

Life Sciences Forward Supply Chain Dynamics

Therapeutic Areas, Product Archetypes, Benefit Structures, Reform and New Technology are creating massive ripple effects into how manufacturers think about commercialization and the flow of their products

Blue Fin Group

Blue Fin Group is a management consulting Firm focused on the life sciences industry. We have been in business for over 22 years. Our primary client is pharmaceutical/biotech manufacturers. Because **our team is made up of cross-functional commercialization experts**, we are highly skilled at **aligning diverse commercial teams** to develop holistic strategies which ensure that products find their way to patients and that those patients are satisfied with the experience and the product.



Focus Areas

Product and
Launch Strategy

Policy, Pricing and
Reimbursement

Market Access
and Payer Strategy

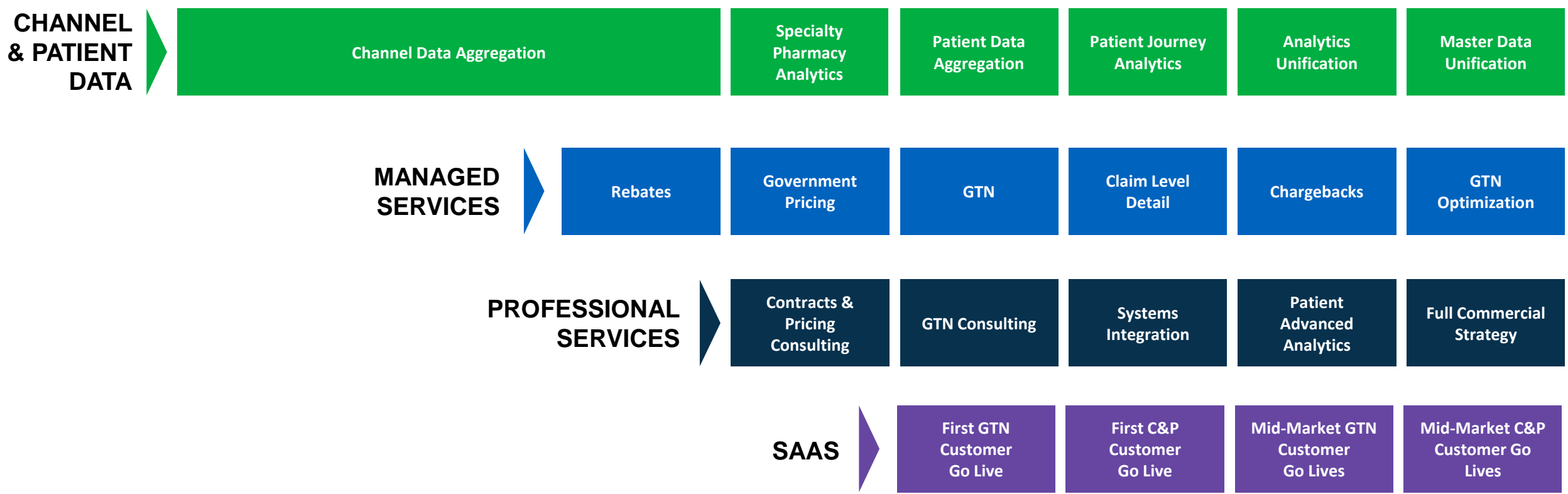
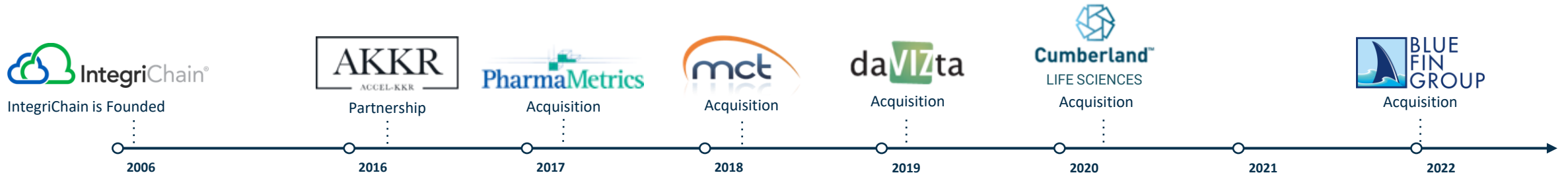
Provider and
Pharmacy

Patient Access
and Affordability

Distribution
and Logistics

Business Data
and Analytics

Consulting Division of IntegriChain as of January 22'

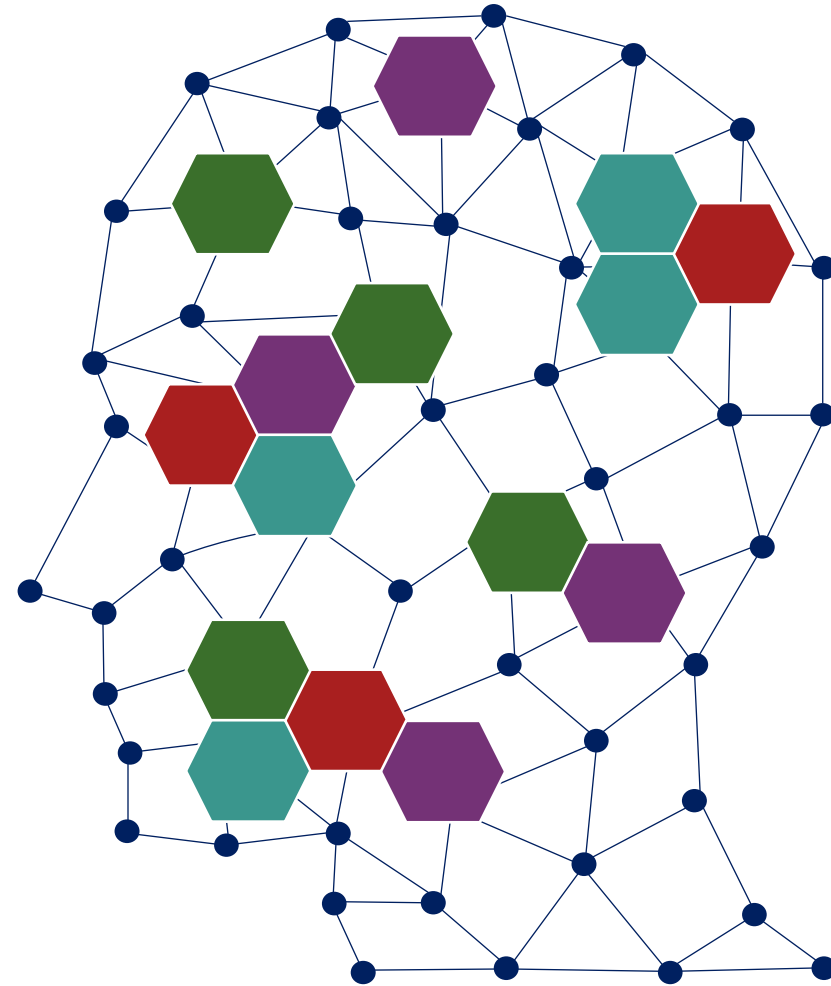


Most Common Mistakes Commercializing Pharmaceutical Product

01 Copy and Paste from one product to another – even when it is not in the same drug class

02 Lack of alignment or misalignment to the 5 function areas – marketing, market access, field sales, trade and distribution and patient support

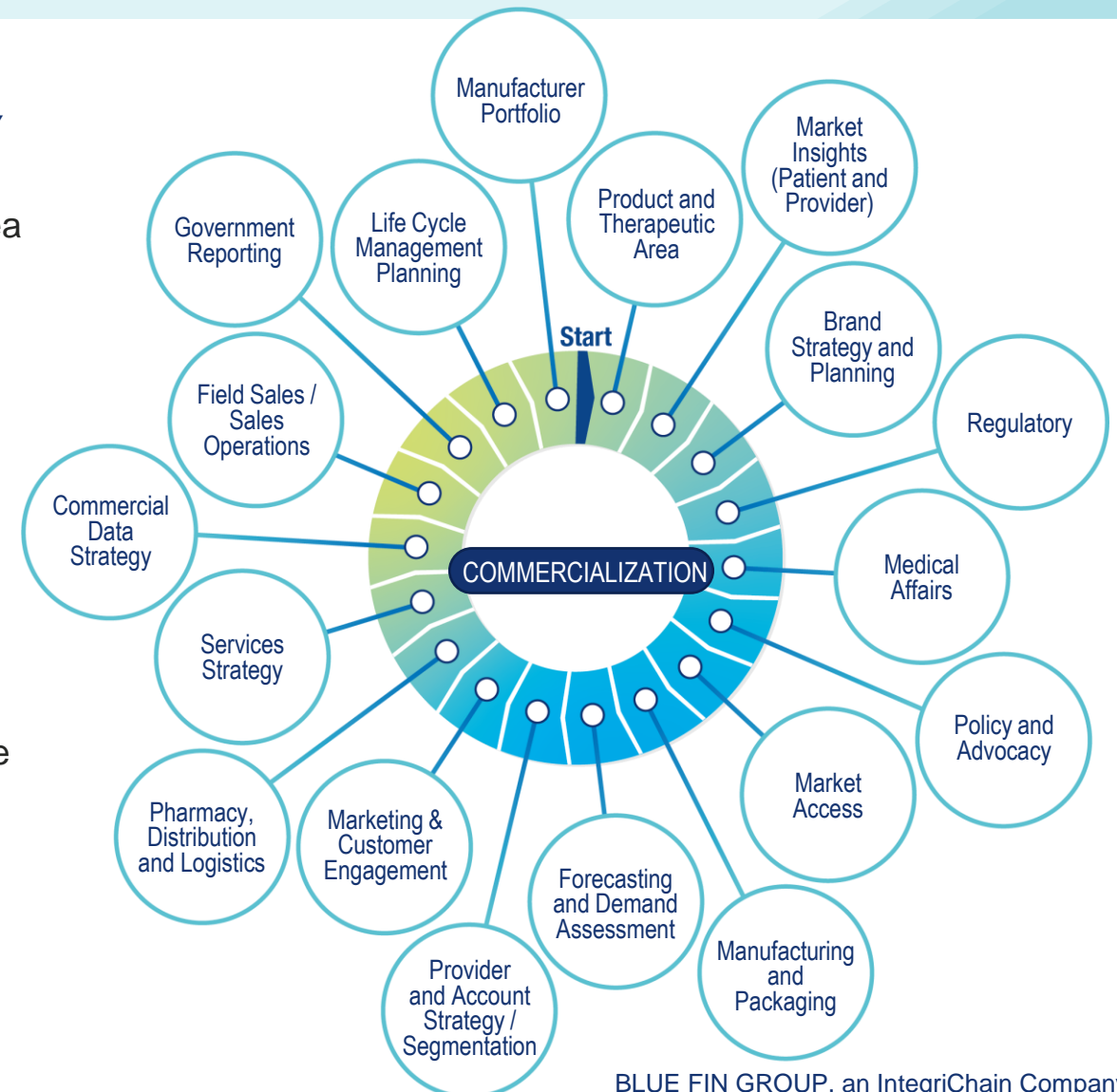
03 Not appreciating the details or nuances for how decisions are made across payers, providers, pharmacies or patients – this is exponentially so when applying the incorrect philosophies and processes to benefit types



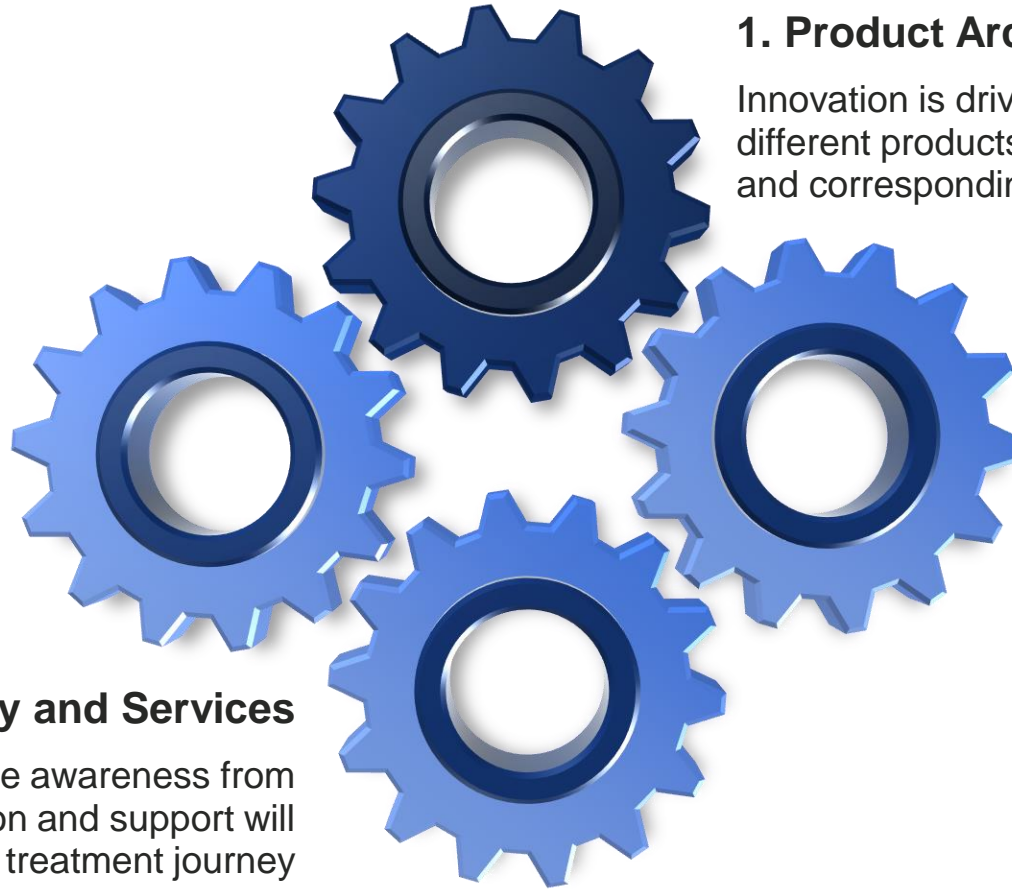
Commercializing a Specialty Product Requires a Detailed Sequencing of Interdependent Functions

INTEGRATED COMMERCIALIZATION STRATEGY

- Starts with the product and how industry views the therapeutic area
- Insights from the patient and provider journey inform the brand strategy and set the tone for the overall commercial approach
- Policy, pricing, and reimbursement determine market access strategy
- Forecasting of demand and patient base, as well as alignment to payer type, informs the distribution and dispensing network
- Considerations provided for economics and how a network strategy could impact these
- Distribution, dispensing, and services strategies are designed to operate cohesively to optimize the patient and provider experience
- Lifecycle management planning maximizes the value of the asset over its lifetime
- Ends with how the commercialization strategy fits into the manufacturer's wider portfolio



4 Key Trends to Have in Focus



1. Product Archetypes

Innovation is driving dramatically different products, treatments, pricing and corresponding access challenges.

2. HC/Rx Costs and Reform

The pressure being applied to industry is coming from the Plan Sponsor with budgets haemorrhaging and patients facing greater concern about rising OOP impacts.

4. Channels/Chessboard

The hardest part of keeping it all straight is alignment of all the moving pieces from payer mix to dispensing and administration support and preference.

3. Technology and Services

The use of technology from disease awareness from prescribing to patient choice to education and support will be enabling the evolution of the patient treatment journey and ultimately outcomes.

Digging into the Foundational knowledge, the trade team needs as much information on TA and drug class, archetype and self or HCP administrated

Therapeutic Area and Drug Class

Therapeutic areas and drug classes matter first and foremost to design as they present a varied set of **product, patient, provider, payer and site of care** situations and options. Primary Care operates differently than specialty. And even specialty areas vary from one another. For example Oncology, Immunology and Neurology all bring marked differences across the 5Ps. Also varies for indication.










Product Archetype

Archetypes are used to better understand impacts from size of the **patient base** for the product, annual and per dispense/admin **cost**, payer or **access hurdles**, and the **logistics** associated with administration

Administration and Benefit Structure

How a product is administered by an HCP or the patient themselves of a caregiver is the third consideration. HCP administration needs sharp focus on pricing and reimbursement at the provider level with great care to discounting strategies. Self administration needs focus on pharmacy reimbursement and cost to serve. GTN and GP impacts vary highly across the two structures.

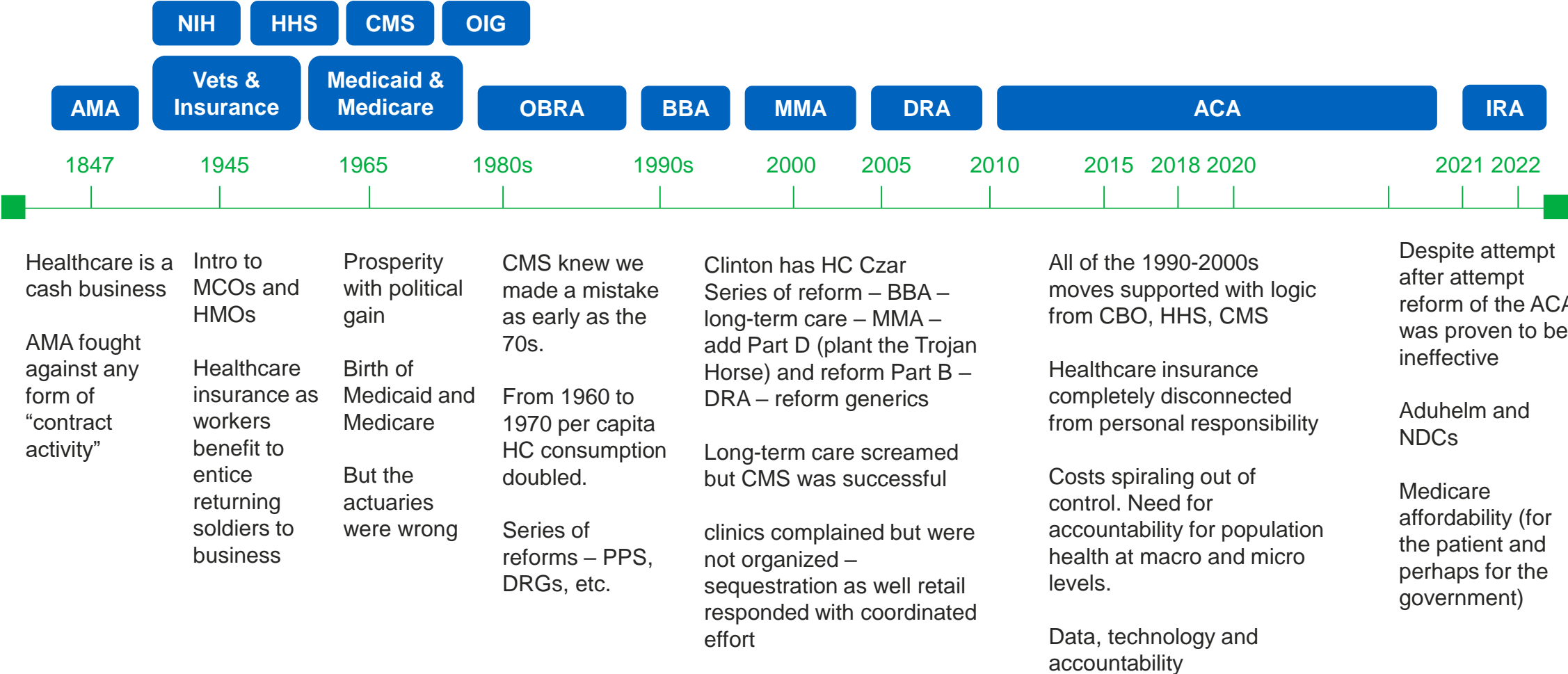
Product Archetypes Are Fundamentally Different Business Models

	 Brand	 Generic	 Vaccine	 Specialty Generic	 Specialty Lite	 Specialty	 Biosimilar	 Orphan and Rare Disease (ORD)	 Precision, Gene and Cell Therapy (GCT)
Patient Base	Very large	Very large	Very large	Small to Medium	Small to Medium	Small to Medium	Small to Medium	Very Small	Very Small (<1000)
Cost	Low	Very Low	Very low-low	Med – High	Med – High	High	Med – High	Very High	Very High
Access Challenges	Tier 2-3	Tier 1	Highly unlikely	PA, Step Edit, Benefit Design, Reimbursement	PA, Step Edit, Benefit Design, Reimbursement	PA, Step Edit, Benefit Design, Reimbursement	PA, Step Edit, Benefit Design, Reimbursement	Find patient, PA, Step Edit, Benefit Design, Reimbursement	Qualify patient, Logistics, PA, Step Edit, Benefit Design, Reimbursement
Therapy Complexities	Low	Low	Low	Med - High	Med-High	High	High	High	High - Very High

Understanding All the Moving Parts of the Chessboard Helps Better Contextualize the Opportunities for Specific Business Models

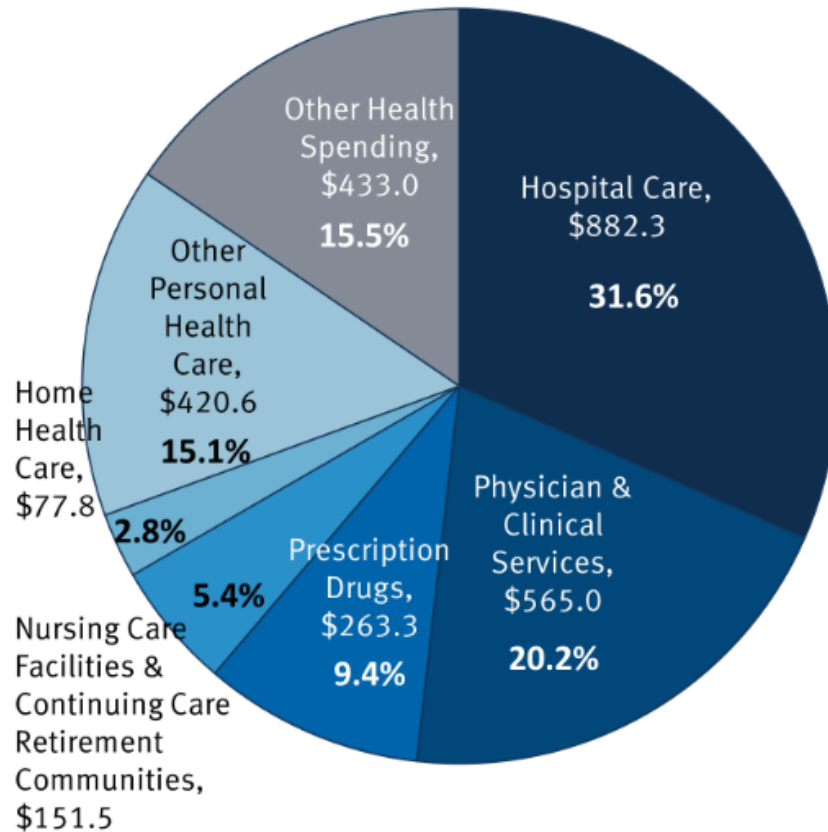
MANUFACTURER											
REGULATORS	HHS	OIG	CMS	FDA	HRSA (OPA)	SEC	FTC	DEA	States		
PLAN SPONSORS	Employers	Federal Government			State Government		Federal Defense		Individual		
PAYERS	MCO	PBM	Medicare	Medicaid	TRICARE	Patient (cash)	Federal Employees Health Benefits Program				
DISTRIBUTORS	Wholesaler	Specialty Distributor	Medical Device Distributor	Warehousing	Retail Chain	Hospital Consolidated Service Center		Manufacturer Direct			
INFLUENCERS	Group Purchasing Organization (GPO)	MACPAC	MedPAC	GAO	Purchasing Alliance	Accreditation Body					
DISPENSERS / SITE OF CARE	Retail	Mail Order	Specialty Pharmacy	Hospital	IDN / IHS	VA	DoD	Long-Term Care	Home Health	Specialty Infusion Provider	Clinic / Office
SERVICE PROVIDERS	Third Party Logistics		Access, Affordability & Treatment Support Services		Contract Field Services			Data Supplier		Data Aggregator	
PRESCRIBER											
PATIENT / CONSUMER / CAREGIVER											

Story Of Healthcare Reform – Putting The Genie Back in the Bottle

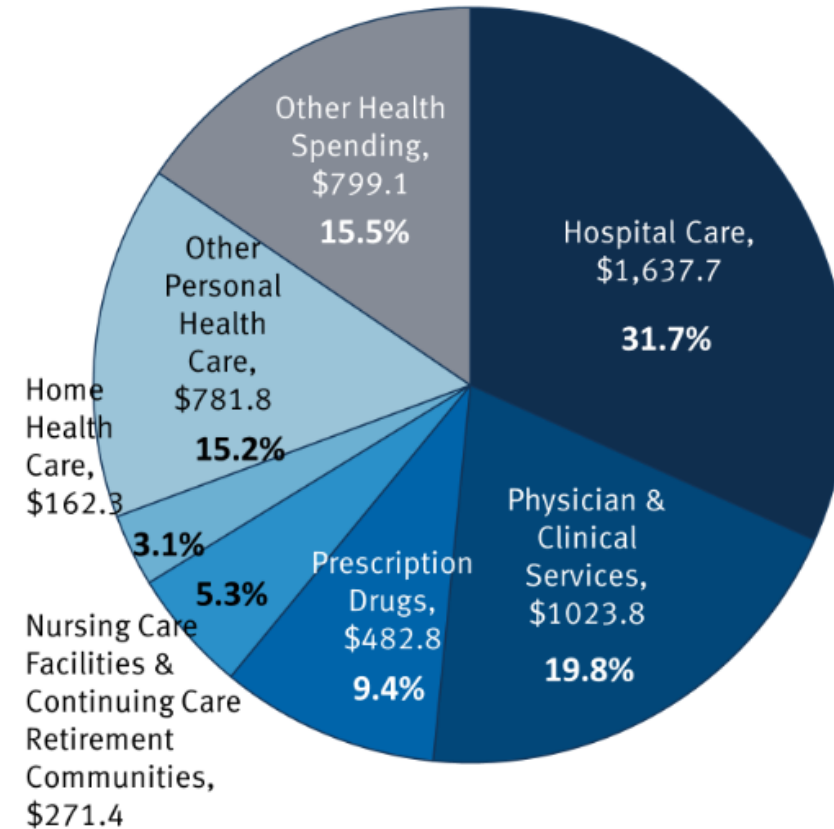


National HC Expenditures 2012 - 2022 Projected

**2012 NHE Total Expenditures:
\$2,793.4 billion**



**Projected 2022 NHE Total Expenditures:
\$5,158.8 billion**



SOURCE: Kaiser Family Foundation calculations using NHE data from Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group, at <http://www.cms.hhs.gov/NationalHealthExpendData/> (For 2012 data, see Historical; National Health Expenditures by type of service and source of funds, CY 1960-2012; file nhe2012.zip. For 2023 data, see Projected; NHE Historical and projections, 1965-2023, file nhe65-23.zip).

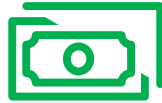
Macros....as it relates to Life Sciences – Fight For The Dollar is ON!!



Payer



Pharmacy



Distributor



Manufacturer

Government and Commercial Payers

- Raising premiums
- Raising deductibles and OOPs
- Record number of NDC blocks
- Copay accumulators and maximizers
- Specialty Carve Outs
- Use of LOAs
- Use of NCDs and LCDs
- Removal of Medicaid Rebate Cap
- Price increase penalties for Medicare Part D/B
- By 2030 – top 80 drugs treated like single payer










Channels

- Hospitals charging Commercial 250% of Medicare
- Hospitals refusing to comply with transparency laws
- Pharmacies charging 4-5X cost on Generics
- Distributors charging 6.5%-15% Emerging/Biosimilars

Manufacturers

- Fighting against 340b abuse
- Lowering WACs
- Offering dual pricing options – High WAC/Low WAC
- Using new pharmacies and forms of distribution

Product Archetypes are fundamentally different business models

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Cost	Low <\$8k/year	Very Low	Very low-low	Med – High	Med – High (\$8k-\$20k)	High (>\$20k)	Med – High	Very High	Very High
Payer Barriers	Tier 2-3	Tier 1	Highly unlikely	PA, Step Edit, Benefit Design, Reimbursement	PA, Step Edit, Benefit Design, Reimbursement	PA, Step Edit, Benefit Design, Reimbursement	PA, Step Edit, Benefit Design, Reimbursement	Find patient, PA, Step Edit, Benefit Design, Reimbursement	Qualify patient, Logistics, PA, Step Edit, Benefit Design, Reimbursement
Therapy Complexities	Low	Low	Low	Med – High	Med – High	High	High	High	High – Very High

Commercial strategies for these product archetypes drive drastically different market access, pricing and contracting strategy decisions

What Drives Channel Strategy and Configuration?



Patient Population

Smaller populations use more direct and limited distribution models. Larger uses distribution intermediaries.



Product Cost

Smaller populations use more direct and limited distribution models. Larger uses distribution intermediaries.



Complex Handling

Less complex handling, storage and shipping leverages large scale distribution. More complex is direct and limited.



Complex Care/Admin

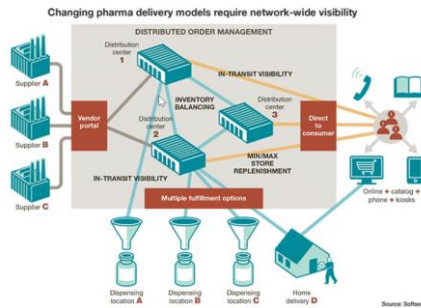
Less complex care and admin uses broad retail and distribution models. More complex uses direct/limited.



Complex Access

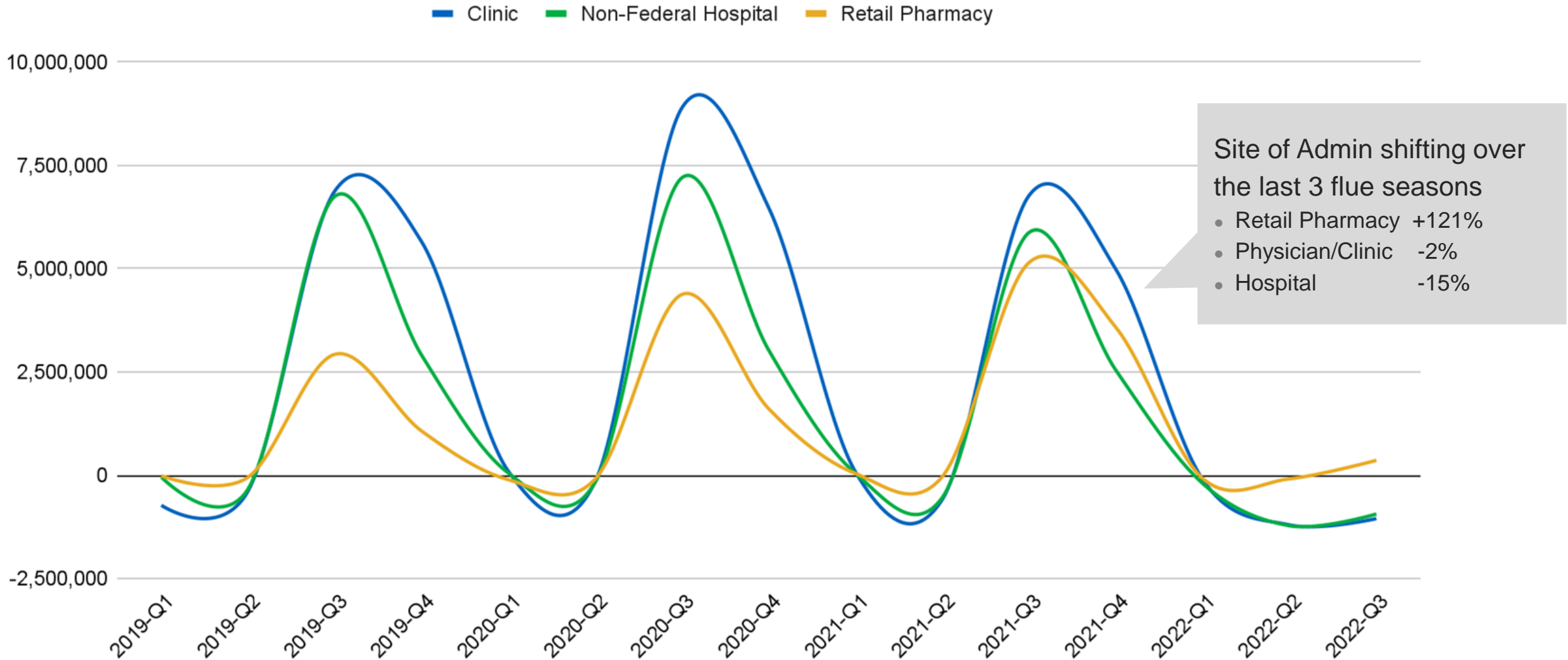
Less complex access uses large access footprints. More complex will use direct or limited models.

What Channel and Distribution Strategic Decisions Are Made?

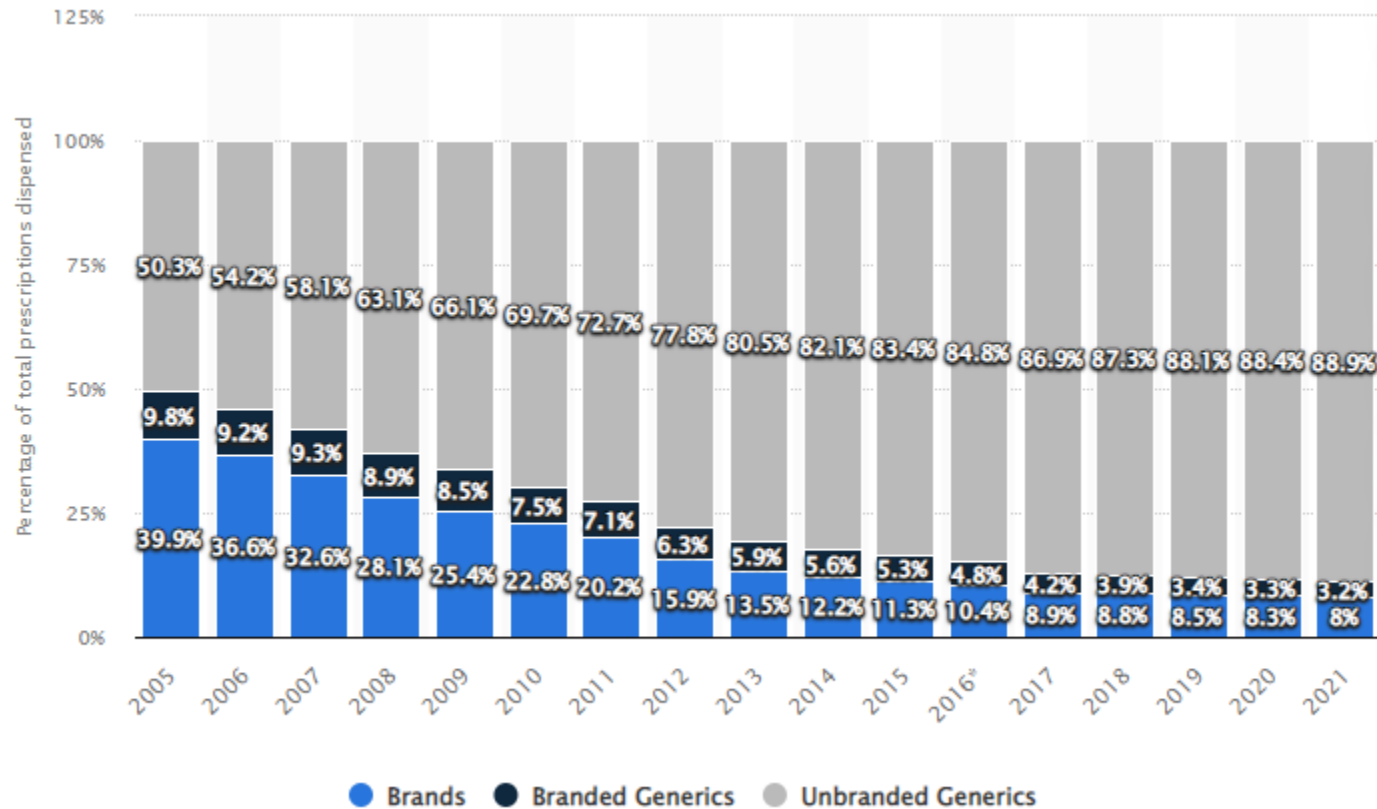


- **Manufacturers choose dispensers, hospitals and home care providers.** At a minimum all product types will be considered for self-administration or Healthcare Provider administration. Hospitals are the preferred channel for HCP admin across the globe but clinics and home care are gaining more ground
- **Distribution options in a particular country or region vary based upon market dynamics and government regulations.** The US is based solely on market dynamics other countries provide fixed margins on distribution businesses allow several players to compete.
- Lastly, **channel and distribution network designs are considered carefully against Fair Trade Regulations** which vary by country but in general more complex product types lean toward direct and narrow networks for product access and distribution.

Seasonal Influenza Vaccinations are Shifting to Retail and Will Likely Continue in the Post-COVID Pandemic Era



Retailers increasingly disregard the importance of innovation



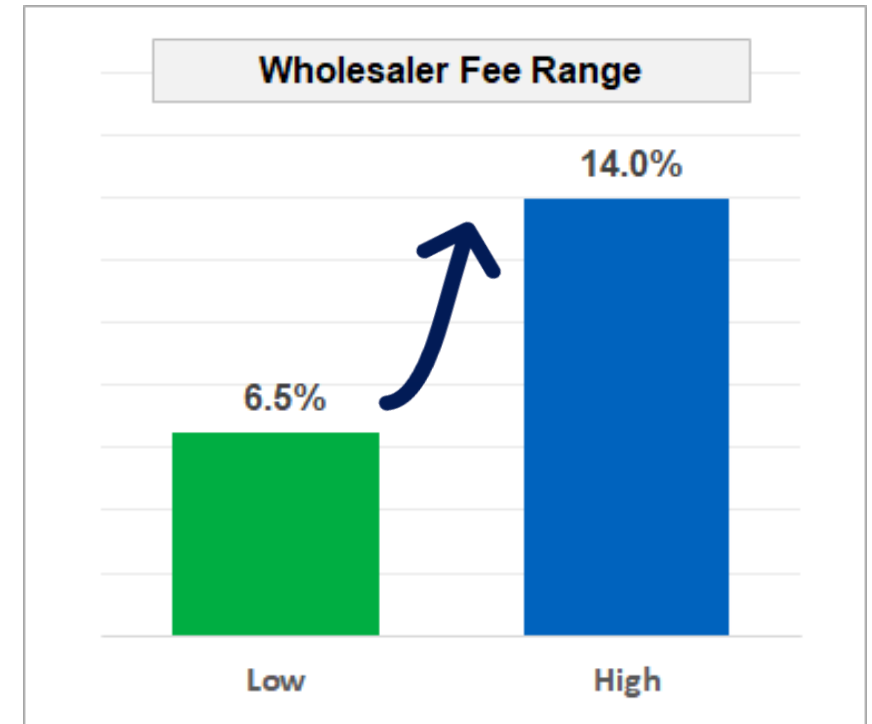
*Source: Statista 2023

** Source: Commonwealth Pharmacy Study August 12, 2021

- Brands represent only 8% of the prescriptions with a 40% rate of abandonment, a 75% adherence rate and represent roughly 3.5% margins
- Generics represent 92% of prescriptions with a 3% rate of abandonment and represent roughly 43% margins
- A \$100M pharmacy is bringing in roughly \$2.3M and \$11M worth of margins on brands and generics respectively
- Wholesalers carry low FDC inventories, place brands on allocations and push their GCRs
- Translation – retailers and wholesalers don't care about brands

Emerging Life Sciences Companies pay exorbitantly for distribution

Category	Service Description
Distribution	Stocking, packing, and shipping product as a part of the general distribution offering. This includes distribution to the downstream customers and submission of product orders to the manufacturer.
Inventory Management	Maintaining consistent inventory levels measured in days of inventory on-hand and projecting future order needs.
Storage & Handling	Safeguarding products using proper storage and transit conditions.
Contract Administration	Maintaining and updating customer master data and contract prices.
Chargeback Processing	Administering and processing customer chargebacks
Data Reporting	<p>Providing electronic transmissions of various data sets for use by the manufacturer</p> <ul style="list-style-type: none"> • 852 - Sales and Inventory • 867 - Wholesaler Sell-Outs • 844 - Chargebacks



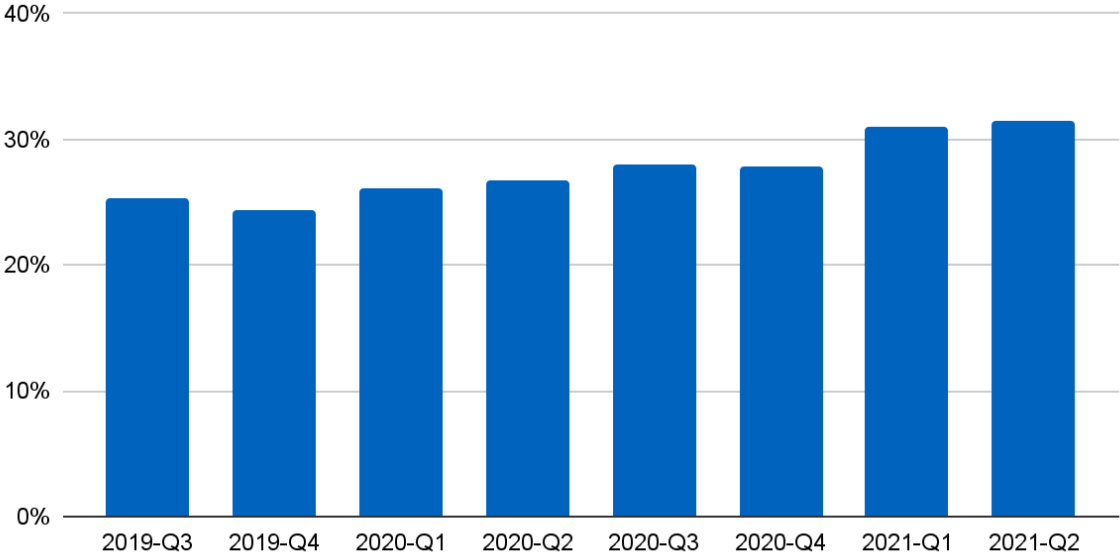
* Rate differential is primarily related to volume.
 *Graph represents emerging pharma range.

As a result of the failures in Retail and Distribution, Manufacturers are remapping how product is dispensed and distributed (Specialty Lite)

Direct shipments grew from 25% to 32% over the last 3 years

Steady Growth % of Direct Sales

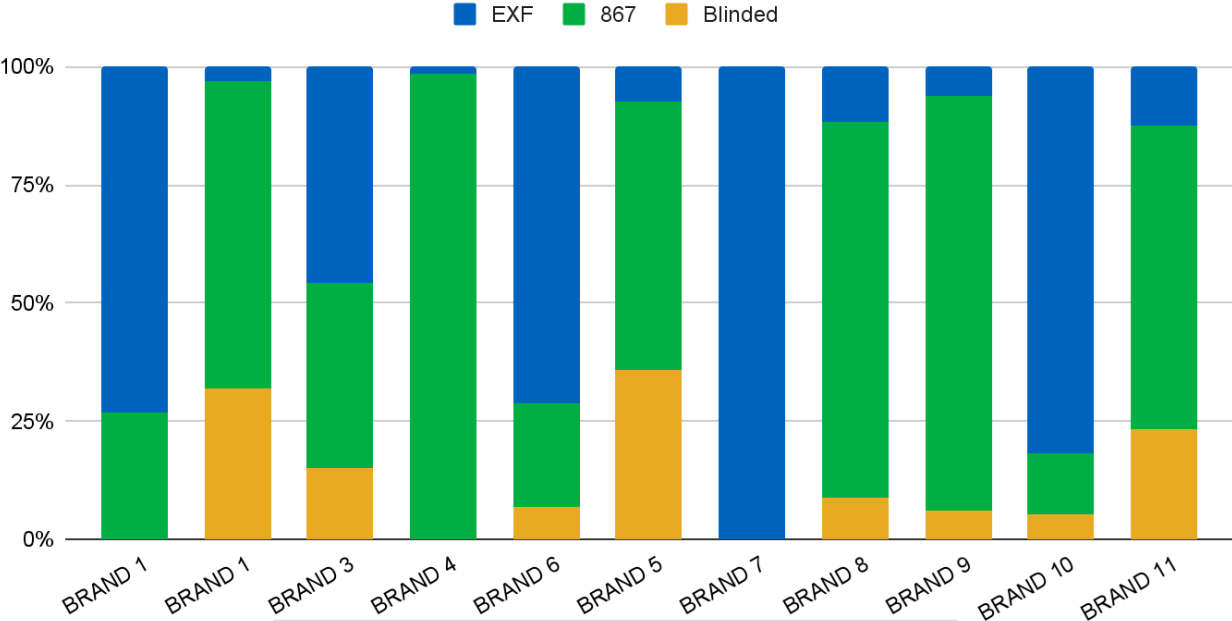
Q3-2019 Through Q2-2021



Percent of the business shipping direct rose steadily 2019-22

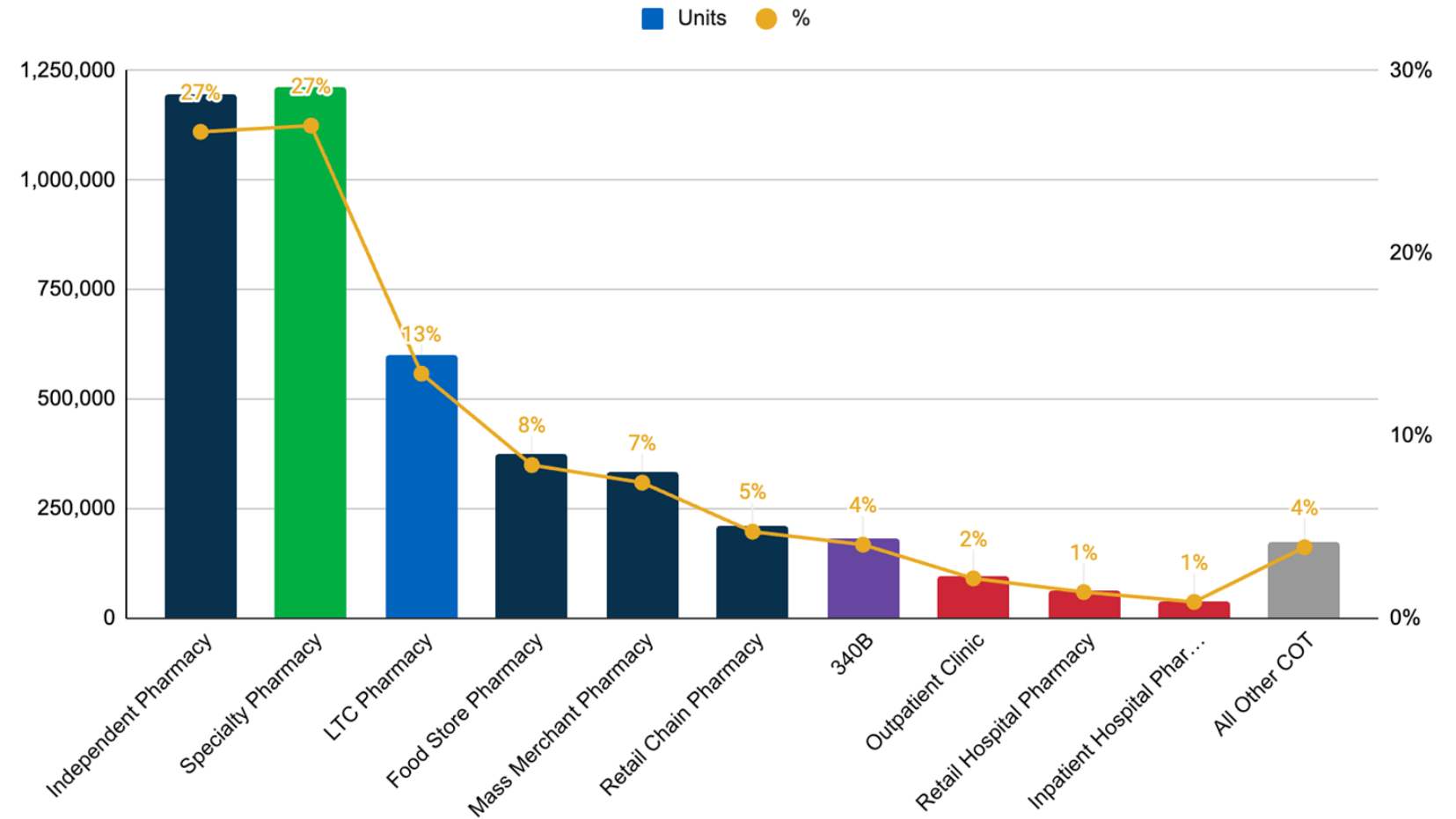
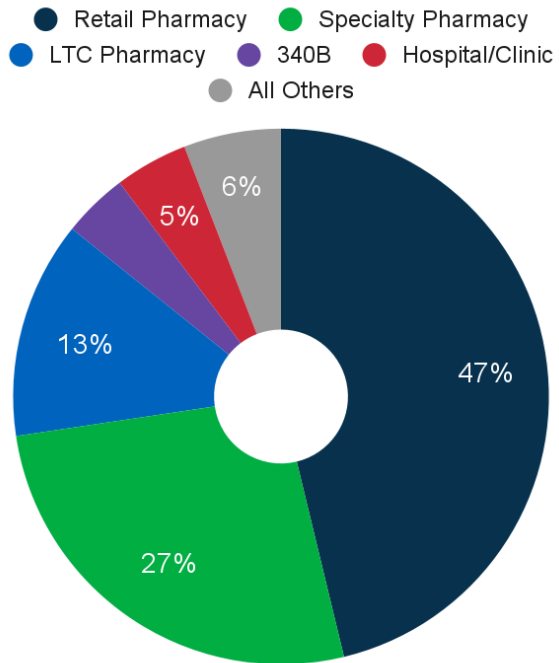
Direct Sales Above 40%

Q3- 2021 Through Q2-2022

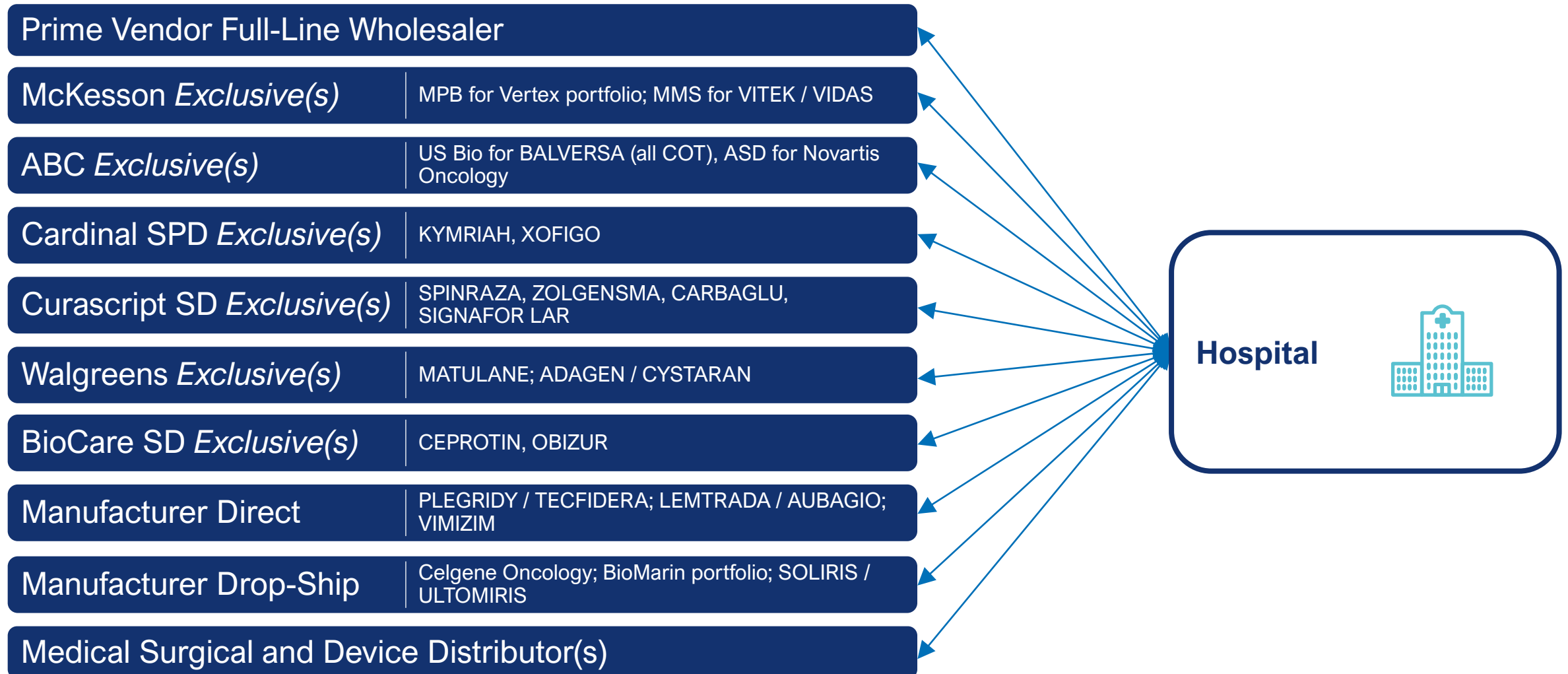


Several newer brands are disproportionately direct

Specialty Lite Drugs Are Increasingly Routed to Independent, LTC, Mail, and Health System Outpatient Pharmacies

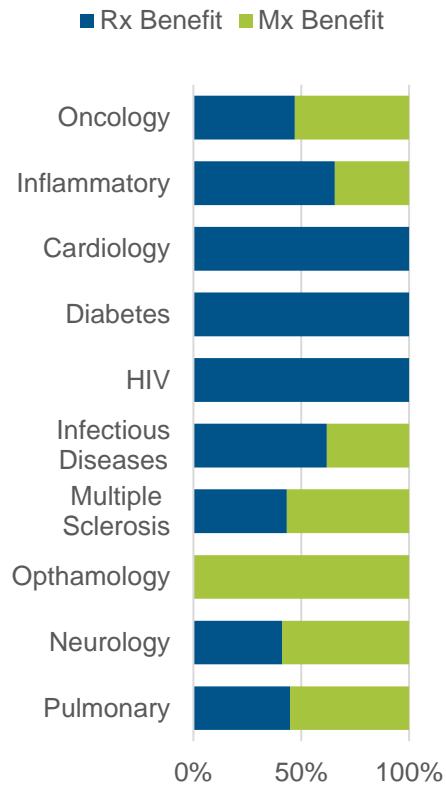


Examples of fragmentating – this is the new direction

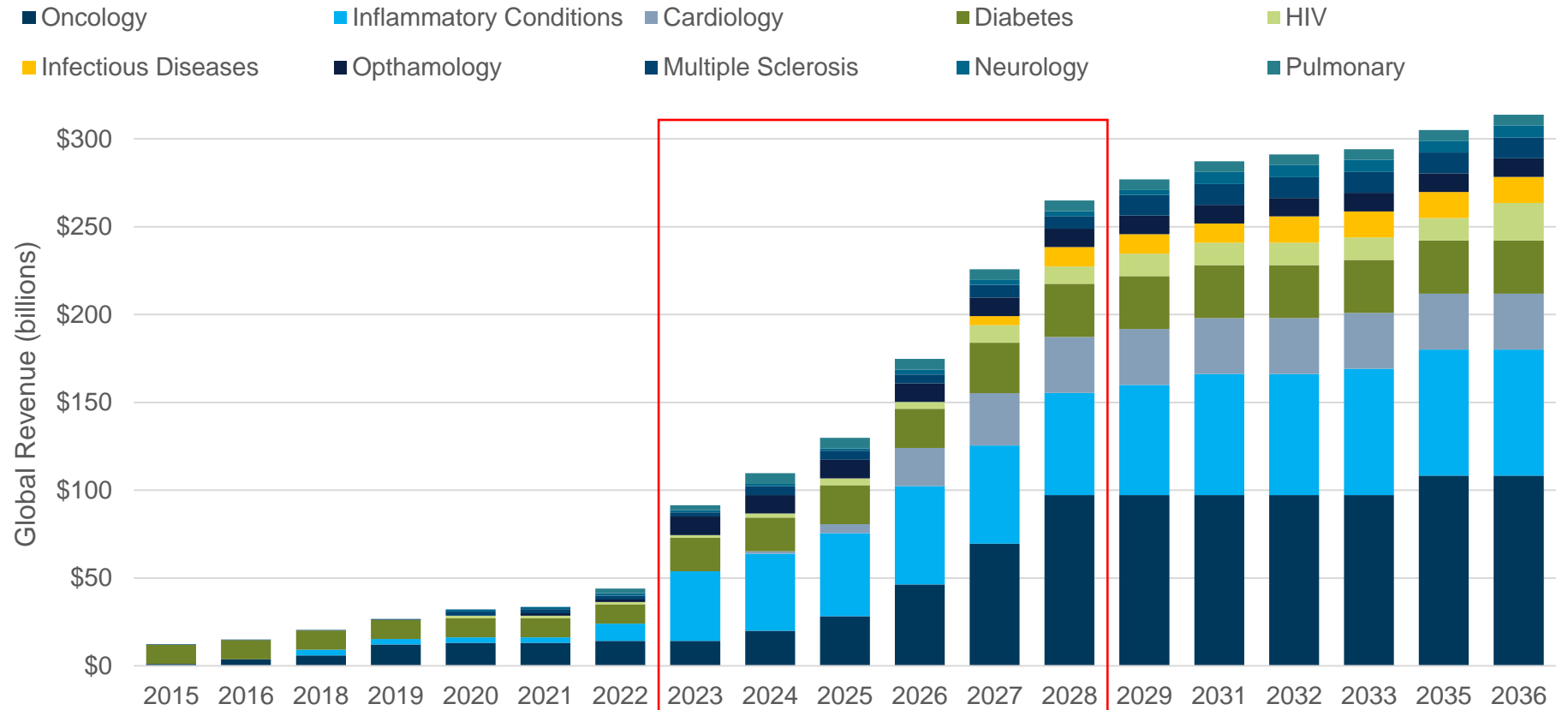


Biosimilars have been an experiment up until now – the coming Specialty LOE Wave in 2023-2028 could replaces over \$225B revenue

Rx vs Mx Benefit



Cumulative Brand Revenue at Risk by Therapeutic Area Through 2036

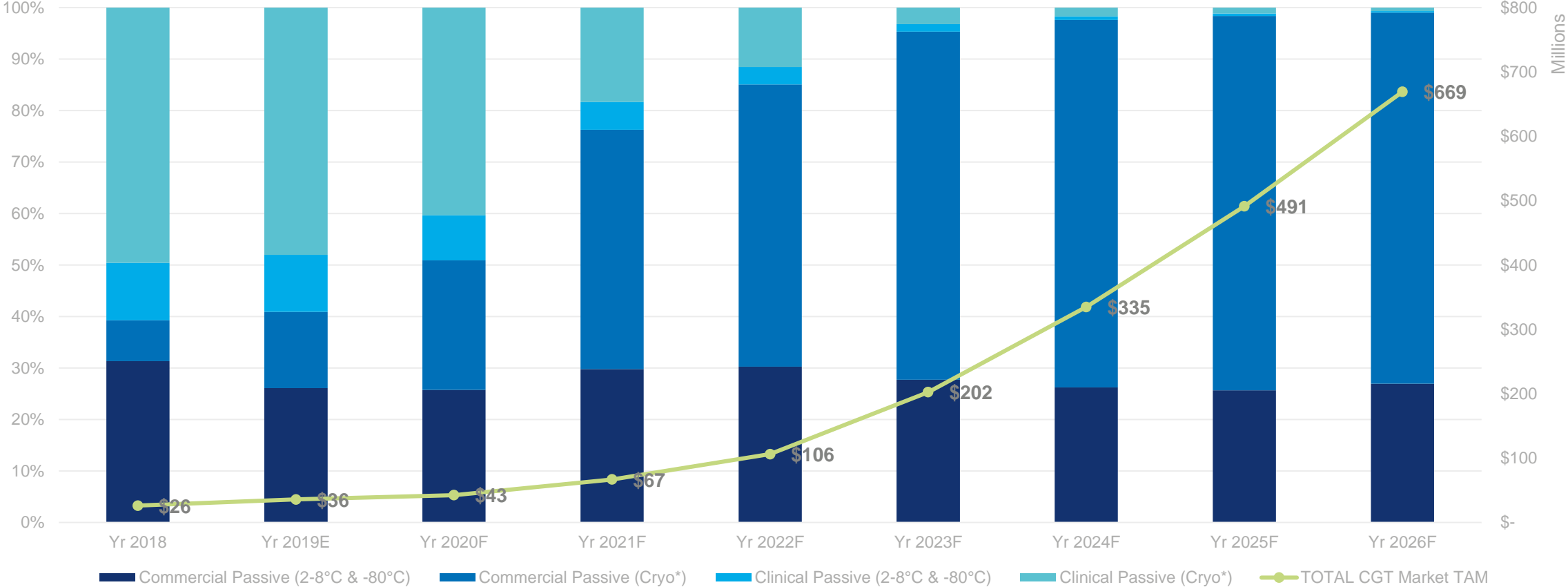


Source: *Based on 2021 revenue figures where available. Internal BFG market sizing research. Figures are based on global annual sales publishes in SEC 10k reports, industry reports, and other trade publications. Product market basket is based on BFG market research of innovator biologic and specialty brands experience or are expected to experience LOE from 2015 – 2036.

CGT category presents an additional annualized TAM growing from \$26M in 2018 to \$669M by 2026

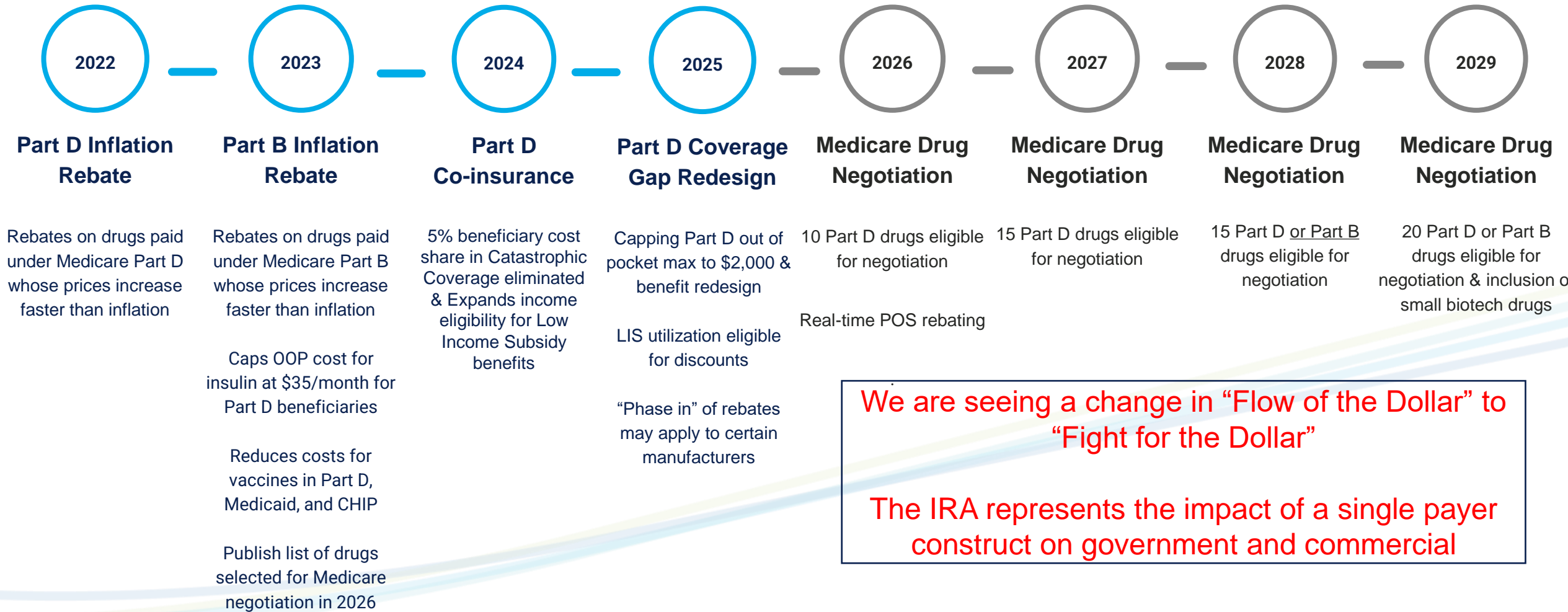
CAGR = +50.0%

CGT Cold Chain Shipping/Logistics TAM Revenue Trend, 2018-2026 and Share of Clinical vs. Commercial Shipments



* BFG Research estimates cryopreserved revenues include dewar lease fee + services (placement and return of dewars, reconditioning, LN2 charging, etc.)

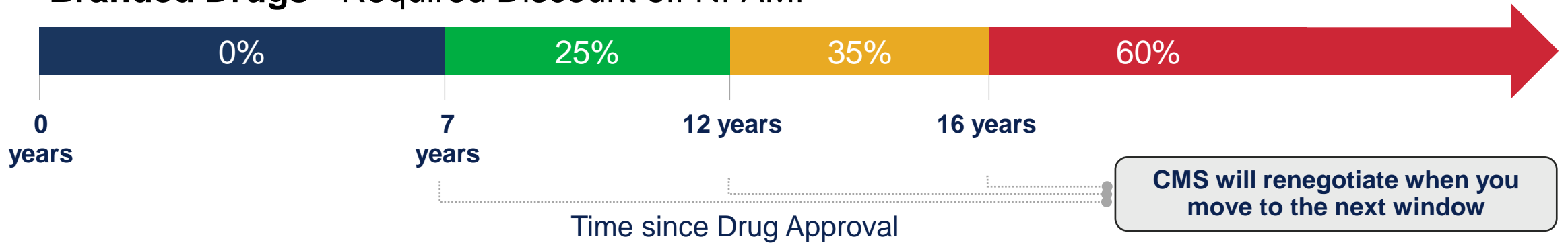
The IRA brings many chilling and sobering implications to Rx commerce



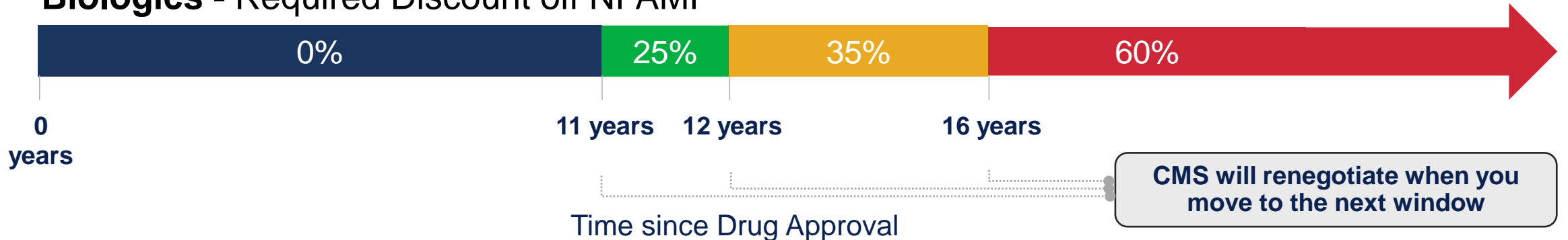
Manufacturers will lower their WACs with new pricing model at Pharmacy

The IRA establishes a new price point, the **Maximum Fair Price (MFP)**, which is a ceiling price used in the Medicare price negotiation process. MFP cannot exceed specified percentages of a drug's non-FAMP based on the type of drug and time since approval. It is unclear how much lower negotiations may go.

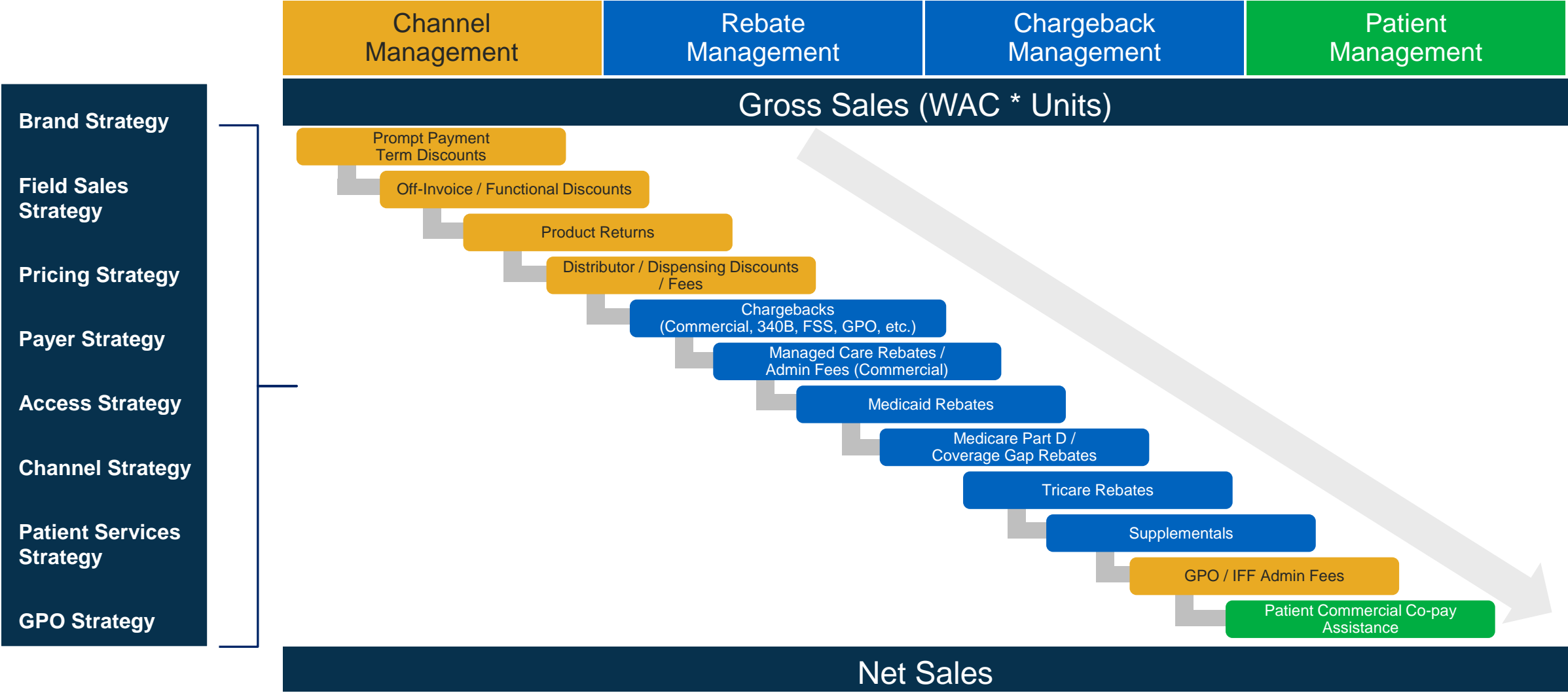
Branded Drugs - Required Discount off NFAMP



Biologics - Required Discount off NFAMP



Manufacturers have to balance a wide-array of pricing considerations that are all eventually associated to one another across payer and channel impacting GTN



As a result of all this distribution is changing across the Product Archetypes

								
Brand	Generic	Vaccines	Specialty Generic	Specialty Ltte	Biosimilar	Specialty	Orphan and Rare Disease (ORD)	Precision, Gene and Cell Therapy (GCT)
Indirect	Open Indirect	Direct Indirect	Direct LD Indirect	Direct Indirect	Direct Indirect	LD Indirect	Direct LD Indirect	Direct



Traditional distributors have shown apprehension when moving to the right of the archetype board. Payer channels are stepping in to control egregious mark-ups on the most innovative therapies and orphan and rare. Medical Benefit products generally can't have discounts making them less attractive to distributors. All these effects change a manufacturers view of the broader topic. Traditional distributors are working to educate their teams on the variations of the therapies but it is a struggle point.

Manufacturer Types drive a contextual view of Trade and Distribution

	Large	Mid-Size	Emerging
Unit and dollar volume	High units and > \$3B in gross sales	Variable unit volume based on archetype <\$3- >1B gross sales	<\$1B in gross sales
Views of Supply Chain	Operate a highly diversified and global supply chain – potentially even outsourcing functionality to other pharmaceutical manufacturers	Given the focus of the portfolio they have a tendency to operate with great visibility and control from back to forward supply chain	Operate a single or very similar focus on supply chain – will be stronger on back-end then forward – dependent on management team
View of Distribution	Thoughts vary based upon product type whether it is brand, generic, biologic, biosimilar, orphan/rare, and cell and gene therapies	Sell primarily to indirect channels – varies based upon the degree of knowledge and control of their forward channels	Tendency to consider direct or highly limited distribution as intermediaries seek to charge excessively for channel access
View of Outsourcing & Services	Depends - Traditionally have been open to W&D but have held OTC and other distribution related activities	Partially outsource - open to W&D – depending upon the \$ outlook and mix of direct channels, have brought OTC and other activities inside	Expect to fully outsource all distribution related activities including, OTC customer service and other activities

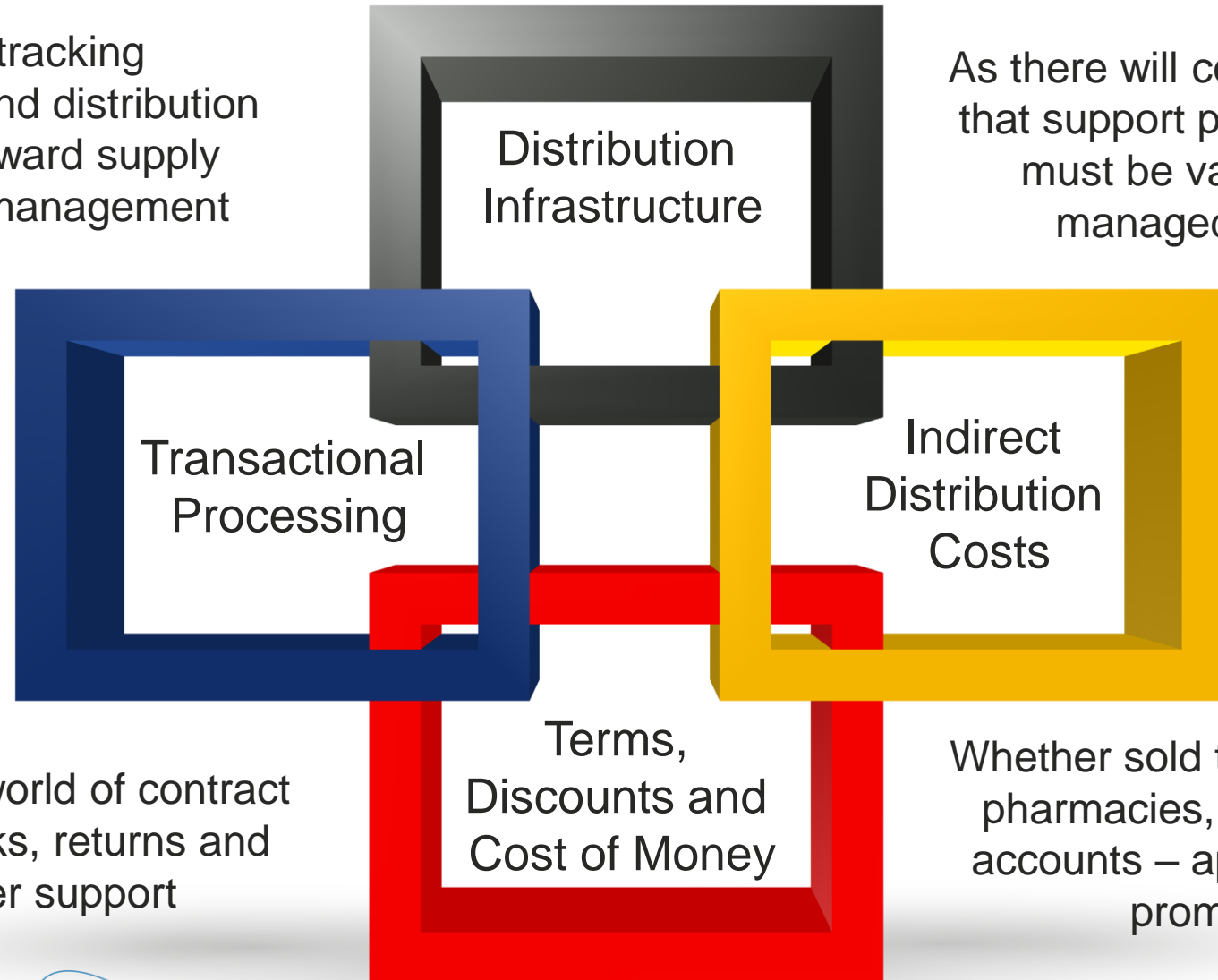
Issues facing Forward Supply Chains

- Setting the right commercial strategy for TA, Product Archetype, Benefit Design, and Lifecycle
- Forecasts that stretch multiple years and are broken down by Site of Care
- Optimization of the patient journey – accounting for abandonment, time to fill and adherence
- Flexibility of the forward supply chain and the ability to have a “Plan B”
- Running proper channel diagnostics to understand full and weighted impact and costs of various configurations

Modeling Full Expenditures Going Forward

Beginning with tracking expenditures, trade and distribution should consider forward supply chain and account management

As there will continue to be distributors that support products these programs must be valued, measured and managed as they are today



Finally there is the world of contract pricing, chargebacks, returns and direct customer support

Whether sold to distributors or directly to pharmacies, hospitals or government accounts – apply thoughtful terms and prompt pay discounts

The options to support manufacturers are growing but not necessarily building capabilities of contemporary order to cash

<p>Order-to-Cash (OTC), Chargeback and other Health Care Services</p>	
<p>HealthCare Warehousing</p>	
<p>Specialized Healthcare Transportation</p>	

*Not a comprehensive list, for illustrative purposes only

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