No. 21-3005

UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

In re: Epipen (EPINEPHRINEINJECTION, USP) MARKETING, SALES PRACTICES AND ANTITRUST LITIGATION,

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SANOFI-AVENTIS U.S., LLC,

Plaintiff Counterclaim Defendant-Appellant,

v.

MYLAN, INC.,
Defendant-Appellee,

and

MYLAN SPECIALTY, LP,
Defendant Counterclaimant-Appellee.

BRIEF OF AMICUS CURIAE ALLERGY & ASTHMA NETWORK IN SUPPORT OF APPELLANT SANOFI-AVENTIS U.S., LLC IN FAVOR OF REVERSAL

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DISCLOSURE STATEMENT

The Allergy & Asthma Network is a non-profit corporation. No public or private corporation owns 10% or more of its stock.

Counsel for the Allergy & Asthma Network previously represented Sanofi-Aventis U.S., LLC in this matter as an associate at Weil, Gotshal & Manges LLP until October 31, 2018. No other counsel for either party authored the brief in any part, or contributed money toward the preparation of this brief. No other person or entity other than amicus curiae contributed money toward the preparation of the brief.

Counsel for the parties to this appeal have consented to AAN filing its amicus brief.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

INTEREST OF AMICUS CURIAE

The Allergy & Asthma Network is a leading nonprofit patient-centered network uniting individuals, families, healthcare professionals, industry leaders and government decision-makers to improve health and quality of life for the millions of people affected by asthma, allergies, and related conditions. It has served as a leading advocate for patients for over 35 years, and seeks to ensure that federal and state laws, policies, regulations, and resources support its goal to achieve optimal health outcomes for people living with these chronic conditions.

ARGUMENT

"Cutting prices in order to increase business often is the very essence of competition." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986). Epipen's role in the epinephrine auto-injector (EAI) device market, then, is a story lacking in competition. Even as a new product entered the EAI device market, prices continued to rise despite no corresponding increase in production costs. True, the makers of these devices offered rebates to distributors. But this helped few consumers. Instead of lower prices and more choice as competition increased, millions of patients paid higher prices but lost the opportunity to choose which EAI device to purchase.

The district court in *In re EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litigation* failed to consider end consumers—patients and caregivers dependent on EAI devices to treat life-threatening anaphylaxis—in analyzing the market and the parties' competitive efforts. The district court focused instead on competition between Mylan, Inc. and Sanofi-Aventis U.S. LLC to be listed in drug formularies health insurers and pharmacy benefit managers (PBMs) approved for coverage. Academics and policymakers recognize that drugmakers' competition for those formularies does not align with the interests of consumers and patients. Nor does it lower consumer prices. Accordingly, any analysis of competition in the EAI device market cannot focus solely, or even primarily, on

rebates offered to woo third party payors. It must focus more broadly on access to EAI devices by consumers, including their costs and choices.

The EAI device pricing and competition for formularies described in the district court's opinion affect consumers much differently from third-party payors. Third-party payors benefit if both prices and rebates increase—higher rebates increase their revenues, and they can pass on higher prices to patients and their caregivers. Patients are worse off for footing the increased bill for their EAI devices and gain little or nothing from rebates to insurers and PBMs. It gets worse—rebates to third-party payors restrict patient choice when they are given in exchange for exclusive coverage. These rebates leave patients with fewer choices in the near-term and less innovation in the long-term. And for patients, no price-cuts offset these detriments.

A. PATIENT CHOICE SHOULD BE A PRIMARY CONSIDERATION FOR EVALUATING THE EAI DEVICE MARKET

1. Background of EAI Devices

EAI devices are used to treat anaphylaxis. *In re Epipen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litig.*, No. 17-md-2785, Dkt. 2254-1 (D. Kan. Dec. 17, 2020) ("Slip Op."), at 4. Anaphylaxis is a life-threatening allergic reaction, caused by food, insect, or pharmaceutical allergens. *Id.* Epinephrine auto-injectors provide first-line treatment for anaphylaxis and are designed for quick, easy administration. *Id.* All EAI devices contain the same active

ingredient—epinephrine. Other products, like antihistamines, are not substitutes for epinephrine. *Id.* Patients must be confident that they will carry the device at all times, and that they and others can use the device in an emergency.

EAI devices must be available quickly in an emergency. Physicians therefore recommend patients carry two EAI devices at all times in case of a severe allergic reaction.[1] Most EAI devices are sold in two-packs, and many patients and caregivers purchase multiple two-packs to keep EAI devices at home, to carry in a pocket or a backpack, and to keep at school. The epinephrine in EAI devices has a shelf life of about 18 months after manufacture, so EAI devices are generally purchased annually—often at the start of each school year.[2]

EAI devices must be simple enough that any patient, parent, caregiver, or teacher can use them under the stress of anaphylaxis. Most EAI devices include

[1] *See Paul A. Greenberger, MD; Dana V. Wallace, MD; Phillip L. Lieberman, MD; and Sean M. Gregory, PhD*, "Contemporary issues in anaphylaxis and the evolution of epinephrine autoinjectors," 119 Annals of Allergy and Asthma Immunology 333, 335 (2017).

[2] *See*, *e.g.*, Kate Talerico, "Parents are struggling to find life-saving EpiPens as school begins," Louisville Courier Journal, Aug. 7, 2018 (available at https://www.courier-journal.com/story/news/2018/08/07/epipen-shortages-could-worsen-school-year-begins/896987002/); Jennifer Clopton, "EpiPen shortage Causing Concern as Schools Start," WebMD Health News, Aug. 24, 2018 (available at https://www.webmd.com/allergies/news/20180824/epipen-shortage-causing-concern-as-schools-start).

labels instructing the patient, caregiver or even an untrained bystander how to administer an injection.[3]

Each EAI device, such as the Epipen, Auvi-Q, and Adrenaclick, requires its own procedure for use. The unique procedure involved for their use means that EAI devices are generally not considered to be interchangeable at the pharmacy. Until 2018, EAI devices including the Epipen were "BX" rated in the FDA Orange Book, meaning they are not considered to be therapeutically equivalent with other EAI devices.[4] In most states, the BX rating meant that pharmacists could not substitute another EAI device for the device a patient was prescribed.[5] Beginning in 2018, pharmacists had access to an approved, generic Epipen and could substitute a generic Epipen for a branded Epipen.[6] But a pharmacist cannot substitute a different type of EAI device. For example, a pharmacist can substitute the authorized generic Epipen

[3] Jay Portnoy, M.D., Rolin L. Wade, M.S., Catherine Kessler, PhD, "Patient Carrying Time, Confidence, and Training with Epinephrine Autoinjectors: The RACE Survey" 7 The Journal of Allergy and Clinical Immunology: In Practice, Issue 7, at 2253 (Sept.-Oct. 2019).

[4] Food and Drug Administration, "Approved Drug Products with Therapeutic Equivalence Evaluations," Preface to the 41st Edition, available at https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface.

[5] Andrew Abe, PharmD, "Path to Approval First Truly Generic Epipen," Pharmacy Times, Oct. 8, 2018 (available at https://www.pharmacytimes.com/view/path-to-approval-first-truly-generic-epipen).

[6] *Id*.

for a prescription for the branded Epipen, but cannot substitute Adrenaclick or Auvi-Q for a prescription for the branded Epipen.[7]

Patients and caregivers are the ultimate purchasers of EAI devices. In a competitive market, patients, along with their physicians, would be the ones who determine which EAI device to purchase. Because the stakes are high, patients want a convenient and reliable EAI device that they will carry and that they and others can properly administer. Patients' failure to carry EAI devices is a documented problem. Slip Op. at 5.[8] When choosing among EAI devices, physicians, patients, and caregivers consider features, reliability, ease of use, and price. Thus, courts should consider consumers' interests regarding choice and price when evaluating EAI device competition.

2. Competition for EAI Devices Prior to the Launch of Auvi-Q

The Epipen was introduced in the 1980s as the first EAI device. It was long the market leader and the only available EAI device. Slip Op. at 6; *id.* at 8. The Epipen has changed little over the years. And it had relatively stable prices until 2007. In that year, Mylan acquired Dey Pharma L.P. and with it, the rights to the

[7] *Id*.

[8] *See also* Jay Portnoy, M.D., Rolin L. Wade, M.S., Catherine Kessler, PhD, "Patient Carrying Time, Confidence, and Training with Epinephrine Autoinjectors: The RACE Survey" 7 The Journal of Allergy and Clinical Immunology: In Practice, Issue 7, at 2255-58 (Sept.-Oct. 2019).

Epipen. Then Mylan sharply increased Epipen prices. Between 2008 and 2016, the Epipen's Wholesale Acquisition Cost price rose six-fold from $98.57 per unit in 2008 to $608.61 in 2016. Slip Op. at 19.

The Epipen's first competitors failed to gain much market share. Twinject launched in 2005, but was discontinued in 2012. Adrenaclick launched in 2010 as both a branded and authorized generic, was discontinued in 2012, and re-launched in 2013. Slip Op. at 8. Both Twinject and Adrenaclick featured designs similar to the Epipen—namely, a cylindrical design like a large pen or magic marker that required a forceful jab to the thigh to administer.[9] Neither device received more than 10% market share at any time they were on the market through 2012. Slip Op. at 87.

In 2009, Sanofi acquired the rights to a new product and launched it in 2013 as Auvi-Q. Unlike other Epipen competitors, Auvi-Q featured a different, rectangular shape, approximately the size of a credit card and thickness of a smartphone. Slip Op. at 7. It also featured audio instructions on how to properly administer the injection. *Id*. Unlike Epipen, Auvi-Q did not require a "swing and jab

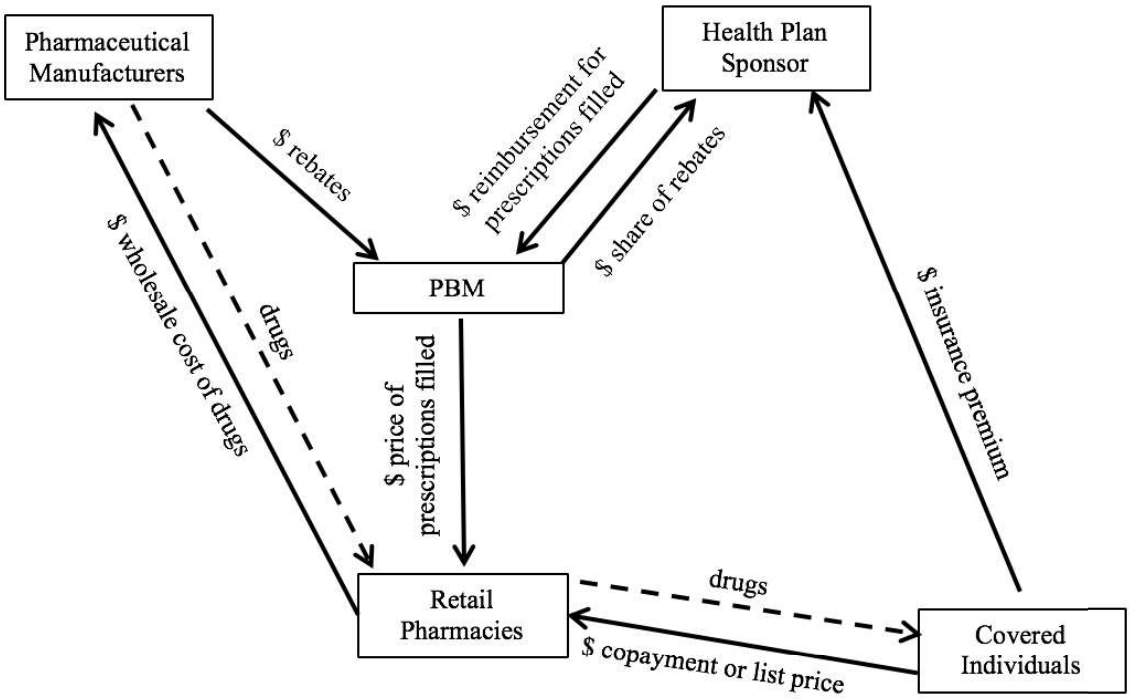
[9] *See* Paul A. Greenberger, MD; Dana V. Wallace, MD; Phillip L. Lieberman, MD; and Sean M. Gregory, PhD, "Contemporary issues in anaphylaxis and the evolution of epinephrine autoinjectors," 119 Annals of Allergy and Asthma Immunology 333, 335 (2017) (comparing Epipen and Adrenaclick as "pen-style EAIs"); Stephanie Guerlain, PhD, Akilah Hugine, MS, and Lu Wang, MS, "A comparison of 4 epinephrine autoinjector delivery systems: usability and patient preference," Ann Allergy Asthma Immunol. 2010 Feb at 172–177 (accessed at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2892620/).

motion." *Id*. As Sanofi prepared to launch Auvi-Q, Mylan investigated redesigning the Epipen to make it more portable, include voice instructions, and require lower pressure to inject rather than the "swing and jab" action. *Id.* at 10. Ultimately, Mylan decided not to redesign the Epipen because of the cost and time of development. *Id*.

B. Patient's Access to EAI Devices

The district court discussed at length the structure of how pharmaceutical products like EAI devices are priced and sold. Slip Op. at 11-18. But it focused almost entirely on mechanisms used by third-party payors (primarily PBMs and health insurers) to manage classes of pharmaceuticals and obtain higher rebates from pharmaceutical manufacturers. *Id.* The court addressed only a few sentences to patients' access to and costs of EAI devices. *See* Slip Op. at 11. The bulk of the district court's subsequent analysis focused almost entirely on mechanisms and formulary decisions used by third-party payors (primarily insurers and PBMs) to obtain rebates from Sanofi and Mylan. *See generally* Slip Op. at 21-113.

In so doing, however, the court ignored the complex flow of pharmaceuticals from manufacturers to patients, and the flow of payments between patients, manufacturers, pharmacies, insurers, and PBMs. This is illustrated as follows:



Joanna Shepherd, Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs, 38 Yale L. & Pol'y Rev. 360, 369 Figure 2 (2020). Pharmaceutical products flow from manufacturers, to retail pharmacies, and then to patients. PBMs typically do not take possession of drugs (other than through their own retail pharmacies).[10] Payments, on the other hand, flow in every direction:

- from patients to pharmacies for the purchase of drugs;
- from patients to health plans in the form of insurance premiums;

[10] Joanna Shepherd, Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs, 38 Yale L. & Pol'y Rev. 360, 368 (2020) (hereinafter "Conflicts of Interest").

- from pharmacies to manufacturers for the wholesale acquisition of drugs;
- from PBMs to pharmacies for the remaining cost of drugs other than the patient's portion;
- from health plans to PBMs as reimbursement for filled prescriptions;
- from manufacturers to PBMs as rebates; and
- from PBMs to health plans as a share of rebates received by the PBM.

A single purchase of an EAI device may include a half-dozen or more different payment flows. And each of those payments is subject to negotiation by the parties involved, such as PBMs' negotiations with manufacturers, pharmacies, and health insurers, or are the result of purchasing and prescribing decisions of patients and physicians.[11]

Nonetheless, the district court's analysis focused almost entirely on only one payment path: rebates from manufacturers to PBMs and insurers. It barely considered patient choice or costs, other than acknowledging that patients can pay the full list price of an EAI device out-of-pocket if they prefer a product that's excluded by their insurance.

The district court assumed that third-party payors' utilization management techniques and negotiations with pharmaceutical manufacturers for rebates function to decrease costs to patients. *See* Slip Op. at 13-16. But third-party payor savings do

[11] *Id*. at 373.

not always benefit patients. They get absorbed in this complex web of payments. Nor do patients get increased options as a result of utilization management.

The district court assumed "competition" for formulary placement through rebates advance consumers' interests. There are three reasons this is not so: (1) rebates to PBMs encourage drugmakers to increase list prices for pharmaceuticals, pushing up patient costs; (2) many patients whose health insurance nominally covers their EAI device still pay the full list price because of their deductibles; and (3) exclusions from coverage deprive patients of choice.

1. Third-Party Payors' Utilization Management Models May Lead to Increased List Prices and Overall Costs to Patients

PBMs are the largest payors—and negotiators—for pharmaceuticals. Three PBMs control 85% of the commercial insurance market.[12] Those three PBMs process about 70% of all prescription claims. Slip Op. at 12. The district court generally described the third-party payors' negotiation for manufacturers' rebates. *See* Slip Op. at 14-18. But it failed to discuss, or largely to even consider, the effects of those negotiations on the patients who ultimately choose which drug to purchase. Instead, it assumed that greater rebates paid to PBMs amounted to lower prices for consumers. But in fact, real-world evidence shows that the PBMs' middleman role

[12] Robin Feldman, "Perverse Incentives: Why Everyone Prefers High Drug Prices-Except for Those Who Pay the Bills," 57 Harvard J. on Legis. 303, 323 (2020) (hereinafter "Perverse Incentives").

often fails to benefit patients. Recognizing this, policymakers have sought to shift the focus of competition between drugmakers from rebating to PBMs to direct discounts to patients. In January 2019, for example, the Department of Health and Human Services proposed regulations to curtail rebates to third-party payors.[13] It noted that rebates reward and encourage increased list prices, and that rebates are not reflected in patients' out-of-pocket costs.[14] The Secretary issued a final rule in November 2020.[15]

Payors' negotiated rebates are opaque, even to the insurers who contract with them. PBMs often do not disclose their rebate levels to health insurers.[16] The portion of rebates PBMs pass along to insurers varies from nothing to 100%.[17] PBMs also

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[13] Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, 84 Fed. Reg. 2340 (Feb. 6, 2019).

[14] "Fact Sheet: Trump Administration Proposes to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients," Department of Health and Human Services (available at https://www.hhs.gov/sites/default/files/20190131-fact-sheet.pdf).

[15] Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, 85 Fed. Reg. 76666 (Nov. 30, 2020).

[16] Mark Meador, Squeezing the Middleman: Ending Underhanded Dealing in the Pharmacy Benefit Management Industry Through Regulation, 20 Annals Health L. 77, 82 (2011) (hereinafter "Squeezing the Middleman").

[17] Shepherd, Conflicts of Interest, 38 Yale L. & Pol'y Rev. at 376.

sometimes recharacterize portions of rebates as administrative or other fees to avoid sharing with insurers.[18]

Rebates are the largest source of revenues for PBMs,[19] and the primary means for manufacturers to compete for placement on PBMs' formularies. *See generally* Slip Op. at 29-43. But rebates creates a perverse incentive for manufacturers to increase their list prices. Rather than create formularies based on which drugs are least expensive overall, PBMs have an incentive to prefer drugs that pay higher rebates, even if the net cost is higher.[20] Drug A, listed at a high price, combined with a high rebate, provides more revenue for a PBM than Drug B with a low list price and low rebate. This is so even if the overall net cost after rebates of Drug B is substantially lower than for Drug A.

A hypothetical calculation bears this out. Suppose Drug A costs $100 and the PBM negotiated a 20% rebate, while Drug B costs $50 and the PBM negotiated a 10% rebate. The net price of Drug A is $80, and of Drug B is $45. The PBM receives rebate checks of $20 from each sale of Drug A, but only $5 from each sale of Drug B. In each instance, the remainder of the cost of the drug is passed through to patients (through co-pays or co-insurance) and health insurers that contract with PBMs, so

[18] *Id.* at 376.

[19] Meador, "Squeezing the Middleman", 20 Annals Health L. at 82 (2011).

[20] Shepherd, Conflicts of Interest, 38 Yale L. & Pol'y Rev. at 376.

the PBM does not absorb the net cost of either drug. The PBM would have an incentive to choose the higher-priced, higher rebate drug despite the higher overall cost.[21] And in fact, PBMs have paid settlements to resolve allegations that they steered patients to higher-cost drugs on the formulary that provide higher rebates to the PBMs.[22]

For similar reasons, PBMs' rebate structures push up list prices. PBMs receive higher revenues if manufacturers offer the same rebate year-to-year, but increase the list price. And manufacturers can raise both list prices rebate offers to "compete" for formulary placement, without reducing their profits:

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[21] *See also* Craig Garthwaite and Fiona Scott Morton, "Perverse Market Incentives Encourage High Prescription Drug Prices," Pro Market, the publication of the Stigler Center at the University of Chicago Booth School of Business, Nov. 1, 2017 (available at https://promarket.org/2017/11/01/perverse-market-incentives-encourage-high-prescription-drug-prices/) ("Suppose the manufacturer raises its list price by $10 and its rebate by $9. The result is a $1 higher net price so the manufacturer is better off. If a lack of competition allows a PBM to return $8 to the payer instead of the full $9, the PBM is better off by $1 also. The PBM has little reason to bargain with manufacturers to keep prices from increasing in the first place; indeed their incentive is to encourage higher prices and higher rebates. Meanwhile, the payer's drug costs increase by $2.").

[22] Express Scripts paid $36.3 million in 2008. Press Release, New York State Office of the Attorney General, Attorney General Cuomo Secures $27 Million Dollar Agreement to Crack Down on Pharmacy Benefit Managers Secretly Switching New Yorkers Prescription Drugs (July 29, 2008), https://ag.ny.gov/press-release/attorney-general-cuomo-secures-27-million-dollar-agreement-crack-down-pharmacy-benefit. Medco paid $29.3 million in 2004. Milt Freudenheim, *Medco to Pay $29.3 Million to Settle Complaints of Drug Switching*, N.Y. TIMES (Apr. 27, 2004), https://www.nytimes.com/2004/04/27/business/medco-to-pay-29.3-million-to-settle-complaints-of-drug-switching.html.

> For example, consider a drug with a list price of $100 and a PBM-negotiated rebate percentage of forty percent. If the manufacturer needed to compete for formulary status by increasing the rebate paid to the PBM, it could raise the list price to $120 and increase the rebate percentage to fifty percent. Doing so would increase the rebate from $40 to $60, but the drug manufacturer wouldn't be any worse off; it would retain the same $60.[23]

In this scenario, the manufacturer maintains its profit margin and the PBM receives a higher share of rebate, but that increased rebate must come from somewhere. It comes from the consumer, either as an increased out of pocket payment, or increased insurance premium.[24]

Drugmakers and the Secretary of Health and Human Services agree that rebates drive up prices.[25] In competitive drug markets, a manufacturer that lowers the list price, thereby reducing rebates to PBMs, may find itself excluded in favor of a higher-priced drug offering higher rebates.[26]

The evidence in this case bears out the contorted structure and compromised incentives of this business model. Facing a new competitive threat from Auvi-Q, Mylan failed to lower its price even after years of double-digit price increases. Slip Op. at 18-19. Instead, Mylan raised the price of the Epipen three times in the year

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[23] Shepherd, Conflicts of Interest, 38 Yale L. & Pol'y Rev. 360, 378 (2020).

[24] Feldman, Perverse Incentives, 57 Harvard J. on Legis. at 342.

[25] Shepherd, Conflicts of Interest, 38 Yale L. & Pol'y Rev. 360, 379 (2020).

[26] *Id.*

before Auvi-Q launched. Slip Op. at 19. After Auvi-Q's launch, Mylan continued to increase the price of the Epipen. *Id.* But Mylan also increased rebates to insurers *Id.* at 25. The Epipen's swiftly increasing price made its rebates more attractive to PBMs, yet illusory to patients.

2. Many Patients Do Not Receive a Benefit from Rebates to Third-Party Payors

Patients lose when drug prices increase. Uninsured patients and even many patients with health insurance must pay the full list price of drugs out of pocket. And all insured patients absorb the increasing costs of drugs through higher premiums.

Uninsured patients—still nearly 10% of Americans—must pay the list price when they fill their prescription.[27] They do not gain any benefit from the rebate competition from drug manufacturers for formulary placement. Rather, they feel the full brunt of the impact of EAI device price increases described by the district court—including continued price increases after the launch of Auvi-Q and competition between Epipen and Auvi-Q for formulary placement. *See* Slip Op. at 18-28.

Many insured patients must meet deductibles before insurance begins to pay for prescriptions. So a significant portion of insured individuals whose drug prices are negotiated by PBMs and subject to rebates from those PBMs pay the full list

[27] Shepherd, Conflicts of Interest, 38 Yale L. & Pol'y Rev. 360, 362 (2020)/

price of their drugs at the pharmacy. PBMs still get rebates when insureds pay full list price, but the rebate does not get returned to the patient or applied to the patient's out of pocket cost.[28] In theory, rebates collected by PBMs and shared with insurers serve to lower patients' premiums. But those indirect savings are spread across all insured members, rather than accruing to purchasers of rebated drugs.

The Affordable Care Act and other trends in employer-sponsored health insurance have made high deductibles more common.[29] As of 2019, more than 58% of covered workers were enrolled in plans with a deductible of at least $1,000,[30] and as of 2020 the average deductible amount for individual coverage was $1,644.[31] Theoretically, these plans make consumers more sensitive to costs. Patient "spending in the deductible phase now accounts for three times the share of total

[28] PhRMA, Follow the Dollar: Understanding How the Pharmaceutical Distribution and Payment System Shapes the Prices of Brand Medicines, at 12 (Nov. 2017) (hereinafter "Follow the Dollar Report"), https://onphr.ma/2MTiXWT.

[29] The Affordable Care Act requires enrollment in a High Deductible Health Plan (HDHP) for access to tax-advantaged Health Savings Accounts. Qualifying HDHPs must meet minimum deductible amounts, set by the IRS each year. *See* "High Deductible Health Plan (HDHP)", Healthcare.gov, available at https://www.healthcare.gov/glossary/high-deductible-health-plan/.

[30] Joseph Antos and Alice Rivlin, "A New Vision for Health Reform," The Brookings Institute and the American Enterprise Institute, September 2019, available at https://www.brookings.edu/wp-content/uploads/2019/09/FP-health-care.pdf.

[31] Kaiser Family Foundation, "2020 Employer Health Benefits Survey," Oct. 8, 2020, available at https://www.kff.org/report-section/ehbs-2020-section-7-employee-cost-sharing/.

drug spending that it did ten years ago."[32] But those high deductibles mean that many patients will have to pay for their drugs, including EAI devices, out-of-pocket at full price, rather than at the net prices negotiated by PBMs after rebates.

Even for patients whose insurance covers their EAI device, savings negotiated between manufacturers and PBMs are generally not shared with patients at the pharmacy. So patients with co-insurance or who have not yet met their deductibles are typically charged the list price, even if the PBM negotiated a rebate with the manufacturer. A patient's cost-sharing amount may even exceed what the patient would pay without insurance. But "language in PBM contracts may discourage or prohibit pharmacists from informing insured patients about the lower cash price, at the risk of the pharmacy being excluded from the PBM's network."[33] Plan sponsors often use the rebates and discounts they receive to help reduce plan costs or premiums, though they are generally not required to do so.[34] Thus, patients face both out of pocket costs (unmitigated by rebates paid only to third-party payors) and higher premiums to cover years of drug price increases.

An EAI device (or multiple devices depending on a patient's needs) must be purchased annually to replace expired units. Thus, many patients spend a significant

[32] Shepherd, Conflicts of Interest, 38 Yale L. & Pol'y Rev. 360, 379 (2020).

[33] Follow the Dollar Report at 6.

[34] Follow the Dollar Report at 6.

portion of their deductible each year on EAI device. But they won't get the benefit of the rebates discussed in the district court's decision.

Many forego necessary care to avoid spiraling costs. "A significant body of evidence establishes that, as out-of-pocket costs for drugs increase, patients are less likely to adhere to their medication routines."[35] Patients at risk of anaphylaxis may thus decide to risk a severe allergic reaction without an EAI device rather than pay hundreds or thousands of dollars.

3. Patients are Harmed by Exclusions of EAI Devices

Even patients who receive the benefit of negotiated rebates in lower premiums or co-pays are harmed by the lack of choice. Patients choose EAI devices in part based on familiarity with the device and confidence that they and others will have the device available and ready to use quickly in an emergency. Many patients therefore have strong preferences for their EAI device—whether for the familiarity of the Epipen, or the convenient size and shape and audio instructions of Auvi-Q. A patient faced with similar rebate offers as the PBM (e.g., lower rebates for coverage of two or more devices to let the patient decide which EAI device to purchase, or a higher rebate for exclusive coverage of one device) may have opted to pay more for choice. But with a closed formulary, a patient with a strong preference for an

[35] Shepherd, Conflicts of Interest, 38 Yale L. & Pol'y Rev. 360, 380 (2020).

excluded EAI device may not be financially able to pay out of pocket for their preferred device, and instead be forced to purchase a disfavored device.

Moreover, patients largely lack ability to shop between PBMs or health plans based on the plans' formularies. Many patients are at the mercy of the health plans negotiated and offered by their employers. Others may be forced to choose the lowest cost plan available to them, without evaluating whether their preferred drugs are available on the plan's formulary. And in any event, payors and PBMs may change the formulary mid-year, after a patient is locked in to a health plan and cannot switch to a new plan that covers their preferred device. Courts have recognized that contracting parties' voluntary arrangements may cause antitrust injuries to downstream participants who are affected by those arrangements. *See Complete Entm't. Res. LLC. v. Live Nation Entm't, Inc.*, 2017 WL 6512223, at *3 & n.5 (C.D. Cal. Oct. 16, 2017) ("[E]xclusive contracts—while voluntary on both sides—may harm competition because the structure of those contracts undermines the incentive of the venues to keep fees down . . . one cannot simply assume that the venues' voluntary economic choices will prevent anticompetitive harm to non-contracting third-parties.").

Yet the district court suggested there was no antitrust injury because any patient had access to Auvi-Q (or other excluded devices) if their physician prescribed it by paying the full list price out-of-pocket. *See* Slip Op. at 127. This is flawed

reasoning. Opting to pay the full price out-of-pocket rather than a reduced price through insurance is simply not realistic for most patients. Patients who preferred Auvi-Q but whose insurance excluded it would have to pay hundreds of dollars for their preferred device, rather than a much lower co-pay or co-insurance for a covered product. That cost would be multiplied by two or three for patients who must keep devices at home, at school, and in their pocket. Being forced to pay a higher price for your preferred product due to a third-party's exclusion of coverage for that product is plainly an antitrust injury. *See Blue Shield of Va. v. McCready*, 457 U.S. 465, 480-81 (1982) ("As a consumer of psychotherapy services entitled to financial benefits under the Blue Shield plan, we think it clear that McCready was 'within that area of the economy . . . endangered by [that] breakdown of competitive conditions' resulting from Blue Shield's selective refusal to reimburse." (citations omitted)). That access would be further limited if physicians knew or were told that their patients' insurance would exclude Auvi-Q, causing physicians to avoid prescribing it in the first place. In reality, exclusions of EAI devices put them out of reach for most patients.

C. EXCLUSIONARY REBATES INSULATE INCUMBENT PRODUCTS FROM COMPETITION AND STIFLE INNOVATION

One effect of the PBM distribution model described above is that incumbent drugmakers can insulate themselves from competition. Dominant market shares, combined with price increases and increasing rebates, can incentivize PBMs to

protect a drug from new competition. For example, consider a drug with no competitors that sells 1 million units annually, at a list price of $100 per unit, with a nominal 1% rebate to PBMs. When a competing drug launches, the first drugmaker could then raise its rebate to 20% with preferred or exclusive formulary placement, increasing annual rebates from $1 million to up to $20 million (depending on its market share). The new drugmaker can offer the same rebate, but it does not have the built-in volume that the incumbent drug already has. Even in a scenario where the new drug achieves a 50% market share in the first year, it would have to offer a 40% rebate at its 50% share to match the 20% rebate offered by an incumbent drug that would maintain its current share.

Rebate-based competition demanded by PBMs discourages list price competition. In the scenario above, if the new drug launched at a lower price than the incumbent, it would have to increase its rebate percentage even more to match the incumbent maker's total rebate offer to PBMs. Combined with incumbents' volume advantages, rebates insulate incumbents from new competition, especially when drugmakers secure exclusive or preferred coverage. This insulation protects incumbents from competitors offering lower net prices or innovative products.[36]

The evidence from this case bears out that hypothetical. Epipen increased its rebates after Auvi-Q launched, and offered greater rebates for exclusive coverage.

[36] Perverse Incentives, 57 Harvard J. on Legis. 303, 329-30 (2020).

Slip Op. at 30-41. And Mylan's incumbency allowed it to gain exclusive coverage with some PBMs despite offering lower rebates than Sanofi offered for exclusive coverage. For example, the large PBM Express Scripts Inc. made Epipen the exclusive EAI device after Mylan offered a 23% rebate, while Sanofi offered a 30% rebate for exclusive coverage. *See* Slip Op. at 30-31. Mylan was thus able to protect itself from a new competitor and avoid improving its own product. It could do this despite offering a higher net price than Sanofi in some instances. As a consequence, millions of patients lost out on both the new Auvi-Q and the possibility of an improved Epipen.

CONCLUSION

Competition tends to decrease prices, increase innovation, and increase consumer choice. Restrictions that increase prices, decrease innovation, and reduce consumer choice may harm competition. *F.T.C. v. Ind. Fed'n of Dentists*, 476 U.S. 447, 459 (1986); *United States v. Visa U.S.A., Inc.*, 344 F.3d 229, 240-41 (2d Cir. 2003). After the introduction of Auvi-Q, the EAI Device market became less competitive. In response to impending competition from Auvi-Q, Mylan declined to invest in an improved Epipen. Instead, it continued to increase the Epipen's price, while blocking patients' access to coverage for Auvi-Q and other EAI devices. The rebates that EAI device makers paid to obtain exclusivity did not result in net benefits to patients. Instead, the end result was higher prices, less choice, and less

innovation. Patients and consumer suffered. The fact that patients and caregivers were at the mercy of their PBMs and insurers, but failed to receive the benefits of rebates offered by Mylan and Sanofi, should be accounted for in any analysis of competition in the EAI device market.

RESPECTFULLY SUBMITTED this 4th day of June, 2021.

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