

Horvath Health Policy

Innovations in Healthcare Financing Policy

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Testimony of Jane Horvath

Before the Oregon Senate Committee on Healthcare

Prescription Drug Market Dynamics and the Need for Public Policy

March 22, 2021

Thank you, Madam Chair and Members of the Committee for the opportunity to testify on prescription drug cost containment policy. This is such an important and complex issue that touches almost everyone. We all need to understand more about the pharmaceutical marketplace to think about what the potential state-level policy approaches could be.

There is a need for strong public policy to address the increasingly critical situation we face today. Oregon Senate bill 844 is a strong public policy approach with practical effects that will benefit individual consumers. A prescription drug affordability board with authority to establish statewide upper payment limits is one of the very few ways to accomplish three critical aspects to lowering drug costs for consumers:

- Create cost transparency and cost certainty.
- Move the lower costs through the supply chain to the consumer at the point of service.
- Reduce the need for rebates for drugs with a UPL.

By way of background, I have worked with states on prescription drug costs for many years. I represented the Medicaid Directors when the Medicaid rebate program was created. I have worked as a consultant to many state policymakers since 2016 on prescription drug policy, with the support of non-profit foundations. I also spent over ten years working in the pharmaceutical industry. I have deep respect for the work of the pharmaceutical industry, but the business model is broken, and I do not see a path forward other than public policy to address the problems.

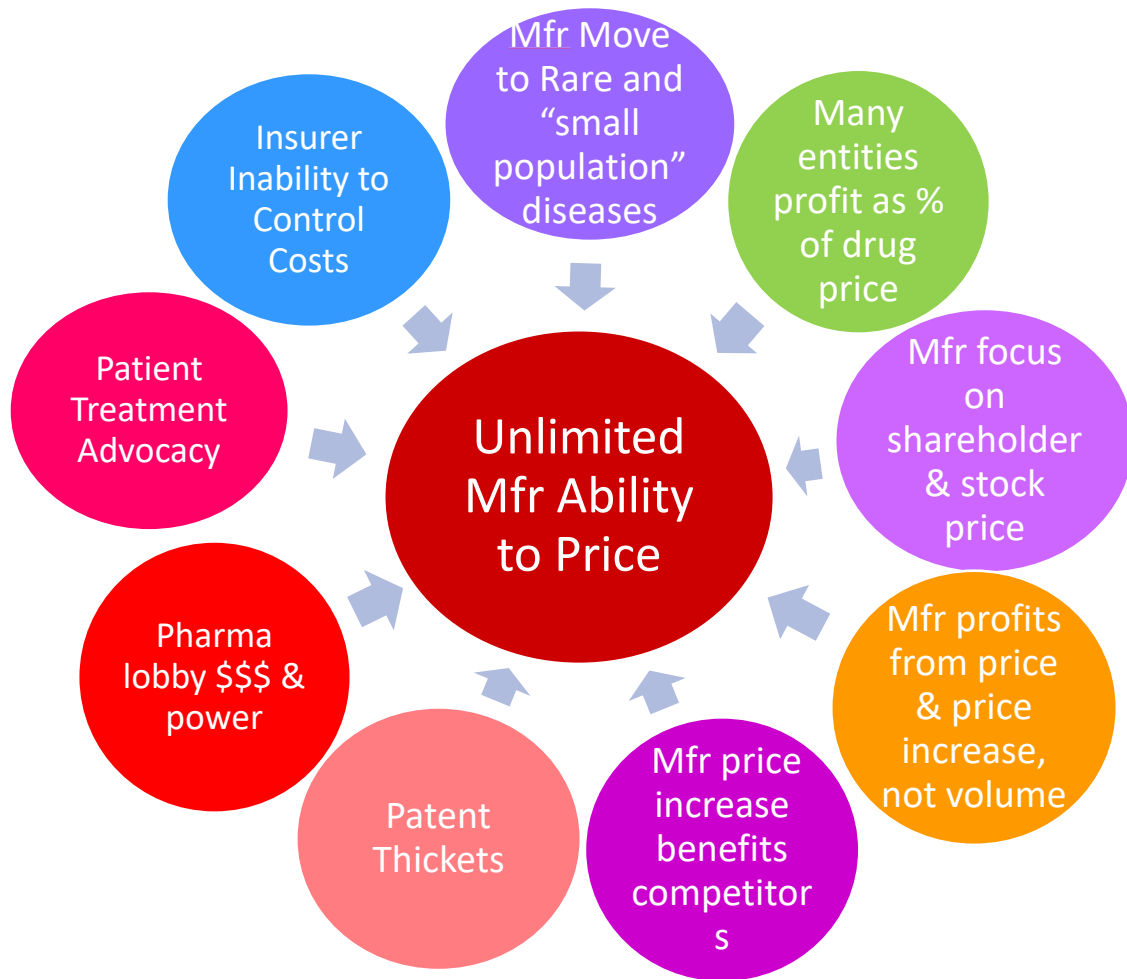
We all know many facts and figures concerning drug costs. I want to start with three facts today that can help properly size the issue of high drug costs.

- 1) The pharmaceutical industry cites that prescription drugs are ten percent of total national health care spending. Importantly, the [federal analysis](#) that generates the ten percent data point includes *many* types of spending that we don't tend to think of as 'healthcare spending'. Included in the total are salaries and benefits for the employees who run Medicare and each state Medicaid program, research funds of the National Institutes of Health, healthcare facilities maintenance, nursing home care and so on. The denominator is huge. Finally, the ten percent includes only retail drugs, not most of the newer biologics that are provided in physician settings rather than retail settings. So, the numerator is unrepresentatively small, and the denominator is exceptionally large. The industry data point is not meaningful.

- 2) Prescription drug costs account for about 25 percent of our healthcare premiumsⁱ which exceeds the proportion spent on provider services.
- 3) State taxes support some or all the pharmacy benefits for as many as 25-30 percent of residents in many states.ⁱⁱ State governments and state residents have a large stake in constraining drug spending.

As the amazing biopharmaceutical science and technology rapidly evolves to produce meaningful products, society's inability to manage the costs of these products without significant trade-offs inside and outside of healthcare has grown even faster than the technology.

How We Got Here in Pharmaceutical Pricing



This graphic summarizes the component factors that create the situation we have today in biopharmaceutical pricing. This constellation of factors has always existed, but to a lesser degree of effectiveness than today and with less synergy between the factors than today. This is all legal activity. This is not malicious activity. This is business activity that supports stock price for shareholders and

executive leadership. Stock price is a key performance metric for the industry and drives decision making. The importance of stock price is an externality, and it is not something that any single company can address, which is why I think public policy is important in this market.

I would like to briefly describe each of the components of the drug price/drug cost dilemma. Finally, I would like to make the case for government policy to modify industry behavior in ways that support continued treatment breakthroughs while assuring that people who need a drug can afford that drug. I think an optimal policy is a Prescription Drug Affordability Board (S. 844), which is the subject of this hearing.

Manufacturers Have Moved to Small Population Diseases

This move has been documented in the trade and business press over the past decade or so.

“[SANOFI CEO] HUDSON SAID HE EXPECTS SALES OF SANOFI’S VACCINES BUSINESS TO GROW AT MID-TO-HIGH SINGLE DIGITS. IT [THE COMPANY] WILL FOCUS ON ONCOLOGY, HEMATOLOGY, RARE DISEASE, NEUROLOGY, AND THE CHINESE MARKET, WHERE SANOFI HAS BEEN STRONG. IT WILL GIVE TOP PRIORITY TO SIX EXPERIMENTAL DRUGS, INCLUDING TWO FOR HEMOPHILIA AND SINGLE ENTRANTS IN RARE DISEASE, CANCER, INFECTION, AND MULTIPLE SCLEROSIS. THAT TRANSITION WILL COME AT A COST. SANOFI WAS BUILT ON PLAVIX, ONE OF THE BEST-SELLING HEART DRUGS EVER. IT CURRENTLY SELLS LANTUS, A LONG-ACTING INSULIN THAT WAS THE BEST-SELLING INSULIN IN THE WORLD. BUT SANOFI WILL EXIT RESEARCH IN DIABETES AND CARDIOVASCULAR DISEASE, FINISHING STUDIES ON A MAJOR DIABETES MEDICINE IT IS DEVELOPING WITHOUT PLANS TO BRING IT TO MARKET.” STAT NEWS 12/9/2019

The industry understands that it is more difficult for insurers to manage utilization and costs of new treatments that serve small groups of people with high unmet needs. The move to address unmet medical needs is especially important, but there have been pricing abuses associated with this trend... extraordinarily costly oncology products that provide small benefits over existing therapies and new million-dollar treatments for rare diseases. We tend to view extremely costly products that treat a small group of people as justifiable, but that is not okay when we look at how many people have these types of diseases:

- Rare diseases – 25M people/330M total population (rare disease affects <200000 people)
- Cancer – 1.7M people
- COPD – 16M people
- Lupus – 1.5M people
- MS -- 1M people
- Epilepsy – 3M people
- Sickle Cell – 1M people

These numbers add up to about 15% of population which means that the current industry pricing model will generate phenomenal costs for society. Amazing drugs will not work if we cannot afford them.

Who Benefits from High Drug Prices?

- Manufacturers – establish the list price/wholesale price
- Wholesalers – attach small markup to large product sales volumes

- Research Centers/Universities – conduct bench science to develop promising molecules (often with federal funding) that they patent, and then lease or sell rights to manufacturers who commercialize the molecule. Royalties can be based revenue, which is based on price.
- Pharmacy Benefit Managers – obtain rebates (some of which is shared with insurer clients). Rebate revenue increases as prices increase. (PBMs do not finance pharmacy reimbursement, they pay pharmacies, but the insurer reimburses the PBMs for that pharmacy payment.)
- 340B Entities (safety net providers and others) – buy low prices drugs through the federal 340B program and ‘sell high’ in charging insurers market rates for dispensed drugs. This is mostly a 340B hospital phenomena.
- Pharmacies – chain pharmacies that can purchase large volumes acting as their own distributors.
- Physician Specialists –depending on the specialty and the insurer reimbursement formula.

Who Does Not Benefit from High Drug Prices?

- Patients – Cost sharing for insured patients is based on the market price. Uninsured also pay market prices.
- Insurers -- High patient out of pocket costs are a symptom of the problem, not the problem. Rebates offset the high cost of drugs, but higher prices with higher rebates does not make the net expense more affordable.
- Government Health Programs – state employee benefits, corrections, even Medicaid which benefits from rebates but still reimburses pharmacies and other providers at market rates.

Industry Focus on Stock Price

The industry is laser focused on maintaining and increasing their stock price. This has lots of ramifications for society and patients. Industry CEO and C-suite leadership compensation is tied to stock price and stock grants are a significant part of executive compensation. Wall Street seems to reward high prices more than low prices and price increases more than strong sales.

Industry Business Model Built on Price and Price Increases, Not Sales Volume

A 2018 BCBS Intelligence Report found that among enrollees, utilization of brand drugs *declined* annually by 6% while net spending on brand products *increased* annually at 10% due to average brand

“THE BIGGEST PHARMACEUTICAL COMPANIES COUNT ON MULTIBILLION-DOLLAR DRUGS TO FUND THEIR EXPENSIVE RESEARCH UNITS AND JUSTIFY HIGH SHARE PRICES. BUT NOW INVESTORS WANT MORE, DEMANDING THAT COMPANIES QUEUE UP THE NEXT CROP OF TOP PRODUCTS BEFORE THE CURRENT GENERATION EVEN HITS PEAK PROFITABILITY.”
(BLOOMBERG NEWS 1/11/2019)

ANALYSTS RECENTLY WARNED INVESTORS THAT MODERNA MAY NOT MAKE AS MUCH MONEY ON COVID VACCINES AS ANALYSTS PREDICTED 4 MONTHS AGO. (FIERCE PHARMA 9/8/2020)

drug price increases of 17%. More recently, the medical journal, *Neurology*, found that Medicare spending for neurological conditions grew 50% between 2013 and 2017 but the number of prescriptions grew only 8%. There is a growing body of literature about this phenomenon, including most recently a

congressional report that found that Teva and Celgene repeatedly raised prices to hit revenue targets and meet Wall Street expectations – representative of an industry that relies on high prices and price hikes to produce revenues. The old business model was to *sell* more drugs, which meant that prices had to be reasonable to hit sales targets. It used to be that increasing sales produced the revenue. Today, prices and price increases produce the revenues even at the expense of reduced sales.

Wall Street rewards high prices and price increases. Unfortunately, the PBM business model, hospital business models, and chain pharmacy business models reinforce the incentive for high prices. The recent US Senate Finance Committee [investigation](#) into insulin pricing highlights the variety of misaligned incentives that benefit the participants in the pharmaceutical market but undeniably harm patients.

Other recent [congressional studies and hearings](#) found high prices and price increases can thwart development of biosimilars and that company revenues are not substantially dedicated to R&D. The reports present evidence that in the biologics space, high prices mean that clinical studies to develop lower cost biosimilars become uneconomical because the cost of the reference product used in clinical trials is too costly to generate a significantly lower cost biosimilar. This point was made by then-FDA Commissioner Gottlieb at a July 2018 meeting at the Brookings Institution. High prices punish patients and distort the entire market.

Manufacturer Price Increases Benefit Competitors

Does competition equal lower prices? MS drugs defied cost logic as challengers swarmed in

*Once only a small group of competitors, the field for multiple sclerosis (MS) therapies has exploded in recent years: By 2016, the number of approved drugs had nearly tripled in just seven years. That’s speedy growth, but something else grew faster—those drugs’ list prices. The average price of self-administered disease-modifying therapies for MS quadrupled between 2006 and 2016 as a rush of competitors flooded the market, according to a new study published in JAMA Neurology. by [Kyle Blankenship Fierce Pharma](#)
Aug 29, 2019 5:56pm*

Manufacturers shadow price each other as a recent [congressional study found](#). This shadow pricing practice has been obvious for years. The first company in a therapeutic class to announce its price increase is followed by therapeutic competitors announcing similar price increases. It is not price competition.

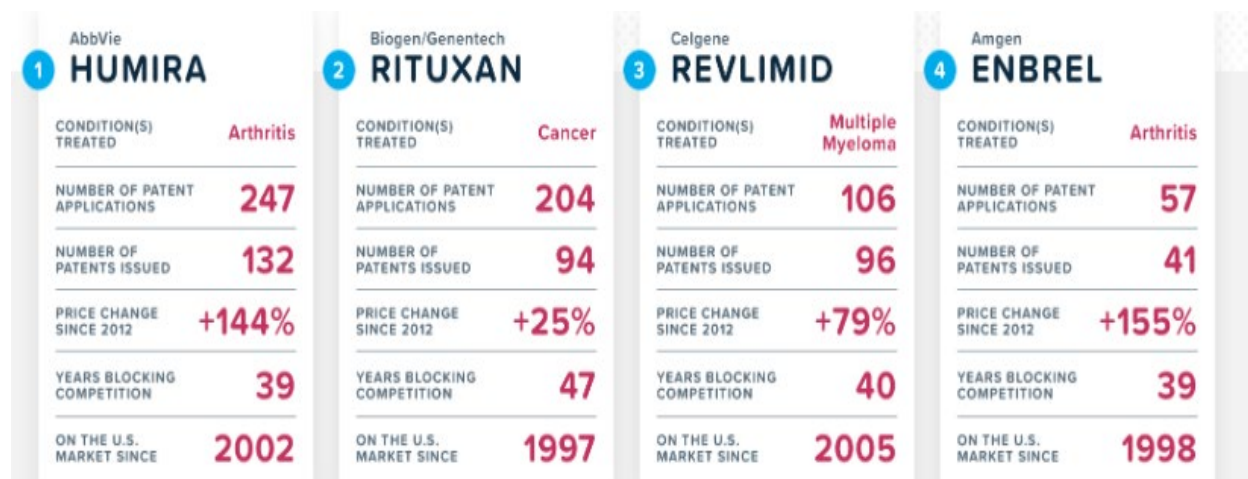
Also, price increases of an in-market product provide benefits to the competitor company with a similar product in development as this simple graphic shows.

Patented Innovator Drug	\$\$\$ Launch Price	\$\$\$\$ Price Increase	\$\$\$\$\$ Price Increase	\$\$\$\$\$\$ Price Increase	\$\$\$\$\$\$\$ Price Increase	\$\$\$\$\$\$\$\$ Price Increase	\$\$\$\$\$\$\$\$\$ Price Increase
Patented Therapeutic Competitor		\$\$\$\$ Launch Price	\$\$\$\$\$ Price Increase	\$\$\$\$\$\$ Price Increase	\$\$\$\$\$\$\$ Price Increase	\$\$\$\$\$\$\$\$ Price Increase	\$\$\$\$\$\$\$\$\$ Price Increase
Generic #1					\$\$\$\$\$ Launch Price	\$\$\$\$\$\$ Price Increase	\$\$ Price <u>Decrease</u>
Generics #2 & 3							\$\$ Launch Price

Patent Abuse/Patent Thickets Delay Product and Price Competition

Extending monopoly position of a product is known as ‘evergreening’. This occurs when a company returns to the US Patent Office again and again for new patents on an existing product. This widely used practice effectively bars market entry of competitors. Humira is a prime example of this practice. Humira is widely used for a host of autoimmune disorders and had annual revenues of \$19.73 billion in 2019 and an annual cost of \$72,000 per patient in 2020. It has 39 years of patent protection. A product generally has 7 to 10 years of patent protection when it comes to market.

The chart below shows some of the more notorious patent extensions. These are considered abuses because the practice is legal; most people agree that the patent system is not intended to provide decades of product monopoly and unfettered price taking. We are also at a point where we grant additional/extended patent protection for product changes that are not significant.



Source: I-Mak August 2018

Industry Lobby Power, Federal and State

The amount the industry spends to lobby federal and state legislators is legendary.

[OpenSecrets](#) tracks federal lobbying money for many industries. They show that industry spent \$161M in lobbying 2020. A recent analysis conducted by STATNews and National Institute for Money in Politics found that the industry gave over \$5 million to almost 2000 state legislators in two years ending September 2020 (STAT 10/15/2020).

The industry also gives to federal and state candidates and political party committees. The industry is reported to outspend all other industries in most years.

Patient Treatment Advocacy

The pharmaceutical industry funds disease advocacy organizations that have historically supported pharma pricing because of the idea that it supports research and development for unmet medical needs in rare diseases. Interestingly, several patient groups raise funds to sponsor research into new treatments for their diseases; Cystic Fibrosis, Hemophilia, and Multiple Sclerosis disease groups are

examples of these incredible patient initiatives, but they have tended in the past to not be concerned with the phenomenal prices of the treatments that are brought to market by manufacturers using the basic research created by the patient groups. Some of the patient groups generate revenues from royalties that are returned to their R&D spending for more treatments. Some of the patient groups, like the MS Society, are increasingly concerned and vocal about extreme product pricing.

The [Kaiser Family Foundation](#) has a database of industry giving and patient group reporting for 2015. They tracked \$163 million in funding to 650 patient groups. Some groups report the funding on their websites, others do not. Nevada has a law that requires patient advocacy groups to report industry funding. Most states do not require such transparency.

Insurer Inability to Keep Pace with Industry Business Model Shifts

Insurers face a growing challenge in managing prescription drug costs, particularly small insurers such as state employee benefit plans and small group insurers. The pressure to cover new treatments for rare diseases or diseases with significant unmet treatment needs is great. Insurers know that high patient cost sharing is not optimal for health outcomes but the tools by which to manage the cost of prescription drugs (retail and physician administered) are increasingly insufficient to the task. Insurers must balance keeping premiums affordable for everyone and providing access to new costly treatments for individuals. As mentioned at the beginning, pharmacy costs consume a significant portion of the premium dollar. The pharmaceutical industry will point out that hospital spending accounts for more healthcare spending than pharmaceuticals. That is true, but most Americans take prescriptions that they increasingly cannot afford, while most Americans do not wind up in the hospital in any year. The pharmaceutical pricing business model is a fast-growing threat to patient access. Our healthcare system has many problems, but that does not mean that the cost of pharmaceuticals is not important.

Layers of Market Dysfunction

As pharmaceutical companies focused on Wall Street and raised prices to satisfy Wall Street, all sorts of [market dysfunctions](#) were created. It is difficult to catalogue and follow all the dysfunction. But the important point is that the dysfunction started with price maximization strategies of the pharmaceutical industry, which gave rise the rebate strategy which created new opportunities for other entities to profit from high and higher prices, which then resulted in PBM monitoring companies and the drug discount card industry. The system is mess and getting worse. While large PBM, insurer, and drug companies can find ways to preserve their businesses, consumers and patients take more and more of the brunt of the dysfunction.

Conclusion

“Affordability” is the piece that is missing from the biopharmaceutical market and from the discussion pharmaceutical costs. Affordability is what consumers and insurers think about. A focus on affordability can stem the need for tradeoffs between spending on healthcare and spending on other important public and private needs.

In contrast to “affordability”, the pharmaceutical industry speaks about the value of their products. The reality is that any product is of high value to the patient for whom the product improves or extends life. But an invaluable product is not necessarily an affordable product for the individual or society. I like to

make a rough analogy to the value of clean water, the value of telecommunications, electricity, or public transportation to our health and welfare. State governments have worked since the earliest days of these industries to assure that these valuable, vital, indeed lifesaving services are affordable to consumers.

I believe the solutions to the issues we face in the pharmaceutical market require new public policy. The industry cannot fix itself at this point. The first mover in a new business model that creates affordability is likely to be punished by Wall Street. The industry cannot act collectively without violating important federal laws.

In my opinion, the focus of policymaking should be regulating consumer costs – and doing so in a way that gets a lower cost product through the supply chain to the point of service where that cost is the basis of pharmacy acquisition costs, the basis of what a patient pays out of pocket, and the basis for the amount an insurer reimburses. SB 844, the Prescription Drug Affordability Board legislation is an approach that accomplishes all three things and goes a long way to eliminating the market dysfunction we have today for certain products.

The data show that there is room in the industry profits and current spending priorities for lower costs while still preserving incentives for research and development and revenues to support that R&D. Indeed, lower cost products should result in higher utilization – more sales.

ⁱ America's Health Insurance Plans, March 2017, and Harvard Pilgrim spending analysis in Health Affairs Blog August 24, 2018,

ⁱⁱ The calculation would include State and local government employees and retirees, public school system employees and retirees, prison system employees, dependents, retirees; inmates; higher education employees, dependents, and retirees; student clinics; Medicaid enrollees – all as a percentage of the total state population.