

# Horvath Health Policy

## *Innovations in Healthcare Financing Policy*

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### Testimony of Jane Horvath before the Pennsylvania House Health Committee Concerning State Prescription Drug Cost Containment Policies February 25, 2020

Thank you for the opportunity to testify about what states are doing to constrain the growth of prescription drug costs. This is such an important and complex issue. This hearing is very important in helping the residents of the Commonwealth understand why drug costs are so high and what the potential state-level policy approaches could be.

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 in 1990. I have been working with many states since 2016 on prescription drug policy. Arnold Ventures (formerly the Laura and John Arnold Foundation) funds my much of my current work with community groups, legislators, and state agencies. I spent over ten years working in the pharmaceutical industry. Even though I have deep respect for the work of the pharmaceutical industry, I worry that the industry is so roundly despised because of their pricing behavior. The pricing model is broken, and I do not see a path forward other than public policy to address the problems.

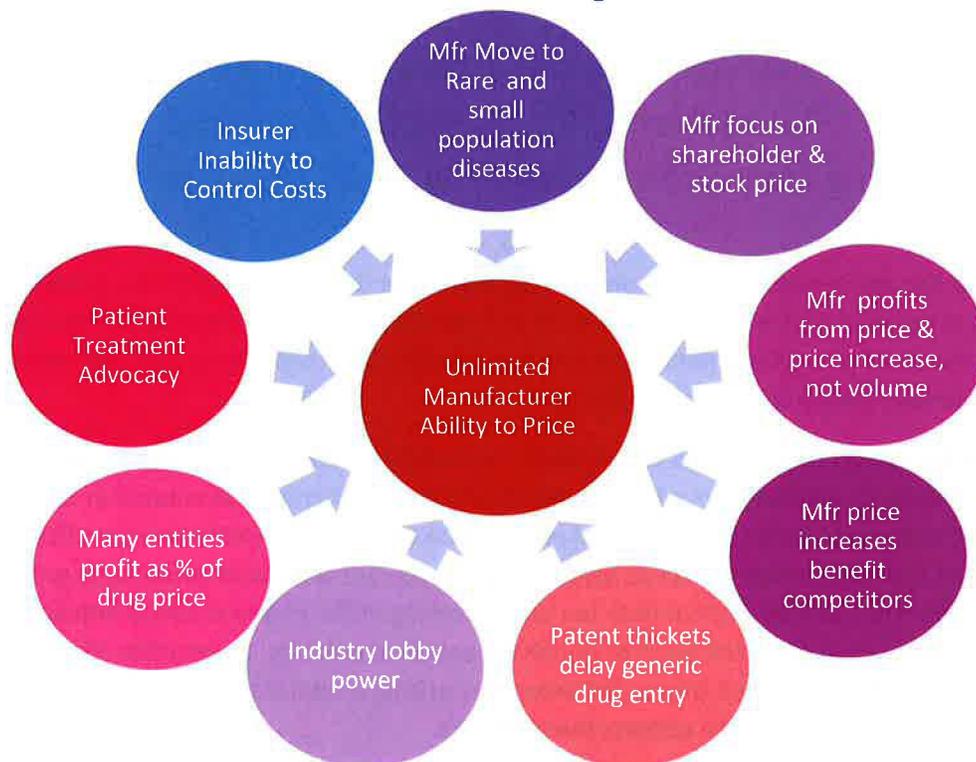
We all know many facts and figures concerning drug costs. I want to stress just three facts today that can help properly size the issue of high drug costs.

- 1) The pharmaceutical industry cites that prescription drugs are ten percent of total national health care spending. Importantly, the [federal analysis](#) that generates the ten percent data point includes *many* types of spending that we don't tend to think of as 'healthcare spending'. Included in the total are salaries and benefits for the employees who run Medicare and each state Medicaid program, research funds of the National Institutes of Health, healthcare facilities maintenance, nursing home care and so on. The denominator is huge. Finally, the ten percent includes only retail drugs, not most of the newer biologics that are provided in physician settings rather than retail settings. So, the numerator is unrepresentatively small, and the denominator is very large. The industry data point is not meaningful.
- 2) Prescription drug costs account for about 25 percent of our healthcare premiums<sup>i</sup> which exceeds the proportion spend on provider services.
- 3) State taxes support some or all the pharmacy benefits for 25-30 percent of residents in many states.<sup>ii</sup> State governments and state residents have a large stake in constraining drug spending.

I would like to describe key features of the U.S. pharmaceutical market and why we are in the current situation of growing numbers of extremely high cost drugs that create real financial challenges for patients, providers and payers/health plans. I will also review the variety of state and pending federal initiatives that are intended to start to turn this situation around. Finally, I think it is important to

understand the federal barriers that constrain different types of state action on prescription drug cost containment.

## How We Got Here in Pharmaceutical Pricing



This graphic summarizes all the component factors that have created the situation we have today in biopharmaceutical pricing. This constellation of factors has always existed, but to lesser degrees than exist today and with less synergy between the factors. This is all legal activity. This is not malicious activity. This is business activity that supports stock price for shareholders and executive leadership, seemingly to a greater degree than in the past. Stock price is a key performance metric for the industry and drives decision making. The importance of stock price is an externality at this point, it is not something that any single company can address, which is why I think public policy is important in this market.

I would also add that the pharmaceutical industry speaks about the value of their products. The reality is that any product is of high value to the patient for whom the product improves or extends life. But an invaluable product is not necessarily an affordable product.

As the amazing biotechnology science rapidly evolves to produce wonderful, meaningful products, society's inability to manage the costs of these products without very significant trade-offs inside and outside of healthcare has grown even faster than the technology.

I like to make a rough analogy to the value of clean water, the value of telecommunications, electricity, or public transportation to our health and welfare. State governments have worked since the earliest days of these industries to assure that these valuable, vital services are affordable to consumers.

“Affordability” is the piece that is missing from the biopharmaceutical market and from the discussion of how to think about pharmaceutical costs. The federal government has been slow to act but assuring health and safety has certainly been the ambit of state governments going back almost to the founding of the country.

In this next section, I would like to review the different policy approaches states have taken to try to address prescription drug costs and perceived problems in the market.

## State Drug Cost Constraint Policy Initiatives

State drug cost containment policies are iterative and build over time within states and across states. The first group of policies are focused more on creating transparency or more in the private sector. The second group of policies affect state program operations.

### Policies Focused on the Private Sector

#### State Transparency Laws and Proposals

##### *Manufacturer Drug Price Transparency:*

Requiring transparency of the prescription drug market is an important first step for states. Transparency is one of the few policy areas where a legal challenge can be avoided, depending on how the transparency policy is structured. However, drug companies have still sued California, Pennsylvania, and Oregon – three of the very first states to enact drug industry price transparency laws. The California and Oregon lawsuits are ongoing; as you know, the industry dropped the Pennsylvania lawsuit after agreement on how trade secrets data would be protected. These laws require companies to submit data justifying their pricing decisions. CA and OR also require companies to provide a 60-day advance notice of price increases. (I discuss this issue in the context of the section on trade secrets later in this testimony.)

State activity around drug price transparency is on hold until the lawsuits are resolved. I will say that Oregon HB 4005 was implemented without challenge but once the legislature enacted the 60-day advance notice of price increase amendment, the industry filed a challenge.

##### *Health Plan and PBM Coverage, Cost, and Rebate Revenue Transparency*

At the drug industry’s urging, state legislative policy shifted to collecting information that inform the public about the role of the entities that finance coverage of prescription drugs. The prescription drug industry takes great exception to high patient cost sharing and the amount of price concessions they provide to pharmacy benefit managers operating on behalf of health insurers. The industry also wants to show that the highest cost drugs account for only miniscule portions of healthcare insurance premiums, which is an interesting tactic.

So, while any one drug may be a very small part of the healthcare premium dollar, collectively, spending on pharmaceuticals is a very significant part of health plan spending and pharmaceutical costs are a major driver of premium increases.

Concurrent with the industry’s interest in more disclosure about how PBM’s function, the pharmacy benefit management industry was, and remains, under the policy microscope in many states because of their impact on independent pharmacies – notably underpaying independents relative to national chain pharmacies, with the effect of driving independents out of business.

The result of these two policy concerns was an array of bills in almost all states that started to regulate heretofore the unregulated PBM industry. The PBM bills established transparency of sources of revenue and how much revenue is shared with health plan clients. More importantly perhaps, the new laws regulated the business relationship between PBMs and pharmacies, setting new rules for contracts and fair dealing. The laws that regulate contracting between PBMs and pharmacies that have been [challenged in court](#) by the PBM trade association, the Pharmaceutical Care Management Association (PCMA). PCMA maintains that the state laws regulating their business relationships violate federal ERISA laws and are thus preempted. There is a total of six PCMA challenges, three of which PCMA has won, one where the state won and three pending cases. The Arkansas Attorney General asked the US Supreme Court to hear their case (*Rutledge v PCMA*) and the Court decided in mid-January to do so. Over 30 states filed an amicus brief in support of Arkansas. There is clearly quite a bit at stake in almost every state in the outcome of *Rutledge*.

I think there is an issue with how PBM/health plan contracts are structured that may impact drug prices and a preference by the PBM for higher cost drugs with higher rebates. I think many PBM/insurer contracts are structured so that the PBM guarantees an average rebate of x% of the health plan pharmacy spend; product-by-product rebates may not be passed through to health plans in favor of this guaranteed average amount of rebates as a percent of total pharmacy spend. To the extent that a lower cost (but still costly) product is on the market without a rebate, that could disrupt the math of existing contracts. Covering the lower cost drug that does not have a rebate may add to the 'spend' and may decrease rebates as a percent of pharmacy spend. (Obviously, the effect would depend on the drug cost and anticipated utilization among other factors.) I don't know that the outcome of this type of contracting is intentional, but I do think there is can be an incentive in that structure that is not fully consistent with the goal of lower drug prices at the pharmacy counter.

#### Caps on Patient Drug Cost Sharing

Colorado was the first state to cap patient cost sharing for insulin products to \$150 per month. There are bills in many states now to impose cost sharing limits on health plans. Some of the bills would cap cost sharing for all drugs to a monthly limit, most bills specifically address insulin.<sup>iii</sup> The insulin cap is expected to have only a negligible impact on healthcare premiums in Colorado. But Colorado has one of the healthiest populations of any state. I am not sure that premiums would remain unaffected by a copay limit in a state with a high prevalence of diabetes or in states that enact very low-cost sharing limits for all drugs.

Cost sharing caps are very consumer-friendly and important, but they do not address the fundamental problem of high prices for life saving medicines. I believe that high patient cost sharing is a *symptom* of the drug pricing problem, not simply a matter of healthcare insurers being ruthless.

#### Emergency Insulin for People Who Cannot Afford Insulin

An alternative to the insulin cost sharing cap is a creating an emergency fund for coverage of insulin for people who cannot afford their insulin. Four states have some version of this legislation introduced.

#### Penalties for Generic Drug Price Gouging

Maryland enacted the first law in 2017 to provide for legal and financial penalties for unconscionable price increases of generic drugs. This first law was found to be unconstitutional in the federal 4<sup>th</sup> Circuit Court of Appeals as a result of a challenge by the generic industry trade association, Association of

Accessible Medicines (AAM). It was found to impact prices outside the state which was, in this case, found to be a violation of the Dormant Commerce Clause. This year, nine states have introduced price gouging bills that improve upon the language of the Maryland law with the intent to sustain the law in a legal challenge.

#### Importation of Prescription Drugs from Canada

Federal law allows the Secretary of the U.S. Department of Health and Human Services to (HHS) approve wholesaler or pharmacy importation of drugs from Canada provided that the approved entity can assure significant consumer savings and create a health risk to consumers that is no greater than the current U.S. drug supply system. I developed the [model](#) legislation that most states are using and in drafting it, it seemed to me that the only way to meet the two federal law criteria would be to have a state administered program. Federal HHS seems to agree; their newly proposed rules specify that only programs run by states will be approved.

A 2018 analysis by [pharmacychecker.com](#) found that fully 70 percent of the top 100 U.S. prescription drugs are manufactured overseas and brought to this country. Federal law limits public importation to Canada, which may create supply limitations since the population of Canada is about 37 million people. The population of Florida (one of four states with importation laws) has a population of about 21 million people. Federal law also prohibits the importation of biologics, a category of drug that is very expensive and driving the spending increases of insurers. Importantly, insulins and vaccines are biologics.

Nineteen states have wholesale importation bills introduced for their 2020 legislative sessions (as of February 19, 2020).

#### Prescription Drug Affordability Boards (PDABs)/Statewide Upper Payment Limits

Two states enacted limited versions of a PDAB last year. At least eight states have introduced full-scope PDAB bills so far in this 2020 session and there are another five have bills with major features of a full drug affordability board.

In order to truly constrain the costs of prescription drugs, it is important to achieve at least three things: get lower cost drugs to the pharmacy counter/physician office, create price transparency throughout the supply chain, and think about affordability rather than drug “value”. A PDAB can accomplish those things.

The model for a PDAB is state regulation of public services and utilities – found in all states, going back to the early 1900’s. A public service commission limits what consumers will pay for vitally important public services such as electric, water, telecommunications, and so on. Certain drugs are as important to life and health as clean water or electricity. Electricity is generally affordable even though it is extremely valuable; the same can be said for clean water. A public service commission regulates monopolies; arguably certain high cost drugs also hold monopoly positions in the market for a period of time. A public service commission has a public process, ombudsman, appeals and judicial review rights for the regulated entity as a PDAB would have.

Years and years ago, public services were owned locally. Today like drugs, public utilities are owned by regional or even national companies and states set different consumer payment rates. This is exactly how the a PDAB would operate. A PDAB would establish a state-specific Upper Payment Limit that would apply to certain drugs that are for sale within a state. A PDAB would not set a national price for a

drug. A PDAB would not ‘value’ a product; clinical value would be the responsibility of medical professionals and health plans. A PDAB, like a public service commission, would balance affordability with support for invention.

A PDAB would ensure that the state’s healthcare systems could afford the drug and that all people in need of the product would have affordable access to the drug. It should mean more sales for a company – reducing manufacturer profits is not the goal here. The goal is affordable access for all residents of a state – not just government payers and programs.

## Policies Focused on the Public Sector

### Consolidation of the Medicaid Pharmacy Benefit

States have debated whether to have each Medicaid managed care plan operate its own pharmacy benefit or whether the pharmacy benefit should be consolidated at the state level and managed as part of the fee for service pharmacy benefit. A permutation of this debate is to keep the pharmacy benefit in each health plan but require a unified drug formulary across fee for service and all managed care plans.

States literally have gone back and forth on this question over the many years I have been involved in Medicaid. I can see the policy weight behind consolidating the pharmacy benefit in fee for service and not with each managed care plan. There would be one pharmacy benefit manager contract. The state would have more market heft to negotiate supplemental manufacturer rebates. States could do more with its pharmacy and therapeutics committee and its drug utilization review board. States could also have more control over claims billing and payment of 340B entities who can charge Medicaid managed care plans market rates on drugs they purchased at Medicaid-level discounts. In contrast, billing fee for service, a 340B entity must decide if it will bill market rates without using a 340B discount drug, or if it will bill fee for service at (very low) 340B acquisition costs. Given that the 340B program is worth \$24 billion dollars and tens of thousands of providers participate, this is not an insignificant consideration for Medicaid decision making on how to manage pharmacy benefits.

### Multi-Agency Drug Procurement and/or PBM Contracting

Several states, most notably California, are working toward consolidation of pharmacy benefits and drug procurements across all state agencies that procure drugs or pay patient drug claims. These are complicated but potentially productive initiatives. The complexity occurs in different procurement processes across agencies, agencies that both procure drugs, agencies that pay claims, agencies that do both. Agencies have different PBM contracts with different contract expiration dates. Different drugs may be driving the spend in different agencies. California is a year into their process and recently announced that it will negotiate for drugs prices for the entire state and refuse to pay more than the lowest price anywhere. (They also announced their intent to manufacturer generic prescription drugs, which is certainly within reach.)

Other efforts to consolidate procurement and pharmacy benefit operations include the state collaborative of the National Governors Association. The NGA supports executive branch efforts to constrain prescription drug costs. There is also an organization called SMART D which is developing a guide to multi-agency purchasing.<sup>iv</sup>

Washington State and Oregon jointly administer an organization, the Northwest Consortium, that provides drug discount cards for the uninsured and employees of participating employers who want this

service. NW Consortium also operates what is essentially a PBM for Oregon and Washington state agencies, commercial insurers and employer plans. Rebates are fully passed through to plans and all participation is on a voluntary basis. The Consortium can include additional states.

Other states are determining if their multi-agency procurement or PBM contracting could include the private sector, which Oregon and Washington currently do.

## Federal Constraints on State Action

There are number of very significant federal-level constraints on state drug cost containment policy.

### Caselaw

In general state options are limited for taking the next step after transparency -- tackling prescription drug costs because of federal law and federal court rulings. We have an Appeals Court decision that says states cannot limit the price of a brand drug because it violates federal patent law that confers unlimited ability to profiteer from an innovation. In the same case, the court also ruled that limiting a manufacturer's drug price violates the dormant commerce clause *if* the state uses a price from another country or other state.<sup>v</sup> There is federal case law that limits state ability to create fair business practices in PBM contracting with pharmacies in the state because those fair business laws could disrupt the PBM ERISA plan book of business (discussed earlier).

### FDA law

In addition to federal case law, federal food and drug laws currently limit state importation programs to Canada, which will likely limit how many states can create wholesale importation programs without a change in federal law. States with an interest in importation need to more aggressive getting support of their congressional delegations for simple changes to the current law. Vermont, Maine, Florida and Colorado are working to implement their 2018 and 2019 importation laws. Ten other states have importation proposals before their legislatures this year and several governors are supporting wholesale importation.

### Medicaid law

Medicaid Best Price Law Limits Commercial and State Agency Price Concession Negotiations: Federal Medicaid law can have a limiting effect on programs such as the multi-agency drug bulk purchase initiative announced by the California Governor in January 2019 and the new 2020 initiative. Unlike *federal* agencies and *federal* programs whose drug discounts are exempt from the Medicaid Best Price calculation<sup>vi</sup>, the drug discounts of *state* agencies and programs are not exempt from best price calculation. While federal programs can get deep price concessions, state agencies cannot. State agencies are quite hobbled and will find it hard to do better than the basic Medicaid discount of roughly 23 percent. This is part because only state Medicaid can know what the Medicaid best price is for any drug. Without knowledge of that best price, non-Medicaid state agency price negotiators don't know where the bottom is and are likely to be limited to no more than the federal minimum Medicaid discount of 23 percent. Of course, it remains to be seen how the market power of California will change this dynamic.

Medicaid Law Limits Formulary Management:

Interestingly, federal law limits Medicaid agencies ability to drive deep discounts beyond what federal law requires. This is because federal law prohibits state Medicaid programs from managing a drug benefit formulary in the same way that commercial insurers and their PBMs can. Private insurers can create a restrictive formulary -- the insurer can choose one drug in a class rather than its competitors based on the price concession the manufacturer offers. Such formulary management can drive manufacturer discounts or rebates which allows health plans to better manage costs. Large PBMs now exclude coverage of more than 100 drugs but the federal government has said there is no authority that would allow this in Medicaid.

Medicaid Drug Rebate Law Limits Medicaid Ability to Join Multi-Agency Cost Containment Initiative:

The Medicaid law's restrictions on formulary management, and its best price provisions can make it difficult (but not impossible) to include the Medicaid program in multi-agency drug contracting. Medicaid could participate through a parallel process for collective negotiation using the existing supplemental rebate agreement structure. Whatever is achieved by the multi-agency group could be translated into a supplemental Medicaid rebate. But there are a lot of other factors at play in this scenario.

## Trade Secrets Laws and Legal Challenges

Most if not all states have laws that protect trade secrets. There is a federal trade secret protection law enacted only in 2016.

The pharmaceutical industry has a very expansive view of what is a trade secret, perhaps overly expansive. The industry generally contends that trade secrets that secure legal protection are merely items of value to a company -- those items could be business confidential information for which the company should have the responsibility to protect itself without trade secret protection.

Another way to think of trade secrets deserving of legal protection should be something that, if revealed, changes the terms of market competition for the relevant products.

Advance notice of price increases is an interesting issue in this context. The industry has sued both California and Oregon on the law that requires 60-day advance notice to health plans of price increases. The industry contends that advance notice to health plans, and if more broadly revealed, are a violation of trade secrets laws. (The industry has several other grounds for objecting to these notice provisions.) However, one could argue that notice of a price increase would only marginally, and only temporarily, change the terms of competition -- if it changes the terms of competition at all.

After the first mover acts to raise a price, the price increase of a competitor product is not truly a trade secret -- even when revealed in advance -- since history shows that competitive products generally shadow each other in price increases and launch prices.

To the extent that notice of price increase is made public, it only has a momentary effect on competition, if any effect at all. If announced price increases affected the market, then the same market effect should occur when a company *publicly* announces their price increase (as they publicly do). We would expect people and institutions to stockpile the other drugs in the class when the first price increase is announced, because they would estimate the size of the price increase of the rest of the

drugs in the class and stockpile those drugs in advance prices of expected increases in those products. But stockpiling doesn't seem to happen once the drug class leader announces their price increase. Arguably, if stockpiling does occur under the industry standard operating procedure of public announcements of these things, then advance notice of a price to a state agency doesn't change anything in the market that would amount to a violation of trade secrets protections.

Industry defends as trade secret the retrospective reporting to states of old data representing decisions already made, decisions that can be seen in the marketplace – such as advertising or drug price. Every drug manufacturer knows the cost of an advertisement in *JAMA* or the *New York Times*. They all know what it costs to buy ad time during the Superbowl or the network evening news. And one can visibly see the ad buys. It doesn't seem that the information should be considered a secret at the point in time for which states request the information – the past.

Finally, I would point out that most of what states want to know, and what the industry is loath to produce, is in the public sphere somewhere but you must dig to find it. It is easiest to have the industry report the data rather than spending lots of state resources cobbling together the information from all the different public, but obscure, places.

A few cases in point:

- In 2018, the World Health Organization published a report on the Return on Investment of company oncology treatment R&D – and it was 14:1.
- Academic researchers published in *JAMA* that their search through SEC filings to trace reported R&D for ten oncology treatments identified \$7.2B in R&D and later, \$67B in revenue from those ten drugs.
- Researchers publishing in *Health Affairs Blog* found that US-based pharmaceutical companies earned 176 percent of their worldwide R&D budget from the portion of US drug prices that exceeded the prices of the drugs charged in other countries.

The information used to produce these analyses came from somewhere. Most likely the companies under study did not provide the data.

I think we would be well-served by a clearer, more focused, definition of a trade secret. The definition should support invention and not be a shield for pricing behaviors that harm patients and our health care system.

## How Congress Can Help States Innovate on Drug Cost Policies

Congress can help states innovate and test new drug cost containment strategies with a few changes to federal law:

- In the Food Drug and Cosmetic Act, expand the list of countries from which a state-administered wholesale importation program may import to the EU and Japan, rather only Canada.
  - Allow these state programs to import biologics, which are safely imported today and include products like insulin and vaccines.
- Clarify that patent law does not limit state ability to protect the health of residents in the regulation of the price of patented products.

- Clarify that any state has authority to regulate in-state commerce even when that regulation causes a global, national or regional out of state company to take specific actions relative to the product that is sold in the particular state (authority similar to state authority over public utilities and insurance, both of which are multi-state operations, if not national).
- Exempt state government drug cost control initiatives and programs from Medicaid best price calculations – thereby extending the same privilege to states from which federal agencies and programs already benefit.
- Allow Medicaid rebates to fully capture the impact of manufacturer price increase behavior by eliminating the cap on rebate amounts and allow rebates to exceed 100 percent of the price if manufacturer price increases produce this actual result. Current law caps manufacturer rebate obligations to 100 percent of the price.

### Take-Aways/Key Aspects of State Pharmaceutical Cost Reforms

- State policy should focus on affordability, not value. Something that is very valuable is not necessarily affordable.
- Create price transparency throughout the supply chain all the way to point of service (which importation and PDAB would do) to get lower cost products to the pharmacy counter.
- Move the system to on-invoice discounts rather than post-payment rebates.

Thank you for the opportunity to share my thoughts on this very important public policy issue.

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<sup>i</sup> America's Health Insurance Plans, March 2017 and Harvard Pilgrim spending analysis in Health Affairs Blog August 24, 2018,

<sup>ii</sup> The calculation would include State and local government employees and retirees, public school system employees and retirees, prison system employees, dependents, retirees; inmates; higher education employees, dependents and retirees; student clinics; Medicaid enrollees – all as a percentage of the total state population.

<sup>iii</sup> About 34 states have insulin copay limit legislation introduced, including PA.

<sup>iv</sup> Both these organizations have support from Arnold Ventures, a foundation that has different areas of focus, one of which is prescription drug costs.

<sup>v</sup> PhRMA BIO lawsuit against the government of the District of Columbia.

<sup>vi</sup> Manufacturers report to CMS their best price in the US market to any purchaser or payor. That best price discount then must be given for all Medicaid utilization of that product in all states. Medicaid covers about 71 million people, to creating a new best price for a drug is significant for a manufacturer. A best price is created to the extent that the discount exceeds the base Medicaid rebate of 23% of the wholesale price.

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## Appendix A

### Federal Initiatives

#### Federal Drug Price and Cost Initiatives

The Administration and Congress have both worked on policies that, if enacted or implemented, would definitely help lower the cost of prescription drugs for consumers and our healthcare system

#### Federal Legislation

##### House HR 3

The House has passed and sent to the Senate HR 3, which is an innovative approach to lowering prescription drug costs by allowing/requiring the federal Medicare program to 25 drugs from the top 250 most costly drugs in Medicare that lack price competition. The upper bound of the price negotiation would be the weighted average price of the drug in six specified countries. The penalty for failure to negotiate would be an excise tax of 65 percent on manufacturer revenues increasing each year to the limit of 95 percent.

The outcome of Medicare price/reimbursement negotiations would be a public price, listed in the Federal Register, which means that reimbursement amount would be available to all other payers and purchasers to establish their payment and reimbursement amounts.

The bill is remarkable in that would accomplish the essential element of what we need to reform the drug price conundrum we face: price transparency and a de facto end to rebates so that the lower cost drug travels through the supply chain with a transparent price all the way to the point of service.

The Senate is unlikely to take up a vote on the House bill specifically

##### Senate Finance Committee-passed Bill

The Senate Finance Committee with jurisdiction over Medicare and Medicaid produced a bill that would lower drug costs in Medicare and do a little bit for Medicaid. It is a good bill for the Senate, although it does not have the broad potential to reform our current oblique pricing system through the supply chain.

#### Federal Administrative Action

The Trump Administration has put forward a variety of proposals to constrain prescription drug costs that do not necessarily need congressional action (although congressional action would help). There have been many proposals but only couple merit discussion here as having the probability of successful (unchallenged) implementation. I believe the efforts of the Administration are all in good faith. They are creative and if allowed to go forward, each proposal would be effective in incrementally tackling our prescription drug price problem.

##### Wholesale Importation of Prescription Drugs

Four states have enacted laws that require the state to seek federal approval to create a program of wholesale importation of drugs from Canada. Federal law limits such a program to drugs from Canada, which is a significant limitation on the prospects for importation as more states, such as Florida, want to

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create such programs. Federal law prohibits the importation of biologics from Canada; it is well known that the real cost drivers in pharmacy spend are biologics, including insulin.

The Administration put forward a Notice of Proposed Rulemaking that is generally facilitative of state wholesale importation. However, a federal rule cannot overcome the limitations of federal law. If Pennsylvania is interested in importation, it really must pursue federal legislative changes through its congressional delegation.

#### International Pricing Index (IPI)

Although there has been no recent forward movement on this proposal, it would limit Medicare Part B biologic reimbursement to 126 percent average of prices in 17 industrialized countries. This proposal has hit a wall of resistance from manufacturers, physicians and even patient groups who have various concerns and fears that needed drugs will become unavailable.

#### Other Administrative Actions

There are other Administration proposals that have been abandoned such as outlawing drug rebates in the Medicare and Medicaid programs, requiring manufacturers to post the list price of a drug in its direct to consumer advertising, and cutting Medicare hospital reimbursement for certain hospitals to capture for Medicare the savings of the low cost 340B program drugs that certain hospitals access.

I think the importation rules and program have the greatest likelihood of moving forward although the industry will likely sue the Administration on whatever basis it can. Even if the Administration is not sued, the federal limitations will remain significant barriers outside the control of the Administration.