# APPENDIX

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**APPENDIX A**

No. 24-598
*Mosaic Health, Inc. v. Sanofi-Aventis U.S., LLC*

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

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August Term 2024
Argued: May 2, 2025
Decided: August 6, 2025
Amended: October 15, 2025

No. 24-598

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MOSAIC HEALTH, INC.,
CENTRAL VIRGINIA HEALTH
SERVICES, INC., INDIVIDUALLY AND ON BEHALF OF
ALL THOSE SIMILARLY SITUATED,
*Plaintiffs-Appellants*,

v.

SANOFI-AVENTIS U.S., LLC, ELI LILLY AND
COMPANY, LILLY USA, LLC, NOVO NORDISK,
INC., ASTRAZENECA PHARMACEUTICALS LP,
*Defendants–Appellees.*

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Appeal from the United States District Court for the
Western District of New York
No. 21-cv-6507
Elizabeth A. Wolford, *Chief Judge*

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Before: PÉREZ, NATHAN, AND KAHN, *Circuit Judges*.

On appeal from a judgment of the United States District Court for the Western District of New York (Wolford, *C.J.*).

Several federally funded health centers and clinics filed a class action complaint against a group of drug manufacturers alleging violations of federal and state antitrust laws, and state common law, through concerted action to restrict drug discounts offered to contract pharmacies. The United States District Court for the Western District of New York dismissed the first amended complaint and denied leave to file a second amended complaint. Plaintiffs timely appealed.

We conclude that the proposed second amended complaint plead enough facts to give rise to a plausible inference of a horizontal price-fixing conspiracy under Section 1 of the Sherman Act, 15 U.S.C. § 1.

Therefore, we **VACATE** the district court's judgment dismissing Plaintiffs' suit and denying leave to amend and **REMAND** for the district court to grant Plaintiffs leave to file their second amended complaint.

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MYRNA PÉREZ, *Circuit Judge*:

While much of this opinion includes doctrinal jargon unique to antitrust cases, at bottom, this appeal is about whether Plaintiffs-Appellants met the low pleading threshold for surviving a motion to dismiss. Here, properly granting all inferences and crediting all non-conclusory facts, Plaintiffs' proposed second amended complaint pled sufficient facts to substantiate their antitrust allegations at the motion to dismiss stage. Accordingly, the district court erred in denying Plaintiffs' motion for leave to amend their complaint as futile and ultimately dismissing Plaintiffs' complaint. We vacate the district court's dismissal of the complaint and remand the case to the district court for further proceedings consistent with this opinion.

## BACKGROUND

Plaintiffs filed a putative class action alleging that Defendants violated state and federal antitrust laws, as well as state common law, by engaging in a horizontal price-fixing conspiracy. Specifically, Plaintiffs allege that Defendants conspired, in violation of Section 1 of the Sherman Act, to limit a drug discount offered to safety-net hospitals and clinics that purchase diabetes drugs filled at retail pharmacies. As is our obligation at this stage of the proceeding, the facts that follow are construed in the light most favorable to Plaintiffs.

Plaintiffs Mosaic Health, Inc. and Central Virginia Health Services, Inc. are two federally funded health centers (collectively, "Plaintiffs") operating safety-net clinics that serve low-income, underserved patient populations and provide medications to patients in need with sliding-fee discounts. Mosaic Health, Inc. operates twenty-two safety-net clinics in New York, and Central Virginia Health Services, Inc. operates eighteen safety-net clinics in Virginia. Defendants Sanofi-Aventis U.S., LLC ("Sanofi"), Eli Lilly and Company and Lilly USA, LLC (together, "Eli Lilly"), Novo Nordisk Inc. ("Novo Nordisk"), and AstraZeneca Pharmaceuticals LP ("AstraZeneca") (collectively, "Defendants") are a group of drug manufacturers who produce drugs covered by Medicare and Medicaid.

Together, Defendants control three diabetes drug production markets: (i) rapid-acting analog insulins, (ii) long-acting analog insulins, and (iii) incretin mimetics. Defendants compete against each other as horizontal competitors in these diabetes drug production markets. Defendants Sanofi, Eli Lilly, and Novo Nordisk compete in the sale of rapid-acting and long-acting analog insulins, and all four Defendants compete in the sale of incretin

mimetics. Within the United States, Defendants report billions of dollars in sales of rapid acting analog insulins, long-acting analog insulins, and incretin mimetics, which contribute significantly to each company's overall financial performance.

The drug discount that Defendants allegedly conspired to limit was offered through their participation in a program created pursuant to Section 340B of the Public Health Service Act, 42 U.S.C. § 256b (the "Section 340B Drug Discount Program"). The Section 340B Drug Discount Program creates a discount for participating healthcare providers by imposing a ceiling price and requiring each manufacturer to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price" (the "Section 340B Drug Discount"). 42 U.S.C. § 256b(a)(1). Importantly, manufacturers providing drugs covered by Medicare and Medicaid, "must offer" the Section 340B Drug Discount.[1] *See Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 115 (2011) (first citing 42 U.S.C. § 256b(a); and then citing *id.* § 1396r-8(a)(1)); *see also Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 730 (2022).

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[1] Since 1996, the United States Department of Health and Human Services has taken the position that because, historically, few safety-net providers operate in-house pharmacies, they might participate in "bill to, ship to" arrangements whereby covered providers purchase the discounted drugs for shipment to community pharmacies (also called "contract pharmacies"), to be dispensed to the safety-net providers' patients there. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43549, 43552 (Aug. 23, 1996); *see also id.* at 43549 ("It has been the Department's position that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price.")

For at least a decade, Defendants offered the Section 340B Drug Discount to safety-net hospitals and clinics for purchase and distribution by retail pharmacies. By regularly offering Section 340B Drug Discounts, Defendants were able to lower healthcare costs for patients in need of discounted medications.

But, beginning in 2020, Defendants collectively lobbied the federal government to limit the Section 340B Drug Discount Program as applicable to diabetes medications. Defendants used the firm Tarplin, Downs & Young LLC to assist with lobbying efforts related to the Section 340B Drug Discount Program. Additionally, Defendants Sanofi and AstraZeneca separately retained the lobbying firm W Strategies, LLC for the same purpose. Defendants Sanofi, Eli Lilly, and Novo Nordisk also retained the lobbying firm Williams and Jensen, PLLC. Tarplin, Downs & Young and Williams and Jensen, PLLC also worked on the same lobbying efforts with PhRMA, a drug manufacturers' association of which all Defendants are members.

The Defendants' lobbying efforts were unsuccessful in limiting the Section 340B Drug Discount Program. On July 24, 2020, President Trump issued Executive Order 13937 entitled "Access to Affordable Life-Saving Medications," which addressed the use of insulin and epinephrine within the Section 340B Drug Discount Program but remained extremely limited in scope and impact on the volume of Section 340B Drug Discounts. That same day, Defendant AstraZeneca informed the United States Department of Health and Human Services ("HHS") privately that beginning October 1, 2020, it would no longer provide the Section 340B Drug Discount to contract pharmacies, except that safety-net providers could ship discounted drugs to one contract pharmacy if

they did not operate an on-site dispensing pharmacy. AstraZeneca publicly announced this plan in mid-August 2020.

On or about July 27, 2020, Defendant Sanofi also publicly announced that starting October 1, 2020, it would cut off Section 340B Drug Discounts at contract pharmacies, except if providers would send prescription-claims data to a Sanofi vendor.

On August 19, 2020, Defendant Eli Lilly sent HHS a private letter stating that on September 1, 2020, it would cease to permit Section 340B Drug Discounts, except where a safety-net provider lacked an in-house pharmacy and instead selected a single community pharmacy to service its patients. Eli Lilly also "added a special exception to permit Contract Pharmacies to pass along certain insulins products at cost," however Plaintiffs allege that the "exception was infeasible for covered entities and pharmacies, as it required Contract Pharmacies to fill prescriptions without any fee." J. App'x 815. Eli Lilly stated that it would offer the Section 340B Drug Discount only when "[n]o insurer or payer is billed for the Lilly insulin dispensed" and "[n]either the covered entity nor the contract pharmacy marks-up or otherwise charges a dispensing . . . fee for the Lilly insulin." *Id.*

On December 1, 2020, Defendant Novo Nordisk informed HHS that on January 1, 2021, it would cease to offer Section 340B Drug Discounts altogether, except for non-hospital covered entities, like clinics.

Collectively, all four Defendants imposed Section 340B Drug Discount restrictions that Plaintiffs allege resulted in significant financial loss to safety-net hospitals and clinics.

Plaintiff Mosaic Health, Inc. filed a class action complaint against Defendants alleging violations of

federal and state antitrust laws, as well as state common law. Central Virginia Health Services, Inc. joined as a plaintiff in an amended complaint. Defendants successfully moved to dismiss the first amended complaint.

Plaintiffs then moved for leave to file the proposed second amended complaint. The district court denied the Plaintiffs' motion, reasoning that Plaintiffs failed to allege parallel conduct and failed to plausibly allege the requisite factual circumstances giving rise to an inference of conspiracy. Plaintiffs timely appealed.

## STANDARD OF REVIEW

We review the grant of a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) de novo. *See Gelboim v. Bank of America Corp.*, 823 F.3d 759, 769 (2d Cir. 2016) (citation omitted). "The denial of leave to amend is similarly reviewed *de novo*" when "the denial was based on an interpretation of law, such as futility." *Id.* (internal quotation marks and citation omitted). At this stage of the proceedings, "we accept all factual allegations as true and draw every reasonable inference from those facts in the plaintiff's favor." *Mayor & City Council of Balt. v. Citigroup, Inc.*, 709 F.3d 129, 135 (2d Cir. 2013). The complaint must provide "enough facts to state a claim to relief that is plausible on its face." *Id.* (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

## APPLICABLE LAW

Plaintiffs' claims here arise from antitrust law. An antitrust plaintiff must plead facts with sufficient particularity in the complaint to state a cause of action or face dismissal of the lawsuit. *Id.* at 136.

Section 1 of the Sherman Act prohibits agreements that unreasonably restrain trade. *See* 15 U.S.C. § 1 (criminalizing "[e]very contract, combination in the form

of trust or otherwise, or conspiracy, in restraint of trade or commerce").[2] This case requires us to examine whether Plaintiffs pled sufficient evidence of an agreement to conspire. Pleading facts sufficient to support an allegation of an antitrust conspiracy may be accomplished in one of two ways. "[A] plaintiff may . . . assert direct evidence," such as a recorded phone call, "that the defendants entered into an agreement in violation of the antitrust laws." *Citigroup,* 709 F.3d at 136. But conspiracies are rarely evidenced by explicit agreements. Nearly always a conspiracy must be proven through "inferences that may fairly be drawn from the behavior of the alleged conspirators," *Michelman v. Clark-Schwebel Fiber Glass Corp.,* 534 F.2d 1036, 1043 (2d Cir. 1976); *see also United States v. Snow,* 462 F.3d 55, 68 (2d Cir. 2006) ("[C]onspiracy by its very nature is a secretive operation, and it is a rare case where all aspects of a conspiracy can be laid bare in court with . . . precision." (internal quotation marks and citation omitted)). Because such a "smoking gun" is "hard to come by," we also accept "circumstantial facts supporting the *inference* that a conspiracy existed." *Citigroup,* 709 F.3d at 136 (emphasis in original).

The Supreme Court first set forth the standard for supporting a plausible inference of an antitrust conspiracy at the motion to dismiss stage in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). There, the Supreme Court held that "stating . . . a [Section 1] claim requires a

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[2] A horizontal price-fixing scheme is a particular type of Sherman Act violation that "involve[s] coordination between competitors at the same level of a market structure." *United States v. Apple, Inc.*, 791 F.3d 290, 313 (2d Cir. 2015) (internal quotation marks and citation omitted) (alteration adopted). Such schemes are, "with limited exceptions, *per se* unlawful" under the Sherman Act. *Id.* at 313–14. Accordingly, we need not evaluate whether trade was unreasonably restrained.

complaint with enough factual matter (taken as true) to suggest that an agreement was made." *Twombly*, 550 U.S. at 556. In other words, the complaint must contain "enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of illegal agreement." *Id.* As a means of smoking out the illegal agreement, courts have required plaintiffs to allege, with the requisite factual support, "certain parallel conduct" by the alleged conspirators and "some factual context suggesting agreement, as distinct from identical, independent action." *Id. at* 548-49.

The requisite factual circumstances are "often referred to as 'plus' factors." *Apex Oil Co. v. DiMauro*, 822 F.2d 246, 253 (2d Cir. 1987). Plus factors

> may include traditional evidence of conspiracy: statements permitting an inference that the defendants entered into an agreement. They may also include evidence of other circumstances giving rise to a less direct inference of conspiracy, such as 'a common motive to conspire, evidence that shows that the parallel acts were against the apparent individual economic self-interest of the alleged conspirators, and evidence of a high level of interfirm communications.'

*Anderson News, L.L.C. v. American Media, Inc.*, 899 F.3d 87, 104 (2d Cir. 2018) ("*Anderson News II*") (quoting *United States v. Apple, Inc.*, 791 F.3d 290, 315 (2d Cir. 2015)).

Recognizing that parallel conduct alone could be because of "chance, coincidence, independent responses to common stimuli, or mere interdependence unaided by an advance understanding among the parties," *Twombly*, 550 U.S. at 556 n.4 (quotation marks omitted), courts require

a plaintiff seeking to plead a Section 1 violation to meet both requirements—parallel conduct and plus factors—in order to nudge their complaint across "the line between possibility and plausibility of entitlement to relief." *Id.* at 557 (internal quotation marks and citation omitted) (alteration adopted).

But to be clear, *Twombly*'s requirement to plead something "more" than parallel conduct does not impose a probability standard at the motion-to-dismiss stage. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). This Court has previously disallowed conflation of probability and plausibility. For example, in *Anderson News I*, this Court reversed a district court's order granting a motion to dismiss where plaintiff, a magazine wholesaler, alleged that defendants, publishers and their distributors, plausibly engaged in parallel conduct by withdrawing their business from the plaintiff following the plaintiff's announcement of a new surcharge on magazine shipments. *Anderson News, L.L.C. v. American Media, Inc.*, 680 F.3d 162, 168–71 (2d Cir. 2012) ("*Anderson News I*"). The district court held that, "[t]he most plausible scenario, however, is that the Defendants each separately came to a similar conclusion—that they did not want to pay a 7–cent surcharge." *Anderson News, L.L.C. v. American Media, Inc.*, 732 F. Supp. 2d 389, 407 (S.D.N.Y. 2010), *vacated and remanded*, 680 F.3d 162 (2d Cir. 2012). This Court concluded that "on a Rule 12(b)(6) motion it is not the province of the court to dismiss the complaint on the basis of the court's choice among plausible alternatives. Assuming that [plaintiff] can adduce sufficient evidence to support its factual allegations, the choice between or among plausible interpretations of the evidence will be a task for the factfinder." *Anderson News I*, 680 F.3d at 190. At the motion to dismiss stage, our precedent makes clear that a plaintiff must simply allege

enough facts to support the *inference* that a conspiracy actually existed. *See Citigroup*, 709 F.3d at 136.

## DISCUSSION

As a threshold matter, Defendants argue that the Supreme Court's decisions in *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011), and *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977), bar Plaintiffs from asserting claims under the Sherman Act and seeking damages, on the grounds that Plaintiffs are indirect purchasers of Defendants' drugs and therefore lack antitrust standing. Before delving into why Plaintiffs pled sufficient allegations to survive a Rule 12(b)(6) motion to dismiss a Sherman Act Section 1 claim,[3] we explain why Defendants are incorrect in arguing that the safety-net providers are barred from challenging their alleged horizontal price-fixing.

### I. *Astra* and *Illinois Brick* Pose No Bar

The Supreme Court's decisions in *Astra* and *Illinois Brick Co.* do not bar Plaintiffs from bringing this action alleging antitrust violations.

#### A. *Astra* Does Not Bar Sherman Act Claims

In *Astra*, a group of medical facilities brought an action against a group of pharmaceutical manufacturers for breach of contract alleging that they overcharged the medical facilities for certain drugs, in violation of the Pharmaceutical Pricing Agreement between the manufacturers and the federal government.[4] 563 U.S. at

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[3] For the purposes of this appeal, we chiefly consider Plaintiffs' proposed second amended complaint, which the district court denied the Plaintiffs leave to file after concluding that they had not cured the deficiencies of the first amended complaint. *See Mosaic Health Inc. v. Sanofi-Aventis U.S., LLC*, 714 F. Supp. 3d 209, 218 (W.D.N.Y. 2024).

[4] "Drug manufacturers opt into the 340B Program by signing a form Pharmaceutical Pricing Agreement (PPA) used nationwide." *Astra*,

113. The Supreme Court determined there is no private right of action for a covered entity, including safety-net providers, to sue manufacturers for violations of Section 340B. *Id.* Similarly, the Supreme Court held that overcharged covered entities also have no right to sue as third-party beneficiaries to enforce the Pharmaceutical Pricing Agreements that drug manufacturers sign with HHS. *Id.* This is because, notwithstanding their name, Pharmaceutical Pricing Agreements are not "bargained-for contracts" incorporating "negotiable terms." *Id.* at 113, 118. Rather, Pharmaceutical Pricing Agreements merely "serve as the means by which drug manufacturers opt into the statutory scheme." *Id.* at 118. The Supreme Court reasoned that "[a] third-party suit to enforce an HHS-drug manufacturer agreement . . . is in essence a suit to enforce the statute itself." *Id.* at 118. Thus, "[t]he absence of a private right to enforce the statutory ceiling-price obligations would be rendered meaningless if 340B entities could overcome that obstacle by suing to enforce the contract's ceiling-price obligations instead." *Id.*

Disallowing the action at issue in *Astra*, the Supreme Court recognized that "a multitude of dispersed and uncoordinated lawsuits" to enforce Pharmaceutical Pricing Agreements, "[w]ith HHS unable to hold the control rein," would ultimately "undermine the agency's efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Id.* at 120.

Defendants make two incorrect *Astra*-related arguments that they claim preclude suit. First, they incorrectly claim that the limits on Plaintiffs to bring

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563 U.S. at 113. Pharmaceutical Pricing Agreements "are uniform agreements that recite the responsibilities § 340B imposes, respectively, on drug manufacturers and the Secretary of HHS." *Id.*

Section 340B contract claims as indirect purchasers means Plaintiffs cannot bring Sherman Act claims. *Astra* says no such thing. Plaintiffs do not seek to enforce the Section 340B Drug Discount mandates nor the Pharmaceutical Pricing Agreements to compel the drug manufacturers to offer the discounted drugs at a specific Section 340B ceiling price. Plaintiffs make clear that the second amended complaint is "agnostic as to [the] question" of whether Defendants violated Section 340B. J. App'x 900. The instant case does not turn on the meaning of the Section 340B statute nor on a determination from this Court as to whether Defendants violated Section 340B. Plaintiffs here would seek to enjoin the Defendants' alleged price-fixing independent of the district court finding that Defendants violated Section 340B.

Second, Defendants claim Plaintiffs' grievances over the limitations or denials of Section 340B pricing are entirely governed by the federal Section 340B program, and their remedy for resolving disputes is within the administrative scheme that Congress established and which the Supreme Court held is exclusive in *Astra*. *See* Appellees' Br. 5. Unlike the overcharge claims at issue in *Astra*, Congress did not intend for the Health Resources and Services Administration ("HRSA"), a unit of HHS, to adjudicate and enforce antitrust price-fixing claims. In *Astra*, the Supreme Court established that Congress "opted to strengthen and formalize HRSA's enforcement authority, to make the new adjudicative framework the proper remedy for covered entities complaining of 'overcharges and other violations of the discounted pricing requirements,'. . . and to render the agency's resolution of covered entities' complaints binding." 563 U.S. at 121-22 (internal citations omitted). This principle makes sense when safety-net providers themselves are not a party to

the Pharmaceutical Pricing Agreements that would be at issue in such an action.

Furthermore, the Supreme Court in *Astra* reasoned that where the Section 340B Drug Discount program is superintended by HRSA, "Congress directed HRSA to create a formal dispute resolution procedure, institute refund and civil penalty systems, and perform audits of manufacturers" to help ensure that "covered entities pay at or below the ceiling price." *Id.* at 121 (internal quotation marks omitted) (alteration adopted); *see also* 124 Stat. 823-827, 42 U.S.C. § 256b(d). At bottom, *Astra* makes plain that Congress vested authority in HHS to oversee compliance with the Section 340B Drug Discount Program and enforce the ceiling price contracts, not to police antitrust violations.

### B. *Illinois Brick* Does Not Preclude this Action

Antitrust standing, at least at the pleading stage, is quite broad. *See Gelboim*, 823 F.3d at 777 (stating that the unrestrictive language of the private action provision of the Clayton Act demonstrates the congressional purpose in enacting this remedial provision and cautioning courts not to cabin its broad remedial objective). All plaintiffs must show is that they suffered an antitrust injury and are efficient enforcers of antitrust laws. *Id.* at 772. Moreover, plaintiffs can bring an antitrust claim alleging a Sherman Act conspiracy even when the underlying act would be lawful if undertaken alone, outside of a conspiracy. For example, in *Apple*, Apple entered into separate contracts with five major book publishers to adopt an agency pricing model for ebooks. 791 F.3d at 296. Plaintiffs alleged that Apple consciously organized a conspiracy among the publisher defendants to raise consumer-facing ebook prices. *Id.* at 314. In response, Apple argued that the

contracts at issue were vertical, lawful agreements that were in Apple's independent economic interest. *Id.* This Court, rejecting Apple's argument, held that "Apple's benign portrayal of its [c]ontracts with the [p]ublisher [d]efendants [was] not persuasive—not because those [c]ontracts themselves were independently unlawful, but because, in context, they provide[d] strong evidence that Apple consciously orchestrated a conspiracy among the [p]ublisher [d]efendants." *Id.* at 316. Similarly, in *Gelboim*, plaintiffs, who were purchasers of financial instruments, accused defendants, the banks issuing the financial instruments, of colluding to depress the London Interbank Offered Rate ("LIBOR") by violating the rate-setting rules. 823 F.3d at 764. This Court held that the plaintiffs plausibly alleged that the defendants were conspiring to artificially depress the LIBOR rate in violation of the Sherman Act. *Id.* at 765. At bottom, *Apple* and *Gelboim* make plain that while individual agreements may be lawful on their own, the defendants' role in organizing a conspiracy to restrict trade triggers Section 1 liability.

*Illinois Brick* does not preclude Plaintiffs from pursuing the federal damages they seek for antitrust violations or injunctive relief. 431 U.S. 720. In *Illinois Brick*, the Supreme Court held that indirect purchasers alleging overcharge claims do not have standing to sue for antitrust violations under the Clayton Act. *Id.* at 746. The Supreme Court barred indirect purchaser claims out of concern for duplicative recoveries and the complexities of tracing overcharges through multiple levels of distribution. *Id.* at 730-35. Here, Plaintiffs have expressly disclaimed damages for overcharges in relation to their

claims that are governed by *Illinois Brick*.[5] Where *Illinois Brick* might apply, Plaintiffs seek damages not for losses incurred due to increasing prices, but instead, for losses incurred as a result of "lost access[.]" Reply Br. at 36-37. Because such damages do not implicate the concerns at the heart of *Illinois Brick*, nor do they concern multiple levels of distribution, the Court holds that Plaintiffs are not precluded from seeking damages in this limited form. *See Blue Shield of Va. v. McCready*, 457 U.S. 465, 475 (1982) (holding *Illinois Brick* does not apply where there is "not the slightest possibility of a duplicative exaction"); *see also In re Brand Name Prescription Drugs Antitrust Litig.*, 123 F.3d 599, 606 (7th Cir. 1997) (noting in dicta that *Illinois Brick* would "fall away" where no overcharge damages were sought). Furthermore, Plaintiffs seek injunctive relief to enjoin the alleged horizontal price-fixing conspiracy under Section 16 of the Clayton Act, 15 U.S.C. § 26. Because standing under Section 16 raises no threat of multiple lawsuits or duplicative recoveries, "some of the factors other than antitrust injury that are appropriate to a determination of standing under § 4 are not relevant under § 16." *McCarthy v. Recordex Serv., Inc.*, 80 F.3d 842, 856 (3d Cir. 1996) (quoting *Cargill, Inc. v. Monfort of Colo., Inc.*, 479 U.S. 104, 111 n.6 (1986)) (internal quotation marks omitted). Therefore, *Illinois Brick* does not apply here.

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[5] In the second amended complaint, Plaintiffs specifically limit their request for damages for the federal antitrust claim to the lost profits described herein and injunctive relief. *See* J. App'x at 871. Plaintiffs do, however, seek damages related to overcharges in connection with the subset of their state law claims that are not governed by the limitations in *Illinois Brick*. *See* J. App'x at 873; *see also* Reply Br. at 37 n.9.

## II. Plaintiffs' Proposed Second Amended Complaint Sufficiently Pleads a Conspiracy

Plaintiffs plead sufficient facts in their proposed second amended complaint to support their allegations of parallel conduct and plus factors.

### A. Plaintiffs Sufficiently Plead Parallel Conduct

Defendants would have us define parallel conduct as conduct with precise similarities, urging us to focus on the differences among the Defendants' conduct.[6] But, the Supreme Court and our binding authority that followed rejects setting a high bar for what constitutes parallel conduct. Rather, conduct is deemed "parallel" when there are general similarities in substance, timing, or effect. In *Twombly*, the Supreme Court agreed that plaintiffs had sufficiently alleged parallel conduct where over seven years the defendant telephone carriers deployed various strategies with the collective effect of inflating charges for local telephone and high-speed internet services. 550 U.S. at 550-53 (ranging from making unfair agreements with competitive local exchange carriers, providing inferior connections to networks, overcharging, and billing in ways to sabotage plaintiffs' customer relations); *see also American Tobacco Co. v. United States,* 328 U.S. 781, 800-01 (1946) (detailing a price-fixing conspiracy in which the defendants used a different methods to achieve the same

[6] When asked at oral argument why Defendants could not have colluded together to cleverly stagger to avoid detection, Defendants responded "so they could have done that but not at the same time that they stupidly clustered AstraZeneca's announcement only one business day away from Sanofi's announcement. That's what doesn't make sense if they are being clever." *See generally* Or. Arg. 19:00–19:42. The law does not require the collusion to be cleverly disguised to constitute parallel conduct.

ultimate objective, an understood and settled price for tobacco). In adequately pleading parallel conduct, the *Twombly* plaintiffs alleged only high-level similarities among the defendants' conduct, including that defendants had "entered into a contract, combination or conspiracy to prevent competitive entry in their respective local telephone and/or high speed internet services markets and ha[d] agreed not to compete with one another and otherwise allocated customers and markets to one another." *Twombly*, 550 U.S. at 551 (internal quotation marks and citation omitted).

Precedent in this Circuit post-*Twombly* has similarly accepted a broad understanding of what constitutes parallel conduct. *See, e.g., Starr v. Sony BMG Music Ent.*, 592 F.3d 314, 325 (2d Cir. 2010) (rejecting the argument that antitrust plaintiffs are "required to mention a specific time, place or person involved in each conspiracy allegation"). Of course, this Court has found parallel conduct where defendants allegedly acted at almost the exact same time in imposing near identical contractual terms or engaging in the same market action. *See, e.g.*, *id.* at 323 (describing alleged parallel conduct where two groups of defendants launched two joint ventures for providing music over the internet; used similar most-favored nation agreements in their licenses with the joint ventures to enforce a wholesale price floor at 70 cents per song raised uniformly on or about May 2005; and refused to do business with the second biggest internet music retailer); *Citigroup,* 709 F.3d at 138 (describing alleged parallel conduct where the largest financial institutions simultaneously ceased buying action-rate securities on the same day). But this Court has also found parallel conduct where plaintiffs alleged that defendants acted with a similar anticompetitive effect but through varied means. *See e.g., Anderson News I,* 680 F.3d at 191 (describing as

the "key parallel conduct allegation" that all publisher and distributor defendants ceased doing business with the plaintiff despite different reactions from the defendants to the plaintiff's announcement of a surcharge).

Our Sister Circuits have similarly held that parallel conduct among defendants should be viewed with a broad lens. *See e.g.*, *SD3, LLC v. Black & Decker (U.S.) Inc.*, 801 F.3d 412, 428–29 (4th Cir. 2015), *as amended on reh'g in part* (Oct. 29, 2015) (explaining that existing authority does not require finding parallel conduct only when defendants move in relative lockstep that achieves common anticompetitive ends by substantially identical means); *Evergreen Partnering Grp., Inc. v. Pactiv Corp.*, 720 F.3d 33, 46 n.3 (1st Cir. 2013) (noting that the examples of parallel conduct outlined in *Twombly* are "very broad" and that allegations supportive of agreement at the pleadings stage may include "conduct that indicates the sort of restricted freedom of action and sense of obligation that one generally associates with agreement" (internal quotation marks omitted)); *In re Baby Food Antitrust Litig.*, 166 F.3d 112, 132 (3d Cir. 1999) (acknowledging that "parallel pricing does not require uniform prices" but can include "prices within an agreed upon range" (internal quotation marks omitted)).

From the precedents in our own Circuit, and drawing upon the reasoning of others, it is plain that antitrust plaintiffs need not plead the exact same conduct within a tight timeline to state a claim under Section 1 of the Sherman Act. Rather, plaintiffs must state facts consistent with defendants' having engaged in conduct that contributes to an inference of concerted action.

The proposed second amended complaint plausibly alleges that Defendants acted similarly enough in substance by restricting Section 340B Drug Discount

pricing and raising prices in the market of certain popular diabetes medication over the course of months. By implementing similar policies of primarily refusing to permit the sale of Section 340B Drugs to covered entities, Defendants eliminated the majority of their Contract Pharmacy Section 340B Drug Discount sales, earned higher profits, and avoided competition from their direct competitors over the availability of Section 340B Drug Discounts on rapid-acting insulins, long-acting insulins, and incretin mimetics at contract pharmacies.

These announced policy changes were also similar in timing, where over four months, these policies prevented covered entities from turning to other competitors, in this case, the other Defendants. Notably, three of the four Defendants announced these changes within one month of each other—a timeframe similar to the one-month period that we deemed sufficiently parallel in *Starr*, 592 F.3d at 320. Defendants' reliance on their subsequent modifications to their new policies does not meaningfully alter our analysis. Specifically, the proposed second amended complaint asserts that following the initially announced changes: (1) in February 2021, Sanofi relayed an alteration to its claims-data policy, "limit[ing] its restrictions to . . . consolidated health center programs, disproportionate share hospitals, critical access hospitals, rural referral centers, and sole community hospitals," J. App'x 817; (2) in December 2021, Eli Lilly announced a policy similar to Sanofi's of allowing continued Section 340B Drug Discounts only if covered safety-net providers agreed to provide Eli Lilly claims data associated with orders to community pharmacies, *id.*; and (3) in January 2022, Novo Nordisk announced that it would permit safety-net providers to designate two, rather than one, community pharmacy to which Section 340B Drug Discount products might ship, *id.* The timing of these

restrictions remains similar enough to support an inference of parallel conduct.

The Defendants' policies also have a similar anti-competitive effect of limiting or eliminating the availability of Section 340B Drug Discounts. Plaintiffs allege that these restrictions by Defendants led to "the end of the overwhelming majority of Contract Pharmacy 340B Drug Discount sales to covered entities." *Id.* at 827. The district court erred when it determined that the Plaintiffs have not plausibly alleged that the "Defendants' disparate conduct ultimately achieved the same or a substantially similar end result." *See Mosaic Health Inc. v. Sanofi-Aventis U.S., LLC*, 714 F. Supp. 3d 209, 220 (W.D.N.Y. 2024). Aggregated data in the second amended complaint shows that these decimated Section 340B Drug Discounts happened in parallel, which significantly decreased the volume of Section 340B Drug Discount sales to contract pharmacies. Novo Nordisk's volume of drugs sold at Section 340B Drug Discount prices dropped by 70% the month of the new policy, while the other Defendants' volumes dropped between 60–90% in similar periods. *See id. at* 217.

The exceptions each Defendant included in their announced policies were the biggest differences among the actions, but these differences are still consistent with parallel conduct. Sanofi offered an exception to providers willing to send valuable prescription-claims data to a Sanofi vendor. AstraZeneca permitted shipping to one community pharmacy but only for safety-net providers without an on-site dispensing pharmacy. Eli Lilly offered an exception to permit pharmacies to pass along certain insulin products at no cost, and Novo Nordisk created an exception for non-hospital entities. These exceptions do not make each Defendant's actions more disparate than

the conduct found to be parallel in *Twombly*. Nor did the exceptions change the overall effect of restricting Section 340B Drugs.

The district court found that there was an "obvious alternate explanation for the facts underlying the alleged conspiracy: the failure of the Defendants' joint lobbying efforts." *Id.* at 222. But Defendants' alternate explanation is hardly "obvious." Even if it made "perfectly rational business sense for Defendants . . . to have independently reacted to the failure of [their] lobbying efforts" to limit their participation in the 340B Drug Discount Program, *Mosaic Health*, 714 F. Supp. 3d at 222–23, that inference does not clearly negate the existence of a *conspiracy* for Defendants to do so. *Cf. N.J. Carpenters Health Fund v. Royal Bank of Scotland Grp.*, 709 F.3d 109, 121 n.5 (2d Cir. 2013) ("[E]ven crediting the Defendants-Appellants' explanations, the [plaintiff's] inference of liability remains reasonable."). And as already explained, those same joint efforts actually support Plaintiffs' inferences by demonstrating a common means and motive for Defendants to conspire. Moreover, because Defendants' alternate explanation is not "obvious," the district court erred in requiring that Plaintiffs "disprove all nonconspiratorial explanations for the defendants' conduct." *In re Publ'n Paper Antitrust Litig.*, 690 F.3d 51, 63 (2d Cir. 2012) (quoting Phillip E. Areeda & Herbert Hovenkamp, *Fundamentals of Antitrust Law* § 14.03(b), at 14-25 (4th ed. 2011)). Indeed, "[a] court ruling on [a Rule 12(b)(6)] motion may not properly dismiss a complaint that states a plausible version of the events merely because the court finds a different version more plausible." *Anderson News I*, 680 F.3d at 185.

Therefore, Plaintiffs sufficiently alleged parallel conduct that contributes to an inference of a horizontal price-fixing conspiracy.

### B. Plaintiffs Sufficiently Plead the Plus Factors

We also require antitrust plaintiffs when relying on circumstantial evidence to supply allegations of "further circumstance pointing toward a meeting of the minds," sometimes called "plus factors." *Twombly*, 550 U.S. at 553, 557; *see also Anderson News II*, 899 F.3d at 104 (explaining that district courts must examine "defendants' conduct and communications . . . in context and with the 'overall picture' in mind"). "[P]lus factors may include: [1] a common motive to conspire, [2] evidence that shows that the parallel acts were against the apparent individual economic self-interest of the alleged conspirators, and [3] evidence of a high level of interfirm communications." *Citigroup*, 709 F.3d at 136 (internal quotation marks omitted). As previously noted, we require plaintiffs at this stage to allege *a* plausible theory based on circumstantial evidence, not *the only* or even *the most* plausible one. *See Anderson News I*, 680 F.3d at 184.

Plaintiffs have alleged sufficient facts suggesting that Defendants had a common motive to conspire to neutralize or mitigate market-share and regulatory threats just before the restrictions were imposed. As direct competitors, these four Defendants control the diabetes drug marketplace, which would make concerted action amongst competing diabetes drug-markers imposing restrictions easy to coordinate and maintain. By jointly adopting a policy that largely denied covered entities the ability to purchase Section 340B Drugs for delivery to contract pharmacies, Defendants effectively eliminated the vast majority of their Section 340B Drug Discount

sales through those pharmacies—thereby increasing their profits and reducing competition over discounted pricing for key diabetes drugs.

Plaintiffs have also sufficiently alleged that restricting Section 340B Drug Discounts would have been against any individual Defendant's own economic self-interest. Plaintiffs alleged that restricting discounts alone would lead to decreased market share and regulatory sanctions that would risk loss of federal healthcare program coverage. Additionally, Plaintiffs allege that if a Defendant alone restricted discounts, its market share and sales volumes for rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics would be threatened. As the second amended complaint suggests, covered entities service both Section 340B Drug Discount eligible patients and those who would not participate in the program, so Defendants would not be losing the market share for those latter patients unless they all acted together.

Plaintiffs' allegation that by acting collectively, Defendants limited their exposure only to civil monetary penalties, is plausible because, if one had acted alone, that Defendant would have been exposed to the greater risk of exclusion from Medicare and Medicaid. Given the need for patients to have these drugs on the market, Defendants at the very least avoid being cut off from the market altogether by allegedly acting in concert. The district court did not credit Plaintiffs' allegation that there was "safety in numbers" in adopting the challenged policies that would risk market share by exposing Defendants to severe regulatory sanctions. *Mosaic Health*, 714 F. Supp. 3d at 224. Indeed, (i) the potential loss of market share if safety-net providers responded to discounts by changing their preferences to move their patients (Section 340B or

otherwise) to competing manufacturers' firms drugs with discounts, and (ii) the potential devastating sanction of exclusion of the manufacturers' drugs from Medicare and Medicaid coverage serve as conceivable plus factors that weigh in favor of plausibility.

This inference of conspiracy is further supported by the alleged "high level of interfirm communications" among Defendants on the issue of Section 340B Drug Discounts. *See Apple*, 791 F.3d at 315 (internal quotation marks omitted). Plaintiffs assert that it is likely that Defendants communicated with each other both indirectly and directly through use of the same lobbying firms and lobbyists in advance of their restrictions on Section 340B Drug Discounts, making coordination even more probable. Moreover, they further assert that the same lobbying firms worked on the Section 340B issue at the same time for PhRMA, an industry association of which each Defendant is a member and on the board of directors. According to Plaintiffs, the "Defendants, as PhRMA board members, communicated among themselves, and their most prominent advocacy issue was 340B Drug Discounts, including Contract Pharmacy 340B Drug Discounts." J. App'x 862. The district court failed to credit the inference that the Defendants' sharing of lobbying services and joint participation on the PhRMA board suggests that the Defendants had ample opportunity to conspire based on months of communications about Section 340B Drug Discount restrictions with the common aim of collusion. *See Mosaic Health*, 714 F. Supp. 3d at 224.

In sum, Plaintiffs have sufficiently alleged parallel conduct and plus factors that support the plausibility of a Section 1 conspiracy.

### III. District Court Must Re-examine the State-Law Claims

The district court dismissed the state law antitrust and unjust enrichment claims for the same reason as it did Plaintiffs' Sherman Act claims. *Id.* at 225 ("[T]he proposed state law antitrust claims and the proposed state law unjust enrichment claims are premised on the allegation that Defendants have unlawfully conspired to overcharge Plaintiffs for their products . . . . As such, their proposed amendments to their state law claims are futile."). In light of our conclusion that Plaintiffs have plausibly alleged that Defendants engaged in a horizontal price-fixing conspiracy, amendment would not be futile. *See Panther Partners Inc. v. Ikanos Commc'ns, Inc.*, 681 F.3d 114, 119 (2d Cir. 2012) ("Futility is a determination, as a matter of law, that proposed amendments would fail to cure prior deficiencies or to state a claim under Rule 12(b)(6) . . . ."). Upon remand, the district court is directed to reexamine its ruling on Plaintiffs' allegations regarding state-law claims in a manner consistent with this opinion.

## CONCLUSION

This Court concludes that the proposed second amended complaint pleads sufficient facts to support a plausible inference of a horizontal price-fixing conspiracy through circumstantial allegations, where both (1) the conduct that Plaintiffs allege was sufficiently parallel, as the Defendants' announced policies were similar enough in substance, timing, and effect; and (2) Plaintiffs alleged sufficient circumstantial plus factors, including a common motive to conspire, parallel conduct contrary to the Defendants' individual economic self-interest, and a high level of interfirm communications.

We therefore **VACATE** the district court's judgment dismissing Plaintiffs' suit and denying leave to amend and

**REMAND** for the district court to grant Plaintiffs leave to file their second amended complaint.

**APPENDIX B**

[FILED: FEBRUARY 1, 2024]

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

| | |
|---|---|
| MOSAIC HEALTH, INC., and CENTRAL VIRGINIA HEALTH SERVICES, INC., *individually and on behalf of all those similarly situated*,<br>*Plaintiffs*,<br>v.<br>SANOFI-AVENTIS U.S., LLC, ELI LILLY AND COMPANY, LILLY USA, LLC, NOVO NORDISK INC., and ASTRAZENECA PHARMACEUTICALS LP,<br>*Defendants*. | **DECISION AND ORDER**<br>6:21-CV-06507-EAW |

## INTRODUCTION

Plaintiffs Mosaic Health, Inc. ("Mosaic Health") and Central Virginia Health Services, Inc. ("CVHS") (collectively "Plaintiffs") allege that defendant pharmaceutical companies Sanofi-Aventis U.S. ("Sanofi"), Eli Lilly and Company and Lilly USA, LLC ("Eli Lilly"), Novo Nordisk Inc. ("Novo Nordisk"), and AstraZeneca Pharmaceuticals LP ("AstraZeneca") (collectively "Defendants") have violated state and federal antitrust laws by coordinating to rescind a long-standing discount

for "safety-net" hospitals and clinics that treat patients who would otherwise be unable to obtain care. (Dkt. 41). The Court previously granted Defendants' motion to dismiss for failure to state a claim, concluding that Plaintiffs had not plausibly alleged parallel conduct. (Dkt. 71). Plaintiffs have now moved for leave to file a second amended complaint. (Dkt. 72). For the reasons that follow, the Court denies Plaintiffs' motion.

## BACKGROUND

### I. Factual Background

The factual background of this case is set forth in detail in the Court's Decision and Order dated September 2, 2022 (Dkt. 71), familiarity with which is assumed for purposes of the instant Decision and Order. The Court summarizes the most salient facts and the new allegations set forth in the proposed second amended complaint below. As required at this stage of the litigation, the Court treats Plaintiffs' factual allegations as true.

In 1992, Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, created the "340B Drug Discount Program," which "require[s] discounts on outpatient drugs purchased by healthcare providers serving underserved populations." (Dkt. 41 at ¶ 21). "The net savings and revenue generated through access to 340B Drug Discounts [are] sometimes referred to as 340B Savings" and "340B Savings are often a critical component of covered entities' ability to provide healthcare services to patients." (*Id.* at ¶¶ 23-24). Mosaic Health, for example, uses 340B savings to "help fund sliding fee discounted medications for patients in need." (*Id.* at ¶ 25). "Since at least 1996, and in greater volumes since 2010, all drug companies participating in the 340B Drug Discount Program have offered Contract Pharmacy 340B Drug Discounts to covered entities. To do so, drug companies

have offered covered entities the 340B Drug Discount on covered outpatient drugs purchased on the covered entities' own accounts but shipped to their registered Contract Pharmacy sites." (*Id.* at ¶ 55).

A typical arrangement involving a contract pharmacy would work as follows: (1) a covered entity's patient arrives at a contract pharmacy for a covered outpatient drug; (2) the contract pharmacy, "sometimes itself and sometimes working with a 340B vendor . . . reviews the pharmacy prescription to identify the patient's prescription as 340B eligible and to match it to a particular covered entity"; (3) the contract pharmacy fills the prescription with inventory from the purchasing account of the covered entity; (4) the contract pharmacy charges the patient for any required co-pay or fee, "adjusted downward as appropriate by any sliding-fee scale arrangement between the pharmacy and the covered entity"; (5) the contract pharmacy collects reimbursements from any third-parties such as private insurers or Medicare Part D; and (6) the contract pharmacy remits any amounts collected to the covered entity and the covered entity pays the contract pharmacy a dispensing fee. (*Id.* at ¶ 56).

"[D]iabetes medications make up a significant portion of 340B covered entities' outpatient prescriptions and 340B Drug Discounts. And three of the most significant diabetes medications are rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics." (*Id.* at ¶ 74). Defendants "dominate three of today's most lucrative markets for diabetes treatments: (i) rapid-acting analog insulins; (ii) long-acting analog insulins; and (iii) incretin mimetics. Defendants compete against each other, as horizontal competitors, in these markets." (*Id.* at ¶ 68). Sanofi, Eli Lilly, and Novo Nordisk compete in the

sale of rapid-acting analog insulins and long-acting analog insulins. (*Id.* at ¶¶ 75-84). Sanofi, Eli Lilly, Novo Nordisk, and AstraZeneca compete in the sale of incretin mimetics. (*Id.* at ¶¶ 85-90). These products collectively represent "hundreds of millions or billions of dollars in annual sales for each company." (*Id.* at ¶ 91).

In 2020, Defendants spent millions of dollars "collectively lobbying the federal government . . . to limit 340B Drug Discounts with respect to diabetes medicines." (*Id.* at ¶ 100). However, those efforts were largely unsuccessful. (*Id.* at ¶¶ 100-116). On July 24, 2020, then-President Donald Trump issued Executive Order 13937, which "addressed the use of insulin (as well as epinephrine) within the 340B Drug Discount Program," but was "extremely limited in scope." (*Id.* at ¶¶ 102-103). "Executive Order 13937 promised to have relatively little impact on the volume of 340B Drug Discounts for insulin medications[.]" (*Id.* at ¶ 104).

On July 24, 2020, AstraZeneca advised the United States Department of Health and Human Services ("HHS") that it intended to limit contract pharmacy 340B drug discounts. (*Id.* at ¶ 118). More particularly, AstraZeneca stated that beginning October 1, 2020, and for certain of its products, it would "recognize one contract pharmacy per covered entity for those covered entities that do not maintain an on-site dispensing pharmacy." (*Id.*).

On or about July 27, 2020, Sanofi informed all 340B Drug Discount Program covered entities that it would be implementing a new initiative that would "cut off all Contract Pharmacy 340B Drug Discounts, which had been in place for a decade, unless covered entities provided new consideration to Sanofi." (*Id.* at ¶ 120). "The newly required consideration was entry into a contract to

provide sensitive prescription claims data to a Sanofi vendor through a software portal on commercially unreasonable terms." (*Id.*). Sanofi announced that its new policy would take effect on October 1, 2020. (*Id.*). The proposed second amended complaint explains that the Sanofi vendor was Second Sight Solutions and that the software portal is called 340B ESP. (Dkt. 72-2 at ¶ 136).

On August 19, 2020, Eli Lilly advised HHS that effective September 1, 2020, it would discontinue voluntarily honoring requests for 340B contract pharmacies except "primarily" where a covered entity did not have an in-house pharmacy. (Dkt. 41 at ¶ 120). Eli Lilly also "added a special exception to permit Contract Pharmacies to pass along certain insulin products at cost," but "that exception was infeasible for covered entities and pharmacies, as it required the Contract Pharmacies to fill prescriptions without any fee whatsoever." (*Id.* at ¶ 122).

On December 1, 2020, Novo Nordisk advised HHS that "it would stop offering Contract Pharmacy 340B Drug Discounts to all hospital covered entities" effective January 1, 2021. (*Id.* at ¶ 124).

The proposed second amended complaint provides additional information regarding the impact of Defendants' changes in their policies regarding contract pharmacy 340B drug discounts, as well as describing subsequent policy changes made by Defendants. By letter dated February 2, 2021, Sanofi indicated that it was limiting its restrictions to "five covered entity types, effective March 1, 2021: consolidated health center programs, disproportionate share hospitals, critical access hospitals, rural referral centers, and sole community hospitals." (Dkt. 72-2 at ¶ 141). On December 16, 2021, Eli Lilly announced "that it was adopting Sanofi's approach of 'utilizing the 340B ESP Second Sight Solutions platform'

to 'permit 340B purchases' by covered entities for drugs shipped to Contract Pharmacies with Contract Pharmacy 340B Drug Discounts if 'the covered entity agrees to provide, and does provide on an ongoing basis, claims-level data associated with such contract pharmacy orders' through the 340B ESP platform." (*Id.* at ¶ 142). On January 24, 2022, Novo Nordisk "announced that it would modify its policy regarding bill-to/ship-to distribution of 340B product to a contract pharmacy such that if a hospital covered entity does not have wholly owned contract pharmacies, that covered entity will be permitted to designate a total of two contract pharmacy locations—one retail pharmacy, and one specialty pharmacy (as determined by Novo Nordisk)—to which product purchased by the covered entity may be shipped." (*Id.* (internal quotation marks omitted)).

Sanofi's new policy caused "an immediate decrease in Contract Pharmacy 340B Drug Discount sales of more than 86% by units and by more than 90% by savings"; Eli Lilly's new policy led to the loss of 89% of sales by unit and almost 95% of prior savings; Novo Nordisk's new policy led to a decline of nearly 70% in savings and a decline of 64% in sales by units; and AstraZeneca's new policy led to a decline of over 85% in savings and a decline of over 90% in sales by units. (*Id.* at ¶¶ 182, 199, 218, 230). In other words, "the immediate impact of Defendants' restrictions was a decline of 60%-90% of [340B] sales by units or 70-95% as measured by lost 340B Savings." (*Id.* at ¶ 275).

## II. Procedural Background

Mosaic Health commenced this putative class action on July 30, 2021. (Dkt. 1). The first amended complaint, which added CVHS as a plaintiff, was filed on October 22, 2021. (Dkt. 41). Defendants filed their joint motion to dismiss the first amended complaint on November 12,

2021. (Dkt. 47; Dkt. 48). On September 2, 2022, the Court granted Defendants' motion, but conditionally granted Plaintiffs leave to amend, contingent on Plaintiffs filing a procedurally proper motion for leave to amend including a viable proposed second amended complaint. (Dkt. 71). Plaintiffs filed the instant motion for leave to amend on October 3, 2022. (Dkt. 72). Defendants filed their response on October 27, 2022 (Dkt. 74), and Plaintiffs filed their reply on November 3, 2022 (Dkt. 75). On February 2, 2023, Defendants filed a notice of supplemental authority. (Dkt. 76). The Court heard oral argument on July 20, 2023, and reserved decision. (Dkt. 78).

## DISCUSSION

### I. Legal Standard

Federal Rule of Civil Procedure 15 provides that the Court "should freely give leave [to amend] when justice so requires." Nevertheless, "it is within the sound discretion of the district court to grant or deny leave to amend." *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 200 (2d Cir. 2007). "A district court has discretion to deny leave for good reason, including futility, bad faith, undue delay, or undue prejudice to the opposing party." *Id.* "[A] request to replead should be denied in the event that amendment would be futile." *Absolute Activist Value Master Fund Ltd. v. Ficeto*, 677 F.3d 60, 71 (2d Cir. 2012). "An amendment to a pleading is futile if the proposed claim could not withstand a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6)." *Lucente v. Int'l Bus. Machines Corp.*, 310 F.3d 243, 258 (2d Cir. 2002) (citation omitted).

"In considering a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6), a district court may consider the facts alleged in the complaint, documents attached to the complaint as exhibits, and documents incorporated by reference in the complaint." *DiFolco v.*

*MSNBC Cable L.L.C.*, 622 F.3d 104, 111 (2d Cir. 2010). A court should consider the motion by "accepting all factual allegations as true and drawing all reasonable inferences in favor of the plaintiff." *Trs. of Upstate N.Y. Eng'rs Pension Fund v. Ivy Asset Mgmt.*, 843 F.3d 561, 566 (2d Cir. 2016). To withstand dismissal, a claimant must set forth "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Turkmen v. Ashcroft*, 589 F.3d 542, 546 (2d Cir. 2009) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).

"While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (internal quotations and citations omitted). "To state a plausible claim, the complaint's '[f]actual allegations must be enough to raise a right to relief above the speculative level.'" *Nielsen v. AECOM Tech. Corp.*, 762 F.3d 214, 218 (2d Cir. 2014) (quoting *Twombly*, 550 U.S. at 555).

## II. Plaintiffs' Proposed Second Amended Complaint

The proposed second amended complaint sets forth the following claims: (1) violations of § 1 of the Sherman Act, 15 U.S.C. § 1; (2) "unreasonable restraint of trade" in violation of the laws of Arizona, California, Connecticut, the District of Columbia, Illinois, Florida, Iowa, Kansas, Maine, Maryland, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode

Island, South Dakota, Tennessee, Utah, West Virginia, and Wisconsin; and (3) unjust enrichment under the laws of Arizona, Hawaii, Illinois, Iowa, Maine, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, New York, Oregon, Rhode Island, South Dakota, Utah, Vermont, Virginia, West Virginia, and Wisconsin. (Dkt. 72-2 at ¶¶ 370-480). Plaintiffs seek both damages and injunctive relief with respect to their Sherman Act claim. (*Id*. at ¶¶ 377-80).

Defendants oppose Plaintiffs' motion for leave to amend on the basis of futility, arguing that: (1) Plaintiffs have not remedied the defects the Court identified in their parallel conduct allegations; (2) the proposed second amended complaint does not allege the "plus factors" required to support an inference of conspiracy; (3) Plaintiffs' federal damages claims are barred by *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977), because they are indirect purchasers of Defendants' drugs; (4) Plaintiffs' claims are an improper attempt to bring a private action to enforce the 340B statute, in contravention of *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011); (5) Plaintiffs' state law antitrust claims fail for the same reasons as their Sherman Act § 1 claim; and (6) Plaintiffs' state law unjust enrichment claims fall with the antitrust claims, are inadequately pleaded, and are futile for other, state-specific reasons. (Dkt. 74 at 11-31).[1] For the reasons that follow, the Court agrees that the proposed second amended complaint, like the first amended complaint, has not sufficiently alleged parallel conduct. The Court further finds that Plaintiffs have not pleaded facts from which a

[1] The Court notes that "the *Illinois Brick* doctrine is not jurisdictional," *Mayor & City Council of Baltimore v. AbbVie Inc.*, 42 F.4th 709, 710 (7th Cir. 2022), and that it accordingly is not constrained to reach this issue first.

factfinder could plausibly infer a conspiracy. Finally, the Court concludes that these defects also render the proposed amendments to Plaintiffs' state law claims futile.[2]

**A. Sherman Act § 1 Claim**

"Liability under § 1 of the Sherman Act, 15 U.S.C. § 1, requires a 'contract, combination . . ., or conspiracy, in restraint of trade or commerce.'" *Twombly*, 550 U.S. at 548 (quoting 15 U.S.C. § 1). "Because § 1 of the Sherman Act does not prohibit [all] unreasonable restraints of trade . . . but only restraints effected by a contract, combination, or conspiracy, [t]he crucial question is whether the challenged anticompetitive conduct stem[s] from independent decision or from an agreement, tacit or express." *Id.* at 553 (alterations in original) (quotations and citation omitted). "[S]tating such a claim requires a complaint with enough factual matter (taken as true) to suggest that an agreement was made." *Id.* at 556.

"The ultimate existence of an 'agreement' under antitrust law . . . is a legal conclusion, not a factual allegation." *Mayor and City Council of Balt., Md. v. Citigroup, Inc.*, 709 F.3d 129, 135-36 (2d Cir. 2013). "[A] plaintiff may . . . assert direct evidence that the defendants entered into an agreement in violation of the antitrust laws." *Id.* at 136. "[A] complaint may, alternatively, present circumstantial facts supporting the *inference* that a conspiracy existed." *Id.* (emphasis in original). "[A]

[2] The Court also has serious doubts about the viability of this matter in light of the Supreme Court's decision in *Astra USA*. Defendants have persuasively argued that this litigation is a backdoor attempt to use the antitrust laws to enforce Plaintiffs' preferred interpretation of the 340B statute. However, because the proposed second amended complaint fails to state an antitrust claim under well-established pleading standards, the Court need not reach this novel legal issue.

horizontal agreement . . . may be inferred on the basis of conscious parallelism, when such interdependent conduct is accompanied by circumstantial evidence and plus factors." *Id.* (quotation omitted). "These 'plus factors' may include: a common motive to conspire, evidence that shows that the parallel acts were against the apparent individual economic self-interest of the alleged conspirators, and evidence of a high level of interfirm communications." *Id.* (quotation and footnote omitted).

"Without more, parallel conduct does not suggest conspiracy, and a conclusory allegation of agreement at some unidentified point does not supply facts adequate to show illegality." *Twombly*, 550 U.S. at 556-57. In other words, allegations of parallel action "must be placed in a context that raises a suggestion of a preceding agreement, not merely parallel conduct that could just as well be independent action." *Id.* at 557. "[W]ithout that further circumstance pointing toward a meeting of the minds, an account of a defendant's commercial efforts stays in neutral territory." *Id.* As the Second Circuit has explained:

> Examples of parallel conduct allegations that might be sufficient under *Twombly*'s standard include "parallel behavior that would probably not result from chance, coincidence, independent responses to common stimuli, or mere interdependence unaided by an advance understanding among the parties," and "complex and historically unprecedented changes in pricing structure made at the very same time by multiple competitors, and made for no other discernible reason."

*Citigroup*, 709 F.3d at 137 (quoting *Twombly*, 550 U.S. at 556 n.4 (quotation omitted)).

### 1. Failure to Allege Parallel Conduct

"'Parallel conduct' refers to the same or substantially similar actions taken by actors on the same level." *North Am. Soccer League, LLC v. U.S. Soccer Fed., Inc.*, 296 F. Supp. 3d 442, 460 n.26 (E.D.N.Y. 2017), *aff'd*, 883 F.3d 32 (2d Cir. 2018); *see also In re Amazon.com, Inc. eBook Antitrust Litig.*, No. 21-CV-00351 GHW VF, 2022 WL 4581903, at *11 (S.D.N.Y. Aug. 3, 2022) ("Under *Twombly*, parallel conduct, such as competitors adopting similar policies around the same time in response to similar market conditions, may constitute circumstantial evidence of anticompetitive behavior." (citation omitted)), *adopted*, 2022 WL 4586209 (S.D.N.Y. Sept. 29, 2022).

"Plaintiffs are not required to plead parallel conduct that is simultaneous or identical." *In re Farm-Raised Salmon and Salmon Products Antitrust Litigation*, No. 19-21551-CIV, 2021 WL 1109128, at *13 n.23 (S.D. Fla. Mar. 23, 2021); *see also In re Domestic Airline Travel Antitrust Litig.*, 221 F. Supp. 3d 46, 69 (D.D.C. 2016) ("Plaintiffs do not need to demonstrate that Defendants cut or limited capacity in exactly the same way in order to adequately allege parallel conduct."). However, where the alleged conspirators engaged in divergent conduct at significantly different times, a plaintiff's "allegations fall far short of demonstrating parallel behavior[.]" *Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 228 (3d Cir. 2011); *see also LLM Bar Exam, LLC v. Barbri, Inc.*, 271 F. Supp. 3d 547, 579 (S.D.N.Y. 2017) (finding the plaintiff had not "established even . . . [the] basic building block" of parallel conduct where "[t]he First Amended Complaint [made] plain that [the defendant] schools banned [the plaintiff] from marketing on their campuses at different times over the span of several years"), *aff'd*, 922 F.3d 136 (2d Cir. 2019).

The Court previously determined that Plaintiffs had not adequately alleged parallel conduct, because "Plaintiffs' own allegations make clear that Defendants adopted four distinct policies regarding contract pharmacies and 340B drug discounts over the course of several months in mid-to-late 2020" and Plaintiffs had not "plausibly alleged that Defendants' disparate conduct ultimately achieved the same or a substantially similar end result." (Dkt. 71 at 11, 15). Plaintiffs argue that the proposed second amended complaint cures this deficiency because it "richly details the common impact of each Defendant's policy, showing that each policy led to the immediate decrease of sales through the Contract Pharmacy 340B Drug Discount channel by 60-90% in volume and 70-95% in lost 340B Savings" and "further details how Defendants implemented common policies . . . and why their various exceptions were so marginal that their policies accomplished the same results." (Dkt. 72-3 at 18).

The Court is unpersuaded by these arguments. Far from demonstrating that Defendants engaged in similar conduct, the second amended complaint's additional allegations provide further confirmation that the policies adopted by Defendants had substantial variations in both their timing and their particulars. To briefly summarize, the first defendant to make a change to its 340B contract pharmacy drug discount policy was Eli Lilly, which advised HHS in May of 2020 that it was ceasing to offer contract pharmacy discounts on one of its products, the drug Cialis. (Dkt. 72-1 at ¶ 139). Two months later, on July 24, 2020—immediately after Defendants' collective lobbying efforts to restrict 340B drug discounts failed—AstraZeneca advised HHS that beginning October 1, 2020, it would "recognize one contract pharmacy per covered entity for those covered entities that do not maintain an

on-site dispensing pharmacy" with respect to a subset of its products. (*Id.* at ¶ 134).

On July 27, 2020—again, in the immediate aftermath of the failure of Defendants' collective lobbying efforts—Sanofi announced a new policy regarding 340B contract pharmacy discounts, completely different from the policy adopted by AstraZeneca. (*Id.* at ¶ 136). Specifically, Sanofi announced that as of October 1, 2020,[3] it would begin requiring covered entities to "provide sensitive prescription claims data to a Sanofi vendor, Second Sight Solutions, through a software portal called 340B ESP on commercially unreasonable terms[.]" (*Id.*). Covered entities that refused to do so would no longer be eligible for 340B contract pharmacy discounts. (*Id.*).

Eli Lilly informed HHS of a further change to its policy on August 19, 2020, indicating that effective September 1, 2020, it would discontinue voluntarily honoring requests for 340B contract pharmacies except "primarily" where a covered entity did not have an in-house pharmacy, and with a special exception allowing contract pharmacies to pass along certain insulin products at cost. (*Id.* at ¶ 137-38). Novo Nordisk did not announce any changes to its 340B contract pharmacy discount policy until months later, on December 1, 2020, when it informed HHS that it would stop offering contract pharmacy 340B drug discounts to hospital covered entities—which notably does not include either of Plaintiffs—effective January 1, 2021. (*Id.* at ¶ 140).

Defendants have continued to make disparate changes to their policies over time. On February 2, 2021,

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[3] Plaintiffs make much of the fact that both AstraZeneca's and Sanofi's policies were effective October 1, 2020. (*See* Dkt. 72-1 at ¶¶ 135-36). However, October 1, 2020, was the beginning of the next fiscal quarter.

Sanofi advised HHS that effective March 1, 2021, it would limit its restrictions to just five covered entity types—consolidated health center programs, disproportionate share hospitals, critical access hospitals, rural referral centers, and sole community hospitals. (*Id.* at ¶ 141). On December 16, 2021—more than a year after Sanofi first adopted the Second Sight Solutions platform—Eli Lilly announced that it too would "permit 340B purchases by covered entities for drugs shipped to Contract Pharmacies with Contract Pharmacy 340B Drug Discounts if the covered entity agrees to provide, and does provide on an ongoing basis, claims-level data associated with such contract pharmacy orders through the 340B ESP platform." (*Id.* at ¶ 142 (internal quotation marks omitted)). Further, on January 24, 2022, Novo Nordisk announced that it would allow hospital covered entities without wholly owned pharmacies to designate two contract pharmacies—one retail pharmacy and one specialty pharmacy. (*Id.*).

There is no question that beginning in 2020, Defendants have implemented restrictions on the use of contract pharmacies to make 340B purchases. However, Defendants' distinct and evolving policies, which have been adopted and updated over multiple years, simply do not amount to parallel conduct, for essentially the reasons discussed by the Court in its original Decision and Order. The new information added in the proposed second amended complaint is fully consistent with this conclusion. In particular, the fact that Eli Lilly, after first adopting its own unique policy in May and August of 2020, changed course in December of 2021 to adopt the Second Sight Solutions platform as Sanofi had done more than a year earlier is clear evidence of the individualized nature of Defendants' actions. In other words, if Defendants' policies were functionally equivalent—as Plaintiffs

contend—there would be no logical reason for Eli Lilly to have made this change.

Plaintiffs try to gloss over the significant differences in Defendants' behavior by contending that their disparate policies have had the "common effect of ending the vast majority of Contract Pharmacy 340B Drug Discounts for their drugs." (Dkt. 72-1 at 56). However, the data cited by Plaintiffs shows significant variation in the reduction of 340B drug sales. Specifically, Plaintiffs allege that Novo Nordisk's volume of drugs sold at 340B discount prices dropped approximately 60% the month after it adopted its new policy, while the other three defendants saw volume decreases of approximately 90%. (*See id.* at ¶¶ 182, 199, 218, 230). This dramatic difference between Novo Nordisk and the other three defendants underscores the differences in their allegedly parallel conduct.

Moreover, and as Defendants correctly point out, the data relied upon by Plaintiffs represents the decrease in 340B drug sales for all of Defendants' products, not just for the diabetes treatments that were allegedly the subject of the anticompetitive conspiracy. The Court agrees with Defendants that "[i]f anything, this multi-drug data undermines Plaintiffs' premise that Defendants were only willing to act in the diabetes-treatment markets where they supposedly moved together." (Dkt. 74 at 15).

In sum, the proposed second amended complaint, like the first amended complaint, fails to plausibly allege that Defendants engaged in parallel conduct. Because this is a necessary element of a claim under Sherman Act § 1, Plaintiffs' request for leave to amend their federal antitrust claim is futile.

**2. Failure to Raise an Inference of Conspiracy**

Assuming *arguendo* that Defendants' adoption of four substantially different policies regarding 340B contract pharmacy discounts over a period of either seven months (from May 2020 to December 2020) or a year and a half (if taking into account subsequent policy modifications made in 2021 and 2022) did constitute parallel conduct, Plaintiffs still must "allege enough facts to support the inference that a conspiracy actually existed." *Citigroup*, 709 F.3d at 136; *see also Twombly*, 550 U.S. at 556-57 ("when allegations of parallel conduct are set out in order to make a § 1 claim, they must be placed in a context that raises a suggestion of a preceding agreement, not merely parallel conduct that could just as well be independent action"). "Post-*Twombly* courts have analyzed § 1 claims based on parallel conduct by horizontal competitors by inquiring whether 'plus factors' and/or other circumstantial evidence are present that, along with the parallel conduct, make it plausible to infer an agreement among competitors." *In re Int. Rate Swaps Antitrust Litig.*, 261 F. Supp. 3d 430, 462-63 (S.D.N.Y. 2017). "An inference of conspiracy will not arise when the alleged conspirators' conduct made perfect business sense, or where there are obvious alternative explanations for the facts alleged." *Litovich v. Bank of Am. Corp.*, 568 F. Supp. 3d 398, 417 (S.D.N.Y. 2021) (quotations and citations omitted); *see also Cenedella v. Metro. Museum of Art*, 348 F. Supp. 3d 346, 358 (S.D.N.Y. 2018) ("[A] plaintiff's complaint can be dismissed where there is an obvious alternative explanation to the facts underlying the alleged conspiracy among the defendants.").

Here, the allegations of the proposed second amended complaint set forth an obvious alternative explanation for

the facts underlying the alleged conspiracy: the failure of the Defendants' joint lobbying efforts. *See In re Treasury Securities Auction Antitrust Litigation*, No. 22-943, Slip Op. at 58 (2d Cir. Feb. 1, 2024) ("It is decidedly not indicative of a conspiracy that a group of similarly situated market participants would object, individually and separately, to a significant market development that could cut into their profits[.]"). Plaintiffs do not contest the legality of those joint lobbying efforts, which they concede were "long-running" and had cost Defendants millions of dollars. (Dkt. 72-1 at ¶¶ 6, 125). Moreover, the proposed second amended complaint acknowledges that the 340B program requires Defendants to sell their products at significantly discounted prices. (*Id.* at ¶ 37). It makes perfectly rational business sense for Defendants, who apparently viewed 340B drug discounts as a significant enough issue to spend millions of dollars lobbying the government for changes to the program, to have independently reacted to the failure of those lobbying efforts. *See, e.g., LaFlamme v. Societe Air France*, 702 F. Supp. 2d 136, 152 (E.D.N.Y. 2010) (finding no plausible inference of conspiracy where there was "an obvious potential stimuli and discernible reason aside from collusion that plausibly could have instigated independent decisions by defendants to impose surcharges" (quotations omitted)).

Plaintiffs' arguments to the contrary are unpersuasive. Plaintiffs contend that Defendants' "proffered theories nowhere account for why these four Defendants imposed their novel restrictions when a thousand others did not." (Dkt. 75 at 9). However, the proposed second amended complaint alleges that other drug manufactures made changes to their 340B contract pharmacy drug discount policies during the relevant time frame. For example, "two top drug manufacturers—

Merck and Novartis—asked covered entities to participate in the same software program mandated by Sanofi." (Dkt. 72-1 at ¶ 159). While Plaintiffs go on to allege that "unlike Sanofi, neither Merck nor Novartis cut off Contract Pharmacy 340B Drug Discounts for covered entities unwilling to participate" (*id.*), that does not change the fact that Merck and Novartis adopted new policies following the issuance of Executive Order 13937. Plaintiffs further acknowledge in the proposed second amended complaint that other drug manufacturers adopted policies similar to those adopted by Defendants in 2021 and 2022. (*Id.* at 160). The adoption of such policies by additional drug manufacturers further confirms that such policies make perfect business sense.

Plaintiffs suggest in the second amended complaint that it "would have been against any single Defendant's unilateral self-interest" to adopt the challenged policies because such action would "risk market share," in part by opening that single defendant up to severe regulatory sanctions. (Dkt. 72-1 at ¶ 278). However, these arguments cannot bear up under scrutiny. Initially, Plaintiffs' market share theory fails entirely to explain why only Novo Nordisk limited its restrictions to hospital covered entities, thus "leaving the entire non-hospital segment for Novo [Nordisk] to claim." (Dkt. 74 at 20). If Defendants were motivated by market share concerns as alleged by Plaintiffs, it would be irrational to leave a substantial market segment entirely to one co-conspirator.

Moreover, and as Defendants point out in opposition to Plaintiffs' motion for leave to amend (*see id.* at 19-20), Plaintiffs have not offered a plausible explanation for why Defendants would be economically incentivized to monopolize the 340B program market, when that market is defined by selling products at significantly discounted

rates. Plaintiffs speculate that "[i]f hospitals and clinics end up preferring a drug because it has a Contract Pharmacy 340B Drug Discount, that preference is most likely to be reflected in prescribing and administration patterns" outside of the 340B program. (Dkt. 72-1 at ¶ 70). However, that assertion is unsupported by any factual allegations. Accordingly, Plaintiffs' follow-up conclusion that "[t]he risk to a drug company's market share in restricting Contract Pharmacy 340B Drug Discounts is thus much larger than simply the loss of the potential sales to 340B eligible patients at Contract Pharmacies" (*id.* at ¶ 71) lacks plausibility.

With respect to the issue of regulatory sanctions, Plaintiffs make a "safety in numbers" argument that is unsupported by the factual allegations in the proposed second amended complaint. According to Plaintiffs, "[n]o rational manufacturer would risk acting alone to limit the sale of Contract Pharmacy 340B Drug Discounts because the United States has maintained that any such limitation violates Section 340B" and "[t]he Government could feasibly restrict a single manufacturer from federal healthcare programs without unduly undermining the mission of those federal healthcare programs in delivering critical medications to others because the exclusion of one manufacturer would not disrupt the availability of drugs of that manufacturer's competitors." (Dkt. 72-1 at ¶ 76). However, "if a manufacturer of critical medications, such as diabetes medications, conspired with all of the competing manufacturers of such medications, the Government could not feasibly restrict that group of manufacturers from federal healthcare programs." (*Id.* at ¶ 77).

The proposed second amended complaint undercuts this argument in multiple ways. First, contrary to

Plaintiffs' argument that "[n]o rational manufacturer would risk acting alone to limit the sale of Contract Pharmacy 340B Drug Discounts because the United States has maintained that any such limitation violates Section 340B" (*id.* at ¶ 76), Eli Lilly did just that in May of 2020 when it announced that it was ceasing to offer 340B contract pharmacy drug discounts on Cialis (*id.* at ¶ 139). Plaintiffs do not allege that Eli Lilly acted in coordination with any other drug manufacturer in making this announcement, nor do they allege that this action did not put Eli Lilly at risk of severe regulatory sanctions. Eli Lilly's unilateral restriction of contract pharmacy 340B drug discounts in May of 2020—before the alleged conspiracy is purported to have begun—directly contradicts Plaintiffs' "safety in numbers" theory.

Second, while Plaintiffs allege that Defendants' new policies "were imposed despite warnings by regulators that such restrictions were illegal" (Dkt. 72-1 at ¶ 165), the earliest "warning" they cite was issued on September 2, 2020 (*id.* at ¶ 166)—*after* Eli Lilly, AstraZeneca, and Sanofi had announced and implemented the policies at issue here. It is implausible that warnings issued *after* the challenged conduct began were an impetus for concerted action.

Nor do the other allegations in the proposed second amended complaint, viewed as a whole, plausibly give rise to an inference of conspiracy. While Plaintiffs' allegations that Defendants shared a common lobbyist and participated in the trade group PhRMA are indicative of an opportunity to conspire, they do not give rise to an inference of conspiracy without something more. *See PharmacyChecker.com, LLC v. Nat'l Ass'n of Boards of Pharmacy*, 530 F. Supp. 3d 301, 336 (S.D.N.Y. 2021). And while Plaintiffs allege that Defendants have been alleged

to have engaged in antitrust conspiracies and price manipulation related to diabetes medication in the past (*see* Dkt. 72-1 at ¶¶ 331-36), they have not tied those past allegations of wrongdoing to the conspiracy alleged in the instant action.

In sum, the Court finds that the proposed second amended complaint fails to set forth a viable claim under § 1 of the Sherman Act, both because it does not plausibly allege parallel conduct and because it does not otherwise plausibly allege conduct giving rise to an inference of conspiracy.

**B. Proposed State Law Claim Amendments**

The Court further finds that the proposed second amended complaint does not plausibly allege either state law antitrust claims or state law unjust enrichment claims. Both the proposed state law antitrust claims and the proposed state law unjust enrichment claims are premised on the allegation that Defendants have unlawfully conspired to overcharge Plaintiffs for their products. (*See* Dkt. 72-1 at ¶¶ 382-385, 389). However, the Court has determined for the reasons discussed at length above that Plaintiffs have not plausibly alleged that Defendants engaged in such a conspiracy. As such, their proposed amendments to their state law claims are futile.

**CONCLUSION**

For the foregoing reasons, Plaintiffs' motion for leave to file a second amended complaint (Dkt. 72) is denied. The Court having previously dismissed the first amended complaint (*see* Dkt. 71), the Clerk of Court is directed to close this case.

SO ORDERED.

*/s/ Elizabeth A. Wolford*
ELIZABETH A. WOLFORD
Chief Judge
United States District Court

Dated: February 1, 2024
Rochester, New York

**APPENDIX C**

[FILED: SEPTEMBER 2, 2022]

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

| | |
|---|---|
| MOSAIC HEALTH, INC., and CENTRAL VIRGINIA HEALTH SERVICES, INC., *individually and on behalf of all those similarly situated*,<br>*Plaintiffs*,<br>v.<br>SANOFI-AVENTIS U.S., LLC, ELI LILLY AND COMPANY, LILLY USA, LLC, NOVO NORDISK INC., and ASTRAZENECA PHARMACEUTICALS LP,<br>*Defendants*. | **DECISION AND ORDER**<br>6:21-CV-06507-EAW |

## INTRODUCTION

Plaintiffs Mosaic Health, Inc. ("Mosaic Health") and Central Virginia Health Services, Inc. ("CVHS") (collectively "Plaintiffs") allege that defendant pharmaceutical companies Sanofi-Aventis U.S. ("Sanofi"), Eli Lilly and Company and Lilly USA, LLC ("Eli Lilly"), Novo Nordisk Inc. ("Novo Nordisk"), and AstraZeneca Pharmaceuticals LP ("AstraZeneca") (collectively "Defendants") have violated state and federal antitrust laws by coordinating to rescind a long-standing discount

for "safety-net" hospitals and clinics that treat patients who would otherwise be unable to obtain care. (Dkt. 1). Presently before the Court is a joint motion to dismiss filed by Defendants. (Dkt. 47; Dkt. 48)[1]. For the reasons that follow, the Court grants Defendants' motion, but conditionally grants Plaintiffs' request for leave to file a second amended complaint.

## BACKGROUND

### I. Factual Background

The instant facts are taken from Plaintiffs' amended complaint, which is the operative pleading. As is required at this stage of the proceedings, Plaintiffs' factual allegations are taken as true.

Mosaic Health is a nonprofit healthcare organization with its principal place of business in Rochester, New York. (Dkt. 41 at ¶ 9). It is "a federally qualified health center that receives funds from the U.S. Department of Health and Human Services, Health Resources and Services Administration to provide healthcare services to people residing in medically underserved areas, regardless of their ability to pay" and operates 22 safety-net clinics. (*Id.*). CVHS is a nonprofit healthcare organization with its principal place of business in New Canton, Virginia. (*Id.* at ¶ 10). It is "a federally qualified health center that receives funds from the U.S. Department of Health and Human Services, Health Resources and Services Administration to provide healthcare services to people residing in medically

[1] Defendants have also filed a motion to stay discovery pending resolution of the motion to dismiss. (Dkt. 51). In light of the Court's resolution of the motion to dismiss, the motion to stay is denied as moot.

underserved areas, regardless of their ability to pay" and operates 18 safety-net clinics. (*Id.*).

In 1992, Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, created the "340B Drug Discount Program," which "require[s] discounts on outpatient drugs purchased by healthcare providers serving underserved populations." (*Id.* at ¶ 21). "The net savings and revenue generated through access to 340B Drug Discounts [are] sometimes referred to as 340B Savings" and "340B Savings are often a critical component of covered entities' ability to provide healthcare services to patients." (*Id.* at ¶¶ 23-24). Mosaic Health, for example, uses 340B savings to "help fund sliding fee discounted medications for patients in need." (*Id.* at ¶ 25).

"Since its inception, the 340B Drug Discount has been a defined discount, specific to each drug, calculated by the 340B Drug Discount Program." (*Id.* at ¶ 29). More specifically, Section 340B imposes a ceiling price for a drug, which is "generally equal to the 'Average Manufacturer Price' minus a 'Unit Rebate Amount.'" (*Id.* at ¶ 30). Pharmaceutical companies report their 340B ceiling prices to the Health Resources and Services Administration ("HRSA") on a quarterly basis, and the HRSA in turn makes those prices available to covered entities via its 340B Office of Pharmacy Affairs Information System ("340B OPAIS"), "an online database that allows covered entities to access ceiling prices for covered outpatient drugs." (*Id.* at ¶ 31).

"Since at least 1996, and in greater volumes since 2010, all drug companies participating in the 340B Drug Discount Program have offered Contract Pharmacy 340B Drug Discounts to covered entities. To do so, drug companies have offered covered entities the 340B Drug Discount on covered outpatient drugs purchased on the

covered entities' own accounts but shipped to their registered Contract Pharmacy sites." (*Id.* at ¶ 55). A typical arrangement involving a contract pharmacy would work as follows: (1) a covered entity's patient arrives at a contract pharmacy for a covered outpatient drug; (2) the contract pharmacy, "sometimes itself and sometimes working with a 340B vendor . . . reviews the pharmacy prescription to identify the patient's prescription as 340B eligible and to match it to a particular covered entity"; (3) the contract pharmacy fills the prescription with inventory from the purchasing account of the covered entity; (4) the contract pharmacy charges the patient for any required co-pay or fee, "adjusted downward as appropriate by any sliding-fee scale arrangement between the pharmacy and the covered entity"; (5) the contract pharmacy collects reimbursements from any third-parties such as private insurers or Medicare Part D; and (6) the contract pharmacy remits any amounts collected to the covered entity and the covered entity pays the contract pharmacy a dispensing fee. (*Id.* at ¶ 56).

Diabetes "is often coincident with low-income populations and in lower-income neighborhoods that are underserved by private healthcare practices" and is "a common area of treatment for 340B covered entity hospitals and clinics." (*Id.* at ¶¶ 72-73). "Consequently, diabetes medications make up a significant portion of 340B covered entities' outpatient prescriptions and 340B Drug Discounts. And three of the most significant diabetes medications are rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics." (*Id.* at ¶ 74).

The defendant pharmaceutical companies "dominate three of today's most lucrative markets for diabetes treatments: (i) rapid-acting analog insulins; (ii) long-acting analog insulins; and (iii) incretin mimetics. Defendants

compete against each other, as horizontal competitors, in these markets." (*Id.* at ¶ 68). Sanofi, Eli Lilly, and Novo Nordisk compete in the sale of rapid-acting analog insulins and long-acting analog insulins. (*Id.* at ¶¶ 75-84). Sanofi, Eli Lilly, Novo Nordisk, and AstraZeneca compete in the sale of incretin mimetics. (*Id.* at ¶¶ 85-90). These products collectively represent "hundreds of millions or billions of dollars in annual sales for each company." (*Id.* at ¶ 91).

In 2020, Defendants spent millions of dollars "collectively lobbying the federal government . . . to limit 340B Drug Discounts with respect to diabetes medicines." (*Id.* at ¶ 100). However, those efforts were largely unsuccessful. (*Id.* at ¶¶ 100-116). On July 24, 2020, then-President Donald Trump issued Executive Order 13937, which "addressed the use of insulin (as well as epinephrine) within the 340B Drug Discount Program," but was "extremely limited in scope." (*Id.* at ¶¶ 102-103). "Executive Order 13937 promised to have relatively little impact on the volume of 340B Drug Discounts for insulin medications[.]" (*Id.* at ¶ 104).

On July 24, 2020, AstraZeneca advised the United States Department of Health and Human Services ("HHS") that it intended to limit contract pharmacy 340B drug discounts. (*Id.* at ¶ 118). More particularly, AstraZeneca stated that beginning October 1, 2020, and for certain of its products, it would "recognize one contract pharmacy per covered entity for those covered entities that do not maintain an on-site dispensing pharmacy." (*Id.*).

On or about July 27, 2020, Sanofi informed all 340B Drug Discount Program covered entities that it would be implementing a new initiative that would "cut off all Contract Pharmacy 340B Drug Discounts, which had been in place for a decade, unless covered entities provided new

consideration to Sanofi." (*Id.* at ¶ 120). "The newly required consideration was entry into a contract to provide sensitive prescription claims data to a Sanofi vendor through a software portal on commercially unreasonable terms." (*Id.*). Sanofi announced that its new policy would take effect on October 1, 2020. (*Id.*).

On August 19, 2020, Eli Lilly advised HHS that effective September 1, 2020, it would discontinue voluntarily honoring requests for 340B contract pharmacies except "primarily" where a covered entity did not have an in-house pharmacy. (*Id.*). Eli Lilly also "added a special exception to permit Contract Pharmacies to pass along certain insulin products at cost," but "that exception was infeasible for covered entities and pharmacies, as it required the Contract Pharmacies to fill prescriptions without any fee whatsoever." (*Id.* at ¶ 122).

On December 1, 2020, Novo Nordisk advised HHS that "it would stop offering Contract Pharmacy 340B Drug Discounts to all hospital covered entities" effective January 1, 2021. (*Id.* at ¶ 124).

## II. Procedural Background

Mosaic Health commenced this putative class action on July 30, 2021. (Dkt. 1). The amended complaint, which added CVHS as a plaintiff, was filed on October 22, 2021. (Dkt. 41). Defendants filed their joint motion to dismiss the amended complaint on November 12, 2021. (Dkt. 47; Dkt. 48).

Defendants filed their joint motion to stay discovery pending resolution of the motion to dismiss on November 24, 2021. (Dkt. 51). Plaintiffs opposed this motion on December 20, 2021 (Dkt. 53), and Defendants filed a reply on December 27, 2021 (Dkt. 54).

Plaintiffs filed their opposition to the motion to dismiss on January 7, 2022. (Dkt. 58; Dkt. 59). Replies were filed on February 4, 2022. (Dkt. 66; Dkt. 67).

## DISCUSSION

### I. Legal Standard

"In considering a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6), a district court may consider the facts alleged in the complaint, documents attached to the complaint as exhibits, and documents incorporated by reference in the complaint." *DiFolco v. MSNBC Cable L.L.C.*, 622 F.3d 104, 111 (2d Cir. 2010). A court should consider the motion by "accepting all factual allegations as true and drawing all reasonable inferences in favor of the plaintiff." *Trs. of Upstate N.Y. Eng'rs Pension Fund v. Ivy Asset Mgmt.*, 843 F.3d 561, 566 (2d Cir. 2016). To withstand dismissal, a claimant must set forth "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Turkmen v. Ashcroft*, 589 F.3d 542, 546 (2d Cir. 2009) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).

"While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (internal quotations and citations omitted). "To state a plausible claim, the complaint's '[f]actual allegations must be enough to raise a right to relief above the speculative

level.'" *Nielsen v. AECOM Tech. Corp.*, 762 F.3d 214, 218 (2d Cir. 2014) (quoting *Twombly*, 550 U.S. at 555).

## II. Plaintiffs' Claims

The amended complaint sets forth the following claims: (1) violations of § 1 of the Sherman Act, 15 U.S.C. § 1; (2) "unreasonable restraint of trade" in violation of the laws of Arizona, California, Connecticut, the District of Columbia, Illinois, Iowa, Kansas, Maine, Maryland, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, West Virginia, and Wisconsin; and (3) unjust enrichment under the laws of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, the District of Columbia, Delaware, Florida, Georgia, Hawaii, Indiana, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, and Wisconsin. (Dkt. 41 at ¶¶ 255-279). Plaintiffs seek both damages and injunctive relief with respect to their Sherman Act claim. (*Id.* at ¶¶ 262-65).

Defendants seek dismissal of all of Plaintiffs' claims, arguing that: (1) Plaintiffs lack standing to sue for damages under federal antitrust law pursuant to *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977), because they are indirect purchasers of Defendants' drugs; (2) Plaintiffs have failed to plausibly allege an agreement among Defendants; (3) Plaintiffs' true claim "stems from their dissatisfaction with the terms on which contract

pharmacies may access each Defendant's 340B drugs," but there is no private right of action under Section 340B; and (4) Plaintiffs' state-law claims are deficiently pled for numerous reasons. (Dkt. 47-1 at 13-14). For the reasons set forth below, the Court agrees with Defendants that Plaintiffs have failed to plausibly allege an agreement among Defendants and that the federal and state antitrust claims accordingly fail.[2] The Court further agrees that Defendants have not complied with the applicable pleading standards with respect to their unjust enrichment claims.

**A. Sherman Act § 1 Claim**

"Liability under § 1 of the Sherman Act, 15 U.S.C. § 1, requires a 'contract, combination . . ., or conspiracy, in restraint of trade or commerce.'" *Twombly*, 550 U.S. at 548 (quoting 15 U.S.C. § 1). "Because § 1 of the Sherman Act does not prohibit [all] unreasonable restraints of trade . . . but only restraints effected by a contract, combination, or conspiracy, [t]he crucial question is whether the challenged anticompetitive conduct stem[s] from independent decision or from an agreement, tacit or express." *Id.* at 553 (alterations in original) (quotations and citation omitted). "[S]tating such a claim requires a complaint with enough factual matter (taken as true) to suggest that an agreement was made." *Id.* at 556.

"The ultimate existence of an 'agreement' under antitrust law, however, is a legal conclusion, not a factual allegation." *Mayor and City Council of Balt., Md. v. Citigroup, Inc.*, 709 F.3d 129, 135-36 (2d Cir. 2013). "[A] plaintiff may . . . assert direct evidence that the defendants

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[2] The Court notes that "the *Illinois Brick* doctrine is not jurisdictional," *Mayor & City Council of Baltimore v. AbbVie Inc.*, 42 F.4th 709, 710 (7th Cir. 2022), and that it accordingly is not constrained to reach this issue first.

entered into an agreement in violation of the antitrust laws." *Id.* at 136. "[A] complaint may, alternatively, present circumstantial facts supporting the *inference* that a conspiracy existed." *Id.* (emphasis in original). "[A] horizontal agreement . . . may be inferred on the basis of conscious parallelism, when such interdependent conduct is accompanied by circumstantial evidence and plus factors." *Id.* (quotation omitted). "These 'plus factors' may include: a common motive to conspire, evidence that shows that the parallel acts were against the apparent individual economic self-interest of the alleged conspirators, and evidence of a high level of interfirm communications." *Id.* (quotation and footnote omitted).

"Without more, parallel conduct does not suggest conspiracy, and a conclusory allegation of agreement at some unidentified point does not supply facts adequate to show illegality." *Twombly*, 550 U.S. at 556-57. In other words, allegations of parallel action "must be placed in a context that raises a suggestion of a preceding agreement, not merely parallel conduct that could just as well be independent action." *Id.* at 557. "[W]ithout that further circumstance pointing toward a meeting of the minds, an account of a defendant's commercial efforts stays in neutral territory." *Id.* As the Second Circuit has explained:

> Examples of parallel conduct allegations that might be sufficient under *Twombly*'s standard include "parallel behavior that would probably not result from chance, coincidence, independent responses to common stimuli, or mere interdependence unaided by an advance understanding among the parties," and "complex and historically unprecedented changes in pricing structure made at the very same time by

> multiple competitors, and made for no other discernible reason."

*Citigroup*, 709 F.3d at 137 (quoting *Twombly*, 550 U.S. at 556 n.4 (quotation omitted)).

Plaintiffs do not contend to have alleged direct evidence of a conspiracy in this case. (*See* Dkt. 58 at 34). Instead, they argue that they have plausibly alleged that Defendants engaged in parallel conduct in a context suggesting collusion. However, the Court agrees with Defendants that Plaintiffs have not plausibly alleged parallel conduct for the reasons that follow.

"'Parallel conduct' refers to the same or substantially similar actions taken by actors on the same level." *North Am. Soccer League, LLC v. U.S. Soccer Fed., Inc.*, 296 F. Supp. 3d 442, 460 n.26 (E.D.N.Y. 2017), *aff'd*, 883 F.3d 32 (2d Cir. 2018). Conduct need not be completely uniform in order to qualify as parallel. *See, e.g., In re Int. Rate Swaps Antitrust Litig.*, 261 F. Supp. 3d 430, 479 (S.D.N.Y. 2017); *In re Broiler Chicken Antitrust Litig.*, 290 F. Supp. 3d 722, 792 (N.D. Ill. 2017). However, where the alleged conspirators engaged in different conduct at different times, a plaintiff's "allegations fall far short of demonstrating parallel behavior[.]" *Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 228 (3d Cir. 2011).

In this case, Plaintiffs' own allegations make clear that Defendants adopted four distinct policies regarding contract pharmacies and 340B drug discounts over the course of several months in mid-to-late 2020. More particularly, in late July of 2020, AstraZeneca determined that as of October 1, 2020, and for certain of its products, it would only recognize one contract pharmacy per covered entity for covered entities without on-site pharmacies. (Dkt. 41 at ¶ 118). Shortly thereafter, Sanofi announced that as of October 1, 2020, it would continue to

allow covered entities to utilize unlimited contract pharmacies, so long as those covered entities agreed to provide certain prescription claims data. (*Id.* at ¶ 120).[3] Then, roughly three weeks later, in mid-August of 2020, Eli Lilly announced that as of September 1, 2020, it would cease recognizing contract pharmacy requests unless a covered entity did not have an in-house pharmacy, but that it would allow contract pharmacies to pass along certain insulin products at cost if those contract pharmacies did not charge a fee. (*Id.* at ¶¶ 121-22).[4] Finally, on December 1, 2020, Novo Nordisk announced that it would "stop offering Contract Pharmacy 340B Drug Discounts to hospital covered entities" effective January 1, 2021. (*Id.* at ¶ 124 (emphasis added)). To summarize: AstraZeneca limited contract pharmacy 340B drug discounts for certain drugs to a single contract pharmacy and only where the covered entity lacked an on-site pharmacy; Sanofi limited contract pharmacy 340B drug discounts to covered entities that agreed to comply with its new reporting

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[3] Plaintiffs make the entirely conclusory allegation that the new reporting requirement imposed by Sanofi was "commercially unreasonable." (Dkt. 41 at ¶ 120). However, they have provided no support for that assertion, and this Court is not required to credit "mere conclusory statements" on a Rule 12(b)(6) motion. *Iqbal*, 556 U.S. at 678.

[4] Plaintiffs contend that this exception was "commercially infeasible," but their explanation for why that is allegedly so is difficult to understand. (Dkt. 41 at ¶ 123). Plaintiffs note that the exception requires the contract pharmacy to dispense the products without charging a dispensing fee, but then states that the exception was "virtually meaningless" because it "prevented the collection of any revenue by a covered entity to offset the dispensing fee the covered entity would have to pay the Contract Pharmacy." (*Id.*). It is unclear how the covered entity could be required to pay the contract pharmacy a dispensing fee when the exception prohibits the contract pharmacy from charging a dispensing fee.

requirements; Eli Lilly largely limited contract pharmacy 340B drug discounts to covered entities without on-site pharmacies but also included a further exception for certain insulin products;[5] and Novo Nordisk limited contract pharmacy 340B drug discounts to non-hospital covered entities.

There is no plausible argument that these disparate policies are "substantially similar" so as to constitute parallel conduct for purposes of federal antitrust law. They are different in their particulars, their timing, and their outcomes. The Court finds instructive the Eighth Circuit's decision in *Park Irmat Drug Corp. v. Express Scripts Holding Co.*, 911 F.3d 505 (8th Cir. 2018). There, the plaintiff claimed that the defendants had unlawfully conspired "to boycott independent mail-order pharmacies." *Id.* at 516. The Eighth Circuit found that the plaintiff had failed to plausibly plead parallel conduct, because while it "claim[ed] that CVS and Express Scripts conspired to terminate [it] from their . . . networks because it operated a mail-order pharmacy that competed with Express Scripts' and CVS's mail-order pharmacies," CVS's and Express Scripts' conduct was insufficiently similar. *Id.* In particular, CVS required the plaintiff to participate in its network three-months after Express

[5] In their opposition papers, Plaintiffs cite to paragraph 121 of the amended complaint to assert that "Eli Lilly stopped shipping 340B-discounted drugs to Contract Pharmacies beginning on September 1, 2020, with a claimed single-pharmacy exception where a covered entity does not have an in-house pharmacy." (Dkt. 58 at ¶ 22). However, paragraph 121 of the amended complaint makes no mention of a limitation to a single pharmacy. Further, a review of the actual letter that Eli Lilly sent to HHS—which Plaintiff references and quotes from in the amended complaint—shows that no such single-pharmacy limitation is set forth therein. (*See* Dkt. 47-4 at 2-4). Defendants confirm that Eli Lilly's policy "allows unlimited contract pharmacies if certain requirements are met." (Dkt. 66 at 18).

Scripts "sent [the plaintiff] a letter demanding that [the plaintiff] abandon its mail-order pharmacy operations," and Express Scripts ultimately terminated Plaintiff from its network six months before CVS did. *Id.* at 516 -517. The dissimilarities in conduct, coupled with the temporal differences, "did not constitute parallel conduct." *Id.* at 517; *Cf. Anderson News, L.L.C. v. Am. Media, Inc.*, 899 F.3d 87, 105 (2d Cir. 2018) (explaining that while the plaintiff had survived at the motion to dismiss stage by alleging that "all of the publisher and distributor defendants ceased doing business with [it] within a span of three business days," the evidence at the summary judgment stage conclusively showed that "defendants' conduct was not, in fact, parallel," because "defendants' responses were not uniform" and the "tight timeframe for those responses . . . was of [the plaintiff's] own making" (originally alterations omitted)).

The cases relied on by Plaintiffs are inapposite. An examination of one such case, *SD3, LLC v. Black & Decker (U.S.) Inc.*, 801 F.3d 412 (4th Cir. 2015), demonstrates why. There, the plaintiff alleged a group boycott, "which generally constitutes a concerted refusal by traders to deal with other traders." *Id.* at 426 (alteration and quotation omitted). The Fourth Circuit found that the plaintiff had "adequately alleged parallel conduct" because it had pled facts "indicating that the defendants acted 'similarly.'" *Id.* at 427 (quoting *Petruzzi's IGA Supermarkets, Inc. v. Darling-Delaware Co.,* 998 F.2d 1224, 1243 (3d Cir. 1993)). The *SD3* court rejected the defendants' argument "that their conduct must be deemed dissimilar at this stage because some licensing negotiations continued after the conspiracy formed," explaining that while the defendants were alleged to have "employed different courses of action" to achieve the same end result, "none of the defendants ultimately took a

license or otherwise implemented [the plaintiff's] technology." *Id.* In other words, the defendants might have used slightly different methods, but they all arrived at the same ultimate outcome. *See also In re Int. Rate Swaps Antitrust Litig.*, 261 F. Supp. 3d at 479 (in group boycott context, although actions were not uniform, every defendant allegedly ultimately aligned and refused to "make markets"); *In re Broiler Chicken*, 290 F. Supp. 3d at 792 (while the defendants' conduct was not entirely uniform, the plaintiffs "alleged that all of the defendants engaged in production cuts at the same time," thus achieving the end result of cutting the relevant industry's production below its "historic annual 3% production increase"); *In re Domestic Airline Travel Antitrust Litig.*, 221 F. Supp. 3d 46, 69 (D.D.C. 2016) (while Defendants "did not reduce or limit capacity in identical amounts," they all took steps that limited capacity growth).

By contrast, in this case, Plaintiffs have not plausibly alleged that Defendants' disparate conduct ultimately achieved the same or a substantially similar end result. While they have alleged in an entirely conclusory fashion that the "net effect" of each of the policies was to "end[] nearly all Contract Pharmacy 340B Drug Discounts for AstraZeneca, Eli Lilly, Novo Nordisk, and Sanofi drugs" (Dkt. 41 at ¶ 181), they have not supported that conclusion with any facts. To the contrary, the facts that are alleged in the amended complaint do not support this conclusion. It is undisputed that Novo Nordisk's new policy does not apply to the clinics operated by Plaintiffs. (*See* Dkt. 58 at 52). Further, Eli Lilly's new policy contains an exception for covered entities without an in-house pharmacy, and Plaintiffs affirmatively allege that "only a very small number" of covered entities use in-house pharmacies. (Dkt. 41 at ¶¶ 43-44, 46, 121). AstraZeneca's policy applies only to particular AstraZeneca products (*id.* at ¶ 118) and

Plaintiffs have not alleged any information regarding what percentage of AstraZeneca's portfolio is subject thereto. Finally, the amended complaint contains no factual allegations regarding the number or percentage of covered entities that have declined to participate in Sanofi's data reporting requirements. The lack of information regarding the impact of Sanofi's policy is particularly problematic, inasmuch as this policy on its face does not limit the number of covered entities that can access contract pharmacy 340B drug discounts.

In sum, the amended complaint contains no facts from which it can plausibly be concluded that Defendants' disparate policies, which were adopted over the course of several months, had the same or even similar impacts on the availability of contract pharmacy 340B drug discounts to covered entities. The adoption of those policies accordingly does not constitute parallel conduct as alleged.

Defendants and Plaintiffs also strenuously dispute whether Plaintiffs have plausibly alleged the presence of plus factors in this case. However, "plus factors without plausible allegations of parallel conduct are insufficient to establish an inference of an agreement." *In re Pork Antitrust Litig.*, No. CV 18-1776 (JRT/LIB), 2019 WL 3752497, at *7 (D. Minn. Aug. 8, 2019) (dismissing antitrust claims because "[w]hile Plaintiffs' cited plus factors are strong, the allegations at this point regarding parallel conduct are sparse and conclusory"); *see also Park Irmat*, 911 F.3d at 517 ("Because [the plaintiff] fails to plausibly plead parallel conduct, no discussion of any 'plus factors' is necessary."). Accordingly, the Court need not and does not reach these additional arguments at this time.

**B. State Antitrust Claims**

As set forth above, Plaintiffs have asserted claims under the antitrust laws of 25 states and the District of Columbia. (Dkt. 41 at ¶ 266-72). Defendants argue, and Plaintiffs do not dispute, that "each of the relevant state statutes requires plausible allegations of a conspiracy to restrain trade[.]" (Dkt. 47-1 at 51; *see also* Dkt. 41 at ¶ 267 (asserting that Defendants violated the state antitrust laws because they "entered into, established, and maintained a continuing contract, combination, or conspiracy in unreasonable restraint of trade."). Plaintiffs' state antitrust claims thus fail for the same reason as their Sherman Act § 1 claim—they have not plausibly alleged the existence of a conspiracy.

**C. State Unjust Enrichment Claims**

Plaintiffs have asserted unjust enrichment claims under the laws of 47 states and the District of Columbia. (Dkt. 41 at ¶¶ 273-79). The Court agrees with Defendants that these unjust enrichment claims are inadequately pled. This Court has previously held that the sort of "generic pleading" engaged in by Plaintiffs in this case—whereby they "pleaded federal antitrust claims and the factual foundation for them, and then merely alleged that those claims are also actionable as unjust enrichment" does "not comply with the relevant pleading standards." *Miami Prod. & Chem. Co. v. Olin Corp.*, 546 F. Supp. 3d 223, 247 (W.D.N.Y. 2021) (citation and original alterations omitted).

Plaintiffs' attempts to distinguish this case from *Miami Products* are unavailing. Plaintiffs claim that they "allege the specific elements required by each state" (Dkt. 58 at 60 (quotation omitted)), but they do not do so in any meaningful way. Instead, they merely recite the elements for each state claim, with no elaboration. (Dkt. 41 at ¶ 275).

As the Court explained in *Miami Products*, Plaintiffs "cannot simply enumerate a long list of state-law claims for states where they might otherwise have no available antitrust recovery and rely on the defendants and the court to sort out whether or how those laws can act as surrogates for antitrust law." 546 F. Supp. 3d at 247. Plaintiffs' unjust enrichment claims are accordingly subject to dismissal.

**III. Leave to Amend**

In their opposition papers, Plaintiffs state as follows: "To the extent the Court concludes that any claim or remedy is insufficiently pled, Plaintiffs respectfully request an opportunity to amend and replead." (Dkt. 58 at 65). This "is not a proper motion for leave to amend, and fails to comply with the Local Rules of Civil Procedure with respect to the process for seeking to amend a pleading." *Wi3, Inc. v. Actiontec Elecs., Inc.*, 71 F. Supp. 3d 358, 363 (W.D.N.Y. 2014) (explaining that, among other things, this District's Local Rules require the party seeking to amend a pleading to "identify the proposed amendments through the use of a word processing red-line function or other similar markings" (quotations omitted)). The Court would accordingly be within its discretion to simply outright deny this "cursory or boilerplate request[] . . ., made solely in a memorandum in opposition to a motion to dismiss." *Malin v. XL Capital, Ltd.*, 312 F. App'x 400, 402 (2d Cir. 2009).

However, the Court cannot, on the record before it, rule out the possibility that Plaintiffs could successfully plead their claims. Accordingly, the Court will conditionally grant Plaintiffs' request for leave to amend, contingent on Plaintiffs filing a motion that comports with the requirements of the Local Rules of Civil Procedure and that includes a viable proposed second amended

complaint, within 30 days of entry of this Decision and Order as set forth below.

**CONCLUSION**

For the foregoing reasons, the Court grants Defendants' joint motion to dismiss. (Dkt. 47). The Court further conditionally grants Plaintiffs' request for leave to file a second amended complaint, contingent on the filing by Plaintiffs of a procedurally proper motion for leave to amend that includes a viable proposed second amended complaint, within 30 days of entry of this Decision and Order. In the event such a motion is filed, the Court will enter a briefing schedule thereon. If no such motion is filed, the amended complaint (Dkt. 41) shall be dismissed with prejudice.

Defendants' motion to stay discovery pending resolution of its motion to dismiss (Dkt. 51) is denied as moot. However, in light of the Court's finding that all of Plaintiffs' claims are subject to dismissal, the Court *sua sponte* orders that no further discovery shall be conducted herein until Plaintiffs' request for leave to amend is finally resolved.

SO ORDERED.

*/s/ Elizabeth A. Wolford*
ELIZABETH A. WOLFORD
Chief Judge
United States District Court

Dated: September 2, 2022
Rochester, New York

**APPENDIX D**

[FILED: DECEMBER 5, 2025]

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

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At a stated term of the United States Court of Appeals for the Second Circuit, held at the Thurgood Marshall United States Courthouse, 40 Foley Square, in the City of New York, on the 5th day of December, two thousand twenty-five.

| | |
|---|---|
| Mosaic Health, Inc., Central Virginia Health Services, Inc., individually and on behalf of all those similarly situated,<br><br>Plaintiffs-Appellants,<br><br>v.<br><br>Sanofi-Aventis U.S., LLC, Eli Lilly and Company, Lilly USA, LLC, Novo Nordisk Inc., AstraZeneca Pharmaceuticals LP,<br><br>Defendants-Appellees. | **ORDER**<br><br>Docket No: 24-598 |

Appellees filed a petition for panel rehearing, or, in the alternative, for rehearing *en banc*. The panel that determined the appeal has considered the request for panel rehearing, and the active members of the Court have considered the request for rehearing *en banc*.

IT IS HEREBY ORDERED that the petition is denied.

FOR THE COURT:

Catherine O'Hagan Wolfe, Clerk
[seal]
*/s/ Catherine O'Hagan Wolfe*

## APPENDIX E

### 15 U.S.C. § 1. Trusts, etc., in restraint of trade illegal; penalty

Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

## APPENDIX F

### 15 U.S.C. § 15. Suits by persons injured

### (a) Amount of recovery; prejudgment interest

Except as provided in subsection (b), any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor in any district court of the United States in the district in which the defendant resides or is found or has an agent, without respect to the amount in controversy, and shall recover threefold the damages by him sustained, and the cost of suit, including a reasonable attorney's fee. The court may award under this section, pursuant to a motion by such person promptly made, simple interest on actual damages for the period beginning on the date of service of such person's pleading setting forth a claim under the antitrust laws and ending on the date of judgment, or for any shorter period therein, if the court finds that the award of such interest for such period is just in the circumstances. In determining whether an award of interest under this section for any period is just in the circumstances, the court shall consider only–

**(1)** whether such person or the opposing party, or either party's representative, made motions or asserted claims or defenses so lacking in merit as to show that such party or representative acted intentionally for delay, or otherwise acted in bad faith;

**(2)** whether, in the course of the action involved, such person or the opposing party, or either party's representative, violated any applicable rule, statute, or court order providing for sanctions for dilatory behavior or otherwise providing for expeditious proceedings; and

**(3)** whether such person or the opposing party, or either party's representative, engaged in conduct primarily for the purpose of delaying the litigation or increasing the cost thereof.

**(b) Amount of damages payable to foreign states and instrumentalities of foreign states**

**(1)** Except as provided in paragraph (2), any person who is a foreign state may not recover under subsection (a) an amount in excess of the actual damages sustained by it and the cost of suit, including a reasonable attorney's fee.

**(2)** Paragraph (1) shall not apply to a foreign state if–

**(A)** such foreign state would be denied, under section 1605(a)(2) of Title 28, immunity in a case in which the action is based upon a commercial activity, or an act, that is the subject matter of its claim under this section;

**(B)** such foreign state waives all defenses based upon or arising out of its status as a foreign state, to any claims brought against it in the same action;

**(C)** such foreign state engages primarily in commercial activities; and

**(D)** such foreign state does not function, with respect to the commercial activity, or the act, that is the subject matter of its claim under this section as a procurement entity for itself or for another foreign state.

**(c) Definitions**

For purposes of this section–

**(1)** the term "commercial activity" shall have the meaning given it in section 1603(d) of Title 28, and

**(2)** the term "foreign state" shall have the meaning given it in section 1603(a) of Title 28.

## APPENDIX G

### 15 U.S.C. § 26. Injunctive relief for private parties; exception; costs

Any person, firm, corporation, or association shall be entitled to sue for and have injunctive relief, in any court of the United States having jurisdiction over the parties, against threatened loss or damage by a violation of the antitrust laws, including sections 13, 14, 18, and 19 of this title, when and under the same conditions and principles as injunctive relief against threatened conduct that will cause loss or damage is granted by courts of equity, under the rules governing such proceedings, and upon the execution of proper bond against damages for an injunction improvidently granted and a showing that the danger of irreparable loss or damage is immediate, a preliminary injunction may issue: *Provided*, That nothing herein contained shall be construed to entitle any person, firm, corporation, or association, except the United States, to bring suit for injunctive relief against any common carrier subject to the jurisdiction of the Surface Transportation Board under subtitle IV of Title 49. In any action under this section in which the plaintiff substantially prevails, the court shall award the cost of suit, including a reasonable attorney's fee, to such plaintiff.

## APPENDIX H

### 42 U.S.C. § 256b. Limitation on prices of drugs purchased by covered entities

#### (a) Requirements for agreement with Secretary

##### (1) In general

The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2). Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the "ceiling price"), and shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.

##### (2) "Rebate percentage" defined

##### (A) In general

For a covered outpatient drug purchased in a calendar quarter, the "rebate percentage" is the amount (expressed as a percentage) equal to–

**(i)** the average total rebate required under section 1927(c) of the Social Security Act with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by

**(ii)** the average manufacturer price for such a unit of the drug during such quarter.

**(B) Over the counter drugs**

**(i) In general**

For purposes of subparagraph (A), in the case of over the counter drugs, the "rebate percentage" shall be determined as if the rebate required under section 1927(c) of the Social Security Act is based on the applicable percentage provided under section 1927(c)(3) of such Act.

**(ii) "Over the counter drug" defined**

The term "over the counter drug" means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drug under State law).

**(3) Drugs provided under State Medicaid plans**

Drugs described in this paragraph are drugs purchased by the entity for which payment is made by the State under the State plan for medical assistance under title XIX of the Social Security Act.

**(4) "Covered entity" defined**

In this section, the term "covered entity" means an entity that meets the requirements described in paragraph (5) and is one of the following:

**(A)** A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act).

**(B)** An entity receiving a grant under section 256a of this title.

**(C)** A family planning project receiving a grant or contract under section 300 of this title.

**(D)** An entity receiving a grant under subpart II of part C of subchapter XXIV (relating to categorical grants for outpatient early intervention services for HIV disease).

**(E)** A State-operated AIDS drug purchasing assistance program receiving financial assistance under subchapter XXIV.

**(F)** A black lung clinic receiving funds under section 937(a) of title 30.

**(G)** A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act.

**(H)** A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988.

**(I)** An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

**(J)** Any entity receiving assistance under subchapter XXIV (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to paragraph (7).

**(K)** An entity receiving funds under section 247c of this title (relating to treatment of sexually

transmitted diseases) or section 247b(j)(2) of this title (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7).

**(L)** A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act) that—

> **(i)** is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under this subchapter;
>
> **(ii)** for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act; and
>
> **(iii)** does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

**(M)** A children's hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act, or a free-standing cancer hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(v) of the Social Security Act, that would

meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under clause (ii) of such subparagraph, if the hospital were a subsection (d) hospital as defined by section 1886(d)(1)(B) of the Social Security Act.

**(N)** An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act), and that meets the requirements of subparagraph (L)(i).

**(O)** An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act, or a sole community hospital, as defined by section 1886(d)(5)(C)(iii) of such Act, and that both meets the requirements of subparagraph (L)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent.

**(5) Requirements for covered entities**

**(A) Prohibiting duplicate discounts or rebate**

**(i) In general**

A covered entity shall not request payment under title XIX of the Social Security Act for medical assistance described in section 1905(a)(12) of such Act with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act.

**(ii) Establishment of mechanism**

The Secretary shall establish a mechanism to ensure that covered entities comply with clause (i). If the Secretary does not establish a mechanism within 12 months under the previous sentence, the requirements of section

1927(a)(5)(C) of the Social Security Act shall apply.

**(B) Prohibiting resale of drugs**

With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

**(C) Auditing**

A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs[1] (A) or (B) with respect to drugs of the manufacturer.

**(D) Additional sanctions for noncompliance**

If the Secretary finds, after audit as described in subparagraph (C) and after notice and hearing, that a covered entity is in violation of a requirement described in subparagraphs 1 (A) or (B), the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug (as described in subparagraph (A)) provided under the agreement between the entity and the manufacturer under this paragraph.

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[1] So in original. Probably should be “subparagraph”.

**(6) Treatment of distinct units of hospitals**

In the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity under this paragraph unless the hospital is otherwise a covered entity under this subsection.

**(7) Certification of certain covered entities**

**(A) Development of process**

Not later than 60 days after November 4, 1992, the Secretary shall develop and implement a process for the certification of entities described in subparagraphs (J) and (K) of paragraph (4).

**(B) Inclusion of purchase information**

The process developed under subparagraph (A) shall include a requirement that an entity applying for certification under this paragraph submit information to the Secretary concerning the amount such entity expended for covered outpatient drugs in the preceding year so as to assist the Secretary in evaluating the validity of the entity's subsequent purchases of covered outpatient drugs at discounted prices.

**(C) Criteria**

The Secretary shall make available to all manufacturers of covered outpatient drugs a description of the criteria for certification under this paragraph.

**(D) List of purchasers and dispensers**

The certification process developed by the Secretary under subparagraph (A) shall include procedures under which each State shall, not later than 30 days after the submission of the descriptions under

subparagraph (C), prepare and submit a report to the Secretary that contains a list of entities described in subparagraphs (J) and (K) of paragraph (4) that are located in the State.

**(E) Recertification**

The Secretary shall require the recertification of entities certified pursuant to this paragraph on a not more frequent than annual basis, and shall require that such entities submit information to the Secretary to permit the Secretary to evaluate the validity of subsequent purchases by such entities in the same manner as that required under subparagraph (B).

**(8) Development of prime vendor program**

The Secretary shall establish a prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs. If a covered entity obtains drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution.

**(9) Notice to manufacturers**

The Secretary shall notify manufacturers of covered outpatient drugs and single State agencies under section 1902(a)(5) of the Social Security Act of the identities of covered entities under this paragraph, and of entities that no longer meet the requirements of paragraph (5) or that are no longer certified pursuant to paragraph (7).

**(10) No prohibition on larger discount**

Nothing in this subsection shall prohibit a manufacturer from charging a price for a drug that is lower than the maximum price that may be charged under paragraph (1).

**(b) Other definitions**

**(1) In general**

In this section, the terms "average manufacturer price", "covered outpatient drug", and "manufacturer" have the meaning given such terms in section 1927(k) of the Social Security Act.

**(2) Covered drug**

In this section, the term "covered drug"—

**(A)** means a covered outpatient drug (as defined in section 1927(k) (2) of the Social Security Act); and

**(B)** includes, notwithstanding paragraph (3)(A) of section 1927(k) of such Act, a drug used in connection with an inpatient or outpatient service provided by a hospital described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section.

**(c) Repealed. Pub.L. 111-152, Title II, § 2302(2), Mar. 30, 2010, 124 Stat. 1083**

**(d) Improvements in program integrity**

**(1) Manufacturer compliance**

**(A) In general**

From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by manufacturers with the requirements of this section in order to prevent overcharges and other violations of the discounted pricing requirements specified in this section.

**(B) Improvements**

The improvements described in subparagraph (A) shall include the following:

**(i)** The development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities, which shall include the following:

**(I)** Developing and publishing through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices under such subsection.

**(II)** Comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary.

**(III)** Performing spot checks of sales transactions by covered entities.

**(IV)** Inquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, such corrective action as is appropriate in response to such price discrepancies.

**(ii)** The establishment of procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers, including the following:

**(I)** Providing the Secretary with an explanation of why and how the overcharge occurred, how the refunds will be calculated, and to whom the refunds will be issued.

**(II)** Oversight by the Secretary to ensure that the refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive adjustment to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered outpatient drugs.

**(iii)** The provision of access through the Internet website of the Department of Health and Human Services to the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary in accordance with this section, in a manner (such as through the use of password protection) that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure.

**(iv)** The development of a mechanism by which—

**(I)** rebates and other discounts provided by manufacturers to other purchasers subsequent to the sale of covered outpatient drugs to covered entities are reported to the Secretary; and

**(II)** appropriate credits and refunds are issued to covered entities if such discounts or rebates have the effect of lowering the applicable ceiling price for the relevant quarter for the drugs involved.

**(v)** Selective auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program under this section.

**(vi)** The imposition of sanctions in the form of civil monetary penalties, which—

**(I)** shall be assessed according to standards established in regulations to be promulgated by the Secretary not later than 180 days after March 23, 2010;

**(II)** shall not exceed $5,000 for each instance of overcharging a covered entity that may have occurred; and

**(III)** shall apply to any manufacturer with an agreement under this section that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1).

**(2) Covered entity compliance**

**(A) In general**

From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and violations of the duplicate discount provision and other requirements specified under subsection (a)(5).

**(B) Improvements**

The improvements described in subparagraph (A) shall include the following:

**(i)** The development of procedures to enable and require covered entities to regularly update (at least annually) the information on the Internet website of the Department of Health and Human Services relating to this section.

**(ii)** The development of a system for the Secretary to verify the accuracy of information

regarding covered entities that is listed on the website described in clause (i).

**(iii)** The development of more detailed guidance describing methodologies and options available to covered entities for billing covered outpatient drugs to State Medicaid agencies in a manner that avoids duplicate discounts pursuant to subsection (a)(5)(A).

**(iv)** The establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered outpatient drugs under this section, including the processing of chargebacks for such drugs.

**(v)** The imposition of sanctions, in appropriate cases as determined by the Secretary, additional to those to which covered entities are subject under subsection (a)(5)(D), through one or more of the following actions:

**(I)** Where a covered entity knowingly and intentionally violates subsection (a)(5)(B), the covered entity shall be required to pay a monetary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity is found liable under subsection (a)(5)(D), such interest to be compounded monthly and equal to the current short term interest rate as determined by the Federal Reserve for the time period for which the covered entity is liable.

**(II)** Where the Secretary determines a violation of subsection (a)(5)(B) was systematic and egregious as well as knowing and intentional, removing the covered entity from the drug discount program under this section and disqualifying the entity from re-entry into such program for a reasonable period of time to be determined by the Secretary.

**(III)** Referring matters to appropriate Federal authorities within the Food and Drug Administration, the Office of Inspector General of Department of Health and Human Services, or other Federal agencies for consideration of appropriate action under other Federal statutes, such as the Prescription Drug Marketing Act (21 U.S.C. 353).

**(3) Administrative dispute resolution process**

**(A) In general**

Not later than 180 days after March 23, 2010, the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(C), of violations of subsections[2] (a)(5)(A) or (a)(5)(B), including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B).

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[2] So in original. Probably should be "subsection".

**(B) Deadlines and procedures**

Regulations promulgated by the Secretary under subparagraph (A) shall–

**(i)** designate or establish a decision-making official or decision-making body within the Department of Health and Human Services to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered outpatient drugs in excess of the ceiling price described in subsection (a)(1), and claims by manufacturers that violations of subsection (a)(5)(A) or (a)(5)(B) have occurred;

**(ii)** establish such deadlines and procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously;

**(iii)** establish procedures by which a covered entity may discover and obtain such information and documents from manufacturers and third parties as may be relevant to demonstrate the merits of a claim that charges for a manufacturer's product have exceeded the applicable ceiling price under this section, and may submit such documents and information to the administrative official or body responsible for adjudicating such claim;

**(iv)** require that a manufacturer conduct an audit of a covered entity pursuant to subsection (a)(5)(C) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity;

**(v)** permit the official or body designated under clause (i), at the request of a manufacturer or manufacturers, to consolidate claims brought by more than one manufacturer against the same covered entity where, in the judgment of such official or body, consolidation is appropriate and consistent with the goals of fairness and economy of resources; and

**(vi)** include provisions and procedures to permit multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding, and permit such claims to be asserted on behalf of covered entities by associations or organizations representing the interests of such covered entities and of which the covered entities are members.

**(C) Finality of administrative resolution**

The administrative resolution of a claim or claims under the regulations promulgated under subparagraph (A) shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction.

**(4) Authorization of appropriations**

There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for fiscal year 2010 and each succeeding fiscal year.

**(e) Exclusion of orphan drugs for certain covered entities**

For covered entities described in subparagraph (M) (other than a children's hospital described in subparagraph (M)),

(N), or (O) of subsection (a)(4), the term "covered outpatient drug" shall not include a drug designated by the Secretary under section 360bb of Title 21 for a rare disease or condition.

**APPENDIX I**

[FILED: OCTOBER 3, 2022]

Exhibit 1–Proposed Second Amended Complaint

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UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF NEW YORK

MOSAIC HEALTH, INC. and CENTRAL VIRGINIA HEALTH SERVICES, INC., individually and on behalf of all those similarly situated,

Plaintiffs,

vs.

SANOFI-AVENTIS U.S., LLC, ELI LILLY AND COMPANY, LILLY USA, LLC, NOVO NORDISK INC., and ASTRAZENECA PHARMACEUTICALS LP,

Defendants.

**SECOND AMENDED COMPLAINT**

Class Action
Jury Trial Demanded

6:21-cv-6507 (EAW)

Plaintiffs Mosaic Health, Inc. and Central Virginia Health Services, Inc., on behalf of themselves and all those similarly situated, by their counsel allege as follows:

## INTRODUCTION

1. This case challenges coordination by four drug companies to boost their profits at the expense of the safety-net hospitals and clinics that care for patients who have nowhere else to turn. Those four drug companies—defendants here—should directly compete with each other. Yet, instead of competing for business, they worked together to boost their profits by coordinating to retract a long-standing discount for safety-net hospitals and clinics. That coordination allowed each defendant to individually avoid competitive pressure and prevent individual market share losses including through adverse government action limiting federal healthcare program coverage, while restricting safety-net hospitals' abilities to deliver robust and affordable healthcare options to patients. Their horizontal agreement was a *per se* violation of state and federal antitrust laws. This antitrust class action seeks injunctive and compensatory relief for the safety-net hospitals and clinics harmed by the drug companies' anti-competitive agreement.

2. The defendants here are four drug companies that dominate three key markets for diabetes treatments. They are: Sanofi-Aventis U.S., LLC (Sanofi); Eli Lilly and Company and Lilly USA, LLC (together, Eli Lilly); Novo Nordisk Inc. (Novo Nordisk); and AstraZeneca Pharmaceuticals LP (AstraZeneca) (collectively, Defendants). They dominate the lucrative diabetes markets for: (i) rapid-acting analog insulins; (ii) long-acting analog insulins; and (iii) incretin mimetics. These markets account for billions of dollars of annual U.S. sales for Defendants and, as such, are among the most

important drug markets for the Defendants. At the time their conspiracy began, Defendants faced no significant competition, apart from one another, in these multi-billion-dollar markets.

3. The discount that Defendants conspired to limit was a special discount offered to safety-net hospitals and clinics, which purchase drugs filled by their patients at retail pharmacies. The discount is calculated by a mathematical formula codified at Section 340B of the Public Health Service Act, 42 U.S.C. § 256b and is known as the 340B Drug Discount. For at least a decade, drug companies offered the 340B Drug Discount to safety-net hospitals and clinics, not only for on-site use but also for purchase and distribution by retail pharmacies. Those pharmacies, typically called contract pharmacies (Contract Pharmacies), have contracts with safety-net providers, which allows the providers to purchase drugs on their own accounts, discounted with the 340B Drug Discount, to be delivered to and dispensed by the Contract Pharmacies. Drug companies, including Defendants, have argued that their provision of 340B Drug Discounts at Contract Pharmacies is voluntary, not mandated by law. But, for at least a decade, nearly all pharmaceutical companies, including Defendants, had offered safety-net providers drugs at 340B Drug Discounts for dispensing at Contract Pharmacies (Contract Pharmacy 340B Drug Discounts). And, with all pharmaceutical competitors regularly offering Contract Pharmacy 340B Drug Discounts, patients benefitted, because safety-net hospitals and clinics have been able to use savings from those discounts to expand healthcare services and lower healthcare costs for patients. Contract Pharmacies have been a multi-billion-dollar discount channel for the sale of drug inventory.

4. But Defendants, in coordination with one another, departed from that industry-wide practice beginning in the summer of 2020 to cripple that discount channel for diabetes treatments by dramatically decreasing the sale of their drug inventory at discounts. After a decade of providing Contract Pharmacy 340B Drug Discounts to safety-net providers through their Contract Pharmacies, Defendants—and Defendants alone among hundreds of leading pharmaceutical companies—suddenly, and in coordination with one another, began refusing to offer Contract Pharmacy 340B Drug Discounts. So, while nearly every pharmaceutical company in the country continued to offer Contract Pharmacy 340B Drug Discounts, Defendants, competitors with one another primarily as to the lucrative diabetes medications described above, coordinated an historically unprecedented change in 340B pricing practices nearly simultaneously.

5. The Plaintiffs and Class Members harmed by those actions are safety-net hospitals and clinics, which provide healthcare services to low-income and underserved patients, funded in significant part through savings from 340B Drug Discounts. The Plaintiffs are Mosaic Health, Inc. (Mosaic Health) and Central Virginia Health Services, Inc. (CVHS). Mosaic Health is a federally qualified health center (FQHC) comprised of 22 safety-net clinics: Charlotte School Based Health Center; Clinton Family Health; Edison Tech Community Health Center; Freddie Thomas Health Center; Genesee Health service; John James Audubon Health Center; Martin Luther King Jr. Health Center; Mosaic Health Rushville; Mosaic Health Mount Morris; Mosaic Health Lyons; Mosaic Health Utica; Mosaic Health Utica Dental; Mosaic Health Ilion; Newark Internal Medicine; Riedman Health

Center; Unity Dental at St. Mary's; Unity Dental at Ridgeway; Unity Family Medicine at Orchard Street; Unity Family Medicine at St. Mary's; Wolcott Primary Care; Women's Center at Clinton Family; and Women's Center at Rochester General Hospital. CVHS is also a FQHC comprised of 18 safety-net clinics: CVHS Brunswick; CVHS Buckingham; CVHS Caroline; CVHS Charles City; CVHS Charlotte; CVHS Charlottesville; CVHS Children's Dental; CVHS Crimson-Clinic; CVHS Downtown Petersburg; CVHS Farmville; CVHS Fredericksburg; CVHS Hopewell - Prince George; CVHS King William; CVHS Louisa; CVHS Petersburg; CVHS Peterson; CVHS Southern Albemarle; and CVHS Westmoreland. Each of these safety-net clinics is a covered entity participating in the 340B Drug Discount Program with contracts with retail pharmacies. For years, these clinics have obtained Contract Pharmacy 340B Drug Discounts from nearly all drug companies, including Defendants, and have been able to use the resulting savings to expand healthcare options and services for patients in their communities.

6. Defendants' conspiracy began in the summer of 2020. Through mid-summer, Defendants had spent millions collectively lobbying the federal government (in efforts not challenged here) to limit 340B Drug Discounts with respect to diabetes medications. A long-running lobbying campaign by drug companies had sought (i) to limit the level of hospital participation in the 340B Program, (ii) to limit which patients could qualify for 340B Drug Discounts, (iii) to require that all discounts be passed through to patients at the point of sale, and/or (iv) to restrict the availability of Contract Pharmacy 340B Drug Discounts. But Defendants' lobbying efforts failed. That failure became evident on July 24, 2020, when President

Trump issued Executive Order 13937 addressing the 340B Drug Discount in the context of insulin medication and injectable epinephrine. The executive order did little to accomplish any of Defendants' goals. But Defendants' collective lobbying efforts offered them an opportunity to develop another plan focused on just the last of those goals—collusively eliminating or limiting Contract Pharmacy 340B Drug Discounts for their drugs, most significantly including their drugs dominating rapid-acting analog insulin, long-acting analog insulin, and incretin mimetic sales. On July 24, 2020, the very same day that the executive order was issued, the first Defendant, AstraZeneca, revealed its intention to restrict Contract Pharmacy 340B Drug Discounts.

7. The other Defendants executed similar plans in short order. While Defendants' Plan A (lobbying the federal government to restrict 340B Drug Discounts) may have been perfectly legal and legitimate, their Plan B (agreeing among themselves to restrict Contract Pharmacy 340B Drug Discounts) was not. The plan worked only with buy-in from each of the other Defendants. If any Defendant had acted alone, it would have risked losing significant market share in the lucrative markets for diabetes treatments, including through severe adverse action from regulators; and, over time, safety-net providers could have purchased drugs from that Defendant's competitors to access Contract Pharmacy 340B Drug Discounts to maximize healthcare services and to lower costs for patients. But, by acting together, Defendants safeguarded themselves against competition in the lucrative diabetes medication markets. Moreover, by acting collectively, Defendants left regulators unable to take the harshest of actions—restricting coverage of their insulins by federal healthcare

programs—because, if regulators took consistent punitive action against all four Defendants, it would leave thousands of healthcare program participants without any options for these critical drugs.

8. Defendants together implemented the common and historically unprecedented policy of refusing to provide 340B Contract Pharmacy Drug Discounts with a number of company-specific exceptions that Defendants used to paint their common policies as distinct and less impactful. Defendants knew, however, that their exceptions were marginal and that their common policies would result in the same outcome and result for each Defendant, as they did, with each Defendants' actions immediately decreasing the sales through the Contract Pharmacy 340B Drug Discount channel by 60-90% (by volume) or 70-95% (by lost 340B Savings).

9. Defendants' conspiracy likewise succeeded immediately in raising prices, by eliminating the overwhelming majority of Contract Pharmacy 340B Drug Discounts and converting drug inventory sales into a non-discount channel, all the while protecting their market position from competition from one another and protecting themselves collectively from the harsh penalty of exclusion from federal healthcare program coverage.

10. That conspiracy is doing immense damage to Plaintiffs and other safety-net hospitals and clinics, and, consequently, to the healthcare options available to the patients they serve. Congress gave safety-net hospitals and clinics "access to [340B Drug Discounts] . . . to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992). Defendants' conspiracy is having the opposite effect—limiting the ability of safety-net hospitals and

clinics to reach more patients and provide more healthcare services by causing significant financial shortfalls for Plaintiffs and other safety-net hospitals and clinics alike. The savings that hospitals and clinics generate from Contract Pharmacy 340B Drug Discounts are used, among other things, to expand the medical services available to the communities served by safety-net facilities, especially for the uninsured or underinsured, and to provide charity care or subsidized pharmacy benefits to help meet the healthcare needs of needy patients. Defendants' conspiracy has threatened those services and benefits. Because Defendants' conspiracy violates state and federal antitrust laws, and the common law, Plaintiffs seek class-wide damages, and injunctive and other equitable relief.

**PARTIES**

11. Plaintiff Mosaic Health, Inc., formerly known as Rochester Primary Care Network, is a nonprofit healthcare organization with its principal place of business in Rochester, New York. Mosaic Health, Inc. is a federally qualified health center that receives funds from the U.S. Department of Health and Human Services, Health Resources and Services Administration to provide healthcare services to people residing in medically underserved areas, regardless of their ability to pay. Mosaic Health, Inc. includes 22 safety-net clinics participating in the 340B Program: Charlotte School Based Health Center; Clinton Family Health; Edison Tech Community Health Center; Freddie Thomas Health Center; Genesee Health service; John James Audubon Health Center; Martin Luther King Jr. Health Center; Mosaic Health Rushville; Mosaic Health Mount Morris; Mosaic Health Lyons; Mosaic Health Utica; Mosaic Health Utica Dental; Mosaic Health Ilion; Newark

Internal Medicine; Riedman Health Center; Unity Dental at St. Mary's; Unity Dental at Ridgeway; Unity Family Medicine at Orchard Street; Unity Family Medicine at St. Mary's; Wolcott Primary Care; Women's Center at Clinton Family; and Women's Center at Rochester General Hospital. Mosaic Health has had contract pharmacy arrangements in place since at least October 2010.

12. Plaintiff Central Virginia Health Services, Inc. is a nonprofit healthcare organization with its principal place of business in New Canton, Virginia. Central Virginia Health Services, Inc. is a federally qualified health center that receives funds from the U.S. Department of Health and Human Services, Health Resources and Services Administration to provide healthcare services to people residing in medically underserved areas, regardless of their ability to pay. CVHS includes 18 safety-net clinics participating in the 340B Program: CVHS Brunswick; CVHS Buckingham; CVHS Caroline; CVHS Charles City; CVHS Charlotte; CVHS Charlottesville; CVHS Children's Dental; CVHS Crimson-Clinic; CVHS Downtown Petersburg; CVHS Farmville; CVHS Fredericksburg; CVHS Hopewell - Prince George; CVHS King William; CVHS Louisa; CVHS Petersburg; CVHS Peterson; CVHS Southern Albemarle; and CVHS Westmoreland. CVHS has had contract pharmacy arrangements in place since at least approximately July 2011.

13. Defendant Sanofi-Aventis U.S., LLC is a Delaware limited liability company with its principal place of business in Bridgewater, New Jersey. Sanofi-Aventis U.S., LLC is a wholly owned subsidiary of the French company, Sanofi.

14. Defendant Eli Lilly and Company is an Indiana corporation with its principal place of business in Indianapolis, Indiana.

15. Defendant Lilly USA, LLC is an Indiana limited liability company with its principal place of business in Indianapolis, Indiana. Lilly USA, LLC is a wholly owned subsidiary of Eli Lilly and Company.

16. Defendant Novo Nordisk Inc. is a Delaware corporation with its principal place of business in Plainsboro, New Jersey. Novo Nordisk Inc. is the United States affiliate of the Danish company, Novo Nordisk A/S.

17. Defendant AstraZeneca Pharmaceuticals LP is a Delaware limited partnership with its principal place of business in Wilmington, Delaware. AstraZeneca Pharmaceuticals LP is a wholly owned subsidiary of the English company, AstraZeneca Pharmaceuticals PLC.

**JURISDICTION AND VENUE**

18. This Court has subject matter jurisdiction over the claims arising under federal antitrust laws under 15 U.S.C. §§ 4, 15, and 26, and 28 U.S.C. §§ 1331 and 1337. This Court has supplemental jurisdiction over the State Law claims arising under 28 U.S.C. § 1367. This Court also has diversity jurisdiction over this class action of the State law claims under 28 U.S.C. § 1332(d) because the aggregate amount in controversy exceeds $5,000,000, there are more than one hundred Class Members, and Members of the Class are citizens of states different from that of one of the Defendants. Likewise, this Court has diversity jurisdiction over the named Plaintiffs' claims under 28 U.S.C. § 1332(a) because all of the named Plaintiffs are citizens of different States than all of the Defendants and the amount in controversy exceeds $75,000.

19. This Court has personal jurisdiction over Defendants under Rule 4(k)(1)(A) of the Federal Rules of Civil Procedure and NY CPLR § 302 because, *inter alia*, Defendants transact and do business within the State of New York, contract to supply goods and services within the State of New York, regularly solicit business and derive substantial revenue from drugs sold in the State of New York, and/or should reasonably expect the acts described in this complaint to have consequences in the State of New York.

20. Venue is appropriate in this District under 15 U.S.C. § 22 because Defendants each transact business in this district and may be found in this district. Venue is also appropriate in this District under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claim occurred in this district; and, in the alternative, venue is appropriate in this District under 28 U.S.C. § 1391 because Defendants are not all residents of the same State and are subject to this Court's personal jurisdiction.

## ALLEGATIONS

### I. Drug companies have long offered Contract Pharmacy 340B Drug Discounts to eligible hospitals and clinics.

#### A. The 340B Drug Discount is a longstanding discount offered by drug companies to hospitals and clinics serving underserved populations.

21. Prior to Defendants' conspiracy, all drug companies participating in Medicaid and Medicare Part B had offered Contract Pharmacy 340B Drug Discounts as part of their participation in the 340B Drug Discount Program.

22. The 340B Drug Discount Program dictates the calculation of the 340B Drug Discount. The 340B Drug Discount is provided by the manufacturer to the covered entities participating in the 340B Drug Discount Program. That program provides the infrastructure for drug companies to offer the 340B Drug Discount through contract pharmacies. And, until the second half of 2020, all drug companies participating in Medicaid and Medicare Part B had offered the Contract Pharmacy 340B Drug Discount.

**1. The 340B Drug Discount Program supports healthcare programs for the underserved.**

23. The 340B Drug Discount Program was created in 1992 by Section 340B of the Public Health Service Act, 42 U.S.C. § 256b (Section 340B), to require discounts on outpatient drugs purchased by healthcare providers serving underserved populations. "Under § 340B," "manufacturers participating in Medicaid must offer discounted drugs to covered entities, dominantly, local facilities that provide medical care for the poor." *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 115 (2011).

24. The program ensures that certain safety-net hospitals and clinics, deemed "covered entities" under the statute, have access to discounts when purchasing outpatient drugs. 42 U.S.C. § 256b(a)(4). As defined by Section 340B, covered entities include a number of health clinics, such as: federally qualified health centers; federally qualified health center look-alikes; native Hawaiian health centers; tribal or urban Indian health centers; Ryan White HIV/AIDS clinics; black lung clinics; comprehensive hemophilia diagnostic treatment centers; Title X family planning projects; sexually transmitted disease clinics; and tuberculosis clinics. *See* 42 U.S.C. § 256b(a)(4). In addition, and as likewise defined by Section

340B, covered entities include hospitals meeting certain statutory criteria, such as: children's hospitals; critical access hospitals; free standing cancer hospitals; sole community hospitals; rural referral centers; and disproportionate share hospitals. *See* 42 U.S.C. § 256b(a)(4).

25. The purpose of the 340B Drug Discount Program is "to enable [covered entities] to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 120-384(II), at 12 (1992). Covered entities with access to 340B Drug Discounts can do so in various ways. For one, a covered entity can save money when paying the ceiling price for a covered outpatient drug needed for an uninsured or an underinsured patient; there, 340B Drug Discounts represent an expense savings for unreimbursed care. Moreover, for patients with insurance, a covered entity can net revenue from the spread between the drug's price—lowered by the 340B Drug Discount—and any reimbursement above that price. The net savings and revenue generated through access to 340B Drug Discounts is sometimes referred to as 340B Savings.

26. 340B Savings are often a critical component of covered entities' ability to provide healthcare services to patients. For some covered entities, including federally qualified health centers, 340B Savings directly subsidize the covered entities' efforts to make drugs affordable to patients at lower costs. For other covered entities, including many hospital participants, 340B Savings helps them fund and expand critical services for the most vulnerable patients, such as addiction and mental health services, and charity care, among other things.

27. 340B Savings are critical to the named Plaintiffs. For example, Mosaic Health's 340B Savings help fund sliding fee discounted medications for patients in need.

28. The clinics that are 340B covered entities predominantly serve low-income or underserved patient populations. For instance, federally qualified health centers are community-based health care providers that receive funds from HHS to provide primary care and other services in underserved areas. They must meet a stringent set of requirements, including providing care on a sliding-fee scale based on patients' ability to pay. Moreover, under federal grant requirements, federally qualified health centers must use any 340B Savings in furtherance of their healthcare safety-net mission. *See* 42 U.S.C. § 254b(e)(5)(A), (D).

29. The hospitals that are 340B covered entities bear disproportionate burdens in serving low-income and underserved patient populations. For instance, disproportionate share hospitals are, by definition, hospitals that serve a significantly disproportionate number of low-income patients. Moreover, to be a covered entity for the 340B Drug Discount Program, a private hospital that meets the disproportionate share hospital definition must also be a nonprofit and must agree to provide charity care. *See* 42 U.S.C. § 256b(a)(4)(L).

30. Section 340B directs the Secretary of the Department of Health and Human Services (HHS) to enter into an agreement with every drug manufacturer participating in State Medicaid programs and Medicare Part B. 42 U.S.C. § 256b(a); *see also* 42 C.F.R. § 10.2. These agreements are known as pharmaceutical pricing agreements (PPAs). Every drug manufacturer participating in Medicaid or Medicare Part B enters into a PPA and offers 340B Drug Discounts. Drug companies

that refuse to sign a PPA cannot participate in Medicaid and Medicare Part B. More than 1,000 drug companies have signed PPAs with HHS, including each of the Defendants and all of the other top 250 drug companies.[1]

**2. Since 1992, the 340B Drug Discount has been calculated in the same manner.**

31. Since its inception, the 340B Drug Discount has been a defined discount, specific to each drug, calculated by the 340B Drug Discount Program.

32. Section 340B and PPAs dictate the methodology for calculating 340B Drug Discounts. Section 340B creates the discount by imposing a ceiling price. *See* 42 U.S.C. § 256b(a)(1); *see also* 42 C.F.R. § 10.10. The ceiling price for a drug is generally equal to the "Average Manufacturer Price" minus a "Unit Rebate Amount." 42 C.F.R. § 10.10(a). The extent to which the ceiling price reduces the available price for drugs is known as the 340B Drug Discount. 340B Drug discounts often provide savings of 20% to 50%.

33. Drug companies must report their 340B ceiling prices on a quarterly basis. *See* 42 U.S.C. § 256b(a)(1). Those reports must be made to the Health Resources and Services Administration (HRSA), the HHS agency that administers the 340B Drug Discount Program. HRSA makes ceiling prices available to covered entities through its 340B Office of Pharmacy Affairs Information System (340B OPAIS), an online database that allows covered entities to access ceiling prices for covered outpatient drugs.

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[1] *See, e.g.*, Torreya Capital LLC, "The Pharma 1000: Top Global Pharmaceutical Company Report" (Sept. 2020).

34. The 340B Drug Discount is thus a defined discount, calculated by statutory rules, and verifiable through 340B OPAIS.

### 3. Drug companies offer 340B Drug Discounts directly to covered hospitals and clinics.

35. Under Section 340B and PPAs, drug companies—not drug distributors—are responsible for offering covered entities the 340B Drug Discount.

36. This is clear from the statute, which states that each PPA "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase" at a price including the 340B Drug Discount. 24 U.S.C. § 256b(a)(1).

37. Defendants themselves have acknowledged that the obligation to provide 340B Drug Discounts to covered entities is theirs alone. As Sanofi has explained, "Section 340B . . . requires drug manufacturers participating in the 340B Program to offer certain drugs at a significant discount to a list of entities (known as 'covered entities') defined by statute." *See* Complaint ¶ 23, *Sanofi-Aventis U.S., LLC v. Azar*, 21-cv-634 (D.N.J. filed Jan. 12, 2021). Similarly, Eli Lilly has stated, "Under the 340B Statute, pharmaceutical manufacturers 'must' offer steep discounts on their products to certain 'covered entities.'" *See* Complaint, *Eli Lilly and Company v. Azar*, 21-cv-81 (S.D. Ind. filed Jan. 12, 2021). For its part, Novo Nordisk has spelled out that "Section 340B of the Public Health Service Act requires pharmaceutical manufacturers to offer their outpatient drugs at deeply discounted prices to an enumerated list of 'covered entities' for the purpose of ensuring that vulnerable and low-income patients have better access to prescription medications." *See* Complaint ¶ 2, *Novo Nordisk Inc. v. Azar*, 3:21-cv-806 (D.N.J. filed

Jan. 15, 2021). So too, AstraZeneca has acknowledged "its statutory obligations . . . to offer 340B drugs to each covered entity on non-discriminatory terms at the 340B price." *See* Complaint ¶ 3, *AstraZeneca Pharmaceuticals LP v. Azar*, 1:21-cv-27 (D. Del. filed Jan. 12, 2021). As AstraZeneca has further detailed, the 340B Program requires that each "manufacturer must 'offer each covered entity covered outpatient drugs for purchase' at a specified [340B] discount price . . . This is known as Section 340B's 'must-offer' requirement." *Id.* ¶ 20.

38. Consequently, as a matter of law and practice, 340B Drug Discounts are offered by, funded by, and provided by drug companies to covered entities.

**4. Oftentimes, drug companies contract with drug distributors to convey 340B Drug Discounts to covered entities.**

39. Often, drug companies rely on distributors and suppliers, such as Cardinal Health, Inc., and McKesson Corporation, to arrange for drug purchasing with covered entities.

40. But those arrangements do not change the nature of the 340B Drug Discount. That discount remains a discount offered and provided by drug companies to covered entities. Indeed, as noted above, drug companies are obligated to provide 340B Drug Discounts to covered entities themselves.

41. As the Federal rules state, "Manufacturers have an obligation to ensure that the 340B discount is provided through distribution arrangements made by the manufacturer." *See* 42 C.F.R. § 10.11(b)(2); *see also* Final Rule, 82 Fed. Reg. 1220, 1224 ("Manufacturers are ultimately responsible for ensuring a covered entity receives a drug at or below the 340B ceiling price" and

"have control over the distribution of covered outpatient drugs, including those distributed by wholesalers, distributers, and agents.").

42. Drug companies ensure that they are offering and providing 340B Drug Discounts to covered entities, even when a distributor serves as an intermediary, by various arrangements. Most commonly, the drug company instructs the distributor to provide the 340B Drug Discount for the sale of any covered outpatient drugs to covered entities. The distributor includes that discount, at the instruction of the drug company, and reports the discounts back to the drug company. The drug company then funds the discount, oftentimes by paying a distributor's invoice for the 340B Drug Discount amount provided (a procedure sometimes called a chargeback). Distributors have no ability to keep any of the 340B Drug Discount. Rather, all of the 340B Drug Discount is conveyed from the drug company to the covered entity.

43. In this way and others, drug distributors do no more than convey 340B Drug Discounts from drug companies to covered entities. Drug distributors themselves have no access to 340B Drug Discounts.

44. Consequently, even when drug distributors serve as intermediaries, the 340B Drug Discount is offered and provided from the drug companies to the covered entities. Drug companies alone can remove those discounts from the distribution stream by refusing to offer them to covered entities or by restricting the circumstances under which such discounts can be accessed by covered entities.

**B. For more than a decade, drug companies have universally offered hospitals and clinics access to 340B Drug Discounts at Contract Pharmacies (*i.e.*, Contract Pharmacy 340B Drug Discounts).**

**1. At the inception of the 340B Program, many clinics struggled to obtain meaningful benefits from the 340B Program.**

45. Following the enactment of the 340B Program in 1992 and "[d]uring the early period of program implementation, it became apparent that only a very small number of the [then] 11,500 covered entities used in-house pharmacies (approximately 500)." Final Notice, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996). Moreover, "many of the larger groups of covered entities, including community and migrant health centers, hemophilia clinics and most of the Ryan White HIV service programs (e.g., State AIDS Drug Assistance Programs) depend[ed] upon outside pharmacy services." *Id.* Yet, "the delivery of pharmacy services [wa]s central to the mission" of these covered entities "and a legal mandate in some instances." *Id.*

46. As HHS has noted, this gap was "not surprising" because "the Program is aimed at benefiting providers" that can be some combination of "small, remote, resource-limited, receiving federal assistance, or serving disadvantaged populations." *See* U.S. Dep't of Health & Human Servs. Office of the General Counsel, *Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program*, at 4 (Dec. 30, 2020). Some of these "are the poster children of providers that one would expect to lack an in-house pharmacy." *Id.*

47. Because of this gap, covered entities sought regulatory assistance in promoting access to 340B Drug

Discounts through Contract Pharmacies. And "[a]s early as 1993, several covered entity groups . . . came forward to assist [HHS] in developing a workable mechanism to use outside pharmacies." *Id.*

48. HHS recognized the problem this gap presented. As it explained, "if these covered entities could not use their affiliated pharmacies in order to participate in the 340B program," "they would be faced with the untenable dilemma of having either to expend precious resources to develop their own in-house pharmacies (which for many would be impossible) or forego participation in the program altogether." Final Notice, 61 Fed. Reg. 43,550 (Aug. 23, 1996).

**2. In 1996 and again in 2010, HHS published guidelines for drug companies to offer Contract Pharmacy 340B Drug Discounts.**

49. In order to expand access to 340B Drug Discounts, in 1996 and 2010, HHS set out guidelines for access to 340B Drug Discounts at Contract Pharmacies.

50. In 1996, HHS issued a final notice with guidelines for drug companies and covered entities to use in setting up Contract Pharmacy arrangements, so that covered entities could access 340B Drug Discounts at Contract Pharmacies. Final Notice, 61 Fed. Reg. 43,549 (Aug. 23, 1996). HHS articulated its position "that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating [340B] manufacturer, the statute directs the manufacturer to sell the drug at the [340B] discounted price." *Id.* at 43,549. When "the entity directs the drug shipment to its contract pharmacy, [there is] no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts

the manufacturer from statutory compliance." *Id.* at 43,549-550.

51. The 1996 final notice provided basic guidelines for implementing Contract Pharmacies to access 340B Drug Discounts. The guidelines encouraged written agreements between the covered entity and the Contract Pharmacy. *See id.* at 43,555. Under the guidelines, the covered entity would purchase the drug, but a "'ship to, bill to' procedure may be used in which the covered entity purchases the drug [and] the manufacturer bills the entity for the drug that it purchased, but [the manufacturer] ships the drug directly to the contract pharmacy." *Id.* The notice included guidelines for limiting the purchase of 340B Drug Discounts to drugs purchased for eligible patients of the covered entity. *See id.*

52. In 2010, HHS issued another final notice with additional guidelines for the use of Contract Pharmacies to access Contract Pharmacy 340B Drug Discounts. *See* Final Notice, 75 Fed. Reg. 10,272 (Mar. 5, 2010).

53. The 2010 final notice included guidelines for the use of "multiple contract pharmacy arrangements," greenlighting the use of multiple retail pharmacies as Contract Pharmacies for a covered entity. *See id.* at 10,273.

54. HRSA's Office of Pharmacy Affairs has facilitated the use of Contract Pharmacies through its 340B OPAIS. In accordance with HHS instructions, covered entities register the names and locations of their Contract Pharmacies in the 340B OPAIS database. Drug companies can access that same database to verify that a particular pharmacy is serving as a Contract Pharmacy for a particular 340B covered entity before making 340B Drug

Discounts available to a covered entity purchasing drugs for shipment to that pharmacy location.

55. The expansion of Contract Pharmacies increased opportunities for covered entities to generate 340b Savings and has provided real benefits for patients, including by expanding patient access and choice. For instance, prior to the expansion, patients of federally qualified health centers were typically able to receive subsidized drugs (on a sliding-fee scale) at a single pharmacy, which might have been far from the health center's patients' homes or otherwise inconvenient. After the expansion, however, patients of federally qualified health centers now typically have a wide range of choices and are able to use a wide variety of Contract Pharmacies. Thus, for example, whereas Mosaic Health patients previously had a single pharmacy location to obtain sliding-fee scale drugs, they can now visit over a dozen different locations.

56. The expansion of Contract Pharmacies has also benefitted patients by expanding the range of covered entities' healthcare services available and by allowing covered entities to fund additional charity care. For instance, 340B Savings have supported hospitals' abilities to provide substantial uncompensated and charity care, including for unreimbursed care for cancer patients, unreimbursed care for substance abuse treatment, subsidizing losses for pediatric care, and supporting community health programs. Those efforts have expanded the breadth and quality of healthcare services available to patients and have reduced the costs of those services, including drugs, to the neediest.

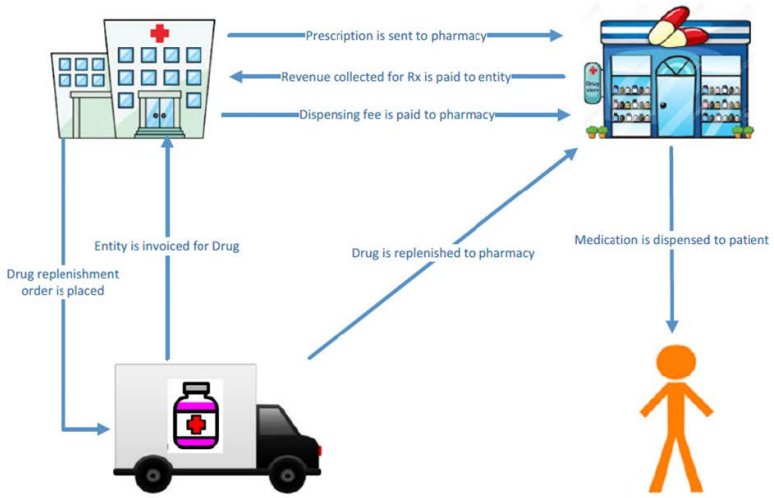
### 3. After that, drug companies participating in the 340B Drug Discount Program universally offered Contract Pharmacy 340B Drug Discounts.

57. Since at least 1996, and in greater volumes since 2010, all drug companies participating in the 340B Drug Discount Program have offered Contract Pharmacy 340B Drug Discounts to covered entities. To do so, drug companies have offered covered entities the 340B Drug Discount on covered outpatient drugs purchased on the covered entities' own accounts but shipped to their registered Contract Pharmacy sites.

58. Oftentimes, this is accomplished through arrangements among covered entities, Contract Pharmacies, distributors, and so-called 340B vendors. A typical arrangement is as follows: A covered entity's patient arrives at a Contract Pharmacy (*e.g.*, a RiteAid) for a covered outpatient drug; the pharmacy fills the patient's prescription. The pharmacy, sometimes itself and sometimes working with a 340B vendor (*e.g.*, CaptureRx) running matching algorithms, reviews the pharmacy prescription to identify the patient's prescription as 340B eligible and to match it to a particular covered entity. If it is so matched, the pharmacy fills the prescription with inventory from the purchasing account of that covered entity—the account through which the covered entity purchases covered outpatient drugs and obtains Contract Pharmacy 340B Drug Discounts from drug companies. The pharmacy then charges the patient for any required co-pay or, if the patient is uninsured, any required fee, adjusted downward as appropriate by any sliding-fee scale arrangement between the pharmacy and the covered entity (as is often the case with federally qualified health centers). To the extent the patient has insurance coverage

from third-parties, such as private insurers or Medicare Part D, the pharmacy collects those reimbursements for the covered entity's account. The pharmacy then remits any amounts collected—whether from the patient or from a third party—to the covered entity, and the covered entity pays the pharmacy a dispensing fee.

59. The arrangements described above can be visualized as follows:




60. Contract pharmacy arrangements have thus allowed covered entities to obtain Contract Pharmacy 340B Drug Discounts and, consequently, to generate 340B Savings. These arrangements have been the status quo for more than a decade.

61. For more than a decade, all pharmaceutical companies participating in Medicaid and Medicare Part B have offered Contract Pharmacy 340B Drug Discounts to covered entities. This has been the universal practice of all drug companies participating in the 340B Program until

the recent events (by just a few companies) described in this Complaint.

62. Recent data published by HHS in June 2021 reflects that more than 4,000 covered entities have Contract Pharmacy arrangements to obtain Contract Pharmacy 340B Drug Discounts. HRSA data as of September 30, 2022, shows that, in New York State alone, more than 2,900 Contract Pharmacies have registered Contract Pharmacy arrangements with covered entities.

63. Until the Defendants' launched their conspiracy, every one of the 1,000-plus drug companies participating in the 340B Program—and every one of the top 250 drug companies—offered Contract Pharmacy 340B Drug Discounts.

**C. Any drug company that, acting alone, restricted Contract Pharmacy 340B Drug Discounts would seriously jeopardize its market share.**

64. Any drug company that restricted the availability of Contract Pharmacy 340B Drug Discounts would put its market share at risk.

65. Hospitals and clinics can and do prefer certain drugs over others. Where drugs are clinically equivalent or therapeutically interchangeable, hospitals and clinics will consider other factors. Those factors can include the cost of the drugs to the patient or hospital/clinic, or the ability of the drug to generate net revenue to support the clinical operations of the hospital/clinic. Typically, a drug with a Contract Pharmacy 340B Drug Discount would be preferred to a clinically equivalent and therapeutically interchangeable drug without a Contract Pharmacy 340B Drug Discount because it would result in 340B Savings.

66. Hospitals and clinics can steer patients towards preferred drugs in various ways. For instance, a hospital or clinic can decide to stock its inventory with one of a series of clinically equivalent or therapeutically interchangeable drugs. If that drug were successfully administered during an outpatient visit, it would more likely be prescribed. As another example, a prescribing physician at a hospital or clinic could choose to start new patients on a particular medicine among a series of clinically equivalent or therapeutically interchangeable drugs. Through these and other actions, hospitals and clinics can influence which drug, out of a series of clinically equivalent or therapeutically interchangeable drugs, is prescribed for their patients.

67. Significantly, however, most efforts to steer patients towards a particular drug, among a series of clinically equivalent or therapeutically interchangeable drugs, require months or years to complete. The efforts are most successful with new patients, who may receive an administered drug for the first time during an outpatient visit or may receive a prescription for a particular type of drug (*e.g.*, an incretin mimetic) for the first time. New patients arrive gradually, which takes time. As for existing patients, any efforts to convert their usage from one drug to another within a series of clinically equivalent or therapeutically interchangeable drugs is typically a slower process.

68. Consequently, the market share of a drug company that limited Contract Pharmacy 340B Drug Discounts would eventually be threatened by competitors that continued to offer clinically equivalent and therapeutically interchangeable drugs to covered entities with Contract Pharmacy 340B Drug Discounts. That

threat, however, would require many months to materialize.

69. Significantly, the threat to each Defendant's market share by restricting Contract Pharmacy 340B Drug Discounts is not limited to the market share of drugs sold at Contract Pharmacies to eligible 340B patients. While the availability of such discounts can influence prescribing patterns—encouraging covered entities to prefer discounted medications over those without discounts—the sweep of such a preference is much broader than drugs dispensed at Contract Pharmacies.

70. If hospitals and clinics end up preferring a drug because it has a Contract Pharmacy 340B Drug Discount, that preference is most likely to be reflected in prescribing and administration patterns through the hospital and clinic. Such a preference thus impacts drugs sold outside of the 340B Program, including drugs dispensed to patients who are not eligible for 340B (*e.g.*, a patient receiving care outside the scope of a grant) or patients who fill their prescriptions at pharmacies that are not participating as Contract Pharmacies.

71. The risk to a drug company's market share in restricting Contract Pharmacy 340B Drug Discounts is thus much larger than simply the loss of the potential sales to 340B eligible patients at Contract Pharmacies. The risk extends to other patients of 340B prescribers, as well as patients who visit pharmacies that are not Contract Pharmacies. These risks would expose a drug company to additional market share losses, and resulting profit losses, if the drug company acted alone in restricting Contract Pharmacy 340B Drug Discounts, when its competitors did not impose such restrictions.

**D. Any drug company that, acting alone and without its competitors, restricted Contract Pharmacy 340B Drug Discounts could seriously jeopardize its participation in federal healthcare programs.**

72. Any drug company that acted alone to restrict the availability of Contract Pharmacy 340B Drug Discounts would also subject itself to exclusion from critical federal healthcare programs, thus jeopardizing its market share and financial viability.

73. Full participation in the 340B Drug Discount Program is required by law for all drug manufacturers participating in Medicaid and certain Medicare federal healthcare programs. Manufacturers must comply with Section 340B for their drugs to be covered under those Medicare and Medicaid programs. *See* 42 U.S.C. §§ 256b(a)(1), 1396r-8(a)(1), (5).

74. Consequently, the market share and financial viability of a drug company that the Government viewed as refusing to fully participate in the 340B Drug Discount Program to the extent required by law would be threatened by the potentially crippling sanction of exclusion from Medicaid and Medicare reimbursements. Such exclusion would, among other things, give competitors an opportunity to gain market share over that excluded manufacturer.

75. No rational manufacturer would risk such sanctions by taking any action that could feasibly lead to that manufacturer's exclusion from these federal healthcare programs.

76. No rational manufacturer would risk acting alone to limit the sale of Contract Pharmacy 340B Drug Discounts because the United States has maintained that

any such limitation violates Section 340B. The Government could feasibly restrict a single manufacturer from federal healthcare programs without unduly undermining the mission of those federal healthcare programs in delivering critical medications to others because the exclusion of one manufacturer would not disrupt the availability of drugs of that manufacturer's competitors.

77. A rational manufacturer would risk acting in coordination with its competitors to limit the sale of Contract Pharmacy 340B Drug Discounts. The reason is that, if a manufacturer of critical medications, such as diabetes medications, conspired with all of the competing manufacturers of such medications, the Government could not feasibly restrict that group of manufacturers from federal healthcare programs. Any effort by the Government to exclude that group of manufacturers would undermine the mission of the federal healthcare programs by disrupting the availability of critical drugs needed by program participants. Thus, any manufacturer could protect itself against the risk of crippling sanctions by conspiring with its competitors.

## II. Defendant drug companies—the same companies that recently limited Contract Pharmacy 340B Drug Discounts—sell competing diabetes medicines, among other competing products.

78. Defendants dominate three of today's most lucrative markets for diabetes treatments: (i) rapid-acting analog insulins; (ii) long-acting analog insulins; and (iii) incretin mimetics. Defendants compete against each other, as horizontal competitors, in these markets.

79. Diabetes occurs when a person has too much glucose (a type of sugar) in their blood stream. Insulin is

involved in the pathway that permits glucose to leave the bloodstream and enter cells. With insufficient insulin, glucose remains at high levels in the blood, leading to high blood sugar levels.

80. There are two types of diabetes. Type 1 diabetes, which is usually diagnosed in children and young adults, is a condition in which the body does not produce any insulin. Type 2 diabetes, which is the more common form, is a condition in which the body either produces insufficient insulin or where cells become resistant to insulin to a certain degree. All patients with Type 1 diabetes require insulin treatments; and about a quarter of patients with Type 2 diabetes require insulin treatments.

81. Diabetes is a widespread disease in the United States. Over 30 million people, making up nearly ten percent of the Nation's population, live with diabetes. It is a life-threatening disease that, for many, requires daily treatments to survive. Absent treatment, diabetes can cause serious harm and organ damage. Moreover, untreated diabetes can lead to diabetic ketoacidosis, which can be fatal. Indeed, according to the Centers for Disease Control and Prevention, diabetes was the seventh leading cause of death in 2019.

82. Diabetes is often coincident with low-income populations and in lower-income neighborhoods that are underserved by private healthcare practices. *See, e.g.*, Gaskin, et al., "Disparities in Diabetes: The Nexus of Race, Poverty, and Place," 104 Am. J. Public Health 2147 (Nov. 2014).

83. Diabetes is likewise a common area of treatment for 340B covered entity hospitals and clinics. According to HRSA, one in seven federally qualified health center

patients has diabetes and nearly one in three of those has uncontrolled diabetes.

84. The National Association of Community Health Centers ("NACHC") has published the results of a survey of federally qualified health centers and look-alike organizations between April and May of 2022. The survey respondents included 302 health centers from 48 States, accurately reflecting, as per NACHC, the general health center patient population. Nearly all the health centers participating in the survey (94%) identified diabetes as a top "disease state[] treated at your health center with medications purchased through the 340B program."

85. Consequently, diabetes medications make up a significant portion of 340B covered entities' outpatient prescriptions and 340B Drug Discounts. And three of the most significant diabetes medications are rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics.

### A. Sanofi, Eli Lilly, and Novo Nordisk compete in the sale of rapid-acting analog insulins.

86. Analog insulins are a type of human insulin. They are an important treatment for diabetes. Indeed, clinicians often prefer analog insulins to other forms of insulin, and the American Diabetes Association recommends analog insulins for the treatment of individuals with both type 1 diabetes and type 2 diabetes.

87. There are both rapid-acting analog insulins and long-acting analog insulins.

88. Sanofi, Eli Lilly, and Novo Nordisk all produce and sell rapid-acting analog insulins. Eli Lilly developed Humalog, the first analog (meaning, man-made) insulin in the mid-1990s; it is a rapid-acting analog insulin that can

be rapidly absorbed. Novo Nordisk then developed its own rapid-acting analog insulin, Novolog, around 2000. And, in 2018, Sanofi launched a follow-on insulin product, Admelog, based on Eli Lilly's Humalog.

89. Since 2019, Eli Lilly has sold Humalog both under the brand name Humalog and as an authorized generic called insulin lispro. Since January 2020, Novo Nordisk has sold Novolog both under the brand name Novolog and as an authorized generic called insulin aspart.

90. Sanofi, Eli Lilly, and Novo Nordisk currently manufacture and sell the following rapid-acting analog insulins, which are clinically equivalent and therapeutically interchangeable, with each drug capturing the approximate market share listed,[2] as of July 2020:

| | **Name** | **Company** | **Approximate Market Share** |
|---|---|---|---|
| **Rapid-Acting Analog Insulins** | Apidra | Sanofi | 6% |
| | Admelog | Sanofi | 5% |
| | Humalog/ Insulin Lispro | Eli Lilly | 44% |
| | Fiasp | Novo Nordisk | 1% |
| | Novolog/ Insulin Aspart | Novo Nordisk | 44% |

[2] *See, e.g.*, Bob Herman, "Insulin net sales over time by company and brand," Axios (Feb. 13, 2020), *at* https://docs.google.com/spreadsheets/d/1PTpcErbuWvUEMhIQpGs0-KnQBdhGgUP4kjygyU1j9b8/edit#gid=0 (based on 2019 sales).

91. Eli Lilly also sells biosimilar versions of Humalog. On June 15, 2020, the FDA approved another Eli Lilly rapid-acting analog insulin, Lyumjev. Eli Lilly began selling Lyumjev in the United States on or about October 7, 2020.

92. In addition to rapid-acting analog insulins, there are rapid-acting recombinant human insulins. Those insulins are Humulin R, sold by Eli Lilly, and Novolin R, sold by Novo Nordisk.

### B. Sanofi, Eli Lilly, and Novo Nordisk compete in the sale of long-acting analog insulins.

93. Another class of insulin are long-acting analog insulins. The American Diabetes Association has described long-acting analog insulin as the "most convenient initial insulin regimen." Am. Diabetes Ass'n, *Approaches to Glycemic Care*, 38 Diabetes Care S52, S57 (2016).

94. Sanofi, Eli Lilly, and Novo Nordisk all produce and sell long-acting analog insulins. Around 2000, Sanofi introduced the first long-acting analog insulin, Lantus. Then, Novo Nordisk introduced its own long-acting analog insulin, Levemir. Those drugs were followed by Toujeo, Sanofi's higher-dose long-acting analog insulin; Tresiba, another long-acting analog insulin from Novo Nordisk; and Basaglar, Eli Lilly's long-acting analog insulin.

95. Sanofi, Eli Lilly, and Novo Nordisk currently manufacture and sell the following long-acting analog insulins, which are clinically equivalent and

therapeutically interchangeable, with each drug capturing the approximate market share listed,[3] as of July 2020:

| | Name | Company | Approximate |
|---|---|---|---|
| **Long-Acting Analog Insulins** | Lantus | Sanofi | 42% |
| | Toujeo | Sanofi | 12% |
| | Basaglar | Eli Lilly | 13% |
| | Levemir | Novo Nordisk | 17% |
| | Tresiba | Novo Nordisk | 17% |

**C. Sanofi, Eli Lilly, Novo Nordisk and AstraZeneca compete in the sale of incretin mimetics.**

96. Another class of diabetes medications, apart from insulins, is the class of incretin mimetics called glucagon-like peptide 1 agonists (GLP-1). These drugs work by increasing the level of hormones called incretins. Incretins help the body produce more insulin and can reduce the amount of excess glucose being produced by the liver.

97. Sanofi, Eli Lilly, Novo Nordisk, and AstraZeneca all produce and sell incretin mimetics. Eli Lilly developed the first incretin mimetic, Byetta (now sold by

[3] *See, e.g.*, Bob Herman, "Insulin net sales over time by company and brand," Axios (Feb. 13, 2020), *at* https://docs.google.com/spreadsheets/d/1PTpcErbuWvUEMhIQpGs0-KnQBdhGgUP4kjygyU1j9b8/edit#gid=0 (based on 2019 sales).

AstraZeneca), from the saliva of a lizard, the gila monster, and introduced it in 2005. Since then, the FDA has approved incretin mimetics by Sanofi, Eli Lilly, Novo Nordisk, and AstraZeneca.

98. Sanofi, Eli Lilly, Novo Nordisk, and AstraZeneca currently manufacture and sell the following incretin mimetics, which are clinically equivalent and therapeutically interchangeable, with each drug capturing the approximate market share listed,[4] as of July 2020:

| | **Name** | **Company** | **Approximate Market Share** |
|---|---|---|---|
| **Incretin mimetics** | Adlyxin | Sanofi | 1% |
| | Trulicity | Eli Lilly | 40% |
| | Victoza | Novo Nordisk | 24% |
| | Ozempic | Novo Nordisk | 28% |
| | Rybelsus | Novo Nordisk | 2% |
| | Bydureon | AstraZeneca | 4% |
| | Byetta | AstraZeneca | 1% |

[4] *See, e.g.*, Bashar Issa, "Things to Consider Before Buying Eli Lilly's Shares," (May 27, 2021), *at* https://seekingalpha.com/article/4431676-things-to-consider-before-buying-eli-lillys-shares (based on year-end 2020 sales data).

**D. In addition, Sanofi, Eli Lilly, Novo Nordisk and AstraZeneca compete in the sale of other drugs.**

99. Defendants manufacture and sell other competing drugs, as well.

100. For instance, Eli Lilly and AstraZeneca both produce competing antipsychotic medications to treat bipolar disorder and schizophrenia. Eli Lilly produces the drug Zyprexa, and AstraZeneca produces the drug Seroquel.

101. But such drugs, along with Defendants' other competing drugs, make up relatively small fractions of Defendants' collective sales of covered outpatient drugs in the 340B Drug Discount Program, compared to their collective sales of rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics.

**E. Defendants report billions of dollars in annual U.S. sales of rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics.**

102. Within the United States, Defendants annually sell billions of dollars of rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics. For each Defendant, these diabetes medications contribute significantly to the company's financial performance, representing hundreds of millions or billions of dollars in annual sales for each company.

103. At Eli Lilly, for instance, rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics are the most significant drugs in the company's portfolio. Trulicity, its incretin mimetic, generated more than twice as much revenue as any other Eli Lilly product in 2020, with U.S. revenues of $3.8 billion. *See* Eli Lilly Annual

Report (2020) at 46. Eli Lilly's second highest revenue generating drugs are its rapid-acting analog insulins, Humalog and Insulin Lispro, which generated U.S. revenue of $1.5 billion. *See id.* Eli Lilly's long-acting analog insulin drug, Basaglar, was also among its highest revenue producing drugs, generating revenue of $842.3 million in the U.S. Together, Eli Lilly's rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics account for $6.2 billion, or nearly 45%, of its 2020 U.S. revenue.

104. These drugs are also a significant part of Eli Lilly's strategy for growth. Eli Lilly announced that its 2020 revenue growth "was driven by increased volume primarily for" a handful of drugs, including Trulicity, *id.* at 45, which had grown by 23% year-over-year, and that Eli Lilly's future "[r]evenue growth is expected to be driven by volume from Trulicity," first among a list of other drugs. *Id.* at 55. Indeed, in 2021, Eli Lilly reported that "[r]evenue of Trulicity . . . increased 28 percent in the U.S." *See* Eli Lilly Annual Report (2021) at 44.

105. At Novo Nordisk, too, rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics are the most significant drugs in the company's portfolio. Together, Novo Nordisk's rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics accounted for approximately $7.3 billion (converted from a reported $44.3 billion DKKs), or 77%, of its 2020 U.S. revenue. *See* Novo Nordisk Annual Report (2020) at 54.

106. These drugs are part of Novo Nordisk's business strategy, as well. Novo Nordisk describes its business, first and foremost, as "a world leader in Diabetes care," with "one of the broadest diabetes product portfolios in the industry, including new generation insulin, a full portfolio of modern insulin and human insulin as well as a portfolio

of GLP-1 receptor agonists [incretin mimetics]." *See* Novo Nordisk Form 20-F (2020) at 5. Novo Nordisk explains that "[d]ue to the increasing number of people with diabetes, the global pharmaceutical market for treatment of diabetes continues to grow." *Id.*at 6. It claims to have "maintained a leading position in the overall diabetes care market" in the United States, among "downward pressure on manufacturers' net prices." *Id.* at 6. It acknowledges that "[i]n the global insulin market, Novo Nordisk, Eli Lilly and Sanofi are the most significant companies measured by market share." *Id.* at 6. As to the incretin mimetics market, Novo Nordisk claims that "the use of glucagon-like peptide-1 (GLP-1) [incretin mimetics] as a treatment option for people with Type 2 diabetes has continued to increase resulting in significant growth of the GLP-1 market." *Id.* at 6. It acknowledges that, in the incretin mimetics market, as in the insulin market, "Novo Nordisk, Eli Lilly and Astra Zeneca are the most significant companies . . . [as] measured by market share," and that, as to incretin mimetics, "Novo Nordisk is the global market leader . . . with a 50% volume market share as of December 31, 2020." *Id.* at 6. Novo Nordisk reported that 2020 sales of diabetes medications increased by 5%, "driven by GLP-1 [incretin mimetics] growth." Novo Nordisk Annual Report (2020) at 29. In reports on 2021 financial results, Novo Nordisk told investors that its "[d]iabetes volume growth remains solid with 4% growth in a large USD 52 billion diabetes market." Novo Nordisk, Investor Presentation at 39 (FY 2021).

107. At Sanofi, rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics make up a significant portion of the company's business and are a defining feature of the company's history. Together, Sanofi's rapid-acting analog insulins, long-acting analog

insulins, and incretin mimetics accounted for approximately $1.7 billion (converted from a reported $1.4 billion Euros) in 2020 U.S. revenue. *See* Sanofi Form 20-F (2020) at 64.

108. Incretin mimetics are a substantial part of AstraZeneca's business, as well as an area targeted for growth. AstraZeneca reported U.S. sales of $382 million for Bydureon in 2020 and $37 million for Byetta. *See* AstraZeneca Annual Report (2020) at 187. Moreover, the company's 2020 annual report highlighted that diabetes is the company's largest therapy area world market, at an estimated size of $99.6 billion, or approximately a full half of the overall therapy markets targeted by the company. *See id.* at 36.

109. Each Defendant is interested in protecting its market share in rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics. Pricing and profits vary for every drug product, but gaining market share is critical to reaping immediate profits or future profits. Thus, all the Defendants have stressed the importance of gaining market shares within these U.S. markets.

110. For instance, Novo Nordisk has highlighted to investors its "strong leadership position within the growing diabetes market," tracking its "market share and share of growth" over time. *See* Novo Nordisk, Investor Presentation at 41 (FY 2021). Novo Nordisk has tracked its insulin market share, by volume and over time, against its competitors, including the other Defendants, highlighting Novo Nordisk's position as the market share leader, *see id.*, and boasting about its leadership position with insulin market share, *see id.* at 42. Novo Nordisk has likewise highlighted its market share in incretin mimetics, emphasizing its market share in the GLP-1 market, and boasting of a "best-in-class marketed portfolio." *Id.* at 49.

111. Likewise, Sanofi has boasted about its "strong position" in the long-acting analog insulin market. *See* Sanofi, IR Thematic Call on Diabetes, Presentation at 29 (June 16, 2014). Sanofi has tracked and highlighted its market share in the United States. *See id.* at 30. Rather than focusing merely on short-term profits, Sanofi has presented the market share issue as one of long-term retention of patients. Sanofi has thus claimed that it is "uniquely positioned to sustain a strong foothold in diabetes with Toujeo® and other new product opportunities." *Id.* at 33.

112. Defendants' concerns with maintaining and growing market share include, but are not limited to, the market share of drugs obtained by 340B eligible patients at Contract Pharmacies. A loss of that market share would be a substantial loss of overall market share. Such a loss would have multiple negative effects on Defendants, including the immediate and longer-term loss of profits relating to those sales.

**F. Defendants' sales of rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics are extremely significant at Contract Pharmacies.**

113. Among the various drugs sold by Defendants, sales of their rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics are particularly significant among sales at Contract Pharmacies serving covered entities' patients.

114. Upon information and belief, the overwhelming majority of Contract Pharmacy 340B Drug Discounts for drugs sold by Defendants at Contract Pharmacies are attributable to their rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics. Upon

information and belief, approximately 80% of covered entities' 340B Savings from Defendants are attributable to Defendants' rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics, whereas all of Defendants' other drugs account for only 20% of 340B Savings at Contract Pharmacies.

## III. In the middle of 2020, Defendants made strident lobbying efforts that failed to limit 340B Drug Discounts for diabetes medicines.

115. Defendants' price-fixing conspiracy began as soon as their collective lobbying efforts failed. Through mid-summer, Defendants had spent millions collectively lobbying the federal government (in efforts not challenged here) to limit 340B Drug Discounts with respect to diabetes medicines. Defendants, as part of long-running lobbying by drug companies, had sought to limit the level of hospital participation in the 340B Program, limit which patients could qualify for 340B Drug Discounts, require that all discounts be passed through to patients, and limit the availability of Contract Pharmacy 340B Drug Discounts. But Defendants' lobbying efforts failed. That failure became evident with the issuance of Executive Order 13937, which did little to limit Contract Pharmacy 340B Drug Discounts.

116. While the lobbying efforts themselves were a failure, the collective effort to lobby brought Defendants together and gave them the opportunity to work together on rolling out coordinated Contract Pharmacy 340B Drug Discount restrictions. Thus, alongside their collective lobbying efforts, Defendants, upon information and belief, developed a fallback plan focused on just one of their goals—collusively eliminating or otherwise limiting Contract Pharmacy 340B Drug Discounts for their drugs, which dominate the rapid-acting analog insulin, long-

acting analog insulin, and incretin mimetic markets of diabetes medications.

**A. The President's July 24th executive order addressing the use of 340B Drug Discounts for insulin promised to have little impact.**

117. On July 24, 2020, then-President Donald Trump issued Executive Order 13937, entitled, "Access to Affordable Life-Saving Medications." *See* 85 Fed. Reg. 45,755 (July 29, 2020). The executive order addressed the use of insulin (as well as epinephrine) within the 340B Drug Discount Program. The order noted that "[i]nsulin is a critical and life-saving medication that approximately 8 million Americans rely on to manage diabetes," and that "[t]he price of insulin in the United States has risen dramatically over the past decade." *Id.* The order further noted that "many Americans still struggle to purchase these products." *Id.*

118. The executive order noted that the 340B Drug Discount lowers the price of insulin for covered entities. The order stated, with significant qualification, that "[t]hese steep discounts, however, are not *always* passed through to low-income Americans at the point of sale." *Id.* (emphasis added). The executive order was aimed at addressing that issue.

119. But the executive order was extremely limited in scope. In particular, it applied only to federally qualified health centers. The President ordered only that HHS should "take action to ensure future grants . . . are conditioned upon [federally qualified health centers] having established practices to make insulin . . . available at the discounted price paid by the [federally qualified health center] grantee or sub-grantee under the 340B Prescription Drug Program (plus a minimal

administration fee) to individuals with low incomes, . . . who: (a) have a high cost sharing requirement for . . . insulin; (b) have a high unmet deductible; or (c) have no health care insurance." *Id.*

120. Executive Order 13937 promised to have relatively little impact on the volume of 340B Drug Discounts for insulin medications for several reasons.

121. *First*, because the order was limited to federally qualified health centers, it would have no impact on any of the other categories of covered entities. The order did not apply to any of the other nine categories of clinics that can be covered entities. Nor did it apply to any hospital covered entities.

122. *Second*, the order appeared to impose largely redundant legal requirements. Federally qualified health centers are funded through Section 330 of the Public Health Services Act, 42 U.S.C. § 254b. Under that authority, HHS "may make grants for the costs of the operation of public and nonprofit private health centers that provide health services to medically underserved populations." 42 U.S.C. § 254b(e)(1)(A). For a health center to obtain such funding, it must provide "the required primary health services" set out in the statute. 42 U.S.C. § 254b(k)(3)(A). And those "required primary health services," by definition, include the provision of "pharmaceutical services." 42 U.S.C. § 254b(b)(1)(A)(i)(V). Moreover, under HRSA's Health Center Compliance Manual, health centers "must operate in a manner such that no patient shall be denied service due to an individual's inability to pay," and are already obligated to provide a "full discount to individuals and families with annual incomes at or below [the poverty line]." So, it was unclear what real effects the executive order might have in changing patient prices for insulin.

123. *Third*, and relatedly, the executive order did not appear to impact sales of insulin medication to federally qualified health centers in the 340B Program. As noted, federally qualified health centers must ensure their patients have access to drugs. Those centers would seek to do so at the best price. Requiring federally qualified health centers to pass all 340B Savings onto patients would not change the health centers' incentives—they would still seek to purchase the same volume of drugs, with Contract Pharmacy 340B Drug Discounts included. So, as long as federally qualified health centers purchased the same volume of drugs and, as per the executive order, continued to do so with Contract Pharmacy 340B Drug Discounts, insulin-manufacturers' profit margins would be unaffected.

**B. The executive order followed Defendants' apparently unsuccessful but coordinated lobbying efforts to limit 340B Drug Discounts for diabetes medication.**

124. Upon information and belief, Defendants worked together to lobby the Federal Government, including HHS and White House, to obtain legal or agency guidance changes to limit 340B Drug Discounts, particularly for diabetes medicines like analog insulin and incretin mimetics. This allegation is supported by Defendants' lobbying records.

125. In the reporting periods that encompassed lobbying in advance of the President's executive order (*i.e.*, April 1 through June 30, and July 1 through September 30), Defendants spent significant resources lobbying the Federal Government. According to their public disclosures, each Defendant in that period lobbied the Federal Government regarding the 340B Program: Sanofi spent upwards of $320,000 on external lobbyists

and upwards of $1.9 million of its own resources on that effort; Eli Lilly spent upwards of $290,000 on external lobbyists and upwards of $3.18 million of its own resources; Novo Nordisk spent upwards of $250,000 on external lobbyists and upwards of $90,000 of its own resources; and AstraZeneca spent upwards of $240,000 on external lobbyists and upwards of $1.23 million of its own resources on that effort. In total then, Defendants report spending upwards of $1.1 million on external lobbyists and upwards of $6.4 million of their own resources lobbying 340B Drug Discounts in this short period.

126. Not only were Defendants lobbying the Federal Government as to 340B Drug Discounts, but they were also lobbying regarding insulin and other diabetes medication issues. The three Defendants dominating the analog insulin markets—Sanofi, Eli Lilly, and Novo Nordisk—all report lobbying insulin issues alongside 340B Drug Discount issues. And both Novo Nordisk and AstraZeneca report lobbying diabetes issues at the same time.

127. Defendants were coordinated in their lobbying during this time period, both in terms of issues as set out above and in terms of lobbyists. They used common lobbyists. For instance, all four Defendants report that, in this period, they used the lobbying firm, Tarplin, Downs & Young LLC to lobby the Federal Government on the 340B Drug Discount issue, and concomitantly, insulin or diabetes. Further, in the same period, both Sanofi and AstraZeneca used the lobbying firm W Strategies, LLC to lobby 340B Drug Discounts. And Sanofi, Eli Lilly, and Novo Nordisk used the common lobbying firm Williams and Jensen, PLLC to lobby the same issue in this same period. Moreover, some of these lobbyists frankly

revealed that their lobbying focused on "Executive Orders regarding drug pricing," including Executive Order 13937.

128. This common effort allowed Defendants to coordinate and communicate about their strategies on limiting 340B Drug Discounts, including Contract Pharmacy 340B Drug Discounts, for diabetes medications such as analog insulins and incretin mimetics. Defendants were speaking with the same lobbying firms about the same issues at the same time. At the very least, they were communicating indirectly, through these common firms.

129. It is much more likely that Defendants were also communicating directly about their lobbying strategies with their common lobbyists. Significantly, the common lobbying firms—including Tarplin, Downs & Young and Williams and Jensen, PLLC—reported working on these same 340B issues during this same period for the drug manufacturers' association, PhRMA. Each Defendant is a member of PhRMA. Given the common lobbying firms working for each Defendant and their common association in the same time period on the same issues, all in advance of an executive order on those issues, it is most likely that Defendants would have been on common calls to discuss strategy. Upon information and belief, in advance of the President's issuance of Executive Order 13937, Defendants communicated directly with each other about strategies for limiting 340B Drug Discounts.

130. Upon information and belief, Defendants' lobbying efforts focused on the four strategies that the pharmaceutical industry and its advocates had long pursued to limit 340B Drug Discounts: (1) limiting the level of hospital participation in the 340B Program, (2) limiting which patients could qualify for 340B Drug Discounts, (3) requiring that all discounts be passed

through to patients, and (4) limiting the availability of Contract Pharmacy 340B Drug Discounts.

131. Defendants lobbying efforts largely failed, as Defendants were unable to obtain meaningful changes to the availability of 340B Drug Discounts through lobbying. The drug companies' perception that Executive Order 13973 was largely meaningless is reflected in the tweets of AIR340B, a drug company association aimed at limiting the scope of the 340B Program, which hosts a webpage dedicated to challenging the propriety of Contract Pharmacy 340B Drug Discounts. *See* AIR340B, "Contract Pharmacies' Troubling Role in the 340B Drug Discount Program" (last visited May 14, 2021). In the wake of the executive order, AIR340B tweeted, "[T]he administration's executive order on insulin and #340B . . . misses the mark by not targeting the large hospitals;" "this narrow change does not address the myriad of remaining issues that prohibit 340B from currently functioning as it was intended;" and "we are disappointed the administration targeted FQHCs, not DSH hospitals."

132. While these lobbying efforts largely failed, the collective lobbying effort provided Defendants with the opportunity to jointly develop a collective fallback plan focused on just one of their strategies—a coordinated restriction of Contract Pharmacy 340B Drug Discounts.

## IV. Joint lobbying efforts gave Defendants an opportunity to coordinate their rollback of Contract Pharmacy 340B Drug Discounts.

### A. Defendants imposed their restrictions in near lockstep in the second half of 2020.

133. Defendants engaged in a coordinated campaign to limit Contract Pharmacy 340B Drug Discounts. That plan went into effect as soon as the President's executive

order was released. Defendants' announcements were so immediate, in fact, that the plan must have been developed before the release of, and not simply in response to, the executive order. While every other major pharmaceutical company continued to offer Contract Pharmacy 340B Drug Discounts, the four Defendants—competitors against each other for diabetes medicines—quickly announced novel restrictions on Contract Pharmacy 340B Drug Discounts. While Defendants did not announce their plans at identical times, they announced restrictions closely enough to each other to prevent covered entities from moving business from one Defendant to another. Defendants' coordinated campaign succeeded in drastically reducing Contract Pharmacy 340B Drug Discounts in the three diabetes medication markets they dominated, dramatically raising prices and gutting 340B Savings for safety-net hospitals and clinics.

134. On Friday, July 24, 2020, the same day that President Trump issued Executive Order 13937, AstraZeneca informed HHS of the drug company's intention to limit Contract Pharmacy 340B Drug Discounts. It did so by letter from Christie Bloomquist, AstraZeneca's Corporate Affairs Vice President for North America, to Rear Admiral Krista Pedley, the Director of HRSA's Office of Pharmacy Affairs. The letter stated that, "Beginning on October 1, 2020, AstraZeneca plans to adjust [its] approach for the products listed," "such that AstraZeneca will recognize one contract pharmacy per covered entity for those covered entities that do not maintain an on-site dispensing pharmacy." The products listed included AstraZeneca's incretin mimetics, Bydureon and Byetta.

135. In its Friday, July 24th letter to HHS, AstraZeneca did not explain the timing of its sudden

change in approach to Contract Pharmacy 340B Drug Discounts. Rather, AstraZeneca made a legal argument based on the text of the 1992 statute, as well as the text of the 1996 notice. The letter also referenced audits that had been taking place since 2017. But, significantly, nothing in the letter explained why AstraZeneca was deciding, in late 2020, to completely change its approach to Contract Pharmacy 340B Drug Discounts. AstraZeneca did not make its plan public until mid-August 2020, when it told covered entities that, beginning on October 1, 2020, it would no longer provide "340B pricing" to all Contract Pharmacies but, instead, "recognize [only] one Contract Pharmacy per Covered Entity" and only "for those Covered Entities that do not maintain an on-site dispensing pharmacy."

136. Yet, within days of AstraZeneca's privately communicated letter to HRSA, Sanofi publicly announced its sudden plans to impose similarly novel restrictions on Contract Pharmacy 340B Drug Discounts—and on the exact same timeline. Sanofi was, at the time, a $132 billion company; and it would have been virtually impossible for Sanofi to have vetted and cleared such a dramatic and unprecedented change in its pricing practices on a few days' notice. Yet, just a single business day after AstraZeneca's Friday announcement, on Monday, July 27, 2020, Sanofi informed all 340B Program covered entities that Sanofi would be "implementing a new 340B program integrity initiative." That "initiative" would cut off all Contract Pharmacy 340B Drug Discounts, which had been in place for a decade, unless covered entities provided new consideration to Sanofi. The newly required consideration was entry into a contract to provide sensitive prescription claims data to a Sanofi vendor, Second Sight Solutions, through a software portal called 340B ESP on

commercially unreasonable terms (as more fully explained below). Otherwise, "340B claims data [would] no longer be eligible" for Contract Pharmacy 340B Drug Discounts. Significantly, Sanofi announced that the date it would begin limiting Contract Pharmacy 340B Drug Discounts was October 1, 2020—the same date that AstraZeneca would limit Contract Pharmacy 340B Drug Discounts, too. As described in further detail below, the immediate impact of Sanofi's restrictions was the same as that resulting from AstraZeneca's restrictions—nearly eliminating 340B Drug Discounts on diabetes drugs as of October 1, 2020.

137. Only three weeks later, Eli Lilly informed HHS of the drug company's intention to limit Contract Pharmacy 340B Drug Discounts in nearly the precise manner AstraZeneca had privately outlined in its letter to HHS. By letter dated August 19, 2020, Eli Lilly's Senior Director of Government Strategies sent a letter to Rear Admiral Krista Pedley, the Director of HRSA's Office of Pharmacy Affairs, just as Christie Bloomquist at AstraZeneca had done. The letter stated the same plan as AstraZeneca, albeit commencing one month earlier: "[E]ffective September 1, [2020], we . . . [will] discontinue our practice of voluntarily honoring requests for 340B 'contract pharmacies' for orders on all Lilly products except where," primarily, "a covered entity does not have an in-house pharmacy."

138. Eli Lilly added a special exception to permit Contract Pharmacies to pass along certain insulin products at cost. But that exception was infeasible for covered entities and pharmacies, as it required the Contract Pharmacies to fill prescriptions without any fee whatsoever. Specifically, Eli Lilly stated that it would offer the Contract Pharmacy 340B Drug Discount only where "[n]o insurer or payer is billed for the Lilly insulin

dispensed" and "[n]either the covered entity nor the contract pharmacy marks-up or otherwise charges a dispensing…fee for the Lilly insulin." This exception was so narrow that it was virtually meaningless: Lilly prevented the collection of any revenue by a covered entity to offset the dispensing fee the covered entity would have to pay the Contract Pharmacy. This exception was commercially infeasible, as Eli Lilly understood.

139. Eli Lilly, like AstraZeneca and Sanofi, offered no explanation why suddenly, after a decade of offering Contract Pharmacy 340B Drug Discounts, Eli Lilly decided to stop them in late 2020. The absence of an explanation was particularly strange because, months earlier, Eli Lilly had informed HHS of a much narrower change to its Contract Pharmacy 340B Drug Discounts—ceasing to offer discounts on a single drug, Cialis. Eli Lilly informed HHS of that decision just two months earlier, by letter dated May 18, 2020. But while the May 18 letter cited global concerns with Contract Pharmacies, it announced the decidedly narrower action of simply ceasing to offer discounts on Cialis. In May 2020, Eli Lilly did not inform HHS that it would cease to offer Contract Pharmacy 340B Drug Discounts altogether. Significantly, Eli Lilly did not then announce any restrictions on Contract Pharmacy 340B Drug Discounts for its rapid-acting analog insulins (Humalog and Insulin Lispro), its long-acting analog insulin (Basaglar), or its incretin mimetic (Trulicity). Eli Lilly first announced those restrictions, instead, only in coordination with AstraZeneca and Sanofi in the summer of 2020.

140. Novo Nordisk waited several more months before announcing that it would stop offering Contract Pharmacy 340B Drug Discounts to hospital covered entities. On December 1, 2020, Novo Nordisk informed

HHS of the drug company's policy. In particular, Novo Nordisk, along with its competitors AstraZeneca, Eli Lilly, and Sanofi, would limit the availability of Contract Pharmacy 340B Drug Discounts. The Novo Nordisk restrictions were a variation on the competitors' theme—it would stop offering Contract Pharmacy 340B Drug Discounts to all hospital covered entities. Novo Nordisk announced that this restriction would be effective on January 1, 2021.

141. Defendants have since made minor changes to their exceptions, while maintaining their common approach of refusing to offer Contract Pharmacy 340B Drug Discounts for the overwhelming majority of potential Contract Pharmacy sales. By letter dated February 2, 2021, Sanofi purported to limit its restrictions to five covered entity types, effective March 1, 2021: consolidated health center programs, disproportionate share hospitals, critical access hospitals, rural referral centers, and sole community hospitals.

142. On December 16, 2021, Eli Lilly announced that it was adopting Sanofi's approach of "utilizing the 340B ESP Second Sight Solutions platform" to "permit 340B purchases" by covered entities for drugs shipped to Contract Pharmacies with Contract Pharmacy 340B Drug Discounts if "the covered entity agrees to provide, and does provide on an ongoing basis, claims-level data associated with such contract pharmacy orders" through the 340B ESP platform. And, on January 24, 2022, Novo Nordisk announced that it would "modify its policy regarding 'bill-to/ship-to' distribution of 340B product to a contract pharmacy," such that if "a 'hospital' covered entity does not have wholly owned contract pharmacies, that covered entity will be permitted to designate a total of *two* contract pharmacy locations—one retail pharmacy,

and one specialty pharmacy (as determined by Novo Nordisk) —to which product purchased by the covered entity may be shipped."

143. Each Defendant attributed its restrictions to purported concerns about program integrity. No Defendant cited any immediate cause for its sudden and unprecedented restrictions. None claimed the failure of their lobbying efforts was the trigger. None offered any explanation why it alone would impose such restrictions at that point in time. Eli Lilly claimed it was acting in response to abuses of the 340B Program that had been increasing over the years. *See* Eli Lilly Letter dated Aug. 19, 2020, at 1. AstraZeneca referenced audits that had been taking place since 2017. *See* AstraZeneca Letter dated July 24, 2020, at 3. Novo Nordisk offered no explanation, but has since publicly stated its restrictions were likewise based on concerns of "systemic abuses," *see* Compl., *Novo Nordisk, Inc. v. HHS*, 21-cv-806, Dkt. 1 (D.N.J. Jan. 15, 2021). And Sanofi cited general program integrity concerns. *See* Sanofi Letter of July 2020. None of those rationales explained why Defendants suddenly announced and imposed their discount restrictions in late 2020.

### B. Defendants imposed their restrictions in the same manner—primarily, by refusing to permit sales of 340B Drugs to covered entities for shipment to Contract Pharmacies.

144. Defendants imposed their restrictions through a common and shared policy of primarily refusing to permit the sale of 340B Drugs to covered entities for shipment to Contract Pharmacies. Until Defendants simultaneously implemented this novel and common policy, it was unprecedented in the history of the 340B Drug Program.

145. Sanofi imposed its restrictions primarily through Defendants' shared policy of refusing to permit the sale of 340B Drugs to covered entities for shipment to Contract Pharmacies. As part of Sanofi's announcement of its restrictions to covered entities on July 27, 2021, Sanofi explained that "340B covered entities that elect not to provide 340B claims data will no longer be eligible to place Bill To / Ship To replenishment orders for Sanofi products dispensed through a contract pharmacy."

146. Sanofi has since repeatedly explained that its policy is not to permit the sale of its drugs to covered entities for shipment to Contract Pharmacies. Sanofi restated this position in a complaint against HHS filed on January 12, 2021, stating that, under its restrictions, a covered "entity simply may not order discounted drugs for shipment to contract pharmacies." Compl., ¶ 48, *Sanofi-Aventis v. HHS*, 3:21-634, Dkt. 1 (D.N.J. Jan. 12, 2021). In its amended complaint in the same action, Sanofi stressed that its policy means that "a covered entity is not 'overcharged'—indeed, it typically is not charged at all," because Sanofi sells such drugs directly to pharmacies, not to the covered entities. Second Am. Compl., ¶ 177, *Sanofi-Aventis v. HHS*, 3:21-634, Dkt. 78 (D.N.J. May 25, 2021). Then, again, by letter to HRSA dated June 1, 2021, Sanofi reiterated that its primary method for restricting covered entity access to 340B Drugs is by refusing to make its drugs available to covered entities, such that "[o]nly the pharmacy is charged, and . . . no covered entity is charged." *See* Letter to HRSA, dated June 1, 2021, at 24.

147. Likewise, Eli Lilly imposed its restrictions primarily through Defendants' shared policy of refusing to permit the sale of 340B Drugs to covered entities for shipment to Contract Pharmacies. As part of Eli Lilly's initial announcement of its restrictions to covered entities,

it explained that "[e]ffective September 1, 2020, Lilly is limiting distribution of all 340B ceiling priced product directly to covered entities and their child sites only." "Covered entities," it announced, would no longer "be eligible to purchase Eli Lilly and Company products at the 340B ceiling price for shipment to a contract pharmacy."

148. Eli Lilly has also since repeatedly explained that its policy is not to permit the sale of its drugs to covered entities for shipment to Contract Pharmacies. By letter dated December 16, 2021, Eli Lilly reiterated to covered entities that, "since September 1, 2020," it had "limited distribution of all 340B ceiling-priced products" directly to covered entities, excluding Contract Pharmacies. Similarly, Eli Lilly told the U.S. District Court for the Southern District of Indiana that it has a "policy of not delivering 340B drugs to contract pharmacies," explaining that its refusal to sell means that "Lilly's policy will not result in any overcharge because there is no order and no sale." Eli Lilly Mem. at 29, *Eli Lilly*, 1:21-cv-81, Dkt. 129 (S.D. Ind. July 14, 2021).

149. Novo Nordisk similarly imposed its restrictions primarily through Defendants' shared policy of refusing to permit the sale of 340B Drugs to covered entities for shipment to Contract Pharmacies. When Novo Nordisk announced its restrictions on December 1, 2020, it explained that it would impose its restrictions by "curtail[ing]" any "Novo Nordisk-facilitated shipment of [its] product to contract pharmacies." To impose their restrictions, Novo Nordisk would "no longer facilitate 'bill-to/ship-to' distribution of 340B product to a contract pharmacy."

150. Novo Nordisk has since repeatedly explained that its policy is not to permit the sale of its drugs to covered entities for shipment to Contract Pharmacies. In

a letter to HRSA dated June 1, 2021, Novo Nordisk explained that it "refus[es] to transfer drugs to contract pharmacies," such that there is generally "no charge to any covered entity" for such drugs." In this litigation, Novo Nordisk has explained to the Court that its policy, along with the "other manufacturers" in this case is not "to transfer their discounted drugs to contract pharmacies for the convenience of covered entities." Novo Nordisk Mem. at 2, Dkt. 48.

151. AstraZeneca too has imposed its restrictions primarily through Defendants' shared policy of refusing to permit the sale of its 340B Drugs to covered entities for shipment to Contract Pharmacies. In announcing its restrictions in August 2020, AstraZeneca explained that covered entities would not "be able to purchase [the companies'] products" at Contract Pharmacies, except under limited circumstances.

152. AstraZeneca has since repeatedly explained that its policy is not to permit the sale of its drugs to covered entities for shipment to Contract Pharmacies. AstraZeneca told the U.S. District Court for the District of Delaware that, under its policy of refusing to ship, "[t]o the extent that a patient of the covered entity fills her prescription at a pharmacy not [permitted by] AstraZeneca's policy, the dispensed medicine," going forward, would not have been "sold to the covered entity, but rather" would have been "purchased by the pharmacy." AstraZeneca Mem. at 23, *AstraZeneca Pharm. LP v. Becerra*, 21-cv-27, Dkt. 91 (D. Del. July 23, 2021). Under this policy, "there is no sale at all to the covered entity," who typically cannot obtain AstraZeneca's drugs for shipment to Contract Pharmacies, and thus is "never charged."

153. Although each Defendant has primarily imposed its restrictions through the common policy of refusing to sell drugs to covered entities for shipment to Contract Pharmacies, none of the Defendants has been able to implement this policy comprehensively. Accordingly, at times, drugs from each Defendant have been shipped to Contract Pharmacies and charged to covered entities; in those instances, the drugs were sold to the covered entities at wholesale, rather than 340B Drug Discount, prices. Under this scenario, covered entities pay significantly more for their purchases of 340B eligible drugs than they would have paid if the drugs had been purchased through their own accounts with 340B Drug Discounts.

### C. Defendants' abrupt changes in pricing practices were historically unprecedented.

154. Defendants' abrupt limitation of Contract Pharmacy 340B Drug Discounts were historically unprecedented.

155. Prior to Defendants' actions in late 2020, each company had regularly offered Contract Pharmacy 340B Drug Discounts for a decade.

156. Indeed, prior to Defendants' actions in 2020, the entire pharmaceutical industry—including all of the largest 250 drug companies, as well as every drug company with drugs covered by Medicaid and Medicare Part B—had regularly offered Contract Pharmacy 340B Drug Discounts for their covered outpatient drugs for at least a decade.

157. Moreover, shortly before its coordination with the other Defendants, Eli Lilly had considered withdrawing Contract Pharmacy 340B Drug Discounts and decided against doing so, outside of a very narrow set

of certain Cialis formulations. Eli Lilly abruptly changed its approach in coordination with the other Defendants.

**D. Defendants—direct competitors in three diabetes medication markets—were alone in imposing these restrictions, as thousands of other pharmaceutical companies did not.**

158. Not a single other major pharmaceutical company joined the Defendants in their coordinated scheme to limit or eliminate Contract Pharmacy 340B Drug Discounts at the time they did so.

159. In 2020, two top drug manufacturers—Merck and Novartis—asked covered entities to participate in the same software program mandated by Sanofi. But, unlike Sanofi, neither Merck nor Novartis cut off Contract Pharmacy 340B Drug Discounts for covered entities unwilling to participate. A much smaller drug company, United Therapeutics, announced plans to restrict Contract Pharmacy 340B Drug Discounts, but it has not implemented that policy.

160. It was not until late 2021 that any major drug company implemented any similar restrictions on Contract Pharmacy 340B Drug Discounts. They did so more than a year after Defendants announced their restrictions. Specifically, Boehringer Ingelheim imposed restrictions beginning on August 1, 2021, and Merck imposed restrictions beginning on September 1, 2021. Merck, however, limited its restrictions mainly to antidiabetic drugs, such as Januvia, Janumet, Segluromet, and Steglatro. Other manufacturers initiated restrictions later, in 2022.

161. Defendants comprise fewer than 0.4% of the more than 1,000 drug companies that have signed PPAs with HHS.

162. Defendants, as direct competitors with each other in three key markets for diabetes medications, have restricted Contract Pharmacy 340B Drug Discounts.

163. When Defendants imposed their restrictions, the other more than 99.6% of drug companies continued to offer Contract Pharmacy 340B Drug Discounts without restrictions. Those drug companies include some of the largest drug companies, such as Roche, Johnson & Johnson, Pfizer, AbbVie, Amgen, Bristol Myers Squibb, GlaxoSmithKline, Gilead, Bayer, Biogen, Takeda, Bausch Health, Alexion, and Regeneron, as well as more than a thousand others.

164. Defendants' common attribute, as the very few drug companies that had announced substantial restrictions on Contract Pharmacy 340B Drug Discounts by the end of 2020, is their joint domination of the three key diabetes medication markets. As of July 2020, Defendants controlled the entire market for each of those markets: (i) rapid-acting analog insulins; (ii) long-acting analog insulins, and (iii) incretin mimetics. They had no competition.

**E. Defendants imposed these restrictions, despite Government warnings that doing so could violate other laws and may result in severe sanctions.**

165. Defendants' novel restrictions were unusual not only because they were imposed after a decade of offering Contract Pharmacy 340B Drug Discounts or because they were imposed by Defendants alone among major pharmaceutical companies, but also because they were imposed despite warnings by regulators that such restrictions were illegal.

166. On September 2, 2020, HRSA released a public statement to the *340B Report*, an online media outlet, that HHS was "considering whether manufacturer policies [restricting Contract Pharmacy 340B Drug Discounts], including Lilly's, violate the 340B statute and whether sanctions may apply."

167. On September 21, 2020, HRSA posted a letter to its public website warning manufacturers of potentially dire consequences for restricting Contract Pharmacy 340B Drug Discounts. The letter was signed by HHS General Counsel, Robert P. Charrow. The letter was addressed to Eli Lilly, but shared publicly. In it, HRSA stated that it had "significant initial concern with Lilly's new policy" to "cease extending 340B pricing to pharmacies under contract with covered entities." HRSA went so far as to warn Eli Lilly, and, by extension, any other manufacturers who might impose restrictions on Contract Pharmacy 340B Drug Discounts, that a "False Claims Act suit . . . against Lilly is a potential consequence in the event that Lilly knowingly violates a material condition of the program that results in over-charges to grantees and contractors." False Claims Act violations trigger treble damages and penalties.

168. On October 6, 2020, the Office of the Attorney General of the State of Connecticut sent letters to Sanofi, AstraZeneca, and Eli Lilly, "urg[ing] [each] to abandon its recent actions of unilaterally restricting access to low cost drug pricing by covered entities." The letters stated that the companies' "threats to flout federal requirements and discontinue appropriate 340B drug pricing are especially appalling given that these critical safety-net healthcare institutions are on the front lines of our response to the ongoing COVID-19 pandemic." The letters deemed the companies' actions "outrageous." Moreover, the

Connecticut Attorney General stated that "[d]enying outpatient access to appropriate 340B drug pricing is a clear violation of federal law," which "disrupt[s] long-settled expectations and existing contractual arrangements for dispensing 340B drugs." The Attorney General ended his letter with the threat that his "office will not stand idly by while Eli Lilly and other drug companies prioritize profits over access to affordable prescription medication and other critical medical services for vulnerable communities."

169. The next day, the Connecticut Attorney General issued a press release announcing his letters to Sanofi, Eli Lilly, and AstraZeneca. The press release was entitled, "AG Tong Demands Drug Makers Abandon Unlawful Actions Imperiling Access to Affordable Prescriptions for Low-Income Patients." The press release included a hyperlink to the letters to drug manufacturers.

170. On December 20, 2020, HHS General Counsel Robert P. Charrow issued an eight-page single-spaced advisory opinion concluding that restrictions on Contract Pharmacy 340B Drug Discounts were illegal under the terms of Section 340B. *See* HHS General Counsel, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program (Dec. 30, 2020). The opinion noted, in a reference to the actions of Defendants, that "[r]ecently, certain drug manufacturers participating in the 340B Program are declining to distribute covered outpatient drugs through contract pharmacies at the ceiling price" (*i.e.*, with Contract Pharmacy 340B Drug Discounts). *See id.* at 1. The opinion noted that "[f]or 24-plus years, manufacturers have offered the ceiling price to covered entities using contract-pharmacy distribution." *Id.* at 5 n.5. For reasons detailed in the opinion, HHS concluded that "covered entities under the 340B Program are

entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients." *Id.* at 8.

171. The same day, HHS issued a press release announcing its advisory opinion. The press release was entitled, "HHS Releases Advisory Opinion Clarifying that 340B Discounts Apply to Contract Pharmacies." The press release included a hyperlink to the advisory opinion.

172. Soon thereafter, the United States Department of Justice (DOJ) reiterated the harshest sanction for 340B noncompliance, which the 340B statute makes plain: "Pharmaceutical companies [that] opt out of providing discounted drugs to safety-net healthcare providers and their low-income patients . . . lose access to 'billions of dollars in revenue' annually through drug coverage in federal health-insurance programs," particularly "coverage of their products under Medicaid and Medicare Part B." Gov't Mem. at 2-3, *Sanofi-Aventis v. HHS*, 3:21-cv-634, Dkt. 29 (D.N.J. Feb. 25, 2021); Gov't Mem. at 3, *Eli Lilly v. Becerra*, 1:21-cv-81, Dkt. 88 (S.D. Ind. Apr. 20, 2021) (same); *see also* Gov't Mem. at 7, *Novo Nordisk v. HHS*, 3:21-cv-806 (D.N.J. June 22, 2021) ("The statute conditions Medicaid and Medicare Part B access on Astra's adherence to the 340B statutory scheme . . .."); Gov't Mem. at 11, *AstraZeneca Pharms. LLP v. HHS*, 1:21-cv-27, Dkt. 93 (D. Del. July 23, 2021) (same).

173. On May 17, 2021, HRSA sent letters to each Defendant demanding that each "restart selling, without restriction, covered outpatient drugs at the 340B price to covered entities that dispense medications through contract pharmacy arrangements." The letters stated

HRSA's conclusion that the Defendants' restrictions "are in direct violation of the 340B statute." Moreover, the letters warned each Defendant of potentially massive civil monetary penalties of up to $5,883 per instance of overcharge.

174. On June 18, 2021, the Office of General Counsel for HHS announced its intention to pursue Defendants for unlawfully restricting the availability of Contract Pharmacy 340B Drug Discounts. The Notice withdrew the legal opinion of December 20, 2020, "in the interest of avoiding confusion." But the Notice made clear that "its withdrawal of the Opinion does not impact the ongoing efforts of the Health Resources and Services Administration (HRSA) to enforce the obligations that 42 U.S.C. § 256b places on drug manufacturers, including HRSA's May 17, 2021 violation letters concerning restrictions placed on contract pharmacy arrangements."

175. On September 22, 2021, HRSA sent letters to each Defendant announcing a referral to the HHS Office of the Inspector General (OIG) for violating the law. Each letter recounted that on "May 17, 2021, HRSA instructed" each Defendant "to comply with its 340B statutory obligations and to immediately begin offering [340B Drug Discounts] to covered entities that dispense the discounted medications through their contract pharmacy arrangements," and that HRSA had informed each Defendant "that continued failure to provide the 340B price to covered entities utilizing contract pharmacies could result in civil monetary penalties." The letters then stated that, given each Defendant's "continued refusal to comply, HRSA has referred this issue to the HHS Office of the Inspector General (OIG) in accordance with the 340B Program Ceiling Price and Civil Monetary Penalties Final Rule."

176. Despite these warnings from regulators, Defendants persisted in restricting access to Contract Pharmacy 340B Drug Discounts. Defendants did so, notwithstanding the potential exclusion of Medicaid and Medicare coverage of their drugs.

### F. Defendants' coordinated restrictions had the common effect of ending the vast majority of Contract Pharmacy 340B Drug Discounts for their drugs.

177. The immediate impact of Defendants' coordination was the same across all four manufacturers—the end of the overwhelming majority of Contract Pharmacy 340B Drug Discount sales to covered entities. This outcome was readily predictable and identical among all four drug companies. Notwithstanding variations in the Defendants' sets of exceptions, their common shared innovation of restricting Contract Pharmacy 340B Drug Discounts ultimately achieved the same result among all Defendants—the elimination of the bulk of their Contract Pharmacy 340B Drug sales.

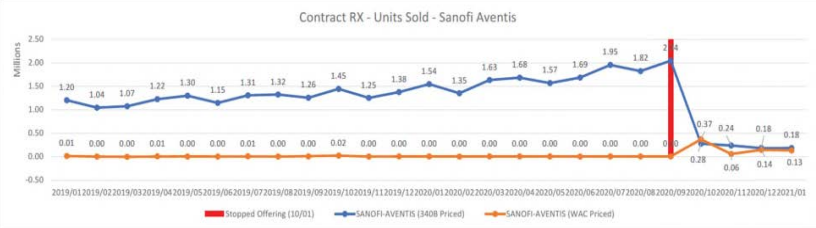
178. These outcomes have had the most significant impact as to diabetes drugs. A September 2021 report by 340B Health, an association of covered entities, concluded that "[t]he impact of these restrictions has been the greatest for diabetes drugs." 340B Health, The Impact on Diabetes of Restrictions on 340B Community Pharmacies (Sept. 15, 2021).

#### 1. Sanofi's restrictions led to the elimination of the overwhelming majority of Sanofi's Contract Pharmacy 340B Drug Discount sales.

179. Sanofi's restrictions led to the immediate and sustained cessation of the overwhelming majority of Contract Pharmacy 340B Drug Discounts sales of Sanofi's

rapid-acting insulins, long-acting insulins, and incretin mimetics, among other drugs.

180. Government-compiled drug sales data demonstrates that the immediate and sustained impact of Sanofi's restrictions, from their inception in October 2020 through at least the end of the period of available data in early 2021, was the near elimination of Contract Pharmacy 340B Drug Discounts. That data shows a dramatic decline in Contract Pharmacy 340B Drug Discount sales as soon as Sanofi introduced its restrictions effective October 2020, with loss of the overwhelming majority of such sales consistently through the remainder of the period of available sales data, at least through January 2021:




181. This same data shows the corresponding dramatic decline in 340B Savings from Contract Pharmacy sales of Sanofi's drugs, immediately following the introduction of its restrictions effective October 2020. Specifically, the Government compiled data showing monthly 340B Savings arising from Contract Pharmacy transactions, expressed as "Savings from WAC." WAC means Wholesale Acquisition Cost, and reflects manufacturer list prices. The Government's data shows an immediate and dramatic decline in October 2020:


182. As DOJ has concluded, Sanofi's so-called "integrity initiative' caused 340B sales to plummet *in one month* from 2.04 million units to only .28 million units," with "[m]onthly savings to covered entities dropp[ing] from $54.2 million just before its 'integrity initiative' to only about $5 million within two months." Gov't Mem. at 10, *Sanofi-Aventis v. HHS*, 3:21-cv-634, Dkt. 89 (D.N.J. June 16, 2021). That reflects an immediate decrease in Contract Pharmacy 340B Drug Discount sales of more than 86% by units and by more than 90% by savings.

183. This "plummet" of Contract Pharmacy 340B Drug Discount sales arose directly from Sanofi's restrictions. As DOJ has further concluded, "[b]y January 2021, Sanofi's restrictions represented an average lost savings to covered entities of $43.4 million monthly."

184. Indeed, in the immediate wake of Sanofi's restrictions, Contract Pharmacies became unable to receive the overwhelming majority of shipments of covered entities' desired drug purchases. An example is Avita Pharmacy, "a national chain that almost exclusively contracts with and dispenses for covered entities, including community health centers and AIDS clinics." Gov't Mem. at 8, *Sanofi-Aventis v. HHS*, 3:21-cv-634, Dkt. 89 (D.N.J. June 16, 2021). According to HHS, Avita Pharmacy serves "270 covered-entity clients—98% of whom do not operate their own pharmacies." *Id.* And "all were being denied 340B pricing" of Sanofi's drugs.

185. Sanofi itself has conceded this impact. As of June 1, 2021, Sanofi admitted that the vast majority of covered entities ("many more covered entities" than otherwise) had lost access to Contract Pharmacy 340B Drug Discounts for Sanofi's drugs. *See* Letter to HRSA, dated June 1, 2021, at 8.

186. This dramatic and immediate impact was predictable.

187. Through its restrictions, Sanofi conditioned Contract Pharmacy 340B Drug Discounts on covered entities' participation in an unattractive and commercially unreasonable data-sharing program, through Second Sight's 340B ESP platform and terms of service.

188. As the United States has concluded, that program comprised "data-collection demands [that] are infeasible for covered entities." Gov't Mem. at 10, *Sanofi-Aventis v. HHS*, 3:21-cv-634, Dkt. 89 (D.N.J. June 16, 2021) (emphasis added). As the Government has summarized, Sanofi's demand was "infeasible" because, among other things, (i) it "could increase the risk of unauthorized access to patients' health information and thereby expose covered entities to significant liability under various federal and state privacy laws, including HIPAA," (ii) its terms might "contravene the terms of [various] covered entities' contract-pharmacy agreements," (iii) it "impose[d] undue administrative burden[s] on covered entities," and (iv) through the data-sharing, "Sanofi [was] attempting to co-opt covered entities' resources to support data collection that could be used by private insurance to facilitate the reduction of reimbursement on claims involving 340B drugs, against the interests of covered entities and their patients." *Id.*

189. The regulatory risks presented by Sanofi's demands are significant. Violations of HIPAA can result in government penalties of many millions of dollars, substantial remediation costs (including credit monitoring and other support for affected individuals), and potential liability to patients. Locally, for instance, Excellus Health Plan paid a civil monetary penalty of $5.1 million to the Office of Civil Rights in January 2021 to resolve alleged HIPAA breaches. Sanofi's demands are particularly unreasonable with respect to these risks because the operative terms of use required by Second Sight's 340B ESP software shifts the financial burden for HIPAA noncompliance, through the data-sharing, to the covered entities, even though Sanofi's vendor, Second Sight, is the one creating and controlling the data-sharing system.

190. A recent survey reflects that most covered entities have concerns about the data-sharing and that, of those, 87% have reported concern with potential HIPAA privacy risks through the Sanofi platform. *See* 340B Health, Contract Pharmacy Restrictions Represent Growing Threat to 340B Hospitals and Patients: Survey Results at 9 (Mar. 2022 survey) (hereafter 340B Health Survey).

191. The administrative burdens imposed by Sanofi's demand are extensive. The Government has reported that "Sanofi demands bi-weekly submission of data, which in some instances may require the submitter to organize or reformat the data they otherwise collect to prepare such a submission." Gov't Mem. at 10, *Sanofi-Aventis v. HHS*, 3:21-cv-634, Dkt. 89 (D.N.J. June 16, 2021). The American Hospital Association has detailed, in over five pages of a brief, the "onerous burdens" Sanofi's demands would impose on 340B providers, including extensive data collection and submission. *See* Amicus Br., Am. Hosp.

Assoc. at 25-29, *Sanofi-Aventis v. HHS*, 21-3167, Dkt. 35 (3d Cir. May 17, 2022). And, in a recent survey, more than 80% of covered entities that had concerns about data-sharing were reported that it was "[h]ighly burdensome to compile and submit" the claims data demanded by Sanofi, with three-quarters also concerned that doing so could "conflict with contract pharmacy services agreements" currently in place. 340B Health Survey at 9.

192. Moreover, Sanofi's demands put covered entities at significant financial risk. As DOJ explained in the paragraph above, reporting such data contradicts covered entities' financials interests, as such data can be used to reduce reimbursements for 340B Drugs or otherwise disfavor covered entities. Indeed, the majority of covered entities responding to the 340B Health Survey reported such concerns, with 91% of those concerned reporting that data-sharing could result in "PBMs/Payers reimbursing less for 340B drugs" and 84% expressing concern that such data "[c]ould be used to refuse rebates to employer health benefit plans, making 340B hospitals less attractive to networks." 340B Health Survey at 9.

193. Sanofi's data-sharing demands are thus extremely unattractive and unpopular among covered entities. The 340B Health Survey results reflect that almost all covered entities (more than 90%) reported that, absent the threat of significant financial harm, "they would not consent to sharing data" with Sanofi or other manufacturers. *See* 340B Health Survey at 8.

194. Sanofi's restrictions led to the readily foreseeable immediate cessation of the overwhelming majority of Sanofi's Contract Pharmacy 340B Drug Discounts sales, particularly of its rapid-acting insulins, long-acting insulins, and incretin mimetics.

195. While Sanofi later tweaked its restrictions by limiting their application to the most significant covered entities, effective March 1, 2021, those restrictions have continued to restrict Plaintiffs' abilities to obtain Contract Pharmacy 340B Drug Discounts and continued to restrict the overwhelming volume of Contract Pharmacy 340B Drug Discount sales. Indeed, Sanofi itself recognized, in its announcement of this change, that its restrictions were aimed at the overwhelming volume of Contract Pharmacy 340B Drug Discount sales. Sanofi stated that it was applying its restrictions to those "categories of covered entities that have historically accounted for a significant share of contract pharmacy dispensing."

**2. Eli Lilly's restrictions led to the elimination of the overwhelming majority of Eli Lilly's Contract Pharmacy 340B Drug Discount sales.**

196. Eli Lilly's restrictions led to the immediate and sustained elimination of the overwhelming majority of Contract Pharmacy 340B Drug Discounts sales of Eli Lilly's rapid-acting insulins, long-acting insulins, and incretin mimetics, among other drugs.

197. Government-compiled drug sales data demonstrates that the immediate and sustained impact of Eli Lilly's restrictions, from their inception in September 2020 through at least the end of the period of available data in early 2021, was a substantial reduction in Contract Pharmacy 340B Drug Discounts. That data shows a dramatic decline in Contract Pharmacy 340B Drug Discount sales as soon as Eli Lilly introduced its restrictions effective September 2020, with loss of the overwhelming majority of such sales consistently through the remainder of the period of available sales data, at least through January 2021:


198. This same data shows the corresponding dramatic decline in 340B Savings from Contract Pharmacy sales of Eli Lilly's drugs, immediately following the introduction of its restrictions effective September 2020:


199. As DOJ has concluded, Eli Lilly's restrictions "caused a precipitous decline in drug sales at the 340B prices." Gov't Br. at 20, *Eli Lilly v. HHS*, 21-3405, Dkt. 37 (7th Cir. June 24, 2022). "For example, in the month before announcing its new policy, Eli Lilly had sold 1.55 million units of drugs at the 340B prices—two months later, that number dropped by over 89% to just 170,000 units." *Id.* "In the month before Eli Lilly's new policy took effect, covered entities had saved $67.5 million" "in savings on Eli Lilly products that they had obtained under the 340B Program." *Id.* "[T]wo months later, they only saved $3.8 million, losing almost 95% of the previous total savings." *Id.* HHS thus "calculated that covered entities had lost hundreds of millions of dollars in savings over just the few months after the new policies took effect, and would lose over $3.2 billion over the course of a full year." *Id.*

200. This near elimination of Contract Pharmacy 340B Drug Discount sales arose directly from Eli Lilly's restrictions.

201. Indeed, in the immediate wake of Eli Lilly's restrictions, Contract Pharmacies became unable to receive the overwhelming majority of shipments of covered entities' desired drug purchases. An example is Avita Pharmacy, "a national chain that almost exclusively contracts with and dispenses for covered entities, including community health centers and AIDS clinics." Gov't Mem. at 8, *Eli Lilly & Co.*, 1:21-cv-81, Dkt. 125 (S.D. Ind. June 25, 2021). According to HHS, Avita Pharmacy serves "270 covered-entity clients—98% of whom do not operate their own pharmacies." *Id.* And "all were being denied 340B pricing" of Eli Lilly's drugs.

202. This dramatic and immediate impact was predictable.

203. Eli Lilly's restrictions were broad, with few exceptions. The exceptions that Eli Lilly offered were minimal and did little to stem the massive reduction of sales of drugs with Contract Pharmacy 340B Drug Discounts.

204. First, Eli Lilly offered a narrow single-pharmacy exception. It set out, in its initial announcement, an exception permitting those "[c]overed entities that do not have an in-house pharmacy" to "designate a contract pharmacy location." Eli Lilly reiterated that this exception did not permit more than a single designated Contract Pharmacy. For instance, in a letter to HRSA dated June 10, 2021, Eli Lilly explained that it would "allow[] covered entities lacking an in-house pharmacy to designate one outside contract pharmacy." And, in an announcement to covered entities in December 2021, El Lilly explained that,

"[s]ince September 2020, Lilly has limited distribution of all 340B ceiling-priced product directly to covered entities and their child sites only, plus their wholly owned and affiliated contract pharmacies, with the exception of . . . covered entities that lack an in-house retail pharmacy," "who may designate a single contract pharmacy."

205. In words and practice, Lilly's new policy did not permit any covered entity more than a single pharmacy to be designated for the receipt of drugs with 340B Drug Discounts.

206. The single-pharmacy exception was narrow and altogether insufficient to mitigate the "precipitous decline in drug sales at 340B prices." As the United States District Court for the Southern District of Indiana found, "Lilly's refusal to deliver 340B drugs to more than one contract pharmacy often renders hollow its 'offer' to sell [drugs with 340B Drug Discounts]. Because these are prescription drugs, some of which cover controlled substances, they can be shipped only to locations that provide the proper legal infrastructure, including state licensing, DEA registration, staff pharmacists, etc., to accept delivery or, and dispense, pharmaceuticals. . . . [C]overed entities often serve vulnerable populations scattered over large geographic areas, making it impossible for all patients to fill their prescriptions each month on-site or in a single contract pharmacy location." *Eli Lilly & Co. v. HHS*, 1:21-81, 2021 U.S. Dist. LEXIS 209257, at 61 n.13 (S.D. Ind. Oct. 29, 2021).

207. As DOJ has explained, "covered entities often serve vulnerable populations over huge geographic areas with transportation and timing difficulties, making it impossible for all patients (tens of thousands per provider, in some cases) to fill their prescriptions each month on-site or in just one location." Gov't Reply Mem. at 24, *Eli Lilly*,

1:21-cv-81, Dkt. 125 (S.D. Ind. June 25, 2021). Thus, as DOJ further explained, "it strains credulity that one pharmacy could serve [a covered entity] as well" as multiple Contract Pharmacies. Trans. of July 30, 2021, at 60:11-12, *Eli Lilly & Co.*, 1:12-cv-81, Dkt. 139 (Aug. 5, 2021). Indeed, if the single-Contract Pharmacy exception were effective, "340B sales would not have taken the nosedive" that they did. Gov't Reply Mem. at 25, *Eli Lilly*, 1:21-cv-81, Dkt. 125 (S.D. Ind. June 25, 2021).

208. Second, Eli Lilly offered an exceedingly narrow and completely infeasible insulin-related exception. Eli Lilly announced that it would "grant an exception" for some, but not all, "Lilly insulin products." The exception did not extend to incretin mimetics. To qualify, covered entities need to reach out to Eli Lilly and "be prepared to submit documentation demonstrating that" four specified conditions were met. These conditions were: (1) that "all 340B eligible patients . . . acquire their Lilly insulins . . . at the 340B price," (2) that "[n]either the covered entity nor the contract pharmacy mark[] up or otherwise charge[] a dispensing fee for the Lilly insulin," (3) that no "insurer or payer [be] billed for the Lilly insulin dispensed," and (4) that the "covered entity provides claim-level detail (CLD) demonstrating satisfaction of these terms and conditions." As DOJ has explained, Eli Lilly thus "purported to contain an exception for insulin—but conditioned it on novel, onerous restrictions . . . including that insurance not be billed for insulin, no markup or dispensing fee be charged to the patient, and that the covered entity provide Lilly detailed information demonstrating compliance with Lilly's conditions." Gov't Mem. at 9, *Eli Lilly v. Becerra*, 1:21-cv-81, Dkt. 88 (S.D. Ind. Apr. 20, 2021).

209. Eli Lilly's claimed insulin exception was entirely illusory. As an initial matter, it would require covered

entities to give up all revenues from the sale of insulin at a Contract Pharmacy, while bearing all of the compliance, operational, and related costs of running a Contract Pharmacy program—thus, guaranteeing a loss. As the American Hospital Association has explained, "Lilly is not just requiring [covered entities] to give up 100 percent of the intended benefit of the program; it is causing 340B providers to *lose* money." Amicus Br., Am. Hosp. Assoc. at 27, 21-3128 (7th Cir. July 1, 2022).

210. Even more fatal to this claimed exception's feasibility is the fact that Eli Lilly's stated it would require covered entities to find Contract Pharmacies willing to dispense insulin for free. That is impossible, given the expenses and risks associated with dispensing drugs. As one pharmacist explained in a sworn affidavit, "Lilly has stated that it will allow 340B covered entities to access its insulin products at contract pharmacies if certain conditions are met. One of those conditions is that the pharmacy not collect a dispensing fee as compensation for filling the prescription. This condition makes the Lilly insulin 'exception' entirely impractical because pharmacies will not agree to dispense drugs without any compensation." Affidavit of Peter Johnson, RPh., ¶ 16, *Ryan White Clinics for 340B Access v. Azar*, 1:20-cv-2906, Dkt. 24 (D.D.C. Nov. 23, 2020).

211. As DOJ has explained, "pharmacies provide the necessary infrastructure to allow covered entities to access the benefits of the 340B Program, including paying for all of the retail space, licensing, human resources, and other requirements to store and dispense pharmaceuticals. They collect a reasonable, set fee for that service and pass on savings either to indigent patients or to the covered entity. Lilly cannot demand pharmacies

perform these services *for free*." Gov't Reply Mem. at 24, *Eli Lilly*, 1:21-cv-81, Dkt. 125 (S.D. Ind. June 25, 2021).

212. DOJ has aptly explained that Eli Lilly's insulin exception is thus "not reasonable or workable in practice." *Id.* at 23-24.

213. Third, and only much later, Eli Lilly provided the 340B ESP data-sharing exception that Sanofi offered. Specifically, by letter dated December 16, 2021, Eli Lilly announced that, "[g]oing forward," it would permit covered entities to purchase and distribute 340B drugs in exchange for the same data-sharing demands made by Sanofi, that is, participation of the covered entity in 340B ESP Second Sight Solutions. This demand suffered from all the problems detailed above with respect to the identical demand by Sanofi.

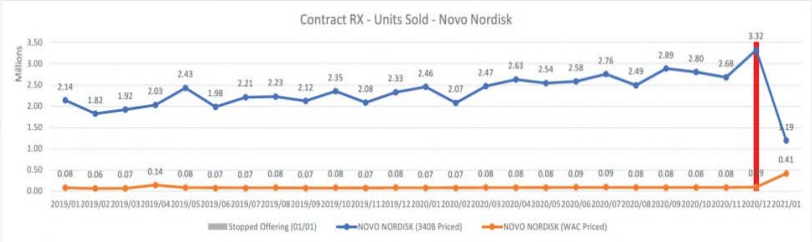
214. Eli Lilly's restrictions led to the readily foreseeable immediate elimination of the overwhelming majority of Eli Lilly's Contract Pharmacy 340B Drug Discounts sales, particularly of its rapid-acting insulins, long-acting insulins, and incretin mimetics. As Eli Lilly's CFO reported to investors, the decline in Contract Pharmacy 340B Drug Discounts sales was "primarily for Trulicity [an incretin mimetic] and Humalog [a rapid-acting analog insulin]." Eli Lilly, Earnings Call (Q4 2020); *see also* Eli Lilly, 10-Q at 52 (Q2 2021) (noting "lower utilization in the 340B segment, primarily for the diabetes portfolio"); Eli Lilly, 10-Q at 49 (Q3 2021) (same).

### 3. Novo Nordisk's restrictions led to the elimination of the overwhelming majority of Novo Nordisk's Contract Pharmacy 340B Drug Discount sales.

215. Novo Nordisk's restrictions led to the immediate and sustained elimination of the overwhelming majority of

Contract Pharmacy 340B Drug Discounts sales of Novo Nordisk's rapid-acting insulins, long-acting insulins, and incretin mimetics, among other drugs.

216. Government-compiled drug sales data demonstrates that the immediate impact of Novo Nordisk's restrictions, from their inception in January 2021, was a substantial reduction in Contract Pharmacy 340B Drug Discounts. That data shows a dramatic decline in Contract Pharmacy 340B Drug Discount sales as soon as Novo Nordisk introduced its restrictions effective January 2021:




217. This same data shows the corresponding dramatic decline in 340B Savings from Contract Pharmacy sales of Novo Nordisk's drugs, immediately following the introduction of its restrictions effective January 2021:


218. As DOJ has concluded, Novo Nordisk's restrictions "caused a precipitous decline in drug sales at 340B prices." Gov't Br. at 18, *Novo Nordisk v. HHS*, 21-3168, Dkt. 49 (3d Cir. July 7, 2022). "For example, in the month before announcing its new policy," Novo Nordisk

"had sold 3.32 million units of drugs at the 340B prices; the month after it adopted the new policy, that number dropped by more than 2 million units—a decline of 64%." *Id.* HHS calculated that covered entities suffered "$100 million in lost savings from Novo [Nordisk] . . . in just a single month." *Id.* at 19. The data shows a decline from $144.6 million in monthly savings in December 2020 to $47 million in savings upon the immediate impact of Novo Nordisk's restrictions in January 2021, a decline of nearly 70%.

219. DOJ has aptly characterized this as Contract Pharmacy 340B Drug Discount "plummet[ing]" as soon as Novo Nordisk "implemented its restrictions." Gov't Mem. at 6–7, *Novo Nordisk v. HHS*, 3:21-cv-0806, Dkt. 53 (D.N.J. June 22, 2021).

220. These plummeting Contract Pharmacy 340B Drug Discount sales arose directly from Novo Nordisk's restrictions.

221. Indeed, as with the other Defendants, in the immediate wake of Novo Nordisk's restrictions, Contract Pharmacies became unable to receive the overwhelming majority of shipments of covered entities' desired drug purchases.

222. This dramatic and immediate impact was predictable.

223. Novo Nordisk restrictions were broad enough to result in the overwhelming elimination of sales of drugs with Contract Pharmacy 340B Drug Discounts.

224. Novo Nordisk limited its restrictions to hospital covered entities. But that limitation did not substantially mitigate the dramatic decline of Novo Nordisk's Contract Pharmacy 340B Drug Discount sales because, as PhRMA

has noted, the "vast majority of 340B sales are to hospitals," approximately 90%. *See* PhRMA, "340B 101" at 16 (Nov. 2017); *accord* GAO, "340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements" at 2 (Dec. 2019).

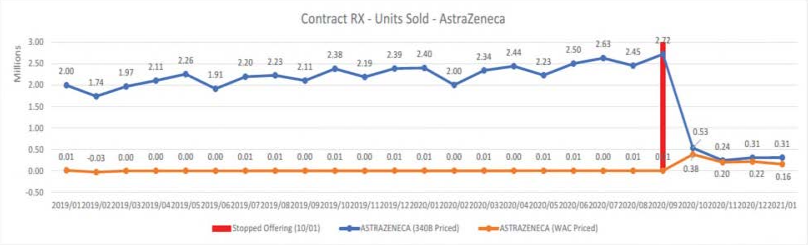
225. Novo Nordisk itself characterized its restrictions as effectively ending shipments of drugs to Contract Pharmacies. Following the conclusion of the first quarter of Novo Nordisk's implementation of its restrictions in Q1 2021, Novo Nordisk's CFO explained those restrictions as "basically, we stopped our shipments . . . to contract pharmacies." Novo Nordisk, Earnings Call (Q1 2021). Throughout the remainder of 2021 and into 2022, Novo Nordisk continued to report to investors that it was obtaining "higher net profit" "driven by [this] changed distribution policy for the 340B program." Novo Nordisk, Earnings Call (Q4 2021).

226. Novo Nordisk's restrictions thus led to the readily foreseeable immediate elimination of the overwhelming majority of Novo Nordisk's Contract Pharmacy 340B Drug Discounts sales, particularly of its rapid-acting insulins, long-acting insulins, and incretin mimetics. As Novo Nordisk itself highlighted, the impact of these restrictions was particularly significant on its diabetes products, emphasizing that the restrictions "impact [] our insulin sales." Novo Nordisk, Earnings Call (Q1 2021).

**4. AstraZeneca's restrictions led to the elimination of the overwhelming majority of AstraZeneca's Contract Pharmacy 340B Drug Discount sales.**

227. AstraZeneca's restrictions led to the immediate and sustained elimination of the overwhelming majority of Contract Pharmacy 340B Drug Discounts sales of AstraZeneca's incretin mimetics, among other drugs.

228. Government-compiled drug sales data demonstrates that the immediate impact of AstraZeneca's restrictions, from their inception in October 2020 through at least the end of the period of available data in early 2021, was a substantial reduction of Contract Pharmacy 340B Drug Discounts. That data shows a dramatic decline in Contract Pharmacy 340B Drug Discount sales as soon as AstraZeneca introduced its restrictions effective October 2020, with loss of the overwhelming majority of such sales consistently through the remainder of the period of available sales data, at least through January 2021:




229. This same data shows the corresponding dramatic decline in 340B Savings from Contract Pharmacy sales of AstraZeneca's drugs, immediately following the introduction of its restrictions effective October 2020:

230. As DOJ has concluded, AstraZeneca's restrictions "caused an immediate and significant decline in its 340B discount drug sales." Gov't Br. at 5, *AstraZeneca v. HHS*, 22-1676, Dkt. 20 (3d Cir. June 21, 2022). "The month before its policy took effect, AstraZeneca sold approximately 2,720,000 units of 340B medications—two months later, that number dropped over 90% to only 240,000 units." *Id.* DOJ concluded that "[c]overed entities also lost almost all of their price savings from the statutory discount." *Id.* at 5-6. "Before the new policy, covered entities saved $53.5 million from wholesale pricing by purchasing AstraZeneca's drugs through the 340B program—two months later, those savings had dropped over 85% to $7.2 million." *Id.* at 6.

231. In the words of DOJ, AstraZeneca's Contract Pharmacy 340B Drug Discount sales took a "nosedive." Gov't Br. at 9, 18, *AstraZeneca Pharm. LP v. Beccera*, 1:21-cv-27, Dkt. 93 (D. Del. July 23, 2021). These were "steep and stark changes to the volume of 340B sales when Astra's policy went into effect." Gov't Counsel, Trans. of Oct. 18, 2021, at 35:23-25, 1:21-cv-27, Dkt. 103 (D. Del. Oct. 22, 2021). AstraZeneca's "340B sales just [fell] off a cliff when they put their restrictions into effect." *Id.* at 36:1-3.

232. This nosedive of Contract Pharmacy 340B Drug Discount sales arose directly from AstraZeneca's restrictions.

233. Indeed, in the immediate wake of AstraZeneca's restrictions, Contract Pharmacies became unable to receive the overwhelming majority of shipments of covered entities' desired drug purchases. An example is Avita Pharmacy, "a national chain that almost exclusively contracts with and dispenses for covered entities, including community health centers and AIDS clinics." Gov't Mem. at 8, *AstraZeneca v. HHS.*, 1:21-cv-27, Dkt. 93

(D. Del. July 23, 2021). According to HHS, Avita Pharmacy serves "270 covered-entity clients—98% of whom do not operate their own pharmacies." *Id.* And "all were being denied 340B pricing" of AstraZeneca's drugs.

234. This dramatic and immediate impact was predictable.

235. AstraZeneca itself has conceded this impact. At oral argument before the United States District for the District of Delaware, counsel for AstraZeneca admitted that its restrictions had caused "a nosedive in the 340B sales." Trans. at 85:6-11, *AstraZeneca*, 1:21-cv-27, Dkt. 103 (D. Del. Oct. 22, 2021).

236. AstraZeneca's restrictions were broad, with a narrow exception "recogniz[ing] one contract pharmacy per covered entity for those covered entities that do not maintain an on-site dispensing pharmacy." This exception was minimal and did little to stem the overwhelming cessation of sales of drugs with Contract Pharmacy 340B Drug Discount.

237. AstraZeneca's single pharmacy exception was narrow and altogether insufficient to mitigate the overwhelming decline in Contract Pharmacy 340B Drug Discount sales for the same reasons that Eli Lilly's single pharmacy exception was narrow and altogether insufficient to mitigate its similar decline in sales.

238. Indeed, AstraZeneca has admitted that its exceptions were too insignificant to prevent the drastic "nosedive" in its sales of drugs with Contract Pharmacy 340B Drug Discounts. Trans. at 85:6-11, *AstraZeneca*, 1:21-cv-27, Dkt. 103 (D. Del. Oct. 22, 2021). AstraZeneca explained "that not every covered entity had designated a contract pharmacy under [the] policy even when they were eligible to do so." *Id.* at 85:12-14. Further, AstraZeneca

conceded that many covered entities use multiple Contract Pharmacies and "can't place purchases through those contract pharmacies." *Id.* at 85:20-22.

239. AstraZeneca's restrictions thus led to the readily foreseeable immediate elimination of the overwhelming majority of AstraZeneca's Contract Pharmacy 340B Drug Discounts sales, particularly of its incretin mimetics.

## CONSPIRACY ALLEGATIONS

240. Defendants engaged in concerted action to restrict Contract Pharmacy 340B Drug Discounts.

### I. Defendants are horizontal competitors.

241. Defendants directly compete with one another, including in their sales of rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics.

#### A. Defendants' rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics are in direct competition.

##### 1. Sanofi, Eli Lilly, and Novo Nordisk are in direct competition in the production and sale of rapid-acting analog insulins.

242. Defendants Sanofi, Eli Lilly, and Novo Nordisk directly compete against each other in manufacturing and/or selling rapid-acting analog insulins.

243. Defendants' competing rapid-acting analog insulins include Sanofi's Apidra and Admelog; Eli Lilly's Humalog and Insulin Lispro; and Novo Nordisk's Fiasp, Novolog, and Insulin Aspart.

244. Apidra, Admelog, Humalog, Insulin Lispro, Fiasp, Novolog, and Insulin Aspart are each clinically equivalent and therapeutically interchangeable with one another.

245. The FDA categorizes drugs into pharmacological classes. The FDA categorizes Apidra, Admelog, Humalog, Insulin Lispro, Fiasp, Novolog, and Insulin Aspart in the pharmacological class of insulin analog. The only other drugs in the same pharmacological class are the long-acting analog insulins listed below.

246. For the last decade, including during and since July 2020, Defendants Sanofi, Eli Lilly, and Novo Nordisk have competed with each other in the manufacture and sale of rapid-acting analog insulins.

**2. Sanofi, Eli Lilly, and Novo Nordisk are in direct competition in the production and sale of long-acting analog insulins.**

247. Defendants Sanofi, Eli Lilly, and Novo Nordisk directly compete against each other in manufacturing and/or selling long-acting analog insulins.

248. Defendants' competing long-acting analog insulins include Sanofi's Lantus and Toujeo; Eli Lilly's Basaglar; and Novo Nordisk's Levimir and Tresiba.

249. Lantus, Toujeo, Basaglar, Levimir, and Tresiba are each clinically equivalent and therapeutically interchangeable with one another.

250. The FDA categorizes Lantus, Toujeo, Basaglar, Levimir, and Tresiba in the same pharmacological class of insulin analog. The only other long-acting analog insulin in this pharmacological class is a new entrant, Semglee, manufactured by Mylan and Biocon Ltd, which was not being sold in the United States in July 2020. The only other drugs categorized in the insulin analog pharmacological class are the rapid-acting analog insulins listed above.

251. Since 2015, including during and since July 2020, Defendants Sanofi, Eli Lilly, and Novo Nordisk have competed with each other in the manufacture and sale of long-acting analog insulins.

**3. Sanofi, Eli Lilly, Novo Nordisk, and AstraZeneca are in direct competition in the production and sale of incretin mimetics.**

252. Defendants Sanofi, Eli Lilly, Novo Nordisk, and AstraZeneca directly compete against each other in manufacturing and/or selling incretin mimetics.

253. Defendants' competing incretin mimetics include Sanofi's Adlyxin; Eli Lilly's Trulicity; Novo Nordisk's Victoza, Ozempic, and Rybelsus; and AstraZeneca's Bydureon and Byetta.

254. Adlyxin, Trulicity, Victoza, Ozempic, Rybelsus, Bydureon, and Byetta are each clinically equivalent and therapeutically interchangeable with one another.

255. The FDA categorizes Trulicity, Victoza, Ozempic, Rybelsus, Bydureon, and Byetta in the pharmacological class of GLP-1 Receptor Agonist. The only other drug in the same pharmacological class, Saxenda (another Novo Nordisk drug), is FDA-approved for weight management, not diabetes.

256. Since 2016, including during and since July 2020, Defendants Sanofi, Eli Lilly, Novo Nordisk and AstraZeneca have competed with each other in the manufacture and sale of incretin mimetics.

**B. Defendants have virtually no other competitors for their rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics.**

257. Defendants' products dominate each market.

**1. Defendants face no competition for rapid-acting analog insulins.**

258. As of July 2020, Defendants sold the only available rapid-acting analog insulins: Sanofi's Apidra and Admelog; Eli Lilly's Humalog and Insulin Lispro; and Novo Nordisk's Fiasp, Novolog, and Insulin Aspart.

259. That remains true today.

260. No other rapid-acting analog insulins are available in the United States.

**2. Defendants faced no competition for long-acting analog insulins.**

261. As of July 2020, Defendants sold the only available long-acting analog insulins: Sanofi's Lantus and Toujeo; Eli Lilly's Basaglar; and Novo Nordisk's Levimir and Tresiba.

262. These drugs continue to dominate the market today.

263. The sole competitive drug, Semglee, has a long way to go before it can capture market share. Around October 2020, Mylan and Biocon introduced Semglee as another long-acting analog insulin. But competition within the diabetic medications market is slow-moving. As Biocon explained on April 29, 2021, it "witnessed [only] a modest uptake of biosimilar Insulin Glargine (*Semglee***) following its launch in FY21." Biocon attributed the slow increase in market share to "the timing of approval impacting formulary contracting cycles for CY21." *See* Biocon Ltd., "Biocon Q4FY21 Revenue at Rs2,044 Cr, Up 26%," (Apr. 29, 2021), at https://www.biocon.com/biocon-q4fy21-results/. Biocon's Chief Operating Officer, Shreehas P. Tambe has explained that there was "a slower than usual ramp-up for these products," and "other similar

products in the market in the first 12-months have had a single-digit market share," before they "get to preferred or exclusive formulary status." Biocon Limited Q3 FY21 Earning Conference Call Transcript (Jan. 22, 2021), at https://www.biocon.com/biocon-q4fy21-results/.

**3. Defendants face no competition for incretin mimetics.**

264. As of July 2020, Defendants sold the only available incretin mimetics: Sanofi's Adlyxin; Eli Lilly's Trulicity; Novo Nordisk's Victoza, Ozempic, and Rybelsus; and AstraZeneca's Bydureon and Byetta.

265. That remains true today.

266. No other incretin mimetics are available in the United States.

**C. Defendants face few competitors—mainly, only each other—in selling rapid-acting analog insulin, long-acting analog insulin, and incretin mimetics sales.**

267. Few competitors compete in the manufacture and sale of rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics.

268. The rapid-acting analog insulin market is dominated by only three companies—Sanofi, Eli Lilly, and Novo Nordisk.

269. The long-acting analog insulin market is dominated by only three companies—Sanofi, Eli Lilly, and Novo Nordisk.

270. The incretin mimetic market is dominated by only four companies—Sanofi, Eli Lilly, Novo Nordisk, and AstraZeneca.

## II. Defendants restricted Contract Pharmacy 340B Drug Discounts in parallel.

271. Defendants acted in parallel to restrict Contract Pharmacy 340B Drug Discounts.

272. Defendants announced their planned restrictions in near lockstep, between July 2020 and December 2020. On July 24, 2020, AstraZeneca privately informed HHS of its planned restrictions. Three days later, on July 27, 2020, Sanofi announced that it would impose its restrictions. Three weeks later, on August 19, 2020, Eli Lilly informed HHS of its restrictions. And within three-and-a-half months, on December 1, 2020, Novo Nordisk informed HHS of its restrictions.

273. Likewise, Defendants imposed their restrictions in near lockstep, between September 2020 and January 2021. Eli Lilly imposed its restrictions beginning on September 1, 2020. Both AstraZeneca and Sanofi imposed their restrictions beginning just one month later, on October 1, 2020. And Novo Nordisk imposed its restrictions just three months later, on January 1, 2021.

274. Each Defendant imposed similar restrictions on Contract Pharmacy 340B Drug Discounts. AstraZeneca, Eli Lilly, and Novo Nordisk, with minor and largely insignificant exceptions, limited the availability of all Contract Pharmacy 340B Drug Discounts. So too, Sanofi limited the availability of all Contract Pharmacy 340B Drug Discounts, with an exception for covered entities agreeing to provide Sanofi with sensitive prescription information through Sanofi's software vendor on commercially unreasonable terms.

275. As detailed above, the net effect of each restriction was the same—ending the overwhelming majority of all Contract Pharmacy 340B Drug Discount

sales for AstraZeneca, Eli Lilly, Novo Nordisk, and Sanofi drugs. Government-compiled data shows, for instance, that the immediate impact of Defendants' restrictions was a decline of 60%-90% of such sales by units or 70-95% as measured by lost 340B Savings.

276. These announced changes were close enough in time to effectively prevent any covered entity from steering prescriptions to competitors (*i.e.*, other Defendants). Because covered entities prescribe drugs, new prescriptions require new doctor-patient interactions. Those occur only periodically. Accordingly, it takes many months to transition a provider's patients from one preferred drug to another. Defendants announced their restrictions on Contract Pharmacy 340B Drug Discounts close enough in time to one another that covered entities could not, and did not, make significant progress in transitioning patients from one drug (for which Contract Pharmacy 340B Drug Discounts had been made unavailable) to another drug (for which Contract Pharmacy 340B Drug Discounts were still, temporarily, available).

277. Government-compiled data shows that Defendants' acted close enough in time to prevent significant market share loss for any one Defendant. That data, reprinted above, shows that Eli Lilly lost the overwhelming majority of its Contract Pharmacy sales as soon as it introduced its restrictions in September 2021. That same data, however, shows no significant increase in the sales of Eli Lilly's competitors—the other Defendants—in the immediate aftermath of those restrictions. Prescribers could not meaningfully react to Eli Lilly's restrictions within the period between September 1 and January 1, when all four Defendants' restrictions had been imposed. Defendants imposed their

restrictions sufficiently simultaneously, within this particular market, to prevent significant loss of market share.

**III. Defendants conspired in imposing their parallel restrictions.**

278. The nature and timing of the parallel conduct described above, set within the context of this industry, is strongly suggestive of conspiracy, rather than of independent action. Among the facts plausibly suggestive of an agreement are the following: (i) acting alone in eliminating or restricting the Contract Pharmacy 340B Drug Discounts would have been against any single Defendant's unilateral self-interest because it would risk market share; (ii) acting alone in restricting Contract Pharmacy 340B Drug Discounts would have been against any single Defendant's unilateral self-interest because it would risk severe regulatory sanctions, including loss of coverage of their diabetes medications by federal healthcare programs; (iii) Defendants shared a common motive to raise prices by avoiding the Contract Pharmacy 340B Drug Discount, if they could do so jointly, to avoid both the loss of market share and the risks of the most severe regulatory sanctions; (iv) Defendants' restrictions were historically unprecedented; (v) indeed, Defendants' restrictions remained anomalous in the pharmaceutical industry for years; (vi) there are a small number of competitors in the rapid-acting analog insulin, long-acting analog insulin, and incretin mimetics areas (*i.e.*, the four Defendants); (vii) there are significant barriers to entry for new competitors; (viii) Defendants engaged in a high volume of communications immediately in advance of their concerted action; (ix) Defendants' alleged antirust conspiracies in the past, including fixing prices for rapid-acting analog insulin and long-acting analog insulin, and

their alleged similar price manipulation of these same drugs; and (x) within three days of AstraZeneca privately informing HRSA of its plan to restrict Contract Pharmacy 340B Drug Discounts, Sanofi publicly announced its corresponding restrictions, which is too close in time to be a coincidence.

### A. Restricting Contract Pharmacy 340B Drug Discounts would have been against any single Defendant's self-interest.

279. It would have been against any single Defendant's self-interest to restrict Contract Pharmacy 340B Drug Discounts for at least two reasons. First, doing so, while a Defendant's competitors continued to offer Contract Pharmacy 340B Drug Discounts, would have put the Defendant at a significant competitive disadvantage. Second, doing so, while a Defendant's competitors offered alternative diabetes medications, would have exposed the Defendant to the most severe regulatory sanction of loss of federal healthcare program coverage for the Defendant's drugs, including its diabetes medications.

#### 1. Any Defendant restricting discounts alone would risk market share.

280. If a single Defendant had restricted Contract Pharmacy 340B Drug Discounts, its market share and sales volumes in the financially important markets for rapid-acting analog insulins, long-acting analog insulins, or incretin mimetics would have been seriously threatened.

281. Access to Contract Pharmacy 340B Drug Discounts is a critically important economic issue for covered entities. Indeed, access to such discounts is oftentimes more important than other attributes of drug pricing. The reason why is that hospitals and clinics may

not directly bear the burden of higher drug pricing. Those burdens often fall on third-party payors, such as insurers and government healthcare programs. By contrast, covered entities directly benefit from the availability of 340B Drug Discounts, including Contract Pharmacy 340B Drug Discounts, which produce 340B Savings for covered entities. Where a series of drugs are clinically equivalent and therapeutically interchangeable, a covered entity has a strong economic incentive to favor the drug(s) that provide access to 340B Drug Discounts, including Contract Pharmacy 340B Drug Discounts.

282. Covered entities' drug preferences are generally more important for Defendants' drug sales and market share than individual consumer preferences. Consumers do not choose prescription medications directly; they must be prescribed by a physician. And physicians are often employed by or associated with covered entities, which can share preferences with physicians as to preferred drugs among a class of clinically equivalent and therapeutically interchangeable medications.

283. If a single Defendant restricted Contract Pharmacy 340B Drug Discounts on its drug, then covered entities, including 340B hospitals, could have taken steps to steer their prescribing physicians towards prescribing the competing drugs that offered Contract Pharmacy 340B Drug Discounts, as the drugs are all clinically equivalent and therapeutically interchangeable. And covered entities would have had strong economic incentives to do so to generate the 340B Savings that the 340B Program was designed to produce for covered entities.

284. Defendants knew that their drugs were considered by the medical community as clinically

equivalent and therapeutically interchangeable with the other Defendants' drugs.

285. Defendants understood that covered entities would have strong incentives to prescribe drugs with Contract Pharmacy 340B Drug Discounts, instead of drugs for which manufacturers had restricted Contract Pharmacy 340B Drug Discounts.

286. Defendants understood that covered entities would have taken steps to prescribe competing drugs that offered Contract Pharmacy 340B Drug Discounts, instead of drugs for which manufacturers had restricted Contract Pharmacy 340B Drug Discounts.

287. Defendants understood that, if they acted alone, they were at risk of losing sales and market share, both in the short-term and the long-term.

288. For these reasons and others, Defendants had strong incentives not to act alone in restricting Contract Pharmacy 340B Drug Discounts.

289. Drug manufacturers' strong incentives not to act alone in restricting Contract Pharmacy 340B Drug Discounts are illustrated by the actions of other drug companies which did not engage in a conspiracy to restrict Contract Pharmacy 340B Drug Discounts. More than 1,000 other drug companies participate in the 340B Program. They sell drugs in markets distinct from the markets for rapid-acting analog insulins, long-acting analog insulins, or incretin mimetics. Those 1,000-plus other drug companies did not impose restrictions on Contract Pharmacy 340B Drug Discounts because, just as for Defendants (if they had acted alone), imposing any such restrictions would be competitively disadvantageous and against their individual economic self-interest.

**2. Any Defendant restricting discounts alone would risk loss of federal healthcare program coverage.**

290. If a single Defendant had restricted Contract Pharmacy 340B Drug Discounts, it would have feasibly faced the potential loss of federal healthcare program coverage of its medications.

291. Defendants understood that they faced this risk if they acted alone in restricting the availability of 340B Drug Discounts. Eli Lilly, for instance, has conceded that its novel 340B restrictions "risk[ed] the possibility of an enforcement action at an uncertain point in the future." Compl.., ¶ 126, *Eli Lilly & Co. v. Azar*, 1:21-cv-81, Dkt. 1 (S.D. Ind. Jan. 12, 2021). Most significantly, such restrictions exposed Defendants to enforcement action that "would prohibit [them] from receiving coverage and reimbursement for pharmaceutical products under Medicaid and Medicare Part B." *Id.*, ¶ 127. "Given the enormous size and importance of those federal programs, continuing participation in them is functionally necessary for . . . any manufacturer . . . to be viable." *Id.* That risk thus presented each Defendant with "crippling financial sanctions." *Id.*

292. Indeed, each Defendant has admitted that it feared such crippling repercussions.

293. Sanofi has publicly pled that, under the federal government's view of the 340B Drug Discount Program, it faced the "revocation of its ability to participate in the Medicare and Medicaid programs" as a result of its 340B Drug Discount restrictions. Compl. ¶ 6, *Sanofi-Aventis U.S., LLC v. HHS*, 21-cv-634 (D.N.J. Jan. 12, 2021).

294. Eli Lilly has affirmatively pled that, by restricting 340B Drug Discounts, it fears "the potential

revocation of [its] ability to participate in and receive reimbursements under the pervasive Medicare and Medicaid programs." Compl. at 4-5, *Eli Lilly & Co. v. Azar*, 21-cv-81, Dkt. 1 (S.D. Ind. Jan. 12, 2021); *see also* Am. Compl. at 4-5, *Eli Lilly & Co. v. Azar*, 21-cv-81, Dkt. 17 (S.D. Ind. Jan. 25, 2021).

295. Novo Nordisk has pointed to the "potential revocation of its ability to participate in the Medicare and Medicaid programs" as a result of its 340B Drug Discount restrictions. Compl. ¶ 9, *Novo Nordisk Inc. v. HHS*, 21-cv-806, Dkt. 1 (D.N.J. Jan. 15, 2021).

296. AstraZeneca has asserted that, as a sanction for its restrictions, it too "face[d] the potential revocation of [its] ability to participate in Medicare and Medicaid." Compl. ¶ 8, *AstraZeneca Pharm. v. Azar*, 21-cv-27, Dkt. 1 (D. Del. Jan. 12, 2021).

297. Given each Defendant's recognition of the potentially catastrophic risk of revocation of participation in Medicaid and Medicare Part D, each had an extremely strong incentive not to expose itself to such risks by imposing restrictions on Contract Pharmacy 340B Drug Discounts.

298. Drug manufacturers' strong incentives not to act alone in restricting Contract Pharmacy 340B Drug Discounts is illustrated by the actions of other drug companies which either never imposed restrictions on Contract Pharmacy 340B Drug Discounts (as most have not) or waited well more than a year before doing so. These drug manufacturers waited until it became clear that the government would not revoke federal healthcare program coverage for manufacturers imposing restrictions like Defendants'.

**B. Defendants had common motives to conspire.**

299. Defendants had common motives to conspire to restrict Contract Pharmacy 340B Drug Discounts, collectively.

300. First, if Defendants could together raise prices by restricting Contract Pharmacy 340B Drug Discounts, without decreasing any Defendant's sales or market share, each Defendant would earn higher profits, thus increasing its already substantial annual sales revenues.

301. Defendants understood that if they collectively restricted Contract Pharmacy 340B Drug Discounts, they would collectively make higher profits.

302. Defendants understood that if they collectively restricted Contract Pharmacy 340B Drug Discounts, they would not need to compete for covered entity prescribing preferences by offering Contract Pharmacy 340B Drug Discounts. Each Defendant controlled U.S. market shares worth hundreds of millions, or billions, of dollars annually, and none wanted to put those market shares at further risk by competing as to the availability of Contract Pharmacy 340B Drug Discounts. Defendants understood that if they jointly restricted Contract Pharmacy 340B Drug Discounts, those discounts would be equally unavailable for each of the competitors' drugs.

303. Defendants ultimately achieved this first objective. By implementing a common and shared policy of primarily refusing to permit the sale of 340B Drugs to covered entities for shipment to Contract Pharmacies, Defendants succeeded in eliminating the overwhelming majority of their Contract Pharmacy 340B Drug Discount sales, earning higher profits, and avoiding competition over the availability of Contract Pharmacy 340B Drug

Discounts on their critical rapid-acting insulins, long-acting insulins, and incretin mimetics, among other drugs.

304. Defendants had a second motive to conspire to restrict the availability of Contract Pharmacy 340B Drug Discounts. If Defendants could do so, Defendants could avoid the risk of the most severe regulatory sanctions for imposing such restrictions.

305. Defendants understood that, by restricting the availability of 340B Drug Discounts, they faced the potential loss of federal healthcare program coverage of their medications. Each has formally acknowledged that it feared such repercussions.

306. Defendants understood that if they collectively restricted Contract Pharmacy 340B Drug Discounts, they would make such a sanction infeasible for regulators.

307. Defendants understood that if they collectively restricted Contract Pharmacy 340B Drug Discounts, they would not need to fear revocation of their ability to participate in Medicare and Medicaid. Regulators could feasibly revoke coverage of any individual Defendant's participation in Medicare and Medicaid without disrupting the critical supply of diabetes medications. But, because Defendants collectively controlled the crucial markets for rapid-acting analog insulin, long-acting analog insulin, and incretin mimetics, regulators could not feasibly revoke coverage over all four Defendants because doing so would deprive beneficiaries of necessary diabetes treatments not otherwise available.

308. By joining together, Defendants effectively deprived regulators of the ability to feasibly sanction them by revoking federal healthcare program coverage. While that sanction was feasible for any single Defendant, Defendants understood that the sanction would be

infeasible if Defendants acted collectively, as they did here.

309. Defendants ultimately achieved this second objective, too. HRSA took action in May 2021, when all Defendants had implemented their common restrictions on Contract Pharmacy 340B Drug Discounts. While HRSA informed each Defendant that it was "in direct violation of the 340B statute," HRSA did not revoke federal healthcare program coverage of any of the Defendants. HRSA could not have feasibly revoked such coverage, because doing so would have jeopardized the ability of federal healthcare programs to deliver critical diabetes medications.

### C. Defendants' sudden restrictions were historically unprecedented.

310. Defendants' restrictions were imposed suddenly after a decade of offering Contract Pharmacy 340B Drug Discounts.

311. Defendants and all other drug companies participating in Medicaid or Medicare Part B had consistently offered Contract Pharmacy 340B Drug Discounts for at least decade. "For 24-plus years, manufacturers have offered the ceiling price to covered entities using contract-pharmacy distribution." *See* HHS General Counsel, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program at 5 n.5 (Dec. 30, 2020).

312. After a decade of consistently offering Contract Pharmacy 340B Drug Discounts, Defendants suddenly announced restrictions on Contract Pharmacy 340B Drug Discounts during the second half of 2020.

313. These changes were made despite warnings from regulators that such changes were viewed as illegal. These changes were made when no other drug manufacturer imposed similar restrictions.

314. The sudden, historically unprecedented change made by four direct competitors within the drug industry is indicative of conspiracy, rather than independent action.

**D. Defendants' restrictions remain anomalous in the pharmaceutical industry.**

315. Defendants imposed restrictions, even though nearly the entire remainder of the pharmaceutical industry—thousands of manufacturers participating in the 340B Drug Discount Program—did not.

316. Throughout 2020 and most of 2021, more than 99.6% of drug companies continued to offer Contract Pharmacy 340B Drug Discounts without restrictions. Those drug companies included some of the largest drug companies, such as Roche, Johnson & Johnson, Pfizer, AbbVie, Bristol Myers Squibb, GlaxoSmithKline, Gilead, Bayer, Biogen, Takeda, Moderna, Bausch Health, Alexion, and Regeneron, as well as more than a thousand others.

317. The fact that Defendants—as each other's sole competitors as of July 2020 for rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics—restricted Contract Pharmacy 340B Drug Discounts, while nearly the entire remainder of the industry did not, strongly suggests that Defendants acted in coordination with each other, rather than out of their own self-interest.

318. Moreover, the fact that Eli Lilly considered restricting Contract Pharmacy 340B Drug Discounts earlier in 2020, but decided against doing so (except for a

narrow band of Cialis formulations) until it could ensure that the other Defendants would also do so, strongly suggests that Defendants acted in coordination with each other, rather than out of their self-interest. If it had been in Eli Lilly's self-interest to independently limit all Contract Pharmacy 340B Drug Discounts, it would have done so when it limited Cialis discounts.

**E. The small number of competitors selling rapid-acting analog insulin, long-acting analog insulin, and incretin mimetics facilitates conspiracy.**

319. The existence of few competitors for a product makes that product more conducive to a price-fixing conspiracy, such as the elimination, reduction, or restriction of a discount.

320. Defendants Sanofi, Eli Lilly, and Novo Nordisk—just three companies—are the sole competitors manufacturing and selling rapid-acting analog insulins in the United States.

321. Defendants Sanofi, Eli Lilly, and Novo Nordisk—again just three companies—were the sole competitors manufacturing and selling long-acting analog insulins in the United States as of July 2020. A fourth competitor, Mylan/Biocon, recently joined the competition, but has had insufficient opportunities to gain market share. Defendants Sanofi, Eli Lilly, and Novo Nordisk still compete in selling long-acting analog insulins among just four competitors, and Defendants Sanofi, Eli Lilly, and Novo Nordisk dominate the market, with more than 90% of sales of long-acting analog insulins.

322. Defendants Sanofi, Eli Lilly, Novo Nordisk, and AstraZeneca—just four companies—are the sole

competitors manufacturing and selling incretin mimetics in the United States.

323. Because so few firms compete in the manufacture and sale of rapid-acting analog insulin, long-acting analog insulin, and incretin mimetics, an effective pricing conspiracy relating to those drugs requires the coordination of only a few firms. That makes the market more conducive to conspiracy.

**F. There are significant barriers for any new competitors.**

324. Defendants' conspiracy is further facilitated by significant barriers to entry, which effectively prevent would-be competitors from seeking a competitive advantage by offering Contract Pharmacy 340B Drug Discounts to compete against Defendants.

325. New market entrants face significant barriers to entry into the rapid-acting analog insulin, long-acting analog insulin, and incretin mimetics markets. These barriers include intellectual property, costs of manufacture, and expenses related to regulatory oversight.

326. As recently reported by the Center for Biosimilars, in the article, "Panel: Insulin Biosimilar Competition May Be Scant at Best," industry experts have explained that "[i]t's not easy to break into the insulin market." "Insulin is a biologic that is very difficult to consistently produce at high purity in large volumes that would be necessary for distribution, and very few manufacturers have the resources to perfect this process and convince regulators that they can get it right, the panelists [at the Festival of Biologics USA] said." "Many companies have attempted to bring rival insulin products . . . and have failed because the pharmacokinetics of these

products are extremely difficult to match precisely with originator products, [Sundar] Ramanan, [PhD, BMA, vice president and head of Global Regulatory Affairs for Biocon] said." "'That's barrier number 1. Barrier number 2 is we need to have economies of scale, and that requires a large capital investment, and not many companies have that to combine with the science. This limits the number of players that are coming in beyond the ones that are truly committed.'" *See* Tony Hagen, "Panel: Insulin Biosimilar Competition May Be Scant at Best," The Center for Biosimilars (Mar. 31, 2021), *at* https://www.centerforbiosimilars.com/view/panel-insulin-biosimilar-competition-may-be-scant-at-best.

327. Those barriers to entry and others allow Defendants to engage in a pricing conspiracy among themselves without being threatened by other firms.

### G. In advance of the conspiracy, Defendants were engaged in high levels of communication that gave them ample opportunity to conspire.

328. Defendants had ample opportunity to conspire and were engaged in high levels of communications in advance of their imposition of restrictions.

329. Defendants engaged in high levels of communication about the subjects of the conspiracy through lobbying. In the second and third quarters of 2020, before and at the time of the commencement of the conspiracy, Defendants were engaged in a joint lobbying campaign. That campaign related to 340B Drug Discounts and diabetes medicines. Defendants used common lobbyists and appear to have communicated directly with each other about their lobbying campaign. Upon information and belief, during that joint lobbying effort, Defendants planned their restrictions on Contract

Pharmacy 340B Drug Discounts as a fallback position if their lobbying efforts failed. Then, when their lobbying efforts did fail, Defendants immediately imposed coordinated restrictions on Contract Pharmacy 340B Drug Discounts.

330. Defendants also engaged in high levels of communications through industry associations, including PhRMA. Each Defendant is a member of PhRMA and on its Board of Directors. In July 2020, PhRMA's Board of Directors included Eli Lilly's CEO, David Ricks (serving as Chairman-Elect); Sanofi's CEO, Paul Hudson; Novo Nordisk's Executive Vice President & Head of North America Operations, Douglas J. Langa; and AstraZeneca's Executive Director & CEO, Pascal Soriot. The most prominent advocacy issue on the PhRMA website, listed first among the only two issues with graphic displays, was "340B." And the 340B page to which that graphic was hyperlinked present "Contract Pharmacies" as an "Area[] for Needed 340B Reform." Defendants, as PhRMA Board members, communicated among themselves, and their most prominent advocacy issue was 340B Drug Discounts, including Contract Pharmacy 340B Drug Discounts.

### H. Most Defendants have been alleged to have engaged in antitrust conspiracies and price manipulation for diabetes medications in the past.

331. Separate and apart from their coordination of restrictions on Contract Pharmacy 340B Drug Discounts, Eli Lilly, Sanofi, and Novo Nordisk have been alleged to have conspired to fix prices on rapid-acting analog insulin and long-acting analog insulin, allowing them to raise prices in lockstep. Private federal court litigation was filed based on those claims. *See generally* Amended Complaint,

*In re Direct Purchaser Insulin Pricing Litig.*, 3:20-cv-03426 (D.N.J. filed Nov. 6, 2020).

332. Similarly, Eli Lilly, Sanofi, and Novo Nordisk have been charged with wrongfully colluding with pharmacy benefit managers (PBMs) to artificially raise insulin prices. Both private and Government entities are pursuing these claims. *See generally* Third Amended Compl., *In re Indirect Purchaser Insulin Pricing Litig.*, 3:17-00699 (D.N.J. Apr. 20, 2021) (presenting RICO and consumer fraud claims, among others); *see also* Compl., *Minnesota v. Sanofi-Aventis US LLC*, 3:18-cv-14999 (D.N.J.) (pursuing unjust enrichment and consumer fraud claims).

333. Moreover, other government entities have reached similar conclusions. On January 14, 2021, the Senate Finance Committee issued a report on its two-year investigation "into the skyrocketing price of insulin," concluding, as stated by Committee Chair Senator Chuck Grassley, that "[t]his industry is anything but a free market." *See* United States Senate Committee on Finance, "Grassley, Wyden Release Insulin Investigation, Uncovering Business Practices Between Drug Companies and PBMs That Keep Prices High: Bipartisan Investigation on Rising Insulin Costs Finds Skyrocketing Prices are a Result of Companies Putting Profits Over Consumers' Interest" (Jan. 14, 2021).

334. And, on June 8, 2021, the Attorney General for the State of Mississippi filed suit against the companies and PBMs for "working in tandem to manipulate and inflate insulin prices." Attorney General Lynn Fitch, Press Release, "AG Lynn Fitch Files Lawsuit Against Insulin Manufacturers and PBMs Over Insulin Pricing Scheme," (June 8, 2021); *see also* Second Am. Compl., ¶¶ 13, 15, Mississippi v. Eli Lilly and Co., 21-cv-674, Dkt. 16-

5 (S.D. Miss. Oct. 29, 2021) ("In the last decade alone, [they] have in tandem increased the prices of their insulins up to 1000%, taking the same increase down to the decimal point within a few days of each other.").

335. Most recently, Albany County filed suit against Sanofi, Eli Lilly, and Novo Nordisk for engaging in an "Insulin Pricing Scheme" to "sharply increase[] the reported prices of their respective diabetes drugs in lockstep, even though the cost to produce these drugs decreased over that period." Compl. ¶ 15, *County of Albany v. Eli Lilly and Company*, 22-981 (N.D.N.Y. Sept. 16, 2022).

336. In addition to these public charges, there are reported investigations of similar conduct by the Attorneys General of Colorado, New Mexico, New York, Vermont, and Washington.

**I. Defendants acted too closely in time for it to be coincidental, especially because AstraZeneca did not publicly reveal its plans.**

337. Defendants coordinated their restrictions in a manner that cannot adequately be attributed to either coincidence or conscious parallelism. This is best illustrated by the first two Defendants to reveal their restrictions—AstraZeneca and Sanofi.

338. AstraZeneca was the first Defendant to reveal its plans to restrict Contract Pharmacy 340B Drug Discounts. But it did not do so publicly. Rather, AstraZeneca informed its regulator, HRSA, that it would restrict Contract Pharmacy 340B Drug Discounts beginning on October 1, 2020. AstraZeneca provided that information to HRSA on July 24, 2020. AstraZeneca did not publish its plans at that time.

339. Yet, Sanofi, the second Defendant to reveal its plans to restrict Contract Pharmacy 340B Drug Discounts, did so within three days of AstraZeneca's non-public announcement. Moreover, Sanofi revealed that it too would implement those restrictions beginning on October 1, 2020, the same date that AstraZeneca had communicated privately to HRSA.

340. The timing coordination between AstraZeneca and Sanofi cannot be attributed to Sanofi responding to AstraZeneca's letter to HRSA revealing its plans because AstraZeneca did not make any public announcement in July about its plans. Nor can the coordination be attributed to coincidence. After at least a decade of offering Contract Pharmacy 340B Drug Discounts, the odds of two direct competitors—AstraZeneca and Sanofi—revealing novel restrictions, starting on the same day (October 1, 2020), just three days apart are near zero.

341. The coordination between AstraZeneca and Sanofi is a result of conspiracy, not coincidence. That conspiracy extended to all of the Defendants. Indeed, the conspiracy was most effective only with the participation of each of the Defendants.

## ANTITRUST INJURY

### I. Defendants' conspiracy has restrained competition.

342. Defendants' actions have restrained competition by eliminating pricing discounts that otherwise would have been available to the Plaintiffs and Class Members.

343. Defendants' conspiracy has been effective at allowing them to increase their profits by restricting Contract Pharmacy 340B Drug Discounts, without

threatening any Defendant's market share and by protecting each Defendant from competition on discounts.

344. Because each Defendant announced and/or imposed its restrictions within a relatively short number of months, covered entities were unable to effectively respond. The time needed to move patients from one drug to another is generally measured in months. The Defendants coordinated their restrictions in near-enough lockstep to prevent covered entities from moving patients.

345. Through their coordination, Defendants have avoided a significant form of price competition, *i.e.*, on Contract Pharmacy 340B Drug Discounts.

346. Defendants have profited by billions of dollars by restricting Contract Pharmacy 340B Drug Discounts. Government-compiled data shows that Defendants profited by avoiding hundreds of millions of dollars of Contract Pharmacy 340B Drug Discounts each month. That data shows Sanofi avoiding $43 million in monthly rebates, Eli Lilly avoiding $63.7 million in monthly rebates, Novo Nordisk avoiding $97.5 million in monthly rebates, and AstraZeneca avoiding $46 million in rebates. Over two years, such avoidance would have permitted each Defendant to increase profits by over one billion dollars a piece.

## II. Plaintiffs have been harmed by Defendants' conspiracy.

347. Plaintiffs and other covered entities have been injured by Defendants' restraint on competition.

348. Defendant drug companies, as horizontal competitors, coordinated their pricing policies in a successful effort to limit access to Contract Pharmacy 340B Drug Discounts, while avoiding competition with one

another on the availability of discounts. This has permitted Defendants to profit at the expense of the covered entities purchasing their drugs, thereby threatening to reduce the healthcare services and discounts available to Plaintiffs' and other covered entities' patients.

349. Horizontal competitors who coordinate their pricing policies engage in "competition-reducing" conduct. The 340B covered entities transact in the commerce directly affected by the conduct and are thus "within that area of the economy endangered by the breakdown of competitive conditions." They have been injured in their business and property as a result and have been unable to offer the level of healthcare services to patients as they would have been able to offer absent Defendants' conduct.

350. Covered entities have been injured by losing access to 340B Savings. Before Defendants' conspiracy, each Defendant offered drugs to covered entities for purchase with Contract Pharmacy 340B Drug Discounts. As a result of the conspiracy, and as its aim, Defendants no longer offer such discounts to covered entities. The covered entities, including Plaintiffs, have lost the ability to generate 340B Savings as a result and, consequently, have also lost the ability to provide the range of healthcare services and savings for patients that they would have been able to offer absent Defendants' conduct.

351. These losses are quantifiable in at least two distinct ways.

352. *First*, at times, covered entities have purchased Defendants' drugs for dispensing at Contract Pharmacies without access to the Contract Pharmacy 340B Drug Discounts. Covered entities, including Plaintiffs, have been overcharged for those purchases because the

purchase price did not include the 340B Drug Discount. The Complaint refers to these damages as "overcharges."

353. *Second*, and most often, covered entities have not purchased drugs for dispensing at Contract Pharmacies because of their lost access to Contract Pharmacy 340B Drug Discounts. Covered entities can show and quantify, through pharmacy dispensing data and otherwise, 340B eligible transactions that would have been filled with 340B Drugs if the Defendants had not restricted access to Contract Pharmacy 340B Drug Discounts, and, therefore, can quantify the 340B Savings lost as a consequence of Defendants' conspiracy. The Complaint refers to these damages as "lost 340B Savings revenues."

354. Together, overcharges, lost 340B Savings revenues, and the threat of ongoing and continued overcharges and lost 340B Savings revenues have injured Plaintiffs and other covered entities and have reduced and/or threaten to reduce the range of healthcare services and options for the patients and communities served by Plaintiffs and other covered entities, including the uninsured and underinsured.

355. Plaintiffs and other covered entities have suffered these harms even though a particular Defendant may have, at some point, provided Contract Pharmacy 340B Drug Discounts to them during the conspiracy. Defendants' succeeded in eliminating the overwhelming majority of Contract Pharmacy 340B Drug Discounts without risking significant market share losses or loss of federal healthcare program coverage. Defendants' success was only possible because of their conspiracy. Thus, overcharges and lost 340B Savings revenues suffered, related to any particular Defendant, arise because of, and from, the conspiracy between all the Defendants.

### III. Only covered entities have been directly harmed by Defendants' conspiracy.

356. Covered entities are the only actors that have been directly harmed by the conspiracy, while their patients and communities have been indirectly harmed. By contrast, wholesalers that deliver drugs have not been directly harmed because they are not entitled to retain and do not retain any portion of the Contract Pharmacy 340B Drug Discounts. Those discounts are made available by the Defendants only to the covered entities. Because 340B Drug Discounts exist by reason of a statutory obligation that runs only to the 340B covered entities, wholesalers were never overcharged and suffer no antitrust injury on account of the Defendants' illegal agreement to restrict Contract Pharmacy 340B Drug Discounts. Accordingly, only covered entities—and not wholesalers—have suffered antitrust injuries.

357. Apart from covered entities, there are no other efficient enforcers. No other class of persons or entities has any self-interest to vindicate the public interest in antitrust enforcement because no other class of persons or entities has directly suffered as a result of the Defendants' conspiracy.

## CLASS ALLEGATIONS

358. Pursuant to Federal Rule of Civil Procedure 23, Plaintiffs bring this action on behalf of the following class:

> All covered entities in the 340B Program with Contract Pharmacy arrangements in place, and which have issued prescriptions for Defendants' drug products since September 1, 2020.

359. There are thousands of Class Members geographically dispersed through the United States. Joinder of all Members of the Class is thus impracticable.

360. Class Members are readily identifiable from public records.

361. Plaintiffs' claims are typical of the claims of the Class embers. Plaintiffs' interests are not antagonistic to the claims of the other Class Members, and Plaintiffs have no material conflicts with any other Class Members that would make class certification inappropriate.

362. Plaintiffs and all class members were damaged by the same wrongful conduct of Defendants. Plaintiffs and all Class Members were unable to obtain Contract Pharmacy 340B Drug Discounts from Defendants and, accordingly, have standing.

363. Plaintiffs will fairly and adequately protect and represent the interests of all Class Members. Plaintiffs' interests are consistent with, and not antagonistic to, those of the class members.

364. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular expertise pursuing class action litigation involving alleged antitrust violations.

365. Questions of law and fact common to Plaintiffs and Class Members predominate over questions that may affect only individual Class Members because the Defendants have acted on grounds generally applicable to the entire class. Determining damages with respect to the class as a whole is thus appropriate.

366. The predominant common legal and factual questions applicable to all Class Members include, but are not limited to, the following:

a. Whether Defendants participated in a contract, combination, or conspiracy to fix prices by restricting access to Contract Pharmacy 340B Drug Discounts;

b. The duration and extent of the alleged contract, combination, or conspiracy;

c. Whether such a contract, combination, or conspiracy is a *per se* violation of the Sherman Act and/or State laws;

d. Whether, and to what extent, Defendants' antitrust violations caused injury to Plaintiffs and Class Members; and

e. The nature and scope of injunctive relief necessary to restore a competitive market and remove the effects of Defendants' conspiracy.

367. These common questions do not vary among the Class Members and predominate over questions affecting only individual class members. The Court may and the jury may thus resolve these issues without reference to the individual circumstances of any Member of the Class.

368. Class action treatment is a superior method for the fair and efficient adjudication of the claims asserted by all Class Members. Such treatment will permit many similarly situated entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender.

369. The benefits of proceeding through a class mechanism, including providing all Class Members a method for obtaining redress on claims that they could not practicably pursue individually, substantially outweigh potential difficulties in the management of this litigation as a class action.

**FIRST CLAIM – FEDERAL ANTITRUST VIOLATIONS**

**Injunctive relief and treble damages for lost 340B Savings revenue On behalf of Plaintiffs and Class Members**

370. Plaintiffs hereby repeat the allegations in the foregoing paragraphs as if fully set forth herein.

371. Defendants and their co-conspirators entered into, established, and maintained a continuing contract, combination, or conspiracy in unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

372. In formulating and effectuating their contract, combination, or conspiracy, Defendants and their co-conspirators engaged in anticompetitive activities, the purpose and effect of which were to artificially fix the prices of drugs by agreeing to coordinate and eliminate, reduce, or limit the availability of Contract Pharmacy 340B Drug Discounts in a manner that deprived covered entity purchasers in the United States of a significant mechanism of price competition.

373. The contract, combination, or conspiracy had the direct, substantial, and reasonably foreseeable effect upon commerce within the United States of: (a) increasing prices available to Plaintiffs and Class Members for drugs offered by Defendants, by artificially raising or fixing such

prices by eliminating Contract Pharmacy 340B Drug Discounts; (b) depriving Plaintiffs and Class Members of 340B Savings revenue; (c) depriving Plaintiffs and Class Members of free, open, and unrestricted competition in the sale of drugs offered by Defendants, by restricting Contract Pharmacy 340B Drug Discounts; and (d) unlawfully restraining, suppressing, or eliminating competition in the prices paid for Defendants' drugs, by eliminating, reducing, or limiting the availability of Contract Pharmacy 340B Drug Discounts.

374. Defendants' contract, combination, or conspiracy was *per se* unlawful price-fixing.

375. Each Defendant has committed at least one overt act to further the conspiracy alleged, including by eliminating, reducing, or limiting the availability of Contract Pharmacy 340B Drug Discounts.

376. The conspiracy is having its intended effect, as Defendants have been benefiting from their collusion and the elimination of competition, both of which artificially inflated the prices of Defendants' drugs for Plaintiffs and Class Members at Contract Pharmacies and deprived Plaintiffs and Class Members of 340B Savings revenue.

377. As a result of Defendants' unlawful conduct, Plaintiffs and other Class Members have been and are being injured in their business and property in that they have been losing 340B Savings through the eliminated, reduced, or limited availability of Contract Pharmacy 340B Drug Discounts, specifically, through lost 340B Savings revenues.

378. Plaintiffs and other Class Members are entitled to treble damages, along with costs and attorneys' fees, as per Section 4 of the Clayton Act, 15 U.S.C. § 15.

379. Defendants' conduct continues to threaten similar loss and damage in violation of the antitrust laws.

380. Plaintiffs and other Class Members are entitled to injunctive relief to prevent Defendants' illegal conduct and remove all of the lingering effects of such conduct, along with costs and attorneys' fees, as per Section 16 of the Clayton Act, 15 U.S.C. § 26.

**SECOND CLAIM—STATE ANTITRUST CLAIMS**
**Damages for overcharges and lost**
**340B Savings revenue**
**On behalf of Plaintiffs and Class members under their respective States' laws**

381. Plaintiffs hereby repeat the allegations in the foregoing paragraphs as if fully set forth herein.

382. Beginning at least as early as July 24, 2020 (the exact date being unknown to Plaintiffs and within the exclusive knowledge of Defendants), Defendants entered into, established, and maintained a continuing contract, combination, or conspiracy in unreasonable restraint of trade.

383. The purpose and effect of the conspiracy was to artificially fix and maintain the prices of 340B drugs by agreeing to eliminate, reduce, or limit the availability of Contract Pharmacy 340B Drug Discounts in a manner that deprived Plaintiffs and Class Members of a significant mechanism of price competition.

384. The contract, combination, or conspiracy had a direct, substantial, and reasonably foreseeable effect upon commerce within the United States and within each of the States by: (a) increasing prices paid by Plaintiffs and Class Members for 340B Drugs sold by Defendants; (b) depriving Plaintiffs and Class Members of 340B Savings

that they would otherwise have received in the absence of the conspiracy; and (c) depriving Plaintiffs and Class Members of free, open, and unrestricted competition in the purchase of 340B Drugs sold by Defendants.

385. As a result of Defendants' unlawful conduct, Plaintiffs and other Class Members have been injured in their business and property by paying inflated prices for 340B Drugs and/or by being deprived of 340B Savings.

386. By engaging in the conduct described above, Defendants formed a contract, combination, or conspiracy in restraint of trade in violation of the following State laws:

a. Ariz. Rev. Stat. §§ 44-1401, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Arizona.

    i. In accordance with the requirements of Ariz. Rev. Stat. § 44-1415, contemporaneously with the filing of this Complaint, counsel is sending letters by certified mail, return receipt requested, to: Mark Brnovich, Attorney General of Arizona, informing him of the existence of the Class Action Complaint, identifying the relevant state antitrust provisions, and enclosing a copy of a Class Action Complaint.

b. Cal. Bus. & Prof. Code §§ 16720, and 16750(a), *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of California.

c. Conn. Gen. Stat. §§ 35-3, et seq., with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Connecticut.

d. D.C. Code §§ 28-4501, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the District of Columbia.

e. 740 Ill. Comp. Stat. §§ 10/1, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Illinois.

f. Fla. Stat. §§ 501.201, *et seq*., with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Florida. This statute has been interpreted in harmony with section 5(a)(1) of the Federal Trade Commission Act and the Sherman Act.

g. Iowa Code §§ 553.1, et seq., with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Iowa.

h. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to Class Members which are Kansas residents.

i. Me. Rev. Stat. Ann. 10, §§, 1101 *et seq.,* with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Maine.

j. Md. Comm. Laws. Ann. §§ 11-204 *et seq.,* with respect to Class Members that have

issued prescriptions for Defendants' drug products within the state of Maryland.

k. Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Michigan.

l. Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. §§ 8.31 *et seq.*, with respect to Class Members which are Minnesota residents.

m. Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Mississippi.

n. Neb. Rev. Stat. §§ 59-801, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Nebraska.

o. Nev. Rev. Stat. Ann. §§ 598A.010, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Nevada.

    i. In accordance with the requirements of Nevada Revised Statute § 598A.210(3) contemporaneously with the filing of this Complaint, counsel is sending letters by certified mail, return receipt requested, to: Aaron Ford, Attorney General of Nevada, informing him of the existence of the Class Action Complaint, identifying the relevant state

antitrust provisions, and enclosing a copy of a Class Action Complaint.

p. N.H. Rev. Stat. Ann. §§ 356:1, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of New Hampshire.

q. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of New Mexico.

r. N.Y. Gen. Bus. L. §§ 340, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of New York.

   i. In accordance with the requirements of N.Y. Gen. Bus. L. § 340(5), contemporaneously with the filing of this Complaint, counsel is sending letters by certified mail, return receipt requested, to: Letitia James, Attorney General of New York, informing her of the existence of the Class Action Complaint, identifying the relevant state antitrust provisions, and enclosing a copy of a Class Action Complaint.

s. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of North Carolina.

t. N.D. Cent. Code Ann. §§ 51-08.1-01, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of North Dakota.

u. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Oregon.

v. R.I. Gen. Laws §§ 6-36-1, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Rhode Island.

   i. In accordance with the requirements of R.I. Gen. Laws § 6-36-21, contemporaneously with the filing of this Complaint, counsel is sending letters by certified mail, return receipt requested, to: Peter Neronha, Attorney General of Rhode Island, informing him of the existence of the Class Action Complaint, identifying the relevant state antitrust provisions, and enclosing a copy of a Class Action Complaint.

w. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of South Dakota.

x. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Tennessee.

y. Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Utah.

i. In accordance with the requirements of Utah Code Ann. § 76-10-3109 contemporaneously with the filing of this Complaint, counsel is sending letters by certified mail, return receipt requested, to: Sean Reyes, Attorney General of Utah, informing him of the existence of the Class Action Complaint, identifying the relevant state antitrust provisions, and enclosing a copy of a Class Action Complaint.

z. W.Va. Code §§ 47-18-1, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of West Virginia.

aa. Wis. Stat. §§ 133.01, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Wisconsin.

387. Defendants' conduct had substantial intrastate effects. Covered entities in the 340B Program with Contract Pharmacy arrangements in place reside within each of the above-listed States and were denied or limited in receiving Contract Pharmacy 340B Drug Discounts from Defendants. Defendants' conspiracy caused those entities to pay inflated prices for Defendants' 340B Drugs and/or to lose 340B Savings at multiple Contract

Pharmacies within each State, thereby threatening to reduce the healthcare services and discounts available to the covered entities' patients in each State. The continuing scheme to limit or eliminate Contract Pharmacy 340B Drug Discounts directly affects and disrupts commerce within each State.

**THIRD CLAIM—STATE UNJUST ENRICHMENT**
**Damages for overcharges**
**On behalf of Plaintiffs and Class Members under their respective States' laws**

388. Plaintiffs hereby repeat the allegations in the foregoing paragraphs as if fully set forth herein.

389. Defendants have benefited from the above-described conduct at the expense of Plaintiffs and the Class, and Defendants continue to retain those benefits under circumstances where it would be unjust to do so. Specifically, by engaging in the foregoing unlawful or inequitable conduct, Plaintiffs and the Class have been deprived of or restrained in their ability to purchase drugs that, but for Defendants' wrongful conduct, would have been eligible for purchase with Contract Pharmacy 340B Drug Discounts (340B eligible drugs), and therefore, Plaintiffs and the Class have been overcharged for purchases of 340B eligible drugs.

390. The financial benefits enjoyed by Defendants because of their wrongful conduct described above are directly traceable to the losses, in the form of overcharges, suffered by Plaintiffs and the Class from not having access to, or having limited access to, Contract Pharmacy 340B Drug Discounts.

391. It would be inequitable under unjust enrichment principles for Defendants to be permitted to retain amounts derived from their collusive and inequitable

conduct as alleged in this Complaint, through any resulting overcharges.

392. Consequently, Defendants have been unjustly enriched by Plaintiffs and Class Members, which made purchases of Defendants' drugs at Contract Pharmacies without access to the Contract Pharmacy 340B Drug Discounts, in violation of the common law of the following states and territories in the United States, as outlined below:

**Arizona**

393. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Arizona at prices that were more than they would have been but for Defendants' actions.

394. Defendants have been enriched by revenue resulting from unlawful overcharges for 340B eligible drugs.

395. Plaintiffs and the class have been impoverished by the overcharges for 340B eligible drugs resulting from Defendants' unlawful conduct.

396. Defendants' enrichment and Plaintiffs' and the Class's impoverishment are connected. Defendants have paid no consideration to any other person for any benefits they received from Plaintiffs and the Class.

397. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

398. There is no justification for Defendants' receipt of the benefits causing their enrichment and Plaintiffs'

impoverishment, because Plaintiffs paid prices higher than they would have been in the absence of the wrongful conduct alleged above that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges.

399. To the extent required, Plaintiffs' and the Class's unjust enrichment claim is alleged where they have no remedy at law.

**Hawaii**

400. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Hawaii at prices that were more than they would have been but for Defendants' actions.

401. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

402. It is unjust for Defendants to retain the benefits received without compensating Plaintiffs and the Class.

**Illinois**

403. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Illinois at prices that were more than they would have been but for Defendants' actions.

404. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

405. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to Plaintiffs and the Class.

406. It is against equity, justice, and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

407. To the extent required, Plaintiffs' and the Class's unjust enrichment claim is alleged where they have no remedy at law.

**Iowa**

408. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Iowa at prices that were more than they would have been but for Defendants' actions.

409. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

410. Defendants have been enriched by revenue resulting from unlawful overcharges for 340B eligible drugs, which revenue resulted from the wrongfully inflated prices paid by Plaintiffs and the Class, which inured to Defendants' benefit.

411. Defendants' enrichment has occurred at the expense of Plaintiffs and the Class.

412. It is unjust for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

**Maine**

413. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Maine at prices that were more than they would have been but for Defendants' actions.

414. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

415. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to Plaintiffs and the Class.

416. Defendants were aware of and appreciated the benefit bestowed upon them by Plaintiffs and the Class.

417. Defendants were unjustly enriched at the expense of Plaintiffs and the Class.

**Michigan**

418. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Michigan at prices that were more than they would have been but for Defendants' actions.

419. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

420. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to Plaintiffs and the Class.

421. Defendants were unjustly enriched at the expense of Plaintiffs and the Class.

**Minnesota**

422. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Minnesota at prices that were more than they would have been but for Defendants' actions.

423. Defendants appreciated and knowingly accepted the benefits bestowed upon them by Plaintiffs and the Class. Defendants have paid no consideration to any other person for any of the benefits they have received from Plaintiffs and the Class.

424. It is inequitable for Defendants to accept and retain the benefits received without compensating Plaintiffs and the Class.

425. To the extent required, Plaintiffs' and the Class's unjust enrichment claim is alleged where they have no remedy at law.

**Mississippi**

426. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Mississippi at prices that were more than they would have been but for Defendants' actions.

427. Defendants retain the benefit of overcharges received on the sales of 340B eligible drugs, which in equity and good conscience belong to Plaintiffs and the Class on account of Defendants' anticompetitive conduct.

**Nebraska**

428. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Nebraska at prices that were more than they would have been but for Defendants' actions.

429. Defendants received money from Plaintiffs and the Class as a direct result of the unlawful overcharges, and have retained this money. Defendants have paid no consideration to any other person in exchange for this money.

430. In justice and fairness, Defendants should disgorge such money and remit the overcharged payments back to Plaintiffs and the Class.

**Nevada**

431. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Nevada at prices that were more than they would have been but for Defendants' actions.

432. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

433. Defendants appreciated the benefits bestowed upon them by Plaintiffs and the Class, for which they have paid no consideration to any other person.

434. Defendants have knowingly accepted and retained the benefits bestowed upon them by Plaintiffs and the Class.

435. The circumstances under which Defendants have accepted and retained the benefits bestowed upon them by Plaintiffs and the Class are inequitable in that they result from Defendants' unlawful overcharges for 340B eligible drugs.

436. To the extent required, Plaintiffs' and the Class's unjust enrichment claim is alleged where they have no remedy at law.

**New Mexico**

437. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in New Mexico at prices that were more than they would have been but for Defendants' actions.

438. Defendants have knowingly benefitted at the expense of Plaintiffs and the Class from revenue resulting from unlawful overcharges for 340B eligible drugs.

439. To allow Defendants to retain the benefits would be unjust because the benefits resulted from anticompetitive pricing that inured to Defendants' benefit and because Defendants have paid no consideration to any other person for any of the benefits they received.

**New York**

440. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in New York at prices that were more than they would have been but for Defendants' actions.

441. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

442. Defendants have been enriched by revenue resulting from unlawful overcharges for 340B eligible drugs, which revenue resulted from overcharges paid by Plaintiffs, which inured to Defendants' benefit. The relationship between Defendants and Plaintiffs and the Class within the state of New York is not too attenuated because Defendants are aware that the 340B eligible drugs they manufacture, sell, and distribute are purchased by Plaintiffs and the Class within the state of New York. Moreover, Defendants' obligation to provide their Drugs at 340B discount prices is an obligation that runs directly to Plaintiffs and the Class.

443. Defendants' enrichment has occurred at the expense of Plaintiffs and the Class.

444. It is against equity and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

445. To the extent required, Plaintiffs' and the Class's unjust enrichment claim is alleged where they have no remedy at law.

**Oregon**

446. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Oregon at prices that were more than they would have been but for Defendants' actions.

447. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

448. Defendants were aware of the benefit bestowed upon them by Plaintiffs and the Class.

449. It would be inequitable and unjust for Defendants to retain any of the overcharges for 340B eligible drugs derived from Defendants' unfair conduct without compensating Plaintiffs and the Class.

**Rhode Island**

450. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Rhode Island at prices that were more than they would have been but for Defendant's actions.

451. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

452. Defendants were aware of and/or recognized the benefit bestowed upon them by Plaintiffs and the Class.

453. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and the Class.

**South Dakota**

454. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in South Dakota at prices that were more than they would have been but for Defendants' actions.

455. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and

flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

456. Defendants were aware of the benefits bestowed upon them by Plaintiffs and the Class.

457. Under the circumstances, it would be inequitable and unjust for Defendants to retain such benefits without reimbursing Plaintiffs and the Class.

458. To the extent required, Plaintiffs' and the Class's unjust enrichment claim is alleged where they have no remedy at law.

**Utah**

459. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Utah at prices that were more than they would have been but for Defendants' actions.

460. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

461. Defendants were aware of or appreciated the benefit bestowed upon them by Plaintiffs and the Class.

462. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and the Class.

463. To the extent required, Plaintiffs' and the Class's unjust enrichment claim is alleged where they have no remedy at law.

**Vermont**

464. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Vermont at prices that were more than they would have been but for Defendants' actions.

465. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

466. Defendants accepted the benefit bestowed upon them by Plaintiffs and the Class.

467. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and the Class.

**Virginia**

468. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Virginia at prices that were more than they would have been but for Defendants' actions.

469. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

470. Defendants accepted the benefit bestowed upon them by Plaintiffs and the Class.

471. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and the Class.

472. To the extent required, Plaintiffs' and the Class's unjust enrichment claim is alleged where they have no remedy at law.

**West Virginia**

473. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in West Virginia at prices that were more than they would have been but for Defendants' actions.

474. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

475. Defendants were aware of or appreciated the benefit bestowed upon them by Plaintiffs and the Class.

476. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and the Class.

**Wisconsin**

477. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Wisconsin at prices that were more than they would have been but for Defendants' actions.

478. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and

flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

479. Defendants appreciated the benefits bestowed upon them by Plaintiffs and the Class and should be reasonably expected to repay Plaintiffs for the benefits conferred upon them.

480. This claim is asserted in the alternative to the extent that Plaintiffs lack an adequate remedy at law.

**JURY DEMAND**

481. Plaintiffs request a jury trial of all issues triable of right by a jury.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

1. Certifying this action as a class action, certifying Plaintiffs as Class Representatives, and appointing Plaintiffs' counsel of record as Class Counsel, all pursuant to Rule 23 of the Federal Rules of Civil Procedure;

2. Declaring Defendants' conduct violated federal and State laws;

3. Awarding money damages in an amount to be proved at trial, plus statutory damages, punitive and treble damages, and other such relief as provided by law, together with all such further relief as may be just and proper, plus pre-judgment and post-judgment interest, to Plaintiffs and Class Members;

4. Awarding the costs of bringing this action, including reasonable attorneys' fees and expenses, as further provided by the statutes cited;

5. Entry of preliminary and permanent injunctive relief prohibiting the anticompetitive conduct alleged herein and eliminating the anticompetitive effects of the same, as well as providing any appropriate restitution and/or disgorgement of all unlawful or illegal profits received by Defendants as a result of the anticompetitive conduct alleged herein; and

6. Granting all other relief to which Plaintiffs and Class Members may be entitled at law or equity.

Dated: October 3, 2022

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