GPS

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Growth. Performance. Success.

2024 ANNUAL CONVENTION

Prospering with Specialty Lite: Optimizing Operations and Resources

NCPA 2024 Annual Convention and Expo

Columbus, Ohio

Speaker

Mark Ey

SVP COO

National Community Pharmacists Association

Disclosure Statement

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Pharmacist and Technician Learning Objectives

1. Define specialty lite and associated practices commonly found within pharmacies.

2. Describe patient-centered approaches to specialty lite pharmacy services to ensure the best possible care for specialty patients.

3. Assess opportunities for workflow optimization and enhanced patient care with specialty lite services.

4. Discuss strategies for effectively positioning your community pharmacy as a valuable partner for health care providers.

Background

Previous 12 years at a cooperative that had a 74% specialty spend but.... 72% of prescriptions filled were traditional

28 multiple accredited pharmacies- URAC, ACHC, TCT, NABP, PCAB

Members specialized in HIV, hepatitis C, multiple sclerosis, cystic fibrosis, rheumatoid arthritis , pediatrics, fertility, pain management, dermatology, hospice, oncology, compounding, veterinary, infusion suites and many others

Annually met with over 250 manufacturers including specialty

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Specialty Lite Defined

Not quite specialty, not quite retail:

"…recognized as products positioned between the specialty and retail spaces, often require specialty services such as access and reimbursement support, while also having a lower-than-specialty wholesale acquisition cost (WAC) that makes full-time equivalent (FTE) models less financially feasible."

April 8, 2022 Michael Carr, AssistRx Pharmaceutical Commerce - April 2022, Volume 17, Issue 2

CMS defines "Specialty" as >$600/month for formulary purposes, for Specialty Pharmacies to make this level of high-touch service economically feasible, they typically look to take on products with a WAC of >$2500/month. This specialty WAC price gap leaves a gray area for products that could benefit from SP services, but their gross-to-net just isn't able support such a program.

(Corsica Life Sciences)

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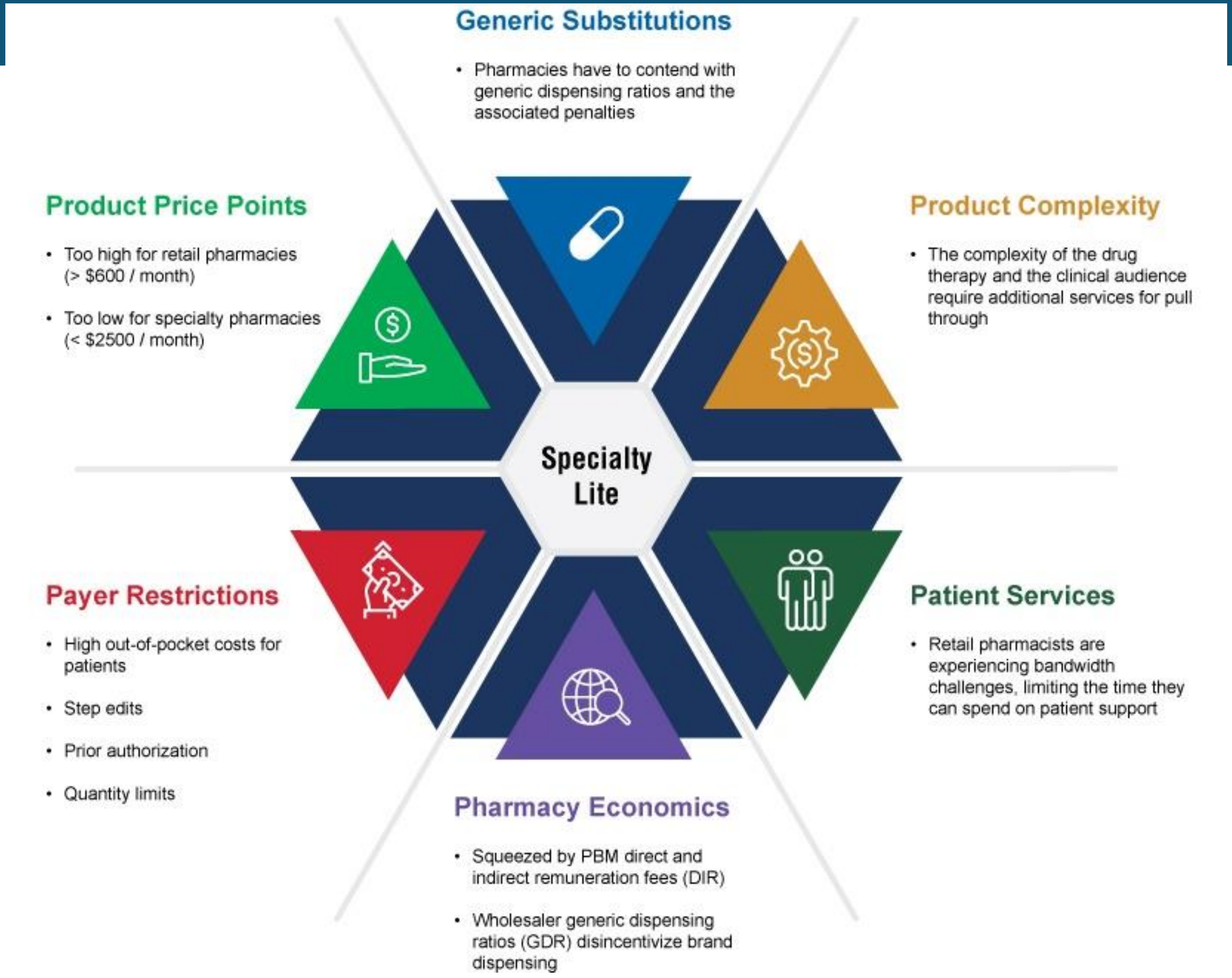
Factors Driving SPL



Specialty lite brands are expected to grow and will dominate FDA approvals in the coming years as manufacturers leverage new technology to treat specific diseases. This means that ***manufacturers will have to pay continuous attention to address the pain of balancing enhanced patient support and provider services while maintaining a profitable gross-to-net*** *in an environment in which both the cost and risk of launching a new drug are rising*

https://www.integrichain.com/blog/the-emergence-of-direct-selling-for-specialty-lite-brands

Administrative Burden on Prescribers

In a December 2022 Survey conducted by AMA, physicians noted:

- 88% of physicians said that burdens associated with prior authorization were high or extremely high.
- The survey offered striking statistics about the administrative burdens of prior authorization.
- Medical practices reported completing an average of 45 prior authorizations per physician per week, a burden that physicians and their staff spent an average of two business days completing.
- More than one-third of physicians (35%) reported employing staff members to work exclusively on PA-related tasks.

New AMA survey finds costs and harms of prior authorization exceed alleged benefits. California Medical Association Docs. March 17, 2023. https://www.cmadocs.org/newsroom/news/view/ArticleId/50082 .

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Administrative Burden on Prescribers

Physicians also reported the following additional harms that resulted due to prior authorization:

33% reported a serious adverse event for a patient in their care, including hospitalization, permanent impairment or death.

89% reported a negative impact on patient clinical outcomes.

94% reported delays to necessary care.

80% reported patients abandoning a recommended course of treatment.

New AMA survey finds costs and harms of prior authorization exceed alleged benefits. California Medical Association Docs. March 17, 2023. https://www.cmadocs.org/newsroom/news/view/ArticleId/50082 .

The National Board of Prior Authorization Specialists, a division for the ACMA, has added a Prior Authorization Certified Specialist Program for pharmacy staff.

The Prior Authorization Certified Specialist (PACS) graduates are expanding patient access, advocating for better patient outcomes, and leading the reimbursement and access industry.

Establish Yourself as an Expert in Prior healthcare system

www.priorauthtraining.org

Indeed.com

How to become a Prior Authorization Specialist Authorization

Increase your effectiveness while making a difference

Demonstrate mastery of the prior authorization and payer landscape
https://www.indeed.com/career/prior-authorization-specialist/career-advice

The Gatekeeper Vision

Physicians do not get paid after the prescription leaves their office and often are looking for help with the administrative burden of payor driven issues including but not limited to: restricted distribution networks, prior authorizations, copay assistance, and benefits mitigation.

Patients with specialty prescriptions often have multiple prescriptions that can be filled locally but often leave the retail location with all of their prescriptions if the specialty prescription can not be filled.

Pharmacies position themselves as the “gate keeper” for referral sources, taking on the administrative burden of assisting the patients and prescribers navigate payor hurdles and clinical management of patient when possible.

Specialty Lite Drugs

Despite making up approximately 2% of overall prescription volume, specialty medications now account for 53% of total annual pharmacy spending.

60% of spending billed under the pharmacy benefit and 40% billed under the medical benefit. (1)

By mid-2024, the FDA has already approved 23 novel drug therapies, with specialty drugs now representing about 75% of the approximate 7000 new drugs under development.[1,2]

Wholesaler economics becoming more and more of a challenge as they exclude many of these products from standard cost of goods calculations and "net price" specialty lite items and biosimilars.

1.Biosimilar Market Report. Samsung Bioepsis. 2024. Accessed August 30, 2024. https://www.samsungbioepis.com/upload/attach/SB+Biosimilar+Market+Report+Q1+2024.pdf
2.Approved cellular and gene therapy products. FDA. Accessed August 30, 2024. https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products

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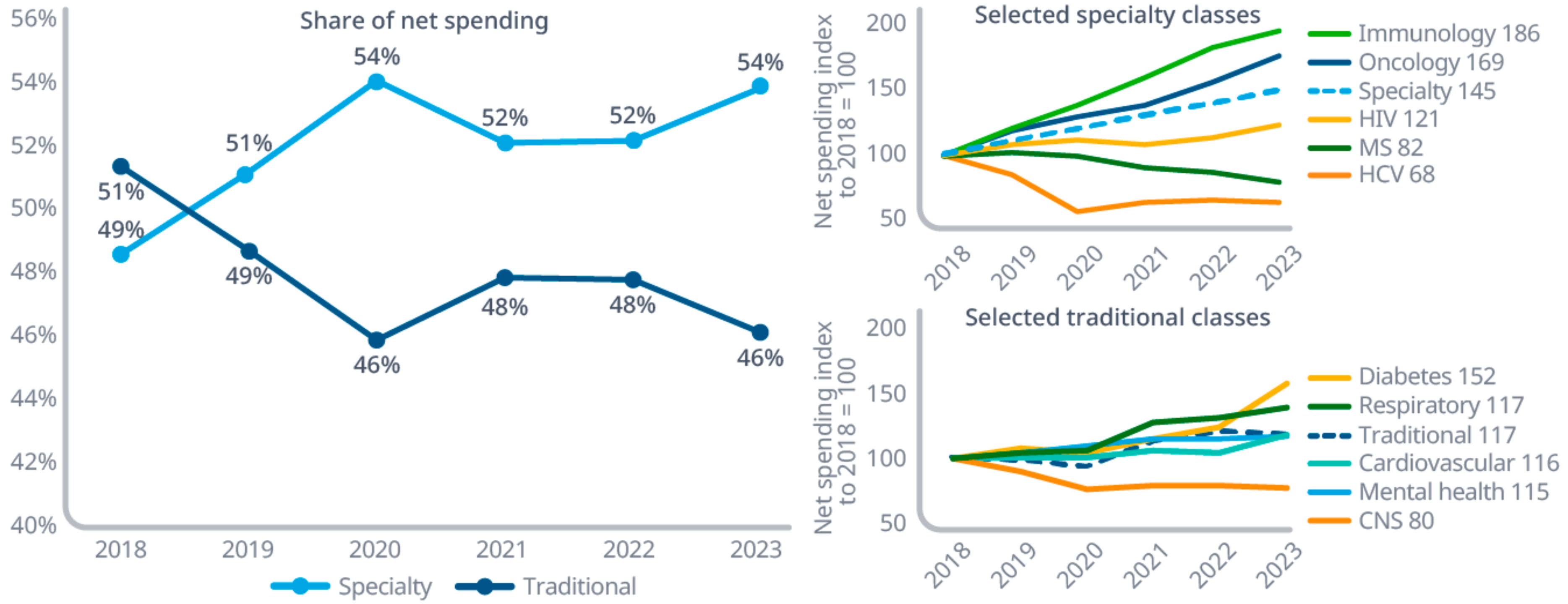
Specialty vs Traditional Growth



Source: IQVIA Institute, Mar 2024.
Notes: Specialty and traditional medicines are defined by IQVIA. Specialty medicines — those that treat chronic, complex or rare diseases, and possess additional distribution, care delivery and/or cost characteristics which require special management by stakeholders. Includes all medicines in both pharmacy and institutional settings, and all brands and generics. Totals may not sum due to rounding.
Report: The Use of Medicines in the U.S. 2024: Usage and Spending Trends, and Outlook to 2028. IQVIA Institute for Human Data Science, April 2024.

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Specialty vs Traditional Growth

In 2023, **63.8% of specialty spend was through the pharmacy benefit**, up from 62.8% in 2022 and 60.2% in 2021. Spend within the medical benefit decreased to 36.2% in 2023. https://drugstorenews.com/report-finds-increase-specialty-drug-trend-spend

The inflammatory disorder category ranked first, representing 38% of 2023 specialty drug spend, followed by oncology (25%) and multiple sclerosis (5%)

https://drugstorenews.com/report-finds-increase-specialty-drug-trend-spend

Prescription Costs Projected to Rise to Nearly 10% According to 2024 Segal Health Plan Cost Trend Survey

https://www.businesswire.com/news/home/20230914211639/en/Prescription-Costs-Projected-to-Rise-to-Nearly-10-According-to-2024-Segal-Health-Plan-Cost-Trend-Survey

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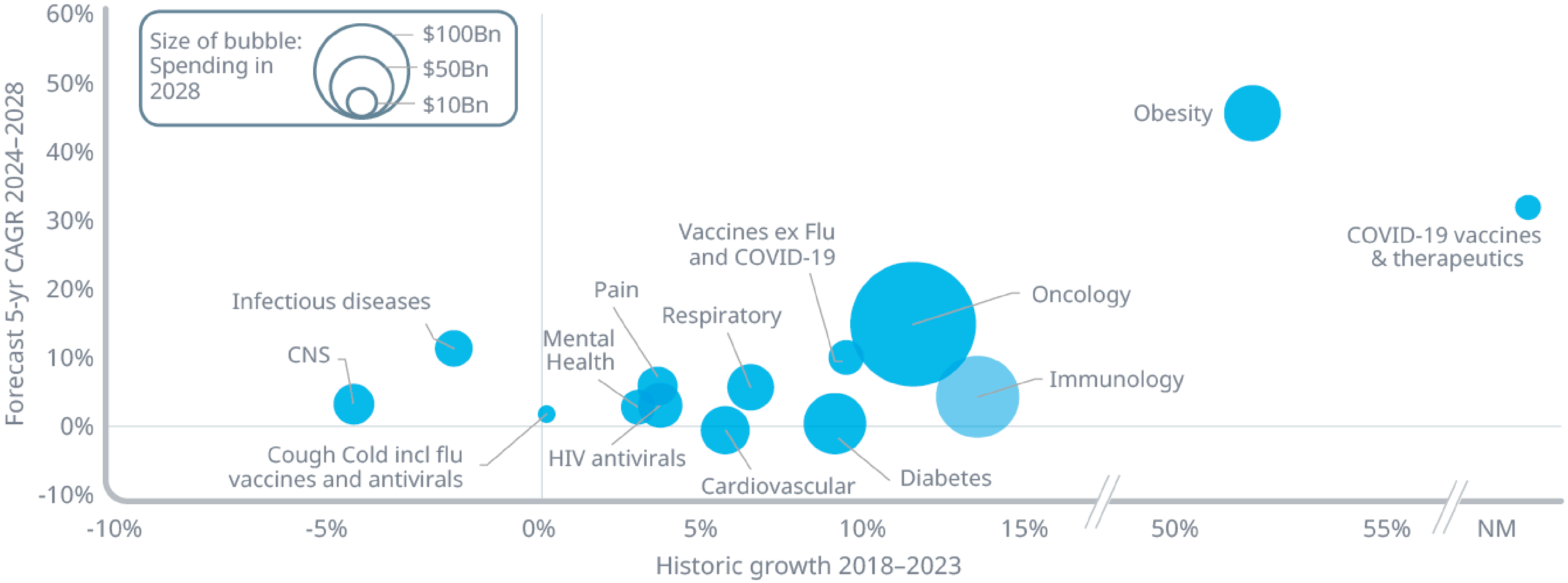
GLP1s

Since the first quarter of 2021, anti-obesity medications have shown the greatest growth, climbing 114 percent. This is due to many factors, including the off-label, weight-loss use stemming from social media buzz and exponential market investments in anti-obesity drugs as well as the American Diabetes Association recommending GLP-1 medication to reduce health complications. GLP-1 drugs will account for more than half of all diabetes drug therapies claim costs by the end of this year.
https://www.businesswire.com/news/home/20230914211639/en/Prescription-Costs-Projected-to-Rise-to-Nearly-10-According-to-2024-Segal-Health-Plan-Cost-Trend-Survey

There are new indications in the pipeline that could expand the usage of GLP-1s to areas such as sleep apnea, chronic kidney disease, MASH (metabolic dysfunction-associated steatohepatitis), heart failure and Alzheimer's Disease
https://insights.covermymeds.com/healthcare-industry/specialty-therapy/asembia-2024-shaping-pipeline-trends

An Overview of the Specialty Therapy Pipeline in 2025



Source: IQVIA Institute, Mar 2024.
Notes: NM = not meaningful, where COVID-19 5-year compound annual growth would reflect a not meaningful growth comparator to the other classes. Selected therapy areas shown. IQVIA Forecast Link modeling of company reported and analyst consensus forecasts has been utilized for therapies with the exception of oncology, immunology, diabetes, and COVID-19 which have been modeled separately by the IQVIA Institute.
Report: The Use of Medicines in the U.S. 2024: Usage and Spending Trends, and Outlook to 2028. IQVIA Institute for Human Data Science, April 2024.

Notable Specialty Pipeline in 2024/25

Resmetirom	NASH (11 drugs coming)	WAC $47k
KarXT	schizophrenia	WAC $1700
Lisocabtagene maraleucel	cellular immunotherapy	WAC $410k
Ozanimod	multiple sclerosis	WAC $6.8k
Risdiplam	spinal muscular atrophy	WAC $11k
Fintepla	childhood epilepsies	WAC $17.4k

Asembia 2024: Shaping Pipeline Trends CoverMyMeds Insights
https://insights.covermymeds.com/healthcare-industry/specialty-therapy/asembia-2024-shaping-pipeline-trends

The Rise of Biosimilars

Another factor to consider is the increase of biosimilars as biological drug patents are starting to expire. The future expiration of patents may drive spending in the biosimilar market to reach $36 billion by 2024.

Biosimilars in the United States 2020-2023. IQVIA Institute. September 29, 2020. https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2020-2024

There are currently 43 biosimilars approved for 13 biologics with 37 for 10 biologics on the market. There are also 8 biosimilars for adalimumab (Humira; AbbVie) currently on the market, and etanercept (Enbrel; Amgen) will have exclusivity until 2029.

Etanercept will be a drug to watch in addition to tocilizumab (Actemra; Genentech), golimumab (Simponil; Janssen Immunology), and ustekinumab (Stelara; Janssen Immunology)

Tharaldson A. Specialty Pharmaceuticals in Development. AMCP Nexus 2023. Orlando, Florida. October 18, 2023. Accessed October 18, 2023.

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New and upcoming biosimilar launches

CardinalHealth™

Year the first anticipated biosimilar launches
Reference biologic (molecule) **#** = Number of biosimilars either in Phase III trials, pending FDA approval or FDA approved

Asthma · Bone health · Diabetes · Immunology (e.g., RA/GI/Derm/Neuro) · Ophthalmology · Oncology · Supportive care

2023 · 2024 · 2025 · 2026+

Year	Reference biologic	Molecule	#
2023	Humira™	adalimumab	10
2023	rHI	recombinant Human Insulin	1
2023	Actemra™	tocilizumab	3
2023	NovoLog™	insulin aspart	3
2023	Neulasta™ Onpro™	pegfilgrastim	3
2023/2024	Eylea™	aflibercept	8
2023/2024	Tysabri™	natalizumab	1
2023/2024	Stelara™	ustekinumab	8
2024/2025	Simponi™	golimumab	1
2025	Soliris™	eculizumab	1
2025	Prolia™/Xgeva™	denosumab	9
2025	Xolair™	omalizumab	2
2025*	Perjeta™	pertuzumab	1
2029	Cosentyx™	secukinumab	1
2029	Enbrel™	etanercept	3

Source: IPD Analytics. Market & Financial Insights. November 2022.

*2025 is the earliest a pertuzumab biosimilar could launch given ongoing patent litigation.

Last updated: 02.20.2023
For the most updated new and upcoming biosimilar launches, please visit cardinalhealth.com/biosimilars

Top 10 Medications 2024

Table 1 | Top product forecasts for 2024

Rank	Product	Company	Pharmacological class	2024 worldwide sales forecast (US$)
1	Keytruda	Merck & Co.	Anti-PD1 mAb	27.19 billion
2	Ozempic	Novo Nordisk	GLP1 receptor agonist	16.13 billion
3	Dupixent	Sanofi/Regeneron	Anti-IL-4/IL-13 mAb	13.45 billion
4	Eliquis	Bristol Myers Squibb/Pfizer	Factor Xa inhibitor	13.31 billion
5	Biktarvy	Gilead Sciences/Yuhan	HIV INSTI/NRTI/NtRTI	12.57 billion
6	Darzalex	Johnson & Johnson	Ant-CD38 mAb	11.98 billion
7	Opdivo	Bristol Myers Squibb/Ono	Anti-PD1 mAb	11.33 billion
8	Comirnaty	Pfizer/BioNTech	SARS-CoV-2 vaccine	10.79 billion
9	Gardasil	Merck & Co./CSL	HPV vaccine	10.03 billion
10	Skyrizi	AbbVie	Anti-IL-23 mAb	9.93 billion

Forecasts include sales booked by global marketing partner, where relevant. Estimates based on sellside equity analyst models, compiled by Evaluate Pharma to generate a consensus view. INSTI, integrase strand transfer inhibitor; GLP1, glucagon-like peptide 1; HPV, human papilloma virus; mAb, monoclonal antibody; NRTI, nucleoside reverse transcriptase inhibitor; NtRTI, nucleotide reverse transcriptase inhibitor; PD1, programmed cell death protein 1; SARS-CoV-2; severe acute respiratory syndrome coronavirus 2. Source: EvaluatePharma and company statements, December 2023.

BioPharma PEG https://www.biochempeg.com/article/382.html

Current State of Pharma

Drug access/distribution is increasingly challenging and expensive (>50% of drug price)

- PBM discounts, rebates, and guarantees –"Pay to Play"
- Fees
- Specialty pharmacy
- Wholesaler
- Chain pharmacy stocking
- Cost of copay cards and PAP programs

Manufacturers are in a direct struggle with PBMs, just as we are

With the rise of managed care in the past, manufacturers gradually abandoned community pharmacy but are looking to re-engage

Medical providers are increasingly more difficult to engage – independent pharmacies have this access

Manufacturers are looking for new patient/provider engagement models

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Purchasing Considerations

Wholesaler contract (PVA)

- Net priced items or classes- do you know what your PVA says?

GPO contracts

- Can you stack GPO contract per your PVA?

Secondary Market

- Many secondaries offer 2Net30 and with a credit card you can get 2.25% cash back bringing the COGs down to WAC – 4.25%

GCR/GPR/BPR

- Are NET priced items scrubbed from your GCR, GPR, BPR?

What does the solution look like?

Independents require a solution that:

- Keeps specialty drug dispensing in independently owned pharmacies
- Provides back-end solutions for specialty, hybrid, and traditional retail pharmacies (ie: prior authorization, copay assistance, benefits review, and available grant monies)
- Provides assistance in accreditation, data collection, and potential for increased access to products

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Solution Needs

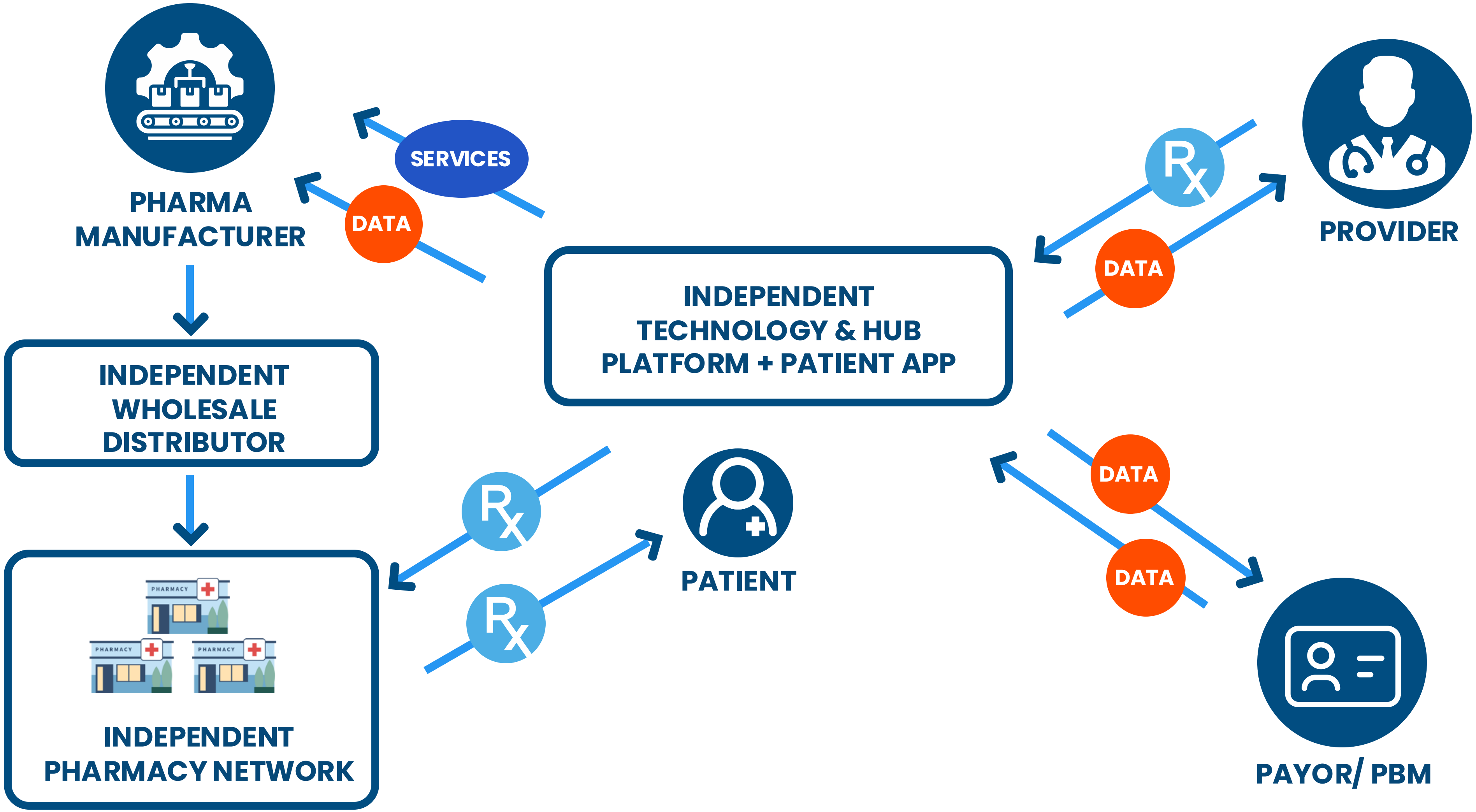
Independents do **NOT** want a partner/program that:

- Simply took all Rxs a pharmacy could not fill without looking at potential independent pharmacy access
- Had the potential to “pilfer” non-specialty Rxs and patients
- Provided distribution only
- Did not provide access to manufacturer clinical and P4P program money
- Did not have solutions for every pharmacy
- Did not have mutual indemnity for pharmacy in contract

Emerging Company – Ecosystem Overview

Distribution	Tech and Hub	Pharmacy
Wholesale Distributor + 3PL + Cold Chain	Digital Pharmacy and Hub Platform	Backend Pharmacy Providing Clinical Concierge Services
NABP Accredited Facility	Patient Rx Adherence Tool	Multi-State Licenses with Focus on "Specialty Lite"
Manufacturer Relationships	Nationwide Network of Pharmacies	Direct-to-Consumer Mail Order for Geographic Gaps

Emerging Company - Business Model



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Emerging Company Highlights

AI Powered Hub
AI driven platform for intelligent and efficient routing of Rx's with auto-application of manufacturer copay cards for eligible patients.

Patient Rx Adherence Tool
Rx notifications through the Patient App ensures medication compliance and prevent therapy abandonment.

Omni-Channel Product Strategy
Market access has many doors - and we hold the keys. We analyze every possible market segment and find the best access points.

320+ EHR Integrations
Drive meaningful connections with Providers through targeted EHR messaging to improve brand visibility and prescribing behavior.

Robust Nationwide Pharmacy Network
Our network of locally owned, independent pharmacies allows patients to receive their Rx same or next-day based on location.

Clinical Concierge Services
Dedicated clinical team providing broad spectrum services including eligibility check, benefits verification, and prior authorizations.

Alternative Channel Strategies
Our NABP Accredited Drug Wholesaler unlocks secondary channel access - saving you time and money.

Data Science Drive Insights
We provide transparent reporting and leverage market intelligence with product-specific KPIs to guide decision making.

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Solutions for Brand, Market Access, and Trade Distribution

01

Product Access through Distribution

Each pharmacy client gains one of our experienced Pharmacy Strategists dedicated to working with them personally through our **E-Commerce Site**.

02

Patient Rx Adherence Made Easy

Our **Patient App** is a health tool that allows patients to order prescriptions, manage household medications, pay online, and coordinate secure and convenient Rx delivery.

03

Our Pharmacy Network Partners are the Data Key

Pharmacy partners provide us with the Rx data in real-time through direct integrations or via secure upload into our HIPAA-compliant **Pharmacy Portal** for non - integrated pharmacies. We filter and scrub for the most accurate insights and metrics.

04

Easy-to-Read Patient Success Dashboard

This **Admin Portal** allows the Clinical Concierge team to effectively facilitate patient engagement between our pharmacy operations and customer service teams.

05

Sales KPI Analytics to Boost Product Performance

With the **Sales Dashboard**, you can view prescription data in real-time. Filter by territory or salesperson to determine the most effective strategies for campaign management.

Independent Pharmacy Differentiation

Our competitive differentiation leverages the bricks and mortar of independent, locally-owned pharmacies to create a powerful combination capable of delivering Rxs in hours.

- 1.3 Billion Rxs Annually
- Rooted in Communities
- 19,000+ Pharmacies
- $47 Billion Market

PATIENT PROVIDER PHARMA

INDEPENDENT TECHNOLOGY & HUB PLATFORM + PATIENT APP

INDEPENDENT PHARMACIES

01 Access to Independent Pharmacy channel for product distribution and other services

02 Prior Authorization services provided

03 Manufacturer copay or discount cards applied

04 Patient compliance and persistency preserved through DTC mobile application

05 Access to providers within those independent pharmacy communities

06 Data extract in real-time from the independent pharmacy channel

07 DTC Mail-order Pharmacy provides dispensing in coverage gaps and pharmacy deserts that index high for various comorbidities (<5% of Rxs)

Contact Information

Mark Ey, RPh

SVP/COO

National Community Pharmacists Association

Mark.ey@ncpa.org

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Questions?