Testimony in Support of Senate Bill 388

Prescription Drug Affordability Board – Authority for Upper Payment Limits and Funding

Lowering Prescription Drug Costs for All Marylanders Act of 2024

Madam Chair, Vice Chair Klausmeier, and members of the Senate Finance Committee, thank you for the opportunity to discuss SB 388 that would give our Prescription Drug Affordability Board authority to set payment rates on what all Maryland consumers will pay for certain high-cost drugs.

Maryland has been a leader and innovator when it comes to healthcare access, thanks in large part to the vision of members of this Committee past and present. A statewide payment rate will address many of the most anti-consumer market behaviors in drug coverage and payment for drugs for which an upper payment limit is created. Statewide prescription drug rate setting is akin to our leadership in statewide all-payer hospital rate setting that began many years ago. We need your leadership to build on the Prescription Drug Affordability Board's set of problem-solving tools and leadership to bring more drug cost relief to more people.

There is a great deal of market dysfunction created in response to rising manufacturer drug prices. The level of dysfunction is so significant and harmful to consumers that is hard to know where to begin. States are hobbled by federal statutes and case law that make protecting residents even more complex to solve. Statewide prescription drug rate setting can improve residents' access to more affordable medicines while addressing much of the dysfunction in our current market system.

By way of background, I have worked on prescription drug access and cost containment for many years. I represented the Medicaid Directors when the Medicaid drug rebate program was created. At the US Senate Finance Committee, I designed the Vaccines for Children Program. I spent over a decade working in the pharmaceutical industry and was an industry point person working with Centers for Medicaid and Medicare Services to implement the Medicare Part D program. Currently I consult with many state lawmakers, executive branch officials, and advocacy organizations on prescription drug cost containment policy across the country. Much of this work is funded by foundations. I am also a board member of the Prescription Justice Institute.

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 25-40 percent of residents depending on the state.

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 for all of us.

I want to briefly discuss the array of dysfunction in today's market to level-set on the scope of the problems so we can consider policy approaches appropriate to 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 even though a rare disease is defined as affecting less than 200,000 people.
- Rare and small population disease markets grow over time – people live longer and take medications throughout their lives precisely because of scientific advances that produce great treatments. The treatments are somatic and do not affect the prevalence of the disease in the population which means these small population markets grow over time owing to the effectiveness of treatments. Cystic Fibrosis is a wonderful example; people with CF used to die in childhood and today survive well into adulthood due to new medicines that must be taken throughout life.[v] Another way rare disease drugs expand market size is treating additional diseases. For example, the number one selling drug in the world until 2023, Humira, started as a rare disease drug. Keytruda, expected soon to be the top-selling drug, started as a rare disease drug. As the treatment portfolio expands, so does the market size. Then there is Trikafta, which treats only Cystic Fibrosis and is the third highest revenue drug in the world. There is much less financial risk in the small disease market than we are generally led to believe as this report describes.

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 have lowered in recent years ($2.7B/drug in 2015, $2B/drug in 2022).
- R&D success rate is higher (10/100 Rx made it to market in 2015, 12/100 Rx make it to market today)
- These positive changes are due to new efficiencies in R&D and new laws that allow faster licensing of rare disease/high unmet need products. All these laws and efficiencies reduce financial risk for companies.
- The costs and risks to bring a rare disease drug are less than drugs for large population illnesses.

Patent thickets

- Companies return repeatedly to the patent office with new, minor modifications to a drug to extend their patent protections and fend off generic or biosimilar competition.
- A 'normal' patent life is 7 to 10 years after a drug comes to market. A patent is 20 years in total 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 by creating a patent thicket. Humira is not unusual, as these charts document.

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 collectively now exclude over 1,000 unique medicines from their formularies, often because of product cost and insufficient rebates. This recent article provides an excellent overview of PBM market strategies relative to formulary exclusions.

- 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 one product 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 national drug code (NDC) identifier.
- Patient cost sharing is based on the list price rather than 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 are often misinformed about the misaligned incentives of their PBM vendors.
- PBMs say they pass 100% of manufacturer rebates back to health plans but there is no way to verify that all rebates received that move through PBM-affiliated entities are reported to payers. Payers likely do not know if there are multiple PBM-affiliated entities managing the rebates – some of which are outside the US.

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. This graphic says it all.
- Alignment is organized to maximize rebate revenue and deny patient access to lower priced generics and biosimilars (CVS whistleblower lawsuit). A more recent investigation by the *Wall Street Journal* demonstrates that this behavior is fairly widespread in the larger corporations.

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 in many states too often oppose efforts to constrain Rx costs without disclosing their financial interest in maintaining high prices.
- There is also the federal 340B program, where thousands of hospital and community clinics that serve insured and uninsured people buy drugs at very deep discounts not available in the market. They then bill insurers at market price and make a profit on the difference. Many of these entities will charge on a sliding scale for uninsured people, but not all do this. 340B program entities, notably hospitals, oppose drug cost containment as a threat to their revenue stream. For reference, there are about 625[1] participating hospital outpatient clinics (oncology, rheumatology, orthopedics, etc.), and many more general practice, stand-alone community clinics. These entities view drug cost containment as a significant threat to their revenue.

Pharma-Funded Patient Groups
Groups created by/supported by industry reliably oppose efforts to reduce drug costs

[1] This data is calculated from the 340B website of the Health Resources and Services Administration as of 1/25/2024. It is the sum of enrolled clinics of eligible, participating Virginia hospitals. This link can be used to calculate other types of 340B program entities in Virginia.

- 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 have supported prescription drug rate setting (or upper payment limits) bills in different states.
- Most other groups are neutral or oppositional, and echo pharma threats that industry will hold patients hostage in retaliation for lowering patient costs, even though lowering costs would improve the manufacturer's access to the market for the drug.

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 (human clinical trials).
- Patent price or royalty payments back to the research entity are based on potential for the in-market drug price and revenue. Higher market price yields higher revenues back to the research institution.
- Some universities and research hospital systems have opposed drug cost reduction as a threat to their 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, state Rx price transparency offices and many others.

- 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, which is then made public.
- 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 seems like it is secret simply for the purpose of pricing file company's profit model. The model puts everyday consumers increasingly in the dark. It would be interesting to know how common this business model may be in other US industries. Imagine if the MSRP for new cars was a secret, accessible only through a service that sold you the information? It seems like this might be the cornerstone of market opacity that harms consumers.

This quick run-down hopefully clarifies a bit why it is so hard to reform the pharmaceutical market in the US. All these business models are built to make 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. In this context, the consumer is collateral damage.

All this dysfunction started with rising prices -- when industry realized it had vast ability to price. However, the system no longer even works for manufacturers and they have legitimate gripes about PBMs and 340B business practices. The industry solutions to parts of the dysfunction 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. One essential element is transparency of list price and the average of manufacturer price concessions. Our current system is built on secrecy that allows anti-consumer, anti-competitive behavior to thrive.
2. Another essential element is for transparent prices to move through the supply chain to the point of service – to the consumer.
3. The final 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, an upper payment limit (UPL) will move 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 statewide rate setting as a market reset for some high-cost drugs. Upper payment limits (UPLs) are just another type of payment rate which is ubiquitous in US healthcare. No one pays what they are charged. Statewide rate setting for certain high-cost medicines could and should 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 lower than the previous market price.

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. This is how a state upper payment limit will work except it will be less administratively burdensome than the Medicare process for a variety of operational reasons.

The Medicare maximum fair price program is a great start but there will still be a need for complementary state action. Medicare will only look at drugs without biosimilar or generic competition – products that are monopolies owing to excessive use of patents or data exclusivities the stymie competition and there is reason to believe that manufacturers will find ways to create competition that meets the letter of the law but not the spirit of the law. We might start to see business practices that evade negotiation for orphan and other products and maintain very high prices. I believe there will be 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 and patient assistance do not always help individual consumers and that patient out of pocket costs are too high. Unfortunately, the industry solutions to their problems are inadequate because solutions would only increase health system costs while lowering patient out of pocket costs. Therefore, better, smarter, approaches are needed.

There are few policies which can effectively improve patient access to treatment and manufacturer access to the market. The intent of UPL is to generate more sales and more patient access. There is no intent to harm manufacturers.

I hope this Committee and the legislature in general will give the Board authority to move forward to help all Marylanders, not just state and local governments and their employees.

I appreciate the opportunity to provide this information and I am happy to talk in more detail about these issues.

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[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 CF Foundation 2021 annual report highlights the success of CF treatments. In 1991 adults were 32% of the population of people living with CF; in 2021 adults were 58% of the CF patient population. The median life expectancy of people with CF born between 2017 and 2021 is 53 years. Half of people with CF born between 2017 and 2021 are expected to live longer than 53 years.

[vi] This is a comparison of a 2017 JAMA article where researchers tried to validate industry R&D claims with 2015 data to a 2023 commentary opposing MN PDAB legislation which provided included updated (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. See also the link to Orphan Drug paper earlier in this testimony.