24-598

To Be Argued By:
BRIAN MARC FELDMAN

IN THE

United States Court of Appeals

FOR THE SECOND CIRCUIT

Docket No. 24-598

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

Plaintiffs-Appellants,

—against—

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

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK

BRIEF FOR PLAINTIFFS-APPELLANTS

BRIAN MARC FELDMAN
Counsel of Record
SHEILA BAYNES
AURELIAN LAW PLLC
3445 Winton Place, Suite 228
Rochester, New York 14623
(585) 542-1200

ELLEN MERIWETHER
CAFFERTY CLOBES MERIWETHER & SPRENGEL LLP
135 South LaSalle Street
Chicago, Illinois 60603
(312) 782-4880

LAUREN R. MENDOLERA
HARTER SECREST & EMERY LLP
50 Fountain Plaza, Suite 1000
Buffalo, New York 14202
(716) 853-1616

Attorneys for Plaintiffs-Appellants

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Corporate Disclosure Statement

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, Plaintiffs-Appellants disclose that there are no corporate parents or publicly held corporations that own 10% or more of their stock.

Preliminary Statement

Plaintiffs-Appellants Mosaic Health, Inc. and Central Virginia Health Services, Inc. (the Clinics or Plaintiffs) are federally-funded health centers, part of the nation's healthcare safety net that cares for uninsured and underinsured patients in need. On behalf of safety-net providers nationwide, the Clinics filed this putative class action to address billions of dollars of mounting losses from abrupt discount-slashing initiated in late 2020 by drugmakers with exclusive control over key diabetes drug markets: Sanofi-Aventis U.S., LLC (Sanofi), Eli Lilly and Company and Lilly USA, LLC (Eli Lilly), Novo Nordisk, Inc. (Novo Nordisk), and AstraZeneca Pharmaceuticals LP (AstraZeneca) (together, Defendants). The Clinics sued Defendants for constricting discounts via concerted action, a *per se* violation of the antitrust laws.

Through their joint conduct, Defendants reaped billions of dollars in additional profits at the expense of safety-net providers and, ultimately, the patients they serve. These restrictions flew in the face of an extremely stable status quo; from 2010 until 2020, a full thousand drug firms, including Defendants, uniformly offered discounts to safety-net providers in amounts calculated under Section 340B of the Public

Health Service Act (340B), codified at 42 U.S.C. § 256b.[1] They consistently offered these 340B discounts to safety-net providers for purchases of drugs dispensed at community pharmacies, such as CVS or Walgreens. Defendants alone exited that status quo in the second half of 2020, when each announced broad restrictions on such discounting.

This was not sheer coincidence. The odds of these four Defendants acting randomly together, while the rest of the drug industry stood back, were virtually nil. The entire drug industry had long advocated against requiring 340B discounting at community pharmacies. Yet these four Defendants acted together when a thousand peers did not. They were not a random group. Instead, they were the four drug companies that together held exclusive control over three blockbuster diabetes drug markets: rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics.

Defendants' total domination of these three markets meant that, by acting together, they protected themselves from serious risks that

[1] Although Title 42 of the United States Code has not been enacted into positive law, *see generally* 1 U.S.C. § 204, this brief refers to the United States Code for the Court's convenience in locating 340B of the Public Health Service Act.

might arise if any one of them had acted alone. Collective action created safety-in-numbers, both against market-share losses and severe regulatory action. For a decade, the U.S. Department of Health and Human Services (HHS) had forbidden the discount restrictions suddenly imposed by Defendants, and HHS had the power to cut off Medicare and Medicaid coverage for an offending firm's drugs—an extraordinarily costly punishment. But, by acting together, Defendants made such a response by the government untenable. HHS could not cut off coverage of all four Defendants' drugs without eliminating Medicare and Medicaid patients' access to entire classes of necessary diabetes medications. That would have been a wholly unacceptable outcome for HHS. Defendants' joint action thus constrained the government.

Defendants tried to hide this concerted action by varying their restrictions slightly and staggering their public announcements over a few months. In fact, the first two Defendants acted a single business day apart—Sanofi publicly announced its 340B discount restrictions one business day after AstraZeneca privately communicated its restrictions to HHS. And just days after AstraZeneca's public announcement, Eli Lilly privately communicated its own strikingly similar 340B discount

restrictions to HHS. Novo Nordisk followed soon after. Defendants' extensive and dramatic policy changes to decades of uniform discounting could not have been feasibly conceived, approved, and rolled out independently by each Defendant—and by none of the one thousand other drug companies that offered 340B discounts for the preceding decade—within just a few months of each other. Certainly, this sea change could not materialize organically within mere days. The restrictions were pre-planned and coordinated.

Defendants' restrictions all achieved the same dramatic outcome, even though each Defendant imposed restrictions in somewhat different ways. One provided a path for providers to earn back discounts by uploading valuable data. Some permitted a single-community-pharmacy exception. And one carved out certain types of safety-net providers. But, despite these variations, Defendants sought and reached the same historically unprecedented result—eliminating the vast majority of 340B discounts on their drugs at community pharmacies. Slashing these enduring discounts has been a multi-billion-dollar success for Defendants and, in equal measure, loss for safety-net providers.

The Clinics sought redress for all safety-net providers by filing a class action under federal and State antitrust laws. But Plaintiffs were shut down at the pleadings phase by the U.S. District Court for the Western District of New York (Wolford, C.J.), which dismissed the complaint and denied leave to amend. In so doing, the court misapplied foundational antitrust and pleading principles.

First, the district court imposed a too-narrow view of parallel conduct. It mistakenly held that, even though Defendants jointly broke a decade-plus status quo by imposing restraints with the same objective of restricting 340B discounting, such conduct was not "parallel" because of "variations in both . . . timing and particulars." (JA-976). But parallel conduct easily encompasses joint efforts to raise prices (here, by eliminating discounts), even where conspirators employ somewhat varied means. Both the Supreme Court and this Court recognized as much in *Bell Atlantic Corporation v. Twombly*, 550 U.S. 544, 550–51 (2007), characterizing diverse tactics to thwart market entrants, rolled out over many years, as parallel conduct. If the law were otherwise, sophisticated firms would have an easy roadmap to escape antitrust liability.

Second, the district court misapplied *Twombly*'s plausibility standard. The complaint pled historically unprecedented restrictions, near-simultaneous action by AstraZeneca and Sanofi hidden from public view, as well as a full spectrum of antitrust plus factors, all of which placed Defendants' parallel conduct squarely "in a context that raises a suggestion of a preceding agreement." *Id.* at 557. Yet the district court strained to give Defendants every benefit of every doubt in an attempt to explain away each fact suggesting collusion. In doing so, the district court contravened *Twombly*'s warning that a "well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of the facts alleged is improbable," *id.* at 556, and this Court's admonition that the "question at the pleading stage is not whether there is a plausible alternative to the plaintiff's theory" but "whether there are sufficient factual allegations to make the complaint's claim plausible," *Anderson News, L.L.C. v. Am. Media, Inc.*, 680 F.3d 162, 189–90 (2d Cir. 2012). The complaint was replete with factual matter showing joint action. Plausibility was easily satisfied.

Third, the district court expressed misplaced concern that adjudicating the antitrust claims would require deciding if the 340B

discount restrictions are legal, even absent collusion. But there is no need to decide whether the restraints are permitted by Section 340B because "it is well settled that acts which are in themselves legal lose that character when they become constituent elements of an unlawful [antitrust] scheme." *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 707 (1962). The evil challenged here is collusion.

For these reasons, this Court should reverse the judgment below to permit this action to proceed on the merits.

Jurisdictional Statement

The district court had subject matter jurisdiction under 28 U.S.C. § 1331. Appellants timely filed a notice of appeal on February 26, 2024 (JA-988) following a final judgment of the district court entered on February 2, 2024 (JA-987). This Court has appellate jurisdiction under 28 U.S.C. § 1291.

Issues Presented for Review

1. Whether parallel conduct must be substantially identical in "timing" and "particulars" in an antitrust complaint against direct competitors for conspiring to reduce longstanding discounts, all announced in the second half of 2020.

2. Whether a complaint plausibly pleads an antitrust conspiracy to restrict discounts when it pleads historically unprecedented parallel behavior, otherwise improbable coincidences, and a full spectrum of plus factors suggesting concerted action.

3. Whether drug companies' agreement to jointly restrict 340B discounts is actionable under antitrust laws even if such restrictions, if undertaken individually, might be permitted under Section 340B.

Statement of the Case

On July 30, 2021, Mosaic Health, Inc. filed a class action against Defendants. (JA-15). On October 22, 2021, Central Virginia Health Services, Inc. joined as a plaintiff in an amended complaint. (JA-92). That complaint alleged that Defendants agreed to restrict 340B discounts at community pharmacies in violation of federal and state antitrust laws, as well as state common law. (JA-92–97). Defendants moved to dismiss on November 12, 2021. (JA-171).

By decision and order dated September 2, 2022, the district court (Wolford, C.J.) granted Defendants' motion to dismiss. (JA-751). On October 3, 2022, Plaintiffs moved for leave to file a Second Amended Complaint (the SAC). (JA-770). The district court held argument on

the motion on July 20, 2023. (JA-892). By decision and order dated February 1, 2024, the district court denied the motion to amend as futile. (JA-964). The district court entered a final judgment in favor of Defendants on February 2, 2024. (JA-987). Plaintiffs filed a timely notice of appeal on February 26, 2024. (JA-988).

Statement of Facts

A. Plaintiffs' allegations

1. The Clinics are safety-net providers that treat low-income patients, including many with diabetes.

The Clinics are federally qualified health centers funded by the Health Resources and Services Administration (HRSA), an agency of HHS. (JA-779–780). Mosaic Health, Inc. has operated twenty-two safety-net clinics in New York (JA-779); and Central Virginia Health Services, Inc. operates eighteen safety-net clinics in Virginia (JA-780). The Clinics serve low-income and otherwise medically underserved patient populations. (JA-784).

The Clinics treat many diabetes patients. (JA-798–799). Diabetes is a widespread and life-threatening disease, which is often coincident with medically underserved populations. (JA-798–799). It is common

among federally qualified health center patients, such as the Clinics' patients. (JA-799).

2. Defendants are drugmakers who control key diabetes treatments with a history of price manipulation.

a. Defendants fully dominate three multi-billion-dollar diabetes drug markets.

Defendants control three of the most lucrative production markets for diabetes drugs: (i) rapid-acting analog insulins; (ii) long-acting analog insulins; and (iii) incretin mimetics. (JA-798–802). Analog insulins are used to manage Type 1 and Type 2 diabetes. (JA-798–801). Diabetes patients use incretin mimetics to increase the level of incretin hormones, which help the body produce more insulin. (JA-801). Defendants competed only with one another in producing these treatments (JA-845–847); as of mid-2020, they faced no other competition (JA-847–849). Defendants collectively controlled all three markets.

These are blockbuster products that drive Defendants' profits. (JA-803–806). Their sales accounted for more than three quarters of Novo Nordisk's U.S. revenue (JA-804), nearly half of Eli Lilly's revenue (JA-803), billions of dollars of revenue for Sanofi (where they have been

a defining feature of the company's history) (JA-805), and nearly half-a-billion dollars in revenue at AstraZeneca, which has also targeted these markets for growth (JA-805).

b. Government officials have repeatedly found price manipulation in these markets.

Federal, state, and municipal officials have repeatedly identified price manipulation by Defendants within these diabetes drug markets, where prices have climbed even as production costs have declined. (JA-863–864). At the close of a two-year Senate Finance Committee investigation into the "skyrocketing price of insulin," Chair Senator Charles Grassley summarized: "[t]his industry is anything but a free market." (JA-863).

3. For over a decade, safety-net providers uniformly received valuable discounts on diabetes drugs and other drugs at community pharmacies.

a. All manufacturers participate in the 340B discount program.

All manufacturers with drugs covered by Medicare and Medicaid, including Defendants, must participate in the 340B drug discount program. (JA-785). *See* 42 U.S.C. §§ 256b, 1396r-8(a)(1),(a)(5)(A). More than 1,000 drug companies, including the top 250 drug companies, participate in the program. (*Id.*) It creates a discount by imposing a

ceiling price (JA-785), and by then requiring each manufacturer to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price," 42 U.S.C. § 256b(a)(1).

b. Safety-net providers, like the Clinics, have access to 340B discounts, which permit them to stretch scarce resources.

Section 340B provides certain safety-net hospitals and clinics access to discounts when purchasing outpatient drugs. (JA-783). As the Supreme Court has explained, "manufacturers . . . must offer discounted drugs to [these] covered entities, dominantly, local facilities that provide medical care for the poor." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 115 (2011). "Covered entities" under Section 340B include safety-net clinics like federally qualified health centers and safety-net hospitals. (JA-783–784). 42 U.S.C. § 256b(a)(4).

Savings from 340B discounts are critical to safety-net providers. (JA-784). The Clinics, as federally qualified health centers, provide medications to patients in need with sliding-fee discounts based on ability to pay. (JA-784). Section 340B discounts "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. 120-384(II), at 12 (1992).

c. For more than a decade, the Clinics and other safety-net providers were offered 340B discounts at community pharmacies.

i. 1996 and 2010 HHS guidance extended 340B discounting to community pharmacies via "bill to, ship to" arrangements.

In 1996, HHS created a framework to extend 340B discounting to drugs dispensed by community pharmacies. *See* Final Notice, 61 Fed. Reg. 43,549 (Aug. 23, 1996). Very few safety-net providers had in-house pharmacies, making it infeasible for them to benefit from Section 340B. *See id.* at 43,550. To address this gap, HHS guidance set out a "bill to, ship to" arrangement so that safety-net providers could purchase 340B discounted drugs for shipment to community pharmacies (often called contract pharmacies) to be dispensed to the providers' patients there. *See id.* at 43,549, 43,555.

In 2010, to widen patient access and permit more utilization of the 340B program, HHS extended its guidance to facilitate safety-net providers contracting with multiple pharmacies throughout their communities. *See* Final Notice, 75 Fed. Reg. 10,272 (Mar. 5, 2010).

HRSA, the HHS agency that administers the 340B program (JA-785), created an electronic system to coordinate this framework. (JA-791).

ii. Since 1996, HHS has argued that drug companies are legally required to offer 340B discounts at community pharmacies.

In 1996, HHS determined that drug companies *must* offer 340B discounts to safety-net providers for drugs shipped to community pharmacies. HHS instructed "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." 61 Fed. Reg. at 43,549.

iii. The drug industry contested HHS's legal position and attacked contract pharmacy arrangements.

The drug industry has always contested HHS's determination (JA-774–775) and sought to limit any mandate for 340B discounting at community pharmacies (JA-776–777, 807, 812). [2] Indeed, challenges to

[2] Until Defendants' conspiracy, the industry refrained from challenging HHS's position in court. Since then, however, Defendants and others have litigated the issue with mixed results. *Compare Sanofi Aventis U.S. v. HHS*, 58 F.4th 696 (3d Cir. 2023); *Novartis Pharms. Corp. v. Johnson*, __ F.4th __, No. 21-5299, 2024 WL 2279829 (D.C. Cir. May 21,

340B discounting became the most prominent drug advocacy issue at the predominant drug industry association, PhRMA, which pressed for "[r]eform" of HHS's position. (JA-862). The industry also formed a stand-alone association, Air340B, opposed to community pharmacy 340B discounts. (JA-812).

iv. Every manufacturer nevertheless provided 340B discounts at community pharmacies for over a decade.

Despite their longstanding objections, drug manufacturers, including Defendants, universally extended 340B discounts at community pharmacies. (JA-782, 792–794). This was uniform: Each of the 1,000-plus drug companies participating in the 340B program offered discounts at community pharmacies, without restriction, for more than a decade. (JA-793–794).

It was an uninterrupted status quo. (JA-793).

v. Market share and exclusion risks prevented any manufacturer from restricting 340B discounts.

Two significant threats kept the status quo in place.

2024), *with Eli Lilly & Co. v. HHS*, 1:21-cv-81, 2021 WL 5039566, at *19 (S.D. Ind. Oct. 29, 2021).

The first was the threat of market share loss. (JA-794). Safety-net providers have choices over which therapeutically interchangeable drug to administer and prescribe. (JA-794–795). Providers typically set such preferences across-the-board, encompassing both 340B-discounted drugs and full-priced sales. (JA-796). Providers' financial incentive is to choose drugs widely offered at community pharmacies with 340B discounts. (JA-794). So, if a drug company were to restrict 340B discounting at community pharmacies when its competitors did not, that company would risk losing valuable market share.

A second, perhaps greater, threat was regulatory. (JA-796–797). Drug companies violating Section 340B are subject to exclusion from federal healthcare programs—a devastating sanction. (*Id.*). *See* 42 U.S.C. §§ 256b(a)(1), 1396r-8(a)(1),(5). HHS had long taken the position that restricting 340B discounting at community pharmacies would violate 340B. (JA-797). Thus, if a drug company limited 340B community pharmacy discounting, it would risk exclusion. No rational manufacturer would take that risk. (*Id.*).

4. In 2020, Defendants abruptly restricted 340B discounts on their drugs at community pharmacies, even as a thousand other drug companies maintained the status quo.

a. Defendants implemented restrictions that decimated 340B discounting for these Defendants' drugs.

Defendants abruptly departed from industry-wide practice in the second half of 2020, dramatically erasing 340B discounting at community pharmacies for their drugs, including the three diabetes treatments they collectively controlled. (JA-775).

i. Each Defendant restricted 340B discounts at community pharmacies.

Specifically, in the second half of 2020, Defendants suddenly, and in coordination with one another, began refusing to offer 340B discounts at community pharmacies. (*Id.*). Each adopted the same core position—that it would stop selling 340B-discounted drugs to covered entities for community pharmacy dispensing. (JA-818–821).

ii. Defendants staggered their public announcements and offered different exceptions.

Defendants staggered their announcements and provided different caveats.

Sanofi made its plans public on July 27, 2020. (JA-814–815). It announced that, starting October 1, 2020, it would cut off all 340B

discounting at community pharmacies. (*Id.*). It offered an exception for providers willing to send valuable patient claims data to Sanofi on terms dictated by Sanofi and its vendor. (*Id.*). HHS deemed such data exchange "infeasible" (JA-830) because it presents significant regulatory risks (*id.*), imposes extensive resource burdens (JA-831), and "put[s] covered entities at significant financial risk" by revealing data that could be used to reduce providers' drug reimbursements. (JA-831–832). Sanofi thus cut off community pharmacy 340B discounts unless providers agreed to unattractive, costly, and commercially unreasonable data sharing. (JA-830).

AstraZeneca made its plans public a few weeks later in mid-August 2020. (JA-814). Like Sanofi, AstraZeneca adopted the starting position that, beginning on October 1, 2020, it would no longer provide 340B discounts at community pharmacies. (*Id.*). But it offered a different exception. It permitted shipping to one community pharmacy (rather than a comprehensive set of local pharmacies used by patients), but only for those safety-net providers without an on-site pharmacy. (*Id.*). HHS likewise deemed this exception "minimal" (JA-844), because a single pharmacy would serve only a fraction of providers' patients,

who live "over huge geographic areas with transportation and timing difficulties." (JA-836).

Eli Lilly then announced planned restrictions effective September 1, 2020. (JA-819). Like Sanofi and AstraZeneca, Eli Lilly took the position that it would stop "voluntarily honoring requests for 340B 'contract pharmacies' for orders on all Lilly products." (JA-815). Eli Lilly then carved out the same narrow, single-community-pharmacy exception offered by AstraZeneca. (*Id.*). Eli Lilly also purported to offer a special exception to permit pharmacies to pass along certain products at cost. (JA-815). But that special exception was illusory, as it would require participating pharmacies to perform services for free. (JA-837–838). It was, as HHS explained, neither "reasonable [n]or workable in practice." (JA-838).

Novo Nordisk announced its planned restrictions on December 1, 2020, to be effective starting on January 1, 2021. (JA-816). Novo Nordisk adopted the same approach of stopping shipment of 340B discounted drugs to community pharmacies. (JA-820). Novo Nordisk then created an exception for non-hospital entities, like the Clinics. (JA-841). But that limitation did not meaningfully dampen the

dramatic decline of 340B discounted sales at community pharmacies because the vast majority (approximately 90%) of 340B discounted sales are to hospitals, which Novo Nordisk restricted. (*Id.*) Novo Nordisk's CFO thus correctly characterized the firm's 340B discounting on the same terms as its competitors: "basically, we stopped our shipments . . . to contract pharmacies." (*Id.*).

Since then, Defendants have made minor changes to their exceptions. (JA-817). But their common approach—refusing to offer 340B discounting at community pharmacies for most drug sales—has remained constant. (*Id.*).

iii. Defendants' public announcements masked an even shorter timeline.

Defendants publicly announced their restrictions within just months of one another. This was a strikingly short window, given the decades-long status quo. But it masked an even shorter timeline. Just days passed between certain Defendants' public announcements and others' private letters committing to restrictions.

The timing was closest between AstraZeneca and Sanofi. On Friday, July 24, 2020, AstraZeneca privately informed HHS of its groundbreaking plan to restrict 340B discounts beginning on October 1,

2020. (JA-813). This was not public information. (JA-864–865). Yet, by the following Monday, July 27, 2020, Sanofi publicly announced that it would also impose unprecedented 340B drug discounts—also beginning on October 1, 2020. (JA-814).

There was a similarly tight interval between the second and third Defendants to publicly announce restrictions. AstraZeneca publicly announced its plan in mid-August 2020. (JA-814, 271). Again, within just days, Eli Lilly privately informed HRSA that it would implement similar restrictions. (JA-815, 191–194).

It remains to be seen when Novo Nordisk privately informed HHS of its intentions and if that private communication was also just days apart from others' announcements (JA-816).

This was all too close to be a coincidence, as the AstraZeneca–Sanofi example reveals. Sanofi was a $132 billion company that could not have vetted and cleared a dramatic and unprecedented change in its decades-long pricing practices over a summer weekend—especially one fraught with commercial and regulatory risks for a company claiming to have acted alone. (JA-813–814). And Sanofi should not have known about AstraZeneca's private Friday letter in the first place, as that

letter was not public. (JA-865). There is nearly zero chance that these two firms would announce their unprecedented restrictions with a mere weekend between them, and both starting on the same day of October 1, 2020, without advance coordination. (*Id.*).

iv. Defendants' variations masked their restrictions' common impact in decimating 340B community pharmacy discounting.

Despite varied exceptions, all four Defendants achieved the same result with their restrictions—the end of the overwhelming majority of 340B discounted community pharmacy drug sales. (JA-827). Each achieved an immediate 70% to 95% decrease in such discounting. (JA-829 (Sanofi, 90% decline); JA-834 (Eli Lilly, 95% decline); JA-840 (Novo Nordisk, 70% decline); JA-843 (AstraZeneca, 85% decline)). HHS thus described the common and dramatic impact of these concurrent restrictions in equivalent terms: Sanofi's community pharmacy 340B sales "plummet[ed]" (JA-829); Eli Lilly's took a "nosedive" (JA-836); Novo Nordisk's "plummet[ed]" (JA-840); and AstraZeneca's "just [fell] off a cliff" (JA-843).

v. Defendants' joint action came on the heels of shared communications about 340B "reform" through lobbyists and the PhRMA board.

Defendants had ample opportunity to conspire during the months leading up to their restrictions. (JA-776–777, 807, 862). They, like the rest of the industry, had been spending millions of dollars lobbying for 340B "reforms" during those months. (JA-776–777, 810–812). While that lobbying itself is not challenged here, Defendants used the same sets of lobbyists. (JA-810–811). Shared lobbyists meant Defendants were speaking with the same people about the same 340B issues at the same time—all right before they rolled out their unprecedented restrictions. (JA-811).

Defendants also all sat together on the PhRMA board at the time. (JA-811–812, 862). There, 340B contract pharmacy "[r]eform" was one of the most prominent advocacy issues (*id.*), yet again with the same set of lobbyists (JA-811–812). Their collaboration at PhRMA and their common lobbying efforts meant Defendants were already discussing limiting 340B discounting via government action. A discount-cutting agreement, via Defendants' joint action, was an easy step to take.

Then-President Trump's issuance of Executive Order 13937 on July 24, 2020 (the E.O.) marked Defendants' shift from joint lobbying to joint discount-slashing. The E.O. did little to accomplish industry goals in limiting 340B discounts. (JA-807–810). It maintained the status quo. (*Id.*). Before the E.O., Defendants collaborated, legally, in lobbying the federal government to restrict 340B drug discounts through a coordinated campaign—their Plan A. After the E.O, however, Defendants collaborated, illegally, to restrict 340B drug discounts in concert with one another—a Plan B. (JA-777, 807). Defendants had ample opportunity to develop that Plan B through their joint lobbying and PhRMA board service immediately in advance of the E.O.

vi. Defendants offered no rationale for the sudden change.

When Defendants ultimately imposed their broad 340B discount restrictions, none offered any explanation for the timing. (JA-817–818). None cited the E.O. (JA-808, 817–818). Rather, each pointed to industry-wide and longstanding allegations about program integrity. (JA-817–818). None offered any rationale that would explain why these four Defendants, alone in a 1,000-firm industry, imposed broad new restrictions or why they did so suddenly in late 2020. (*Id.*).

Eli Lilly left the most unexplained. Months earlier, in May 2020, it placed an extremely narrow limit on 340B discounting at community pharmacies, ending discounts on a single drug, Cialis. (JA-816). It justified that narrow action with rationales that applied equally across its drug portfolio. (JA-816, 859–860). But Eli Lilly rejected any broad-scale restrictions at that time. (JA-816, 821–822). Just two months later, though, Eli Lilly reversed course, ditching its narrow limits on Cialis to embrace Defendants' dramatic joint restraints portfolio-wide. (JA-191–194, 815, 821–822). Eli Lilly never explained why it had been unwilling to take such sweeping action two months earlier, on its own. (*Id.*; JA-816).

b. No other major drug company joined Defendants until the government set a precedent by not excluding Defendants' drugs.

Throughout Defendants' dramatic actions, the remaining 1,000-strong pharmaceutical industry watched and waited. For a year, not a single other major drug company joined the Defendants in restricting 340B discounting at community pharmacies. (JA-822).

By late 2021, when other companies finally began imposing analogous restrictions, the government had set a precedent by choosing

not to exclude Defendants' drugs from Medicare and Medicaid. That had been an open question in late 2020 and early 2021, as HRSA warned of "potentially dire consequences" (JA-823–824), and the U.S. Department of Justice explicitly warned that restrictions could lead to exclusion (JA-825–826). No firm beyond Defendants took that risk at that time. But, in May 2021, HRSA elected to pursue potential civil penalties, rather than exclusion. (JA-826–827). The precedent was thus set, lowering the stakes for other firms. Only then did other major drug firms begin imposing similar restrictions. (JA-822).

5. Defendants' restrictions have caused billions of dollars of losses.

Defendants' restrictions are doing immense damage to safety-net providers and consequently limiting the healthcare options available to patients those providers serve. (JA-778–779). The losses to safety-net hospitals and clinics—and the concomitant gains to Defendants—have amounted to many billions of dollars. HHS calculated that safety-net providers initially lost more than $43 million per month from Sanofi's restrictions (JA-829), $60 million per month from Eli Lilly's restrictions (JA-834), $100 million per month from Novo Nordisk's restrictions (JA-

840), and $46 million per month from AstraZeneca's restrictions (JA-843).

These losses continue to mount.

B. Procedural history

1. Plaintiffs alleged antitrust and related claims.

The Clinics sued Defendants for violating federal and State antitrust laws, and unjustly enriching themselves, through concerted action to restrict 340B discounts at community pharmacies. (JA-845, 871–890). The complaint took no position on what 340B requires or permits. Rather, it alleged an agreement among Defendants to collectively impose 340B discount restrictions together. (JA-871–878). Plaintiffs seek classwide relief on behalf of safety-net providers with community pharmacy 340B discount arrangements in place as of September 1, 2020. (JA-869).

2. The district court dismissed the first amended complaint as not showing impacts similar enough to be "parallel conduct."

The district court dismissed Plaintiffs' first amended complaint in a decision and order dated September 2, 2022, holding that the complaint did not "plausibly allege[] parallel conduct." (JA-761). The court reasoned that Defendants' discount restrictions had not

"ultimately achieved the same or a substantially similar end result." (JA-763–766).

The court reached this conclusion by fully crediting factual claims of Defendants while refusing to credit Plaintiffs' factual allegations. The opinion adopted each Defendant's characterization of its exceptions to restrictions and construed those exceptions as meaningful, robust, and broad, even though Plaintiffs alleged otherwise. (JA-762–763). The court thus credited Eli Lilly's false suggestion, found nowhere in the pleadings, that the company allowed "unlimited contract pharmacies." (JA-763 (n.5), 765). By contrast, the court refused to accept the complaint's allegation that Eli Lilly's pass-through exception was commercially infeasible because it would require a pharmacy to dispense drugs without compensation. (JA-762 (n.4)). Likewise, the court stated that it was "not required to credit" the complaint's allegation that Sanofi's new data requirements were commercially unreasonable. (JA-762 (n.3)). And the court rejected the complaint's key factual allegation that the "'net effect' of each of the [Defendant's] policies was to 'end[] nearly all Contract Pharmacy 340B Drug

Discounts for AstraZeneca, Eli Lilly, Novo Nordisk, and Sanofi drugs'" as "conclusory." (JA-765).

Based on these assumptions, the district court characterized Defendants' policies as "disparate" and "different in their particulars, their timing, and their outcomes." (JA-763). The court accepted Eli Lilly's characterization of its exceptions over what Plaintiffs alleged and inferred that the impact of Eli Lilly's restrictions might be very small. (JA-765). Likewise, after rejecting allegations that Sanofi's data-sharing program was infeasible, the court suggested that the impact of Sanofi's restrictions might similarly be small, stating that the "lack of information regarding the impact of Sanofi's policy is particularly problematic." (JA-766). The court also suggested that the impact of Novo Nordisk's restrictions might be negligible because its policy carved out clinics and that AstraZeneca's policy might not be impactful because those restrictions applied "only to particular AstraZeneca products," even though the court identified no product carve-outs or their significance. (JA-765).

The court summed up that the 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." (JA-766). The court held that "[t]he adoption of those policies accordingly does not constitute parallel conduct as alleged." (*Id.*).[3]

3. Plaintiffs filed a proposed SAC showing similar impacts.

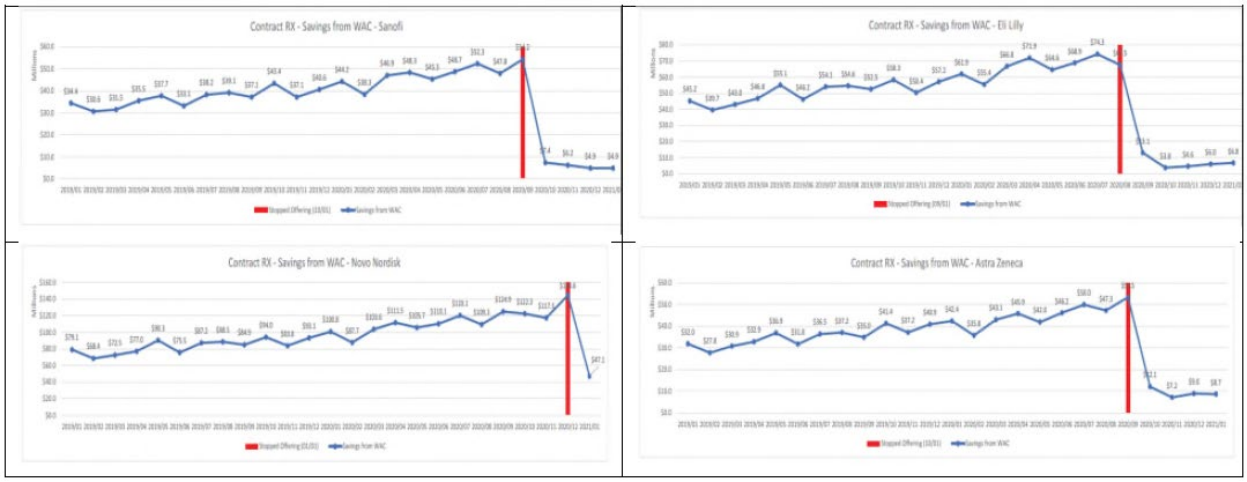
In response to the court's decision, Plaintiffs submitted a proposed Second Amended Complaint (the SAC) explaining that Defendants' 340B discounting restrictions "ultimately achieved the same result among all Defendants—the elimination of the bulk of their Contract Pharmacy 340B Drug sales." (JA-827).[4]

The proposed SAC detailed this common impact. It included data, published by HHS, showing that each Defendant's restriction ended the vast majority of 340B discounting at community pharmacies for its drugs. (JA-828–845). That data showed an immediate impact through

[3] The district court dismissed the State law antitrust claims on the same basis (JA-766–767) and dismissed the unjust enrichment claims as too generic (JA-767–768).

[4] The SAC also further particularized the unjust enrichment claims. (JA-877–890).

precipitous drops in discounts by 70%–95% (JA-778, 829, 834, 840, 843) with graphs illustrating this common result showing the decline of 340B discounts (in blue) following the imposition of Defendant's restrictions (the red line) as follows:



(JA-829, 834, 840, 843 (clockwise from top left: Sanofi; Eli Lilly; AstraZeneca; Novo Nordisk)).

The SAC also explained why Defendants' various exceptions were marginal, such that the common, dramatic, and immediate impact was readily foreseeable. (JA-830, 835, 840, 844). The SAC addressed each of the Eli Lilly exceptions noted by the district court. It debunked the suggestion that Eli Lilly provided for "unlimited contract pharmacies," citing Eli Lilly's own description in other cases, as well as contrary statements by another court and HHS. (JA-835–836). The SAC then

detailed the exceedingly narrow nature of the special pass-through exception, citing HHS's conclusion that it was "not reasonable or workable in practice," the fact that it required covered entities to "*lose* money," and an industry pharmacist's sworn statement that it was "entirely impractical" because it required community pharmacies to "agree to dispense drugs without any compensation." (JA-836–838). Eli Lilly's exceptions were so marginal that the company's restrictions succeeded in eliminating 95% of 340B drug discounts at community pharmacies. (JA-834).

Similarly, the SAC rebutted Sanofi's mischaracterization of its data-sharing exception. The SAC cited HHS's conclusion that the data-sharing demand was "infeasible for covered entities," explaining that the demands created legal and privacy risks, conflicted with existing contracts, imposed serious burden on covered entities, and harmed entities' long-term financial interests. (JA-830–832). The data-sharing exception was so onerous and unattractive that Sanofi succeeded in eliminating 90% of 340B drug discounts at community pharmacies. (JA-829).

Likewise, the SAC showed that both the Novo Nordisk and AstraZeneca restrictions were broad enough that they too led, predictably, to the immediate elimination of the overwhelming majority of each firm's 340B discounting at community pharmacies. (JA-841, 845). The SAC explained that, while Novo Nordisk limited its restrictions to hospitals, the hospital sales segment was so large (approximately 90% of sales) that the restrictions likewise resulted in the overwhelming elimination of discounted community pharmacy sales. (JA-841). Novo Nordisk's 70% decline was the largest gross decline, allowing the company to reap an additional $100 million in revenue each month. (JA-840). As to AstraZeneca, the SAC explained that its exceptions were so marginal that its 340B discounting dropped by over 85%. (JA-843). The SAC cited HHS's statement that "'340B sales just [fell] off a cliff when [AstraZeneca] put their restrictions into effect'" (JA-843), and detailed AstraZeneca's admission that this "nosedive" had resulted from its restrictions (JA-844–845).

4. The district court denied leave to amend.

The district court nevertheless denied leave to amend in a decision and order dated February 1, 2024. (JA-964). It held that amendment

was futile for two reasons: (a) in the court's view, the SAC still did not allege parallel conduct; and (b) in the alternative, the court concluded that the SAC did not otherwise make conspiracy more plausible than other explanations for Defendants' restrictions. (JA-970–985).

a. The court refused to view each Defendant's vast reduction of 340B discounts at community pharmacies as parallel.

First, the court reaffirmed its earlier decision, holding that Defendants' policies "simply do not amount to parallel conduct, for essentially the reasons discussed by the Court in its original Decision and Order." (JA-978). The district court characterized the SAC's data, which showed common, dramatic impacts, as "Plaintiffs try[ing] to gloss over . . . significant differences." (JA-979). The court found no common impact, even as it observed that three of the four defendants had the same "volume decrease of approximately 90%." (*Id.*). Instead, it focused on a lower 60% decline, by transaction volume, for Novo Nordisk, and characterized that number as "dramatic[ally] differen[t]" than the common result among the other three defendants. (*Id.*). The court did not explain why it selected declines by transaction volume for Novo Nordisk's sales, rather than the 70% decline in overall discounts

by savings. (*Compare* JA-979 *with* JA-840 (¶ 218)). Nor did the court offer any explanation as to why the sudden decline in 340B discounts for these four Defendants' drugs at community pharmacies, which had the uncontested effect of eliminating the vast majority of their until-then consistent 340B discounts, "fail[ed] to plausibly allege . . . parallel conduct." (JA-979).

b. In the alternative, the district court credited Defendants' alternative explanations as more plausible than conspiracy.

Second, and in the alternative, the district court held that even if the conduct was "parallel," the SAC still did not plausibly allege concerted action. (JA-980). The district court stated that "the failure of the Defendants' joint lobbying efforts" offered an "obvious alternative explanation" for Defendants' conduct in the SAC. (*Id.*). The court did not identify how that industry-wide effort could explain why just these four Defendants broke the longstanding status quo. (*Id.*). The district court brushed aside the fact that Defendants alone imposed these unprecedented restrictions in late 2020 and early 2021. The court identified two other firms (out of a thousand) that asked covered entities to share data along the lines Sanofi had demanded, but it failed

to recognize that neither such firm actually restricted 340B discounts (the alleged concerted action) in any way. (JA-982). So too, the court stated that other firms eventually adopted similar policies but failed to acknowledge that none did so until much later, after it became clear that the government was not punishing Defendants with exclusion. (*Id.*).

The district court nowhere addressed Plaintiffs' allegation that Defendants had "acted too closely in time for it to be coincidental, especially because AstraZeneca did not publicly reveal its plans." (*Compare* JA-980–985, *with* JA-782, 813–814, 864–865). It offered no explanation as to why Sanofi's public announcement of unprecedented broad 340B discount restrictions on a Monday, following AstraZeneca's private letter stating those same restrictions the prior Friday, did not make their prior coordination and conspiracy plausible. (*Id.*). The court footnoted only the related fact "that both AstraZeneca's and Sanofi's policies were effective October 1, 2020," which the court tried to explain away as "the beginning of the next fiscal quarter," without noting that Eli Lilly (which was on the same fiscal reporting calendar) did not select that same date. (JA-977). But the district court skipped over the eye-

popping one-business-day gap between AstraZeneca's secret plan and Sanofi's public one.

The district court rationalized away other alleged circumstantial evidence as well. It refused to accept the SAC's explanation of the market-share risks drugmakers would face by unilaterally terminating 340B discounting on key products, which would permit competitors to use the lure of 340B discounts to advance their competing products as preferred drugs for safety-net providers. The court further refused to accept the SAC's explanation that a clinic or hospital's drug preferences were typically implemented across-the-board, such that a drugmaker's restriction of 340B discounting would equally imperil market share in non-discounted markets. (*Compare* JA-982–983, *with* JA-794–796).

So too, the district court rejected the SAC's explanation of the regulatory risks faced by any firm limiting 340B drug discounts alone. (JA-983–984). It found that allegation "undercut[]" by the fact that Eli Lilly had imposed a 340B discount restriction narrowly tailored to a single drug, Cialis, in May 2020. (JA-984). But the district court did not address Eli Lilly's inexplicable move from that extremely narrow restriction in May 2020 to its dramatic across-the-board restrictions

eliminating 95% of 340B contract pharmacy discounting just two months later, or how this drastic shift aligned perfectly with the conspiracy pled in the complaint. (*Id.*). And, instead of focusing on the fact that Defendants all rolled out and did not waver from their common restrictions in the face of open threats of devastating government sanctions (JA-165–172, 290–309, 313), the court observed that additional government "warnings" came after three Defendants had announced their plans (JA-984).

The district court discounted other facts, too. It stretched the timeline by including Eli Lilly's earlier narrow restriction on Cialis and later-in-time changes that Defendants made to their restrictions. (JA-980). It did not acknowledge how anomalous Defendants' restrictions were, with 99.6% of drug companies continuing to offer unrestricted 340B discounts. (*Compare* JA-984, *with* JA-859–860). Nor did it give any weight to the fact that the lucrative diabetes market was conducive to a conspiracy because only four competitors sold the key diabetes treatments (c*ompare* JA-984, *with* JA-860), and would-be competitors could not break up the conspiracy without intellectual property rights and immense investments (*compare* JA-984, *with* JA-861). Likewise,

the court discounted the fact that Defendants had ample opportunity to conspire, as they were working together on 340B discounting issues immediately in advance of the conspiracy through common lobbyists and associations. (*Compare* JA-984, *with* JA-810–812, 862). And it set aside persistent allegations of recent price manipulation by these same Defendants in these very markets "in the past" as "not tied" to the allegations here. (*Compare* JA-984–985, *with* JA-863–864).

c. The district court noted "serious doubts" that Defendants could even violate the antitrust laws by conspiring to restrict discounts.

Finally, in a footnote, the district court also stated that it had "serious doubts about the viability of this matter in light of" *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 113 (2011), where the Supreme Court found no private right of action for a covered entity to sue manufacturers for violations of Section 340B. (JA-973 (n.2)). The court engaged in no implied repeal analysis. (*Id.*). Nor did it otherwise explain, even if individually imposed discounting restrictions might be permissible and legal under 340B, why Defendants could escape antitrust liability for conspiring to impose their restrictions jointly. Instead, the court accepted Defendants' argument that "this litigation is

a backdoor attempt to use the antitrust laws to enforce Plaintiffs' preferred interpretation of the 340B statute." (*Id.*).

5. Plaintiffs filed a timely notice of appeal.

Following the district court's entry of final judgment on February 2, 2024 (JA-987), Plaintiffs timely appealed (JA-988).

Summary of Argument

I. The district court erred in holding that historically unprecedented restraints on 340B discounting, all announced in the second half of 2020, could not qualify as "parallel conduct" because of "substantial variations in their timing and particulars." As the Fourth Circuit has explained, there is "no support in any existing authority" for such a conclusion. *SD3, LLC v. Black & Decker (U.S.) Inc.*, 801 F.3d 412, 428-429 (4th Cir. 2015). Defendants' common 340B restrictions varied much less than the parallel conduct in *Twombly*, which consisted of a "variety of activities" to thwart new telephone carriers undertaken over many years. *Twombly v. Bell Atl. Corp.*, 425 F.3d 99, 118 (2d Cir. 2005). And the period of Defendants' conduct was consistent with, and in some cases much closer in time than, other periods this Court has upheld as parallel. If this Court were to affirm here, firms could agree

to fix prices with impunity, so long as each competitor did so in their own way and at slightly different times.

II. The district court misapplied the plausibility standard by rejecting well-supported inferences suggesting conspiracy in favor of Defendants' efforts to explain those inferences away. For example, the court gave Defendants the benefit of the doubt in overlooking nearly impossible coincidences, including the near-zero chance that these four diabetes drug manufacturers would randomly be the first movers towards unprecedented discount slashing, and otherwise impossible-to-explain timing, such as AstraZeneca privately advising of its change one business day before a public announcement by Sanofi. So too, the district court erroneously rejected as implausible the reasons why imposing restrictions alone would be against any one firm's interests, even though those very reasons had prevented any firm from imposing restrictions for more than a decade. The district court took a similarly misguided approach to myriad other plus factors. Under the proper standard, Plaintiffs more than plausibly pled conspiracy.

III. Finally, there was no basis for the district court's footnoted concern about the viability of conspiracy allegations relating to 340B

discounts. Antitrust laws unquestionably prohibit conspiracies to restrict discounts, including discounts on drug sales. The antitrust theory does not turn on the meaning of Section 340B and is equally viable if the restraints were otherwise legal or illegal. It is black letter law that even otherwise legal acts (*e.g.*, raising prices) are illegal when they are the product of conspiracy. The SAC seeks redress only for conspiracy, not violations of Section 340B. This Court should clarify that the district court's concerns provide no basis for dismissal.

For these reasons, this Court should reverse and remand.

A R G U M E N T

Standard of Review

This Court reviews the "grant of a motion to dismiss de novo, accepting as true all factual claims in the complaint and drawing all reasonable inferences in the plaintiff's favor." *Gelboim v. Bank of Am. Corp.*, 823 F.3d 759, 769 (2d Cir. 2016) (quotation marks omitted). "The denial of leave to amend is similarly reviewed de novo," where, as here, "the denial was 'based on an interpretation of law, such as futility.'" *Id.* (quoting *Panther Partners Inc. v. Ikanos Commc'ns, Inc.*, 681 F.3d 114, 119 (2d Cir. 2012)).

POINT I

THE DISTRICT COURT ERRED IN FINDING NO PARALLEL CONDUCT.

The district court erred in granting the motion to dismiss and in refusing leave to amend by holding that Defendants' unprecedented 340B discount restrictions could not be viewed as "parallel conduct" because of "substantial variations in both their timing and their particulars." (JA-976; *see also* JA-763).

A. Common restraints constitute "parallel conduct" even if they vary in time and particulars.

Section 1 of the Sherman Act prohibits any "contract, combination . . . or conspiracy in restraint of trade." 15 U.S.C. § 1. This requires an allegation of "some form of concerted action." *Cap. Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs., Inc.*, 996 F.2d 537, 542 (2d Cir. 1993). One way to show concerted action is by alleging "parallel conduct" in "a context that raises a suggestion of a preceding agreement." *Twombly*, 550 U.S. at 557; *see In re Publ'n Paper Antitrust Litig.*, 690 F.3d 51, 62 (2d Cir. 2012).

Parallel conduct is a broad concept that encompasses firms engaged in acts with shared objectives, even by varied means. *Twombly* is instructive. There, the Supreme Court and this Court agreed that

the plaintiffs had sufficiently alleged parallel conduct (but ultimately failed to allege sufficient additional facts). *See Twombly*, 550 U.S. at 564; *Twombly*, 425 F.3d at 103–04. The complaint had described two sets of parallel conduct by incumbent telephone carriers, one of which was that the incumbents had allegedly acted in parallel in "dragging their feet in allowing competitors to interconnect" with their telephone networks as Congress had mandated in 1996 legislation. 425 F.3d at 104, 118; *accord* 550 U.S. at 549-50. That multi-year foot-dragging was aimed at "interfer[ing] with the ability of" newcomers "to compete successfully." 425 F.3d at 104. But the means of foot-dragging included "a variety of activities." *Id.* at 118. Among other things, incumbents "negotiat[ed] 'unfair agreements,'" "provid[ed newcomers] with poor quality connections," and "interfer[ed] with [newcomers'] relationships with the[ir] own customers, such as by continuing to bill customers even after they have entered agreements for services with [the newcomers]." *Id.* at 104, 118 (quotation marks omitted). Both the Supreme Court and this Court understood the incumbents to be engaged in parallel conduct, even though, during the *seven-years*-long conspiracy, different defendants took these different "steps to keep the [newcomers] out."

550 U.S. at 559, 565; *accord Twombly v. Bell Atl. Corp.*, 313 F. Supp. 2d 174, 177–78, 183 (S.D.N.Y. 2003) (Lynch, J.) (describing as "parallel action" various means by which incumbents thwarted newcomers).

This Court applied the same broad parallel conduct test in *Anderson News, L.L.C. v. American Media, Inc.*, 680 F.3d 162 (2d Cir. 2012). Anderson, a magazine wholesaler, alleged that "publisher and distributor defendants ceased doing business" with it in early 2009, after Anderson proposed a distribution surcharge. *Id.* at 170–171, 190. The district court had dismissed the antitrust claims, finding that "defendants had a 'variety of reactions' to Anderson's announcement of its [s]urcharge." *Id.* at 191. Some defendants sought to negotiate alternatives, with different defendants "suggesting alternatives that varied." *Id.* Others refused to negotiate at all. *See id.* But this Court reversed, setting aside differences in the reactions in favor of "'the *key* parallel conduct allegation' . . . that all of the publisher and distributor defendants ceased doing business with Anderson." *Id.* It was enough that the defendants adopted a common approach and aim, even if their means varied.

This Court has applied this broad parallel conduct test as a matter of course. For instance, in *Ross v. Citigroup, Inc.*, 630 Fed. Appx. 79, 81–82 (2d Cir. 2015) (summary order), this Court agreed with the late Judge Pauley that credit-card-issuing banks acted in parallel by adopting and maintaining mandatory arbitration clauses in card member agreements. *See id.*, *aff'g Ross v. Am. Express Co.*, 35 F. Supp. 3d 407, 438–41 (S.D.N.Y. 2014). That was so even though the defendants adopted such clauses at different times over four-and-a-half years. *See* 35 F. Supp. 3d at 439. Moreover, it was so even though the banks adopted different clauses—with one notably offering an exception to allow cardholders to fully opt-out of arbitration. *See id.* at 414, 430; *see also sub nom. Ross v. Bank of Am., N.A.*, 05 Civ. 7116, 2012 WL 401113, at *5, 8 (S.D.N.Y. Feb. 8, 2012). Notwithstanding the long and staggered timeline and this significant variation, this Court held that parallel conduct "was well supported by the record." 630 Fed. Appx. at 82 & n.3.

In this Circuit and elsewhere, it is thus "well settled . . . that the law does not require every defendant to participate in the conspiracy by identical means throughout the entire class period." *In re Broiler*

Chicken Antitrust Litig., 290 F. Supp. 3d 772, 792 (N.D. Ill. 2017). Antitrust conspiracies "are not always tidy and symmetric." *In re Interest Rate Swaps Antitrust Litig.*, 261 F. Supp. 3d 430, 479 (S.D.N.Y. 2017). Accordingly, "[p]laintiffs are not required to plead parallel conduct that is simultaneous or identical." *In re Farm-Raised Salmon & Salmon Prods. Antitrust Litig.*, 19-21551, 2021 WL 1109128, at *13 n.23 (S.D. Fla. Mar. 23, 2021); *PharmacyChecker.com LLC v. Nat'l Ass'n of Bds. of Pharm.*, 530 F. Supp. 3d 301, 334 (S.D.N.Y. 2021) ("Simultaneous action is not a requirement to demonstrate parallel conduct."); *Int'l Const. Prods. LLC v. Caterpillar Inc.*, 15-108-RGA, 2020 WL 4589775, at *3 (D. Del. Aug. 10, 2020) ("[A]ctions do not have to be simultaneous to be considered parallel."). Nor do they need to show that Defendants imposed restraints in "exactly the same way." *In re Domestic Airline Travel Antitrust Litig.*, 221 F. Supp. 3d 46, 69 (D.D.C. 2016).

This broad view of parallel conduct ensures that sophisticated conspirators cannot evade liability simply by varying their methods and timing. Antitrust conspiracies can be accomplished by firms agreeing to an objective without agreeing to "a common manner" of achieving that

objective. *SD3, LLC*, 801 F.3d at 428. "Commercially sophisticated parties like the defendants could well understand the red flags" raised by identical action and timing. *Id.* If "defendants employed different courses of action, then their conspiracy might better avoid detection." *Id.* One defendant may choose to fully stop sales, while another may slash sales through "highly unfavorable terms." *Klor's, Inc. v. Broadway-Hale Stores, Inc.*, 359 U.S. 207, 209 (1959). "It is more than plausible that conspirators would leave the precise means . . . up to each conspirator, where multiple options would accomplish the intended goal" because "[p]ermitting flexibility, where possible, in the means of effectuating price increases, would enable a greater number . . . to participate in the conspiracy, and might help to conceal the collusive nature of their conduct." *In re Boiler Chicken Antitrust Litig.*, 290 F. Supp. 3d at 792. Thus, as the Fourth Circuit has held, finding "'parallel conduct' only when defendants move in relative lockstep, achieving their common anticompetitive ends . . . only by substantially identical means . . . finds no support in any existing authority." *SD3, LLC*, 801 F.3d at 428–29.

B. Defendants imposed discount restrictions in parallel.

Here, the SAC clearly alleged parallel conduct under the governing standard. The four Defendants imposed unprecedented and broad 340B discounting restrictions that they announced during the second half of 2020. (JA-775, 818–821). The restrictions all had the same immediate and likewise unprecedented effect: "the end of the overwhelming majority of Contract Pharmacy 340B Drug Discount sales to covered entities." (JA-827). And this was not normal discount cutting. The actions shattered a decades-plus status quo at a time when no other manufacturer imposed any similar restriction. (JA-793–794, 822).

The district court erred by elevating variations in how Defendants imposed their restrictions over "the *key* parallel conduct allegation," *i.e.*, that Defendants had agreed to restrict 340B discounts at community pharmacies. *Anderson News, L.L.C.* 680 F.3d at 191 (emphasis in original). The district court compounded its error by adopting Defendants' characterizations of their exceptions as capacious and unlikely to lead to significant declines in 340B discounts, rather than crediting the well-pled facts of the complaint, including published

government data. (*E.g.*, JA-762 (n.3) (stating court was "not required to credit" complaint's allegation that Sanofi's data-sharing terms were commercially unreasonable).) The SAC identified precipitous declines in 340B discounts for all Defendants with rich detail. (*See, e.g.*, JA-778, 828–830, 833–835, 839–840, 842–844). This was "parallel behavior, consisting of [Defendants' various] steps to keep" prices high, *Twombly*, 550 U.S. at 565, by slashing discounts. Further, "the unambiguous increase in . . . prices"—here, from decimated discounts—"confirm[s] that price fixing was the goal, and the result, of" such parallel conduct. *United States v. Apple, Inc.*, 791 F.3d 290, 327 (2d Cir. 2015).

The district court had no basis to reject these restrictions as not constituting parallel conduct merely because some Defendants obtained greater percentage declines than others. (JA-979). It cited an alleged "dramatic difference" between Novo Nordisk, in particular, and the other Defendants because Novo Nordisk had achieved somewhat less of an immediate percentage decline in 340B discounts than the others. (*Id.*). But the court offered no reason to distinguish the massive 70% decline in 340B discounts at Novo Nordisk from the similarly massive 85–95% declines at the other firms. There was none. In fact, Novo

Nordisk's restrictions were the most successful, achieving the largest gross 340B discounting decline—a whopping $100 million per month. (JA-840). That dramatic decline paralleled declines enjoyed by the other Defendants.

The district court likewise erred in suggesting that Defendants imposed restrictions too far apart from one another to be considered parallel. (JA-766, 980). As an initial matter, the court overstretched the timeline by reaching backwards to include Eli Lilly's narrow Cialis restriction and reaching forward to include Defendants' later tweaks to their restrictions. (JA-980). These gymnastics ignored what mattered—the dramatic discount-slashing that each Defendant imposed across their drug portfolios during the second half of 2020. Those moves were sufficiently fast to corner Defendants' regulator, which did not act until May 2021. (JA-858). In fact, most of Defendants' actions were separated by mere days, not months: AstraZeneca privately committed to restrictions in a letter to HHS only one business day before Sanofi's public announcement (JA-813–814, 864–865), and Eli Lilly made a similar private commitment just days after AstraZeneca's public announcement (JA-191–194, 217, 814–815). *See supra* 21–23. And,

while any private commitment by Novo Nordisk remains undisclosed, its public announcement followed within months, close enough in time "to prevent covered entities from moving patients" (JA-866) given the many months needed "to move patients from one drug to another" (*id.*; *see also* JA-850).

This timeline is parallel. "Not all conspiracies require swift, simultaneous parallelism." *Ross*, 35 F. Supp. 3d at 439, *aff'd, sub nom.*, *Ross v. Citigroup, Inc.*, 630 Fed. Appx. 79. That is why this Court affirmed findings of parallel conduct over four-and-a-half years, *see id.*, and long ago accepted that four competitors' acts over several months constituted "parallel conduct," *see Modern Home Inst., Inc. v. Hartford Accident & Indem. Co.*, 513 F.2d 102, 105–108, 110 (2d Cir. 1975). Indeed, in *Twombly*, the Supreme Court agreed with this Court that acts constituted "parallel conduct" even though they "occurred over a period of seven years." 550 U.S. at 551, 559, 564 & n.2. The much shorter timeline than here was likewise parallel.

The SAC thus sufficiently alleged "parallel conduct."

POINT II

THE SECOND AMENDED COMPLAINT EASILY SATISFIED *TWOMBLY*.

The district court erred in holding that the SAC failed to plausibly allege conspiracy. It reached that decision by misapplying *Twombly*.

A. A complaint must plead only context suggesting agreement, not facts that compel a conclusion of conspiracy.

This appeal turns on the correct application of the plausibility standard. Under *Twombly*, "[a]n allegation of parallel conduct is [treated like] a naked assertion of conspiracy in a § 1 complaint [that] gets the complaint close to stating a claim" but needs "some further factual enhancement" to "nudge[] the[] claims across the line from conceivable to plausible." 550 U.S. at 557, 570. Yet "[a]sking for plausible grounds to infer an agreement does not impose a probability requirement at the pleading stage." *Id.* at 556.

Importantly, factual enhancements plausibly suggest conspiracy even when such facts can also be explained away as non-conspiratorial. "The question at the pleading stage is not whether there is a plausible alternative to the plaintiff's theory; the question is whether there are sufficient factual allegations to make the complaint's claim plausible."

Anderson News, L.L.C., 680 F.3d at 189. "[A] given set of actions may well be subject to diverging interpretations, each of which is plausible," but "[t]he choice between two plausible inferences . . . is not a choice to be made by the court on a Rule 12(b)(6) motion." *Id.* at 184–85.

For conspiracy allegations to survive a Rule 12 motion, conspiracy need not be "the most plausible scenario." *Id.* at 189–90. As *Twombly* explained, a "well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of the facts alleged is improbable." 550 U.S. at 556. A complaint may "plausibly suggest an inference of conspiracy, *even if* the facts are susceptible to an equally likely interpretation," *Gelboim*, 823 F.3d at 782, and even if a "court finds a different version more plausible" than conspiracy, *Anderson News, L.L.C.*, 680 F.3d at 185.

So-called "plus factors" and other circumstantial evidence suffice to advance allegations of parallel conduct into plausible allegations of concerted action. *See Gelboim*, 823 F.3d at 781. This Court has identified plus factors including: (1) "evidence that shows that the parallel acts were against the apparent individual economic self-interest of the alleged conspirators," (2) "a common motive to conspire,"

and (3) "evidence of a high level of interfirm communications," *see id.*, as well as (4) concentrated market control, *see Starr v. Sony BMG Music Entertainment*, 592 F.3d 314, 323–24 (2d Cir. 2010), (5) the fact that "defendants' price-fixing is the subject of a pending investigation" by government agencies, *id.*, and (6) "complex and historically unprecedented changes in pricing structure made at the very same time by multiple competitors, and made for no other discernible reason," *Twombly*, 550 U.S. at 556 n.4; *Apple, Inc.*, 791 F.3d at 315.

This Court has instructed that "in antitrust cases, '[t]he character and effect of a conspiracy are not to be judged by dismembering it and viewing its separate parts, but only by looking at it as a whole.'" *Apple, Inc.*, 791 F.3d at 319 (quoting *Cont'l Ore Co.*, 370 U.S. at 699). This is necessary because "conspiracies are rarely evidenced by explicit agreements, but nearly always must be proven through 'inferences that may fairly be drawn from the behavior of the alleged conspirators.'" *Anderson News, L.L.C.*, 680 F.3d at 183–84 (quoting *Michelman v. Clark–Schwebel Fiber Glass Corp.*, 534 F.2d 1036, 1043 (2d Cir.1976)). It is error to "tak[e] the allegations in isolation and fail[] to draw

reasonable inferences in the [plaintiffs'] favor." *Nat'l Rifle Assoc. of Am. v. Vullo*, __ U.S. __, 22-842, slip op. at 15 (2024).

B. Plaintiffs pled powerful—and certainly plausible—circumstantial evidence of conspiracy.

Here, there are "numerous allegations that clear the bar of plausibility." *Gelboim*, 823 F.3d at 781. That includes allegations that Defendants acted too closely in time to be mere coincidence, that Defendants made complex and historically unprecedented changes in pricing structure, and that abundant other plus factors exist.

1. The timeline firmly suggests conspiracy.

The district court failed to acknowledge the improbability that AstraZeneca would, by chance, privately communicate unprecedented restrictions just one business day before Sanofi publicly did so. On Monday, July 27, 2020, Sanofi announced its 340B discount community pharmacy restrictions (JA-813–815). These restrictions immediately wiped out 90% of those discounts (JA-829) and swept far beyond Eli Lilly's extremely narrow Cialis limitation (JA-816). It was groundbreaking—shattering a stable decade-plus status quo. (JA-782, 813–815, 864–865). Yet, what the public did not know was that the prior Friday, Sanofi's rival, AstraZeneca, sent a private letter to HHS

stating those same unprecedented restrictions (JA-782, 813–815, 864–865), which would lead to a comparably precipitous decline in AstraZeneca's discounts (JA-843). Both Defendants identified the same start date, three months ahead of October 1, 2020. (JA-813–815.). That date appeared first in the nonpublic letter from AstraZeneca.

Absent conspiracy, these would have been beyond-extraordinary coincidences. The chance that two competitors independently chose to impose unprecedented discounts at that time was impossibly small. And the E.O. issued on July 24 was not a "common stimuli" that would naturally trigger "independent responses" from Defendants, *Twombly*, 550 U.S. at n.4, because the E.O. maintained the status quo. (JA-808–810, 812). Under that status quo, no manufacturer had ever been willing to impose such broad restrictions. And the order provided no new economic or legal impetus to impose them suddenly in July 2020. In any event, as plausibly alleged, "it would have been virtually impossible" for these massive, multinational companies "to have vetted and cleared such a dramatic and unprecedented change in [their] pricing practices on a few days' notice" or, in AstraZeneca's case, on the very same day of the E.O. (JA-814–815). The timeline strongly

suggests conspiracy, not coincidence. Given this and the other "well-pleaded factual allegations" set out below, "this Court cannot simply credit [the] assertion" that independent reaction to the E.O. is the true explanation. *Vullo*, slip op. at 16–17; *accord Anderson News, L.L.C.*, 680 F.3d at 185.

So too, absent conspiracy, the selection of October 1 as a start date would be a remarkable coincidence. The date was months into the future. The district court noted October 1 is the start of a new fiscal quarter (JA-977 (n.3)), but that is mere observation, not explanation—and not a reason offered by AstraZeneca or Sanofi at the time. Nor is it consistent with Eli Lilly's start date, which did not begin on a new fiscal quarter. There were 365 days AstraZeneca or Sanofi could have tagged as a start date. That they chose the same one strongly suggests that they were coordinating with each other and supports the inference of conspiracy.

The district court erred in ignoring the fair inference that these coincidences were too improbable absent advance knowledge by Sanofi of AstraZeneca's plans. "In these circumstances[,] it is plausible to infer that [one defendant] knew in advance, with certainty, that [another]

would [impose its restraint]; and from that certain foreknowledge, an inference of advance agreement is plausible." *Anderson News, L.L.C.*, 680 F.3d at 191. Advance knowledge and conspiracy are plausible given these allegations, whether or not "there is a[nother] plausible alternative to the plaintiff's theory." *Id.* at 189–90.

The inference of conspiracy is strengthened further by a pairing of choices: (a) AstraZeneca's choice not to publicize its planned restrictions at the time but to instead keep its letter secret; and (b) Eli Lilly's choice a month later to do the same. In August 2020, within days of AstraZeneca finally revealing its restriction plans publicly, Eli Lilly informed HHS of its own planned restrictions. (JA-191–194, 271, 814–815). But Eli Lilly, like AstraZeneca before it, communicated that information in a private letter. (*Id.*). As this Court has elsewhere recognized, it is reasonable to infer that Defendants did so in an "attempt to hide their [planned parallel restrictions] because they knew they would attract antitrust scrutiny." *Starr*, 592 F.3d at 324. That also presents a fair inference of consciousness of guilt—that Defendants "were aware that their communications and related actions . . . violated the law." *In re Publ'n Paper Antitrust Litig.*, 690 F.3d at 65.

This otherwise improbable timing is powerful circumstantial evidence of conspiracy. It is more than enough to "nudge the[] claims across the line from conceivable to plausible." *Twombly*, 550 U.S. at 570.

2. The Second Amended Complaint amply alleges plus factors.

The SAC is also replete with facts matching each of the plus factors identified by this Court.

a. Defendants abruptly departed from a historic and universal status quo maintained by a thousand drug companies.

As *Twombly* itself explained, parallel conduct supports an inference of conspiracy if there has been "complex and historically unprecedented changes in pricing structure made at the very same time by multiple competitors, and made for no other discernible reason." *Twombly*, 550 U.S. at 556 n.4; *Apple, Inc.*, 791 F.3d at 315.

That is every bit the case here. For "more than a decade," "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." (JA-793–794). "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." (JA-822). "It was not until late 2021 that any major drug company implemented any similar restrictions," "more than a year after Defendants announced their restrictions" (*id.*), and at a time when it was clear that doing so would not lead to exclusion from federal healthcare programs. *See supra* 27. All drugmakers could benefit from fewer discounts. But only Defendants controlled key diabetes markets, giving them a special safety-in-numbers motive to conspire. *See infra* 65–67. There was nearly zero chance that Defendants only randomly became the first movers out of 1,000. Their unprecedented changes give rise to a strong inference of conspiracy.

The district court set aside this entire critical factor with the observation that Eli Lilly imposed a 340B restriction in May 2020. (JA-983–984). But that exceedingly narrow restriction, limited to a single drug, was not precedent for Defendants' watershed 340B discount restrictions. To the contrary, the fact that Eli Lilly imposed its single drug restriction in May 2020 and then, just three months later, announced dramatic across-the-board restrictions eliminating 95% of its

340B contract pharmacy discounts strongly supports the inference that it was taking this massive leap because it reached a deal with the other Defendants. Even if it remains possible that Eli Lilly simply changed its mind on its own, or even if the district court found that "version more plausible" than conspiracy, Plaintiffs' alternative inference pled is certainly plausible too and cannot be rejected under *Anderson News, L.L.C.*, 680 F.3d at 189–90.

b. Market share and regulatory risks pitted independent action against Defendants' economic self-interest.

Powerful forces kept drug manufacturers from acting alone to restrict 340B discounts. These included both (i) the potential loss of market share if safety-net providers responded to discounts by changing their preferences to move their patients (340B or otherwise) to competing firms' drugs with discounts (JA-852–854), and (ii) the potential devastating sanction of exclusion of the firm's drugs from Medicare and Medicaid coverage (JA-854–856).

To find otherwise, the district court refused to accept well-pled allegations in the complaint. On market share, it posited that no drugmaker would care to be in the 340B program market. (JA-982–983). But this ignored two facts: first, that discounted sales are still

sales with a range of corresponding profits, and second, that as detailed in the SAC, drugmakers could easily have believed that safety-net providers would change their prescribing practices in response to 340B discount restrictions. (JA-853–854). On this latter point, there was nothing conclusory about the SAC's explanation that entity-level drug preferences would affect non-340B discounted drugs, too. (JA-794–796).

The regulatory sanction risk was amply pled, as well, with citations to the Defendants' own expressions of fear of exclusion specified in court pleadings. (JA-854–856). But the district court erroneously set these allegations aside. First, it mistakenly cited Eli Lilly's minor single-drug restriction as proof that, despite Defendants' own averments, drugmakers had no fears of exclusion. (JA-983–984). Yet that minor restriction was a world apart from Defendants' massive discount-slashing in late 2020. Second, the district court erred by concluding firms could not fear sanctions because the government issued warnings "*after* the challenged conduct began." (JA-984). That was wrong. The statute itself authorizes exclusion for violations of 340B, *see* 42 U.S.C. §§ 256b(a)(1), 1396r-8(a)(1), (5), and since 1996, HHS had warned manufacturers that they had "to sell the drug[s] at

the [340B] discounted price" at community pharmacies. (JA-790 (quoting 61 Fed. Reg. at 43,549)). There was ample cause for fear.

Indeed, these forces maintained a decade-plus status quo, during which no firm took on these risks by imposing broad-based 340B restrictions. (JA-794–797). These risks from independent action support the inference of conspiracy. *See Starr*, 592 F.3d at 325.

c. Because conspiracy created safety-in-numbers, it offered a motive to conspire to increase profits.

The SAC details how Defendants could overcome, or at least significantly mitigate, the disincentives of imposing these otherwise profitable discount restrictions by joining together. (JA-856–858). This is another plus factor. *See Gelboim*, 823 F.3d at 781.

Concerted action mitigated the threat of market share losses. As the SAC explains, "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)." (JA-850–851, 866).

Perhaps more importantly, concerted action also promised to protect Defendants from the risk of Medicare and Medicaid exclusion. Defendants were needed by the government to ensure the delivery of rapid-acting analog insulin, long-acting analog insulin, and incretin mimetics to federal healthcare beneficiaries. Any one Defendant could have been excluded without cutting off those drug classes. But they could not all be excluded without putting beneficiaries at risk. Thus, "[b]y joining together, Defendants effectively deprived regulators of the ability to feasibly sanction them by revoking federal healthcare program coverage." (JA-858). That part of their plan worked, too, as the government "did not revoke federal healthcare program coverage of any of the Defendants." (*Id.*).

Contrary to the district court's suggestion, these motives were consistent with Defendants imposing discount restrictions across their drug portfolios (*i.e.*, not just diabetes drugs). (JA-979). The SAC detailed that diabetes drugs were drivers of each Defendants' revenues (JA-803–806) and an outsized portion of community pharmacy 340B discounted sales (JA-806–807). That drove Defendants' motive to conspire, even if other drugs were exposed to market share losses.

Moreover, Defendants' control of the diabetes drugs was what fully mitigated the threat of regulatory sanction. Once the government was painted into a corner, Defendants were free to restrict 340B discounts on all their drugs with impunity from sanction.

Defendants, direct competitors, thus had a common motive to conspire to neutralize or mitigate market-share and regulatory threats. They suddenly punctured a decade-plus status quo together by acting on these shared motives—a strong basis for inferring conspiracy. *See*, *e.g.*, *Gelboim*, 823 F.3d at 781; *Apex Oil Co. v. DiMauro*, 822 F.2d 246, 254 (2d Cir. 1987); *see also Interstate Cir., Inc. v. United States*, 306 U.S. 208, 222 (1939).

d. Defendants engaged in a high level of interfirm communications on these very issues.

The inference of conspiracy is further supported by the fact that Defendants were communicating about 340B discounting immediately in advance of their unprecedented discount restrictions. (JA-810–812, 862). Up through the day the first Defendant put its discount restrictions in writing, on July 24, 2020, Defendants were lobbying

340B issues through common lobbyists.[5] This was in addition to Defendants' work together on 340B contract pharmacy "reform" as board leaders of PhRMA. (JA-862).

The district court recognized that "Defendants shared a common lobbyist and participated in the trade group PhRMA," facts "indicative of an opportunity to conspire." (JA-984). Yet it concluded opportunity alone would "not give rise to an inference of conspiracy without something more." (*Id.*). But there was much more, as this brief details. Moreover, Defendants' lobbying was focused on 340B, which meant months of communications in advance of their 340B restrictions, making coordination even more probable. (JA-811).

[5] While Defendants are immune from any liability for their "legislative efforts," they are not immune for any "anti-competitive discussions or agreements" as alleged here. *Hendershot v. S. Glazer's Wine & Spirits of Okla., LLP*, 20-CV-0652, 2021 WL 3501523, at *7 (N.D. Okla. Aug. 9, 2021). Moreover, even otherwise immune activities are "nevertheless admissible to prove matters such as motive, opportunity, and intent." *Merck-Medco Managed Care v. Rite Aid Corp.*, 22 F. Supp. 2d 447, 470 n.55 (D. Md. 1998). Unlike litigation privileges, "there is no blanket rule of inadmissibility." *In re Brand Name Prescription Drugs Antitrust Litig.*, 186 F.3d 781, 789 (7th Cir. 1999).

e. Defendants completely dominated highly profitable diabetes markets, making conspiracy practical.

Conspiracy is also supported by Defendants' total control of the diabetes drug markets. Market control—even at far lower level—is a plus factor because it makes effective conspiracy more attainable. *See Starr*, 592 F.3d at 323–24; *Todd v. Exxon Corp.*, 275 F.3d 191, 208 (2d Cir. 2001). Such markets are "conducive to collusion." *In re Publ'n Paper Antitrust Litig.*, 690 F.3d at 65. As Judge Posner aptly explained, if "four defendants sell 90 percent of [the product], it would not be difficult for such a small group to agree on prices and to be able to detect 'cheating,' . . . without having to create elaborate mechanisms . . . [and to] escape discovery by the antitrust authorities." *In re Text Messaging Antitrust Litig.*, 630 F.3d 622, 628 (7th Cir. 2010). Here, the four Defendants held absolute control (100%) of the marketplace. (JA-847–849). Concerted action among all competing diabetes drug-makers to impose restrictions—and to create safety-in-numbers—was thus relatively easy to coordinate and maintain. This plus factor also weighs heavily in favor of plausibility.

f. Defendants have been the subject of price manipulation investigations in this same market.

This Court has also cited "pending investigation[s]" by government entities as supporting plausibility. *Starr*, 592 F.3d at 325. Here, the raft of investigations into price manipulation by Defendants as to the very diabetes treatments at issue (whose prices have repeatedly gone up even as costs have dropped) strengthens the inference that Defendants also manipulated discounts here. (JA-863–864). That and the Senate Judiciary Committee Chair's finding that "[t]his industry is anything but a free market" (JA-863) is "context that raises a suggestion of a preceding agreement, not merely parallel conduct." *Twombly*, 550 U.S. at 557.

3. Together, the unprecedented restrictions, otherwise improbable coincidences, and ample plus factors more than suffice to make conspiracy plausible.

Considered all together, this circumstantial evidence, including plus factors, places Defendants' parallel 340B discount restrictions "'in a context that raises a suggestion of a preceding agreement, not merely parallel conduct that could just as well be independent action.'" *Starr*, 592 F.3d at 323 (quoting *Twombly*, 550 U.S. at 557).

Yet the district court improperly attempted to "explain how each piece of evidence standing alone is 'ambiguous' and therefore insufficient to support an inference of conspiracy.'" *Apple, Inc.*, 791 F.3d at 319 (cleaned up). That was an impermissible approach to antitrust conspiracies, *see id.*, which must be viewed "as a whole, rather than piecemeal," *Anderson News LLC*, 680 F.3d at 190. Moreover, by improperly searching for "an innocuous interpretation" of Plaintiffs' allegations, the district court violated the plausibility standard this Court articulated in *Anderson*. *Id.*

Because, permitting all fair inferences, conspiracy is plausible on the face of the complaint, the district court erred by dismissing the case on the pleadings.

POINT III

NOTHING IN SECTION 340B EXCUSES COMPETING DRUG COMPANIES FROM THE ANTITRUST LAWS' PROHIBITION ON CONSPIRACIES TO REDUCE DISCOUNTING.

This Court should also address the district court's misplaced concern "about the viability of this matter in light of" *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 113 (2011). (JA-973 (n.2)). This Court has "authority to decide issues that were argued before but not

reached by the district court." *Hartford Courant Co. v. Pellegrino*, 380 F.3d 83, 90 (2d Cir. 2004). The Court should do so here because this is a purely legal question, *see id.* at 91, and "delay may affect not only the parties, but may also have a significant adverse impact on the public interest." *Cent. Hudson Gas v. EPA*, 587 F.2d 549, 557–58 (2d Cir. 1978); *Booking v. Gen. Star Mgmt. Co.*, 254 F.3d 414, 419 (2d. Cir. 2001). Delay would harm both class members and their underinsured and uninsured patients, as continued financial injuries "threaten[] to reduce the healthcare services and discounts available to [the Clinics] and other covered entities' patients." (JA-866–867).

This Court should clear up the district court's concern. *Astra* presents no obstacle because this case arises entirely from concerted action, not from any construction of Section 340B. The Supreme Court in *Astra* held that covered entities do not have the statutory authority, either by an implied right of action or by virtue of any third-party beneficiary status, to enforce Section 340B's drug discount mandates. 563 U.S. at 113. *Astra* is irrelevant here because Plaintiffs' suit is based, instead, entirely on an illegal conspiracy. *See infra* III.A. The price-fixing claims here are in no way "one and the same" as the

"statutory and contractual obligations" set out in 340B as in *Astra*, 563 U.S. at 118; rather, they are antitrust claims, agnostic to what 340B requires. *See infra* III.B. Plaintiffs seek only antitrust remedies. *See infra* III.C.

A. The antitrust laws unquestionably prohibit Defendants' alleged conspiracy to restrict discounted drug sales.

It is undisputed that Defendants, as horizontal competitors with competing diabetes medications, cannot agree to roll back discounts for their goods. "Horizontal price-fixing conspiracies traditionally have been, and remain, the 'archetypal example' of a per se unlawful restraint on trade." *Apple, Inc.* 791 F.3d at 321 (*quoting Catalano, Inc. v. Target Sales, Inc.*, 446 U.S. 643, 647 (1980)). Where price-fixing proceeds by way of a "concerted refusal" to deal by "horizontal arrangement among competitors," it is "unquestionably a 'naked restraint' on price." *FTC v. Superior Ct. Trial Lawyers Ass'n*, 493 U.S. 411, 422–23 (1990). The Supreme Court has "consistently and without deviation adhered to the principle that price-fixing agreements are unlawful per se under the Sherman Act," no matter if the "particular price-fixing schemes are wise or unwise, healthy or destructive" and

despite any "good intentions." *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 218, 221 (1940).

Accordingly, regardless of whether Defendants were motivated by the billions of dollars in profits they have reaped or otherwise, their agreement to reduce 340B discounts is a *per se* violation of the antitrust laws. Every "agreement between private competitors to eliminate discounts is per se an illegal price fixing scheme." *Hertz Corp. v. City of New York*, 1 F.3d 121, 129 (2d Cir. 1993) (cleaned up); *see also Freeman v. San Diego Ass'n of Realtors,* 322 F.3d 1133, 1146 (9th Cir. 2003) ("Agreements not to offer discounts are per se violations of section 1."); *TFWS, Inc. v. Schaefer*, 242 F.3d 198, 210 (4th Cir. 2001) (a "discount ban" is a "per se violation of the Sherman Act"). Thus, Defendants' collusion "to eliminate discounts" thus "falls squarely within the traditional per se rule against price fixing," *Catalano*, 446 U.S. at 647–48, and within the framework of the antitrust laws.

B. Plaintiffs' claims do not depend in any way on whether the underlying 340B restrictions are themselves illegal.

Moreover, Plaintiffs have not attempted to use Section 340B as a cause of action. Indeed, as they have consistently made clear, their complaint is wholly agnostic to how 340B is properly construed. (*E.g.,*

JA-899–901). That is the subject of separate litigation. *See supra* n.2. The antitrust claims here rise and fall based on proof of concerted action to restrict discounts, not on the meaning of 340B.

To be clear, if conspiracy is proven, Defendants will have committed *per se* antitrust violations even if they prevail in other fora in showing that Section 340B nowhere prohibited their restrictions. This is commonplace in antitrust law. "[I]t is well settled that acts which are in themselves legal lose that character when they become constituent elements of an unlawful scheme." *Cont'l Ore Co.*, 370 U.S. at 707; *United States v. Reading Co.*, 226 U.S. 324, 352–53 (1912). The evil is collusion. That is why competitors cannot collude even to prevent others from violating the law. *See FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 465 (1986) ("That a particular practice may be unlawful is not, in itself, a sufficient justification for collusion among competitors to prevent it."); *Fashion Originators' Guild, Inc. v. FTC*, 312 U.S. 457, 486 (1941). A century of precedent holds that "price-fixing combinations . . . are illegal per se; they are not evaluated in terms of their purpose, aim, or effect." *Socony-Vacuum Oil*, 310 U.S. at 228. A conspiracy to impose terms reducing 340B discounts thus violates the antitrust laws while

"say[ing] nothing about their broader legality" outside that conspiracy. *Apple, Inc.*, 791 F.3d at 319–20.

This case does not turn on Section 340B's meaning or mandates.

C. Plaintiffs seek to enjoin conspiracy, not violations of 340B.

Nor are Plaintiffs asking the court to impose any interpretation of Section 340B. Plaintiffs seek both injunctive relief and damages. (JA-890–891). But the requested injunction would enjoin conspiracy, not violations of 340B.

The injunction sought would be aimed at Defendants' concerted action. As this Court has explained, "normally, after a finding of price-fixing, the remedy is an injunction against the price-fixing." *CBS v. Am. Soc'y Composers*, 562 F.2d 130, 140 (2d Cir. 1977), *rev'd on other grounds sub nom., Broadcast Music, Inc. v. CBS*, 441 U.S. 1 (1979). That may mean "eliminat[ing the] anticompetitive effects" of the conspiracy. *Wilk v. Am. Med'l Ass'n*, 895 F.2d 352, 371 (7th Cir. 1990); *see also Bd. of Regents of the Univ. of Okla. v. NCAA*, 546 F. Supp. 1276, 1328 (W.D. Okla. 1982) ("Having found a violation of the Sherman Act, the Court is duty-bound to render impotent the monopoly power which violates the Act."), *aff'd in relevant part*, *NCAA v. Bd. of Regents of the*

Univ. of Okla., 468 U.S. 85 (1984). Any such terms could only be crafted when a remedy is being imposed.

What is clear, however, is that Plaintiffs are *not* seeking to enjoin violations of 340B. Plaintiffs take no position on the meaning of the statute in this case and would seek to remedy Defendants' price-fixing even if it does not independently violate Section 340B. But even if Defendants are also violating Section 340B, Plaintiffs are not asking—and do not intend to ask—for an injunction addressing those violations. If that were the aim of this lawsuit, Plaintiffs would have included other manufacturers that imposed similar restrictions later in time. But it is not the suit's aim; such manufacturers were not included; and no injunction to enforce 340B is sought here. The district court's concerns were misplaced.

This Court should clarify that *Astra* is no basis for dismissal.

CONCLUSION

The judgment of the district court should be reversed.

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Respectfully submitted,

/s/ Brian Marc Feldman

BRIAN MARC FELDMAN
SHEILA BAYNES
AURELIAN LAW PLLC

ELLEN MERIWETHER CAFFERTY
CLOBES MERIWETHER &
SPRENGEL LLP

LAUREN MENDOLERA
HARTER SECREST & EMERY LLP

Attorneys for Plaintiffs-Appellants

CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(g) of the Federal Rules of Appellate Procedure, the undersigned hereby certifies that this brief complies with the type-volume limitation of Rule 32(a)(7)(B) and Local Rule 32.1(a)(4). As measured by the word processing system used to prepare this brief, there are 13,939 words in this brief.

By: BRIAN MARC FELDMAN
AURELIAN LAW PLLC