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HDA ABMM

IntegriChain Consulting

September 15, 2026

1

Our Discussion Topics Today

1. Science Drivers of Change
2. Policy Drivers of Change
3. What It Means For Us

2

Science Drivers of Change

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3

We view pharma pipelines, launches and science through the lens of archetypes









	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 <$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

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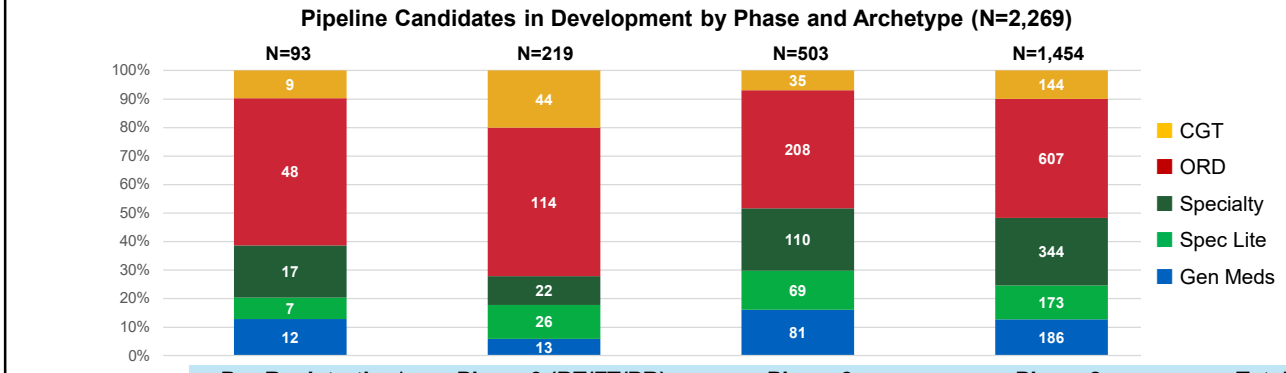
4

75% of the innovative pharma pipeline is specialty, ORD and CGT, and most of that action will be in oncology and neurology



	Pre-Registration*	Phase 3 (BT/FT/PR)	Phase 3	Phase 2	Total
Gen Meds	13%	6%	16%	13%	**13%**
Specialty Lite	8%	12%	14%	12%	**12%**
Specialty	18%	10%	22%	24%	**22%**
ORD	52%	52%	41%	42%	**43%**
CGT	10%	20%	7%	10%	**10%**
Total	**100%**	**100%**	**100%**	**100%**	**100%**

Note: Based on BioMedTracker data; 2,269 expected approvals over 2026–2031. Biosimilars, generics, specialty generics, and vaccines are outside the scope of this analysis. For assets with multiple indications, archetype reflects the indication with the smallest US prevalence population.

*Pre-Registration includes NDAs and BLAs. **BT**: Breakthrough; **FT**: Fast Track; **PR**: Priority Review.

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5

5

60% of 223 ORD and CGT launches 2020–2026 YTD had exclusive or highly limited channel models

Model for ORD / CGT Drugs	ORD Pharmacy Benefit	ORD Medical Benefit	ORD Oncology	CGT Allogeneic / AAV	CGT Autologous	Total
Direct	2	12	17	8	12	**51**
Exclusive	40	13	16	4	3	**76**
Highly Limited (2-3 SPs)	19	7	27	3	1	**57**
Limited (4+ SPs)	10	7	12	2		**31**
Preferred / Open	3	1	4			**8**
Total	**74**	**40**	**76**	**17**	**16**	**223**

Market for exclusive and highly-limited SP networks is competitive:
- PantheRx
- Orsini
- *Biologics*
- *Onco360*
- Curant
- VytlOne
- Vanscoy
- Zeal
- *Accredo*
- *CVS*
- *Optum Frontier*
- A long tail of SPs

* Excludes 3 ORD / 1 CGT products that have been withdrawn with launch configuration data unavailable. Lacking available distribution model public information on 6 ORD launches.
Sources: FDA New Drug Approvals data, Biomedtracker data, secondary research, BFG analysis.

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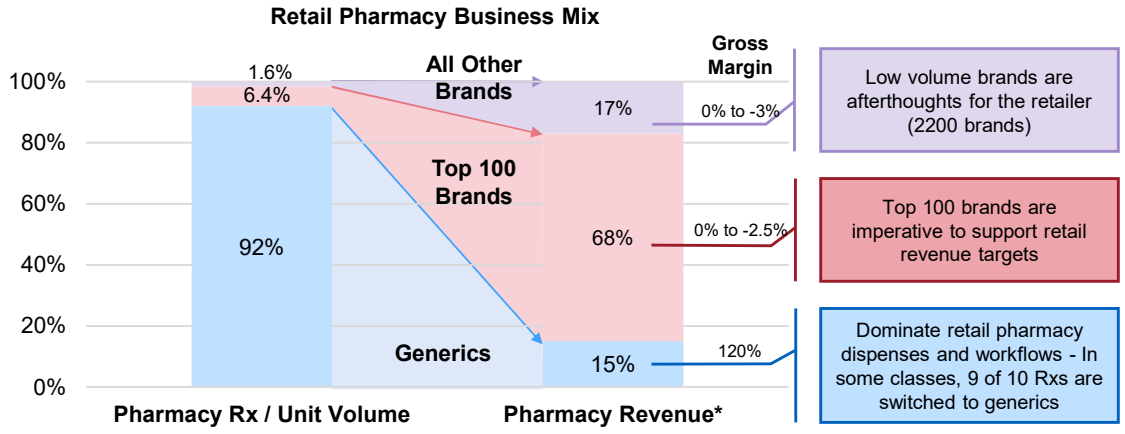
6

6

13% of the innovative pharma pipeline is Gen Meds, and these launches will be pressured from multiple angles



- PBMs are restraining growth when new science launches into markets with established old science, using onerous prior authorizations and step edit requirements
- Retail pharmacies are squeezed with increasing COGs, decreasing reimbursement and increasing cost to serve
- Gen meds brand launches in recent years have consistently disappointed

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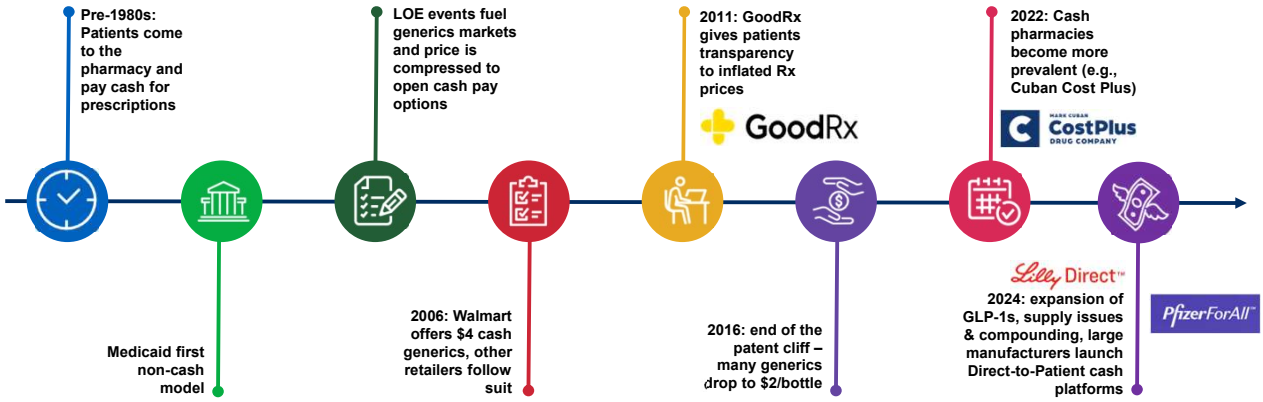
*Cost to serve and OPEX not included in gross margin. Sources: BFG Proprietary Research

Retail pharmacy struggles with brands force manufacturers to alternate channels: Cash, DTC/DTP, digital pharmacy, etc.



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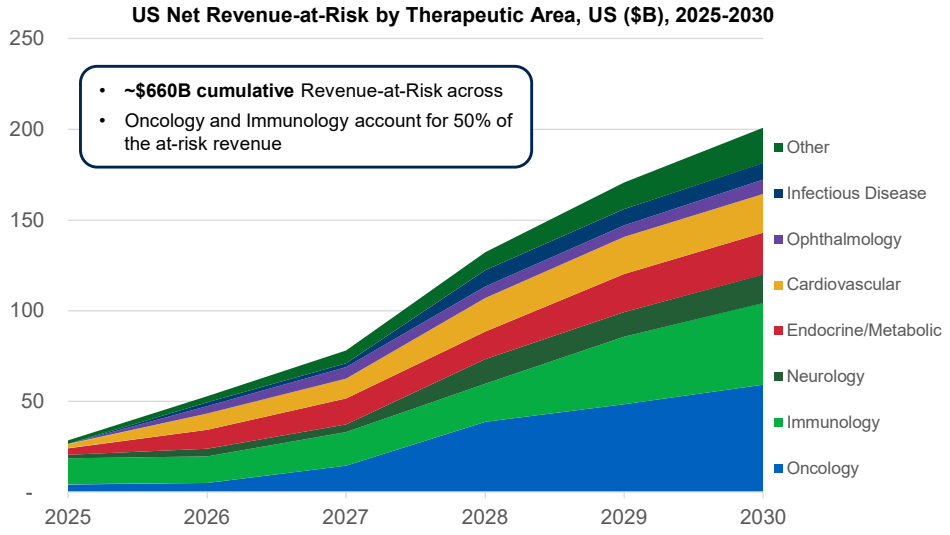
$660 billion of at-risk revenue becomes $129 billion in lost revenue 2025-2030 due to loss of exclusivity (LOE)



Specialty LOEs don't play out like gen meds generics

- On the Rx benefit side, brands have many tactics to delay LOE erosion
- On the Mx benefit side, generics and biosimilars have more success because there's less that brands can do to defend, but all of the volume stays in SD
- But even Gen Meds generic launches are changing

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Source: Biomedtracker / Data Monitor, IQVIA (US Use of Medicines report), BFG research and analysis

9

Small molecule LOE opportunities are becoming smaller in size and shorter in duration

Multiple paragraph IV first to files dilute 180-day exclusivity period	GDUFA accelerates price erosion, as 4th, 5th, 6th, 7th, 8th, 9th, 10th, etc ANDAs get approved faster	AMP cap removal does not allow price increases when the generic market shakes out	Brand LOE defense tactics are becoming more effective	MFP and WAC reductions lower the generic price; MFP can extend brand coverage after an LOE

Pressure on US Generic Drug Launch and Ongoing Revenue

Overall, there is instability in US generics market – the margin opportunities for generics get compressed into smaller windows and price descends more quickly

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10

10

Policy Drivers of Change

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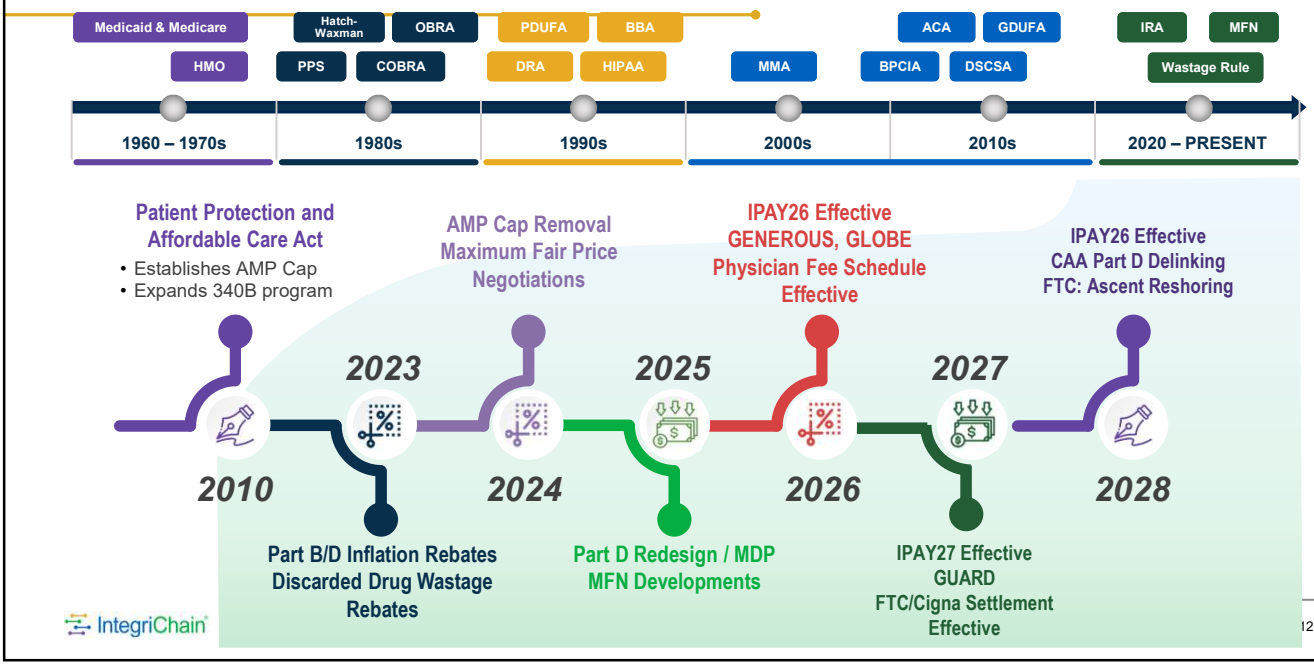
11

11

Red or Blue… government policy to reduce costs will continue



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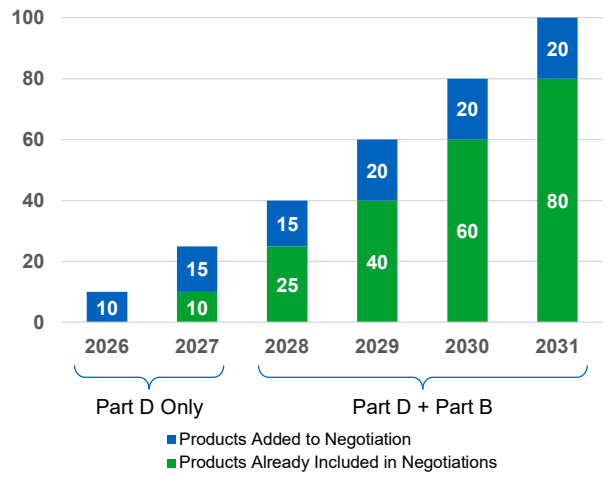
12

12

6 of 10 IPAY26 drugs lowered WAC - Medicare negotiation is causing manufacturers to take unprecedented actions

Medicare Price Negotiation Selection Process



6 of 10 IPAY26 drugs lowered WAC:

- Eliquis: -43%
- Jardiance: -44%
- Januvia: -42%
- Farxiga: -37%
- Imbruvica: -42%
- Novolog/Fiasp: -75%

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Source: Biomedtracker / Data Monitor, IQVIA (US Use of Medicines report), BFG research and analysis

13

2026 PFS Final Rule: ASP and BFSF/FMV warnings to manufacturers

On Oct 31, 2025, CMS released CY 2026 Medicare Physician Fee Schedule (PFS) Final Rule. The biggest implication IntegriChain is navigating with clients is the Gov't Price Reporting changes that impact the ASP calculation, which are centered around BFSF and FMV issues.

Beginning with 2Q26 ASP submissions, manufacturers must submit the following each quarter:

- Reasonable Assumptions applied in calculating ASP (CMS has provided a Reasonable Assumptions Form[2])
- Provide a detailed documentation of methodology for FMV determinations and evidence of FMV analysis (part of Reasonable Assumptions Form)
- Bona Fide Service Fee Certification Form indicating fees are not passed on (signed by customers – wholesalers, SDs, SPs, GPOs, payers, etc.)

Implications

- Customer not signing certification may force manufacturer to include a service fee in its ASP calculation as a price concession
  - Leads to decline in ASP, decline in reimbursement paid to provider
- Manufacturers are struggling with the compliance and operational aspects of this rule.
  - It was delayed from 1Q to 2Q, but was finalized for 2Q very late, making it very difficult to implement changes to GP calculations in time.
- Introduces complex operations, compliance, and pricing and contracting considerations for medical benefit drugs

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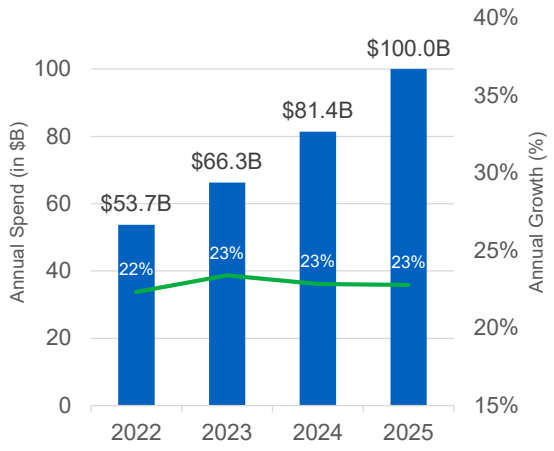
14

14

20% growth drives 340B program to $100 billion of spread revenue ($180 billion at list price and 53% average 340B discount)

2025 Covered Entity Purchases over ~$100 Billion



Source: HRSA, 2022–2025 340B Covered Entity Purchases (340B Prime Vendor Program). accurate as of June 30, 2026.

Examples of Key Drivers

In-House Shift in Site of Care
- Greater utilization at existing hospitals, especially DSHs
- Acquisition of independent practices and listing as a child site
- Continued new shipping address locations
- Contract Pharmacy Policy workarounds (ADM, VCRM, etc.)

Increase in Capture Rate
- Loosened regulatory environment and expansion of Patient Definition.
- Covered Entities capturing a large share of prescriptions written by affiliated prescribers, via telehealth and referrals

Contract Pharmacies
- Retail and specialty arrangements growing
- Vertical business relationships

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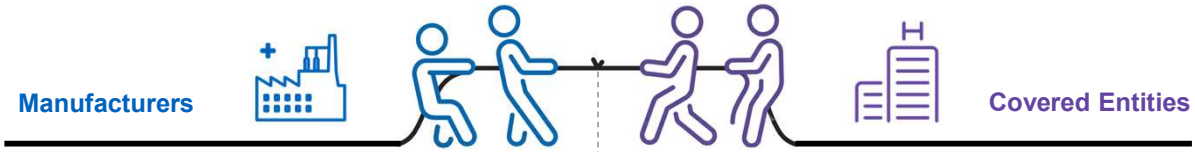
15

15

340B tensions will expand to include payers (commercial payers and state Medicaids lost $18.7 billion in rebates to 340B program)



Manufacturers	Covered Entities
Rebate Model – Initial 340B Rebate Model was implemented in 2025 only to be withdrawn. HRSA fast-tracked 340B Rebate Model v2 and is scheduled to go-live January 1, 2027	**Rebate Model** - Sued and won over administrative procedural reasons on initial 340B Rebate Model. Submitted over 5,000 comments to HRSA on v2., however, HRSA moved past concerns with announcement of v2.
Contract Pharmacy Policies – Policies started in 2020 but have evolved leading to state-level access laws that now include claim restrictions and lawsuits	**Contract Pharmacy Policies** – There have been over 20 state laws introduced, with some evolving to include 340B claim restrictions, and now AK has sued manufacturers and Second Sight Solution for not complying.
In-House Policies – Policies started in Q4 2025, with significant movement in 2026, 14 total, with one manufacturer cutting off access and others threatening.	**In-House Policies** – One hospital has sued Lilly for removing access.
Patient Definition – One manufacturer sued HRSA over the definition and created their own version.	**Patient Definition** – Stakeholders are seeking to intervene with the case and get it thrown out.
MFP Effectuation and 340B de-duplication - Manufacturers of 2026-MFP drugs, absent 340B claims, are denying MFP rebates for 340B.	**MFP Effectuation and 340B de-duplication** - Covered Entities are not getting MFP rebates and having difficulty in reconciling denials and payments.

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16

16

What it means for us?

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17

17

Channel Players Well-Positioned for the Next 3-5 Years

Specialty Pharmacy

- Darlings of PE
- Benefit from Pipeline Trends
- Benefit from Specialty LOEs; can play either side
- Intense competition for ORD exclusives and limited networks of 1-3
- Competition for inclusion in competitive non-ORD networks of 5-12+, with Big 3 PBM SPs and other SPs

Specialty Infusion Providers

- Darlings of PE
- Benefit from Pipeline Trends, specifically specialty med ben
- Capture hospital infusions by offering lower reimbursements to payers (hospitals get ASP + 30 to 300%, SIP gets ASP + 15%)
- Have diverse assets to service a patient in most financially viable manner, across home infusion, brick & mortar infusion and accredited SPs

Specialty Distribution

- Manufacturers are happy with SD channel - it meets the requirements for med ben drugs
- Benefits from pipeline - though ORD launches in many TAs often have only one SD
- Benefit from many future oncology med ben launches
- Benefit from policy trends (BFSF/FMV focus)
- Will benefit from increasing interest in MID/OID

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18

18

Channel Players Facing Headwinds for the Next 3-5 Years

Retail Pharmacy

- Generic launches are lucrative, but margin opportunities are compressed
- Gen meds brands are suppressed by PBM utilization management, which forces smaller manufacturers to alternative channels
- Squeezed on all sides: COGS increasing, reimbursements decreasing, cost to serve increasing (for brands)
- MFP and WAC reductions lower brand revenue
- Slight reimbursement benefit from MFP

Full-Line Wholesale

- Pipeline trends not favorable – most pipelines are specialty and ORD, and gen meds brand launches suppressed by PBMs
- Policy trends not favorable – MFP leads to large WAC reductions, brand price increases don't exceed CPI
- Generic launch opportunities suppressed by many reinforcing factors
- Retail pharmacy customer base struggles

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19

19

Our future will have three distinct ecosystems, how these evolve will be impacted by unprecedented drivers of change

Specialty / ORD / CGT
- Where we see channel and service innovation and investment
- Where the growth is
- Numerous market entrants: SP, SIP, patient services, MID/IOD
- Heavy use of SD

Gen Meds Brands / Specialty Lite
- Legacy models are not aligned to needs of gen meds and specialty lite launches
- Manufacturers are forced to alternative channels
- Obesity drives channel innovation like we have never seen before, and this innovation gets applied for other brands

Generics
- Could become 95% of US dispenses (currently 90%) driven by pipelines and pressures on brand launches
- Will generics be sufficient to maintain legacy channel models in the US?

- Pipeline mostly Specialty / ORD / CGT
- Gen Meds and Specialty Lite launches pressured
- Specialty LOEs pressured

Industry Evolution Next 3-5 Years

- Retail pharmacy struggles
- US Generics market instability
- MFP and WAC reductions
- 340B pressure

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20

20