24-598

IN THE

United States Court of Appeals

FOR THE SECOND CIRCUIT

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

Plaintiffs-Appellants,

---v.---

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

Defendants-Appellees.

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

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DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure:

Defendants-Appellees Eli Lilly and Company and Lilly USA, LLC, by and through undersigned counsel, hereby certify that neither entity has a parent corporation and that no publicly held corporation owns 10% or more of either entity's stock.

Defendant-Appellee AstraZeneca Pharmaceuticals LP, a limited partnership organized under the laws of the State of Delaware, with its principal place of business in Wilmington, Delaware, by and through undersigned counsel, hereby certifies that it is an indirectly wholly owned subsidiary of AstraZeneca PLC. AstraZeneca PLC is a public company organized under the laws of England and Wales and is publicly traded. Upon information and belief, no other publicly held company owns 10% or more of the voting interest in AstraZeneca Pharmaceuticals LP.

Defendant-Appellee Novo Nordisk Inc., by and through undersigned counsel, hereby certifies that Novo Nordisk Inc. is a privately held corporation wholly owned by Novo Nordisk US Commercial Holdings, Inc. Novo Nordisk US Commercial Holdings, Inc.

is a privately held corporation wholly owned by Novo Nordisk US Holdings, Inc. Novo Nordisk US Holdings, Inc. is a privately held corporation wholly owned by Novo Nordisk A/S. No publicly held company owns 10% or more of the stock of Novo Nordisk A/S.

Defendant-Appellee Sanofi-Aventis U.S., LLC, by and through undersigned counsel, hereby certifies that it is a wholly owned subsidiary of Sanofi, a French *société anonyme*, and that no publicly held company owns 10% or more of its stock.

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INTRODUCTION

This case involves an improper attempt to use the antitrust laws to change the regulatory requirements of the federal 340B drug-pricing program and to penalize pharmaceutical manufacturers for implementing policies designed to address well-documented abuses of that program—policies that have been upheld as reasonable and lawful by the courts. The district court dismissed the action, recognizing that Plaintiffs' allegations fall short of pleading a viable antitrust conspiracy. That decision is correct and should be affirmed.

Congress designed the federal 340B statute to help low-income and underserved patients. The statute requires pharmaceutical manufacturers that participate in federal healthcare programs to sell their drugs at steep discounts (as low as a penny per unit) to certain non-profit providers called "covered entities," which are supposed to use the discounted drugs to benefit the low-income and underserved patients who visit their facilities for treatment. In recent years, however, the program has been undermined by widely reported arbitrage and abuse, as documented by the Inspector General for the Department of Health and Human Services ("HHS"). One source of this abuse is that covered

entities have contracted with for-profit outside pharmacies and enriched themselves and their contract partners by reselling manufacturers' discounted drugs to pharmacy customers at much higher prices.

The 340B statute does not require manufacturers to sell or transfer their drugs to for-profit pharmacies. Nor does it require manufacturers to permit for-profit pharmacies to profit by selling 340B-discounted drugs to their own customers at marked-up prices. In fact, the statute expressly prohibits selling or transferring manufacturers' drugs to anyone who is not a patient of a covered entity. Nonetheless, over the past decade, there has been an explosion in the use of "contract pharmacies." In response to ongoing abuse, more than 30 manufacturers, including the four Defendants here, reasonably decided to limit—in different ways and at different times and with different consequences—when they will agree to facilitate the transfer of their drugs at 340B-discounted prices to contract pharmacies.

The federal government contended that these manufacturer policies violated the 340B statute, but court after court has disagreed, including the Third and D.C. Circuits, which held that manufacturers have no obligation to deliver 340B-priced drugs to contract pharmacies

and upheld as reasonable several of the specific policies at issue here. *See Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452 (D.C. Cir. 2024); *Sanofi-Aventis U.S. LLC v. HHS*, 58 F.4th 696 (3d Cir. 2023).

Plaintiffs-Appellants Mosaic and Central Virginia Health Services are dissatisfied with those decisions and have attempted to cast Defendants' program-integrity policies—but not other manufacturers' similar policies that were adopted around the same time—as the product of an antitrust conspiracy. Even as pled by Plaintiffs, however, this theory makes no business sense. Although Plaintiffs fail to allege a single meeting or discussion where Defendants might have conspired, Plaintiffs hypothesize that Defendants were somehow not individually motivated to minimize 340B abuse. Instead, they allege that, over a 19-month time frame, these Defendants entered into an unlawful conspiracy and that they did so to avoid losing share in the 340B-discounted drug market, to avoid losing share in the non-340B drug market, and to avoid the possibility of some (though not all) government sanctions. According to Plaintiffs (and contrary to all logic), Defendants sought to *continue* to sell their drugs for as low as a single penny per unit.

The district court rightly dismissed Plaintiffs' first amended complaint and denied leave to amend further, recognizing that the Defendants' independent actions are insufficient to support a conspiracy claim, and Plaintiffs' far-fetched theory is implausible on its face. Defendants acted independently in their own self-interest when they implemented varying policies to govern their individual 340B sales to individual covered entities, and Plaintiffs do not offer any plausible allegations to the contrary. The timing and particulars of each Defendant's policy changes are far too divergent to constitute parallel conduct. And, in fact, the sequence of alleged events demonstrates Defendants acted independently—there was an initial mover, followed by subsequent actors, each of which reacted individually and differently over many months. And regardless, Plaintiffs fail to allege any "plus factors" that make it plausible that Defendants entered into an anticompetitive agreement instead of acting individually. This case is, thus, in the heartland of *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007).

Plaintiffs' real complaint is that they wish the 340B statute required Defendants to allow Plaintiffs to use contract pharmacies

without restriction, so they could sell more 340B-discounted drugs and generate more revenue at the expense of manufacturers and underserved patients. But that is not the law. *See Novartis*, 102 F.4th at 459; *Sanofi-Aventis*, 58 F.4th at 707. Moreover, Plaintiffs' purported grievances over limitations or denials of 340B pricing under varying policies are entirely governed by the federal 340B program, and their remedy for resolving disputes about 340B drug policy is within the administrative scheme that Congress established—and which the Supreme Court has held is exclusive. *See Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110 (2011). This contrived antitrust lawsuit cannot circumvent a congressionally established administrative scheme and fabricate a private cause of action for what are ultimately complaints by covered entities hoping to change the 340B statute's requirements.

Finally, even if Plaintiffs could overcome these fatal defects, their damages claims are barred under *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977), because Plaintiffs are indirect purchasers.

For any and all of these reasons, this Court should affirm.

STATEMENT OF ISSUES

1. Whether manufacturers act in parallel when they adopt different policies at different times, with different terms covering different drugs and having different impacts on the market.
2. Whether an anticompetitive agreement is plausible here, even assuming parallel conduct, where Plaintiffs' hypothesized motives are implausible at best and there is an obvious alternative explanation.
3. Whether Plaintiffs may use the antitrust laws to enforce their own interpretation of the 340B statute in order to obtain below-market prices, when that statute does not provide covered entities with a private cause of action.
4. Whether Plaintiffs' damages claims are barred under *Illinois Brick* because they are indirect purchasers of Defendants' drugs.

STATEMENT OF THE CASE

I. BACKGROUND

A. In 1992, Congress Establishes the 340B Program to Help Underserved Populations.

In 1992, Congress established the 340B program, a drug discount program named for the relevant section of the Public Health Service Act.

The program requires pharmaceutical manufacturers that participate in Medicaid and Medicare Part B to offer certain drugs at a significant discount to "covered entities"—a defined term that includes fifteen specifically enumerated types of healthcare providers that serve vulnerable and underserved populations. 42 U.S.C. §256b(a)(1), (4); JA-782-783 (SAC ¶21-23). Those statutory discounts drive the price of covered drugs significantly lower than market prices and often as low as one penny per unit. JA-666, 782-783, 785, 803 (SAC ¶¶23, 31-32, 101-102); 85 Fed. Reg. 45755. Indeed, as Plaintiffs explained in their first amended complaint, JA-44-45,[1] many of Defendants' insulin products may be purchased through the 340B program for a single penny, *see* 85 Fed. Reg. 45755.

Congress originally intended the 340B program to benefit the underserved communities covered entities serve by allowing covered entities to pass on the discounts to their patients. JA-783-784 (SAC ¶¶25-26); *Sanofi-Aventis*, 58 F.4th at 699. But over time, covered entities

[1] Defendants take as true all factual allegations in Plaintiffs' complaints, as they must at the pleadings stage. *Twombly*, 550 U.S. at 555.

realized that if they *did not* pass on the full 340B discount, they could use manufacturers' drugs to generate revenue. Covered entities could purchase manufacturers' drugs at steeply discounted 340B prices, bill patients and insurers for the full price of the drugs, and pocket the difference. JA-783-784 (SAC ¶25).

The parties are participants in the 340B program. Defendants Sanofi-Aventis U.S., LLC, Eli Lilly and Company and Lilly USA, LLC (collectively, "Lilly"), Novo Nordisk Inc., and AstraZeneca Pharmaceuticals LP are among the world's leading manufacturers of life-saving pharmaceuticals, including diabetes treatments, and all offer their drugs to covered entities at 340B-discounted prices. JA-774, 802-803 (SAC ¶¶2, 99-101). Plaintiffs Mosaic Health, Inc. and Central Virginia Health Services, Inc. are federally qualified health centers made up of several clinics that each qualify as a covered entity.

B. The Increasing Use of Contract Pharmacies Raises Program-Integrity Concerns.

The 340B statute requires drug manufacturers to "offer" their drugs to "each covered entity" for purchase at discounted prices. 42 U.S.C. §256b(a)(1); JA-782-783, 786 (SAC ¶¶23, 36). The statute says nothing about for-profit pharmacies like CVS and Walgreens. Nevertheless, for-

profit pharmacies have increasingly dispensed 340B-discounted drugs in exchange for a cut of covered entities' 340B revenues. *Novartis*, 102 F.4th at 457.

In 1996, the Health Resources and Services Administration ("HRSA"), an agency within HHS, JA-785-786 (SAC ¶¶30, 33), issued non-binding guidance purporting to allow covered entities that lacked an in-house pharmacy to contract with a single for-profit pharmacy (*i.e.*, a "contract pharmacy") to dispense 340B-discounted drugs on behalf of the covered entity. 61 Fed. Reg. 43549. For the next 14 years, a covered entity could contract with one (and only one) contract pharmacy to dispense 340B-discounted drugs, and it could do so only if the covered entity lacked an in-house pharmacy.

That all changed in 2010, when HRSA issued new non-binding guidance purporting to permit all covered entities—not just those without an in-house pharmacy—to use an *unlimited* number of contract pharmacies to dispense 340B-discounted drugs. 75 Fed. Reg. at 10275, 10277-78; *see* JA-790 (SAC ¶¶52-53). That guidance fundamentally altered the 340B landscape. As the D.C. Circuit explained, between 2010 and 2018, the number of contract pharmacies participating in the

program increased 1,438%, from about 1,300 to 23,000. *Novartis*, 102 F.4th at 457. The country's largest for-profit pharmacy chains, like Walgreens and CVS, make up most of this market. *See id.*

Contract pharmacies profit by purchasing 340B-discounted drugs using covered entities' accounts, charging their customers or their insurers a higher price, and then "divvy[ing] up the spread between the discounted price and the higher insurance reimbursement rate." *Id.*; *see* JA-792-793 (SAC ¶¶58-60). "Only after dispensing the drugs do these pharmacies attempt to discern whether individual customers were patients of covered entities" and thus eligible for the discount in the first place. *Novartis*, 102 F.4th at 457. And because of the reimbursement scheme, "these actors [have] a financial incentive to catalog as many prescriptions as possible as eligible for the discount." *Id.* at 457-58.

The contract-pharmacy explosion raises serious program-integrity concerns. To ensure the program's steeply discounted prices are used for the benefit of uninsured patients, the 340B statute prohibits both "diversion" (which occurs when a covered entity sells or transfers a 340B-discounted drug to a person or entity who is not a patient of a covered entity) and "duplicate discounting" (which occurs when a manufacturer

is forced to pay both a 340B discount and a Medicaid rebate for the same drug). 42 U.S.C. § 256b(a)(5)(A)-(B). But when 340B sales are made through for-profit contract pharmacies, rather than covered entities themselves, the risks of abuse skyrocket—as the HHS Inspector General documented in a 2014 report. *Novartis*, 102 F.4th at 458.

With respect to diversion, "the concern is that pharmacies rely on manipulable algorithms to code whether prescriptions warrant the discount" after the fact, and the pharmacies are incentivized to count more customers as patients of covered entities. *Id.* "For example, suppose a physician practices at a covered entity and somewhere else. The physician writes a prescription for a patient of his private practice. Yet the contract pharmacy, connecting the physician to the covered entity, classifies the prescription as eligible for the discount." *Id.* That is unlawful diversion.

With respect to duplicate discounts, "the Inspector General found that some contract pharmacies do not track and exclude 340B-eligible prescriptions from Medicaid rebate claims, leading to impermissible duplication," which can drive drug prices so low that manufacturers lose money on a sale (to the extent the steep 340B discount does not already

do that). *Id.* The rise of contract pharmacies has exacerbated both forms of unlawful abuse and is slowly transforming the 340B program from what was intended to be a limited form of assistance for underserved populations into a multibillion-dollar financial boon for for-profit pharmacies.

With abuses surging, a number of manufacturers, including Defendants here, and the Pharmaceutical Research and Manufacturers of America ("PhRMA"), a trade association that represents dozens of manufacturers nationwide, JA-811 (SAC ¶129), allegedly "spent millions" to "lobby[] the federal government" to "limit the level of hospital participation in the 340B Program, limit which patients could qualify for 340B Drug Discounts, require that all discounts be passed through to patients, and limit the availability of Contract Pharmacy 340B Drug Discounts," JA-807 (SAC ¶115). But those "lobbying efforts failed," which "became evident" when the President issued an executive order on July 24, 2020, that "did little to limit Contract Pharmacy 340B Drug Discounts." *Id.* Executive Order 13937 directed HHS to take steps to ensure that future grants available to federally qualified health centers be conditioned upon making specific drugs available to certain patients

at the 340B-discounted price. *Id.* That requirement, however, "was extremely limited in scope" and "appeared to impose largely redundant legal requirements" that "promised to have relatively little impact." JA-809 (SAC ¶¶119-122). In other words, the lobbying efforts "failed" because the Executive Order "was largely meaningless." JA-812 (SAC ¶131).

C. Some Manufacturers Respond by Implementing Different Controls on the Use of Contract Pharmacies.

Left without a legislative or regulatory fix, many manufacturers began individually developing and implementing a variety of policy changes that sought to limit waste and abuse—though each policy differed in its timing, particulars, and impact. Plaintiffs allege that AstraZeneca, Sanofi, Novo Nordisk, Merck, Novartis, United Therapeutics, Boehringer Ingelheim, and additional unnamed manufacturers announced policy changes following the Executive Order. *See* JA-813-817, 822 (SAC ¶¶133-142, 159-160); JA-817-818 (SAC ¶143) ("Each Defendant attributed its restrictions to purported concerns about program integrity."). And Lilly, which had months earlier implemented its own policy related to a single drug (Cialis), expanded its policy to cover *all* its drugs, while exempting insulins altogether where discounts were

passed on to patients. JA-816 (SAC ¶139). By 2024, more than 30 manufacturers had adopted some form of program-integrity policy. Nonetheless, Plaintiffs take issue with the policy changes of only the four Defendants: Lilly, AstraZeneca, Sanofi, and Novo Nordisk.

Lilly. On May 18, 2020, months before the Executive Order, Lilly informed HHS that because of its concerns about the use of contract pharmacies, it would no longer allow contract pharmacies to purchase Cialis—a drug that treats enlarged prostates and erectile dysfunction—at the 340B-discounted price (at least absent an exemption). JA-816 (SAC ¶139).

About three months later, after it became clear that the Executive Order would not bring about meaningful change, on August 19, 2020, Lilly announced that it would expand its 340B policy changes. JA-815 (SAC ¶137). Beginning on September 1, 2020, Lilly would no longer honor 340B contract-pharmacy orders for *any* Lilly product except in limited circumstances, including where "a covered entity does not have an in-house pharmacy." JA-815, 849 (SAC ¶¶137, 273). Lilly also provided a detailed exception for its insulin products that allowed covered entities to use an unlimited number of contract pharmacies for the sale

of insulin so long as the contract pharmacies passed on the discount to the covered-entity patients the 340B program was designed to help. JA-815-816 (SAC ¶138).

Against the backdrop of ensuing litigation with the federal government over what the 340B statute requires, Lilly made subsequent changes in December 2021, announcing that it would honor all contract-pharmacy requests if covered entities provided certain claims-level data for the orders they transferred to contract pharmacies so that Lilly could better detect unlawful diversion and duplicate discounting. JA-817 (SAC ¶142).

AstraZeneca. On July 24, 2020, the same day as the Executive Order, AstraZeneca notified HHS that it would "adjust [its] approach" to contract pharmacies for 27 products that included—but were not limited to—its diabetes drugs. JA-813 (SAC ¶134). AstraZeneca publicly announced its new policy on July 27, 2020. JA-849 (SAC ¶272). It explained that as of October 1, 2020 (the first day of the fourth fiscal quarter), it would "recognize one contract pharmacy per covered entity" if the covered entity "do[es] not maintain an on-site dispensing pharmacy." JA-813, 849 (SAC ¶¶134, 272). AstraZeneca did not include

any insulin-specific exception akin to Lilly's exception, in part because it does not sell insulin, only an incretin mimetic.

Sanofi. On July 27, 2020, a few days after the Executive Order, Sanofi announced it would be "implementing a new 340B program integrity initiative." JA-814-815 (SAC ¶136). Sanofi announced that it would honor 340B orders from an unlimited number of contract pharmacies so long as the covered entity submitted claims data that would allow Sanofi to better detect unlawful duplicate discounts. Sanofi's policy also took effect on the first day of the next fiscal quarter, October 1, 2020. JA-814-815 (SAC ¶136). On February 2, 2021, Sanofi clarified that its policy did not apply to all 15 types of covered entities; instead, it was limited to only "five covered entity types"—"consolidated health center programs, disproportionate share hospitals, critical access hospitals, rural referral centers, and sole community hospitals"—and it allowed those covered entities to designate one contract pharmacy if they lacked an in-house pharmacy. JA-817 (SAC ¶141).

Novo Nordisk. Novo Nordisk did not take any action for "several more months" after the Executive Order. JA-816 (SAC ¶140). It was not until December 1, 2020 (more than four months after Sanofi's

announcement), that Novo Nordisk informed HHS that, as of January 1, 2021, it would no longer honor contract-pharmacy orders if made on behalf of hospital covered entities—a unique policy that no other manufacturer adopted. *Id.*

A year later, on January 24, 2022, Novo Nordisk modified its policy to permit hospital covered entities without an in-house pharmacy to designate up to two contract-pharmacy locations—one retail pharmacy and one specialty pharmacy—for 340B deliveries. JA-817 (SAC ¶142). Notably, it remains undisputed that no version of Novo Nordisk's policy has ever affected *these* Plaintiffs, which are not hospitals.

The below chart summarizes Defendants' varying policies as of January 2022 (after each made the changes discussed above):

	AstraZeneca	**Sanofi**	**Lilly**	**Novo Nordisk**
Allows one contract pharmacy for each covered entity that does not have an in-house pharmacy (irrespective of claims data) (JA-813-814 (SAC ¶¶134, 137))	✓	✓	✓	
Allows two contract pharmacies for each hospital covered entity that does not have an in-house pharmacy (JA-817 (SAC ¶142))				✓
No limit on contract pharmacies passing along insulin products at cost if dispensed without fee (JA-815 (SAC ¶138))			✓	
No limit on contract pharmacies if minimal claims data provided (JA-814-817 (SAC ¶¶136, 142))		✓	✓	
Applies only to specific products (JA-813 (SAC ¶134))	✓	✓		
Applies only to specific facilities (JA-816-817 (SAC ¶¶140-41))		✓		✓
Applies to *all* products and facilities (JA-815 (SAC ¶137))			✓	

Even beyond the differences in their timing and express terms, these policies led each Defendant to avoid 340B losses to varying degrees. To begin, Plaintiffs fail to allege any statistics relevant to the markets at issue here: the "markets for diabetes treatments." JA-798 (SAC ¶78). But even the statistics they do allege—for *all* 340B drugs—confirm that Defendants' varied policies yielded different results. For example, between September 2020 and January 2021, AstraZeneca's 340B-discounted sales (which do not include any insulin sales at all) allegedly declined from about 2.7 million to about 310,000 units sold, and it avoided losses of about $44.8 million. JA-842-843 (SAC ¶¶228-229). Meanwhile, between December 2020 and January 2021, Novo Nordisk's 340B-discounted sales allegedly declined from about 3.3 million to 1.2 million units sold, and it avoided losses of about $97.5 million. JA-839-840 (SAC ¶¶216-17). Taking as true Plaintiffs' own numbers (which misleadingly measure the impact of Defendants' policies before covered entities began voluntarily complying with them), Defendants' policies decreased 340B-discounted drug volume anywhere from 60-90% (and presumably had divergent impacts on the purported diabetes markets, too). JA-778 (SAC ¶8).

D. HHS Threatens Regulatory Penalties, but the Courts Repeatedly Vindicate Defendants.

HHS responded to each manufacturer that had restricted contract-pharmacy sales in any way, declaring their program-integrity policies to be unlawful and threatening each with an array of regulatory sanctions. JA-825-827 (SAC ¶¶170-175). On December 30, 2020, the HHS General Counsel issued an Advisory Opinion arguing that manufacturers are obligated by law to offer and deliver 340B product to contract pharmacies without limitation. JA-825 (SAC ¶170). When the manufacturers refused to retract their program-integrity policies, HRSA issued letters declaring the policies illegal under the 340B statute and threatening manufacturers, including each Defendant, with "potentially massive civil monetary penalties of up to $5,883 *per instance of overcharge*," as well as expulsion from Medicaid and Medicare Part B. JA-825-826 (SAC ¶¶172-173).

In response, Defendants here, as well as other manufacturers, individually sued HRSA in cases across the country to vindicate the legality of their program-integrity policies. Manufacturers largely prevailed, and the two courts of appeals to decide the issues have fully vindicated Defendants' positions.

Last year, the Third Circuit approved each of the individual policies adopted by Sanofi, Novo Nordisk, and AstraZeneca. *Sanofi-Aventis*, 58 F.4th at 704. The court concluded that no language in the 340B statute "requires delivery to an unlimited number of contract pharmacies"; that "[u]nder the three drug makers' policies … , all covered entities can still use the Section 340B program"; and that "[t]hough the covered entities cannot squeeze as much revenue out of it as they once could, drug makers need not help them maximize their 340B profits." *Id.*

Over a year later, the D.C. Circuit approved distinct policies adopted by United Therapeutics Corp. and Novartis Pharmaceuticals Corp. *Novartis*, 102 F.4th at 464. Like the Third Circuit, the D.C. Circuit concluded that "[S]ection 340B does not categorically prohibit manufacturers from imposing conditions on the distribution of covered drugs to covered entities." *Id.*[2]

[2] A district court vacated HRSA's violation letter against Lilly, and the Seventh Circuit is now considering cross-appeals. *See Eli Lilly & Co. v. Becerra*, No. 21-3128 (7th Cir.).

E. Covered Entities Challenge Defendants' Policies Before HRSA.

The 340B statute does not grant covered entities a private right of action. The statute instead grants HHS exclusive authority to ensure compliance, and covered entities can challenge only certain manufacturer actions in administrative dispute resolution (ADR) proceedings before HHS. 42 U.S.C. §256b(d)(3); *see Astra*, 563 U.S. at 113.

HRSA first issued ADR regulations in 2020, and recently issued a new final ADR rule effective June 18, 2024. 89 Fed. Reg. 28643. The rule provides a mechanism by which covered entities and manufacturers may resolve pricing disputes, such as "[c]laims by a covered entity that it has been overcharged by a manufacturer for a covered outpatient drug." *Id.* at 28657.

Before and after HRSA issued this rule, covered entities—including Plaintiffs—filed ADR petitions against drug manufacturers (including certain Defendants) to challenge their program-integrity policies as unlawful. *See*, *e.g.*, JA-212 (petition by association of federally qualified health centers, including Plaintiffs, against AstraZeneca and Sanofi, alleging overcharges resulting from 340B policy changes). And courts dismissed or stayed covered-entity lawsuits that sought to challenge

manufacturer policies outside of ADR. *See*, *e.g.*, *Am. Hosp. Ass'n v. HHS*, 2021 WL 616323, at *4-5, 8 (N.D. Cal. Feb. 17, 2021).

II. PROCEDURAL HISTORY

A. Plaintiffs File Suit.

While HHS litigated the legality of Defendants' policies in federal court and while Plaintiffs' own claims of illegality remained pending in ADR proceedings, Plaintiffs attempted to repackage their grievances by wrapping them in the language of antitrust law. In 2021, they filed this class-action lawsuit alleging that Defendants compete with one another to sell certain diabetes drugs and violated §1 of the Sherman Act by agreeing at some unknown point in 2020 to restrict the availability of all 340B-discounted drugs to contract pharmacies.

According to Plaintiffs, Defendants agreed to this scheme for two reasons. *First*, Defendants allegedly sought to prevent any one Defendant from individually gaining share in the market for discounted drug sales and non-discounted drug sales. According to Plaintiffs, where two drugs are clinically equivalent, covered entities prefer to prescribe 340B-discounted drugs instead of non-340B discounted drugs. Because "it takes many months to transition a provider's patients from one preferred drug to another," Defendants' alleged conspiracy allowed them

to impose their new policies before covered entities could successfully transition their patients from one Defendant's drugs to another Defendant's drugs. JA-850 (SAC ¶276); *see* JA-852-853 (SAC ¶¶281-287). The premise of this theory is that each Defendant did not want any other Defendant to steal their penny-priced and other substantially discounted sales.

Perhaps recognizing that no Defendant would rationally conspire to preserve sales of penny-priced and substantially discounted products, Plaintiffs also vaguely allege that the conspiracy could have been aimed at maintaining share in the *non*-340B market because a hospital's or clinic's preference for a 340B-discounted drug "is most likely to be reflected in prescribing and administration patterns through the hospital and clinic" and "thus" Defendants' policy changes could have, absent the conspiracy, "impact[ed] drugs sold outside of the 340B Program." JA-796 (SAC ¶70). Plaintiffs do not further elaborate on whether and how any manufacturers could be selling both 340B and non-340B drugs to the same covered entities.

Second, Plaintiffs hypothesize that Defendants feared the specific government sanction of expulsion from Medicaid and Medicare Part B.

According to Plaintiffs, Defendants conspired so that HHS would feel compelled to allow them to stay in the program for fear that Medicaid and Medicare patients would lose access to diabetes drugs. JA-857 (SAC ¶307). Plaintiffs acknowledge that the government threatened other sanctions in the form of severe civil monetary penalties, and they do not allege that the conspiracy could have prevented those sanctions. JA-826 (SAC ¶173). They also acknowledge that Lilly's Cialis policy, which was presumably subject to the same government sanctions, was *both announced and implemented months before any of the policies at issue here*. JA-816 (SAC ¶139).

B. The District Court Dismisses the First Amended Complaint.

The district court first dismissed the Sherman Act claim because Plaintiffs failed to plausibly allege parallel conduct, let alone plus factors sufficient to raise an inference that Defendants entered into an anticompetitive agreement. The district court explained that "Plaintiffs' own allegations make clear that Defendants adopted four distinct policies regarding contract pharmacies and 340B drug discounts over the course of several months." JA-761. Those policies were "different in their particulars, their timing, and their outcomes." JA-763. For example:

> AstraZeneca limited contract pharmacy 340B drug discounts for certain drugs to a single contract pharmacy and only where the covered entity lacked an on-site pharmacy; Sanofi limited contract pharmacy 340B drug discounts to covered entities that agreed to comply with its new reporting requirements; Eli Lilly largely limited contract pharmacy 340B drug discounts to covered entities without on-site pharmacies but also included a further exception for certain insulin products; and Novo Nordisk limited contract pharmacy 340B drug discounts to []hospital covered entities.

JA-762-763. And those divergent policies did not have "the same or a substantially similar end result," which is unsurprising given that each policy permits and prohibits different contract-pharmacy arrangements. JA-765. The district court therefore concluded that "[t]here is no plausible argument that these disparate policies are 'substantially similar' so as to constitute parallel conduct for purposes of federal antitrust law." JA-763.

C. The District Court Denies Plaintiffs' Motion for Leave to Amend.

On February 1, 2024, the district court denied Plaintiffs' motion for leave to file a second amended complaint because amendment would be futile. *First*, the district court concluded that Plaintiffs again failed to allege parallel conduct. To the contrary, the proposed "additional allegations provide[d] further confirmation that the policies adopted by Defendants had substantial variations in both their timing and their

particulars." JA-976. The court reasoned that "[t]here is no question that beginning in 2020, Defendants have implemented restrictions on the use of contract pharmacies to make 340B purchases," but "Defendants' distinct and evolving policies, which have been adopted and updated over multiple years, simply do not amount to parallel conduct." JA-978.

Among other things, Lilly changed its policy in December of 2021 to be analogous to other manufacturer policies that had recently been approved by the D.C. federal district court. *See Novartis*, 2021 WL 5161783, at *9, *aff'd Novartis*, 102 F.4th 452. That change is "clear evidence of the individualized nature of Defendants' actions" because if all of the policies were "functionally equivalent—as Plaintiffs contend—there would be no logical reason for Eli Lilly to have made this change." JA-978-979. In addition, "the data cited by Plaintiffs shows significant variation in the reduction of 340B drug sales," with each Defendant realizing a decrease of between 60% and 90% in the volume of drugs sold at 340B prices, and that alleged reduction (taking Plaintiffs' allegations as true) affected all of Defendants' drugs, not just the diabetes drugs at issue here. JA-979.

Second, the district court concluded that, even if Plaintiffs had alleged parallel conduct, they still failed to allege enough "plus factors" to permit an inference of conspiracy. The court explained that "the allegations of the proposed second amended complaint set forth an obvious alternative explanation for the facts underlying the alleged conspiracy: the failure of the Defendants' joint lobbying efforts." JA-980-981. "[T]he proposed second amended complaint acknowledges that the 340B program requires Defendants to sell their products at significantly discounted prices," so "[i]t makes perfectly rational business sense for Defendants, who apparently viewed 340B drug discounts as a significant enough issue to spend millions of dollars lobbying the government for changes to the program, to have independently reacted to the failure of those lobbying efforts." JA-981.

The district court observed that other manufacturers—none accused by Plaintiffs of conspiring together—have adopted similar program-integrity policies, and "[t]he adoption of such policies by additional drug manufacturers further confirms that such policies make perfect business sense." JA-982.

The district court also rejected Plaintiffs' motive theories. It explained that "Plaintiffs have not offered a plausible explanation for why Defendants would be economically incentivized to monopolize the 340B program market, when that market is defined by selling products at significantly discounted rates." *Id.* Plaintiffs speculated that "if hospitals and clinics end up preferring a drug because it has a Contract Pharmacy 340B Drug Discount, that preference is most likely to be reflected in prescribing and administration patterns outside of the 340B program." JA-982-983. But "that assertion is unsupported by any factual allegations." JA-983. And although Plaintiffs alleged that "Defendants' new policies 'were imposed despite warnings by regulators that such restrictions were illegal,' the earliest 'warning' they cite was … *after* Eli Lilly, AstraZeneca, and Sanofi had announced and implemented the policies at issue here." JA-984. "It is implausible that warnings issued *after* the challenged conduct began were an impetus for concerted action." *Id.*

The district court concluded that "the proposed second amended complaint fails to set forth a viable claim under §1 of the Sherman Act, both because it does not plausibly allege parallel conduct and because it

does not otherwise plausibly allege conduct giving rise to an inference of conspiracy." JA-985. In a footnote, the court also noted that it had "serious doubts about the viability of this matter in light of the Supreme Court's decision in *Astra USA*" because Defendants had "persuasively argued that this litigation is a backdoor attempt to use the antitrust laws to enforce Plaintiffs' preferred interpretation of the 340B statute." JA-973 n.2.

Finally, the district court ruled that Plaintiffs' proposed amendments to their remaining state antitrust and unjust enrichment claims were futile. JA-985.

STANDARD OF REVIEW

"Because the district court determined that it was futile to allow plaintiffs to file a second amended complaint," this Court reviews the decision *de novo* and must "evaluate th[e] proposed complaint as [it] would a motion to dismiss, determining whether it contains enough facts to state a claim to relief that is plausible on its face." *Force v. Facebook, Inc.*, 934 F.3d 53, 62 (2d Cir. 2019).

SUMMARY OF ARGUMENT

Plaintiffs' Sherman Act claim fails on at least four grounds.

First, Plaintiffs fail to allege the parallel conduct necessary to state a horizontal price-fixing claim. Plaintiffs argue that each Defendant's individual policy changes amount to "parallel conduct" by zooming out to an impracticable level of generality. On their face, Defendants' policies vary in their scope, products covered, subject matter, adoption date, and consequences.

Second, even if Plaintiffs had alleged parallel conduct, they have not alleged enough circumstantial evidence to "nudge[] their claim[] across the line from conceivable to plausible." *Twombly*, 550 U.S. at 570. Plaintiffs do not identify a single communication in support of a conspiracy, and Plaintiffs' own allegations demonstrate that Defendants' individual policies each made perfect business sense in light of the financial losses caused by the 340B program and the failure of PhRMA's lobbying campaign. Plaintiffs fail to identify any plus factors that overcome that obvious alternative (and lawful) explanation.

Third, Plaintiffs' complaint should be dismissed as an improper attempt at private enforcement of the 340B statute. The antitrust laws are designed to protect the market and prevent collusion; they are not designed to regulate the circumstances under which a regulated party is

entitled to access deeply discounted prices under the 340B statute. The Supreme Court, the Executive Branch, and Congress all agree that the 340B statute endows HHS with exclusive authority to police compliance with the 340B statute, and HHS has promulgated ADR rules to allow for the resolution of pricing disputes before the agency. Plaintiffs cannot short-circuit that comprehensive scheme through an antitrust back door.

Fourth, Plaintiffs' damages claims are barred under *Illinois Brick* because Plaintiffs are indirect purchasers of Defendants' products.

ARGUMENT

Plaintiffs appeal only the district court's decision denying leave to amend their Sherman Act claim. Because they do not appeal the district court's dismissal of their state-law antitrust and unjust enrichment claims, those claims are forfeited. *Tripathy v. McKoy*, 103 F.4th 106, 118 (2d Cir. 2024) ("It is … settled that an appellant forfeits any argument not raised in his opening brief."). As to the disputes that are raised, Plaintiffs do no better defending their contrived theory before this Court than they did below.

I. PLAINTIFFS DO NOT PLAUSIBLY ALLEGE AN ANTICOMPETITIVE AGREEMENT.

The Sherman Act bans "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States." 15 U.S.C. §1. Because the Act "does not prohibit all unreasonable restraints of trade but only restraints effected by a contract, combination, or conspiracy, the crucial question is whether the challenged anticompetitive conduct stems from independent decision or from an agreement, tacit or express." *Twombly*, 550 U.S. at 553.

"[I]t is not enough" at the pleadings stage "to make allegations of an antitrust conspiracy that are consistent with an unlawful agreement; to be viable, a complaint must contain enough factual matter (taken as true) to suggest that an agreement to engage in anticompetitive conduct was made." *In re Elevator Antitrust Litig.*, 502 F.3d 47, 50 (2d Cir. 2007). Where, as here, the plaintiffs rely on circumstantial evidence of an agreement, they must plausibly allege *both* "parallel conduct" *and* "additional circumstances, often referred to as 'plus' factors, which, when viewed in conjunction with the parallel acts, can serve to allow a fact-finder to infer a conspiracy." *Mayor & City Council of Baltimore v. Citigroup, Inc.*, 709 F.3d 129, 136 (2d Cir. 2013). Indeed, even if

"consistent with conspiracy," parallel acts may "be 'just as much in line with a wide swath of rational and competitive business strategy unilaterally prompted by common perceptions of the market'—or the product of 'chance, coincidence, independent responses to common stimuli, or mere interdependence unaided by an advance understanding among the parties.'" *City of Pontiac Police & Fire Ret. Sys. v. BNP Paribas Sec. Corp.*, 92 F.4th 381, 391 (2d Cir. 2024) (quoting *Twombly*, 550 U.S. at 553-54, 556 n.4).

Plaintiffs fail to plausibly allege either parallel conduct or plus factors. Instead, their complaint establishes an "obvious alternative explanation," *Twombly*, 550 U.S. at 567: that each Defendant acted independently in its own self-interest to address 340B abuse.

A. Plaintiffs' Allegations Make Clear Defendants Acted Independently in Their Own Self-Interest.

There is an obvious, non-conspiratorial explanation for Defendants' different program-integrity policies limiting the availability of 340B pricing to contract pharmacies: the exponential increase in the use of contract pharmacies, which caused manufacturers to suffer significant financial losses. That common problem allegedly caused Defendants (and others) first to attempt to effect change through a lobbying

campaign. When that lobbying campaign failed, manufacturers' (including Defendants') only recourse was to act individually to address the problems they each faced—and they each did so in their own individual ways.

Plaintiffs admit the 340B statute requires manufacturers to sell their drugs at steep discounts. JA-786-787, 808 (SAC ¶¶37, 118). In fact, the 340B statute commonly requires manufacturers to sell drugs like insulin for a single penny—in other words, to give it away, in effect for free and plainly at a loss. 85 Fed. Reg. 45755. And where covered entities and contract pharmacies cause duplicate discounting, a manufacturer can lose even more money because it must sell the drug at a discount under the 340B statute and then pay a Medicaid rebate for the same drug. *See Novartis*, 102 F.4th at 458. Plaintiffs assert that "discounted sales are still sales with a range of corresponding profits." Br.63-64. But they offer no factual allegations—plausible or implausible—to support their facially naive belief that all 340B sales are profitable, and the record correctly refutes that notion. After all, manufacturers can hardly be said to profit off products they essentially give away.

Plaintiffs also admit Defendants (among others) publicly expressed concern about the significant and growing 340B abuse involving contract pharmacies, which has significantly exacerbated the risk of both diversion and duplicate discounting ever since 2010, when HRSA purported to begin permitting the use of unlimited contract-pharmacy arrangements. *See, e.g.*, JA-817-818 (SAC ¶143); JA-452-454. In response, Defendants and other manufacturers sought to address contract-pharmacy abuses through lobbying. JA-776-777 (SAC ¶6). But that lobbying campaign "failed" when the President issued an executive order that "did little to accomplish any of Defendants' goals" and "promised to have relatively little impact on the volume of 340B Drug Discounts" and corresponding contract-pharmacy abuses. JA-776-777, 807-808 (SAC ¶¶6, 115, 120).

Against this backdrop, as the district court explained, it "makes perfectly rational business sense for Defendants, who apparently viewed 340B drug discounts as a significant enough issue to spend millions of dollars lobbying the government for changes to the program, to have independently reacted to the failure of those efforts." JA-981. Defendants' reactions were "in line with a wide swath of rational and

competitive business strategy unilaterally prompted" by a "common" impetus: the financial toll of 340B abuses and the failure of the Defendants' lobbying efforts. *Elevator Antitrust Litig.*, 502 F.3d at 51. And "it is decidedly not indicative of a conspiracy that a group of similarly situated market participants would object, individually and separately, to a significant market development that could cut into their profits." *BNP*, 92 F.4th at 409.

Although Plaintiffs' own allegations point to this obvious alternative explanation, they hypothesize a conspiracy that would turn Defendants' economically rational behavior into entirely irrational behavior. According to Plaintiffs, Defendants agreed at some unspecified time in 2020 to "restrict Contract Pharmacy 340B Drug Discounts," JA-849 (SAC ¶271), beginning on or after July 24, 2020 (the date of the Executive Order, JA-800 (SAC ¶133)), for two reasons: (i) to avoid a "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"; and (ii) to avoid "the potential devastating sanction of exclusion of [each] firm's drugs

from Medicare and Medicaid coverage," Br.63. Neither theory withstands scrutiny.

First, Plaintiffs fail to provide any plausible explanation why Defendants would have sought to avoid losing share in a discount market characterized by forced penny-pricing and significant financial losses. *See* JA-982 (district court reasoning similarly). Seeking to dominate that market would be irrational, not rational.

Perhaps sensing the absurdity of their proposed motive targeting the unprofitable 340B market, Plaintiffs argue that Defendants feared covered entities would respond to the loss of 340B discounts by changing their prescribing preferences for *non*-340B drugs. Br.64. But as the district court explained, that "assertion is unsupported by any factual allegations" and thus "lacks plausibility." JA-983. Plaintiffs do not offer any allegations suggesting that prescribers, who may only have a tangential relationship to a covered entity, are aware of either the 340B pricing or whether the individual to whom they are prescribing a medication would qualify as a 340B patient. Prescribers and covered entities are distinct, and Plaintiffs allege nothing to support that a physician's prescribing decisions and a covered entity's 340B policy

concerns might be aligned. In all events, Plaintiffs certainly do not allege that any effect (if one even exists) of any program-integrity policy on any *non*-340B sales could be significant enough to incentivize manufacturers to want to maximize sales of their penny-priced and other substantially discounted drugs in the 340B market. Plaintiffs' unadorned speculation about the possibility that manufacturers might care about some (at best) small but unknown number of non-340B prescriptions is not sufficient to avoid dismissal. *See Yamashita v. Scholastic Inc.*, 936 F.3d 98, 104 (2d Cir. 2019) ("the mere possibility of misconduct" is insufficient to survive dismissal and "raise a right to relief above the speculative level").

Second, Plaintiffs' theory that Defendants sought to avoid expulsion from Medicaid and Medicare Part B also makes no sense. Plaintiffs argue that Defendants conspired to restrict 340B discounts on diabetes drugs because they believed they had "safety-in-numbers" and regulators would be unlikely to expel all diabetes drugs at the same time for fear of the effect on patients. JA-857 (SAC ¶307). But Plaintiffs admit Lilly implemented its policy for Cialis—a non-diabetes drug—by itself and "months earlier" than the policies involved in the supposed conspiracy. JA-816 (SAC ¶139). As the district court explained, that

"unilateral restriction of contract pharmacy 340B drug discounts in May of 2020—before the alleged conspiracy is purported to have begun—directly contradicts Plaintiffs' 'safety in numbers' theory." JA-984. After all, at least one Defendant apparently thought it was rational to act unilaterally despite the threat of exclusion and civil monetary penalties. Plaintiffs have no response; they simply cannot explain why Lilly would bear the risks of government sanctions as the sole actor (for months) but would later join some safety-in-numbers conspiracy. Moreover, Plaintiffs admit other manufacturers not alleged to be part of the conspiracy took similar steps, *e.g.*, JA-822 (SAC ¶160), which confirms that implementing a program-integrity policy was rational in the absence of any agreement.

The supposed conspiracy becomes more inexplicable when the threat of civil monetary penalties is considered. Plaintiffs admit that, separate from expulsion, HRSA threatened "potentially massive civil monetary penalties of up to $5,883 *per instance of overcharge*," meaning per order. JA-825-826 (SAC ¶172-173). Thus, every day that passed without a change in a Defendant's policy (assuming it violated the 340B statute) could have resulted in potentially massive fines ($5000 per individual violation, increased by inflation, multiplied out across

hundreds of thousands of transactions). And although Plaintiffs claim (without substantiation) that Defendants could have avoided expulsion through their purported conspiracy, they do not allege that Defendants could somehow avoid the threatened civil monetary penalties by acting together. Likewise, Plaintiffs fail to offer any plausible (or even implausible) explanation why Defendants would fear expulsion more than the possibility of catastrophic penalties.

In any event, Plaintiffs' allegations make clear that Defendants continued to fear government sanctions (including expulsion) even after they entered the supposed conspiracy. *See* JA-855 (SAC ¶¶295-96). That is why each Defendant independently initiated costly litigation in different forums, making a variety of different arguments, and seeking declarations that their policies were lawful. If Defendants truly believed they had "safety-in-numbers," they had no reason to sue and no basis to represent their fear of exclusion in their pleadings. In reality, Defendants did not act (collaboratively or otherwise) to avoid expulsion, but instead acted individually to protect their own self-interest based on a view that the government did not have the authority to impose any

regulatory sanction at all—and they were right. *See Novartis*, 102 F.4th at 458; *Sanofi-Aventis*, 58 F.4th at 699.

Finally, Plaintiffs implausibly suggest that Defendants must have agreed to different policies "in an attempt to hide" their conspiracy from "antitrust scrutiny." Br.60. Yet they have no explanation why some Defendants would choose policies that, because of their unique terms, had far less "success" than others. For instance, Plaintiffs allege that Sanofi's policy resulted in lost savings to covered entities—and therefore presumably avoided losses for Sanofi—of $43 million per month, while Novo Nordisk's policy resulted in lost savings to covered entities—and avoided losses to Novo Nordisk—of $100 million per month. Br.27-28. But Plaintiffs fail to explain why one Defendant would agree in some hypothesized backroom meeting to adopt a policy that would benefit another Defendant so much more.

These gaping holes in Plaintiffs' theory explain why the district court correctly concluded that Plaintiffs could not plausibly allege either parallel conduct or plus factors sufficient to raise an inference of conspiracy.

B. Plaintiffs Fail to Allege Parallel Conduct.

To plead parallel conduct, a complaint must allege conduct that, even if not identical, is substantially similar and occurs sufficiently close in time to suggest an agreement. *Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 228 (3d Cir. 2011); *In re Musical Instruments & Equip. Antitrust Litig.*, 798 F.3d 1186, 1193 (parallel conduct occurs when competitors adopt "similar policies around the same time in response to similar market conditions"). "Circumstances must reveal a unity of purpose or a common design and understanding, or a meeting of minds in an unlawful arrangement," because "[i]ndependent action is not proscribed." *Anderson News, LLC v. Am. Media, Inc.*, 680 F.3d 162, 183 (2d Cir. 2012). Plaintiffs' allegations fail this test on both counts.

The Eighth Circuit's holding in *Park Irmat Drug Corp. v. Express Scripts Holding Co.* is instructive. 911 F.3d 505 (8th Cir. 2018). There, the plaintiff brought an antitrust claim against Express Scripts, alleging that it conspired with CVS to boycott independent mail-order pharmacies. The allegations included that both CVS and Express Scripts terminated the plaintiff from their networks. CVS required the plaintiff to participate in CVS's own mail-order network in August 2016 before

terminating it from the same network in February 2017. *Id.* at 516. And Express Scripts demanded that the plaintiff abandon its mail-order pharmacy operations in May 2016, before removing the plaintiff from its network in September 2016. *Id.* at 512, 516. Even though the two terminations occurred within six months of each other, the Eighth Circuit held that there was no plausible parallel conduct: "the terminations lack[ed] temporal proximity" and the "circumstances" of each termination were too "dissimilar." *Id.* at 516-17.

Other courts have likewise dismissed claims that fail to allege the defendants engaged in similar conduct with sufficient "temporal proximity." *See Burtch*, 662 F.3d at 228 (allegations fell "short of demonstrating parallel behavior by [creditors] because the [creditors] were choosing to decline, decrease, or even increase credit to [retailer] at different time periods").

Plaintiffs argue that Defendants' conduct was parallel because their different policies were announced or instituted within several months of each other and there was an allegedly common "effect." Br.50. These arguments fail.

1. Defendants' Program-Integrity Policies Are Not Similar and Were Not Instituted at the Same Time.

Plaintiffs allege that each program-integrity policy "end[ed] … the overwhelming majority of Contract Pharmacy 340B Drug Discount sales to covered entities." *Id.* But that broad statement hides a multitude of distinctions that would affect the calculus for any reasonable and economically self-interested decisionmaker.

"[T]he policies adopted by Defendants had substantial variations in both their timing and their particulars." JA-976. Certain manufacturers (Sanofi and Lilly in its subsequent 2021 policy) permitted unlimited contract pharmacies as long as covered entities submitted claims data—a policy that can hardly be considered to impose any meaningful "restriction" at all. *See Novartis*, 102 F.4th at 463 ("[T]he only record evidence … indicates that the burden of providing the claims data is 'minimal.'"). Others (Lilly in its May 2020 policy and AstraZeneca) applied their policies only to specific products, while others extended their policies to most or all of their products (Sanofi, Lilly as of August 2020, and Novo Nordisk). Still others (Novo Nordisk and Sanofi as clarified in February 2021) adopted policies that applied only to a subset of covered entities. And Lilly stood alone in permitting unlimited

contract pharmacies to dispense 340B-priced insulins if they were dispensed at cost, without additional fees. In other words, Lilly would continue to incur the same costs for penny-priced insulins so long as the benefits from those steep discounts actually reached patients; no one else implemented anything similar.

These disparate policies are not parallel; instead, they reflect differing individual responses to solving the then well-known (and well-documented) concerns posed by widespread use of contract pharmacies. These policy differences alone are dispositive. *See Park Irmat*, 911 F.3d at 516-17.

Plaintiffs suggest that even if the policies themselves were different, they had a common effect. *See* Br.50. That is incorrect. Among other things, Defendants' policies affected different drugs, diabetes-related and otherwise. AstraZeneca's policy applied to a limited subset of 27 products. Lilly's first policy applied only to one product that does not treat diabetes. Sanofi's policy applied to many of its drugs. And while Lilly's second policy applied to all of its products, it permitted unlimited contract pharmacies to dispense 340B-discounted insulin if the covered entity and pharmacy agreed to pass on the discount to the patient.

The policies also affected different covered entities: Novo Nordisk, for example, imposed restrictions on hospital covered entities (not Plaintiffs), whereas Sanofi later clarified in February 2021 that its 340B data policy applied to just "five covered entity types" and further allowed these covered entities to use one contract pharmacy without providing claims data if they lacked an in-house pharmacy.

The policies also had different effects on contract-pharmacy practices. Novo Nordisk permitted hospitals to designate two contract-pharmacy locations, whereas Lilly's August 2020 policy permitted covered entities without an in-house pharmacy to designate a single contract pharmacy. And Sanofi placed no limitation at all on the number of contract-pharmacy relationships permitted per covered entity when claims data was submitted (a condition that, as noted, is not properly characterized as a restriction at all).

True, as Plaintiffs point out, Defendants each saw some reduction in some 340B sales. But that alleged reduction varied dramatically and especially as to diabetes drugs—the drugs at issue here where the alleged conspiracy purportedly concerned only diabetes markets. For example, AstraZeneca does not sell insulin, and its sales of incretin mimetics (the

diabetes drug it does sell) constitute only 5% of the alleged market. JA-800-802 (SAC ¶¶90, 95, 98). Logically then, the financial effect of AstraZeneca's program-integrity policy on its diabetes sales was far different than the financial effect of the program-integrity policy of any other Defendant on its diabetes sales.

Plaintiffs' only response is to offer government statistics reflecting the purported effect of Defendants' policies on *all* 340B sales, not just the diabetes drugs that purportedly drove Defendants to participate in a diabetes-specific conspiracy. JA-828, 833, 839, 842 (SAC ¶¶181, 197-98, 216-17, 228-29). But this data sheds no light on whether the policies had the same effect on diabetes drugs. If anything, it "undermines Plaintiffs' premise that Defendants were only willing to act in the diabetes-treatment markets where they supposedly moved together." JA-979.

Regardless, even assuming Plaintiffs' data could be probative of a question in this case, drastic differences pervade the depicted 340B sales reductions and avoided losses. For example, according to Plaintiffs, Novo Nordisk's policy left close to 40 percent of its 340B sales in place, while AstraZeneca's policy allegedly left less than 10 percent of its previous 340B sales in place. JA-840, 843 (SAC ¶¶218, 230). And the different

policies allegedly resulted in a difference of a half a billion dollars annually in avoided losses. *See supra* p.42. As the district court rightly found, these dramatic differences confirm that the conduct at issue was not parallel. *See* JA-979.

Finally, the timing of each policy further undercuts Plaintiffs' theory. Rather than demonstrating "temporal proximity," *Park Irmat*, 911 F.3d at 516, Plaintiffs' allegations demonstrate that Defendants instituted the challenged policies over a period of *19 months*, *see supra* p.14-17. On May 18, 2020, Lilly implemented its original Cialis-only policy. Several months later, on July 24, 2020, AstraZeneca announced a new policy that would apply to just 27 products. On July 27, 2020, Sanofi announced its own policy that applied to most Sanofi products. Almost another full month later, on August 19, 2020, Lilly revised its policy to extend to all of its products (with an exception for insulin). And almost four months later, on December 1, 2020, Novo Nordisk announced it would implement its own unique policy.

Still other changes followed Novo Nordisk's announcement, as the federal courts resolved HHS's challenges to different manufacturers' policies. In February 2021, Sanofi clarified its claims-data policy. About

one year later, in December 2021, Lilly amended its policy to adopt a claims-data requirement. And one month later, in January 2022, Novo Nordisk announced that it would further modify its own policy.

Altogether, the SAC alleges a purported conspiracy extending from May 2020 to January 2022. That 19-month time period during which Defendants implemented an array of distinct policies simply does not plausibly establish "parallel conduct." *See, e.g.*, *Park Irmat*, 911 F.3d at 517 (six-month interval not proximate enough).

Plaintiffs attempt to narrow the relevant time period to "the second half of 2020" by urging the Court to ignore both Lilly's first Cialis-only policy and each Defendant's subsequent policy changes. Br.52-53. But there is no reason for such gerrymandering. Plaintiffs' inability to explain away the Cialis-only policy or to explain Defendants' subsequent policy changes—which suggest that Defendants did not believe that each policy had the same effect and instead suggest that each Defendant made independent decisions to implement an appropriate policy specific to the abuses they were confronting—requires dismissal. *See* JA-978-979 ("[T]he fact that Eli Lilly, after first adopting its own unique policy in May and August of 2020, changed course in December of 2021 to adopt

the Second Sight Solutions platform as Sanofi had done more than a year earlier is clear evidence of the individualized nature of Defendants' actions.").

Plaintiffs also zoom in on a few particularly close-in-time announcements. For example, Plaintiffs note that "AstraZeneca privately committed its restrictions in a letter to HHS only one business day before Sanofi's public announcement." Br.52. But Plaintiffs offer no theory explaining why private communications with an agency should be treated as equivalent to a public announcement, nor why some manufacturers communicated with HHS in advance but others did not.

In any event, a handful of supposed coincidences in a conspiracy alleged to have spanned many months is not enough to establish parallel conduct—and certainly not when those events are close in time to an obvious external stimulus, namely, the July 24, 2020 Executive Order. If anything, the single-business-day difference Plaintiffs highlight only makes more conspicuous Novo Nordisk's apparent decision to wait *four months* to institute its own program-integrity policy (as well as Lilly's decision to act many months earlier). Plaintiffs have no explanation (because there is none) for why Novo Nordisk would have agreed to take

a back seat for four months while its conspirators reaped the alleged benefits of their earlier instituted policies—or, for that matter, why the other Defendants would have ceded the supposedly desirable discount market to Novo Nordisk for months.[3] As the district court concluded: "Defendants' distinct and evolving policies, which have been adopted and updated over multiple years, simply do not amount to parallel conduct[.]" JA-978.

2. Plaintiffs' Cases Do Not Support Their Theory.

Plaintiffs respond with a series of citations intended to bolster the unremarkable point that an agreement can violate the Sherman Act even if the alleged conduct is not "identical" and does not occur "simultaneous[ly]." Br.48. True, but irrelevant given the breadth and divergent timing here.

[3] Plaintiffs suggest that Lilly and AstraZeneca first announced different versions of their program-integrity policies in private letters to HRSA because they were aware their actions "violated the law" and sought to avoid scrutiny by antitrust regulators. Br.60. This argument is difficult to follow. Of course, all of the policies had to become (and did become) public in order to take effect. And it would be strange for a conspirator to attempt to avoid scrutiny by the government by informing *the government* of its plans.

Plaintiffs cite the *Twombly* trilogy, but *Twombly* focused on (and found lacking) the plaintiffs' allegations of plus factors, not parallel conduct. And although the plaintiffs alleged an array of anticompetitive conduct, such as interfering with customer relationships and denying potential competitors access to essential network equipment and facilities, the complaint alleged that *all* the defendants engaged in *all* those activities. *Twombly*, 550 U.S. at 550-51; *Twombly v. Bell Atl. Corp.*, 425 F.3d 99, 118 (2d Cir. 2005); *Twombly v. Bell Atl. Corp.*, 313 F. Supp. 2d 174, 177-78 (S.D.N.Y. 2003). *Twombly*'s facts therefore have little bearing here, where each Defendant took a different action that led to a distinct outcome.

Plaintiffs' reliance on *Anderson News* is similarly mistaken. There, a magazine wholesaler brought antitrust claims against national magazine publishers and distributors alleging they took different steps to drive the plaintiff out of business after the plaintiff imposed a surcharge on each magazine it received and distributed. 680 F.3d at 170-71. Although this Court permitted the claims to proceed, it did not suggest that there are no limits on the types of means and the time interval necessary to allege parallel conduct. The Court acknowledged

the defendants had different initial reactions to the surcharge, which suggested "disagreement as to how to deal conspiratorially with their common problem." *Id.* at 191. But that "disagreement," the Court reasoned, did not mean that there was not *later* an agreement to achieve the same end with similar means over the course of only *three days*. The Court explained: "[T]he key parallel conduct allegation was that all of the publisher and distributor defendants ceased doing business with Anderson," and the district court's "reliance on the variety of defendants' *original* reactions failed to take into account that, notwithstanding their responses initially, some two weeks later *every defendant publisher and distributor acted, within a span of three business days, to cut Anderson off*." *Id.* Of course, the conduct here occurred over the course of 19 months, not three days (and while other non-defendant manufacturers were also implementing their own policies), and it did not achieve a similarly common outcome.

Plaintiffs also cite this Court's summary order in *Ross v. Citigroup, Inc.*, 630 Fed. App'x 79 (2d Cir. 2015), which involved an alleged conspiracy among banks that sought to adopt arbitration clauses in cardholder agreements. This Court held that the district court correctly

credited allegations of parallel conduct, but it ultimately affirmed the district court's dismissal because the plaintiffs failed to sufficiently allege plus factors (in part because the banks were individually motivated to adopt arbitration clauses, *id.* at 82). Focusing on the parallel-conduct reasoning, Plaintiffs note that the "banks adopted different clauses—with one offering an exception to allow cardholders to fully opt-out of arbitration"—over the course of "four-and-a-half years." Br.47. But Plaintiffs neglect to explain that all the arbitration clauses contained a class-action bar and that all but one defendant "implemented clauses within a month" of a group meeting. *Ross v. Am. Exp. Co.*, 35 F. Supp. 3d 407, 439 (S.D.N.Y. 2014). Here, by contrast, the Defendants' policies were unevenly spaced across a 19-month period; there is no similarly common provision across all the policies; and Plaintiffs have not alleged a similarly specific meeting that immediately preceded the bulk of the policy changes.

Moreover, the circumstances in *Ross* were unique because of the conspiracy alleged. The *Ross* district court specifically distinguished cases like this one that involve allegations of price-fixing: "Unlike price fixing, which may quickly impose a negative toll on the first firm to raise

its price unless others soon follow, an agreement to impose and maintain arbitration clauses would not require immediate, concerted action to be successful because arbitration was not salient to consumers at that time." *Id.* Instead, because the goal of the *Ross* conspiracy was to "establish[] arbitration as the accepted industry standard for dispute resolution," "a more studied and staggered approach … made sense." *Id.* Plaintiffs do not attempt to explain why the lengthy time period in this case makes sense here, where every day of delay caused Defendants to give more 340B discounts and therefore lose out on the alleged benefits of the policies that the first movers were reaping.

C. Plaintiffs Fail to Allege Plus Factors.

Plaintiffs also fail to allege sufficient plus factors to suggest an agreement. Parallel conduct alone is insufficient to withstand dismissal. "Parallel conduct … needs context suggesting an antecedent agreement, rather than parallel conduct that could just as well be independent action." *BNP*, 92 F.4th at 391. Interdependence and even conscious parallelism are not illegal. "In an interdependent market, companies base their actions in part on the anticipated reactions of their competitors," and "because of this mutual awareness, two firms may

arrive at identical decisions independently, as they are cognizant of—and reacting to—similar market pressures." *Musical Instruments*, 798 F.3d at 1193. But interdependence "does not entail collusion, as interdependent firms may engage in consciously parallel conduct through observation of their competitors' decisions, even absent agreement." *Id.* at 1195.

That is why "allegations of parallel conduct must be reinforced by 'plus factors' that provide a basis to infer that a conspiracy arose." *BNP*, 92 F.4th at 391. Plus factors can include "a common motive to conspire, evidence that shows that the parallel acts were against the apparent individual economic self-interest of the alleged conspirators, and evidence of a high level of interfirm communications." *Id.*

Plaintiffs argue that the timing of the policy changes; the Defendants' ability to communicate with each other; the policy changes' departure from 10 years of practice (following HHS's 2010 guidance permitting unlimited contract-pharmacy arrangements); the supposed contrary self-interest of Defendants; the concentration of the diabetes market; and the existence of past, unrelated government investigations

establish plus factors sufficient to raise a plausible inference of an anticompetitive agreement. None of these assertions withstand scrutiny.

1. There Is No Plausible Allegation of a High Level of Interfirm Communications.

Plaintiffs contend that "Defendants engaged in a high level of interfirm communications on these very issues," Br.67, but "on these very issues" obscures the fact that Plaintiffs *do not allege a single communication about this alleged conspiracy.* Plaintiffs vaguely allege that Defendants had "ample opportunity to conspire" because Defendants had "common lobbyists" who "appear to have communicated directly with each other during their lobbying campaign" to reform the 340B program, and "Defendants also engaged in high levels of communications through industry associations." JA-862 (SAC ¶¶328-330). From there, Plaintiffs conclude: "Upon information and belief, during th[e] joint lobbying effort, Defendants planned their restrictions on Contract Pharmacy 340B Drug Discounts as a fallback position if their lobbying efforts failed." JA-862 (SAC ¶329).

None of these allegations about Defendants' "opportunity to conspire" are sufficient to establish this plus factor. JA-862 (SAC ¶328). Plaintiffs bear the burden of pleading "evidentiary facts"—such as "who,

did what, to whom (or with whom), where, and when"—to state a plausible claim for relief. *Musical Instruments*, 798 F.3d at 1194 n.6. Plaintiffs cannot cure their failure to plead evidentiary facts by throwing in the words "upon information and belief." *Citizens United v. Schneiderman*, 882 F.3d 374, 384 (2d Cir. 2018). Instead, the details of any communication among Defendants are critical to establishing a conspiracy because businesses can agree to conspire only by engaging in some form of communication.

Plaintiffs have not met this burden. They have not alleged any evidentiary facts sufficient to establish any interfirm communications. As this Court has held, "the mere opportunity to conspire"—what Plaintiffs allege here—"does not by itself support the inference that … an illegal combination actually occurred." *Gamm v. Sanderson Farms, Inc.*, 944 F.3d 455, 466 (2d Cir. 2019); *see BNP*, 92 F.4th at 391, 396 (allegation of "constant communications" insufficient because it did not reveal whether, and if so which, of the defendants participated in the conversations or the conspiracy); *Citigroup*, 709 F.3d at 139 (allegations of "only two actual communications *between* competitors" insufficient).

And that Defendants have common lobbyists and are members of a common advocacy group is not sufficient to establish this plus factor either. *See Gamm*, 944 F.3d at 466 (allegations of "opportunities to conspire" through "participation in trade associations" is insufficient); *Honey Bum, LLC v. Fashion Nova, Inc.*, 63 F.4th 813, 823-24 (9th Cir. 2023) (permitting trade-association involvement to preclude summary judgment "would run counter to the Supreme Court's instruction that trade associations often serve legitimate functions").[4]

2. Defendants' Policies Were Not "Historically Unprecedented," and Have Been Upheld by Courts.

Plaintiffs also argue that Defendants' policies amounted to "complex and historically unprecedented changes in pricing structure." *Twombly*, 550 U.S. at 557 n.4; *see* Br.61. But there was nothing "unprecedented" about Defendants' policy changes. For the first 18 years of the 340B program's existence, covered entities were able to use only *at most* a single contract pharmacy and only if they lacked an in-house

[4] Defendants are not arguing that any anticompetitive discussions at a lobbying meeting are "inadmissib[le]" or otherwise "immune" from antitrust scrutiny. Br.68 n.5. Plaintiffs' problem is that they have not sufficiently alleged that any anticompetitive discussions actually occurred at any such meeting.

pharmacy. *See* JA-790 (SAC ¶¶50-51); 61 Fed. Reg. 43549. It was not until 2010 that HRSA issued "unprecedented" guidance permitting covered entities to engage an unlimited number of contract pharmacies. *See* JA-790 (SAC ¶¶52-53). And the financial and program-integrity effects of that sea change were not immediate, but felt later, after contract pharmacies flocked to the program, as documented by the HHS Inspector General and others who studied the impact and raised program-integrity concerns.

If anything, Defendants' policy changes in 2020 and 2021 were an effort to return to the status quo that reigned for the majority of the program's existence. And far from being "unprecedented," federal courts have now repeatedly held that Defendants' various efforts to restore that status quo were lawful, and that the claims-data information several of these policies required was merely "standard information." *Novartis*, 102 F.4th at 458, 463; *see Sanofi-Aventis*, 58 F.4th at 699.

3. The Program-Integrity Policies Were in Each Defendant's Individual Economic Self-Interest.

Plaintiffs next argue that instituting the policies independently would not have been in each Defendant's individual economic interest

and instead made sense only if implemented jointly. Br.63-67. That is wrong.

Each Defendant had every unilateral incentive to limit when contact pharmacies could access 340B discounts, given the deep-discount pricing imposed on their drugs (penny-pricing in many cases), and the increasing prevalence of diversion and duplicate discounting, which were exacerbated by contract pharmacies—all of which could cause manufacturers to *lose* money on 340B sales. As the district court put it, "Plaintiffs have not offered a plausible explanation for why Defendants would be economically incentivized to monopolize the 340B program market, when that market is defined by selling products at significantly discounted rates." JA-982. And even assuming that such behavior would be rational (it would not be), it is unclear why the conspirators would allow Novo Nordisk to enforce its policy against only hospitals and thereby "leav[e] the entire non-hospital segment" of the 340B and non-340B markets "for Novo Nordisk to claim." *Id.* The allegations belie any rational conspiracy.

Nor do Plaintiffs explain why the alleged conspirators would have agreed to policies that so unevenly accomplish any intended goal. It is

unclear, for example, why any conspirator would agree to save the least amount of money. And the same unexplained difference in outcomes also appears to the extent Plaintiffs define success as minimizing the total volume of drugs sold at a 340B discount. As the district court observed, "Plaintiffs allege that Novo Nordisk's volume of drugs sold at 340B discount prices dropped approximately 60% the month after it adopted its new policy, while the other three defendants saw volume decreases of approximately 90%." JA-979. Yet Plaintiffs never attempt to explain why Novo Nordisk agreed to such a bad deal if it, like the other Defendants, sought to minimize 340B sales.

It is also significant that other manufacturers beyond the four Defendants implemented their own program-integrity policies between 2020 and 2022. Plaintiffs allege that in 2020, Merck and Novartis implemented their own policies, and United Therapeutics announced another one. JA-822 (SAC ¶159). Boehringer Ingelheim then imposed its own policy on August 1, 2021. JA-822 (SAC ¶160). And "[o]ther manufacturers" did the same in 2022. *Id.* These allegations "further confirm[] that such policies make perfect business sense," and that

Defendants' policies were not the product of anticompetitive collusion. JA-982; *see also supra* Section I.A.

4. Plaintiffs' Remaining Arguments Fail.

Plaintiffs conclude by throwing in two final plus factors: (i) Defendants "completely dominate[]" the market for diabetes drugs and (ii) Defendants have been the subject of unrelated price-manipulation investigations. Br.69-70.

First, it is well-settled that market concentration is insufficient to infer a conspiracy. *See Citigroup*, 709 F.3d at 139; *see also Elevator Antitrust Litig.*, 2006 WL 1470994, at *10 ("[C]ourts have repeatedly stated that allegations of oligopoly are insufficient to state a claim under the antitrust laws."); *E.I. du Pont de Nemours & Co. v. FTC*, 729 F.2d 128, 139 (2d Cir. 1984) ("The mere existence of an oligopolistic market structure in which a small group of manufacturers engage in consciously parallel pricing of an identical product does not violate the antitrust laws."). In any event, this alleged plus factor is mismatched to Plaintiffs' theory. Plaintiffs argue that Defendants were supposedly able to take "[c]oncerted action" with respect to diabetes drugs. But Plaintiffs allege

a conspiracy that limited *all* 340B discounts, not just discounts for diabetes drugs.

Even with respect to diabetes drugs, Plaintiffs implausibly link together products that do not compete with one another. For instance, AstraZeneca does not manufacture insulins, only incretin mimetics, and its sales account for only 5% of that market. JA-800-802 (SAC ¶¶90, 95, 98). Plaintiffs' allegations thus paper over significant differences between Defendants' market positions.

Second, it is irrelevant that certain of the Defendants have been the subject of government investigations about topics entirely unrelated to the 340B program. Plaintiffs do not—and could not—link any of those investigations to the Sherman Act claim here. Far from it: Plaintiffs admit that these investigations (and other alleged government and private actions) are "[s]eparate and apart from" their 340B allegations. JA-863-864 (SAC ¶¶331-336). And "without an adequate allegation of facts linking" the allegations here to the alleged investigations and other actions, "plaintiffs' conclusory allegations do not nudge their claims across the line from conceivable to plausible." *Elevator Antitrust Litig.*, 502 F.3d at 52; *see id.* ("[a]llegations of anticompetitive wrongdoing in

Europe—absent any evidence of linkage between such foreign conduct and conduct here"—are insufficient).

* * *

Plaintiffs come nowhere close to alleging a plausible antitrust conspiracy. They ignore the obvious explanation for Defendants' various policies: that Defendants independently acted to limit the fallout of a government program that—due in large part to an unprecedented government policy change in 2010—presented well-documented concerns over rising levels of abuse, around the time when the government declined to take meaningful action. Instead, Plaintiffs conjure a horizontal price-fixing conspiracy purportedly designed to accomplish the nonsensical goals of (i) preserving share in the discount, penny-pricing 340B market and (to some unknown extent) the non-340B market, and (ii) avoiding expulsion from Medicaid and Medicare Part B while still facing crippling civil monetary penalties. Moreover, according to Plaintiffs, Defendants sought to avoid detection of their scheme by adopting evolving and distinct policies with distinct effects that purportedly led some manufacturers to reap immediate and substantial

cost savings while others chose policies that resulted in less than half those savings. That tale is not just implausible; it is fantastical.

II. PLAINTIFFS' SHERMAN ACT CLAIM IS AN IMPERMISSIBLE ATTEMPT TO CIRCUMVENT THE EXCLUSIVE 340B ADMINISTRATIVE SCHEME.

In the alternative, Plaintiffs' claim is also independently barred because it impermissibly seeks to circumvent the 340B remedial scheme and *Astra*. Congress established the 340B program as part of a comprehensive statutory scheme. The 340B statute establishes a pricing formula to determine the amount of specific discounts, provides rules regarding how such discounts must be made available and how discounted drugs may be dispensed, and contains a complete remedial scheme that provides for the administrative resolution of pricing disputes between covered entities and manufacturers. *See* 42 U.S.C. §256b. Because the statute uses the sale of manufacturers' drugs to fund the 340B program, Congress appropriately limited the ability of covered entities to enforce the rights granted by statute. The Supreme Court has thus held that covered entities (like Plaintiffs) may not enforce the statute through unilateral federal litigation; they must resolve their

disputes before HHS using the statute's remedial scheme. *Astra*, 563 U.S. at 119-20.

Plaintiffs seek to use the antitrust laws to do through the backdoor what Congress has prohibited. Plaintiffs' purported injury is essentially that they were denied 340B discounts to which they believe they were entitled. But pricing disputes are *exactly* what Congress committed to agency adjudication in the first instance. 42 U.S.C. §256b(d)(3); *Astra*, 563 U.S. at 119. There is no additional role for antitrust law to play, particularly when Plaintiffs are claiming entitlement to a below-market price that is entirely a creature of statute, not market forces. Thus, even if *Astra* does not preclude the application of the antitrust laws in the 340B context altogether, at minimum, it forbids the claims here, where Plaintiffs are attempting to use the antitrust laws to obtain the precise relief that 340B's exclusive remedial scheme provides.

"Antitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue," and "[p]art of that attention to economic context is an awareness of the significance of regulation." *Verizon Commc'ns Inc. v. L. Offs. of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004). Accordingly, "careful account must be taken of

the pervasive federal and state regulation characteristic of the industry." *Id.* Even "[w]here regulatory statutes are silent in respect to antitrust, courts must determine whether, and in what respects, they implicitly preclude application of the antitrust laws," which is a "determination[] [that] may vary from statute to statute, depending upon the relation between the antitrust laws and the regulatory program set forth in the particular statute, and the relation of the specific conduct at issue to both sets of laws." *Credit Suisse Sec. (USA) LLC v. Billing*, 551 U.S. 264, 271 (2007).

The Supreme Court has, for example, found that antitrust law and securities law are "incompatible" after considering "(1) the existence of regulatory authority under the securities law to supervise the activities in question; (2) evidence that the responsible regulatory entities exercise that authority; … (3) a resulting risk that the … laws, if both applicable, would produce conflicting guidance, requirements, duties, privileges, or standards of conduct," and "(4) [the fact that] the possible conflict affected practices that lie squarely within an area of financial market activity that the securities law seeks to regulate." *Id.* at 275-76.

Similarly, this Court in analogous circumstances has respected the relevant legislature's choice of remedial scheme and held that plaintiffs may not, through creative pleading, use a more general law to effectively enforce a law (like the 340B statute) that lacks a private right of action. *See, e.g.*, *Conboy v. AT&T Corp.*, 241 F.3d 242, 258 (2d Cir. 2001) (holding that because a New York statute lacked a private cause of action, the plaintiff could not circumvent that result by bringing a claim under a different provision); *Norman v. Niagara Mohawk Power Corp.*, 873 F.2d 634 (2d Cir. 1989) (plaintiff could not use civil RICO to avoid the Energy Reorganization Act's specific remedial scheme). Courts simply do not allow plaintiffs to creatively plead their way out of the Legislature's chosen remedial scheme.

Yet that is exactly what Plaintiffs seek to do here. The Supreme Court has made clear that covered entities "have no right of action under §340B itself" and may not "su[e] to enforce the statute itself." *Astra*, 563 U.S. at 117-18. "Congress vested authority to oversee compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to covered entities." *Id.* at 117. Instead, Congress "directed HRSA to create a formal dispute resolution procedure, institute refund and civil penalty

systems, and perform audits of manufacturers," and thus Congress "opted" to "make the new adjudicative framework the proper remedy for covered entities complaining of 'overcharges and other violations of the discounted pricing requirements.'" *Id.* at 121-22 (quoting 42 U.S.C. §256b(d)(1)(A)). As the Supreme Court explained, permitting covered entities to circumvent that carefully crafted remedial scheme "would undermine the agency's efforts to administer both Medicaid and §340B harmoniously and on a uniform, nationwide basis." *Id.* at 120; *see id.* ("With HHS unable to hold the control rein, the risk of conflicting adjudications would be substantial.").

HRSA has developed an "adjudicative framework," *id.* at 122, and issued an ADR rule that provides an administrative process "designed to assist covered entities and manufacturers in resolving disputes," including pricing disputes, 89 Fed. Reg. 28643; *see* 85 Fed. Reg. 80632 (2020 ADR Rule). And here, the only injury from the alleged price-fixing conspiracy is just that—Plaintiffs claim that they have been denied 340B pricing. That is no doubt why Plaintiffs themselves filed an ADR claim against AstraZeneca and Sanofi on the ground that the manufacturers'

new program-integrity policies resulted in unlawful overcharges. *See supra* p.22-23; *see also*, *e.g.*, JA-212.

Plaintiffs' antitrust claim is therefore an impermissible attempt to circumvent Congress's choice of remedial scheme and prevent the "harmonious[]," "uniform, and nationwide" enforcement of the 340B statute by HHS. *Astra*, 563 U.S. at 120. Consider the *Credit Suisse* factors. As *Astra* recognized, HHS possesses the "regulatory authority" to "supervise the activities in question," namely, manufacturers' implementation of their new policies, which some argue have led to overcharging covered entities. *Credit Suisse*, 551 U.S. at 275. HHS has also repeatedly "exercise[d] that authority." *Id.* HHS has, after all, established an ADR process and even litigated against each Defendant in federal court on the theory that the 340B statute prohibited any limitations whatsoever on the use of contract pharmacies (a position the courts have repeatedly and rightly rejected, *see Sanofi-Aventis*, 58 F.4th at 706; *Novartis*, 102 F.4th at 464).

Finally, there is a "resulting risk" of conflicting standards in an area the 340B statute "seeks to regulate." *Credit Suisse*, 551 U.S. at 275-76. Plaintiffs' lawsuit distills to a complaint—albeit an incorrect one—

about manufacturers declining to offer them the 340B discount price. *See, e.g.*, JA-867-868, 890-891 (SAC ¶¶352-354 and p.118-19) (seeking damages and injunctive relief). That is precisely the sort of complaint the ADR process contemplates. *See* 89 Fed. Reg. at 28657. And HHS has (unsuccessfully) sought to prohibit Defendants' program-integrity policies by threatening them with sanctions and pursuing litigation. Permitting Plaintiffs to now obtain both remedies would not only effectively read a private right of action into the 340B statute in direct violation of *Astra*, but it would also risk conflict with the future outcomes of agency ADR proceedings and the holdings of multiple appellate courts.

Plaintiffs protest that their "requested injunction would enjoin conspiracy, not violations of 340B." Br.76. But they do not and cannot dispute that the net effect of their requested relief would be the same as the relief the government sought and failed to obtain by challenging the legality of Defendants' policies in federal court and the relief Plaintiffs themselves have sought by challenging the legality of Defendants' policies in ADR proceedings. Moreover, what Plaintiffs seek is a *departure* from market pricing, which is the antithesis of antitrust law

and the entire point of the carefully calibrated 340B statute that they cannot themselves enforce.

Plaintiffs' effort to sow discord across the otherwise uniform and centralized 340B regulatory scheme should be rejected. Try as they might, Plaintiffs cannot overcome *Astra*'s rejection of a private cause of action and this Court's creative-pleading precedents.

III. PLAINTIFFS' DAMAGES CLAIMS ARE BARRED BY *ILLINOIS BRICK*.

Alternatively, this Court should affirm because Plaintiffs are indirect purchasers and therefore lack antitrust standing under *Illinois Brick* to seek federal antitrust damages. *See Coulter v. Morgan Stanley & Co. Inc.*, 753 F.3d 361, 366 (2d Cir. 2014) (this Court "may affirm on any basis supported by the record").

Under *Illinois Brick*, "the immediate buyers from … alleged antitrust violators may maintain a suit against the antitrust violators," but "*indirect* purchasers who are two or more steps removed from the violation in a distribution chain may not sue." *Apple Inc. v. Pepper*, 587 U.S. 273, 279 (2019). Put differently, "*Illinois Brick* established a bright-line rule that authorizes suits by direct purchasers but bars suits by indirect purchasers." *Id.*

That "bright-line rule" bars Plaintiffs' claims here. Plaintiffs are undisputedly indirect purchasers of Defendants' drugs. They nowhere allege that they are direct purchasers; instead, they concede that "drug companies rely on distributors and suppliers" to "arrange for drug purchasing with covered entities," and these distributors "serve as intermediaries." JA-787 (SAC ¶¶39, 42). Courts regularly reject antitrust suits in analogous circumstances, where a provider that purchased drugs through a wholesaler or distributor tried to sue a manufacturer. *See, e.g.*, *Lakeland Reg'l Med. Ctr., Inc. v. Astellas US, LLC*, 763 F.3d 1280, 1285 (11th Cir. 2014); *Warren Gen. Hosp. v. Amgen Inc.*, 643 F.3d 77, 87 (3d Cir. 2011); *Delaware Valley Surgical Supply, Inc. v. Johnson & Johnson*, 523 F.3d 1116, 1122-25 (9th Cir. 2008).

In the district court, Plaintiffs tacitly conceded that *Illinois Brick* barred their "overcharge" damages theory and instead argued that *Illinois Brick* at least does not bar their "lost 340B Savings" damages theory because that theory "does not implicate *Illinois Brick*'s concerns." Dist.Ct.Dkt. 75 at 7. But as the Supreme Court recently explained, there is no reason to "engage in an unwarranted and counterproductive exercise to litigate a series of exceptions" to *Illinois Brick*. *Apple*, 587

U.S. at 285. "[T]he bright-line rule of *Illinois Brick* means that there is no reason to ask whether the rationales of *Illinois Brick* apply with equal force in every individual case." *Id.*

It thus makes no difference that Plaintiffs seek the equivalent of lost profits. As the Third Circuit has recognized, "when antitrust plaintiffs claim that anticompetitive behavior caused prices to increase, two measures of damages could theoretically be used: (1) the overcharge … or (2) lost profits," which "result[] from the lost opportunity to buy and resell a greater volume of goods." *Howard Hess Dental Lab'ys Inc. v. Dentsply Int'l, Inc.*, 424 F.3d 363, 373-74 (3d Cir. 2005). But regardless, it is widely accepted that *Illinois Brick* "foreclose[s] the possibility of indirect-purchaser standing in price enhancement suits, even if the indirect-purchaser plaintiffs seek lost profits as opposed to overcharge damages." *Id.* at 375. To hold otherwise would allow creative damages pleading to eviscerate *Illinois Brick*. *See id.* at 376. That is not the law.

CONCLUSION

For these reasons, the Court should affirm the District Court's judgment.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Second Circuit Local Rule 32.1(a)(4) and Federal Rule of Appellate Procedure 32(a)(7) because this brief contains 13,775 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

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CERTIFICATE OF SERVICE

I hereby certify that on September 9, 2024, a true and correct copy of the foregoing was filed electronically using the CM/ECF system, which will send notification of such filing to all counsel of record.

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