drug market to be skewed include:

► **PATENT LAW** Pharmaceutical companies have become adept at coming up with strategies to extend their monopoly on a drug beyond the expiration of its original patent. For example, they can seek approval for a “new” product that is a slight variation on the original, such as extended release formulations, or by creating therapies that combine two existing drugs into one pill. “The longer that a drug company is able to maintain its monopoly, the longer it can continue to charge whatever it wants for its product,” Purvis says.

► **LIMITS ON MEDICARE** One of the largest purchasers of prescription drugs, Medicare is blocked by law from negotiating prices. When Congress was debating the law that created Medicare Part D (which took effect in 2006), lobbyists from the pharmaceutical industry convinced legislators that giving Medicare negotiating power would amount to price control.

Compare Medicare with the Veterans Health Administration (VHA), the part of the Department of Veterans Affairs that handles medical care. The VHA does have the ability to negotiate drug prices. As a result, it pays 80 percent less for brand name drugs than Medicare Part D pays, according to a 2015 report by Carleton University in Ottawa, Ontario, and Public Citizen, a public advocacy group. The VHA gets its negotiating power from its formulary, a list of prescription drugs that it will cover. Medicare and Medicaid, by contrast, are required to cover almost all drugs ap-

proved by the FDA, regardless of whether a cheaper, equally effective drug is available.

► **MULTIPLE MIDDLEMEN** When you pick up a drug at the pharmacy, you often don't know what its real price is—that is established between the manufacturer and your insurer. You just pay the agreed-upon copay rate. Today, insurance companies rarely negotiate prices directly with drug manufacturers. Instead, most insurers work with pharmacy benefit managers, who negotiate rebates and discounts on the company's behalf—often in exchange for preferential placement on their list of covered medicines. Pharmacy benefit managers add yet another participant to what is already a complex system.

## THE R&D EXPLANATION

The pharmaceutical industry offers several responses to the charges of excessively high prices. First, it notes that prescription drugs account for just 10 percent of the nation's health care costs; by comparison, 32 percent of costs go to hospital care, according to a 2016 report from Medicare.

It also notes that an open market means that “patients in the U.S. can access the most innovative treatments far earlier than any other country,” says Robert Zirkelbach, executive vice president at the Pharmaceutical Research and Manufacturers of America (PhRMA), the industry trade group. For example, data from PhRMA show that patients in Europe wait an average of nearly two years longer to get access to cancer medicines than American patients.

But the industry's primary defense of rising medicine prices are the high costs associated with drug development.

Drug companies spend over 10 years and up to \$2.6 billion bringing a drug to market, according to a 2016 *Journal of Health Economics* article based on research by the Tufts Center for the Study of Drug Development (which gets a minority of its operating funds from the pharmaceutical industry). Of that amount, \$1.4 billion is actual costs—items like salaries, labs, clinical-trial expenses and manufacturing. The remaining \$1.2 billion is “capital costs”: what the company sacrifices by investing time and money in an unproven drug. Some experts dispute these numbers, saying they overstate the true costs.

Even after accounting for their research investments, however, drug companies are among the most profitable public businesses in America. And an analysis from the research company Global Data revealed that 9 out of 10 big pharmaceutical companies spend more on marketing than on research. Most of them also have big budgets for lobbyists to ensure the laws continue to work in their favor. The Center for Responsive Politics puts the number of pharmaceutical industry lobbyists at 804 in 2016.

Further, some drug companies are moving away from doing all of their research in-house and instead are buying smaller companies with promising products. About 70 percent of industry sales come from drugs that originated in small companies, up from 30 percent in 1990, according to a Boston Consulting Group survey.

In addition, drug companies increasingly focus on products that can generate the highest profits. The majority of drugs approved by the FDA are now expensive specialty drugs. Many drug companies are also pursuing “orphan drugs”—medicines targeting diseases that afflict fewer than 200,000 people. These medications cost an average of \$140,000 a year. The catch: Many orphan drugs eventually receive additional approvals as a treatment for other conditions, dramatically increasing the market for the drug.

The government supports orphan drug development with tax breaks and other incentives. In 2016, the pharmaceutical industry netted \$1.76 billion in orphan drug tax credits.

Meanwhile, just five of the top 50 drug companies are spending money on much-needed new antibiotics—largely because these drugs aren't lucrative, the

## THE DRUG CRISIS BY THE NUMBERS

**18,130**

The number of approved prescription drugs available in the U.S.

**49%**

Americans using at least one drug in the past 30 days

**19%**

Those on prescription drugs who say they have skipped taking a drug or cut it in half to reduce the cost

**\$19.8 MILLION**

Amount drug company PACs and employees gave politicians in 2016

*AARP Bulletin* reported in November 2016. “In most cases, people only need to take an antibiotic for a couple of weeks to get rid of an infection. Compare that to medications for chronic conditions—which people go on taking every day for years—and you can understand why drugmakers aren't particularly interested,” says Erik Gordon, a professor at the University of Michigan Ross School of Business.

There is nothing illegal with any of this: As publicly owned corporations, pharmaceutical firms focus on their bottom line. “Pharmaceutical executives say they have to be more aggressive to satisfy Wall Street,” says John Rother, executive director of the Campaign for Sustainable Rx Pricing.

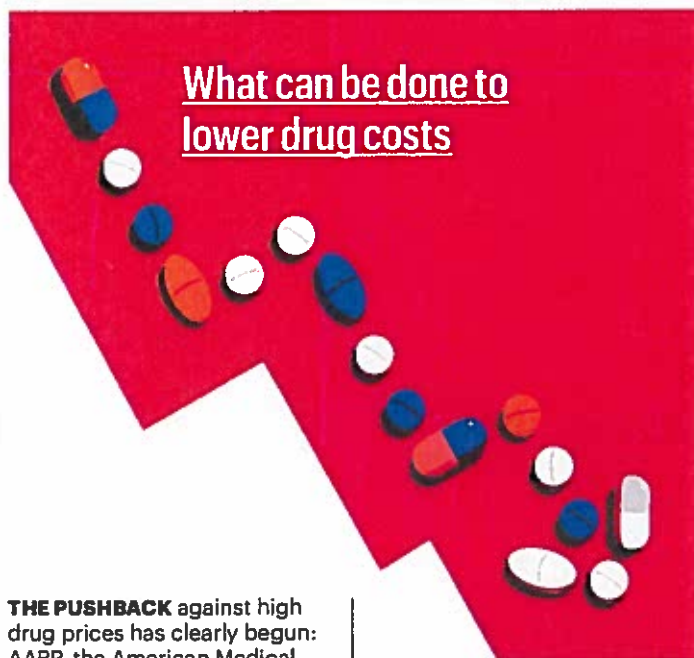
But there's evidence that drug companies will respond if pressured to lower prices. One example is patient-assistance programs. Kristin Agar, a 65-year-old clinical social worker in Little Rock, Ark., was diagnosed with lupus in 2009. Her doctor prescribed Benlysta, the only medication specifically approved for lupus. Her insurer would pay 80 percent, about \$2,500 per

infusion, but Agar had to pay the remaining \$450 per dose.

“I couldn't afford that,” says the self-employed professional. But when she applied for assistance, she was told she made too much money. “That just infuriated me,” she says. Agar appealed the decision—and got her copay covered by the drugmaker for two years.

But a consensus is building that more must occur. “People are concerned about drug prices; more are being forced to make trade-offs between paying for their drugs and for food or rent,” says AARP's Purvis. “The trends that we're seeing are simply unsustainable.”

# [THE REMEDIES]



## What can be done to lower drug costs

**THE PUSHBACK** against high drug prices has clearly begun: AARP, the American Medical Association, the American Hospital Association, the American College of Physicians and groups such as Patients for Affordable Drugs have called for making prescription drugs more affordable. Policymakers have started to push for laws that could bring prices down. It won't be easy, but experts say these moves could help improve the situation.

**1. Let Medicare negotiate drug prices.** Using the clout of the program's 57 million beneficiaries to bargain with pharmaceutical companies could certainly lower prescription drug prices. (The term for this is "secretarial negotiating authority.") Such a move could produce as much as \$16 billion in annual

savings, according to a 2015 report by Carleton University in Ottawa, Ontario, and Public Citizen, a public advocacy group.

**2. Allow more drugs to be imported.** The prices of brand name prescription drugs are typically much higher in the United States than in other developed countries, but right now there are strict limits on when and how consumers can buy drugs from other countries. Setting up a system that would ensure the safe and legal importation of less expensive prescription drugs could help put pressure on drug prices and allow consumers to save on medications.

**3. Create transparency in drug pricing.** There is no way now to verify the claim by drug companies that high prices are linked to the costs associated with research and development. In fact, the public has very little information about how drug companies actually set the initial price of a drug or decide on subsequent price increases. Improved understanding of how drug companies price their products could help the public

determine whether high costs are justified.

**4. Provide for easier drug comparisons.** The public has no means of knowing whether a newly approved medicine is better than ones already on the market. Increasing the availability of research that compares the safety and effectiveness of drugs treating the same conditions will help create price competition and reduce spending on unnecessary or ineffective treatments.

**5. Implement "value-based pricing."** Shift the United States to a system in which drug pricing is based on how well drugs work ("value") rather than what the market will bear. For example, a drug that cures a disease would be priced higher than a drug that doesn't improve on existing treatments. However, there is no universal definition of value, and developing one will not be easy. Consequently, the possibility that value-based pricing will have a meaningful impact on prescription drug prices and spending is likely years—if not decades—in the future.

# [THE PROCESS]

## Why it often takes 10 years to launch a new prescription drug

**DETERMINING** an accurate timeline or cost for developing a new medicine is difficult. The 128-month estimate at right is based on a 2016 study by the Tufts Center for the Study of Drug Development in Boston. It is considered the most comprehensive report on the subject to date, though some disagree with aspects of the study.



**INITIAL RESEARCH**  
**31 months**  
Scientists first study the disease to find vulnerabilities on which to focus. From there, they seek a chemical that attacks that weakness.



**FIRST TRIAL**  
**20 months**  
Once researchers have a medicine they believe will work, it is tested on 20 to 80 healthy volunteers to verify its safety. This is called a phase 1 clinical trial.



**SECOND TRIAL**  
**30 months**  
Roughly 60 percent of phase 1 trials proceed to a phase 2 trial, which usually involves 100 to 300 people with the disease taking the drug at different dosages.

(CONTINUED)

# [THE NEW LAWS]

## What lawmakers are doing to rein in drug prices

BY LINDA MARSA

**A**t a nighttime rally in Louisville, Ky., in late March, President Trump revisited a favorite campaign topic: the high cost of drugs. “Medicine prices will be coming way down,” he promised. “Way, way, way down.”

The new Congress appeared to match the president’s fervor for taking on high drug prices, introducing several bills aimed at cutting the cost of prescription pharmaceuticals.

But no clear path to reduced costs has yet emerged. Here’s what policymakers are doing today to address high drug costs.

### WHITE HOUSE

The president has had meetings with drug company executives, at which he said “price fixing” would stifle innovation. Administration officials say he thinks costs can best be cut by speeding up the FDA approval process for drugs and devices.

### CONGRESS

On Capitol Hill, several legislative efforts seem to be gaining traction.

► Democrats have gotten behind legislation that would allow Medicare to negotiate prices directly with drug companies, a change that could translate to up to \$16 billion in savings.

► Other Democrats have introduced legislation to allow for the safe importation of less-expensive medications from other countries, such as Canada. A number of Republican senators have also embraced the idea of allowing medicines to be imported.

► The bipartisan FAIR Drug Pricing Act would establish price transparency standards for drug companies when they raise prices.

► Three other bipartisan bills would remove some of the barriers to cheaper generic drugs.

But these proposed laws face headwinds. The pharmaceutical industry and some Republican lawmakers have opposed drug importation. They say imports would cut

away at profit margins that enable companies to seek cures for grave illnesses, and could jeopardize patient safety. And the industry, along with allies in Congress, oppose measures that would speed up the process of getting generic drugs on shelves. Without today’s 20-year patents, they say there would be no financial incentive to produce needed but costly drugs.

### STATES

State governments are deeply involved in the drug-price battle. Many are moving forward with their own cost-containment remedies.

► In November, California voters turned down a proposal requiring state agencies to negotiate with drugmakers for discounts as steep as those given to the U.S. Department of Veterans Affairs. The pharmaceutical industry spent more than \$100 million to fight it.

► Last June, Vermont was the first state to pass cost-transparency legislation that penalizes drug companies for price gouging. Similar initiatives are moving forward in Ohio, Oregon, Maryland and New York.

► Utah is also studying the feasibility of importing drugs from Canada.

► In more than a dozen states, including New York, Connecticut, Illinois, Kansas and Massachusetts, bills are pending that would require pharmaceutical companies to disclose their true expenses and justify price hikes.



#### THIRD TRIAL 31 months

In a phase 3 trial, 1,000 to 3,000 volunteers with the disease are tested and watched closely both for efficacy and side effects.



#### SUBMISSION AND GOVERNMENT APPROVALS 16 months

If trials succeed, a New Drug Application is filed with the Food and Drug Administration. The FDA needs up to a year to make an approval decision.



#### DRUG LAUNCH Year 1-3

The drug is put on sale, often with a large marketing campaign. The FDA may require a phase 4 trial to examine additional risks. The company must report on any adverse reactions seen by doctors.



#### ONGOING SALES Year 4 and beyond

Drug companies manage a medicine like any product: adjusting the price, creating new promotions, seeking new customers and researching new usages for it. As the patent expiration date gets closer, companies create plans for keeping sales strong after competitors introduce generic versions.

## WHAT YOU CAN DO

### Ways to reduce your own medication costs

BY LINDA MARSA

- 1. Go generic.** Bypassing a brand-name prescription drug can save up to 80 percent.
- 2. Know your coverage.** Each insurance company has its own formulary—a tiered list of medications that its drug plan covers. Generally, the higher the tier, the higher the copay. So check the tier level when you get a prescription and ask your doctor if there's a drug in a lower tier that would work as well. Also, consider that an insurance plan with higher premiums may still save you money if copays or deductibles are lower.
- 3. Order by mail.** Many health plans offer this option. Ordering a 90-day supply can save up to a third on copays for brand-name drugs.
- 4. Use a preferred pharmacy.** Some 36 percent of employers have a preferred pharmacy that has agreed to provide discounts to enrollees.
- 5. Use discount cards.** There are many drug discount cards that can offer some savings on your prescription drugs. But they can't be used in combination with health insurance, including Medicare.
- 6. Seek assistance.** Pharmaceutical companies often offer assistance programs to qualified individuals. Many organizations help connect patients to such programs, including NeedyMeds.org, the Partnership for Prescription Assistance (pparx.org) and the Patient Advocate Foundation's National Financial Resource Directory (PatientAdvocate.org). Find a list of programs that work with Medicare Part D at medicare.gov.
- 7. Split pills when safe.** Instead of getting a 10 milligram version of a pill, buy the 20 mg one and divvy it up. Get a pill splitter; don't try to cut it with a kitchen knife. Never do this without talking to your doctor or pharmacist: Certain medicines cannot be split safely.



## Your AARP Where We Stand

BY JO ANN JENKINS, CEO

## Let's Cut Drug Costs

### Prices doubled in 10 years. That's too much



**T**he high cost of prescription drugs is at the top of the list of concerns Americans have about their health care. It's easy to understand why. The average cost for a year's supply of medication for someone with a chronic illness has more than doubled since 2006 to over \$11,000. That's about three-fourths of the average Social Security retirement benefit.

Too many people struggle to pay for drugs and end up waiting to fill a prescription, taking less medication to make it last longer or deciding to not fill the prescription at all. Unless costs come down, people will not be able to afford the drugs they need, leading to poorer health and higher health care costs.

Both Republicans and Democrats have called for measures to lower drug costs. These proposals include allowing Medicare to negotiate prices and making it legal to buy prescription drugs in Canada and Europe. In his first address to a joint session of Congress, President Trump declared that we need to "work to bring down the artificially high price of drugs and bring them down immediately." Let's hold the president to his promise.

The concern Americans have over drug prices is part of the larger issue of health care. That was demonstrated in the recent

debate over the proposed American Health Care Act (AHCA). As the potential impact of the bill emerged, Americans urged their lawmakers to oppose it.

The bill was flawed from the beginning. It would have added an age tax on older Americans, increased their insurance rates dramatically and reduced health insurance subsidies. It would have left 24 million people who now have health insurance without coverage. It also would have provided tax breaks worth \$200 billion to insurance and drug companies.

The decision to shelve the AHCA was a victory for the American people—won, in large part, by tens of thousands of engaged AARP members like you who wrote letters, sent emails and called their members of Congress.

The demise of the AHCA, however, doesn't mean Americans don't want change or that they are satisfied with their health care. That is clearly demonstrated by the outrage over drug prices that are just too high in many cases. We have a long history of advocating for lower prescription drug prices, and we will work with the administration and Congress to continue that fight.

If you are concerned about the high cost of drugs, let your member of Congress know by calling 844-453-9952.

### [FOR HELP WITH HIGH DRUG PRICES]

- Medicare enrollees with limited income may be eligible for help with Medicare Part D. Go to [ssa.gov/prescriptionhelp](http://ssa.gov/prescriptionhelp) or call 800-772-1213.
- To talk with trained counselors who can help navigate Medicare and Medicaid, call the Eldercare Locator at 800-677-1116.
- If you can't afford your medications and need financial help, go online to [needymeds.org](http://needymeds.org) and click the Patient Savings tab.
- Read the latest report on drug prices from AARP Public Policy Institute's Rx Watchdog at [aarp.org/rxpricewatch](http://aarp.org/rxpricewatch).

# R&D Cost Estimates: MSF Response to Tufts CSDD Study on Cost to Develop a New Drug

 [commondreams.org/newswire/2014/11/18/rd-cost-estimates-msf-response-tufts-csdd-study-cost-develop-new-drug](http://commondreams.org/newswire/2014/11/18/rd-cost-estimates-msf-response-tufts-csdd-study-cost-develop-new-drug)

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NEW YORK - "The pharmaceutical industry-supported Tufts Center for the Study of Drug Development claims it costs US\$2.56 billion to develop a new drug today; but if you believe that, you probably also believe the earth is flat.

"GlaxoSmithKline's CEO Andrew Witty himself says the figure of a billion dollars to develop a drug is a myth; this is used by the industry to justify exorbitant prices. We need to ask ourselves, if the CEO of a top pharmaceutical company says it's a myth that it costs a billion dollars to develop a drug, can we really take this new figure 2.56 billion seriously?

"We know from past studies and the experience of non-profit drug developers that a new drug can be developed for just a fraction of the cost the Tufts report suggests. The cost of developing products is variable, but experience shows that new drugs can be developed for as little as \$50 million, or up to \$186 million if you take failure into account, which the pharmaceutical industry certainly does—these figures are nowhere near what the industry claims is the cost.

"Today nearly half of R&D spending is paid for by the taxpayer or by philanthropy, and that figure continues to rise as governments do more and more to make up for the pharmaceutical industry's R&D shortcomings. Not only do taxpayers pay for a very large percentage of industry R&D, they are in fact paying twice because they then get hit with high prices for the drugs themselves.

"Regardless of how much R&D costs, the system is failing people in developing countries, as the latest example of Ebola shows, with over 5,000 deaths so far because there is no treatment or vaccine on the market; meanwhile millions of people continue to die from diseases such as tuberculosis. The R&D system as we know it is broken and must be fixed."