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Thank you, Chairman Frankel, and Members of the Committee, for the opportunity to discuss the problems in the US pharmaceutical market and how a state prescription drug affordability board can improve residents' access to more affordable medicines and address much of the dysfunction in our current market system.

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 spent over a decade working in the pharmaceutical industry. I have worked as a consultant to many state policymakers since 2016 on prescription drug cost containment policy, much of it funded by foundations, including Arnold Ventures.

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 numerous problems that have developed in response to rising drug prices.

As the amazing biopharmaceutical science and technology rapidly evolve to produce meaningful products, society's inability to manage the very 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 the pharmaceutical marketplace to identify the multiple problems and 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] which slightly exceeds the proportion spent on inpatient hospital services.
5) State taxes support some or all the pharmacy benefits for as many as 25-35 percent of residents in many states.[v] A back of envelope estimate for Pennsylvania is 34%. [vi]

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. The treatments are somatic and do not affect the prevalence of the disease in the population which can be steady state. These small population markets actually grow over time owing to the effectiveness of treatments. Cystic Fibrosis is an example of this.

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[vii]

- 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 had 23 years of patent protection after it came to market. Humira is not unusual.

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, ten high-cost settlements.

Rebates are king

- As an industry, PBMs now exclude ~600 drugs from their formularies because of insufficient rebates
- PBMs often refuse to cover lower cost therapeutics (including biosimilars and generics) in a class when there are higher priced, higher rebate innovator products available.
    - Because of this PBM practice, drug manufacturers increasingly launch 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.
- Patient cost sharing based on the list price, not the net, rebated cost.
- 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 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 move through PBM affiliated entities are reported to payers and payers may not know if there are multiple entities managing the rebates. It is simply an unknown.

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). (I was naïve to expect such integration would create alignment around optimal patient outcomes as a profit center rather than maximizing rebates.)

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 other 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 development
- Patent price or royalties back to the research entity are based on potential for the drug price and revenue. Higher market price yields higher revenues back to the research institution
- Universities and research hospital systems are known to oppose drug cost reduction as a threat to revenues
- Federal legislation in the works for several years would require disclosure of federal funding when filing for drug patents is stymied

Wholesale Acquisition Cost/Retail Price Subscription Services:
'Pricing services/pricing files' receive manufacturer list price and price increase information. This is an issue that has recently come to my attention.

- Pricing services sell subscriptions for launch prices and drug price changes to insurers, researchers, and 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 WAC reporting for some drugs
- In the US, the wholesale price is synonymous with list price (price before price concessions)
- 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 clarifies why it is so hard to reform the pharmaceutical market in the US. It is maddening really. All these business models are built around making money off drug prices. The only market participant without a profit-making business model is the consumer – the consumer who pays dearly for this dysfunction.

Arguably, all this dysfunction started with rising prices -- when industry realized they really could put everyone over a barrel. However, the system does not really work for manufacturers anymore and they have legitimate gripes, but 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 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.
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. The pharmaceutical marketplace cannot change without public policy and public rate setting to establish what consumers will pay for certain high-cost products. With transparent, statewide, all payer, all purchaser rate setting for certain drugs, the upper payment limit (UPL) will through the supply chain to the consumer at the point of service. People and market participants can pay less, but they cannot pay more.
    - I think of this as a market reset for some high-cost drugs. UPLs could still allow the whole supply chain to continue to make a margin on a drug but the UPL is where the price concessions start. If a market player can make a better deal than the upper payment limit and improve their profit margin, that is fine but the deal making is not at the consumer's expense. An upper payment limit should be set to reduce the need for rebates since the on-invoice price for suppliers, providers, and insurers will be reduced.

The statewide, all-payer, all-purchaser UPL model has been around since 2017. In fact, the new Medicare price negotiation program is very similar to the model in key features. The Medicare-manufacturer negotiation begins with a federally calculated ceiling price – based in part on the price concessions in the Medicare market. The final Medicare 'Maximum Fair Price" must, under federal law, be delivered to the consumer at the point of service. The government places the onus on manufacturers, Medicare health plans, and Medicare providers to see that the lower price gets to the point of service. This is how a state upper payment limit will work.

The Medicare maximum fair price program is a great start but there is still a need for complementary state action. Medicare will only look at drugs without biosimilar or generic competition -- monopoly products owing to excessive use of patents or data exclusivities. In fact, the federal law may unwittingly allow more price shenanigans to persist by exempting from negotiation products that have generic or biosimilar competition; it will behoove innovator product manufacturers to loosen access to their proprietary data before the end of market protections so the innovator and generic/biosimilar can evade federal price negotiations and the competitor product can shadow price the unrestrained innovator. Any competition between the two will occur at the secret rebate level – with no benefit to the consumer. There is plenty of need for additional state efforts to wrap around the nascent federal effort.

There are few, if any, policies that create all three necessary conditions mentioned above to lower costs for consumers at the point of service while avoiding new distortions in a dysfunctional market. A well-functioning affordability policy can and should solve the manufacturers' big complaints – that their hefty rebates do not help individual consumers and that patient out of pocket costs are too high. Unfortunately, the industry solutions to

their problems are inadequate because they would only increase health system costs. Therefore, better, smarter, approaches are needed.

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 rough estimate includes state and local employees plus dependents, Medicaid (which includes pandemic enrollment policies that are phasing out), prisons and jails although available data is somewhat old. The estimate does not include state rehabilitation and other residential treatment facilities, or first responder medicines such as opioid reversal agents.

[vii] This is a comparison of a 2017 JAMA article where researchers tried to validate industry R&D claims with 2015 data and 2023 commentary opposing PDAB legislation in Minnesota that provided lower R&D costs and higher rates of R&D success. 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.