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Testimony of Elizabeth (Betsy) M. Imholz
before the
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Good morning. I'm Betsy Imholz, Special Projects Director for Consumers Union, the policy and advocacy arm of nonprofit Consumer Reports. Consumer Reports has more than 8 million paid subscribers nationwide, and we also have a long history of engaging in advocacy and policy analysis. Health care, including medications, has been a core issue for the organization since our founding in 1936. I am based in our California Office, and work on drug pricing issues nationally and in the states.

I'm here today to address the consumer perspective on rising prescription drug prices, a top concern for consumers. Our nation still pays the most for health care overall of all high-income countries, but with worse outcomes. And drug prices are the fastest rising part of our health spending.

It's important to note that drug spending occurs not just at the retail pharmacy, but also in the medical setting (doctors' offices and health facilities). Our data is less complete about spending in facilities and doctors' offices, but for Medicare as of 2013 the total for the retail and medical settings was **19% of total health spending** (twice the 10% usually cited as drug costs as a % of overall health spending).

Public awareness, anxiety and anger are rising about prescription drug pricing. According to a Kaiser Family Foundation survey from Sept. 2016[1], while a majority (though diminishing percentage) of people believe prescription drugs developed over the past 2 decades generally have made people's lives better, **77% (an increased percentage) say that the cost of drugs is unreasonable**. There is a building public outrage about drug prices.

[1] http://kff.org/health-costs/report/kaiser-health-tracking-poll-september-2016/

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That drug pricing is top of mind for consumers in America is not surprising– roughly half of Americans take one or more prescription drugs on a regular basis, and on average take 4 to 5 medications. In a Consumer Reports nationally representative survey this March—described in our August 2016 issue (see the reprints I have provided)--- nearly 1/3 of respondents told us that within the past 12 months they have been hit with an unexpected drug cost for a medication they take regularly. We found price increases on everything from longtime generics used to treat common conditions such as high blood pressure, to new treatments for diseases such as hepatitis C.

Our survey shows that when people are hit with higher drug costs, they were more likely to take unhealthy steps such as skipping doctor appointments, tests and procedures, not filling their prescriptions, or not taking them as directed. And where people were dealing with higher drug costs, other financial setbacks were not far behind. One in four of those facing higher costs was unable to pay their medical bills, had to cut grocery spending, or even lost their health coverage. In fact, one in ten of those facing increases said they had postponed retirement in order to maintain coverage.

Even those with insurance are feeling the squeeze. High-deductible plans and other rising out-of-pocket costs imposed by insurers are making it hard for consumers to afford needed medications. On the one hand, insurance companies point to very high-priced drugs for which there are few or no alternatives, which they say they must build into premiums and out- of- pocket costs. At the same time, pharmaceutical companies blame insurers for passing along high costs to consumers. The point is, consumers are caught in the middle of this battle with rising premiums, deductibles and out-of-pocket costs.

So, let's look at the trend in drug spending. Prescription drug spending rates were declining from 2000 to 2013, in part due to patent expirations and decreases in generic prices. But this downward trend is reversing; spending on prescriptions has spiked upwards, starting in 2014. Prescription drugs had represented a shrinking share of total health spending in recent years, but now drug spending is projected to increase faster than overall health spending for the next few years.

Why did we see the big spike in 2014? The main drivers of increased pharmaceutical spending in 2014 were **growth in brand-name drug prices**, the emergence of **new brand medications**, and to a lesser extent, price growth for generic drugs.

Specialty drugs are a primary driver of recent drug spending. Specialty drugs are used for the treatment of complex, chronic, or rare conditions such as cancers, multiple sclerosis, rheumatoid arthritis, and hepatitis C. From 2013-14, the Express Scripts 2014 Drug Trend Report, indicates the traditional drug trend (utilization and cost) increased from 2.4 percent in 2013 to 6.4 percent in 2014, the **trend for specialty drugs jumped from 14.1 percent to 30.9 percent** in that time.

There is no standard definition, though the federal government defines them as costing more than $600. The monthly treatment cost can exceed tens of thousands of dollars, creating access concerns for consumers. Approximately half of specialty drug spending is billed through the medical benefit--not the pharmacy benefit-- and hence this spending is not reflected in common sources that report prescription drug spending. Specialty drug spending is projected to account for 50 percent of drug spending by 2018.

Specialty drugs are one thing, but even for common drugs, prescription drug prices in the US outstrip other, wealthy, industrialized countries by a mile. For example, the average price for a very common drug—Nexium for heartburn/acid reflux– is nearly **10 times the price in the Netherlands**, more than 3 times the price in Switzerland. Why is this? I want to focus our attention on this fundamental question: how are drug prices are determined?

The real answer for policymakers and the public is we do not know. We don't have publicly available data on research and development (R&D) costs—without that there's no way to validate what the companies are asserting about the costs of development. We do know that overall about **38% of all basic science research is paid for with tax money** through federal and state governments, but we need the data by drug to show specifically how much money, if any, the company spent on R&D from its own coffers, and how much came from NIH grants, academic centers, or *other drug companies that the current one has bought*.

We also need to compare R&D expenditures to marketing costs for particular drugs. Drug companies may spend twice as much or more on marketing and advertising their drugs than on developing them. A 2014 BBC report sourced from Global Data found that 9 out of 10 major pharmaceutical companies spent more on marketing than on R&D. Consumer Reports' review of the 2015 annual reports of 10 of the world's largest drug companies revealed that all spent more on marketing and administration costs than on R&D.

Our complex drug *pricing chain*—even more complex than the distribution chain--is replete with intermediaries, with the price at each step involving hidden mark-ups, discounts, rebates and contract terms that make actual costs unknowable. See attachment "Rx Pricing Along the Supply Chain". It is no wonder that members of the Congressional House Oversight and Governmental Operations Committee holding a hearing this Fall on the EpiPen pricing crisis expressed extreme frustration and dismay at the incomprehensibility of prescription drug pricing in this country.

The CEO of GlaxoSmithKline, summed it up on NPR's Marketplace radio show last Spring:

> **The problem in the U.S., bluntly speaking, is there's no transparency around what the real price of everything is.** We…need to know what the real price is so we can figure out what the real cost-benefit is to the system.[2]

Let's look at a few drugs for particular conditions. Diabetes prevalence is growing –1 in 11 people in US have diagnosed or undiagnosed diabetes; expected to be 1 in 3 by 2050. I understand it's the 4th leading cause of death in New Mexico. The Express Scripts 2014 Drug Trend Report found that in 2014, diabetes medications were the most expensive of the top ten traditional therapy classes. In fact, **spending on insulin and other diabetes medications is expected to rise more than 18% over next 3 years**.

Insulin is the essential drug to treat diabetes, and has been around for nearly 100 years. Yet, between 2010 and 2015, the three major manufacturers (Eli Lilly, Sanofi, and Novo Nordisk) -- the ones that hold the patents on insulin products -- **more than doubled their prices**. During this time, by making incremental tweaks to their products, they have been able to extend the patents on the most expensive forms of insulin, blocking competition from cheaper generic options and keeping prices high. And the companies' increases for these essential medicines have been in lock-step—a practice known as "shadow pricing." [3] There is no generic form of insulin in the US. In 2014, these companies made more than $12 billion in profits, with insulin accounting for a large portion.

[2] Andrew Witty, CEO GlaxoSmith Kline, NPR Marketplace, May 10, 2016.
[3] http://www.businessinsider.com/insulin-prices-increase-2016-9

In much of Europe, insulin costs about a sixth of what it does here. That's because the governments there negotiate with the manufacturer directly and have been very effective at driving down prices. In the United States, we rely on the private sector and a free market for drug pricing.

Another example is Valeant, a company that made the headlines with its extreme, overnight price hike of Nitropress, a staple of emergency medical care for decades. It was off-patent and had no generic competition; once it was bought by Valeant the **price tripled**—without any improvement to the drug. The big change: the drugs' ownership.

Similarly, over the past few months a furor has been brewing about the EpiPen, a life-saving medication for those with allergies, to prevent anaphylactic shock. The drug in the EpiPen device, epinephrine, dates back to the early 1900s and costs pennies to make. Since a new company, Mylan, bought EpiPen in 2007 the list price has risen by nearly 550%-- from $94 in January 2007 to more than $609 in May 2016—without significant research and development investment. In the Medicare Part D program, total spending for the EpiPen grew an astronomical **1151% since 2007**, while the total number of Part D EpiPen users grew by just 164%.[4] There is no generic form of the EpiPen available currently.

Valeant's and Mylan's drug price hikes are extreme, to be sure. They exemplify profit-taking based not on recouping research and development costs—of which these companies had little to none—but simply upon these companies raising the price on essential drugs after they were purchased from other companies which had invested in and done the research and development—what's known as an "acquisition strategy." So, R&D had little to nothing to do with the steep price hikes for these drugs.

As physicians Peter Bach and Steven Pearson have said: "Prescription drugs is the only major category of health care services for which the producer is able to exercise relatively unrestrained pricing power."[5] So, in summary, what do we see as the drug price increase drivers?

[4] Cubanski, Juliette, Sept. 20, 2016, Kaiser Family Foundation, "How Much has Medicare Spent on the EpiPen Since 2007?", http://kff.org/medicare/issue-brief/how-much-has-medicare-spent-on-the-epipen-since-2007/
[5] Bach, Peter B, MD, Pearson, Steven D., MD, MSc, *JAMA* Viewpoint, December 15, 2015

First, there is often **little competition**. Government-granted monopolies in the form of patents and FDA-granted exclusivity periods range from 7-12 years. And "evergreening"-- re-formulating older drugs with slight tweaks— re-starts the patent protections. While intellectual property protections are important for encouraging innovation, the extent of those protections is out of balance with the need to reduce cost pressures on consumers and foster competition. Some of the drug breakthroughs have been extraordinary; but a great majority of "new" drugs are not new at all, but merely variations of older drugs, so offer little or no therapeutic gain.

Secondly, we see **pricing simply pegged at what the market will bear, maximizing profits,** with little or no relationship to R&D or manufacturing costs. As I noted previously, the largest drug manufacturers spend more on marketing than on R&D.

When drug companies can raise the price of a drug overnight 300%-500% --even 5,000% in the case of Turing Pharmaceuticals' AIDS drug Daraprim-- and when the prices of old drugs rise to shadow the prices of comparable new drugs, that is not a healthy, functioning market. Given the significant impact of pharmaceuticals on our health care system and on consumers' medical wellbeing and financial security, it is a time for action.

What is the solution to containing drug prices while preserving access to needed, life-saving medications? Broadly speaking, there are two approaches, which could work together:

- One is to **make the currently dysfunctional marketplace work by creating true competition**. We need to encourage firms to produce more of what people need —products that improve health —and thereby further stimulate innovation. This requires transparency around costs and curbing monopoly power.

- The other, or additional approach, is **greater government intervention in pricing** through direct government negotiation with drug manufacturers, formulary creation, government exercising what is known as "march-in rights" for essential medicines, or price setting, as in other countries.

That is the conversation we are starting to have on the national level, as well as in many states. Many of these approaches to reach underlying costs require federal action, but states also have some opportunities.[6] Here are four:

- Pressing your Congressional delegation to act on the federal level;
- Requiring transparency by drug manufacturers about how prices are set—a policy solution supported by 86% of the public[7];
- Creating an independent entity to review prescription drug effectiveness and oversee pricing—or joining with other states or purchasers that have one—and empowering it to challenge price gouging;
- Consumer protections, like capping out-of-pocket monthly expenses and requiring fair formulary designs that do not discriminate against particular conditions and keep medications affordable.

In our wealthy nation, consumers should not have to choose between paying the rent, putting food on the table, and getting medications they need to cure or control health conditions. The time is now for action to curb the unrestrained pricing for medications in our nation—action that is essential to ensure consumer health and financial security, as well as sustainability of our state and federal budgets.

[6] In August 2016, Consumer Representatives to the National Association of Insurance Commissioners, of which I am one, issued a report, *Promoting Access to Affordable Prescription Drugs: Policy Analysis and Consumer Recommendations for State Policymakers, Consumer Advocates, and Health Care Stakeholders*, containing recommendations on steps for state officials and others to promote affordability, nondiscrimination, transparency, and meaningful oversight of prescription drug coverage. Underlying costs are not, however, the focus of the report.

[7] http://kff.org/health-costs/report/kaiser-health-tracking-poll-september-2016/

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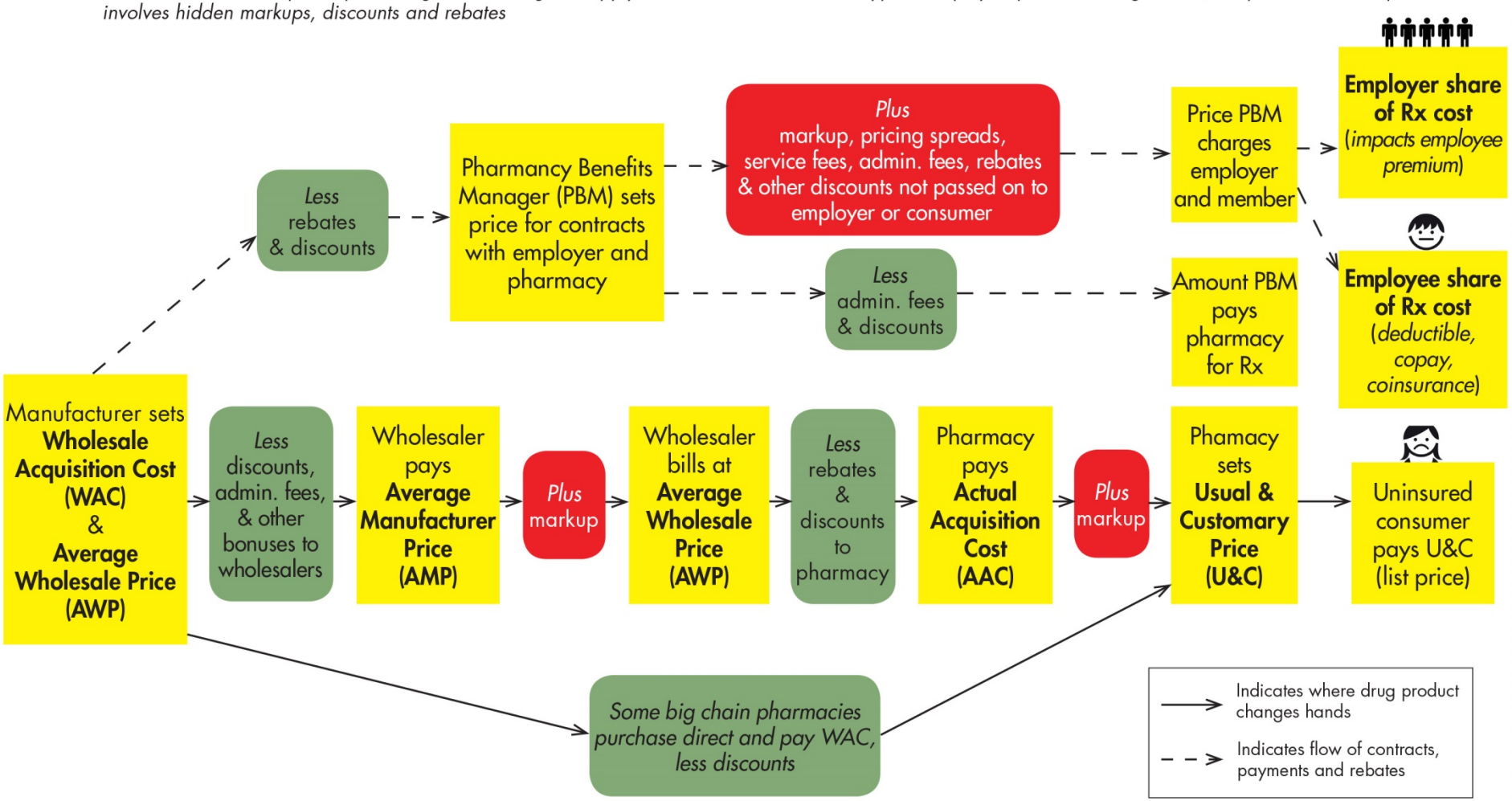
Rx Pricing Along the Supply Chain

This chart shows how prescription drugs move along the supply chain to consumers. For a typical employer-sponsored drug benefit, the price at each step involves hidden markups, discounts and rebates



Note: This graphic is intended as a simplified overview of the drug pricing supply chain, showing how important pricing concepts fit together. As such, it does not reflect myriad other connections between parts of the system. Source: Adapted from The Prescription Drug Supply Chain Black Box: How it Works and Why You Should Care, *Eickelberg, H.C., American Health Policy Institute (2015).*