No. 21-3005

UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

IN RE: EPIPEN (EPINEPHRINE INJECTION, USP) MARKETING, SALES PRACTICES AND ANTITRUST LITIGATION

SANOFI-AVENTIS U.S., LLC,

Plaintiff, Counterclaim Defendant, and Appellant,

V.

MYLAN INC.,

Defendant and Appellee,

MYLAN SPECIALTY L.P.,

Defendant-Counterclaimant and Appellee.

On Appeal from the United States District Court for the District of Kansas
Case No. 2:17-MD-02785-DDC-TJJ
Honorable Daniel D. Crabtree, U.S. District Judge

BRIEF OF AMICUS CURIAE PHARMACEUTICAL CARE MANGEMENT ASSOCIATION (PCMA) IN SUPPORT OF APPELLEES

John S. Linehan
General Counsel
PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION
325 7th St NW
Washington, DC 20004
(202) 756-5700

Ruthanne M. Deutsch
Hyland Hunt
DEUTSCH HUNT PLLC
300 New Jersey Ave. NW
Suite 900
Washington, D.C. 20001
(202) 868-6915

Counsel for Amicus Curiae

CORPORATE DISCLOSURE STATEMENT

As required under Federal Rule of Appellate Procedure 26.1, Amicus Curiae PCMA certifies that it is a non-profit § 501(c)(6) corporation duly organized under the laws of the State of Delaware. It has no parent corporation, and no publicly traded corporation owns 10% or more of its stock.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Other Authorities

INTEREST OF AMICUS CURIAE[1]

The Pharmaceutical Care Management Association (PCMA) is the national association representing America's pharmacy benefit managers (PBMs), whose mission is to increase affordable access to prescription drugs for everyone. PBMs administer prescription drug plans for more than 266 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and the health insurance marketplaces. Over the next decade, PBMs will save health plan sponsors and consumers more than $1 trillion on prescriptions.

PBMs work hard to drive costs down for health insurance plans and patients, primarily by negotiating with drug manufacturers and pharmacies for price concessions, or rebates. Consumers are the ultimate beneficiaries of this pro-competitive process that makes prescription drugs more affordable for patients and payers across the country. PCMA writes to explain how the undisputed facts of this case illustrate the general rule: Consumers benefit from these negotiated price concessions. If Sanofi were to prevail in this case, beneficial price competition would be forestalled, and consumers would be the ultimate losers.

---

[1] No counsel for any party authored this brief in whole or in part, and no person or entity other than amici, their members, or their counsel made a monetary contribution intended to fund the brief's preparation or submission. All parties have consented to the filing of this brief. *See* Fed. R. App. P. 29(a)(2), (4).

INTRODUCTION AND SUMMARY OF THE ARGUMENT

PBMs are the only entities in the supply chain whose mission is to lower drug costs for health plans, health insurance issuers, and consumers. PBMs are engaged by health plans to lower drug costs and maximize the value of prescription drug benefits. They do this not only by negotiating price concessions from drug manufacturers and pharmacies, but also by developing formularies with strong clinical foundations that encourage the use of generics and promote patient choice of safe, effective medications, and by supporting medication adherence to the prescribed plan of care. PBMs' critical role in the pharmaceutical market fosters competition that results in lower overall prescription drug costs while also benefiting patient health outcomes.

Applying clinical expertise, bargaining leverage, and the benefit structure set by a particular health plan, PBMs design and construct lists of drugs covered by health insurance, known as formularies, that encourage patients and their doctors to choose lower-cost alternatives when multiple drugs will serve the same medical need. Because formulary placement can drive demand for their products, manufacturers are often willing to offer discounts to enhance their formulary position vis-à-vis their competitors. Those rebates are typically passed on to health plans, under the terms of their contracts with the PBMs. The health plans, in turn, use these discounts to reduce health care costs for all their enrollees. Throughout the

process, PBMs continually evaluate the marketplace for opportunities to secure greater discounts, opportunities which often emerge when a new therapeutically similar or equivalent drug enters the market. Flexible, short-term contracts and customized formularies enable PBMs to seize those opportunities to facilitate price competition when they arise.

This virtuous cycle has been the predominant method of reducing prescription drug prices for consumers for decades. And it works. Using the very tools that Sanofi decries as anti-competitive, PBMs have often held drug cost increases near zero in recent years, and even secured year-over-year decreases in costs for the most aggressively managed plans. In the commercial market alone, PBMs pass tens of billions in savings to health plans each year, and plans use those savings to reduce consumers' health care premiums and out-of-pocket costs. Far from diverging, the interests of PBMs, health plans, and consumers are right in line. Contrary to the assertions made by Appellants' amici, PBMs are succeeding in their mission to drive down drug costs, and the ultimate winners are health plans and consumers.

The only interests that diverge are those of drug manufacturers who are unwilling to compete on price. The largely undisputed record in this case corroborates the results of market-wide studies: As soon as a therapeutic alternative emerged in the epinephrine auto-injector category, PBMs seized the opportunity to foster beneficial manufacturer competition, resulting in lower prescription drug

costs. The record shows that when Sanofi finally began to compete on price, Auvi-Q became more readily available to more consumers, and the cost of Mylan's EpiPen fell. As the rival manufacturers competed by offering deeper discounts to PBMs to obtain preferred formulary placement, health plans and their members benefited. Drug costs for epinephrine auto-injectors were driven lower by PBMs' ability to induce manufacturers into a bidding war for enhanced formulary placement.

At bottom, PBMs are doing their job by fostering beneficial price competition between brand name drugs that are therapeutic alternatives, redounding to the benefit of plans and patients by keeping prescription drugs affordable. Judge Crabtree got it right in concluding that the antitrust laws pose no obstacle to this healthy competition between rivals, where plans and patients are the ultimate winners.

ARGUMENT

I. PBMs Are Integral To Reducing Prescription Drug Costs For Health Plans, Health Insurance Issuers, And Consumers.

The market for prescription drugs is complex. Prices are set by negotiations among drug manufacturers, wholesalers, pharmacies, PBMs, and health plans and health insurance issuers. Treatment choices are made by both patients and doctors. Expertise is required to determine what drugs should be made available to any given patient, considering drug efficacy, similarity or equivalence, safety, cost, and other factors. Coherent systems are needed to guarantee safety, from facilitating safe storage and handling, monitoring compliance with course of treatment, and ensuring

that patients' prescriptions, especially those from different prescribers, do not have unwanted interactions.

PBMs play a central role across this market, by negotiating price concessions from pharmacies and manufacturers. PBMs also encourage consumers to make cost-conscious choices among drugs that are determined, after thorough vetting by medical experts, to be therapeutic alternatives. These efforts, among others, all further PBMs' mission of reducing the cost of prescription drugs.

Formulary placement and utilization management are levers that enable PBMs to secure price concessions from drug manufacturers. A formulary is a list of drugs that are covered by a particular health plan. 12-JA-2602; *see also* PCMA, *What Is A Formulary?*, https://tinyurl.com/pkp7h3nw ("PCMA, Formulary Overview").[2] Formularies are typically organized into tiers, through which "[p]lan sponsors offer different copays or other financial incentives to encourage participants to use preferred formulary drugs" in a lower tier, "but will still pay a portion of the cost of the non-preferred drug" in a higher tier. PCMA, Formulary Overview, Formulary Types. Utilization management refers to a suite of tools, like requiring prior authorization for a particular drug, that encourage or require consumers to choose medically appropriate, safer, and lower-cost options among similar drugs. Together,

[2] This brief cites the Joint Appendix using both volume and page range (*e.g.*, Volume Number-Joint Appendix-Page Range).

formulary placement and utilization management guide consumers to lower-cost options. They thereby create an incentive for drug manufacturers to offer more attractive pricing and deeper price concessions to improve their drugs' formulary position as compared to competing drugs.

As a therapeutic category grows more crowded, PBMs are better able to leverage these tools to facilitate price competition and thereby lower drug costs. That is why negotiations and agreements are structured so that PBMs can respond flexibly and dynamically to changes in the marketplace, and thereby maximize the savings passed on to consumers through their health plans.

A. Formulary Structure and Utilization Management Enable PBMs to Encourage Cost-Efficient Consumer Choices and Obtain Price Concessions from Manufacturers.

1. To understand the central role of PBMs in the prescription drug market, it helps to trace a typical transaction involving a brand-name drug. The pricing begins with the manufacturer setting a list price, but—largely due to the efforts of PBMs—the net cost that ultimately will be incurred by health plans and their enrollees is much lower.[3]

The drug enters the stream of commerce when the manufacturer sells the drug to a wholesaler. 12-JA-2601. The wholesaler then sells the drug to a pharmacy to be later dispensed to a patient. *Id.* Separately, each pharmacy or pharmacy chain

[3] The discussion here is limited to the commercial market, as relevant to this case.

negotiates a discounted reimbursement rate with PBMs, "and this negotiated, discounted price is used to calculate the prescription cost for" the patient. 18-JA-3945 (Navarro Expert Report ¶ 49). The insured patient must sometimes pay a portion of that price, as determined by her health plan's benefit design. 12-JA-2601. She may pay the full amount (depending on her coverage or whether she's satisfied her deductible), a flat co-pay, or a percentage of the price (called coinsurance). *Id.* Once the insured patient satisfies any cost-sharing requirement under her plan, the PBM reimburses the pharmacy for the remainder (on behalf of the health plan). *Id.*

Before purchasing the drug from a pharmacy, however, the patient needs a prescription. And in obtaining that prescription, the patient will likely discuss different options with her doctor. Using increasingly available digital tools to review the formulary applicable to her health plan and her precise out-of-pocket costs, the patient's doctor learns that two different brand-name drugs can meet her needs, but (due to the PBM's formulary design on behalf of the health plan), one option is subject to a significantly lower co-pay. *See* 12-JA-2604; Michael A. Fisher, et al., *Effect of Electronic Prescribing With Formulary Decision Support on Medication Use and Cost*, 168 Arch Intern. Med. 2433 (2008) (describing e-prescribing systems that use formulary data to prompt prescribers to choose lower cost medications). So the patient and her doctor choose the drug with lower cost-sharing (generally the drug with lower net costs to the plan)—the second time in this transaction that the

PBM's efforts have lowered costs and delivered value. *See* Fisher, *supra*, at 2433 (finding physicians using e-prescribing systems with formulary information "were significantly more likely to prescribe tier 1 [*i.e.*, lower cost] medications" and "the potential financial savings were substantial").

After the patient exercises her medically-advised choice and fills her prescription, the manufacturer then pays a price concession to the PBM retrospectively in the form of a rebate. 18-JA-3946 (Navarro ¶ 53). The drug's net cost after that concession typically ends up far below the initial list price—sometimes less than half the list price, and on average 30% less. 18-JA-3949, 3951 (Navarro ¶¶ 60, 64); Visante, Inc., *Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers*, at 3 (Feb. 2020), https://tinyurl.com/c3ya7mp6 ("Visante Study"). Finally, the health plan reimburses the PBM for the drug, and as determined by the contract between the PBM and the health plan, the PBM passes the lion's share (and sometimes all) of negotiated rebate paid by the manufacturer on to the plan.[4]

[4] PBMs are sometimes compensated in part based on their ability to lower drug prices, including being allowed by the plan to retain a portion of the price concessions negotiated on behalf of the plan as part of their service fee. *See* Written Testimony of Joanna Shepherd, Ph.D, Emory University, for the ERISA Advisory Council Hearing on PBM Compensation and Fee Disclosure, at 4-5 (June 19, 2014), https://tinyurl.com/2uz8zr99 ("Shepherd Testimony"). But regardless of the compensation structure, and as explained in detail in Part II.A, the vast majority of savings are passed through to PBMs' plan customers.

2. PBMs obtain such deep cost reductions for plans and patients by leveraging health plans' decisions about whether and how—consistent with clinical imperatives—millions of consumers can access insurance coverage for prescription drugs. 18-JA-3930 (Navarro ¶ 14).

There is no requirement that prescription drug plans in the commercial market cover every single prescription drug available in the United States, 12-JA-2602, just as there is no requirement for medical benefit plans to cover every physician. Rather, the predominant type of health coverage is known as "managed care," where patients' access to physicians, procedures, and prescription drugs is managed by insurance issuers and health plans to control costs. 12-JA-2601. Health plans offer a wide variety of benefit designs, and PBMs implement health plans' benefit designs for prescription drugs primarily through formulary design and utilization management.

a. PBMs develop national formularies, which are akin to template lists of covered drugs that health plans can choose to adopt in whole, or to customize in response to a particular plan's needs. 12-JA-2603; PCMA, Formulary Overview, Development Process. Formulary design begins with an assessment of "clinical appropriateness" using evidence-based criteria, *i.e.*, "what is the most appropriate therapy for a given disease or condition?" PCMA, Formulary Overview, Development Process. PBMs use Pharmacy and Therapeutics (P&T) Committees,

made up of experts, to determine the most clinically appropriate drugs for a given medical need. *Id.*; *see* 18-JA-3944 (Navarro ¶¶ 43-44). The P&T Committee considers only clinical appropriateness, *not* cost or value. *See* Express Scripts ("ESI"), *White Paper: Formulary Development at Express Scripts*, at 2 (Dec. 2020), https://tinyurl.com/yfu83uxh ("ESI White Paper"). Where the P&T Committee determines that a drug has therapeutic competitors, *i.e.*, "a significant proportion of its use is clinically similar to other currently available drug alternatives," only then will net cost be considered in deciding whether and where a drug will be included on a formulary. *See id.*; 18-JA-3944 (Navarro ¶ 45). In other words, only after a P&T review "focused on efficacy, safety, and availability" and only if therapeutic similarity is established, is there then a "separate review [to] determine the most cost-effective therapies" where formulary placement decisions are made based on cost. Am. Acad. Actuaries, *Prescription Drug Spending in the U.S. Health Care System: An Actuarial Perspective*, at 3 (Mar. 2018), https://tinyurl.com/u6hnbadx.

Formularies are typically organized into "tiers" that provide customers incentives (usually through lower cost-sharing) to choose lower-cost options among therapeutically similar or equivalent drugs. 12-JA-2604; PCMA, Formulary Overview, Formulary Types.

With an "open" formulary, the plan sponsor will generally pay a portion of the cost of all drugs, although it may exclude certain categories, such as "lifestyle"

drugs. 12-JA-2603; PCMA, Formulary Overview, Formulary Types. More common (and more effective at reducing drug costs) is a "closed" formulary, which generally covers only those drugs that are listed on the formulary. 12-JA-2603. Even when a drug is not listed on the formulary or otherwise "excluded" from coverage, however, it may be covered if the patient establishes medical necessity. *See* PCMA, Formulary Overview, Formulary Types (describing "formulary override process"); ESI White Paper, at 4 (explaining that "plan sponsors should offer an efficient process for the timely procurement of non-formulary drug products").

b. Beyond formulary design, PBMs have utilization management tools that plan sponsors may incorporate into their benefit designs to encourage consumers to engage with their doctors regarding lower-cost drug options. 12-JA-2605. For example, plan sponsors can require prior authorization for a particular drug, meaning a physician must make a formal request to approve coverage. *Id*. Another management option, sometimes called a "step edit," effectively requires a patient to try a lower-cost alternative first, before the brand-name drug will be covered. 12-JA-2605.

c. As the undisputed facts here establish, the combination of formulary design and utilization management provides incentives for multiple market participants to reduce costs. 12-JA-2604-05. Consumers are encouraged to ask their doctors to prescribe the lowest-cost option among several therapeutic alternatives, because

their out-of-pocket costs are lower for drugs on a lower tier. *Id.* Doctors are encouraged (or required by plans) to prescribe lower-cost options, while also able to submit requests for coverage of higher-cost options when medically necessary. And manufacturers are encouraged to offer price concessions so that their product is placed in a lower tier and not subject to special procedures, making more consumers likely to choose it. 12-JA-2604; Charles Roehrig, *The Impact of Prescription Drug Rebates on Health Plans and Consumers*, Altarum, at 7 (Apr. 2018), https://tinyurl.com/je8ubu4f ("Roehrig, Altarum Study") ("[M]anufacturer rebates are generally granted in exchange for making a drug cheaper to the patient in the formulary, thereby boosting sales.").

3. Through formulary design and utilization management techniques, PBMs are thus "able to create 'some degree of price competition between sellers of substitutable treatments by incentivizing pharmaceutical firms to offer rebates'" off their list prices to enhance their product's formulary position and freedom from special procedures. 12-JA-2605-06 (quoting Sanofi's expert). Retrospective rebates are the dominant form of price concessions from manufacturers; they are paid to PBMs after a prescription is filled, and then passed on to health plans per the plan's contract with the PBM. 12-JA-2607. Manufacturers sometimes also offer price protection—an agreement that if manufacturer list price increases by more than a certain percentage, the manufacturer will rebate a specified amount above the agreed

threshold. 12-JA-2606. Collectively, such price concessions reduce a drug's net cost, and—at least when there are multiple therapeutically similar or equivalent options—net cost is the primary driver of whether a drug is included on a formulary and under what conditions. 18-JA-3947-48 (Navarro ¶ 56). The result is beneficial "competition in a therapeutic drug class [that] encourages manufacturers to offer more favorable pricing and rebates," i.e., lower net costs, to maintain or improve position on a formulary. 12-JA-2607.

B. PBMs Respond to Changing Market Conditions Using a Dynamic Set of Formulary Design and Utilization Management Tools.

The interplay of PBMs' array of cost-saving tools—including formulary design, utilization management techniques, and negotiated price concessions—is not rigidly defined. Through use of "bid grids," customized formularies, and short-term contracts that may be terminated and subject to periodic modification and re-negotiation, PBMs and their health plan clients are able to respond agilely to changes in the marketplace, such as the entry of new therapeutic alternatives, leveraging those changes to maintain downward pressure on net drug prices.

At the outset of the negotiation process—after the careful vetting process for clinical appropriateness—PBMs solicit multiple price concession offers from different manufacturers. 12-JA-2606. These offers are multi-faceted and flexible, with each manufacturer usually submitting a "bid grid," a table with "a number of cells, each of which represents a different level of formulary control," corresponding

to a different level of price concessions. 12-JA-2606 (quoting Navarro Expert Report). As the sample bid grid presented in this case and reproduced below indicates, a manufacturer typically offers its highest price concessions in situations where the PBM tightly controls access to therapeutic competitors, with lesser price concessions for simple inclusion among a list of several equally preferred options. 18-JA-3955 (Navarro Figure 5):

Figure 5: Example of Rebate Bid Matrix (or Grid)

		Total Number of Brands in Competitive Product Category (CPC*)		
		Limited (3 or more brand drugs in CPC)	**Preferred** (2 brand drugs in CPC)	**Exclusive** (1 brand drug in CPC)
Level of Formulary Control	**Low Control**	**Cell 1** Lowest rebate percent	**Cell 2** rebate percent	**Cell 3** rebate percent
	Moderate Control	**Cell 4** rebate percent	**Cell 5** Medium rebate percent	**Cell 6** rebate percent
	High Control	**Cell 7** rebate percent	**Cell 8** rebate percent	**Cell 9** Highest rebate percent

*CPC = includes brand drugs considered to be therapeutic alternatives

When a PBM and manufacturer reach agreement about price concessions, the agreement typically includes the entire bid grid. 12-JA-2607. This preserves flexibility for a PBM's clients to, on a plan-by-plan basis, select different types of coverage. *See* Kaiser Family Found., *2018 Employer Health Benefits Survey*, Section 9 (Oct. 3, 2018), https://tinyurl.com/9myapp8x (describing wide variety of benefit

designs, including different forms of cost-sharing and varying tier structures). And even after the negotiated array of options is agreed upon, it sets only the possible terms for future transactions—neither the PBM nor its clients are obligated to make specific coverage or formulary decisions. 18-JA-3957 (Navarro ¶ 81). Only if and when a coverage option is selected is the manufacturer obligated to provide the agreed-upon level of price concessions. *Id.*

This flexible bidding arrangement, including retrospective rebates, allows PBMs and their plan clients ample maneuvering room to shift among different levels of control for a particular drug without the need to renegotiate the contract. As the district court's opinion detailed, the undisputed record conforms to the usual practice; both Mylan and Sanofi responded to PBM solicitations by offering a range of rebates associated with different formulary positions and controls. *See* 12-JA-2620-31.

Beyond the flexibility provided by "bid grids," PBMs and their health plan clients regularly customize formularies for particular health plans or situations. 18-JA-3930 (Navarro ¶ 15); PCMA, Formulary Overview. Accordingly, even if a PBM excludes or limits access to a particular drug on one of its national formularies, health plans can and often do make different decisions. 18-JA-3941 (Navarro ¶ 37) (summarizing various PBM practices that include the tailoring of formulary design to the demands of individual health plans). On this point, too, the record evidence

reflects the usual practice. For example, when one PBM decided to exclude Auvi-Q from several national formularies, many of its clients chose not to adopt those formularies, and the PBM's decision affected only about 35% of the people covered by its commercial health plan clients. 12-JA-2621.

Flexibility is further enhanced by the short-term and easily terminable nature of agreements between PBMs and manufacturers. The agreements in the record here generally were for terms of a few years or less, with provisions permitting termination without cause at any time on 90 days' notice. 13-JA-2679. PBMs regularly invoked these termination provisions to renegotiate the agreements annually or even more frequently. *Id.*

Collectively, these features of PBM-manufacturer agreements enable PBMs to adapt quickly to changing market conditions and to agilely accommodate the varied needs of individual health plans. Agreements are also structured to allow PBMs to respond when a new therapeutic alternative provides an opportunity to enhance price competition and secure lower net drug costs for health plans and their enrollees. 18-JA-3970 (Navarro ¶ 110). Formularies are thus not static. They are "dynamic lists of drugs that change as new drugs enter or leave the market," 18-JA-3936 (Navarro ¶ 27), and are generally updated quarterly, PCMA, Formulary Overview, Maintaining Formularies. PBMs take seriously their mission to

continuously monitor the marketplace for opportunities to secure additional savings and pass them on to plans and, ultimately, consumers.

II. PBMs Facilitate Pro-Competitive Price Competition Between Drug Manufacturers And Thereby Promote Affordable Access To Prescription Drugs.

A. Formulary-Placement-Driven Price Concessions Are One of the Few Proven Methods of Lowering Prescription Drug Costs.

There is a reason that PBMs manage prescription drug benefits for over 90% of the U.S. population, using the commonplace and widespread tools assailed by Sanofi as anti-competitive here: PBMs have a proven track record of reducing prescription drug costs and passing those savings through to health plans and consumers.

1. Leveraging formulary placement and utilization management to encourage manufacturers to offer steeper price concessions is not a rare occurrence relegated to a few dusty corners of the market. It is the predominant way that price competition is generated in the prescription drug market. 18-JA-3965 (Navarro ¶¶ 97-100). As Sanofi's own expert testified before Congress, "the way you get low prices in the pharmaceutical industry is by the ability to exclude drugs…. When you can do that, you force price competition." 12-JA-2608. Why so prevalent? It works.

Compared to medical price inflation exceeding 2% in 2018, the customers of several PBMs benefited from either a decrease in net drug prices or only a nominal increase of 0.2-0.4%. 18-JA-3931 (Navarro ¶ 18). In 2019, net drug prices fell by

4.8% for the most tightly managed commercial plans. ESI, *2019 Drug Trend Report*, https://tinyurl.com/n9c52dxc. Considering manufacturer price concessions alone, the savings are dramatic: PBMs paid $89 billion in manufacturer price concessions to plans in the commercial and Medicare/Medicaid contexts in 2017. 18-JA-3949-50 (Navarro ¶ 60). In the commercial market, PBMs negotiated $23 billion in manufacturer price concessions in 2016, with a "net overall impact" that "is decisively beneficial to consumers at the point of purchase." Roehrig, Altarum Study, at 7, 18. The bottom line is that, "[f]or individuals with prescription drug insurance coverage, the final price that they and their insurer together pay for a prescription drug is significantly influenced by the rebate the manufacturer grants to … the pharmacy benefit manager[.]" Cong. Budget Off., *Increasing Transparency in the Pricing of Health Care Services and Pharmaceuticals*, at 6 (June 5, 2008).

When the full range of formulary design, utilization management, and business tools employed by PBMs is considered—including manufacturer rebates, encouraging the use of generic drugs, pharmacy discounts, and other techniques—the savings are even greater. A study commissioned by PCMA estimated that PBMs will save health plans and customers more than $1 trillion over ten years. Visante Study, at 3. Manufacturer price concessions were a primary driver for increased savings; from 2016 to 2020, the average level of rebates increased from 15% to 30%. *Id.* This adds up to real savings for consumers: an average of nearly $1,000 per

person, per year. Visante, Inc., *The Return on Investment (ROI) on PBM Services*, at 2 (Feb. 2020), https://tinyurl.com/kdsd75d5.

2. Such savings can be tied directly to PBMs' ability to exercise bargaining power to counteract the pricing power of manufacturers. As the Pharmaceutical Research and Manufacturers of America (PhRMA), an organization representing the interests of brand-name prescription drug manufacturers, has explained "PBMs … are able to leverage their market power to obtain substantial discounts and rebates on brand medicines." 18-JA-3959 (Navarro ¶ 84); *see also id.* (quoting Eli Lilly report stating that PBMs "increased negotiation leverage [has] resulted in consistently deeper discretionary discounting over the past several years"). That bargaining power depends on PBMs' ability to appropriately calibrate patient access and costs, facilitating access to therapeutic competitors that manufacturers are willing to offer at lower net costs, and limiting access to those drugs where manufacturers are not willing to reduce costs.

When only one drug can meet a medical need, PBMs have less market leverage to work with. That is why PBMs "welcome new drug entrants," because it "forces manufacturers to compete on drug clinical value and net price." 18-JA-3950 (Navarro ¶ 61). The more crowded the drug category, the more savings PBMs can typically achieve. *See* 12-JA-2607 (summarizing PBM testimony that "competition in a therapeutic class encourages manufacturers to offer more favorable pricing, and

rebates in exchange for better placement"); 18-JA-3951 (Navarro ¶ 64) (giving example of 60% rebates in particularly competitive categories).

As Sanofi's expert stated in congressional testimony, when a PBM identifies "a few therapeutic substitutes," it can say that "[w]hoever gives me the best prices is the one I am going to buy from" and "that is how you get a low price." 18-JA-3966 (Navarro ¶ 101). This is called "moving market share." *Id.*

To generate this competitive leverage, PBMs have repeatedly demonstrated their willingness and ability to shift market share to a new entrant, if it is therapeutically similar or equivalent and offers lower cost. The record here shows that Sanofi itself experienced an increase in market share when it finally began to compete on price. *E.g.*, 12-JA-2640. That is not a unique occurrence; the record also contains nine documented examples, for other competitive drugs, of PBMs and their health plan clients influencing market share away from an incumbent market leader toward a lower-cost alternative. 18-JA-3960-62 (Navarro ¶¶ 87-88). Likewise, a published study from the 1980s describes how a formulary change reduced the market share of dominant brand-name drugs from 80% to 20% in six months. 18-JA-3971 (Navarro ¶ 115).

3. Shifting market share to lower-cost alternatives benefits health plans and consumers alike. Market imperatives require PBMs to stay laser-focused on maximizing and passing on savings to their health plan clients and the consumers

that they serve. PBMs compete with one another to deliver greater savings to health plans (and through plans, to consumers), because benefit costs are often the paramount consideration for health plans choosing a PBM. 18-JA-3931 (Navarro ¶ 17); *see also* PCMA, *The Highly Competitive PBM Marketplace* (Apr. 28, 2021), https://tinyurl.com/6truvyu9. And although PBMs perform a wide variety of services, their core mission is to reduce net drug costs for health plans and consumers.

To this end, PBMs pass on the vast majority of negotiated price concessions to health plans and health insurance issuers. In the commercial context, PBMs pass on about 90% of rebates, and that rate has been steadily increasing. Pew Charitable Trusts, *The Prescription Drug Landscape, Explored*, at 1 (Mar. 8, 2019), https://tinyurl.com/328t54xr (91% passed through in 2016); Shepherd Testimony at 5 (describing survey of large employers indicating 90% pass through); 18-JA-3933 (Navarro ¶ 14c); *Drug Pricing in America: A Prescription for Change, Part III: Hearing Before the S. Comm. on Fin.*, 116th Cong. at 68, 117, 150, 178, 211-12, 216 (2019) (PBM testimony to Congress regarding pass-through of manufacturer rebates).

Many PBM contracts with health plan customers contain minimum rebate pass-through guarantees, and some require every dollar to be passed through. Shepherd Testimony at 5; 18-JA-3930 (Navarro ¶ 14); *In re EpiPen ERISA Litig.*,

2020 WL 4501925, at *4 (D. Minn. Aug. 5, 2020) ("[M]any plans required the PBMs to pass along 100% of any negotiated rebate or discount from Mylan[.]"). For Medicare prescription drug plans, virtually all (99.6%) of manufacturer rebates are also passed on to plans. *See* U.S. Gov't Accountability Off., GAO-19-498, *Medicare Part D: Use of [PBMs] and Efforts to Manage Drug Expenditures and Utilization*, at 16 (July 2019), https://tinyurl.com/zmb2dnwn ("GAO Report").

Plans and health insurance issuers then use the price concessions to lower enrollees' health spending, usually in the form of reduced premiums and sometimes in the form of reduced cost-sharing. *See id.* at 13 (documenting how rebates lead to reduced premiums for Medicare plans); Charles Roehrig, *Rebates, Coupons, PBMs, And The Cost Of The Prescription Drug Benefit*, Health Affairs (Apr. 26, 2018), https://tinyurl.com/yvsx64hx ("The beneficiaries of [drug manufacturer] rebates include … health plan enrollees via lower premiums, … and consumers at the point-of-purchase via lower copays."); Roehrig, Altarum Study, at 7 ("[B]illions of dollars in prescription drug rebates have flowed through to insurers, and these have been used to lower beneficiary premiums in private health plans[.]").

The supposition of Appellant's amici that PBMs' interests in securing lower drug costs somehow diverge from patients' interest in paying less for their prescriptions is thus flat wrong and does not square with the reality of how pharmaceutical markets work. Regardless of what happens in *other* health care

markets—like the hospital group purchasing organization study cited by one amicus, *see* COSAL Br. 10 & n.5—in *this* market PBMs are driving down drug costs and almost entirely passing those savings on to health plans and consumers.

Nor are these phantom savings created by a combination of inflated list prices with steeper discounts, as another amicus posits. *See* AAI Br. 15-16. The undisputed evidence for the commercial market, including testimony from PCMA members in this case, is that PBMs choose among therapeutically similar drugs based on the *net* drug cost—that is, which drug costs less after price concessions are deducted from the list price—*not* the difference between list prices and net prices or the nominal rebate rate. 18-JA-3947-48 (Navarro ¶ 56) ("When … making coverage determinations after drugs have been deemed clinically appropriate for coverage, PBMs … primarily consider net prescription cost[.]"). For "clinically interchangeable" drugs, the "comparative net prescription cost (after rebates) becomes a pivotal formulary coverage criterion." 18-JA-3962 (Navarro ¶ 90) (summarizing testimony from multiple payor deponents). And data confirm that manufacturer drug price increases are not correlated with PBM-negotiated rebates. PCMA, *New Data Shows That Manufacturer Drug Price Increases Are Unrelated to PBM-Negotiated Rebates* (2020), https://tinyurl.com/xkts2ev2.

What's more, if these savings were artificial, PBMs would not have been able to hold year-over-year increases in drug spending at near zero. Yet they often have.

See 18-JA-3931-32 (Navarro ¶ 18); *cf.* GAO Report at 13 (noting that price concessions negotiated by PBMs had enabled Medicare drug benefit plans to hold premiums near constant for five years). Recent evidence further confirms that the more active the PBM formulary management practices, the greater the savings. Evernorth, *2020 Drug Trend Report*, https://tinyurl.com/ekm63vp3 (reporting 9.2% decrease in drug costs for the most progressively managed plans from 2019 to 2020 and some decrease for nearly one-third of commercially managed plans). The district court did not merely "assume[]" (AAI Br. 16) that deeper price concessions are indicative of healthy competition. That is the reality.

B. PBMs' Formulary Design and Utilization Management Practices Lowered Net Drug Costs in this Case.

Beneficial competition in pharmaceutical markets "often involves manufacturers and payers entering into rebate agreements that provide rebates to payers in exchange for market-share guarantees or preferred formulary placement." FTC, *Report on Rebate Walls*, at 1 (May 28, 2021), https://tinyurl.com/33zuxerb. Rebates generally work to lower drug costs, as the studies above demonstrate. Of course, whether and how any specific rebate arrangement might nonetheless fall afoul of antitrust law is, as the FTC recognizes, a highly fact-specific inquiry dependent upon the specifics of the market involved. *See id.* But on the comprehensive record built here, there is ample *undisputed* evidence that the district court got it right. PBM's use of formulary management practices to foster

competition between therapeutic alternatives worked, the better competitor won better placement, and consumers were the ultimate beneficiaries.

Before the launch of the Auvi-Q, the epinephrine auto-injector category was a difficult one for PBMs, given limited therapeutic alternatives to the EpiPen. Nonetheless, even then, PBMs were able to extract significant savings and pass them along to consumers. As a result, even as list prices increased significantly, average patient co-pays remained relatively stable, and the overall average patient cost share paid for EpiPens—including both copays and coinsurance—decreased from 26% of list price in 2009 to 11% in 2016. PCMA, *Infographic on the Facts on EpiPen Costs* (Oct. 2016), https://tinyurl.com/75p7akep.

After the launch, opportunities to negotiate lower prices increased. Some PBMs "viewed Auvi-Q's introduction as an opportunity to manage the … class and push for more competitive pricing." 12-JA-2618. PBMs therefore quickly informed both manufacturers that they were considering covering only one epinephrine auto-injector and encouraged price competition. 12-JA-2618-19. Net prescription cost became "an extremely important formulary decision factor," because PBMs did not consider it "therapeutically necessary to cover more than one" epinephrine auto-injector. 18-JA-3970 (Navarro ¶ 112). In the words of one plan representative, once a therapeutic alternative entered the market, formulary placement decisions were "drive[n] by cost." 18-JA-3970 (Navarro ¶ 112, n.174).

PBMs, in competition with one another to lower costs for plans and patients, seized on the opportunity to leverage cost-savings on the two "interchangeable" products. 12-JA-2617. Many PBM and health plan deponents testified that they viewed the category as one where either product "could have been preferred without significant member disruption," and therefore ripe for moving market share to a lower-cost alternative. 18-JA-3971 (Navarro ¶ 116). PBMs got to work doing just that.

At first, however, Sanofi was unwilling to compete on price, because it did not "want to set off a whole cascade of price discounts," 12-JA-2613. Why? Sanofi held the strategic view that there are "no winners in a price war." Appellee Br. 18 (quoting Auvi-Q Strategy Discussion). Sanofi's strategic perspective, of course, did not include consumers.

Even so, Mylan was responsive to PBMs' requests for price concessions, including price concessions for preferred or exclusive coverage. And whether or not PBMs chose to grant exclusivity (or other preferred formulary placements) to EpiPen or Auvi-Q was dependent on net price: When PBMs "agreed to exclude Auvi-Q, Mylan had *offered a lower price* on EpiPen." 13-JA-2687 (emphasis added). Thus, one PBM chose EpiPen over Auvi-Q for its national formulary (which was only one of the many formularies it managed) because it was "able to get a lower net cost for our plans." 12-JA-2621. As Appellees highlight, there is not a single

instance in the record where Auvi-Q was excluded or restricted when Sanofi had offered a better net price. *See* Appellee Br. 20.

When Sanofi finally did start competing on price (at least until its product was voluntarily recalled), PBMs were able to leverage that competition and consumers benefited: net prices decreased. According to *Sanofi's* expert's analysis, "both EpiPen and Auvi-Qu's net prices dropped sharply" during the "period when Sanofi started to make more aggressive rebate offers" in late 2014 and 2015. 13-JA-2715. Sometimes this was to Mylan's benefit, and sometimes to Sanofi's, but always to the benefit of plans and patients.

One PBM noted that it was able to use competitive negotiations—which resulted in it mostly covering both products, but excluding EpiPen from one of its formularies—to "lower[] the overall net cost for [its] plans, and in many cases, for members." 12-JA-2637. And an EpiPen profitability analysis prepared by Mylan for Congress, which Sanofi's expert relied upon for part of her report, 14-JA-2895 n.166, shows that Mylan sold EpiPen at a lower net price in 2015 as compared to 2014. Mylan, *U.S. EpiPen Profitability Analysis*, https://tinyurl.com/ys87ca (documenting lower total sales revenue in 2015 than 2014, despite selling more EpiPens).

Sanofi's access to the market shifted in tandem with these price reductions, as PBMs' formulary management practices both encouraged and responded to

manufacturers price concessions. By April 2015, Auvi-Q had "regained 80% commercial marked access overall." 12-JA-2640 (internal quotation marks omitted). PBMs proved perfectly willing to exclude EpiPen from some of their formularies when Sanofi out-competed Mylan by offering a net better price, thereby shifting market share to Auvi-Q and away from EpiPen. *See* 12-JA-2642-43.

In short, as Appellees explain (Br. 51), the comprehensive and undisputed evidentiary record in this case establishes beyond genuine dispute that "Sanofi could and did beat Mylan in price competition when it chose to compete." And belying Sanofi's assertion that price wars have no winners, consumers won: Mylan's rebates for EpiPen increased—meaning its net prices decreased—after Auvi-Q's launch. 12-JA-2615. This helped not only patients who needed the EpiPen, but other health care consumers as well. *See In re EpiPen ERISA Litig.*, 2020 WL 4501925, at *5 (explaining that even plan participants who "did not purchase EpiPens … would have received the benefit of the plan applying EpiPen rebates to lower premiums and/or prescription drug prices across the board.").

Ultimately, there is no reason to disturb the district court's holding that the market here displayed lawful price competition, not unlawful anticompetitive behavior. If Sanofi were to prevail—and the undisputed facts here ignored or disregarded—consumers would be the ultimate losers. What happened in the

epinephrine auto-injector market exemplifies how the market can work for the greater benefit even as it creates winners and losers between rivals.

The antitrust laws are "concerned with the protection of competition, not competitors." *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962). Here, PBMs' pivotal role in negotiating prescription drug price concessions through formulary structure and utilization management practices worked, as it generally does, to benefit consumers. Mylan's success at out-competing Sanofi did not violate the antitrust laws.

CONCLUSION

This Court should affirm the grant of summary judgment.

Dated: September 22, 2021

Respectfully submitted,

s/ *Ruthanne M. Deutsch.*

John S. Linehan
General Counsel
PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION
325 7th St NW
Washington, DC 20004
(202) 756-5700
jlinehan@pcmanet.org

Ruthanne M. Deutsch
Hyland Hunt
DEUTSCH HUNT PLLC
300 New Jersey Ave. NW
Suite 900
Washington, D.C. 20001
(202) 868-6915
Fax: (202) 609-8410
rdeutsch@deutschhunt.com
hhunt@deutschhunt.com

Counsel for Amicus Curiae PCMA

CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitation in this Court's June 17, 2021 Order because it contains 6,466 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f); and that this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the typestyle requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point font.

Dated: September 22, 2021

/s/ *Ruthanne M. Deutsch*
Ruthanne M. Deutsch

CERTIFICATE OF DIGITAL SUBMISSION

I certify that all required privacy redactions have been made in accordance with Circuit Rule 25.5, that any hard copies submitted to the clerk are exact copies of the ECF submission, and that the digital submissions have been scanned for viruses using Bitdefender Endpoint Security Tools and are free of viruses.

Dated: September 22, 2021

/s/ *Ruthanne M. Deutsch*
Ruthanne M. Deutsch

CERTIFICATE OF SERVICE

I certify that on September 22, 2021, I electronically filed the foregoing with the Clerk of Court for the United States Court of Appeals for the Tenth Circuit by using the CM/ECF system. All participants in this case are registered with CM/ECF and service upon them will be accomplished by the CM/ECF system.

Dated: September 22, 2021

/s/ *Ruthanne M. Deutsch*
Ruthanne M. Deutsch