***Why We Need a Prescription Drug Affordability Board (PDAB)***

*Why is a PDAB Important?*

The price of drugs continues to escalate – even during a global pandemic. A June 2020 Gallup [survey](https://news.gallup.com/poll/312641/nine-concerned-rising-drug-costs-due-covid.aspx) found that 90% of Americans worry that drug companies will take advantage of the pandemic to raise drugs prices. [One hundred companies](https://patientsforaffordabledrugs.org/2021/01/14/2021-price-hikes-pr/) raised prices on 636 drugs in the first days of 2021 with the median increase of 5% and those were only the early announcements. In 2020, prices were raised an average of 5.5% on 860 drugs. The public has reason to worry. List prices are the basis of what pharmacies pay and what patients pay.

Drugs prices consistently [rise](https://www.goodrx.com/blog/drug-prices-growing-faster-than-commodities-and-services/) faster than inflation and rise higher than other consumer goods. As a result, drugs 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 and diverse 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 most likely 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 the charges and payments made for a particular drug among state-licensed healthcare entities – wholesalers, other distributors, pharmacies, hospitals, physicians, and insurers. The PDAB would set an “upper payment limit” (UPL) for certain high-cost drugs. UPLs are common in the healthcare industry – limits to what providers and suppliers charge and what insurers will reimburse. A statewide UPL limits what can be billed and paid statewide. The UPL uses the standard operating procedures of the existing supply chain where supply chain participants negotiate what they will charge and what they will pay. Manufacturers routinely respond to this market dynamic every day for every drug in every market. Manufacturers routinely adjust their charges through negotiations with providers or the supply chain when payer reimbursement does not cover the providers cost to stock the product.

*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 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. The PDAB function is not punitive.

Most likely, the PDAB will access publicly available pricing and cost information – some of which will come from subscription data services that track drug prices and price increases (called pricing files). There are many such services but these two links give a sense of the service available: [Medispan](https://www.wolterskluwercdi.com/price-rx/) or [FirstDataBank](https://www.fdbhealth.com/applications/drug-pricing-analysis). There is also a dataset from [SSRHealth](https://www.ssrhealth.com/dataset/) that estimates the commercial rebates in the US market for brand name drugs. 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](https://www.va.gov/oalc/foia/library.asp#two) and [Federal Supply Schedule (FSS)](https://www.va.gov/opal/nac/fss/pharmPrices.asp)[[1]](#footnote-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 price and price concession 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 (all different package sizes and dosage strengths). 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. Policymakers could start to estimate savings by comparing current state employee claims costs/spending for the drugs below with costs/spending if there was a UPL set at one of the discount benchmarks provided below.

*Rheumatoid Arthritis/Autoimmune:* Drug Channels reports that the rheumatoid arthritis drug Humira ([costing $60,000/year](https://www.reuters.com/article/us-abbvie-fda-idUSKCN1V61MJ)) is sold to US public and private hospitals in the federal 340B program for $01/unit.[[2]](#footnote-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](https://www.enbrel.com/support/financial-support) 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](https://www.goodrx.com/blog/how-much-does-insulin-cost-compare-brands/) 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](https://www.healthline.com/health-news/ms-why-are-ms-drug-prices-so-high-071913#1) 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.

*Oncology:* Ibrance [costs](https://www.drugs.com/medical-answers/ibrance-cost-3539523/) $13,000 for 21 capsules and Imbruvic a [costs](https://www.drugs.com/medical-answers/imbruvica-cost-3539120/) $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]](#footnote-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 could learn the net cost to state payers, purchasers, and patients for a drug. A PDAB may decide to establish a UPL that provides an even lower cost than state payer net costs if that is what is needed to make the drug affordable for everyone in the state.[[4]](#footnote-4)

It is important to understand that if the only action a PDAB takes is to convert the current average payer/manufacturer rebates to publicly known, publicly required discounts in the state supply chain, the entire state supply chain will benefit from those discounts. Those discounts will have to travel through the supply chain to patients at the point of service (rebates to payers by their very nature do not/cannot benefit the supply chain). So even if a PDAB did no more than take the estimated average discount in the market to create a statewide UPL, large and small insurers would obtain *at least* the average discount. Payers who negotiated bigger rebates could certainly continue to lower their net costs.

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?*

Affordability starts with the idea that at a certain cost, health plans can afford to provide ready access to 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 and insurance premiums rise.

The drug industry wants us to see each drug as a separate financing issue when in fact, our 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. Per patient cost $100,000 treatment for a widespread disease epidemic is an obvious 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.

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 or monetize the value of the treatment relative to the severity of the disease, or monetize the value of hope a treatment brings to patients. In other words, the price of the product should reflect absolutely every individual and societal benefit. This pricing scheme will only create unaffordable treatments.

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.

*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 discounts with large direct purchasers, like wholesalers. Wholesalers in turn negotiate price concessions with the people and entities they supply with the 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 not involved in that final transaction and should not be held accountable by a state for the charges and payments of 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.

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

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.

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. [↑](#footnote-ref-1)
2. 340B 2019 total sales are estimated to total $30B, or 8% of total US drug sales. *Drug Channels* July 23, 2020. [↑](#footnote-ref-2)
3. A 14ml dose costs $5,500 and is typically given every 3 weeks (17 doses). [↑](#footnote-ref-3)
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. [↑](#footnote-ref-4)