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Strategic Advisory Analytics

Feedback note #3: The frictional cost break up in drug pricing - it's not me, it's you.

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Note: This deck is an abbreviated version of our original full pricing report published on November 16th 2016, which can be found www.mtspartners.com/news

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Feedback #3 on Principled Drug Pricing Report: The frictional cost break-up in drug pricing - it's not me, it's you (1/3)

- We published our first "Strategic Analytics" report "Principled Drug Pricing Centered on Innovation and Choice: Part 1" (link) in November 2016. The principal purpose of the report is to act as a forum for debate on this important contemporary societal issue. With this in mind, we have been communicating the key feedback items post our continued interactions with both corporates and investors and Feedback #1 related to the likely impact of the new administration on drug pricing (link) and #2 related to the impact of drug price rises (link).
- This #3 feedback item, discusses the "frictional costs" in the US drug pricing ecosystem. We define frictional costs in the drug pricing debate as money (ultimately) paid by the public/consumer for drugs that do not end up as revenues for Biopharma companies.

- **Bottom line:**
  1. Frictional costs of drugs in the US ecosystem is excessively high – 17% in the US vs. 4% in the comparative developed world
  2. PBMs account for the largest frictional cost in the US – while overall PBM's theoretically save the system money, there is a high cost to those savings and moreover a significant conflict of interest
  3. Frictional costs could be lowered by a combination of value-based and transparent drug pricing and choice within the Rx element of the insurance system

- **Details:**
  - The payers/PBMs (and public media) point the proverbial "You are the bad ones" finger to the Biopharma industry for high drug prices and price rises. The mainstay reaction from the Biopharma industry is counter finger-pointing with a "and you [PBMs] take too large a cut from drug revenues - you are actually the bad ones". This does not make for a happy marriage between biopharma and PBM industries.
  - We introduced the terminology of "frictional costs" in our original report and this sub-point of the report has become one of the biggest feedback focal points, unsurprisingly, from the Biopharma industry. In keeping with our trifecta approach to most problems, within this feedback note we consider this topic and feedback in three buckets:
  1. How much are the frictional costs for drugs in the US vs. comparative developed world?
  2. Is this level of frictional costs in the US system justified?
  2. The future of frictional costs?
- We have made a Frictional costs "mini" deck with the relevant exhibits take from our original deck – all exhibit references below relate to "mini" deck.

1. **How much are the frictional costs in the US vs. comparative developed world?** As described in Exhibit 6, one of the three foundations of our report was to generate real data upon which to base an accurate debate (the other two foundations of the report were to describe the complex drug pricing ecosystem and provide our views on how to correct the totality of the system). The high level of interest and feedback from companies came from the description and more so the accurate quantification of money flows in the US drug pricing ecosystem and hence the determination of frictional costs (Exhibit 7; Exhibit 8). FYI, these numbers were determined by using a little knowledge of accounting principles, detailed examination of financial statements, use of prescription databases and a lot of spadework/proprietary database generation.

- Long story very short, we determined that for a nominal/average $100 list price:
  1. Branded drug manufacturers receive $73;
  2. Wholesalers and pharmacies together receive $4;
  3. PBMs and insurers receive $8 and $3, respectively;
  4. The remaining $12 difference is the real pass through discount to the end consumer.

Source: MTS analysis

Feedback 3 on Principled Drug Pricing Report: The frictional cost break-up in drug pricing - it's not me, it's you (2/2)

In other words, for a nominal $100 list price drug the consumer actually pays $88 (via insurance premiums and copays), of which $73 goes to the manufacturer and $15 is absorbed in frictional costs. Frictional costs make up 17% of the total consumer cost. For comparison, the frictional costs in the CDW is around 4% (to distributors and pharmacies) due to direct payment of drugs by a single payer on a list price that generally equates to the net price and the exclusion of insurer and PBM driven frictional costs.

2. **Is this level of frictional costs in the US system justified?** By far, the main focal point in our discussions with Biopharma manufacturers was the $8 of a nominal $100 list price drug that ends up in the hands of PBMs (via a complex system of rebates and fees). There are two ways of looking at this:

   1. What does the ecosystem get out of this $8 frictional cost?
   2. Is the level of cost, i.e. 8% of list price justified amount for frictional cost?

   - Point 1 is relatively easy to answer - PBMs have evolved into the main cost/benefit gatekeepers (and theoretical drivers of cost benefit – Exhibit 9 and Exhibit 10) in the US drug ecosystem. If they did not exist then there would be no discounting mechanism (via rebates). So the average ca23% (or $23/$100 list price) discount on list price that PMB's enable would not exist. It is important to remember that $12 of this is passed through to consumers and $8 taken by the PBM. This brings us to point 2: is 8% justified?
   - On Point 2, the 8% frictional costs associated with the PBMs pays for 1. "administrative" functions and 2. cost/benefit implementation and the resulting 3. discount facilitation (Exhibit 11). This 8% is generated via a complex mixture of "processing" fees and rebates, and we estimate that rebate associated money flows make up the majority of the 8%. So addressing the point is 8% worth it?
   - There are many ways of looking at this; one interesting way is to look at the PBM and Biopharma industry on a return of capital basis as shown on Exhibit 12. This illustrates that cumulatively for the totality of the Biopharma industry for every $100 of drug revenues, an $80 cost base (and a ton of risk and time) is required to deliver the resulting $20 operating profit. Conversely for that same $100 of drug revenues, the PBM industry requires $4 of cost base (and in reality little risk and time) to deliver $4 operating profit (via $8 of "real" top-line). Another way of looking at the same cost is that PBM's take 20% of drug profits (with the Biopharma industry taking 80%) on a PBM cost base that is just 5% of the Biopharma industry.

- When looking at the justification of the 8% for PBM, a point is made that PBMs are the cost/benefit gatekeepers and without PBMs there would be no rebates and thus discounting, resulting in reduced cost for the consumer. We 100% agree that PBMs are gate-keepers (Exhibit 9) but question is "Are PBMs "pure" cost/benefit drivers?" (Exhibit 10). The rebate system makes sense, in theory, in being a component to drive cost/benefit (the other being incentivization) - e.g. Drug X costs $200, twice as much as Drug Y ($100) with the same benefit - get a 50% rebate on Drug X (thus an effective price of $100) and theoretically the cost/benefit has been equalized. The problem is rebate retention and the concomitant conflict of interest that it generates. PBMs pass through about 80% of the rebate (to the insurance payers and thus ultimately to consumers) but keep 20%. So in the above example the prescribing of Drug X captures the PBM normal processing fees (normally on the list price - let's say 4% or $8) and 20% of the $100 rebate retention, i.e. $20 - a cumulative $28. The prescribing of Drug Y, using the same math generates just $4 of revenues for the PBM (4% of $100 + 20% of $0 rebates). On the basic principles of insurance all costs are ultimately passed onto the consumer - so Drug X is still more expensive to the system. This is the major conflict of interest – PBMs are financially motivated towards drugs that do not have the best (real)cost(to the consumer)/benefit.

Source: MTS analysis

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- As a final point on frictional costs, the illustrative numbers in point 1. are based on a nominal $100 list drug price for the overall US branded drug market, i.e. it represents the "cumulative average" frictional costs. However, for drugs with higher % rebates the frictional costs are higher. As we illustrated in Exhibit 13, rebates on the top 20 drugs (by revenues) in the US range from ~15% to >70%. This further demonstrates the conflict of interest PBMs face for high % rebate drugs – i.e. the consumer is still effectively paying near list price for high % rebate drugs but the PBMs are getting significantly higher revenue streams for those same drugs. Of course the converse is true, i.e. for very low % rebate drug, the consumer is effectively paying near list price, while PBMs essentially make none or very little revenue. One view of this complex system is that higher % rebate drugs/therapeutic areas are subsidizing lower % rebate drugs/therapeutic areas. Bottom line is that the rebate system drives both, a lack of transparency of "real" drug prices, as well as potential conflicts of interest. If drug pricing was truly transparent and list prices equaled net price, then there would be minimal frictional costs and conflicts of interest (Exhibit 14). Watch this space for feedback note on the "Transparency"" issue.

- Umm... the above described combination of high frictional costs and conflicts of interest that drives the finger pointing and harsh commentary from the Biopharma industry to the PBM industry becomes clear now.

3. **The future of frictional costs?** As described above the central component of the high frictional costs in the US drug pricing ecosystem is driven by PBMs and rebates. As we highlighted in our original report the central problems of the US drug pricing ecosystem is due to the fact that the ecosystem evolved into the unsustainable beast that it is, rather than being built by design. The role, function and problems associated there within for PBMs are a perfect example of this evolutionary move to a precipice.

- The original purpose and functionality of PBMs when they first were created (around 1970's) was valid, needed and did save the system money - at this time the insurance market was very fragmented and the administrative hurdles of drug facilitation high. Moreover, the efficient practices of PBMs lead to the world's most efficient generic substitution system (Exhibit 15). But the increase in rebates (and gross to net - Exhibit 16) as being the principal revenue driver (and concomitant conflict of interest) and the consolidation of the insurance industry (Exhibit 17), let alone the current debate, truly brings into question the future of the PMB industry and what form it will exist in.

- There is a need for a gatekeeper in any cost/benefit system where the manufacturer is set to set its own price for a product that is essential to society (see feedback #2). Our two suggested solutions/actionables for drug pricing (Exhibit 6) are that: 1. the biopharma industry should move uniformly to an innovative value based drug pricing, and 2. an increase in transparency and choice in the Rx element of the insurance system. This would move the burden of cost/benefit to within the pricing initial pricing of drug and the check within the system would be consumer choice in the Rx element of the insurance system.

- Break-ups are never easy but sometimes necessary and for the best.

- We hope you find the report informative and thought-provoking. We further highlight that the report's purpose is to act as a forum for continued debate.

- We welcome comments and questions to the coordinating author, Ravi Mehrotra (mehrotra@mtspartners.com) and/or to any of the Partners at MTS.

The Key Take-Homes from Our Analysis of the US Drug Pricing Ecosystem

Data

Totality of $1,052/capita of US drug spend (~1.9% GDP or ~10% healthcare spend), or even the average US/comparable developed world drug price premium (~2.1x) is NOT the problem

Ecosystem

The evolutionary direction of the totality of the current **drug pricing ecosystem is the problem** – it fails to efficiently and proportionally reward innovative value

Non-value driven drug pricing	**Low transparency** across multiple parts of the ecosystem		**High frictional costs** not proportionally rewarding contributors of value
Cost/Benefit ≠ Value	Low transparency of net drug prices	Differential contributions/ benefit for insurance with little/no choice	~14% of drug's list price is attributed to ecosystem frictional cost; Conflicts of interests are being masked as frictional costs at multiple points in the ecosystem

Possible outcomes

The emphasis is on the Biopharma industry to base drug pricing to a value- (cost/benefit) and outcomes-based principal, moving away from the current free market "what the ecosystem can bear" system. Drug price rises are not the cause of the problem but rather a symptom. True value based pricing could still lead to dynamic prices after launch (both up and down) based on post-launch changes in benefit assessment.

Differential and non-transparent **rebate levels are now a headwind rather than a tailwind to drive appropriate cost/benefit value**.

The rebate system needs a dramatic overhaul via coordinated efforts of all parties involved.

Introduction of choice, of level of contribution, and consequent transparent level of benefit for the Rx element of insurance cover. Change driven by insurers/PBMs and central governing bodies.

Frictional costs across all parts of the ecosystem should be reduced to a minimum. The largest frictional cost is the insurance based intermediator cost, which is in turn principally driven by the rebate system. **Value based pricing and transparent net-pricing can reduce/eliminate the rebate system**. Other (non-direct) frictional costs include level and content of **S&M/OTC spend by manufacturers.**

Two key actionables:

(1) Biopharma industry should move uniformly to an innovative value based drug pricing

(2) Increase in transparency and choice in the Rx element of the insurance system

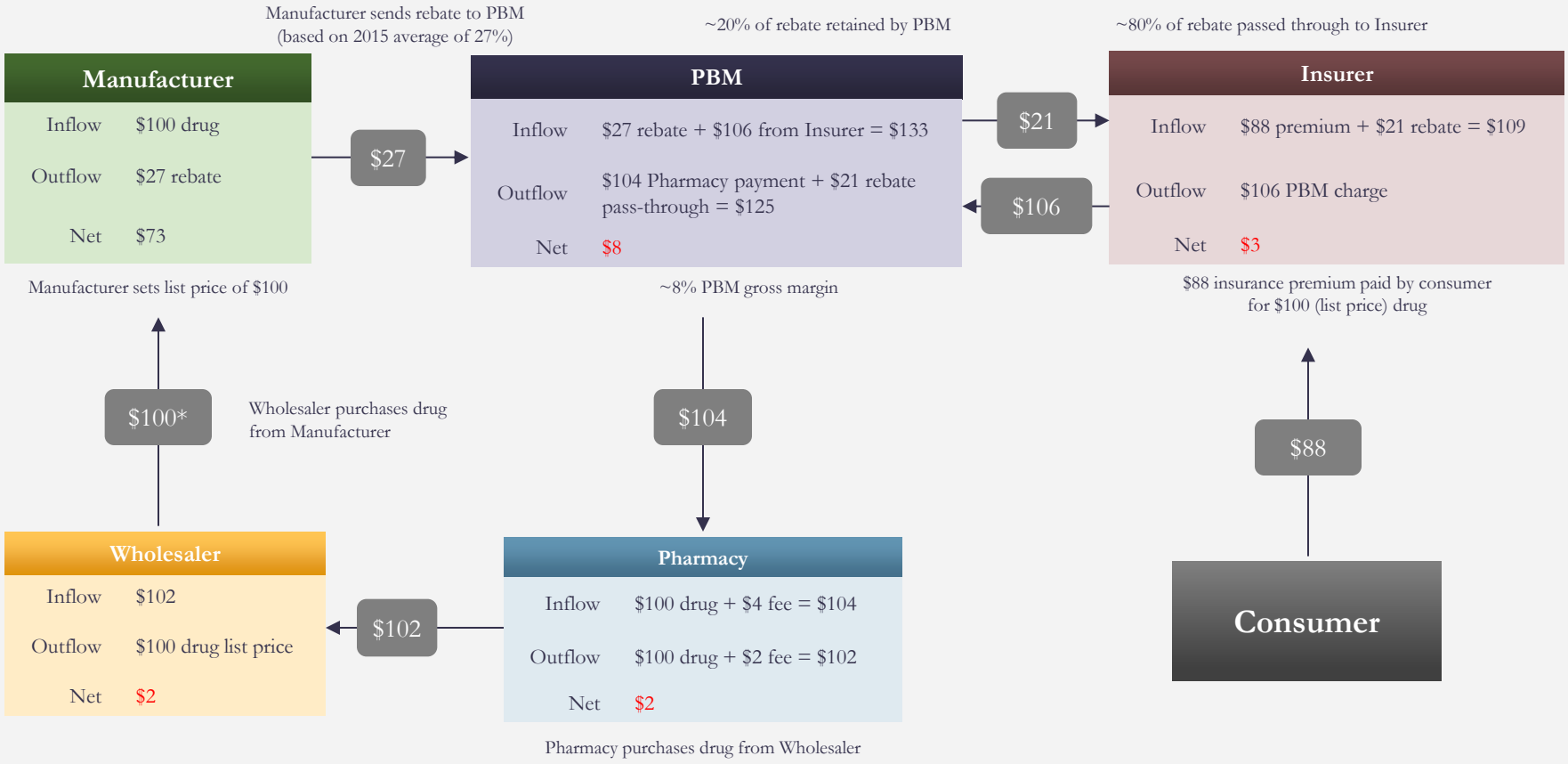
Source: MTS analysis

MTS Calculated Money Flows in Totality (Using a Nominal $100) Within the US Drug Pricing Ecosystem

In the "totality" of the ecosystem for every $100 of list price drug sales, manufacturers receive $73 net dollars, Wholesalers and Pharmacy $4, PBM's $8 and Insurers $3. Direct frictional costs are marked in red

The effective pass through price for the consumer (for $100 list price drug) is $88, paid via insurance premiums

PBM-based Healthcare System



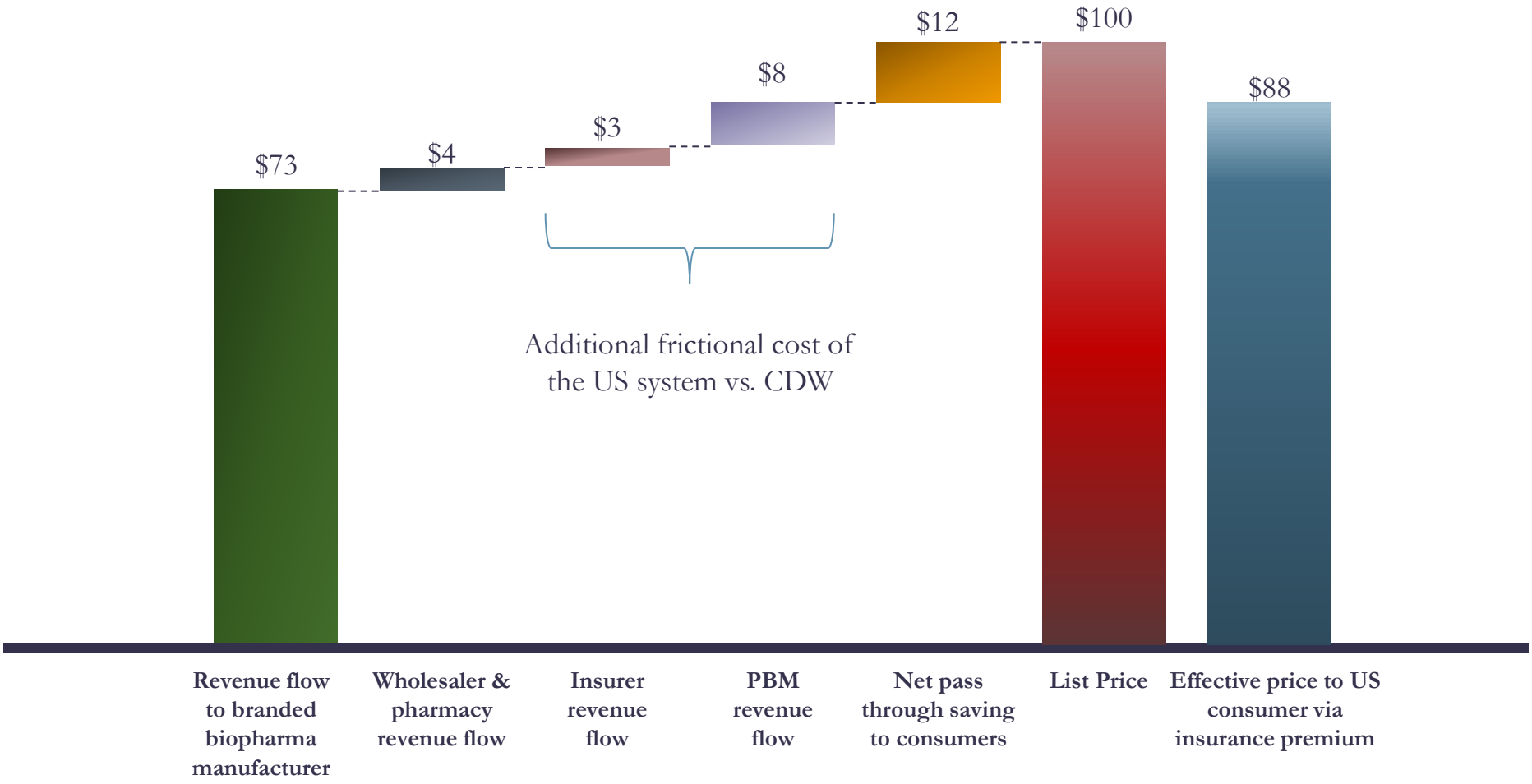
(*) In reality, the Wholesaler negotiates a small discount to the list price from the Manufacturer, further driving down the effective price of the drug.

Source: MTS analysis

Overview of MTS' Estimated Frictional Costs for (a Nominal $100) List Price Branded Drug in the US Drug Pricing Ecosystem

For an average $100 list price branded drug, the effective cost to the end-user is $88, $15 are absorbed in frictional costs and the biopharma manufacturer receives $73

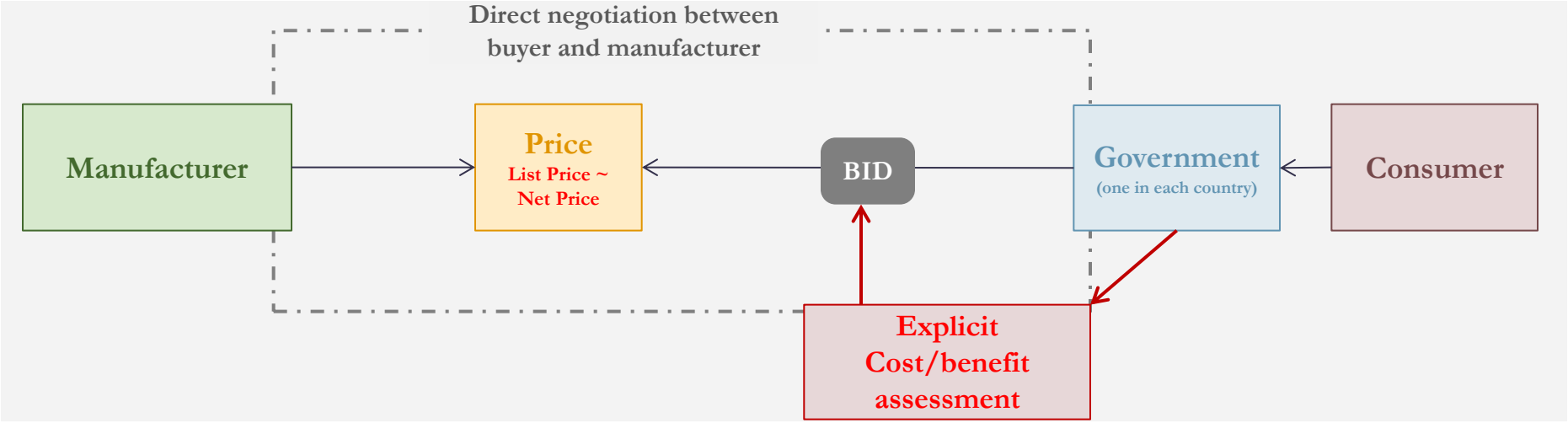
The "intermediator" insurance/PBM system is unique to US drug pricing ecosystem and drives a 23% savings from the list price, of which around half flows to the end-user



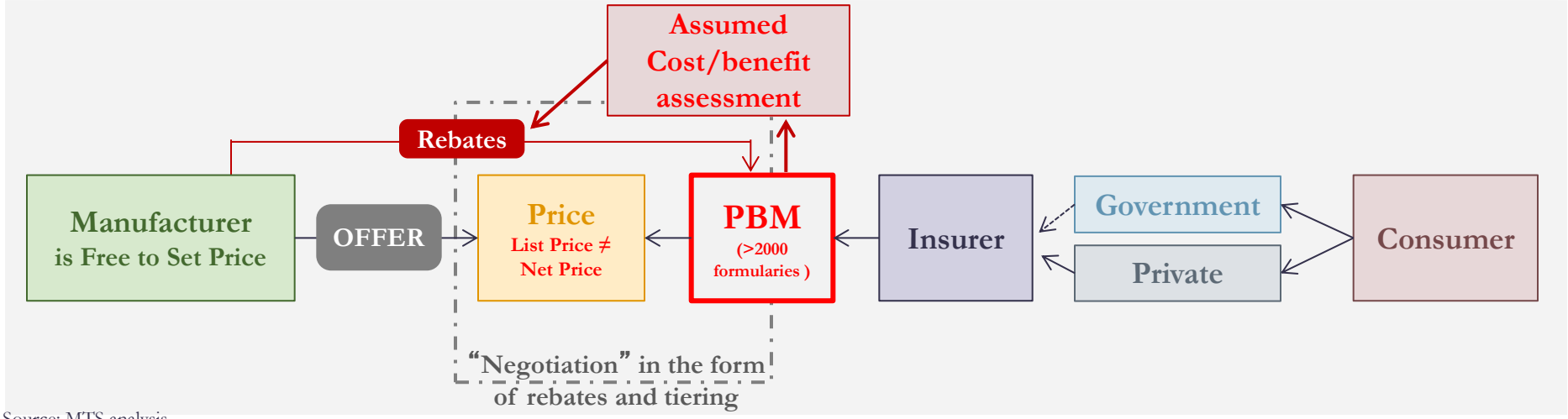
Source: MTS analysis

The Extremely Complex "OFFER" Drug Pricing Ecosystem in the US vs. the Relatively Simple "BID" Drug Pricing Ecosystem in the CDW

Comparable Developed World (CDW) = "BID" System, transparent prices and low frictional cost

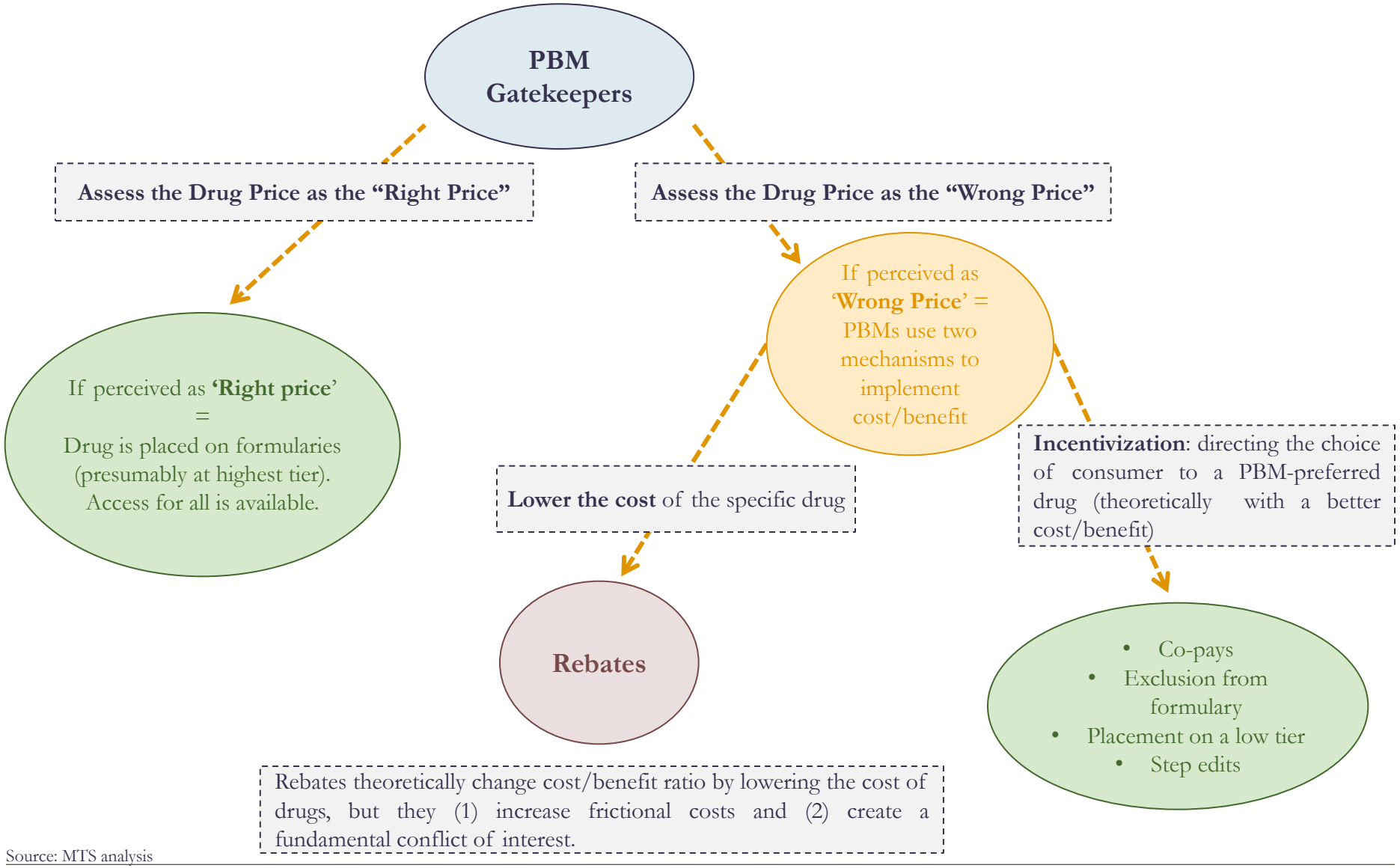


US = "OFFER" System, non-transparent prices and high frictional cost



Source: MTS analysis

PBMs Theoretically Drive Cost/Benefit in the US Drug Pricing Ecosystem via Lowering Costs or Incentivization



Source: MTS analysis

What are Pharmacy Benefit Managers (PBMs)? They have 3 Key Roles in the US Drug Pricing Ecosystem

Administration

- Act as the administrator of Rx benefit of insurance plans

What is a PBM?

- PBM's administers, or handles, the prescription drug benefit component of employer's health plans. PBMs process and pay for prescription drug claims and are responsible for assisting employers with managing their prescription benefits.
- They serve as an intermediary between the payor and everyone else in the healthcare system.

How do they make money?

- PBMs earn profits through "spread pricing" – by paying one price to pharmacies and charging employers or unions at higher prices PBMs keep the difference.
- Health plans are unaware of the spread because it is not transparent.
- On top of the spread price, PBMs earn "administration fees", as well as "rebates" and "discounts".

Cost/benefit implementation

- Assessment via P&T committee
- Facilitation via formularies and **access**

Assessment of cost benefit

- PBMs decide on formularies using Pharmacy and Therapeutics (P&T) Committees, which consists of Clinical Review Committees (CRC) and Value Assessment Committees (VAC) – these process are not transparent.
- CRCs provide evaluations and make clinical recommendations for each product and pass these recommendations to the VAC.
- VACs provide reviews of the financial components and make final tier placement decisions for drugs.

Formulary

- A formulary is a list of the pharmaceuticals an insurer covers.
- Types of formularies: open (a relatively unrestrictive list of prescription drug choices available through an insurer) and closed (a specific list of covered prescription drugs).
- PBMs often reshuffle their formularies due to drugs losing their patent protection. Primary incentive for reshuffling is to continue to obtain rebates from manufacturers.
- After the P&T review – drugs are placed on a tiered benefit plan design according to clinical and cost data. Insurers often offer plans with 3 or more tiers.

Lower costs of drugs

- Consolidate buying power
- Capture rebates

Consolidate buying power for smaller companies

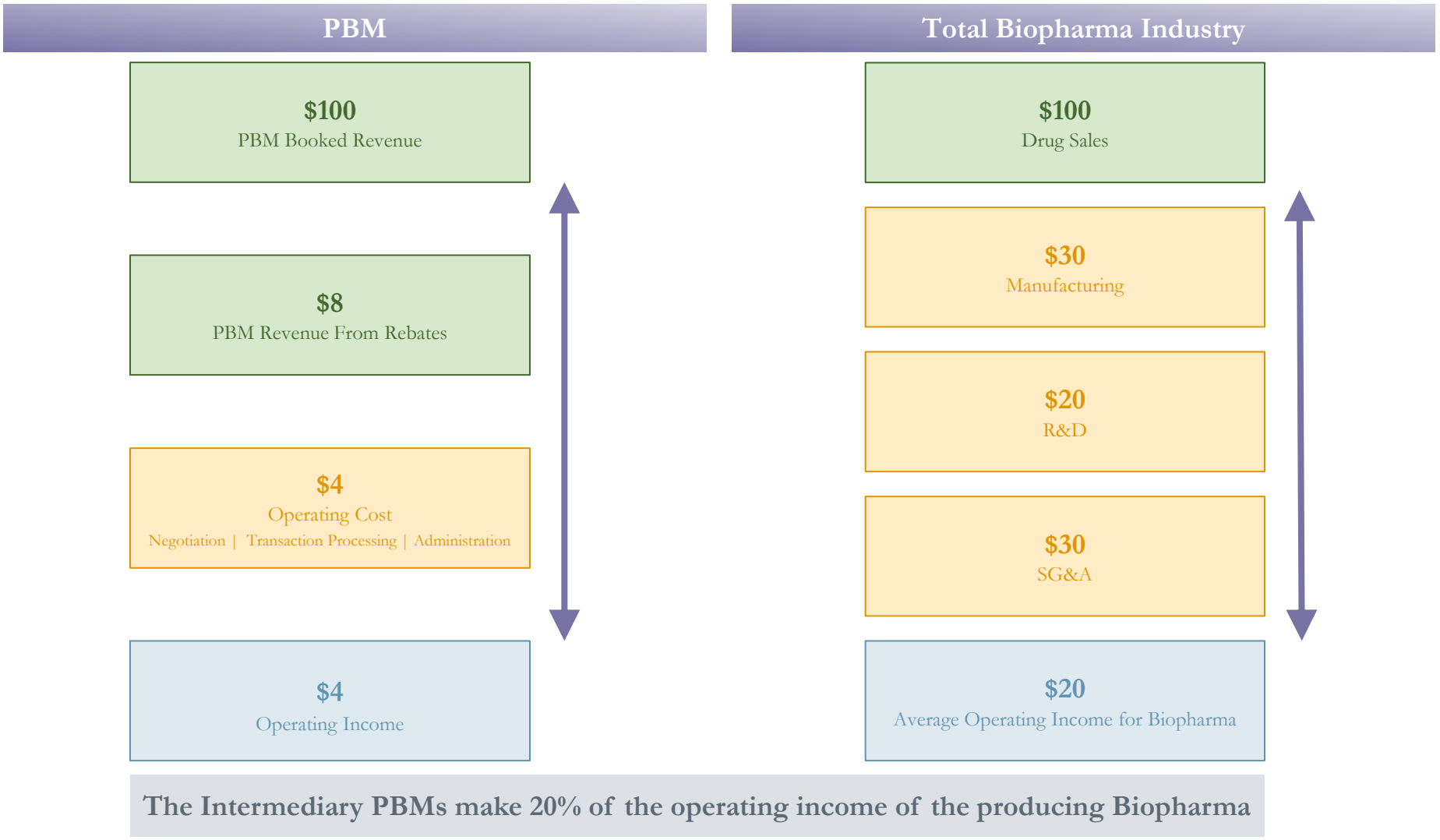
- Conceptually, PBMs consolidate multiple smaller companies and provide "numbers" for negotiation purposes.

Rebates

- Drug manufacturers pay rebates to PBMs, essentially only to the party responsible for adjudicating the pharmacy claim. Only PBMs can demonstrate to the manufacturer an adequate ability to control and manage utilization rates.
- Various types of rebates:
  - ✓ Flat/access discounts – a rebate typically offered for formulary positioning
  - ✓ Performance discounts (adjusting) – a rebate typically affiliated and compared to quarterly national market share figures
  - ✓ Performance discounts (fixed) – a rebate typically affiliated and compared to a fixed-non-adjusting market share
  - ✓ Combination discounts – a rebate combination of flat/access discounts and performance discounts.

Source: National Health Expenditure (NHE) data from Centers for Medicare and Medicaid Services; MTS analysis

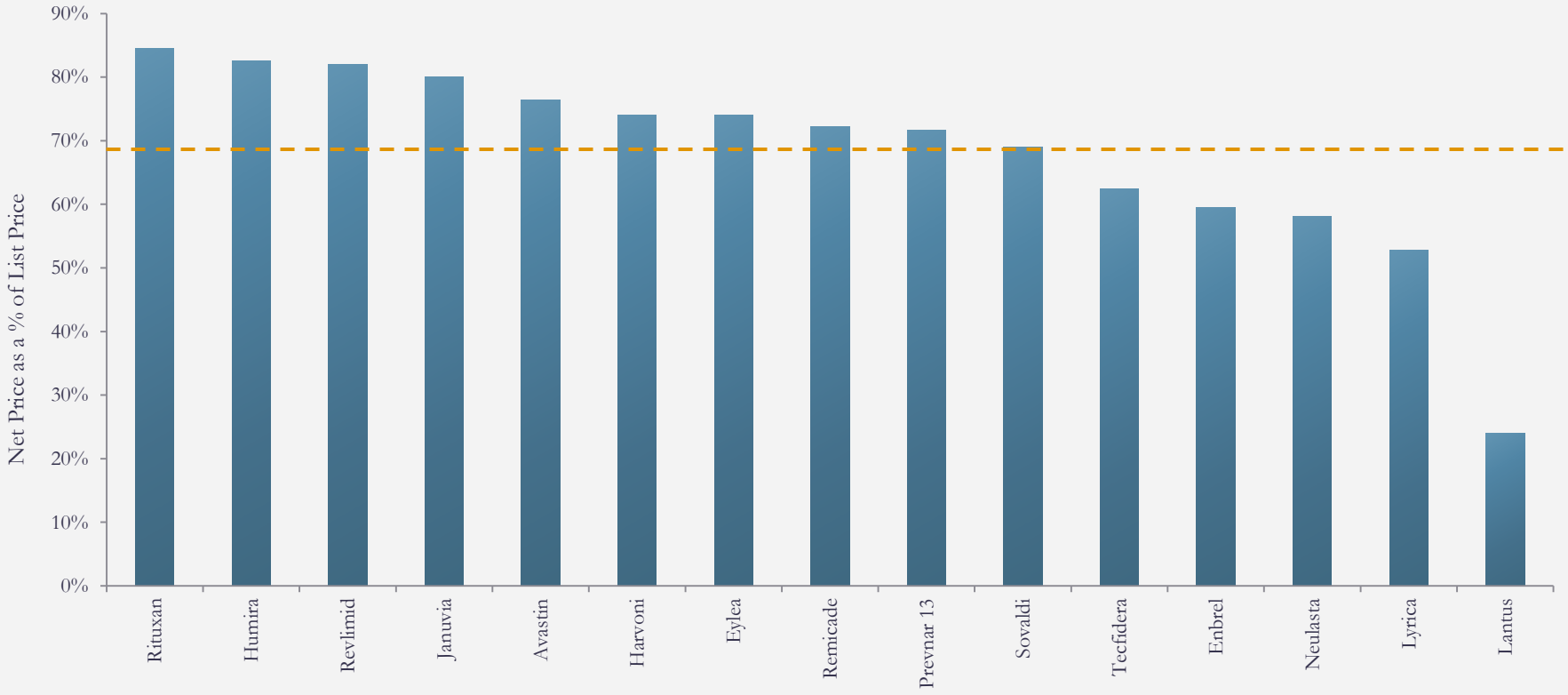
Quantifying the Profitability of Drugs and Rebates in the US Drug Pricing Ecosystem: PBMs vs. Biopharma - Does the Work Justify the Margins?



The Intermediary PBMs make 20% of the operating income of the producing Biopharma

Disclaimer: The drug operating costs are for the totality of the whole industry
Source: MTS analysis

High Variability of List to Net Drug Price Discount in the US



Sources: PriceRx, MTS analysis

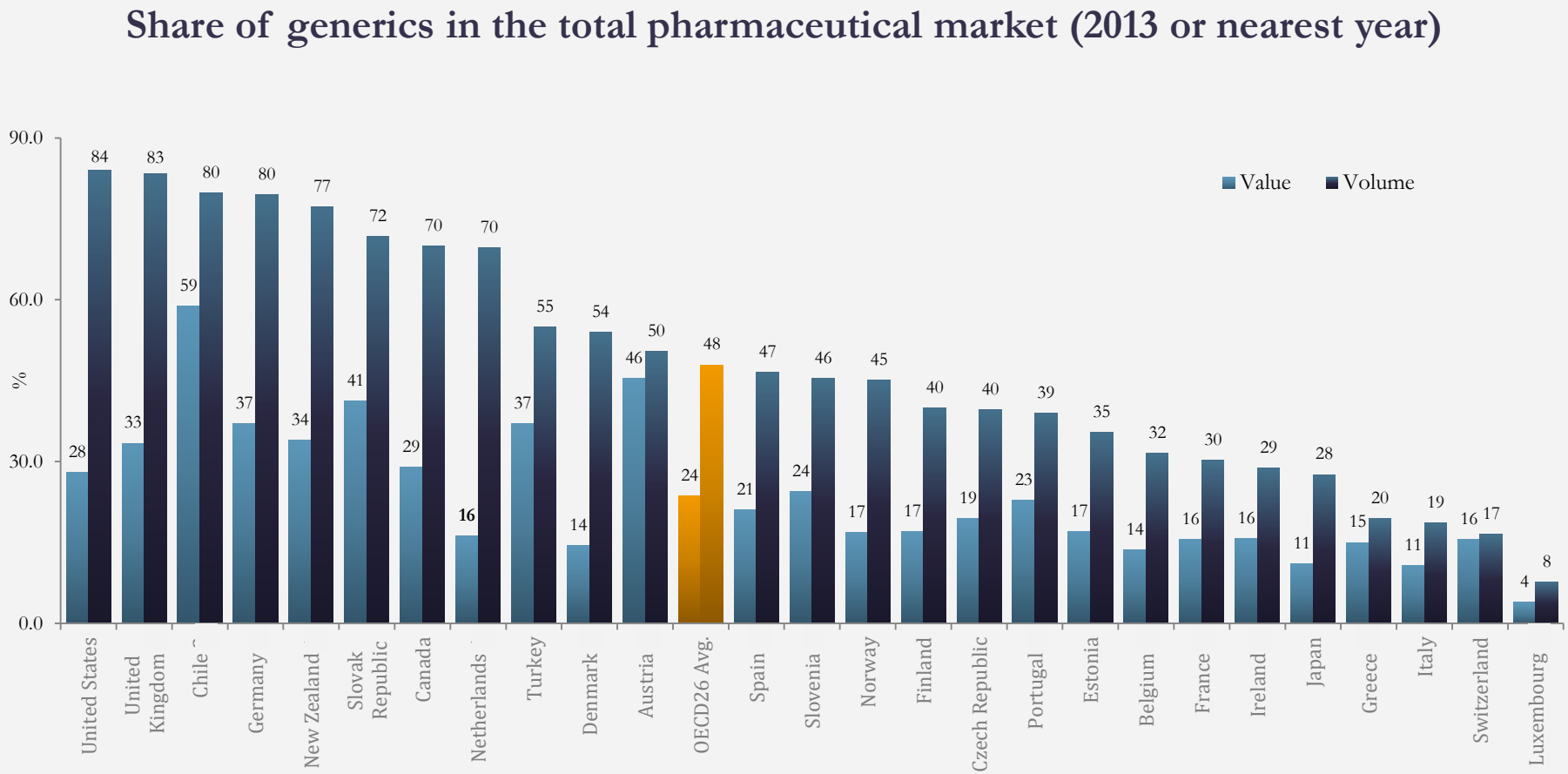
Solution for the List Price/Net Price/Rebate Conundrum: List Price = Net Price = Less Frictional Costs and Conflicts of Interest

For an individual drug, higher rebates flow through to the PBM and obviously increase frictional costs to the system. Higher drug prices and rebates benefit both the manufacturers and PBMs but increase frictional costs. Net price = List price results in the lowest frictional costs.

	List Price	Rebate	Net Price	% Fric. Cost
Higher Rebate (Fixed List Price) = Increased Frictional Costs; Incentive to the PBM	$100	$27	$73	27%
	$100	$36	$64	36%
	$100	$48	$52	48%
Higher List Price (Fixed Net Price) = Increased Frictional Costs; Incentive to the PBM	$100	$27	$73	27%
	$150	$74	$76	49%
	$200	$124	$76	62%
Today: Higher List Price, Higher Rebate, Higher Net Price = Increased Frictional Costs; Incentive to the Manufacturer and PBM	$100	$27	$73	27%
	$150	$48	$102	32%
	$200	$72	$128	48%
Future (?) : List Price = Net Price; Both Manufacturer and PBM are incentivized to make drug choice based on true cost/benefit	**$73**	**$0**	**$73**	**0%**

Sources: MTS analysis

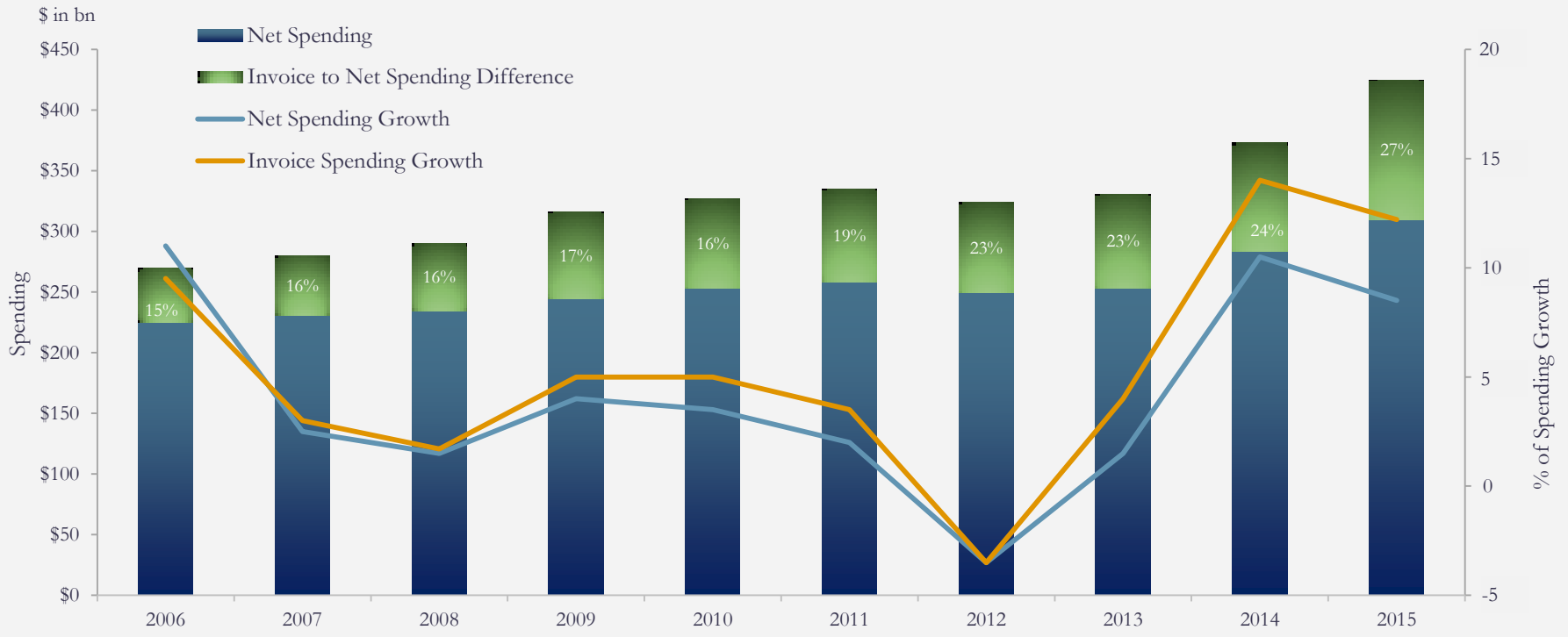
Access can be Logical in Controlling Costs…
US has Highest Generic Utilization Rates due to PBM Access Control Points



Sources: OECD, MTS analysis

Granularity Underlying Drug Spending in the US: Total List (Gross) And Net US Drug Spending Over Last 10 Years

High rebates, which are unique to the US ecosystem, are responsible for List (Gross) to Net but also drive high-frictional system costs. Rebate levels have increased notably over the last 10 years.

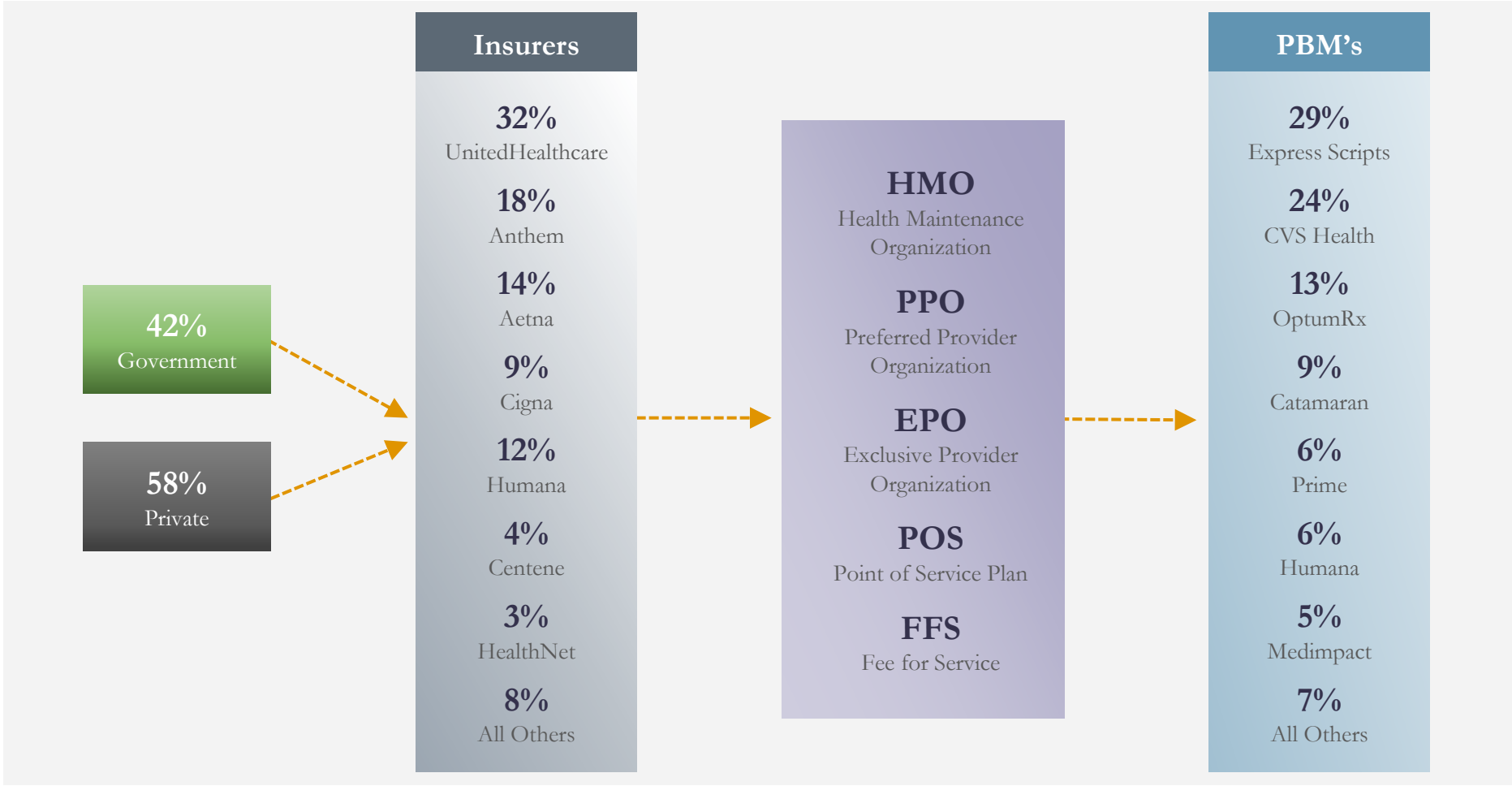


Sources: IMS Health, MTS analysis

In the "Bundled" US Insurance-based System Rx Drug Benefits are Actually Administered By PBMs

There are 5 main types of insurance mechanisms for medical expenses (e.g. doctor visits, hospital stays, procedures, etc.)

Essentially all insurers "sub-contract" the prescription drug administration to PBMs (approximately 10% of total premiums)



Source: National Health Expenditure (NHE) data from Centers for Medicare and Medicaid Services; MTS analysis