**PhRMA: Price controls on patented products are unconstitutional and run counter to patent law: PDAB** implements **a price control for certain medicines *by way of* an “upper payment limit” across all stakeholders in the supply chain**.

*Response:* An upper payment limit is the same as state healthcare rate setting, which the US Supreme Court unanimously affirmed state’s authority to do (Rutledge v PCMA). An upper payment limit that applies only to state-licensed healthcare entities is not a price control on manufacturers. In fact, the long-standing Maryland Health Services Cost Review Commission (HSCRC), which imposed limits on what hospitals will charge and what payers will pay for inpatient services (including prescription drugs) is constitutional. The point of the Maryland statewide, all payer, all hospital payment limit was to constrain hospital costs and force greater hospital efficiencies. The limit made no provision for how hospitals were to manage new high-cost drugs and devices. Hospitals had to negotiate. Neither PhRMA nor the medical device industry ever alleged that the MD HSCRC violated patent law. An upper payment limit would operate in the same way.

**PhRMA: PDAB does not solve the basic problem that drug company rebates do not flow to the patient when paying for a medicine at a pharmacy**.

*Response:* A well-functioning PDAB upper payment limit lowers the cost of a product at each stop in the supply chain*.* The point of an upper payment limit is intended precisely to get a lower cost to the patient at the pharmacy or other place of service. This is exactly the outcome PhRMA demands in its massive advertising campaign. An upper payment limit will necessitate on-invoice discounts rather than back-end secret rebates. A statewide all-payer upper payment limit is the only way to accomplish the dual goals of PhRMA – getting their price concessions directly to patients and reducing the need for rebates.

**PhRMA: The PDAB *could* affect prices out of state, which could be a violation of the Constitution’s Dormant Commerce Clause.**

*Response:* PDAB upper payment limits (UPLs) apply to all state-licensed healthcare providers, facilities, and organizations. A UPL applies only to drugs intended for sale inside the PDAB state. The UPL addresses some key criteria of constitutionality.

* It is intended to improve health and welfare of PDAB state residents.
* It builds on the existing pharma industry business model which provides different discounts for the same drug to different providers and different rebates to different health plans/pharmacy benefit managers. A UPL creates no new burden on the industry relative to the industry standard operating procedures.
* It does not require a manufacturer to change its list price, just as market price concessions do not change the list price of a drug.

**PhRMA: The price of a drug is not determined solely by drug manufacturers.**

*Response:* The national list price of a drug *is* determined by manufacturers. It is this national price that is the basis of PDAB review. Similarly, drug price increases are determined by manufacturers. It is the national, announced price increase that is the basis of a PDAB review. A UPL would mean that the supply chain does not get to affect/change what consumers will pay.

**PhRMA: The biopharmaceutical industry is already heavily regulated and discloses significant information to the public.**

*Response:* It is correct that the biopharmaceutical industry must comply with regulatory scientific standards, manufacturing standards and marketing standards. It is also correct that hospitals, clinics, laboratories, nursing homes, wholesalers, and pharmacies are heavily regulated for safety and clinical care.

The difference is that the pharmaceutical industry prices are not regulated whereas most other healthcare industry entities are regulated in the amount they can change for services. Those entities whose fees are not regulated are price takers, not price setters. The market works to constrain what non-pharma healthcare entities can charge or what they will be paid.

Our problem is that the biopharmaceutical prices are not regulated, and the market does not work to constrain those costs.

**PhRMA: A PDAB looks at the costs of approved medicines while ignoring the costs of the drug discovery and development process, and the failures in that process.**

*Response:* A PDAB would look at whatever data a pharmaceutical company chooses to provide to explain the cost of its product. Manufacturer provision of information is completely voluntary for a manufacturer. Confidentiality of that information is assured.

PhRMA states that it takes more than 10 years and $2.6 billion to bring a drug to market. Federal law in recent years has created several ‘expedited’ FDA approval pathways for companies – faster review, lessening clinical trial standards regarding number of participants and/or how efficacy is measured. A reduction in time and cost of trials for most drug approvals in recent years makes the 10-year-old, $2.6 billion data point outdated and irrelevant.

More recently, researchers[[1]](#footnote-1) found that the average cost of drug approval clinical trials was just $48 million for 101 drugs approved 2015-2017 that required 225 clinical trials. The per trial cost ranged from $20 million to $102 million. It is hard to see how to get to $2.8 billion/drug *average* R&D cost.

Other recent work[[2]](#footnote-2) used SEC filings for 63 drugs (of 355) approved between 2009-2018. They looked at reported R&D and estimated opportunity costs to arrive at an average per drug R&D cost of $1.3 billion. SEC filings require companies to report financial information that is important to current and potential shareholders, so lesser cost product R&D that is not material to shareholder decision making would not be reported. So, it is hard to see how average drug R&D is $2.8 billion.

**PhRMA: A PDAB *could* adversely impact innovation and harm a state’s economy.**

*Response:* Large pharmaceutical companies generate ~40-50% of their worldwide revenues from the US market. It has been estimated[[3]](#footnote-3) that for the 20 top-selling drugs in the global market, *just the difference* between US and EU prices is enough revenue to finance 176% of a US-based company’s global R&D (and 143% of global R&D spend for ex-US based companies). A state PDAB, with upper payment limits on some drugs, is not going to change that revenue dynamic.

**PhRMA: The industry offers to assist to develop market-based solutions that help patients better afford their medicines at the pharmacy counter.**

*Response:* PhRMA’s market-based solutions do not address the excessive cost of drugs that broadly, adversely, impact public and private healthcare financing systems. PhRMA is only concerned with:

* Preserving their market list price as “the price” so that other countries will not use it to set its drug prices.
* Keeping secret, the amount of their drug-specific price concessions to any and all customers.
* Somehow getting those price concessions directly to the patient to reduce out of pocket costs *while* maintaining secrecy of the price concession amount.
* Eliminating rebates without committing to dropping the price of drugs to a level equal to the rebate.

**How PDAB (model) legislation addresses PhRMA objections to *other* proposed drug cost containment policies**:

* No data is required of a manufacturer.
* Any industry data that is voluntarily provided remains confidential.
* PhRMA has a seat on the PDAB advisory council.
* The PDAB can use US market-based price concession data to determine a UPL (rather than international prices or other methods that are not market-based).
* The PDAB is not punitive to drug manufacturers.
* The PDAB is designed to improve access to important drugs without no intention to reduce company revenues
	+ A PDAB action would increase product sales at lower cost relative to lesser sales at higher cost.
1. BMJ June 11, 2020 [↑](#footnote-ref-1)
2. JAMA March 3, 2020 [↑](#footnote-ref-2)
3. Health Affairs Blog March 7, 2020 [↑](#footnote-ref-3)