Testimony of Jane Horvath
Before the Oregon House Behavioral Health and Health Care Committee
May 24, 2023

Thank you, Chairman Nosse, and Members of the Committee, for the opportunity to discuss aspects of the US pharmaceutical market including misaligned market incentives. Oregon is a recognized leader due the efforts of the Chairman and the Committee on hard Rx issues. I'm honored to be here to today.

For me, the key point is that the only part of the pharmaceutical marketplace lacking a business model and a revenue strategy is the consumer. In the constant market tussle among powerful manufacturers, insurers/pharmacy benefit managers and large pharmacy chains, the consumer is collateral damage.

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 was staff on the US Senate Finance Committee where I and others developed the Vaccine for Children law. As Deputy Assistant Secretary for Legislation in the US Health and Human Services Department, I was part of a group working on the first iterations of a possible Medicare drug benefit. I also spent over a decade working in the pharmaceutical industry. While at the National Academy for State Health Policy, I developed the model drug importation and drug affordability board legislation. I have worked on a non-partisan basis with many state policymakers in recent years on prescription drug cost containment policy. Much of my work is funded by foundations, including Arnold Ventures.

You may know that I am currently a contracted consultant to the Oregon Prescription Drug Affordability Board. I am here today representing myself and do not/cannot speak for the PDAB.

I have deep respect for the work of the pharmaceutical industry, but the business model is broken. Public policy is needed to promote change and address the numerous problems that have developed in response to rising drug prices.

Amazing biopharmaceutical science and technology rapidly evolve to produce meaningful products, but society's inability to manage the extremely high costs of innovation has grown commensurately. Increasingly, pharmaceutical market pricing requires significant societal and individual trade-offs to finance access to important medicines. Those trade-offs occur inside and outside of healthcare and become harder and harder to accept.

Pharmaceutical costs and pricing are complex issues that touch almost all of us. We all need to understand more about this marketplace to identify the multiple problems and then the policies most able to help individual consumers and the healthcare system afford appropriate access to medicines.

I want to start with some data points which explain concern about high US drug costs.

1) The average launch price of new chronic illness medicines jumped from $2115 in 2017 to $180000 in 2021[i]
2) The average launch price of new cancer medicines rose 53% since 2017 to $283000 in 2022.[ii]
3) The median launch price for all new medicines (chronic illness, rare disease, cancer) was $257,000 in 2022.[iii]
4) Net (after rebates) prescription drug costs consume 23 percent of our healthcare premiums.[iv]

5) State taxes support some or all the pharmacy benefits for as many as 25-35 percent of residents in many states.[v]

I want to briefly discuss the array of dysfunction in our market today in order to level-set on the scope of the problems as we consider policy approaches to mitigate the problems of the current market.

Drug Makers:

Move from large population diseases to small population disease treatments

- Small population illness treatments ensure greater ability to price and decreased insurer ability to manage costs.
- Rare and small population diseases affect up to 15% of the population.
- Rare and small population disease markets grow over time – people live longer and take medications throughout their longer lives. There have been wonderful treatment advances in Cystic Fibrosis for example. The treatments treat or cure the physical or mental illness; they do not change genes of one's reproductive cells. The number of people born with the condition will not change but the number of people with the condition will grow as people live longer because of the treatment. While not exactly on point, Humira, the #1 selling drug in the world until recently, launched as a rare disease drug. Keytruda, expected to be the #1 selling drug soon, launched as a rare disease drug.

Industry revenue comes from pricing rather than sales volume

- Congress and others have documented that launch price and price increases are used to meet Wall Street expectations –even at the expense of sales and patient access.

Costs to bring drugs to market have declined but prices still skyrocket[vi]

- Costs of R&D are lower ($2.7B/drug in 2015, $2B/drug today)
- R&D success rate is higher (10/100 Rx made it to market in 2015, 12/100 Rx make it to market today)

Patent thickets

- Companies return repeatedly to the patent office with new, minor modifications to a drug in order to extend their patent protections and fend of generic or biosimilar competition.
- A 'normal' patent life is 7 to 10 years after a drug comes to market. A patent is 20 years but many of those years are used up in the pre-approval research years. Humira garnered 23 years of patent protection <u>after</u> it came to market. Humira is not unusual.

Paying patient cost-sharing

- Companies with expensive drugs may provide tens of thousands of dollars per year per patient to 'buy down' patient cost sharing to $0, $5 or $10 per prescription fill. This is not allowed in Medicare. I view it as a tacit admission that the drug is not affordable. High patient copays are a symptom of the problem, not the problem itself. But high patient copays are a very significant problem.

Pharmacy Benefit Managers:

Do not disclose their business practices to their clients (employers, Medicaid, commercial insurers)

- Ten state Attorneys General investigated Centene Medicaid business practices and there are ten high-cost settlements.

Rebates are the coin of the realm

- As an industry, PBMs now exclude ~600 drugs from their formularies generally because of insufficient rebates.

- PBMs often refuse to cover lower cost therapeutics (including biosimilars and generics) in a drug class when there are higher priced, higher rebated, innovator products available.
    - Because of this PBM practice, some drug manufacturers have launched products at TWO market prices – a higher price for PBMs/insurers that will not accept lower priced versions of products (with less rebate) and a lower price version either for people without insurance or for insurers/PBMs that will accept the lower cost without large rebates. It is the same product with different NDCs.
    - Because of this, biosimilars need higher launch prices than expected in order to have the margin to offer hefty rebates to compete for market share with the innovator drug.
- PBM business practices keep patient cost sharing high when it is based on the list price of high-cost innovator products, not less expensive alternatives.
- Manufacturer patient cost share assistance may not count toward patient annual out of pocket costs (deductible and cost sharing). This delays when a patient reaches the annual cost sharing cap or gets through their deducible. When annual assistance runs out, the patient starts paying for the cost of the drug (so-called accumulator model). The newer, more prevalent model applies the total annual patient assistance amount evenly, each month. to patient cost sharing so there is no financial 'cliff' for the patient (so-called maximizer model).
- PBMs guarantee health plans a set reduction in total Rx spend (for instance, 19%) after rebates but PBMs do not guarantee efforts to reduce or manage *total spend* before rebates. Clients are misinformed about the misaligned incentives.
- PBMs, say they pass 100% of manufacturer rebates back to health plans but there is no way to verify that all rebates that might move through PBM affiliated entities are reported to payers. Payers may not know if there are multiple entities managing the rebates.

Industry-wide Vertical Integration:

Corporate linkages operate to the detriment of consumers

- National insurers are corporately linked to national PBMs, national retail pharmacy chains, national specialty pharmacy services, and mail order services.
- Alignment is organized to maximize rebate revenue (CVS whistleblower lawsuit).

Hospitals and Medical Specialists:

Significant profit on administered and dispensed drugs

- Profits as a percentage of price means higher priced products produce higher profits.
- Hospitals and medical specialists too often oppose efforts to constrain Rx costs without disclosing their financial interest in maintaining high prices.

Pharma-Funded Patient Groups:

Groups created by/supported by industry reliably oppose efforts to reduce drug costs

- Patient groups that support patient access and affordability are few in number, notably Multiple Sclerosis Society, Leukemia/Lymphoma Society, National Alliance for the Mentally Ill.
- Most patient groups are neutral or oppositional, and echo pharma threats that industry will hold patients hostage if their pricing decisions are questioned.

Bench Science Institutions:

Universities do basic research and patent promising molecules they develop

- Universities sell or lease their patents to pharma companies which then conduct the "go-to-market" research and development.
- Patent price or royalties back to the research entity can be based on potential for the drug price and revenue. Higher market prices can yield higher revenues back to the research institution depending on the financial arrangement.
- Universities and research hospital systems are known to oppose drug cost reduction as a threat to revenues.

Wholesale Acquisition Cost/Retail Price Subscription Services:

'Pricing services/pricing files' receive manufacturer list price and price increase information.

- Pricing services sell subscriptions for launch prices and drug price changes to insurers, researchers, prescription drug affordability boards and state Rx price transparency offices.
- Subscribers cannot reveal the wholesale acquisition cost (WAC) information provided under the subscription even though many state Rx transparency laws require manufacturer WAC reporting for some drugs – which they provide.
- Is there another industry where a product list price is a proprietary secret – and where the entity making list price proprietary does not own the product or control the list price? It would be interesting to know how common this business model may be in other US industries.

This quick run-down hopefully sheds a bit of light on why it is so hard to reform the pharmaceutical market in the US. All these business models are built around making money off drug prices--to the detriment of the consumer.

Arguably, all this dysfunction started with rising prices -- when industry realized the market would bear extremely high prices. But the system created by high prices does not really work for manufacturers anymore. While they have legitimate gripes, their solutions are too self-serving – intended to put them back in the driver's seat and reset their ability call all the shots on price and access.

In addition to state laws, policies, and audits that have started to rein in bad market behavior, there is market disruption – initiatives designed to lower costs for consumers and payors/health plans.

- CIVICARx started a few years ago as a consortium of hospital systems to fund the manufacture of inpatient generic drugs that are/were in regular shortage status. Hospital systems continue to join the effort. CIVICA announced it will produce outpatient drugs – starting with insulins and sell at very low prices. Supply will be distributed to pharmacies that agree to limit markup – a specific distribution system. This effort dovetails with CIVICA's work with a consortium of Blues plans to get lower cost drugs to plan enrollees as it starts to produce other outpatient generics.
- California and Washington have laws to manufacture drugs at low cost for in-state distribution. California just announced it has contracted with CIVICA to operationalize the law.
- Eli Lilly led insulin makers with a significant drop in the product list price. This is a big breakthrough. Lilly will create its own distribution system. Health plans that want access the lower cost supply for their enrollees must commit to a $35 patient copay. As an aside, most observers believe Lilly and its competitors have been offering deep rebates on these products.

- Cost Plus Drugs started as an online pharmacy for generic drugs for *cash* paying consumers (insured and uninsured). The company would not interact with insurers/PBMs which drives up costs. They have a stated mark-up of 15% above production costs.
  Recently, the company announced that a patent-protected diabetes product from Janssen will go on their formulary at a price much lower than list price. An employer coalition is working with Cost Plus to make Cost Plus drugs available to health plan enrollees. The Coalition created its own PBM that presumably has designed a reimbursement system to cover patient costs and not drive-up administrative costs for Cost Plus. Cost Plus is setting up its own distribution system similar to what CIVICA is doing.
- Medicare Price Negotiation and drug price increase penalty rebates are also market disruptors. Together, the Medicare and Medicaid price increase penalty rebates will result in fewer price increases but may result in higher launch prices – which are also incentivized by the structure of the negotiation program. The negotiation program should also incentivize manufacturers to ensure there is market competition – in order to avoid a Medicare negotiated price (which only applies to drugs that lack generic or biosimilar competition). This would be a full reversal of the current industry practice of blocking competition for as long as possible. This may have an impact on how the industry uses patents and rare disease/orphan drug designations to block competition for years and years. Medicare negotiated prices and faster access to generics and biosimilar products are good news for consumers.

These disruptive innovations could pose significant, and possibly conflicting, pressures on the industry business model.

State governments should consider what if their policies could amplify and support the disruption.

In summary, in my view, there are a few essential policy elements that can unwind our dysfunctional pharmaceutical marketplace to better serve patients, the healthcare system, and even manufacturers.

1. The first essential element is transparency on costs and discounts. Our current system is built on secrecy that allows anti-consumer, anti-competitive behavior to thrive. The Oregon price transparency law provides some important transparency.
2. The second essential element is for transparent prices to move through the supply chain to the point of service – to the consumer.
3. The third essential element is rate setting to establish what consumers will pay for certain high-cost drugs, particularly since there are now market signals that favor increased launch prices.
   - I think of rate setting as a market reset for some high-cost drugs. Rate setting could still allow the whole supply chain to continue to make a margin on a drug, but the set rate is where the price concessions start. If a market player can make a better deal than the set rate and improve their profit margin, that is fine but the deal making is not at the consumer's expense. Rate setting should reduce the need for rebates since the on-invoice price for suppliers, providers, and insurers would be less than the prevailing market price.

I appreciate the opportunity to provide this testimony and I am happy to answer any questions.

[i] https://www.bloomberg.com/news/articles/2022-06-07/new-drug-prices-soar-to-180-000-a-year-on-20-annual-inflation?leadSource=uverify%20wall;

[ii] https://www.usnews.com/news/top-news/articles/2022-11-02/new-u-s-cancer-drug-prices-rise-53-in-five-years-report

[iii] https://www.reuters.com/business/healthcare-pharmaceuticals/newly-launched-us-drugs-head-toward-record-high-prices-2022-2022-08-15/

[iv] https://www.ahip.org/your-health-care-dollar-new-ahip-analysis-shows-where-it-goes/, accessed 3/15/21

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

[vi] This is a comparison of a 2017 JAMA article where researchers tried to validate industry R&D claims using 2015 data and a 2023 industry commentary opposing PDAB legislation in Minnesota that presented lower R&D costs and higher rates of R&D success than the industry has previously used. This shows what we would expect – that new, faster FDA product approval pathways together with new R&D technologies and efficiencies had precisely the desired effect – more products on the market with lower manufacturer development costs. The change in costs and success rates in a relatively short period of time is notable. The fact that these lower costs apply to small population products is noteworthy relative to industry claims that they need excessive pricing for small population products because of R&D and development failures.