STATEMENT

PhRMA
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In Opposition to Advance Price Notification in
Minnesota Senate File 2995, Senate Health and Human Services Omnibus Bill

April 11, 2023

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) opposes the advance price notification provisions in the Senate Health and Human Services Omnibus Bill, Senate File 2995 (SF 2995), legislation that would require reporting of confidential trade secret information by biopharmaceutical manufacturers. The provisions of this legislation could be harmful to the market and to future innovation and raise constitutional concerns.

SF 2995 amends the Prescription Drug Price Transparency Act to require drug manufacturers to report pricing information for prescription medicines with a wholesale acquisition cost (WAC) of $100 or more for a 30-day supply annually and give the insurance commissioner 90 days' written notice prior to increasing the WAC of a prescription medicine.

Specifically, the concerning language is:

> *If a drug subject to price reporting under subdivision 2 is included in the formulary of a health plan submitted to and approved by the commissioner of commerce for the next calendar year under section 62A.02, subdivision 1, the manufacturer may increase the wholesale acquisition cost of the drug for the next calendar year only after providing the commissioner with at least 90 days' written notice.*

Requiring advance notice of price increases could harm consumers, interfere with market competition, and raises constitutional concerns.

SF 2995 would require manufacturers to provide 90 days advance notification of WAC price increases. The WAC price does not account for rebates, discounts, and other price concessions provided for prescription medicines and therefore, does not accurately reflect the true cost to an insurer or pharmacy benefit manager. According to the IQVIA Institute, in 2021, net prices for brand medicines were, on average, 49% lower than WAC prices.[1] Such notification could also result in voluminous reporting that will in no way assist in making thoughtful changes to formulary design or budgeting decisions.

The Federal Trade Commission has acknowledged that disclosure of competitively sensitive information could undermine beneficial market forces within the industry,[2] so advance notice and other disclosure requirements could have the opposite of their intended effect and undermine competitive bidding in the

[1] IQVIA. "Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2026." May 2022

[2] FTC's comment to the Honorable James L. Seward concerning the competitive effects of the pharmacy benefit manager provisions of NY SB 58, March 31, 2009, available at: https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf.

market.[3] In addition, advance notification of WAC price increases creates financial incentives for secondary distributors to enter the pharmaceutical supply chain, thus creating a "gray" market. Gray market distribution networks consist of a number of different companies – some doing business as pharmacies and some as distributors – that buy and resell medicines to each other before one of them finally sells the drugs to a hospital or other health care facility. As the medicines are sold from one secondary distributor to another, the possibility of counterfeit medicines infiltrating the supply of legitimate medicines increases, thereby threatening patient safety.

PhRMA has challenged the constitutionality of a law requiring advance notification of price increases in Oregon on a number of grounds, including under the First Amendment and the Dormant Commerce Clause. The litigation is pending. If the law is invalidated, a similar analysis would apply to similar legislation in other states. The U.S. Court of Appeals for the Fourth Circuit overturned a Maryland drug pricing law in 2019 on Dormant Commerce Clause grounds because it regulated the price of transactions that occurred outside of the state.[4]

It is unclear how advance price notification would work when notice is based on the "for the next calendar year."

Our understanding is that the advance price notification language is meant to align with the language in the bill which describes what changes a health plan may make during the health plan contract term. It is important to note that drug price increases do not always align with the health plan contract term because 1) drug manufacturers contract with many health plans who have varying start and end dates of their contracts with plan sponsors and 2) drug manufacturer price increases may occur at various points during the calendar year.

Because of this potential misalignment, PhRMA is concerned that it is unclear what the language in requires of drug manufacturers. We request the language be changed so that a drug manufacturer gives 90 days notice prior to the effective date of a price increase. We believe this change makes clear and does not change the intent of the bill.

This legislation does not account for insurance benefit design issues that prevent discounts from flowing to patients, and SF 2995 assumes incorrectly that the price a patient pays is determined solely by drug manufacturers.

This legislation singles out the biopharmaceutical industry and ignores the variety of stakeholders involved in determining what consumers ultimately pay for a medicine, including insurers, pharmacy benefit managers (PBMs), wholesalers, and the government. The important role that these entities play in determining drug coverage and patient out-of-pocket costs is overlooked by the requirements of this legislation. For example, PBMs and payers—which dictate the terms of coverage for medicines and the amount a patient ultimately pays—negotiate substantial rebates and discounts.

According to research from the Berkeley Research Group (BRG), rebates, discounts, and fees account for an increasing share of spending for brand medicines each year, while the share received by manufacturers has decreased over time. In 2020 manufacturers retained only 49.5% of brand medicine spending while members of the supply chain retained 50.5%.[5]Increased rebates and discounts have largely offset the modest increases in list prices and reflect the competitive market for brand medicines.

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[3] FTC Letter to Terry G. Kilgore, Member, Virginia House of Delegates, re: H.B. 945 (Oct. 2, 2006); FTC Letter to Representative Patrick McHenry, re: North Carolina Bill 1374 (July 15, 2005); FTC Letter to California Assembly Member Greg Aghazarian, re: AB 1960 (Sept. 7, 2004). FTC Letter to The Honorable Mark Formby, Mississippi House of Representatives, re: SB 2445 (March 22, 2011).
[4] *Ass'n for Accessible Medicines v. Frosh* ("*AAM*"), 887 F.3d 664 (4th Cir. 2018), *cert. denied*, 139 S. Ct. 1168 (2019).
[5] BRG: The Pharmaceutical Supply Chain 2013-2020. January 2022.

This, of course, does not necessarily reconcile with what patients are feeling at the pharmacy counter, which is why looking at the whole system is so important. For example, despite manufacturers' rebates and discounts negotiated by health plans, nearly half of commercially insured patients' out-of-pocket spending for brand medicines is based on the medicine's list price rather than the negotiated price that health plans receive.[6]

PhRMA is increasingly concerned that the substantial rebates and discounts paid by pharmaceutical manufacturers, approximately $236 billion in 2021,[7] do not make their way to offsetting patient costs at the pharmacy counter. Patients need concrete reforms that will help lower the price they pay for medicines at the pharmacy, such as making monthly costs more predictable, making cost-sharing assistance count toward a plan's out-of-pocket spending requirements, and sharing negotiated savings on medicines with patients.

Innovative therapies provide unique value in the health care system.

It is important to remember that advances in medicine help control health care spending. Greater patient access to prescription medicines means fewer doctor visits and hospital stays and a decrease in costly medical procedures, all of which translate into lower health care costs overall. For example, in 2014, a new drug came to the market that provided a cure for more than 90% of patients with hepatitis C, eliminating a lifetime of hospitalizations, debilitating symptoms, and treatments with harsh side effects and replacing it with a complete cure in just 12 weeks. Often, patients with hepatitis C needed liver transplants, which could cost almost $500,000. Since 2014, several new treatments have come to the market, further driving down the price of the medicine and recent research indicates that these medications have saved Medicaid $15 billion, with the cost of a cure now lower than a single year of disease burden.[8] Innovation and progress in the pharmaceutical industry means better outcomes and quality of life for patients and their families as well as reduced health care costs to patients and the system.

PhRMA opposes SF 2995 for the above stated reasons and respectfully urges it not be enacted.

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The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Since 2000, PhRMA member companies have invested more than $1.1 trillion in the search for new treatments and cures, including $102.3 billion in 2021 alone.

In Minnesota the biopharmaceutical industry employs over 11,000 individuals and the industry generates a total economic output of over $16.9 billion per year while contributing over $1.1 billion in state and federal taxes annually. Additionally, according to the Minnesota State Medicaid Program, the industry rebates more than $632 million back to the federal and State governments through Medicaid prescription drug rebates, which is 55% of the total Medicaid drug spend in the State.

[6] IQVIA Institute for Human Data Science. Medicine spending and affordability in the United States. Published August 2020. Accessed August 2020. https://www.iqvia.com/insights/theiqvia-institute/reports/medicine-spending-and-affordabilityin-the-us
[7] Drug Channels Institute. The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. March 2022
[8] Roebuck, M. Christopher "Impact of Direct-Acting antiviral use for chronic Hepatitis C on health care costs in Medicaid: Economic Model Update." The American Journal of Managed Care December 2022, Vol. 28 Issue 12.

POLICIES TO HELP PATIENTS PAY LESS FOR THEIR MEDICINES

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America's biopharmaceutical companies agree that, for too many Americans, the health care system is not working and needs to change. While medical innovation has made the United States a world leader in the discovery of new medicines, these treatments won't benefit patients who can't get them.

There are no easy solutions, but patients need real leadership from everyone involved in our health care system to make it work better. That's why our companies are calling for everyone in the health care system to join us in supporting common-sense reforms to make insurance work like insurance and ensure that patients can access and afford the medicines their doctors prescribe.

We believe the following policies are the best way to achieve these goals and make sure that *patients pay less* for their medicines.

1 Share the Savings

On average, nearly half of spending on brand medicines goes to health insurers, PBMs, the government and others, not the manufacturer that researched and developed the medicine. However, patients often do not benefit from these significant discounts in the form of lower out-of-pocket costs for their medicines. That's not right, and it needs to change. If insurance companies and middlemen don't pay the full price for medicines, patients shouldn't have to either. These rebates and discounts must be directly shared with patients at the pharmacy counter.

2 Make Coupons Count

In some cases, health insurance companies are not allowing the coupons manufacturers provide to patients to count towards deductibles or other cost sharing requirements, meaning patients could be paying thousands more at the pharmacy than they should be. We need to end this practice so that patients are getting the full benefit of programs meant to help them access their medicines.

3 Offer Lower, More Predictable Cost Sharing Options

Actual spending on medicines is growing at the slowest rate in years. Unfortunately, it doesn't feel that way for patients. Insurers are increasingly using high deductibles and coinsurance that result in patients paying more for certain medicines out of pocket. Patients should have more choices when it comes to their medicine coverage. Every state should require health insurers to offer at least some health plan options that exclude medicines from the deductible and offer set copay amounts instead of forcing patients to pay an amount based on the full list price of their medicines.

4 Cover Medicines from Day One

Insurers increasingly require patients to pay high deductibles before receiving coverage of their medicines. This can lead to patients rationing or not taking their medicines, which can result in devastating consequences to their health. Policymakers can help patients from day one by requiring all plans to cover certain medications used to treat chronic conditions with no deductible. Additionally, insurers should be mandated to offer some plans that cover all medicines from day one.

5 Cap Patient Cost Sharing

Many commercially insured patients are being exposed to high out-of-pocket costs due to increasing use of deductibles and coinsurance. High cost sharing is a barrier to prescription medicine access, especially for patients with chronic, disabling or life-threatening conditions, who shoulder the largest share of the burden. Cost sharing should not be so burdensome that it prevents patients with insurance from accessing necessary prescription medicines.

DID YOU KNOW?

PBMs, Plans and Wholesalers Continually Rank Higher on Fortune 500 Lists than Biopharmaceutical Companies

THE TOP 10

2022
Fortune 500 Rankings

1. Walmart
2. Amazon
3. Apple
4. CVS Health
5. UnitedHealth Group
6. Exxon Mobil
7. Berkshire Hathaway
8. Alphabet
9. McKesson
10. AmerisourceBergen

Health Plan, PBM, Pharmacy
Health Plan, PBM
Wholesale Distributor

FORTUNE

https://fortune.com/ranking/fortune500/2022/search/

PBMs, Plans and Wholesalers Continually Rank Higher on Fortune 500 Lists than Biopharmaceutical Companies

TOP RANKED PBMS AND PLANS

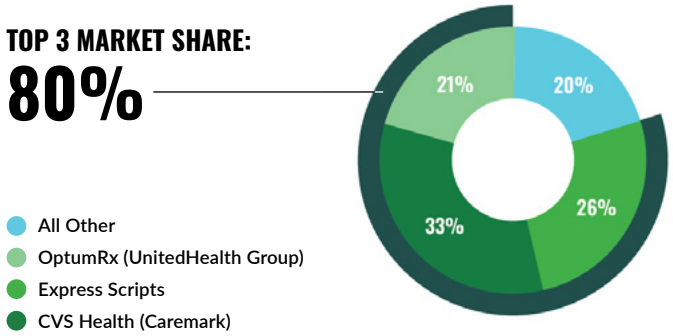
4. CVS Health (Caremark and Aetna)
5. UnitedHealth Group (OptumRx)
12. Cigna (Express Scripts)

TOP RANKED BIOPHARMA COMPANIES

37. Johnson & Johnson
43. Pfizer
63. AbbVie

Insurers and PBMs Control Access to Pharmacies and Leverage for Medicine Costs

TOP 3 MARKET SHARE:
80%



INSURERS DETERMINE:

FORMULARY
if a medicine is covered

TIER PLACEMENT
patient cost sharing

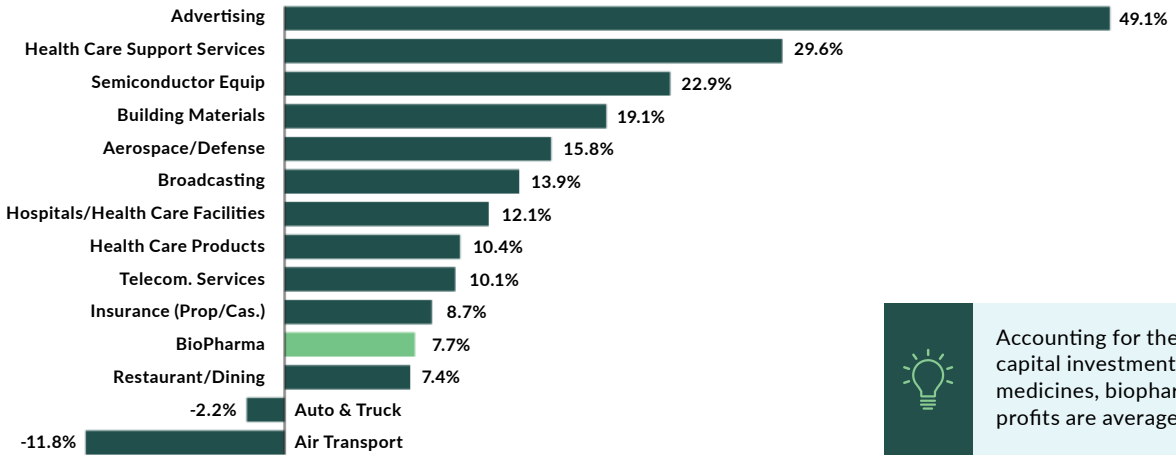
ACCESSIBILITY
utilization management through prior authorization or fail first

PROVIDER INCENTIVES
preferred treatment guidelines and pathways

HOW DOES THE BIOPHARMACEUTICAL INDUSTRY COMPARE TO OTHER INDUSTRIES?

Biopharmaceutical Profits Are in Line With Those of Other Industries

AVERAGE ECONOMIC PROFIT FOR SELECTED INDUSTRIES, 2019-2021*



Accounting for the significant risk and capital investments required to develop medicines, biopharmaceutical industry profits are average among industries.

*Economic profits are accounting profits minus capital expenses.

†Represents the weighted average of pharmaceuticals (8.2%) and biotechnology (2.2%), which are listed as separate industries in the source data.

Source: Adapted from R. Manning and A. Subramaniam, Intensity, LLC. Economic Profitability of the Biopharmaceutical Industry, 2022. https://intensity.com/news/economic-profitability-of-the-biopharmaceutical-industry-2022

[The Use of Medicines in the U.S. 2022: Usage and Spending Trends and Outlook to 2026]

IQIVA • April 21, 2022

Key Findings

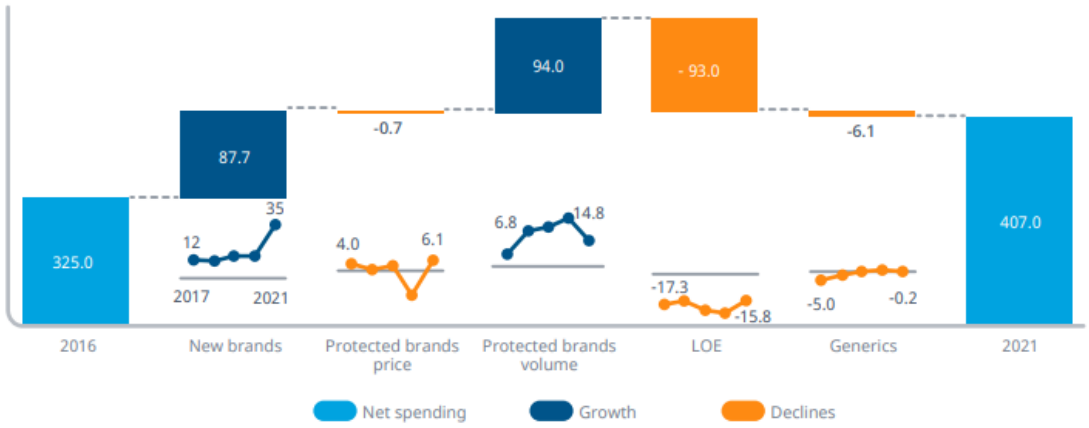
- Net prices for brand medicines increased 1.0% in 2021, below the rate of inflation for the fifth year in a row. Looking ahead, net price growth is projected to be 0% to -3% per year through 2026.
- Overall net spending on medicines (net manufacturer revenue) increased 12.1% in 2021, driven by the "unprecedented contribution" of the COVID-19 vaccine and treatments. Excluding spending on COVID-19 vaccines and treatment, spending on medicines increased just 4.9% in 2021.
- Excluding spending on COVID-19 vaccines and treatment, net per capita spending on medicines *declined* by 1% in 2021.
- Looking ahead, net spending growth is projected to return to pre-pandemic trends, increasing 1% to 4% per year, on average, through 2026.
- Brand medicine net prices are, on average, 49% lower than their list price.
- Savings from loss of exclusivity (LOE) totaled $93 billion between 2016 and 2021, more than offsetting the $87 billion spent on newly launched brand medicines over this period.

Full Summary

Medicine Spending

- Total net manufacturer revenue on medicines increased 12.1% in 2021, driven by the "unprecedented contribution" of the COVID-19 vaccine and treatments, reaching $407 billion.
    - Excluding spending on COVID-19 vaccines and treatment, spending on medicines increased 4.9% in 2021.
- Total net manufacturer revenue on medicines is projected to increase 1-4% per year, on average, through 2026.
- Real per capita net medicine spending (net manufacturer revenue) grew by 5.8% in 2021 when factoring in COVID-19 spending.
    - Excluding spending on COVID-19 vaccines and treatment, real per capital net medicine spending would have *declined* by 1% in 2021.
    - Medicine spending per capita has increased just $204 since 2011, a 1.8% compound annual growth rate, from $1,028 to $1,232.
- Total net spending on medicines increased by $82 billion from 2016 to 2021, driven by new products and increased utilization
    - COVID-19 vaccines and treatments accounted for $29 billion of this growth
    - Savings from loss of exclusivity (LOE) totaled $93 billion between 2016 and 2021, more than offsetting the $87 billion spent on newly launched brand medicines
    - Between 2016 and 2021, changes in brand medicine prices *reduced* total spending on medicines by $700 million.

Exhibit 22: Spending and growth at estimated net manufacturer prices 2015–2020, all channels, US$Bn



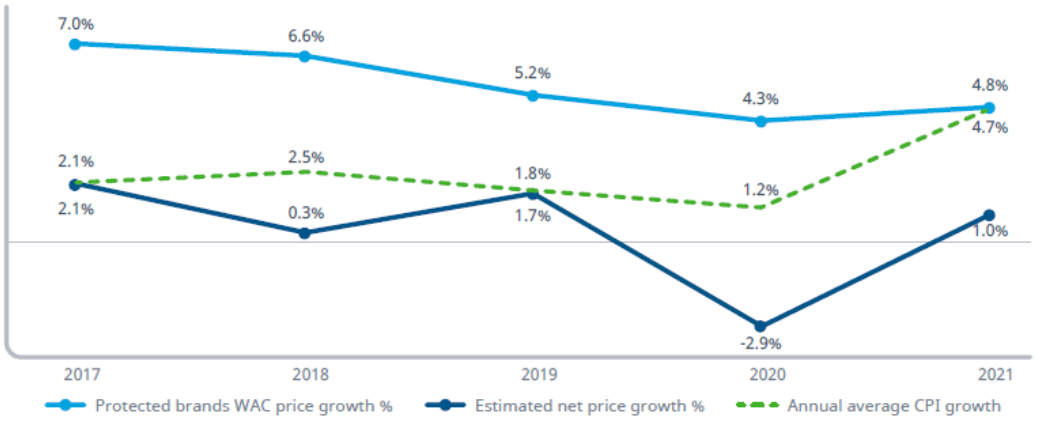
Source: IQVIA Institute, Mar 2022.

- Specialty medicines accounted for 55% of total medicine spending in 2021 but accounted for 3% of total prescription volume.

Medicine Prices

- Net prices for brand medicines increased 1.0% in 2021, below the rate of inflation for the fifth year in a row. Looking ahead, net price growth is projected to be 0% to -3% per year through 2026.
- Brand medicine net prices are, on average, 49% lower than their list price.
- List prices for brand medicines increased 4.8% in 2021, below the rate of inflation.

Exhibit 24: Wholesaler Acquisition Cost (WAC) growth and net price growth for protected brands

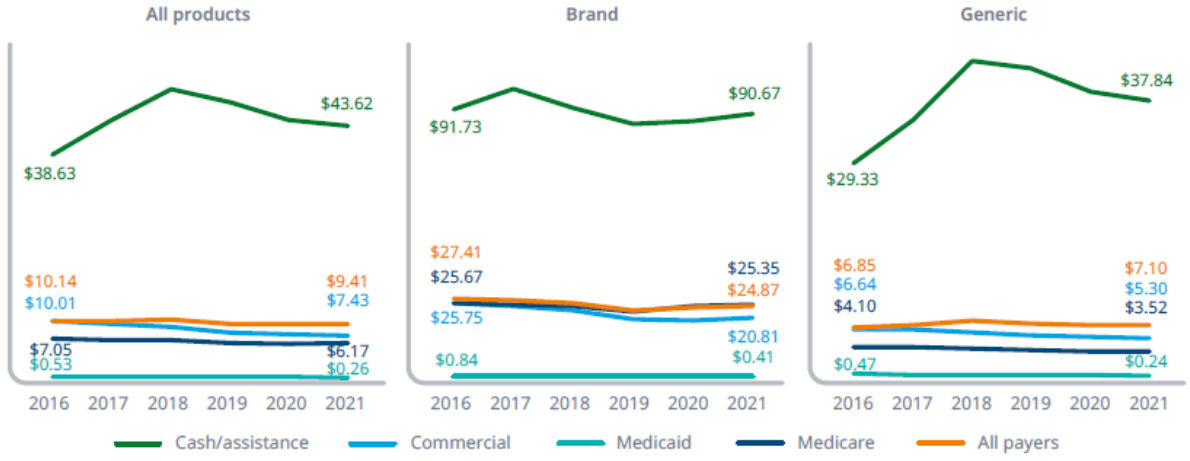


Source: IQVIA Institute, National Sales Perspectives, Dec 2021; Bureau of Labor Statistics, Annual Average Monthly CPI Growth, Dec 2021.

Patient Out-of-pocket (OOP) Spending

- The average OOP cost per retail prescription was $9.41 in 2021 (down from $10.14 in 2016)
- The average OOP cost per brand retail prescription was $24.87 in 2021 (down from $27.41 in 2016)

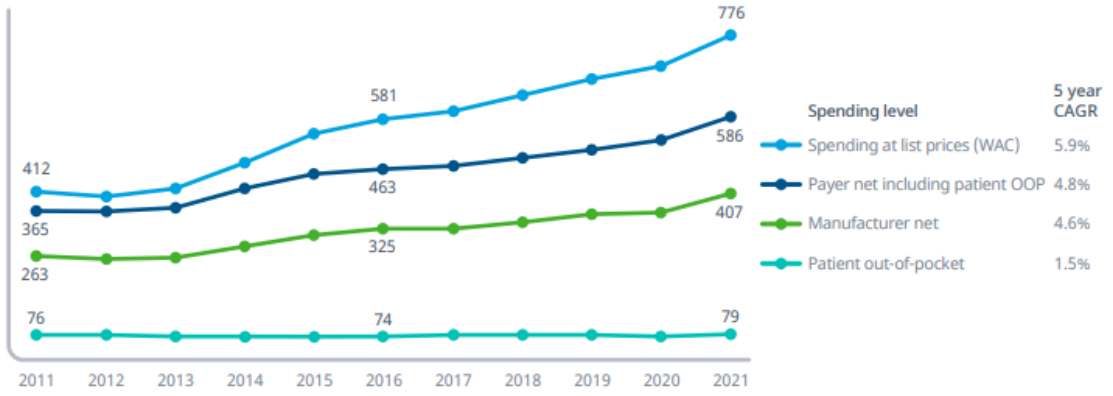
Exhibit 31: Average final out-of-pocket cost per retail prescription by product type and method of payment, 2016–2021



Source: IQVIA LAAD Sample Claims Data, Dec 2021.

- Across all patients, 29% had no annual medicine OOP costs, 8% reached annual OOP costs above $500, and 2.1% paid more than $1,500 OOP in 2021.
    - Among Medicare beneficiaries, 22% had no annual medicine OOP costs, 16% reached annual OOP costs above $500, and 4% paid more than $1,500 OOP.
    - Among commercially insured patients, 23% had no annual medicine OOP costs, 7.3% reached annual OOP costs above $500, and 1.6% paid more than $1,500 OOP.
- Over 92% of total prescriptions (brand and generic) had a final OOP cost below $20 in 2021, while 0.9% (totaling 64 million prescriptions) had a final OOP cost above $125.
- 73% of brand prescriptions had a final OOP cost below $20 in 2021, while 4% had a final OOP cost above $125.
- Coupons and debit cards provided by brand manufacturers totaled $12 billion in 2021.
- Total patient OOP spending increased by an average of 1.5% per year over the past five years, slower than the growth rate of payer spending on medicines, manufacturer net revenue growth, and spending at list price.

Exhibit 17: Medicine spending at selected reporting levels, US$Bn



Source: IQVIA Institute, Mar 2022; CMS National Health Expenditures (NHE), Dec 2020.

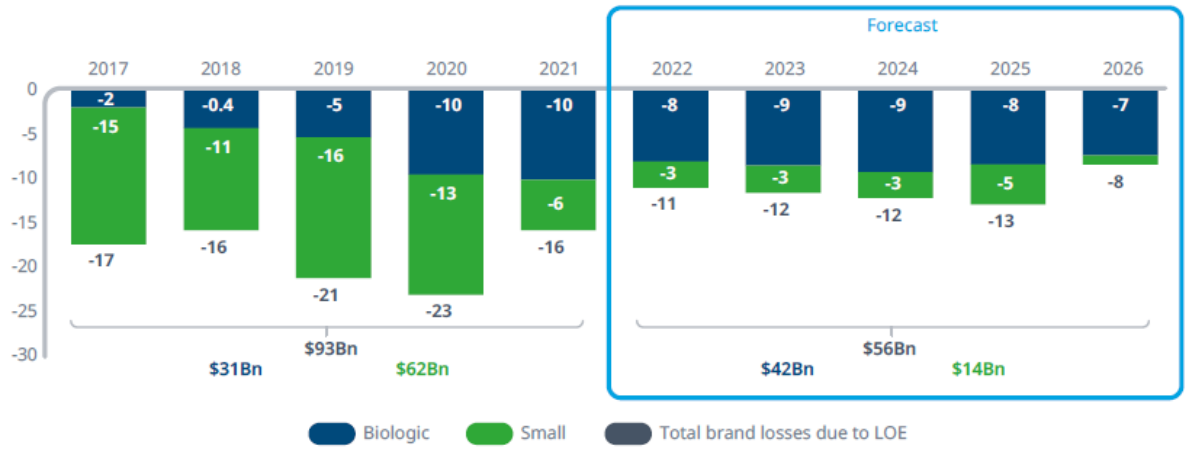
Abandonment

- Patients starting a new therapy abandoned 81 million prescriptions in total at the pharmacy in 2021.
- 61% of patients did not fill their new prescription when OOP costs exceeded $250, while just 7% of patients abandoned their prescriptions when OOP costs were less than $10.
- Abandonment of medicines to treat chronic conditions resulted in 5.3 billion fewer patient days of therapy in 2021.

Market Dynamics

- There were 72 novel active substances (NAS) launched in 2021, including emergency use authorizations (EUA) for COVID-19.
- Over the next five years, a projected 250–275 NAS will enter the market but are anticipated to represent an average 6–7% of brand spending compared to 11% in the past five years.
- LOE reduced net spending on brand medicines by $93 billion over the past five years, with a $62 billion savings from small molecules and $31 billion savings from biologics
- LOE is expected to lower brand spending by $56 billion from 2022 to 2026, with $41.6 billion from reduced spending on biologics.

Exhibit 42: U.S. impact of brand losses of exclusivity 2017–2026, US$Bn



Source: IQVIA Market Prognosis, Sep 2021; IQVIA Institute, Mar 2022.

Medicine Use

- Medicine utilization, measured by days of therapy, grew by 3.3% in 2021
- In total, dispensed prescriptions increased by an average of 2.1% per year over the past five years, driven mainly by the aging population.
- Retail drugs currently represent 86% of medicine use (by days of therapy), with non-retail accounting for the remaining 14%.

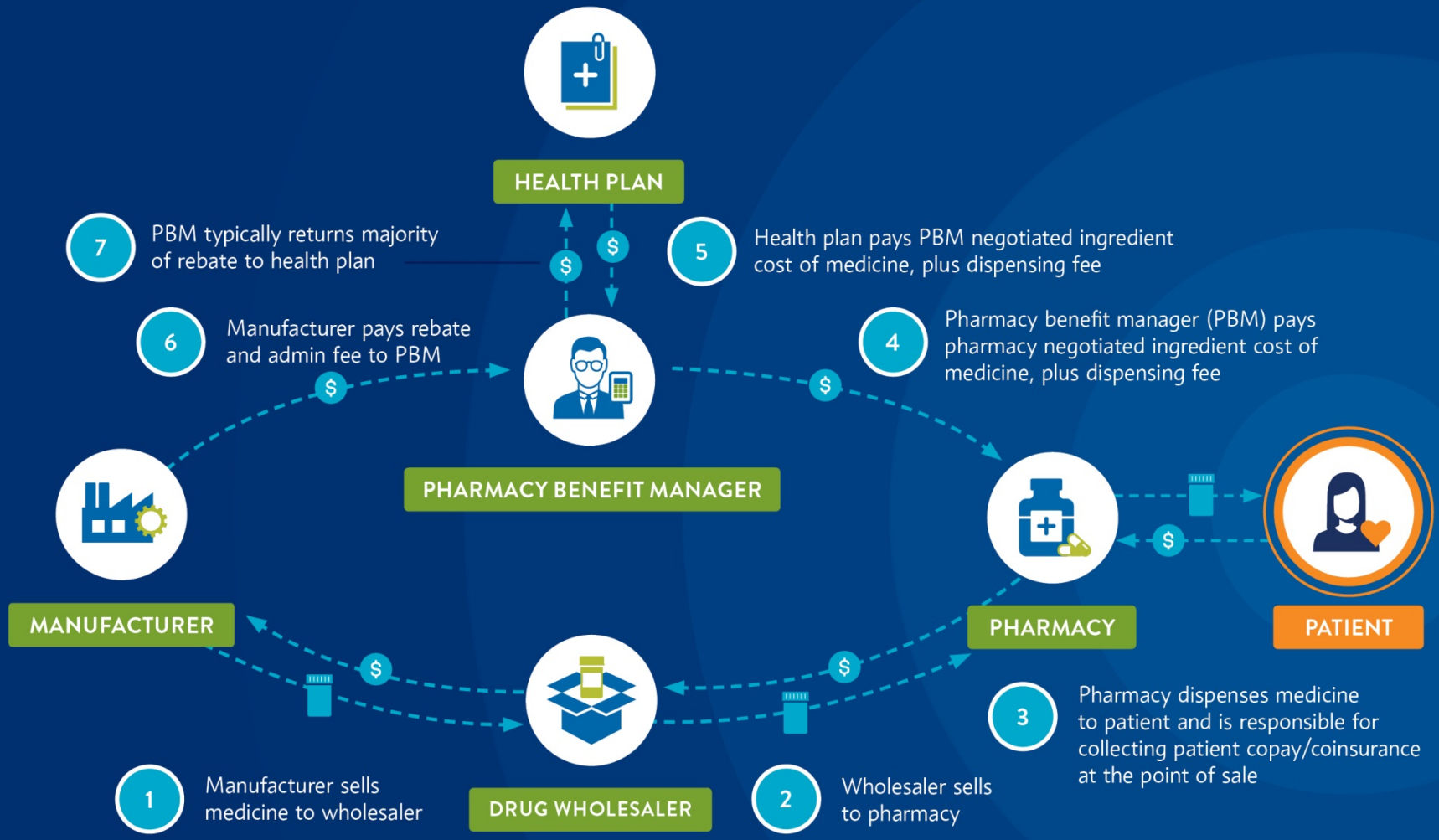
Condition Specific Findings

- Oncology
  - Oncology spending is projected to exceed $113 billion by 2026, with annual growth slowing to 9% due to competitive pressure from biosimilars
  - Net prices for brand oncology products are, on average, 7% lower than the list price.
- Cell, Gene, or RNA Therapies
  - There are currently 33 cell, gene or RNA-based therapies launched globally to-date, with 18 currently marketed in the U.S.
  - An additional 55–65 new therapies are expected to launch globally by 2026
  - “Even considering the large numbers of these products, they will not be more than 20% of all new drugs expected to be launched in the next five years and less than 10% of the spending on new drugs in the same period.”
  - Spending on these treatments is projected to reach $11 billion by 2026, estimates range under different assumptions ($7 to $20 billion).
- Diabetes
  - Net prices for brand diabetes products are, on average, 78% lower than the list price.
  - Total OOP costs paid by patients with insulin prescriptions amounted to $1.27 billion in 2021
    - 44% of this total is from the 20% of prescriptions that cost patients more than $35
  - Insulin OOP costs have declined by $500 million since 2018

        - If insulin OOP costs were capped at $35, patient spending would have been further decline by $555 million.
    - Net spending (manufacturer revenue) on diabetes medicines is projected to decline 12% through 2026, while list prices are estimated to grow 10-13% annually
- Autoimmune
    - Net prices for brand autoimmune products are, on average, 49% lower than the list price.
    - Net spending on autoimmune disorder treatments is expected to exceed $70 billion by 2026, slowing after 2022 due to key biosimilars

Distribution and Financial Flow

FOR RETAIL BRAND DRUGS



Source: Adapted from Pembroke Consulting

Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, and Providers, 2022

1. In September 2022, CVS Health announced its acquisition of Signify Health. The transaction is expected to close in 2023.
2. Since January 2021, Prime's Blue Cross and Blue Shield plans have had the option to use Express Scripts or AllianceRx Walgreens Prime for mail and specialty pharmacy services. On Dec. 31, 2021, Walgreens purchased Prime Therapeutics' 45% ownership interest in AllianceRx Walgreens Prime, so this business has no PBM ownership in 2022. Effective June 2022, the company has been known as AllianceRx Walgreens Pharmacy.
3. In 2021, Centene has announced its intention to consolidate of all PBM operations onto a single platform and outsource its PBM operations to an external company.
4. In 2021, Centene sold a majority stake in its U.S. Medical Management to a group of private equity firms.
5. Since 2020, Prime has sourced formulary rebates via Ascent Health Services. In 2021, Humana began sourcing formulary rebates via Ascent Health Services for its commercial plans.
6. Cigna also partners with providers via its Cigna Collaborative Care program.
7. In 2022, Humana announced an agreement to divest its majority interest in Kindred at Home's Hospice and Personal Care Divisions to Clayton, Dubilier & Rice. In 2022, Kindred at Home was rebranded as CenterWell Home Health.

Source: *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Exhibit 212. Companies are listed alphabetically by insurer name. Published on *Drug Channels* (www.DrugChannels.net) on October 13, 2022.

DRUG CHANNELS INSTITUTE