Why is a PDAB Important?

The price of drugs continues to escalate – even during a global pandemic. A June 2020 Gallup survey found that 90% of Americans worry that drug companies will take advantage of the pandemic to raise drugs prices. In July 2020, drug prices increased 3.5%, in addition to the January 2020 average 6.8% increase. The public has reason to worry.

Drugs prices continue to rise and are increasingly unaffordable for the average consumer; escalating drug prices force insurers to increase premiums for all of us. Government programs are similarly challenged to manage ever rising drug costs in the context of budgets that must provide an array of services to large populations. A PDAB with statewide authority to set upper payment limits for some high cost/high spend drugs can help patients, payers, purchasers, and providers manage this increasingly challenging situation. The Appendix provides a quick review of the trends among the most expensive drugs and what these drugs mean for prescription drug affordability in the future.

How Would a PDAB Work:

A PDAB would operate much like a state's public service commission – determining what consumers will pay and suppliers can charge for vital public services. PDAB, like public service commissions, would balance consumer affordability with revenue needs of suppliers – revenues that allow service improvements. The public service commission analogy is apt because the drugs of concern to a PDAB will be drugs that hold a relative monopoly position – drugs with only one or few competing manufacturers where the price increase of one company is followed by the other drugs with similar therapeutic effects.

A PDAB Would Not Regulate Manufacturer List Prices

The PDAB would regulate in-state charges and payments for a particular drug among state-licensed healthcare entities – wholesalers, other distributors, pharmacies, hospitals, physicians, and insurers. This would be done by setting an "upper payment limit" (UPL) for certain high cost drugs. UPLs are common in the healthcare industry – limits to what insurers will reimburse. So, a statewide UPL places limits on what can be billed and paid statewide. The UPL uses the standard operating procedures of the existing supply chain where supply chain participants negotiate price concessions and those negotiated price concessions are fulfilled by wholesalers. In the routine business practice, wholesalers are "made whole" financially by manufacturers. This process happens today when a manufacturer raises prices but Medicare and Medicaid (or other insurers) have not updated their reimbursements. This also happens when a new, very costly, drug or device comes to market, and its costs are not covered by the existing Medicare (or other insurer) reimbursement. Manufacturers routinely adjust their price concessions through negotiations with providers or the supply chain when payer reimbursement does not cover the product list price.

How Would a PDAB Decide the Amount That Can Be Billed or Paid for a Drug?

Every PDAB will approach their task differently. The overarching goal of any PDAB is to find the upper payment limit (UPL) at which insurers, purchasers, and government programs can afford to provide the drug to everyone in the state who should get the drug. The point of an UPL is to *expand* sales and patient access. The purpose is not to reduce manufacturer revenue for a drug.

Most likely, the PDAB will access publicly available pricing information – some of which will come from subscription data services that track drug prices and price increases –pricing files. There are many such services but these two links give a sense of the service available: Medispan or FirstDataBank. There is also a dataset from SSRHealth that estimates the commercial rebates in the US market for brand name drugs. (ICER has used this dataset that is commonly used by the industry and academic researchers are also beginning to use it to examine market behavior.) A PDAB will also consult with state payers and purchasers to learn, confidentially, their net costs for a drug the PDAB is studying. Another data point would the Veterans Administration National Contract Price and Federal Supply Schedule (FSS)[1] prices, each of which are publicly available. All these public and publicly available data points will help a PDAB establish an affordable price that is benchmarked against *current US market conditions*. This is a quite different approach than benchmarking US prices to international prices. It is also vastly different from price controls. A PDAB would examine what is already available in the US market and be able to discern the best discounts in the existing market to set state-wide upper payment limit based on existing US market information.

Examples of US Market Pricing That a PDAB Might Use in Analysis

The following examples are from public databases, which may be subscription-based. The data are average costs/prices across all the national drug codes (NDCs) of a product. A PDAB could sort the data in different ways to arrive at more precise information. These data points are based on information about prices in the U.S. market, which is why there are not more drug examples provided because the commercial market prices and discounts are not readily available without a paid subscription service for list prices and commercial market discounts.

Rheumatoid Arthritis/Autoimmune: Drug Channels reports that the rheumatoid arthritis drug Humira (costing $60,000/year) is sold to US public and private hospitals in the federal 340B program for $01/unit.[2] The estimated average Humira commercial market rebate is about 30-40% and the discounts to the VA and the FSS top out at 70%. The annual cost of Enbrel is $67,000 and the estimated average market discount is 35%, while FSS and VA discounts are over 50%. A PDAB would have those data points plus net cost data from state-licensed health plans when considering an upper payment limit.

Diabetes: The pricing of insulin can be difficult – annual usage, pens, vials, concentrations, long acting, short acting. There are a variety of ways to compare prices but in general, a vial of insulin, which lasts 2 weeks to a month for a patient, costs about $300. Newer insulin biosimilars such as Basaglar (~$81/pen) and Toujeo (~$160/pen) are estimated to have private market discounts of 60-75% which could be a starting point for PDAB consideration. Lantus and Levemir (~$168/pen and ~$397/pen respectively) are in the market with estimated average discounts of 70-75 percent.

Multiple Sclerosis: Healthline reported 2019 *monthly* treatment costs of Aubagio (~$4,760), Gilenya (~$5000/month) and Rebif (~$5,200/month). The estimated average commercial discount is 8%, 22%, and 26% respectively, while the FSS and VA discounts are 30% to 40% for Aubagio and Gilenya, but 84% for Rebif.

[1] Sometimes the FFS price might be higher than market but that could be due to changes in the market during the period of the FFS contract.

[2] 340B 2019 total sales are estimated to total $30B, or 8% of total US drug sales. *Drug Channels* July 23, 2020.

Oncology: Ibrance costs $13,000 for 21 capsules and Imbruvica costs $13,500 for 28 capsules. Average commercial discounts are estimated at 12% and 9% respectively while FSS discounts are the same or slightly better and VA discounts are above 30%. A newer drug, Perjeta costs about $93,500 per year[3] with an estimated average commercial market payer discount/rebate of 10% and a VA discount of 35%.

In addition to knowing price and costs in the national market, a PDAB would learn the net cost to payers, purchasers, and patients for a drug in the PDAB's state. A PDAB may decide to establish a UPL that provides an even lower cost if that is what is needed to make the drug affordable for everyone in the state.[4]

It is important to understand that if the only action a PDAB takes is to convert the current average price concessions in the market to an upper payment limit for the drug in the state, the entire supply chain will benefit from those price concessions and those discounts will get to patients. Without a conversion of a post-sale rebate to an on-invoice discount, the pharmacy pays and charges close to list price and insurers must reimburse the pharmacy. With a change from rebate to on-invoice discount, the upper payment limit becomes the basis of the pharmacy purchase cost and then its charges, which benefits the patient at the pharmacy counter and benefits the insurer because the UPL lowers pharmacy billings and insurer payments. So even if a PDAB did no more than take the estimated average discount in the market as the statewide upper payment limit, that ensures that large and small insurers obtain *at least* the average discount. Payers who received bigger rebates could certainly continue to pay even less than the UPL. Moving back-end rebates to front-end discounts creates transparency which addresses a significant problem in the market that hurts consumers.

The PDAB could decide that the upper payment should be the upper end of the average US market discount or something altogether different if the current market activity still does not provide affordability.

How is Drug Affordability Different from Value Based Pricing?

A focus on affordability starts with the idea that at a certain cost, health plans and consumers can afford to get needed treatments. When drug costs put stress on the healthcare financing system, patients and consumers suffer with high out of pocket costs and lack of access. The drug industry wants us to see each drug as a separate financing issue when in fact, the healthcare financing systems (health plans, government, patients and consumers) have to pay for all drugs for all the people who need them. The perfect example of this was Hepatitis C treatments Sovaldi and Harvoni. These drugs had a high cure rate for Hepatitis C – an epidemic at the time – at a cost of $100,000 per course of treatment. A $100,000 treatment for an epidemic is a problem from a financing point of view. Part of the reason we still have a Hep C epidemic is the high cost of treatments –even at their current, much-discounted cost. Hep C treatment is important for society, but so are all the other drugs we must finance for everyone. Premiums cannot go sky high and governments need to have resources to fund all the other important government services we expect. That is affordability.

[3] A 14ml dose costs $5,500 and is typically given every 3 weeks (17 doses).
[4] There are issues concerning Medicaid best price that would have to be considered by a PDAB that can be worked through using these data sources.

Value, in contrast, attaches a monetary amount to a drug that represents all the different ways a drug helps an individual and even society. Researchers with strong ties to the industry have recently suggested that it is appropriate to monetize the value of mitigating fear, the value of the treatment relative to the severity of the disease, the value of hope the treatment brings and other elements. In other words, the price of the product should reflect absolutely every individual and societal benefit. Which truly will not be affordable for any one drug much less every drug.

In fact, if these products are virtually priceless with respect to public health and well-being, then perhaps they should be regulated like public utilities whose actual value to society is almost incalculable (clean water, telecommunications, electricity, public transportation). State entities determine what consumers will pay to balance consumer access and service innovation in these vital utilities and services.

Does an Upper Payment Limit Violate the Constitution's Commerce Clause?

The federal government does not get sued for violations of the Dormant Commerce Clause (DCC), only states can be sued. The Federal government, by virtue of the Constitution, regulates all commerce between the states; states regulate in-state commerce even if state action has some effect outside the state. This notion is not written into the Constitution but has been the logical, legal extension of the Commerce Clause.

Because the pharmaceutical market segment is so complex and so opaque, the pharmaceutical industry has been able to capitalize on lack of knowledge relative to the Commerce Clause. The industry uses the complexity of its business model to make the point that virtually any law is utterly onerous for them and radically upends their standard operating procedure. This in fact, is not the case.

Caselaw on the DCC has, until recently, held that a state may regulate in-state commerce that might have out of state impacts *if* any of the following are true:

- The benefits to consumer health and safety outweigh the impact on trade outside the state;
- The state action is not intended to benefit business located in the state to the detriment of out of state competitors;
- The action does not affect the price of a good outside of the state relative to the price of the good in the state (state law cannot demand that a supplier's in-state product price must be lower than the supplier's price in a neighboring state);
- The action is taxation of business with sales in the state but not located in the state; or
- The impact on industry activity outside the state is minimal and only incidental to complying with the state law.

Two more recent Court rulings[5] found that regulating the manufacturer prescription drug price is a violation of the DCC. While these two rulings are questioned by legal scholars, regulating the charges

[5] Association for Accessible Medicines v. Frosh, 887 F.3d 664 (4th Cir. 2018) (state price gouging law barred by dormant Commerce Clause); Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362 (Fed. Cir. 2007) (District manufacturer price limits ruled a violation of dormant commerce clause).

and payments of state-licensed healthcare entities and supply chain participants does not affect the manufacturer national list price for a drug. A statewide UPL also:

- Provides benefits to consumer health and safety that outweigh the impact on trade outside the state;
- Does not benefit in-state business to the detriment of out of state competitors operating in the state;
- Does not affect the manufacturer price of drugs to any purchaser of drugs destined to another state;
- Does not exclusively target the in-state sales of businesses located outside the state; and
- Has only incidental impact on manufacturer operations outside the state.

Why Establish a Statewide Upper Payment Limit Rather Than a Direct Price Control?

A direct price control on a manufacturer will be hard, if not impossible, to enforce. Manufacturers set the factory price and then negotiate drug discounts with large direct purchasers, like drug wholesalers. Wholesalers in turn negotiate price concessions with the people and entities they supply with drugs they purchased from a manufacturer. Pharmacies or doctors' offices determine what they will charge the patient and bill the insurer for the drug. The manufacturer is far away from that final transaction and should not be held accountable by a state for that transaction.

A statewide upper payment limit, in contrast, uses the everyday operations of the supply chain, pharmacies, providers, and insurers. Negotiations between sellers and buyers will meet the obligations of state-licensed healthcare entities to pay and bill no more than the upper payment limit. These UPL-related negotiations will be a subset of all the discount negotiations going on around the country every day.

A manufacturer may also strike price concession deals with large purchasers such has hospitals. But those hospitals buy from wholesalers. Wholesalers sell the drug at the price discount to which the manufacturer and hospital agreed. Then the wholesaler goes back to the manufacturer with a bill for the difference between what the amount the wholesaler sold the drug to the hospital and what the wholesaler paid the manufacturer for the drug originally

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These negotiations between manufacturers, large purchasers such as wholesalers and large end user purchasers like hospitals happen repeatedly for all sorts of drugs for all manufacturers everyday. The UPL uses the industry business model of negotiated price concessions for drugs intended for sale in the PDAB's state.

Appendix

The Most Expensive Drugs, Period

August 2020, GoodRx, https://www.goodrx.com/blog/most-expensive-drugs-period/

Rank	Drug Name	Manufacturer	Annual Cost/course of treatment	
1	Zolgensma	AveXis, Inc	$2,125,000	*spinal muscular atrophy*
2	Myalept	Amryt Pharma	$855,678	*lipodystrophy*
3	Luxturna	Spark Therapeutics	$850,000	*retinal dystrophy*
4	Folotyn	Acrotech Biopharma	$793,870	*T-cell lymphoma*
5	Brineura	BioMarin Pharmaceuticals	$716,040	*Batten disease*
6	Soliris	Alexion Pharmaceuticals, Inc	$678,392	*blood disorders*
7	Blincyto	Amgen, Inc	$672,968	*acute lymphoblastic leukemia*
8	Ravicti	Horizon Therapeutics	$664,092	*urea cycle disorders*
9	Lumizyme	Sanofi Genzyme	$643,243	*Pompe disease*
10	Actimmune	Horizon Therapeutics	$633,325	*osteopetrosis, granulomatous*

*This list includes prescription drugs and drugs only administered by a healthcare professional

The drugs listed above are generally for rare diseases – diseases that affect a limited number of people. However, it is estimated that

A specific industry strategy is to pursue treatment areas where insurer cost containment power is reduced, the disease is life threatening, and there are few treatments available. Each disease affects a relatively limited number of people so we tend to accept extremely high prices. But, up to 15% of the US population (49 million people out of 330 million) has either a rare disease (affecting fewer than 200,000 people) or a disease that is life threatening in the absence of treatment and affects a relatively small number of people:

- Rare diseases – 25M people
- Cancer – 1.7M people
- COPD – 16M people
- Lupus – 1.5M people
- MS -- 1M people
- Epilepsy – 3M people
- Sickle Cell – 1M people

If treatments are $1 million or $2 million per year per person for each drug that treats these diseases, these products will become 'financially toxic' for people who need them and our healthcare system. We are going to have to find a way to afford these products so that people have real access to them without becoming bankrupt. If we can afford these products, manufacturers will sell more than if we cannot afford these products, so innovation will be rewarded. A Prescription Drug Affordability Board will establish the costs at which access is assured and innovation is appropriately rewarded.