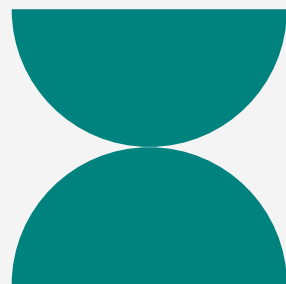


PHIL

Optimizing Patient Access for Sustainable Growth

**A playbook for
life sciences
manufacturers**



Playbook Overview

Market and economic realities increasingly challenge life science companies' efforts to meet forecasts and unlock the sustainable growth required to continue to offer their therapies to patients that need them. Investing in responsive patient support services is now critical to ensure access and adherence as payer drug utilization management requirements continue to expand. Pharmaceutical manufacturers can no longer afford to overlook gross-to-net (GTN) when designing, managing, and measuring their patient support services and channels. Lacking a GTN focus, investment in patient services is often unsustainable thus impact a brand's ability to continue to serve patients effectively. With siloed channels all too common across the pharmaceutical ecosystem, building effective, GTN incremental hub and patient services programs is challenging – but it's entirely possible with the right approach.

Who is this guide for?

This guide was developed for life sciences organizations' teams that seek to deliver a patient centric experience while effectively stewarding brand growth– including **Marketing, Sales, Market Access, Patient Services, and Trade**. The guide offers meaningful insights and practical strategies designed to balance positive GTN margins with effective patient access programs.

Table of Contents

Understanding Gross-To-Net	02
The GTN Dilemma	03
Making The Case For Taking A GTN Lens	04
The Core Tension	05
Key Strategies For Developing A Sustainable Access Program	06
Ready To Position Your Brand For Long-Term Growth?	15
Sources	16

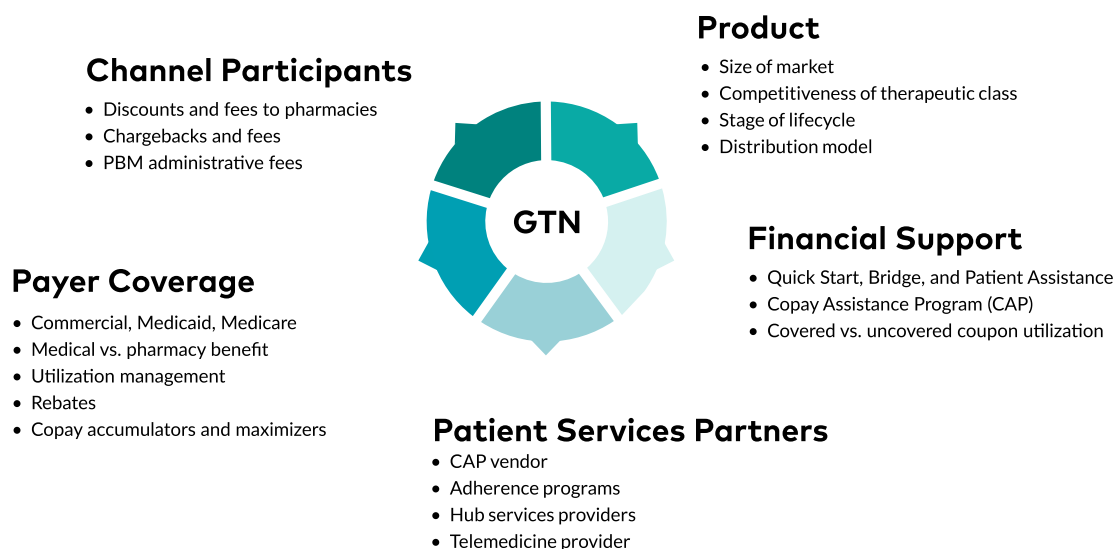
Understanding Gross-To-Net

GTN represents the difference between the gross revenue from sales at a product's wholesale acquisition cost (WAC), also known as the drug's list price, and the actual revenue received by the manufacturer after accounting for various discounts, rebates, chargebacks, and fees (net sales). Essentially, it refers to the shift from the initial list price to the actual realized revenue. The expanding Gross-to-Net bubble in the life sciences industry has received increased attention over the past decade as a result of evolving payer formulary rebate and utilization management requirements as well as an increased focus on drug pricing reform amongst law makers.

Core elements that impact GTN for branded specialty and specialty-lite therapies

While it may seem self-evident that a commercial entity should judiciously manage their gross-to-net, three factors have resulted in a traditional disconnect between patient access programs and the economic realities that are inextricably linked:

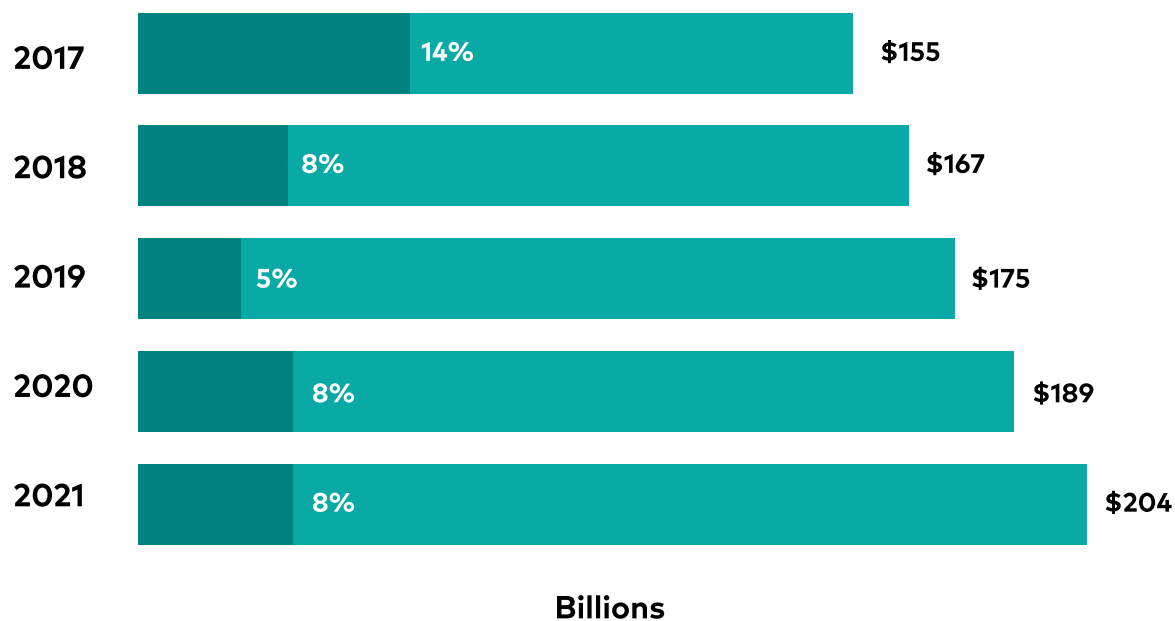
- GTN has traditionally been a responsibility of the commercial or financial executives that have a limited operational stake in patient access programs
- This disconnect has resulted in prevailing bias amongst commercial teams that patient services programs are detrimental to GTN
- Patient services programs have often over indexed on the patient experience at the expense of brand GTN



For every \$100 spent at retail pharmacies, about \$17 compensates for direct production costs, \$41 accrues to the manufacturer (\$15 of which is net profit), and \$41 accrues to intermediaries in the distribution system: wholesalers, pharmacies, pharmacy benefit managers and insurers (with \$8 of net profit split among them).¹

The GTN Dilemma

Many life sciences companies are experiencing declining net drug revenue as they offer larger rebates, cover a higher percentage of prescriptions for patients, and offer other price concessions to remain on formulary to offset increases in list prices, as depicted below.²



*Figure: Total Value of Pharmaceutical Manufacturers
Gross-to-Net Reductions for Patent-Protected, Brand-
Name Drugs, 2017 to 2021*

GTN trends

-0.8%

Decline in net prices
through Q3 of 2022

<5%

Average list price
increases 2019-2022

-8.7%

Inflation adjusted list
price changes in 2022

>\$200B

Total value of branded drug
GTN reductions in 2021

Making The Case For Taking A GTN Lens

The average cost of developing a new drug now exceeds \$2 billion, the return on investment is at its lowest in over a decade at 1.2%, and the average peak sales forecast for a pipeline drug fell 22% between 2021 and 2022.⁴ Considering these economic realities and the ongoing downward pressure on net sales, it's clear that GTN should be a critical factor in guiding prospective market and patient access strategies.

Optimizing brand GTN is essential for maintaining profitability, negotiating contracts, making informed business decisions, ensuring that innovative treatments remain accessible to patients who need them. Understanding how GTN management can benefit internal stakeholders' efforts will help you gain their buy-in for new approaches.

Marketing	Free up more marketing dollars to put toward growing the patient and HCP base
Commercial	Enable field team expansion and investment in innovative sales enablement tools
Market Access	Free up more marketing dollars to put toward growing the patient and HCP base
Patient Access	Create opportunities to maximize coverage and prior authorization navigation



Catherine Wood Hill
VP, Marketing
Phil Inc

“A key benefit of optimizing brand GTN is that it frees up additional dollars to reinvest in programs that can grow brand awareness, maximize patient access, and optimize the experience with patients, HCPs, and payers.”

The Core Tension: Balancing The Patient Experience And Managing Gross-To-Net

Mounting drug utilization management requirements and out-of-pocket obligations are squeezing access to specialty and specialty-lite therapies. Manufacturers have responded by developing patient access programs – now mission critical to clearing a successful trajectory for branded medications. At the same time, rising copay offsets, rebates, and other fees continue to exert downward pressure on net sales, which can lead to budget cuts in these vital programs.

Without the **\$18.7 Billion** in manufacturer copay assistance in 2022, out-of-pocket costs would have exceeded **\$100 Billion**⁵

Balancing timely access to therapy and GTN can be tricky as it evolves over a brand's lifecycle. Typically, brand teams sacrifice GTN at the launch phase prioritizing speed to treatment to ensure prescribers see results and create positive experiences that will help establish the brand in its therapeutic area. By mid-cycle, most brands can no longer afford to over-subsidize access and must shift towards prioritizing maximizing covered dispenses at the pharmacy. At this stage, they must closely evaluate GTN and refine their programs to shore up profitability. As they approach loss of exclusivity (LOE), the focus must shift to maximizing the product's value, ensuring it is dispensed as intended.

Patient Experience



Managing Gross-to-Net



Sahil Naik

Chief of Staff
to the CEO, Phil Inc.

“Striking the right balance between therapy access and GTN comes down to optimizing the percentage of total dispensed prescriptions that are covered by insurance.”

01. Establish Program Success Metrics Aligned To Patient And Brand Outcomes

A wealth of evidence shows that patient support services can improve patient access, adherence, clinical outcomes, and satisfaction. Despite the significant investments made to address the needs of patients across the prescription journey, there is often a lackluster uptake of these services.

\$5B

Spent annually by pharmaceutical manufacturers on patient support programs⁶

3%

Eligible patients enroll and use manufacturer programs⁶

60%

of HCPs do not have a good understanding of pharma patient services programs⁷

42%

Spent annually by pharmaceutical manufacturers on patient support programs⁶

These programs can only deliver value and positive ROI if a high percentage of patients use them and can successfully obtain coverage. A poorly utilized program or permanent bottlenecks in the prior authorization process can result in a heavy reliance on manufacturer subsidies, creating a snowball effect that can have a significant drag on gross-to-net and undermine a brand's success across the lifecycle. **To avoid this scenario, Phil has developed a set of key program success factors that should be established (and continuously measured) for patient access program success:**

01. Establish Program Success Metrics Aligned To Patient And Brand Outcomes

Field & Prescriber Adoption

The success of your field team in promoting the program to target prescribers measured by NRx at the territory level

Patient Education & Adoption

The effectiveness of HCPs at delivering program education evidenced by patient enrollment in the program

Script Quality

The rate at which HCPs send prescriptions to the hub for the correct indication and contain the appropriate info (ICD-10)

Prescriber Engagement

The frequency and success of provider completion and plan submission of utilization management requirements

Payer Response

The success of meeting payer requirements resulting in higher prior authorization approval rates and covered prescriptions

Through the monitoring and optimization of these key metrics, patient services programs can be incremental to both patient outcomes and brand GTN. Teams should deprioritize over dependence of operational metrics that are loosely correlated to brand outcomes if they wish to succeed in the era of utilization management.



Andrew Duncan

VP, Business
Operations & Analytics,
Phil Inc

“Along the entire prescription journey – from writing the script to dispensing the medication through refill adherence – brands have opportunities to reduce or eliminate sources of friction that are inhibiting access and to optimize gross-to-net.”

02. Build Channel Partnerships Using A GTN Lens

The pharmaceutical channel ecosystem, which comprises multiple entities involved in starting a patient on therapy, is typically significantly siloed resulting in misaligned incentives. As a result, some entities capture disproportionately more value than they contribute, making it difficult – or even impossible – to optimize patient access and GTN. The best way to counteract this problem is to ensure your channel partners are value-aligned by considering the following:

- **Distribution intermediaries**

Distributor costs must be commensurate with the quality of their service, which for the most part is largely undifferentiated throughout the ecosystem despite many making the argument otherwise. Most small to medium sized manufacturers lack the scale to negotiate favorable DSA rates from the Big 3 distributors. Thus, manufacturers should closely evaluate their distribution service agreements (DSA) and strongly consider alternative models and strategies that are financially advantageous. For example, is your wholesaler able to implement a consignment program for free goods, which will avoid buy-downs at the pharmacy and improve overall brand GTN?

Impact Analysis of Consignment on GTN	Commercial Uncovered	Consignment
Revenue (weighted WAC price)	\$457.40	\$20 (patient copay)
Revenue net of DSA discount (3%)	\$425.38	\$20 (discount N/A)
Coupon Buydown	(\$437.40) \$20 patient copay	\$0
Coupon Buydown	(\$10)	(\$10)
Shipping to wholesaler/pharmacy	(\$2)	(\$2)
Coupon fee	(\$3)	\$0
Consignment Fee (per TRx)	\$0	(\$30)
GTN	(\$27.02)	(\$21)

Figure: Impact analysis of Consignment Program Generating 25% Savings for Specialty-Lite Product

02. Build Channel Partnerships Using A GTN Lens

- **Pharmacy network**

Reimbursement rates and plan contract coverage across different pharmacies can vary substantially, with some pharmacies incentivized to over utilize uncovered manufacturer coupons to compensate for “underwater” scripts, negatively impacting GTN. The key to mitigating this risk is to drive prescriptions through a channel that routes the dispenses of your brand through an incentive-aligned pharmacy network that maximizes plan contract coverage. An integrated network model leveraging retail locations can ensure that pharmacies are reimbursed at the highest rates to minimize uncovered coupon usage and ensure coupon usage is driven by the business rules determined by your team.

- **Telemedicine**

Many innovative therapies are adopting telemedicine as a novel access pathway to eliminate friction in the traditional patient journey. This channel should not be any different than traditional ones in its ability to deliver sustainable brand value. When deciding to invest in a cash pharmacy model vs. integration with a digital fulfillment partner, you want to make sure it will have a positive effect on your GTN margins, leaving more dollars to commit to patient access.



Deepak Thomas

Founder & CEO,
Phil Inc

“All stakeholders along your distribution channels should be working toward the common goals of getting scripts covered and making sure that most patient access dollars go to the patient to underwrite the cost of their care.”

03. Align Field Team Incentives

In this era of intricate (and expanding) drug utilization management (UM) requirements, reliance solely on the traditional pharma sales model is unlikely to secure levels of product adoption and coverage needed to secure the long-term financial viability of your brand. Commercial teams should take an integrated approach with your patient services programs. In addition to generating demand, they should also prioritize patient access to be more responsive and relevant to key stakeholders, encourage high utilization of patient services programs via preferred channels, and seek to support the highest overall percentage of covered dispenses.

86%
of HCPS

want market access information personalized to their practice and the specific healthcare plans of their patients⁹

70%
of HCPS

feel that reps “do not completely understand their needs and expectations”¹⁰

62%
of HCPS

believe the most significant area where sales reps can add value is by understanding their needs and sharing only relevant content for more insightful interactions¹⁰

03. Align Field Team Incentives

With an integrated team of sales and reimbursement specialists focused on collaborative UM problem-solving, you can drive brand performance and access more effectively. Before this can happen, educating your field team and ensuring their incentives are aligned with corporate goals is essential.

- **Educating and getting buy-in**

Field teams must understand the tools they have at their disposal, how these tools facilitate success, the structure of their copay assistance program, and how the patient access support program benefits them and their customers.

- **Aligning incentives**

Ensuring the field sales team's compensation structure aligns with corporate goals is critical. For example, if promoting your patient services hub and driving covered dispenses are important, but the bonus plan only incentivizes new scripts – with or without insurance coverage – it's not driving sustainable brand growth. Your brand will see new prescriptions, but a smaller percentage will be covered, limiting adherence and negatively impacting GTN.

- **Monitoring performance by territory**

Program optimization is an ongoing process that requires meaningful collaboration between manufacturers and hub providers. Teams invested in the ongoing success of the program should be continuously monitoring performance across territories to develop benchmarks, identify trends, and ultimately take action to scale the impact of your program nationally. This approach can have a significant incremental impact on overall brand performance.



Patrick Leary

Chief Commercial Officer,
Phil Inc

“Life science field teams need to command a mastery of what is occurring specific to the payer landscape to communicate effectively with their core audience—health care providers. Market realities require a shift from the traditional model focused on promoting clinical efficacy to one that incorporates support for navigating the complexities of patient access.”

04. Implement Effective And Sustainable Financial Assistance Programs

Most specialty and specialty-lite pharmaceutical manufacturers invest significantly in financial support programs to facilitate improved access and adherence. In today's environment, it can be a challenge to ensure these programs are not overutilized to deplete margins to the point that they are detrimental to your company's overall financial health. A number of factors can lead to overutilization of these programs including high utilization management requirements, limited market access, poor controls, and a dispense network with significant coverage gaps. Overutilization of your uncovered offering diminishes overall net revenue hampering your overall ability to support patient access.

As many as **70% of patients** on newly-launched specialty drugs use a patient assistance program subsidized by the manufacturer¹⁰

Life sciences manufacturers must analyze the financial implications and evaluate the balance between supporting patients and managing their GTN performance to sustain the long-term viability of their brands. Keys to sustainability include:

- An integrated dispense network – ideally an exclusive channel via a hub partner – that maximizes plan coverage
- Controls set through business rules to incentivize appropriate utilization
- An integrated, streamlined PA process to foster high submission rates
- Ensuring that they highly accessible to patients with insurance coverage
- The copay amount is optimally set to improve long-term therapy adherence

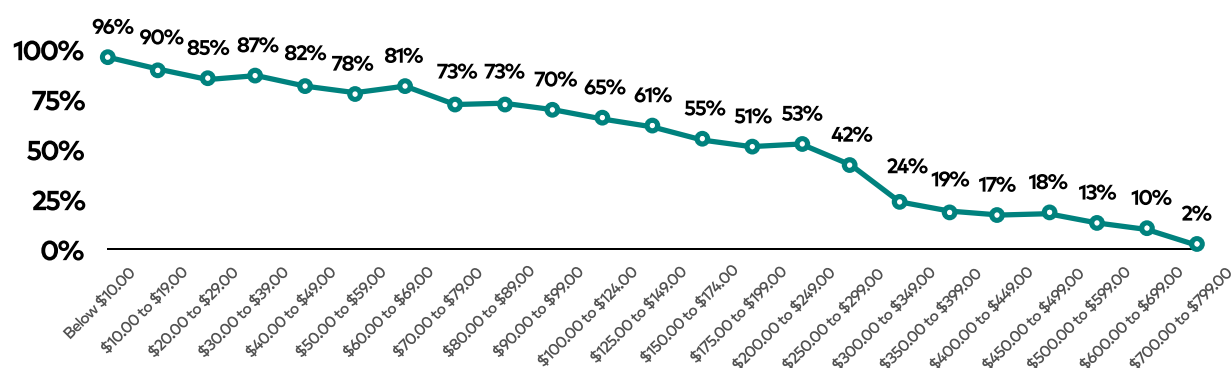


Figure: GTN impact of different copay amount

05. Effectively Support Utilization Management Efforts

Building a brand's go-to-market strategy around the most productive channels and channel partners will deliver long-term success. A critical part of that strategy involves maximizing the percentage of submitted and approved PAs. The PA process is prone to errors and challenges, such as changing payer rules, variability amongst plans, lack of transparency, and the use of multiple UM measures, which can create gaps in coverage.

Many pharmaceutical companies turn to point solutions to help HCPs meet UM requirements while others assume their product will get sufficient support in the retail pharmacy channel. However, point solutions are siloed and reliant on other entities to initiate prior authorizations, limiting their ability to support PAs adequately. Since they rely on the pharmacy for the visibility needed to process PAs, the number of PAs successfully initiated and ultimately submitted typically take a significant hit, limiting coverage at the pharmacy and resulting in abandonment. The best strategy is to work with a partner that integrates a non-dispensing pharmacy with sophisticated PA tools to enable them to initiate and follow through on all required PAs taking the responsibility out of the hands of the dispensing entity. Direct visibility into payer behavior is essential to:

- Staying on top of ever-evolving payer UM requirements
- Respond to payer behavior and differentiate dispense workflows
- Take proactive steps to ensure timely submissions of prior authorizations to reduce abandonment
- Offering your field team a real-time view into the prior authorization and other utilization management processes



Angie Stigliano

PharmD,
Operational Lead
Pharmacist, Phil Inc

“Historical context regarding why PA requests were denied, what forms were used, and what information was needed for approval is vital to improving the process. Technology enables us to gain historical context by looking at the PA data at a very granular level and using data analytics to extrapolate meaningful trends that can help providers submit more accurate PA forms and expedite the process.”

06. Optimize With Data And Metrics

Complete visibility across the prescription journey – from when a script is written until it is either dispensed or abandoned – is crucial to brand success. Failure to leverage this information puts your brand at a competitive disadvantage as it adversely impacts patient access and GTN. Many specialty and specialty-lite commercial teams struggle to meet their objectives if they rely on incomplete or unactionable data provided by third-party partners or aggregators.

“At retail, brands lose up to 80% of prescriptions to abandonment and substitution. Even when purchasing expensive data from third party vendors, it’s onerous to map the patient journey and translate it into actionable insights.”

Andrew Duncan, VP, Business Operations and Analytics

To get a handle on the effectiveness of your patient access strategy and program, you should be monitoring the following KPIs:

Number of new scripts written

Percentage of covered dispenses
(vs. % of plans on formulary)

Access program enrollment rate

Pharmacy reimbursement rates

% of successful patient starts

Number of refills per patient

PA submission and approval rates

Brands that face steep PA requirements should be tracking how frequently individual HCPs submit PAs, how long it takes each HCP to submit a PA and respond to a missing information request, how long it takes different payers to adjudicate a PA, and the utilization of uncovered coupons. Data analysis can then reveal stakeholder behaviors that enable brand teams to adjust their strategies and business rules to better support patient access.

Ready To Position Your Brand For Long-Term Growth?

PhilRx is an end-to-end commercialization platform that helps specialty-lite brands protect their GTN margins while facilitating patient access, unlocking coverage, and maximizing reimbursement. Life sciences companies have access to an integrated, nationwide pharmacy network that helps patients receive prescribed therapy quickly, conveniently, and affordably. Real-time insights give our manufacturer partners strategic visibility across the prescription journey.

“At Phil, we take a very comprehensive approach to drug commercialization and patient access by making the patient experience our North Star. Delivering the ideal patient experience involves many stakeholders locking hands to orchestrate a cohesive process. By eliminating operational inefficiencies and informational asymmetries with information technology and partnering with life science brands to realign incentives, we can provide a patient experience that is on par with what consumers are used to and unlock access to affordable therapy.”

Deepak Thomas, CEO & Founder, Phil Inc

Accelerate the Access Journey

**Book a meeting with
our access experts**

Manufacturerinquiry@phil.us

[!\[\]\(10f8862fc183b400327470ea85afe9ae_img.jpg\) linkedin.com/company/phil-inc-](https://www.linkedin.com/company/phil-inc-)

www.phil.us

Sources

¹ Neeraj Sood, et al., “The Flow of Money Through the Pharmaceutical Distribution System,” USC Shaeffer, June, 2017, https://healthpolicy.usc.edu/wp-content/uploads/2017/06/The-Flow-of-Money-Through-the-Pharmaceutical-Distribution-System_Final_Spreadsheet.pdf

² Adam J. Fein, “Warped Incentives Update: The Gross-to-Net Bubble Exceeded \$200 Billion in 2021,” Drug Channels Institute, July 26, 2022, <https://www.drugchannels.net/2022/07/warped-incentives-update-gross-to-net.html>

³ Adam J. Fein, “Brand-Name Drug Prices Fell for the Fifth Consecutive Year—And Plummeted After Adjusting for Inflation,” Drug Channels Institute, January 4, 2023, <https://www.drugchannels.net/2023/01/brand-name-drug-prices-fell-for-fifth.html>

⁴ Alex Philippidis, “The Unbearable Cost of Drug Development: Deloitte Report Shows 15% Jump in R&D to \$2.3 Billion,” Genetic Engineering & Biotechnology News, February 28, 2023, <https://www.genengnews.com/gen-edge/the-unbearable-cost-of-drug-development-deloitte-report-shows-15-jump-in-rd-to-2-3-billion/>

⁵ “The Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025,” IQVIA Institute, May 27, 2021, <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us>

⁶ “Industry Perspectives: Expanding Awareness of Patient Support Programs,” Phreesia Life Sciences, 2022, https://engage.phreesia.com/rs/867-GML-252/images/Phreesia_Industry_Perspectives_Patient_Support_Programs.pdf

⁷ “Infographic: HCPs must deal with communication breakdown,” Haymarket Marketing Communications, December 2017, <https://www.mmm-online.com/home/channel/commercial/infographic-hcps-must-deal-with-communication-breakdown/>

⁸ Andrea B. Neiman, et al., “CDC Grand Rounds: Improving Medication Adherence for Chronic Disease Management — Innovations and Opportunities,” CDC, November 17, 2017, <https://www.cdc.gov/mmwr/volumes/66/wr/mm6645a2.html>

⁹ “The Digitally-Savvy HCP Learnings to Engage HCPs Around the World More Effectively and Efficiently,” Indegene, accessed August 18, 2023 at <https://www.indegene.com/what-we-think/reports/digitally-savvy-hcp>

¹⁰ Laura Joszt, “Specialty Pharmacy Controls Limit Patient Access, Fein and Long Explain: 2022 Asembia Specialty Pharmacy Summit,” Managed Healthcare Executive, May 4, 2022, <https://www.managedhealthcareexecutive.com/view/specialty-pharmacy-controls-limit-patient-access-fein-and-long-explain>