JOHNS HOPKINS
UNIVERSITY

The Center for Hospital
Finance and Management
624 North Broadway / Third Floor
Baltimore MD 21205
410-955-3241 / Fax 410-955-2301

November 7, 2018

Honorable Shane Pendergrass
241 House Office Building
6 Bladen Street
Annapolis, MD 21401

Honorable Delores Kelley
302 James Senate Office Building
11 Bladen Street
Annapolis, MD 21401

Dear Chairman Pendergrass and Senator Kelley:

We are writing for a group of national drug policy experts, including the Johns Hopkins Drug Access and Affordability Initiative, to present to you our responses to concerns raised about last Session's Drug Cost Review Commission legislation, HB 1194 and SB 1023 (now to be known as the "Prescription Drug Affordability Board" proposal). Since the Session ended we have carefully reviewed all of the major concerns raised by the drug corporations and others to this legislation. We believe that the attached document fully addresses the concerns raised and the you should therefore give similar legislation very serious consideration in the 2019 General Assembly. We would be happy to meet with you anytime to discuss our work.

Thank you very much.

Sincerely,

Gerard Anderson, PhD, Professor
Johns Hopkins Bloomberg School of Public Health

Jane Horvath, Principal
Horvath Health Policy

cc: Honorable Brian Feldman, Honorable Joseline Peña-Melnyk, & Honorable Katherine Klausmeier

Responses to Concerns About a Maryland Prescription Drug Affordability Board

During the course of the 2018 Maryland State Legislative Session, several important stakeholders raised concerns about HB 1194 which would have established a state Prescription Drug Affordability Board. The Board would set drug payment or reimbursement rates for consumers, payers and purchasers for certain high cost drugs. This document reviews and addresses the concerns that arose.

Concern 1: A *Prescription Drug Affordability Board will hurt industry and innovation.*

(A) *The creation of a Prescription Drug Affordability Board will stifle competition in the market, reduce jobs in the biopharmaceutical and building trades, and drive up prices.*

(B) *A Prescription Drug Affordability Board will hurt innovation and it disincentivizes development of new therapeutic breakthroughs, driving away investors and threatening Maryland's clinical trials.*

These concerns have been offered many times whenever drug cost containment policy is discussed. The reality is that the current market is not competitive and the prices are rising every day.

Instead of driving away jobs and businesses, a process to control drug costs will make Maryland exceptionally attractive for business and employees.

But besides making Maryland attractive to all types of business if the State controls costs, we looked at how industry responded in countries that control drug costs. The research shows these drug cost control countries have active pharmaceutical markets as well as active research and development efforts. Innovative markets exist in many European and Asian countries with established government drug payment rate setting boards. As of 2017, more than half (12 of the 22) of the highest grossing pharmaceutical corporations in the world ($10+ billion) have their corporate headquarters in cost control board countries:

-Denmark: Novo Nordisk
-France: Sanofi
-Germany: Bayer; Boehringer Ingelheim; Merck Group
-Ireland: Shire
-Israel: Teva
-Japan: Takeda
-Switzerland: Roche; Novartis
-United Kingdom: GlaxoSmithKline; AstraZeneca

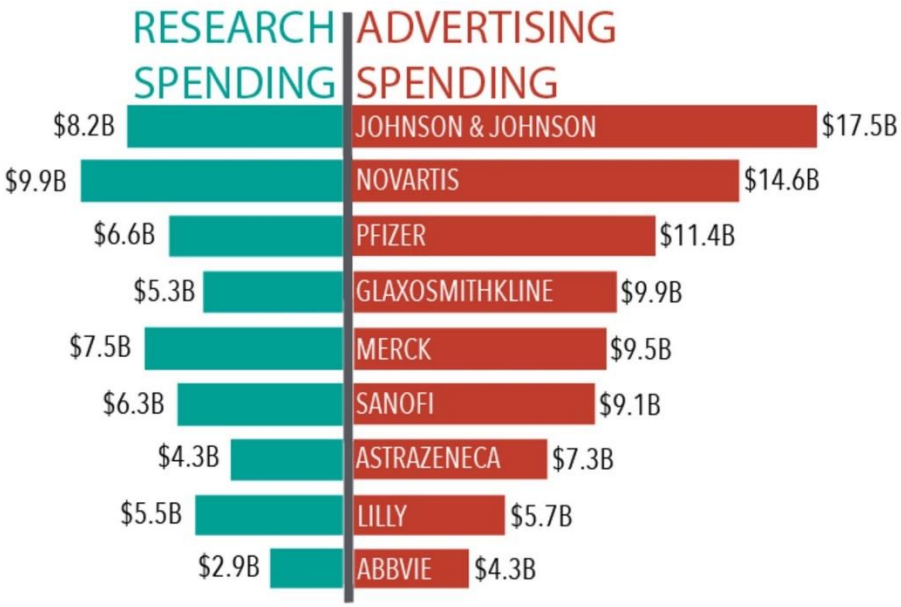
Based on this, there is no reason to believe that the drug corporations would leave Maryland because a Board created affordability for a small number of high cost drugs.

In fact, innovative corporations are attracted to strong researchers, and the presence of the NIH, University of Maryland and Johns Hopkins assures a pipeline of innovative researchers

Where a corporation locates is more of a product of taxes and acquisitions than any other single cause. Consider the case of Pfizer and Allergan, which in 2015 planned a merger and relocation to Ireland to avoid $160 billion in U.S. taxes and consolidate employee resources. This merger was only avoided when public pressure kept Pfizer in the U.S. In 2014, Pfizer announced it was buying the UK corporation, Astra Zeneca, and moving its entire corporate headquarters to the UK – which has one of the most significant government drug cost control panels in Europe. Pfizer did not go through with either move – but not because of the governments' cost control regimes.

Maryland is only a small portion of the global market and having Maryland costs set closer to the international prices will not adversely affect innovation.

Finally, for the large innovative corporations, research and development (i.e. "innovation") is only 17% of total spending. Marketing represents much more spending than what is invested in innovation.



The Washington Post, Big Pharmaceutical Companies are Spending Far More on Marketing than Research; February 11, 2015

Concern 2: *A drug rate-setting component will compromise Maryland's CMS waiver and a drug rate setting Board will create dual drug cost regulation for Maryland hospitals.*

The U.S. Centers for Medicare and Medicaid Services (CMS) has approved the Maryland waiver. The structure and function of a drug cost review Board would not affect the agreement with CMS. We have met with HSCRC staff and while they were nervous as the new agreement with CMS was being negotiated, they are no longer concerned since the agreement has been finalized.

The HSCRC and Maryland hospitals now work with global budgets and overall revenue limits. The HSCRC does not review or regulate the price or hospital cost of individual inpatient or outpatient drugs.

The global budget system formula includes a hospital-specific 'drug cost center' where the total hospital spending on drugs is included and used in global budget determinations. If the Prescription Drug Affordability Board were able to obtain a lower acquisition cost of a drug for the hospitals in Maryland it would not have a significant impact on that aggregate amount in the drug cost center. If it did then the hospital could find it easier to operate within the global budget since HSCRC does not regulate individual drug costs.

On the outpatient side, a Prescription Drug Affordability Board could limit what a hospital, pharmacy, or wholesaler can bill for a drug. This payment/charge limit is not regulated by the HSCRC. In fact, compliance with a rate established by a Board is likely to be enforced by commercial and government payers that reimburse providers for outpatient drugs and will use their billing and payment systems to see they are not overcharged. So, again, there is no particular role for the HSCRC here and there is no dual regulation of hospital drug costs or policies.

Finally, because of the way the inpatient global budget operates, a lower drug cost would make it easier to stay within the global budget. Thus, it is likely that the new Prescription Drug Affordability Board

would impact the HSCRC inpatient hospital bundled payment in a positive direction.

Concern 3: *The Prescription Drug Affordability Board will threaten qualified institutions' eligibility to participate in the 340B program.*

We do not believe there would be a conflict between institutional eligibility and existing 340B policies. Nothing in this proposal would affect a hospital's ability to participate in the 340B program. The hospital could still procure 340B drugs and bill for those drugs at a higher rate than it pays for the drugs. The billing rate could be lowered because of the actions of the Prescription Drug Affordability Board. Hospitals would be able to provide input directly to the Board during its analysis and deliberations. Since the 340B program is designed to help the most vulnerable populations, having drug rates set at a manageable level would benefit low-income individuals in Maryland.

We are working with hospitals and other 340B providers to make sure that the Prescription Drug Affordability Board has a minimal impact on their activities. It is important to keep in mind that the legislation only applies to high cost drugs or drugs that create affordability challenges for Maryland health care systems, which includes Maryland hospitals.

Concern 4: *The brand drug industry warns that payment rate setting will disrupt availability of important medicine because manufacturers will halt sales of drugs in Maryland. In addition, unless the Board makes exceptions for generic and biosimilar medicine, the generic industry will raise generic prices and residents will be at increased risk for drug shortages.*

It is unlikely for a number of reasons that manufacturers will cease sales of drugs in Maryland because of an action of a payment rate setting Board.

First, to the extent that drug manufacturers behave in ways that are anti-competitive or otherwise violate Maryland consumer protection laws, there can be actions by the Maryland Attorney General's office.

Second, every insurer in the US has a drug reimbursement payment rate setting system, for every drug in the US today. Each state Medicaid program has a different rate for different drugs. And yet the industry sells it drugs quite successfully in every state.

Third, the public would react unfavorably to a pharmaceutical manufacturer that decided not to sell drugs in Maryland after a public deliberative group of non-conflicted experts determined a cost at which all residents who needed the drug could get it and which would actually boost sales of the drug relative to sales at the manufacturer price.

Fourth, exiting the market for a specific drug is difficult for any drug corporation to do. For example, assume that Corporation A was affected by a reimbursement decision by the Prescription Drug Affordability Board. It is unlikely that Corporation A would abandon the Maryland market to Corporation B, which has a similar product. Corporation B would then have all the market share. Even if the drugs of both corporations came under payment rate setting, for them to exit together could be viewed as anti-consumer behavior, and for one corporation to leave, it would cede the market to its competitor. Most drugs have therapeutic equivalents and Corporation A would not want to give the entire market to Corporation B.

Fifth it appears that the federal 340B program requires manufacturers to continue to sell in Maryland. The federal program requires corporations to sell drugs at low, *federally mandated* prices to all health care providers enrolled in the program. Manufacturers must supply the quantity of drugs requested by each participating provider. There are over 700 Maryland 340B providers. There may also be interpretations of federal Medicaid laws that limit manufacturer discretion to exit the Maryland market

for one or more drugs.

Sixth, to the extent that Maryland rate setting addresses a growing branded industry complaint – that consumers do not benefit from the significant, current price concessions in the market already because they are absorbed by PBMs – the industry will benefit from a system that lowers costs for consumers at the point of consumer service. And, a drug sold at an affordable cost will provide for greater sales and revenues than would otherwise occur for the manufacturer.

Finally, it is very unlikely that a generic drug will cost more than $30,000 or have a price increase of more than $3,000. However, it is possible that this could occur. For such reasons, the manufacturer a generic or off-patent branded drug shall notify the Board if the manufacturer is increasing the wholesale acquisition cost of the drug by more than 25% or by more than $300 during any 12-month period.

Concern 5: *As proposed, the Prescription Drug Affordability Board fails to include members of the supply chain, has too small of a scope (does not review enough data), and five seats is insufficient to complete the necessary work.*

The current structure of the proposed Prescription Drug Affordability Board will review only expensive drugs – drugs that create financing strains for Maryland health plans and consumers. We estimate that a 5-person Board could handle this demand. We calculated that there are only 244 drugs currently on the market that cost more than $30,000. Many of these have been around for many years. Few corporations raise their prices more than $3,000 per year.

There are numerous entities that review drug prices both domestically and internationally and publish the results. The Board would have access to these reports and will analyze both price and cost in determining a payment rate is needed.

Importantly, the legislation is designed to create an impartial Board of expert board members and staff who have no financial conflicts to influence their decisions. Including people with clear financial conflicts on the Board would run counter to the purpose of deliberative, independent decision-making. Stakeholders, with and without conflicts of interest, will participate in the Board's advisory board and also can have independent input through the Board's public process.

Concern 6: *The transparency and reporting components of the legislation require onerous disclosure of pricing information, and this places undue burden on small/emerging biotech corporations.*

This point is moot for multiple reasons.

The corporation has the opportunity to disclose whatever information it wants to disclose. If some information is too burdensome to assemble they do not have to present that information, even if requested by the Board. Disclosure by the drug corporations is ultimately voluntary and is designed to help the Board make decisions. Whereas, in California and Oregon the passage of drug price transparency laws has made these disclosures a requirement. Maryland will be able to access this data from California and Oregon.

A small/emerging biotech company with a limited portfolio of products that it is launching itself would have the bandwidth to provide documentation for a single product. They need to provide this data to the FDA and to other countries in order to sell their product.

A corporation that is growing quickly should be prepared to invest in the administrative capacity to deliver information to the Board that will support that could help the Board analyze cost.

Few small, emerging companies have historically launched their own product without partnership from a larger enterprise (e.g. Johnson & Johnson, Amgen). These companies have the experience and personnel to provide such documentation.

The bill specifies *reporting* to the Board, not *disclosure* to the public. The legislation protects proprietary information (of payers and manufacturers alike) from public release, consistent with Maryland trade secrets protection laws.

Concern 7:

- **(A)** *Drug costs are a federal issue and should not be addressed by the State – having different cost controls in each state would be too complicated. Additionally, Maryland cannot regulate drug prices charged by drug corporations in line with other health care spending. It will do little to lower out of pocket costs.*
- **(B)** *Rate setting is the same as price control.*

First, to be clear, the Prescription Drug Affordability Board would not exist to regulate list prices. It establishes maximum payment amounts – just like all commercial and government payers do for all drugs on the market today. The difference is that a state Board can better protect consumers and pharmacists who currently have little ability to drive their own drug purchasing costs. It creates a strong, protective state reimbursement limit that treats all parts of the drug supply chain fairly and equally and leverages the current supply chain cost negotiation processes.

Second, the federal government is unlikely to act unless states take action first. Most of the significant health policy innovations have occurred first at the state level. Maryland has independently led in the development of all payer rate setting and now hospital global budgets to control costs and assure top notch medical care. Diagnosis-Related Group (DRG) and State Children's Health Insurance Program (SCHIP) programs were both adopted by states before they became nationwide federal programs.

Third, Maryland is similar in terms of population size to many Western nations that have drug payment rate setting agencies. These countries include Switzerland, Norway, Israel, Denmark, Finland and Ireland.

Concern 8: *A Prescription Drug Affordability Board is not necessary, as drug costs account for only 14% of health spending and just 6% of the Maryland Medicaid budget. The growth in pharmaceutical costs is slowing, with drug costs projected to grow in line with other health care spending. It will do little to lower out of pocket costs.*

"In 2017 drug cost, from both the medical and pharmacy benefit, was the single largest contributor to overall spending at CareFirst at approximately 33%. This is larger than specialists, inpatient or outpatient, and any other cost at CareFirst, and continuing to rise." Chet Burrell, former CEO, CareFirst BlueCross BlueShield

Hospitals are adversely affected by high drug costs. Patients are adversely affected by high drug costs. Doctors are concerned that the high drug costs make the drugs they prescribe unaffordable to many patients. Health plans are concerned that drug costs are fully 25% of their total annual medical costs and are driving premium increases. High drug costs are the public's main health care concern according to public opinion polls. The rising cost of drugs is a regular news item in mainstream national and local media.

To suggest that there has been no increase in the cost of pharmaceuticals would be to ignore the historical economics of drug pricing since the 1950s.

The current five most expensive drugs in the U.S. are now drugs for cancer, in the following order:

1. Actimmune: $52,321 per month
2. Daraprim: $45,000 per month
3. Cinryze: $44,140 per month
4. Chenodal: $42,570 per month
5. Myalept: $42,137 per month

Each of these drugs has high levels of consumer cost sharing

Examples such as Daraprim could have been prevented in advance by a Prescription Drug Affordability Board, which would have been able to engage Turing Pharmaceuticals and Martin Shkreli in its price hike scandal.

Finally, the 14% figure the industry uses is very misleading. That number is the percentage of all national health expenditures – including state and federal employees that work in Medicaid, Medicare, public health, military and veteran's health, the National Institutes of Health and including all the federal and state health research funds. As part of any and all national health expenditures, drugs would look like a small part. Once you know how big the spending base actually is,
14% looks quite high.

Concern 9: *A Prescription Drug Affordability Board would impermissibly violate federal patent law and a Board would fail to protect confidentiality of proprietary information.*

Maryland Attorney General Brian Frosh analyzed this issue prior to the introduction of HB1194 in 2018 and determined that the law would not violate federal patent laws. Patent laws would continue to protect ownership of the technology and intellectual property. The legislation specifies that proprietary information provided by any manufacturer or health plan is protected from public disclosure.

Concern 10: *A Prescription Drug Affordability Board unnecessarily adds a layer of bureaucracy and there are better ways to address this issue (through transparency alone).*

If you know a drug is very expensive, how does this help you to afford the very expensive drug? What power does an individual with cancer or heart disease have to pay an affordable cost?

Drug payment rate setting is a more effective way to protect consumers and create access to affordable treatments. Manufacturers do not really prefer transparency – the public disclosure of important corporate information that could help consumers including information on: drug effectiveness; the rationale for launch prices the strategy behind a launch price; how many people should be taking the drug relative to manufacturer sales estimates (typically representing a much lower number of people able to afford the drug). If pharmaceutical manufacturers would prefer public disclosure of strategic and proprietary information they use to create pricing, this could be explored. We think this public process would be unwieldly with uncertain outcomes – and the industry would be quite opposed. Instead, protected reporting of key information to an expert, impartial group that can assess it fairly and establish reimbursement levels, is more rational and better for industry competition.

Importantly, it should be noted that public outcry about Martin Shkreli and Daraprim, or Mylan and

EpiPen, despite their price transparency, did not impact the price of these drugs as seen in CNN's latest report of the most expensive drugs as of May 2018. Congressional hearings also did little to get beyond transparency to impact costs.

Concern 11: *As it stands, the current method of Board appointments favors a single political party.*

In 2018, the legislation received bipartisan support in both chambers, as did the Anti-Price Gouging Law which passed in 2017. The structure of the Prescription Drug Affordability Board is meant to represent Maryland's bipartisan viewpoints in proportion to the affiliation of those who make the appointments. Currently, the following members of Maryland State government would be positioned to appoint board members: the Governor, the President of the Senate, the Speaker of the House, and the Attorney General, with the fifth member, the Chair of the Board, jointly appointed by the Speaker of the House and President of the Senate.

Concern 12: *The creation of a board will ultimately lead to litigation, costing the State and Maryland taxpayers money.*

Maryland taxpayers and State programs already pay significantly for the cost of high priced pharmaceuticals. The cost of litigation to defend a bipartisan law that protects consumers would be trivial in comparison to what the whole State pays for pharmaceuticals.

By creating a Prescription Drug Affordability Board now, the State stands to have a return on investment in the short-run from reduced costs for programs that pay for pharmaceuticals. It would save money for Medicaid prisons and for State employees. Savings can in turn be used to invest in other areas such as infrastructure and other health care needs.

Concern 13: *A rate setting board could affect national Medicare Part B payments and that should not be allowed.*

Maryland is a small state. To the extent that administered, infused, drugs come under the scrutiny of the Prescription Drug Affordability Board, Maryland health systems' percentage of total sales is too low to materially affect the Medicare program's average sales price (ASP) calculation. The ASP is reported by manufacturers to CMS and is the weighted by sales volume for their physician-administered drug. The volume of sales in Maryland, at a Maryland reimbursement rate, is not going to overwhelm the total volume in the calculation.

Concern 14: *A Prescription Drug Affordability Board will not help consumers with out of pocket costs or premiums.*

People pay a significant portion of drug costs out of pocket and the amounts are rising faster than drug prices.

The legislation specifies that a drug payment rate established by the Board is to apply throughout the supply and financing chain including pharmacy-insurer transactions, pharmacy-consumer transactions, insurer-consumer transactions, PBM-insurer transactions; and wholesaler-pharmacy transactions for entities operating in the State of Maryland. Thus, a consumer cannot be charged more than the payment rate at the pharmacy counter and a health plan cannot set copays or coinsurance on amounts greater than the reimbursement amount.