White Paper

Battling the Big Squeeze

How understanding demand and margin can improve brand performance

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Impact of COVID-19 on the pharmaceutical industry

At the time the "Battling the Big Squeeze" whitepaper was moving through the final stages of editing, news of COVID-19 was just beginning. The impact on our daily lives has been, at least in the short-term, significant to say the least. With the increase of social distancing becoming reality, there will also be an impact on nearly every aspect of the pharmaceutical industry.

IQVIA is closely watching market, brand, payer, prescriber, and patient trends amongst many others. News of nearly every manufacturer moving to a work from home environment, healthcare professionals limiting visitors to the office to only those in immediate medical need, and many people deciding to stay home will impact demand and manifest itself in both top- and bottom-line revenue pressures. The longer the disruption lasts, the more pressure we will see.

At the core of the big squeeze is the combination of demand and margin pressures. Specifically called out is the impact on eroding market size as one of the factors that contributes to the challenges. As such, the impacts of COVID-19 could include:

DEMAND PRESSURE

- Fewer treatment naïve patients seeking care – at least in the short term
- Declines in rep access impacting the ability to detail prescribers which will make it harder for brands to move market share
  - » This may be a benefit to incumbent products as market share erosion from competitive switching slows
  - » Prolonged declines of rep access could also necessitate a shift in promotional mix
- Launch products being adversely affected as both patient inflow and prescriber access are simultaneously curtailed
- Patient, payer, and pharmacy pushing to mail order and increasing 90-Day utilization
- Distribution challenges threatening supply chain management and active ingredient availability
- Patient care disruption driven by economic rationalization impacting patient adherence, and subsequently, patient value
- An increase in the use of telemedicine as patients and providers seek to limit in-person interaction
- Many others…

MARGIN PRESSURE

- Top-line pressures escalating the need to tighten access spend
- Shifting patient demand from Commercial channels into Medicaid could impact the total cost of access as patients move to more costly payer channels
- Revenue leakage through contract management, 340B de-duplication, and copay spend will take increased focus as manufacturers work to preserve revenue

- Downstream impacts on SG&A being driven by both top- and bottom-line challenges
- Many others…

PUBLIC PRESSURE

- Policymakers are already called upon to address healthcare reform and patient affordability, which could could be exacerbated by an economic downturn, vulnerability in the supply chain, and calls for pricing regulation

With uncertainty on the duration or magnitude of the COVID-19 impact, the entire world is moving into unchartered waters. We must collectively deal with a rapidly evolving social, economic, and political landscape.

Globally and within the US, IQVIA is well positioned to help clients strategically identify how, where, why, and when challenges in demand and margin will impact business, operations, and strategic decision-making. Through gaining a better understanding of demand and margin forces, our clients are better informed and prepared for dealing with both known and unknown challenges as they emerge from this situation.

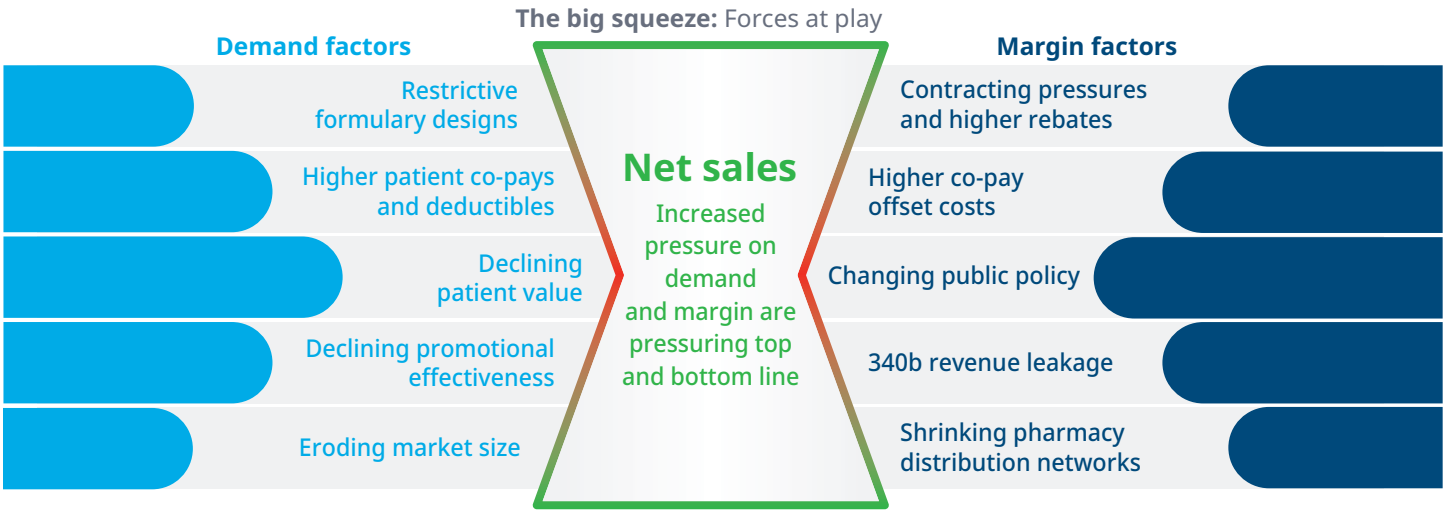
Thanks,
Luke Greenwalt
VP Market Access Center of Excellence

Introduction

Brands everywhere are under pressure, as both demand and margin challenges converge. Symptoms of the big squeeze can be seen in cut budgets, restricted and/or misallocated sales resources, incorrect financial accruals, investment uncertainty, and more missed forecasts than can easily be counted. Manufacturers across the industry – large and small – struggle to diagnose and adjust to market and margin dynamics in time to to be effective in developing and implementing mitigation strategies.

Just a few of the end results are the year-over-year continued downward pressure on net sales, the turnover of brand and market access teams, the cutting of SG&A expenses, the inability to invest and innovate, and the kicking of the proverbial can down the road by burdening future launches with unrealistic sales expectations.

The Life Sciences industry is under more pressure today than at anytime in its history. In this whitepaper, we will look at several demand and margin factors that impact brand performance as well as strategies and tactics that manufacturers can explore to help battle the big squeeze.



Demand factors

The last decade has seen an increase in the frequency and effectiveness of payer restrictions. At the same time, patient cost sharing has inflated due to the expansion of high cost health plans, the increased prevalence and magnitude of deductibles, and most recently, through the introduction of copay accumulator adjuster and maximizer programs by the large PBMs. Greater utilization management and higher cost sharing has resulted in declines in demand efficiency – or in simpler terms, a brand's batting average.

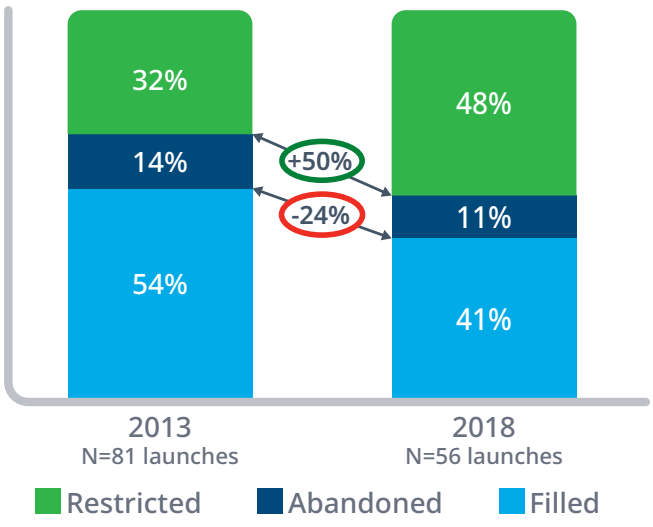
DEMAND EFFICIENCY

Demand efficiency measures how likely a patient is to, first, negotiate access and formulary barriers and to, second, pay their cost sharing portion. The end result for a successful patient is a filled prescription. Demand efficiency is best measured by examining new patient behavior - or as it is more commonly known – the NBRx.

Since 2013, demand efficiency in the Commercially insured market for newly launched products has declined by nearly 24%, while at the same time, utilization of payer restrictions has grown by 50%. These statistics reflect the increased review time that payers are taking for new launch products and the usage of prior authorizations/step edits/NDC blocks to restrict utilization amongst other key drivers.

In practical terms, this change in demand efficiency requires brands to work harder to maintain historical levels of demand. For example, in 2013 across all launch products (products were equally weighted), for every 1,000 new to brand patients, 540 patients successfully filled, one-year post launch. In order to get the same number of 540 new patients in 2018, a brand would have to generate more than 1,300 new patient attempts - or nearly 1/3 more demand than five years prior. While that may be possible for some markets, many new products are geared towards smaller patient populations or are later entries into established markets - thus lowering the likelihood of matching historical demand analogs. Misunderstanding true demand and the impact on market sizing is one of the key failure points for new launch products and complicates understanding promotional effectiveness.

Figure 1: Commercial new patient utilization management, 1-12 months post-launch

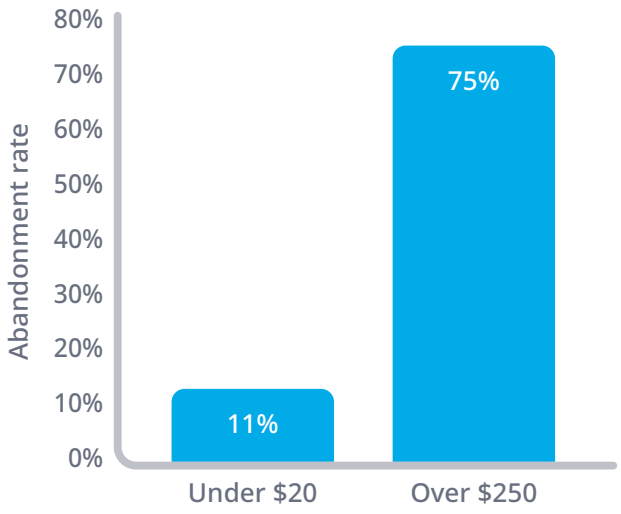


Source: IQVIA Analogue Performance Library

PATIENT BEHAVIOR

Patients are being asked to pay more than ever before. Numerous patient demand studies have proven that the more patients are asked to pay, the less likely they are to do so – even for much needed, often life-saving, medications. The impact on patient behavior of prescription cost can be seen through examination of IQVIA's longitudinal patient data sets. For example, in 2018, nearly 25% of all new to brand prescriptions were abandoned with clear differences in abandonment and adherence existing between patients who were asked to pay under $20 to those who were asked to pay more than $20. For patients asked to pay over $250, the average abandonment skyrocketed to greater than 70% - or 7 out of 10 new patients abandoning prescription therapy.

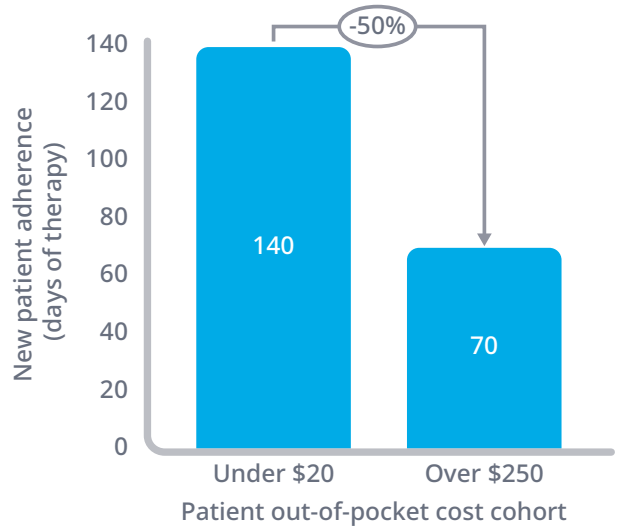
Figure 2: 14-day new-to-product abandonment rate (all payer channels, 2018)



Source: IQVIA LAAD Dataset

Not only are patients more likely to abandon prescription therapy based upon high cost sharing, but they are also less likely to be compliant over time. In a measurement of adherence in 2018, it was observed that patients who were asked to pay more than $250 were only half as adherent as those who were asked to pay under $20. **Cost sharing is indeed a very effective barrier to prescription utilization.**

Figure 3: 14-day new-to-product adherence (all payer channels, 2018)



Source: IQVIA LAAD Dataset

Complicating the examination of these demand drivers is a high degree of variability. Demand efficiency and payer utilization management are different by therapeutic category, order of entry in the market, degree of innovation, patient demographics, time of year, payer, and payer channel, amongst many other dynamics. Additionally, there can be significant variations by geography with patients in California potentially behaving differently than those in Texas or New York.

The combined effect of greater utilization management and higher cost sharing has significantly eroded demand efficiency over time. Today's patients are much more likely to face payer access restrictions and much less likely to navigate them than at any time in the past decade. Even when they do successfully navigate payer access, many are still faced with significant cost sharing hurdles further eroding patient demand and, for the brand, "patient value", as patients discontinue therapy earlier.

Margin factors

The big squeeze is not limited to functions of patient demand. Increased rebate pressure, payer consolidation, higher copay offset costs, greater 340B utilization, and higher statutory rebates like Coverage Gap liabilities are just a few of the market dynamics also driving down margins. So, for the prescriptions that manage to get through the demand barriers, their value is not what it used to be.

Gross to net pressures have caused many manufacturers to alter strategy, make drastic restructures, and drive mergers and acquisitions thereby leading to many other difficult downstream decisions that have contributed to industry volatility. Effectively managing these dynamics is complex, as there are many intertwined drivers that need to be addressed.

Further complicating margin dynamics is the potential for significant market disruption due to altering public policy. Current policy proposals from President Trump (American Patients First - APF), the US Senate (Prescription Drug Price Reduction Act – PDPRA), and the US House (HR.3) are also in the process of being debated, which could have significant impacts on manufacturer liabilities for years to come.

ACCESS REBATES

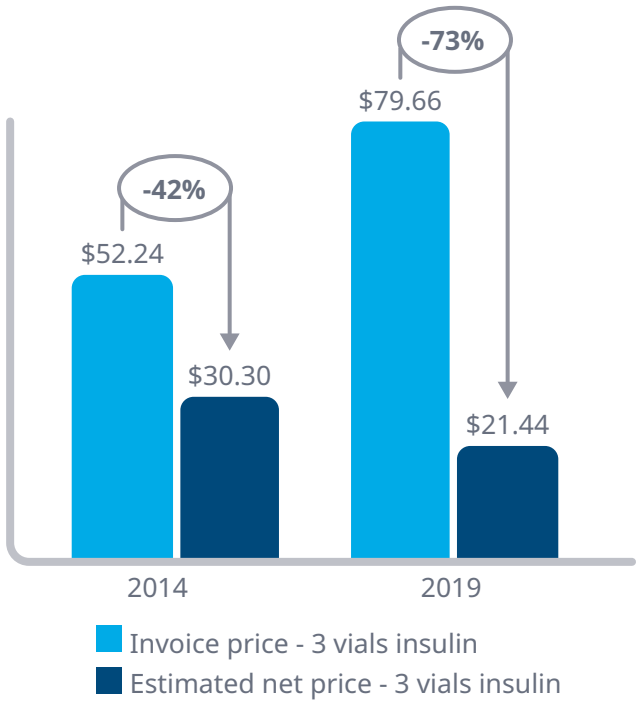
The cost of access has increased over the past decade with many drug classes impacted by higher rebates, resulting in lower realized net prices for manufacturers. As an example, the diabetes class represents a large retail market where significant increases in the cost of access have occurred in a very short period. While there are multiple factors that have led up to the current levels of discount, the net result has seen a significant decrease in margin.

THE BIG GET BIGGER – PAYER CONSOLIDATION & INTEGRATION

Adding to pressure on access rebates is the consolidation of major contract entities, the continued integration with specialty pharmacies, and the closing of distribution networks. With the recent announcement that Express Scripts and Prime Therapeutics will share the ESI contracts and distribution networks, the big payers continue to gain market leverage.

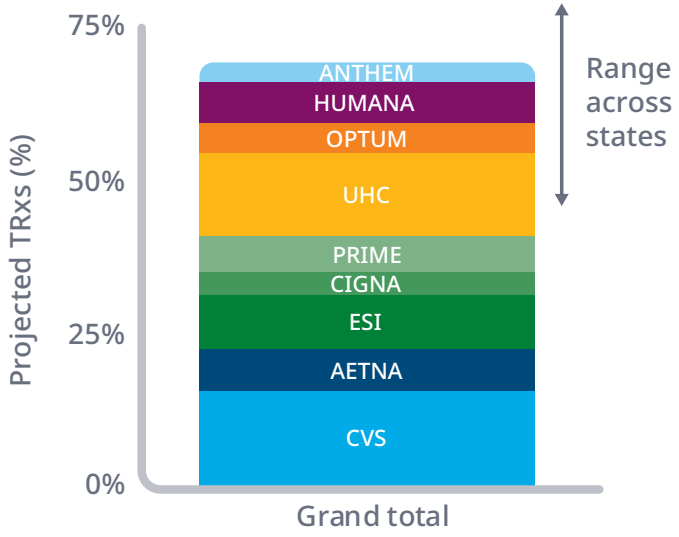
In 2018, the nine largest contract entities made up over 75% of the total prescription market – of those nine entities, seven now share some form of relationship either through merger or partnership. The cost of gaining access increases as payers grow, gain market share, increase the footprint of contracted books of business, force volume into limited distribution networks, and become more effective at enforcing restrictions through improvements in technical infrastructure.

Figure 4: Average cost of 3 vials of insulin, invoice and estimated manufacturer net revenue



Source: IQVIA Institute, National Sales Perspectives, Dec 2018

Figure 5: Distribution of projected TRxs by contract entity (commercial and Medicare Part D, 2018)

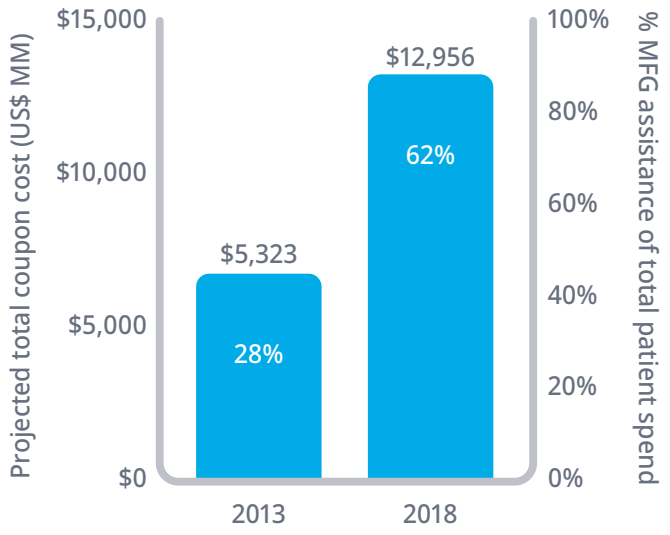


Source: IQVIA analysis

COPAY OFFSET COSTS

Higher patient cost sharing has, in part, been offset in the Commercially insured market through the utilization of patient access and affordability programs. However, this has come at a cost to manufacturers as the total level of investment has more than doubled over the past 5 years. In an IQVIA analysis of copay offset expenditures across all brands, copay offset buydowns totaled $5.3 billion in 2013. By 2018, buydowns had reached $13 billion when $6 out of every $10 dollars of Commercial patient cost sharing was offset by manufacturer assistance.

Figure 6: Projected total coupon cost trends (all pharmacy brands, commercial)



Source: IQVIA LAAD and Projected datasets

Key drivers in this trend are the mix of retail vs. specialty products, higher levels of cost sharing, increased prevalence and magnitude of deductibles, full cost manufacturer buy-downs in lieu of payer coverage, greater proliferation and penetration of copay programs, and most recently, the introduction of payer controls like copay accumulator adjusters and maximizers.

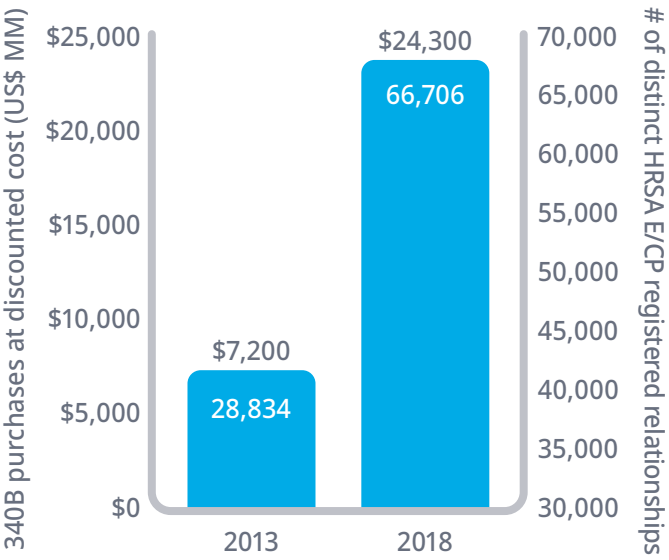
Another driver of increased copay offset costs is the misuse and abuse of copay programs through cash discount cards and program fraud. High cost claims and misaligned program benefits drive up overall program costs and must be rigorously monitored.

340B - BUY LOW SELL HIGH

The 340B program is a drug discount program enacted by Congress that requires drug manufacturers to provide outpatient drugs at significantly reduced prices to qualifying entities (aka covered entities). Manufacturers must participate in 340B in order to receive Medicaid coverage for their products. The program is designed to aid the covered entities spread thin resources and help more patients.

Over the past five years, the industry has seen the number of qualifying covered entities grow from approximately 23,000 in 2013 to nearly 45 thousand in 2018, directly resulting in expanded utilization of the program. Adding to this complexity is the dramatic increase of contract pharmacy relationships with covered entities, which over the same period grew from roughly 28,000 to more than 66,000. With no requirement that savings be passed back to patients, covered entities are free to use the discounts earned as they see fit, creating profit incentives to utilize the program.

Figure 7: 340B purchases at discount and growth of contract pharmacies



Source: HRSA Covered Entity and Contract Pharmacy Daily Reports active entities at 12/31 of given year accessed June 2019

The margin challenge created by 340B utilization is caused when contracted pharmacies inappropriately process or dispense a product purchased under the program. By law, the covered entity is required to exclude any claim that is subject to a Medicaid rebate amongst other restrictions. In reality, enforcement and government oversight are lax, which results in double, triple, and in some cases even quadruple dipping when 340B is misused. All these scenarios quickly erode prescription value with many cases resulting in net negative revenue where a prescription is costing a manufacturer more than they receive.

THE DONUT HOLE

The Coverage Gap, or as it is more colloquially known – the Donut Hole – is a phase of coverage in Medicare Part D where manufacturers are required to pay a statutory rebate of 70% for all prescriptions consumed by eligible patients. Growth in Coverage Gap liabilities are driven by population demographics, shifts in Part D benefit designs, and overall drug spend of the enrollees. Predicting these trends is challenging as many of the underlying data points are not readily available to manufacturers and require a fully wholistic analysis of patient populations and patient spend.

Over the past several years, there has been volatility in manufacturer Coverage Gap liabilities as benefit designs have changed. A significant change from 2018 to 2019 occurred when the Coverage Gap rebate increased from 50% to 70% amongst other benefit design changes. Unfortunately, forecasting changes is not as easy as accruing additional rebates. Many manufacturers struggle to accrue accurately for Coverage Gap liabilities leading to both under, and over, accruing. This can result in scrambling to cover shortfalls or needlessly tying up revenue on the balance sheet that could have been invested elsewhere.

This year (2020) will also see benefit designs change as the patient spend limit for Catastrophic coverage increases by 25% to $6,350. That means that there will be more Coverage Gap eligible prescriptions consumed as patients stay in the Gap for longer than they did in 2019. Like past benefit design changes, the resulting impact from the new Catastrophic threshold will be difficult to predict because not all patients who enter the Coverage Gap will exit it.

PUBLIC POLICY UNCERTAINTY

Currently, there are multiple legislative proposals being discussed. While APF, PDRPA, and HR.3 come from across the political spectrum, there are several overlaps between the differing proposals where agreement is possible. These overlaps include policies that would expand the utilization of the Consumer Price Index (CPI) penalties into Medicare, a reshaping of the Medicare Part D phases of coverage, and a restructuring of statutory manufacturer liabilities. All three proposals are designed to improve the long run stability of Medicare, reduce overall CMS liability, rein in drug pricing, and reduce patient cost sharing.

CPI PENALTY EXPANSION

CPI penalties and best price policies exist in the Medicaid channel today and come into play when manufacturers take price increases greater than the Consumer Price Index, which is closely tied to the rate of inflation. At the core of how these penalties work is that when a manufacturer increases price faster than the rate of inflation, the additional increase is rebated back to the Medicaid payer. For example, if a manufacturer takes a 10% price increase, and the CPI index is 2%, they will be required to pass on an additional 8% discount to Medicaid payers until such time as the brand reaches penny pricing.

PENNY PRICING is a term in Medicaid used to describe when a manufacturer is paid one cent for a product at which point rebates are equal to or greater than the price of the drug. This is possible due to the price increase penalties a brand might incur as well as best price rebate requirements. Penny pricing also extends to 340B discounts.

The proposal to expand CPI penalties into Medicare would act as a form of price protection and greatly increase the cost of access for brands who take moderate to large annual price increases. With price protection clauses common in many Commercial payer contracts today, CPI penalties in Medicaid, and the expansion of pricing penalties to Medicare, the net result to manufacturers would be nearly to negate the practice of annual price increases. This change would place great pressure on the industry to get pricing right upon launch as the tools to change price over time are legislatively removed. Importantly, while price increases may become more difficult to realize, high prices are not prohibited. The end result may very well be higher launch prices as manufacturers look at future market dynamics when setting launch pricing strategy.

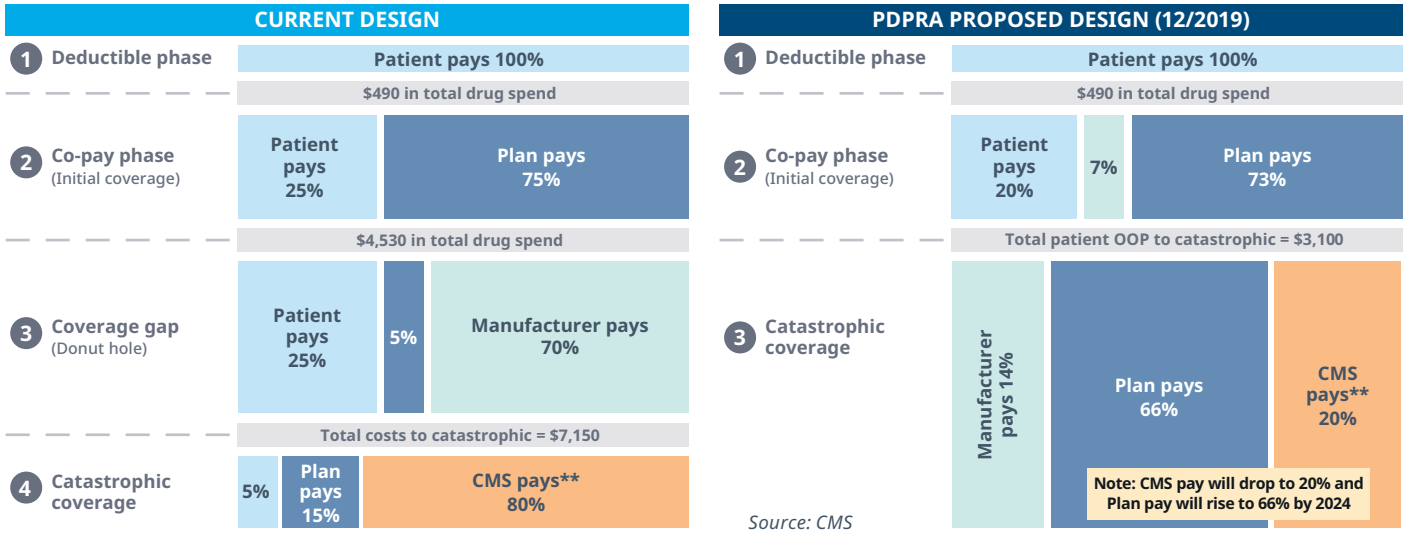
MEDICARE PART D BENEFIT REDESIGN

As previously mentioned, the last few years have seen substantial changes, and subsequent financial challenges for manufacturers concerning Coverage Gap liabilities under the current Part D benefit design. New proposals emerging from Congress would further make substantive changes by eliminating patient out of pocket in the Catastrophic phase of coverage, altering patient benefit designs, and changing how statutory manufacturer rebates are calculated.

The reduction in patient out of pocket is significant as patient cost sharing in Medicare Part D is routinely cited as a reason for patients not to seek care, rationalize the care they do seek, and to take – or not take - prescribed medications. The barriers created by today's cost sharing structure make it difficult for patients living on fixed incomes to afford medication consistently. The elimination of patient cost sharing in the Catastrophic phase of coverage provides an important political rationale for enacting benefit design changes. Understanding how changes to cost sharing impact demand should be a high priority for manufacturers as the impact on top and bottom-line revenues will be important to forecast accurately.

In addition to limiting patient out of pocket, the proposed polices would also collapse the Coverage Gap and associated statutory rebates. Replacing the Coverage Gap liability would be a new structure which would levy rebates throughout the early phase of coverage and introduce a new "Catastrophic Rebate." Additionally, the current portion paid for by CMS in the Catastrophic phase of coverage would decrease dramatically with a large portion passed back onto the plan.

Figure 8: 2024 Medicare Part D standard prescription drug benefit design



Source: CMS

PUBLIC POLICY UNCERTAINTY

While the actual manufacturer and plan responsibilities are yet to be determined, the shift from today's benefit design will have significant consequences on manufacturer margins and payer per member per year costs (PMPY). Under the current benefit design, high cost medications do not face the same level of Coverage Gap rebates as less expensive medications. Patients consuming high cost brands move through the current phases of coverage and quickly reach the Catastrophic phase where the manufacturer no longer incurs Gap rebates, plan responsibility drops to 15%, and CMS responsibility jumps to 80%. As such, legislators and CMS are concerned that the increased utilization of specialty priced drugs will continue to be a cost driver to the government.

The proposed changes will alter rebate dynamics such that all products will incur a statutory rebate throughout all phases of coverage instead of just during the Coverage Gap. The introduction of an initial phase rebate, collapsing of the Coverage Gap rebate, and introduction of the Catastrophic Rebate will impact manufacturers and brands differently. Depending on the market, brand, and patient dynamics retail brands may benefit as costly Coverage Gap rebates of 70% are replaced with a lower, more consistent, initial and Catastrophic phase rebate. However, high cost specialty brands could see overall liabilities skyrocket as statutory rebates are now owed on a larger patient population and throughout the entire year.

Regardless of how the change in statutory rebates impact an individual brand or manufacturer, the shift of Catastrophic costs from CMS to payers will have downstream consequences. Today, payers are reliant on CMS picking up 80% of Catastrophic costs. As CMS' contribution reduces, the cost shift to payer PMPY will have significant actuarial impact. Payers will only have a few tools to mitigate the PMPY cost of these legislative changes – increase member premiums, increase rebates, and/or increase formulary and network restrictions. Since the first will be difficult to do and maintain a competitive position in the market, the more likely immediate outcome will be increased contracting pressures driven by much tighter, and more restrictive, formulary and network management.

Understanding how policy proposals impact demand and margin is important for manufacturers as legislative changes will disrupt current market dynamics. The policies discussed in this paper are only a few of the many different proposals currently being debated. As political tides ebb and flow, getting in front of the possible changes requires flexibility, a strong analytic approach, and a wholistic understanding of patient populations and their spending.

Battling the big squeeze

With so many complex market forces converging at the same time, developing mitigation strategies can be difficult even for the most advanced and well-funded in the industry. Many demand and margin dynamics are interrelated where decisions made on one side of the ledger impact the other. It is no wonder that so many have been caught in the pressures of the big squeeze and that it often seems like you are chasing your own tail into a downward spiral of budget cuts and missed revenue expectations.

Addressing demand and margin pressures requires a wholistic and detailed view of a brand, market, and patient population. The need for strategic execution, gross to net precision, and flexibility increases as margin pressures mount.

STRATEGIC EXECUTION

Not all prescriptions are created equal, and significant subnational variation exists. Differences in baseline payer rebates, exposure to high cost health plans, payer density & footprint, payer channel mix, and population demographics are just a few of the dynamics that can impact prescription, patient, and market value. Knowing

and growing where value is highest is one strategy that can be implemented without radically altering field force deployment, contracting, or patient acquisition/ retention strategies.

Three questions that can help drive discourse on strategic execution are:

1. Where is your most valuable territory?
2. Who is your most valuable prescriber?
3. What is your most valuable contract?

While these three questions may seem simplistic, the answers can be very complex. By answering these questions, insights into the range of value can also be determined to find the least valuable, and more costly, business segments which can be reduced in priority or otherwise be addressed.

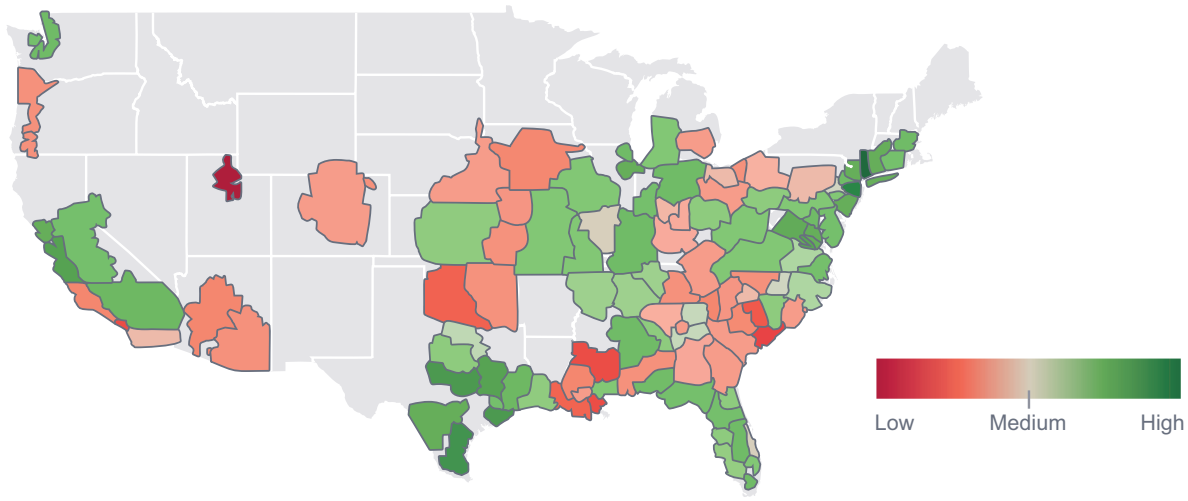
distribution costs, or brand-specific margin drivers that impact value.

A key element to this approach is understanding demand efficiency and net patient value. The impact of payer restrictions and patient cost sharing can dramatically impact market sizing and the ability for a patient to get on, and stay on, therapy successfully. Examining how patient populations are impacted by these demand drivers in combination with the various margin drivers can direct manufacturers to where value is highest. This should be considered when making deployment, targeting, promotion, contracting, resource deployment, and other investment decisions.

GROSS TO NET PRECISION

Gross to net precision is also required to combat the big squeeze. Precision goes beyond accrual accuracy – although it is critical – and extends into making optimal margin investments and decisions. Examples of this include contract decision making & post deal analysis, rebate validation, 340B de-duplication & audit, forecast accuracy & deconstruction, copay program benefit design, and active copay program management to mitigate the impact of high cost claims.

Figure 9: Gross margin performance



This strategic approach requires a wholistic view of margin drivers, linking them directly to demand through the examination of the "Total Cost of Access." The Total Cost of Access combines margin drivers like baseline rebates plus patient affordability program expenditures in the Commercial payer channel or baseline rebates plus Coverage Gap rebates in Medicare Part D. Other elements that can also be added are 340B expenditures,

CONTRACT ANALYTICS AND REBATE VALIDATION

Contract analytics are performed by nearly all manufacturers, yet decision making is rarely validated with actual post-deal contract performance. Building stronger contract decision making tools that examine the ability of a payer to control a market, the effectiveness of its restrictions, contracted vs. non-contracted books of business, and the impact of patient affordability are important as they all impact contract value. Building these stronger, more nuanced assumptions into contracting tools allows for more detailed post deal analytics to be performed, which will help to continually improve decision making and protect margin over time. Pull-through efforts also become more actionable with improved tools as key performance metrics become established and ongoing utilization is monitored.

There are many ways that revenue can unintentionally be lost that manufacturers can influence. Ensuring that rebates are being appropriately paid according to contract is important to slowing access pressures. In 2018, IQVIA helped clients scrub over 500 million rebate claims that amounted to over $40 billion in rebates, of which $600 million was identified as being outside of contracted terms and resulted in direct savings back to manufacturers. Payers are being more aggressive than ever in contract negotiations, so manufacturers need to respond by upping the accuracy of their internal controls on contract and formulary validation.

Protecting against 340B revenue leakage is also important as covered entity and contract pharmacy footprints continue to expand. As more hospitals utilize 340B purchasing, it is important for manufacturers to have processes in place that help stop program misuse. With lax regulatory oversight and only a handful of government audits being performed, it is important that 340B strategies be a core component of any gross to net strategy. IQVIA has access to rich data sources and experience in helping manufacturers understand how much misuse is occurring, monitoring ongoing utilization, and helping protect budgets by stopping these funds from going out the door through de-duplication efforts.

$40B

IQVIA processes upwards of **$40 billion in** Managed Care and Medicare rebates annually saving clients

$600M

Another of the many challenges that manufacturers face is the high rate of turnover in key strategic functions. Over time, this turnover leads to a loss of institutional knowledge on why key decisions were made and can often create distance between decision making and accountability to those decisions. Building a strong foundation of assumptions that are validated, data-driven, and documented improves financial performance and flexibility over time as more rigor is applied. Through partnering with third parties like IQVIA, and in some cases, outsourcing key financial functions, manufacturers can ensure they are applying the latest industry standards, appropriately benchmarking their performance, and creating consistency to their controls over time.

Closely managing a P+L can build financial capacity to improve long term strategic flexibility. Protecting margin can provide necessary financial bandwidth to make

strategic investments when the opportunity arises. Having a long-range view of potential market dynamics, accounting for the impact of increased payer controls, and keeping a close eye on public policy changes like those that are being debated today are ways to plan ahead.

PATIENT AFFORDABILITY PROGRAMS

Patient affordability programs are another key area where manufacturers can apply financial rigor. Ensuring that benefit designs are appropriately set is important to optimizing product demand and access budgets. A benefit design that is not generous enough leaves demand - and revenue - on the table as patients struggle with affordability or physicians grapple with access. Conversely, an overly generous benefit design can dramatically inflate budgets as manufacturers buy down patient cost sharing that they do not need to. IQVIA has deep experience in copay program design and implementation of brands across all market spectrums – from large retail products to the smallest niche rare and orphan disease brands. Each brand, market, and therapeutic area can be unique, so industry wide experience is important to getting the most out of a program.

Another driver for inflated program costs comes from the increase prevalence of high cost claims. On average, the most costly 1% of copay program volume accounts for 25% of program spend*. Ensuring that proper controls are in place to protect against copay program fraud and abuse are essential to preserving program integrity. This includes macro examination of a program, cross program analytics, pharmacy level utilization reviews, and if needed, the ability to audit and retract payments.

IQVIA copay optimization and operations have saved clients over $400 million in the last five years

Actively managing patient affordability programs can help control budgets from ballooning. Ensuring that utilization and budget are defendable can help improve investment while also protecting program integrity against inappropriate usage. That means manufacturers must build more advanced tracking, understand what KPIs are meaningful, and establish trigger points for more timely intervention. Many clients have engaged IQVIA to help build out these capabilities through the establishment of Patient Affordability Centers of Excellence where new levels of partnership can be achieved.

**Findings from a 2019 IQVIA study using co-pay card redemption and pharmaceutical claim data.*

ACTIVE PROGRAM MANAGEMENT INCLUDES:

- **Real-time** monitoring of important trends and KPIs
- **Linking evaluation of Payer Control** program impact to program redemptions
- **Strategic guidance** on investment opportunities and program deployment
- **Integrated reporting** on prescriber, patient, and payer trends
- **Patient CRM** enrollment and outreach
- **Prescriber trend** identification and messaging
- **Financial reporting and forecasting**
- **Integrated gross to net strategies** utilizing many data sources
- **Program compliance reports** to ensure legal, financial, and regulatory alignment
- *And More...*

Summary

Pressures on demand and margin are mounting and will continue to impact all stakeholders in the healthcare system. Payers are struggling with the higher cost of specialty medications, legislators are concerned with the overall rising cost of healthcare to the public coffers, prescribers are faced with declining reimbursement and the increased time it takes to navigate access challenges, patients are forced to make economic rationalizations as they pay more with each passing year, pharmacies are struggling as networks close and reduce prescription volume, and manufacturers get caught in the vice of these forces coming together to squeeze demand and margin as stakeholders respond to the issues they face.

There are no simple answers, easy buttons, or silver bullets for manufacturers trying to navigate these challenges. Mitigating the forces of the big squeeze starts with a deeper, more strategic understanding of value and cost drivers. Moreover, manufacturers must include tight fiduciary management and pull-through of access investments of all types. Accurately assessing market, brand, and patient value through the lens of demand efficiency and affordability can aid in setting performance expectations and in crafting more focused strategic execution.

Whether it be through a deeper understanding of market or brand dynamics, rebate validation & 340B management, copay program management & optimization, or understanding of public policy changes, IQVIA is well positioned to help clients address the big squeeze. Industry wide experience and deep subject matter expertise help ensure that the best and most up to date strategies are being applied to help clients **get in front and stay in front** by protecting demand and preserving margin.

LOOKING FORWARD THE FORCES OF THE BIG SQUEEZE CONTINUE TO GROW. FIVE TRENDS TO MONITOR ARE:

Pressure from all sides – Every stakeholder is struggling with affordability. The result? A tremendous lack of certainty in today's environment and a crumbling pricing model.

Payer consolidation/technology/ integration – adds to the problem as effective pharmacy utilization management, ability to control medical spend, technical integration, and contracting leverage increase.

On the precipice of a new model – With so much impetus for change, stakeholders must consider alternative business strategies, focus on commercial and gross to net precision, and be ready to adapt to rapid change.

Public policy uncertainty – Rising costs of healthcare are increasing the pressures from public stakeholders to address price and other structural reforms. The greatest risk lies in Medicare Part D where benefit redesigns could dramatically alter strategy and long-term value.

Counterintuitive action likely – Profitable strategies for manufacturers will vary based on portfolio, pipeline, historical price increases, commercial/Part D mix, and biosimilar alternatives. The degree of variance increases as market, competitive, patient, and payer pressures converge.

About the author

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With more than 20 years of experience in the Life Sciences industry, Luke has held a variety of roles from sales and marketing to managed markets and brings real-world experience on co-pay offset programs, market access, and gross-to-net management to his clients. His analytical focus includes longitudinal patient and payer data assessments that combine demand and margin management in order to provide actionable insights. Luke holds a B.A. from the University of Iowa and an M.B.A. from St. Ambrose University.

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