UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF NEW YORK

MOSAIC HEALTH, INC. and CENTRAL VIRGINIA HEALTH SERVICES, INC., individually and on behalf of all those similarly situated, Plaintiffs, v. SANOFI-AVENTIS U.S., LLC, ELI LILLY AND COMPANY, LILLY USA, LLC, NOVO NORDISK INC., and ASTRAZENECA PHARMACEUTICALS LP, Defendants.	No.: 6:21-cv-06507-EAW

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO AMEND THEIR COMPLAINT

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Plaintiffs' First Amended Complaint ("FAC") failed to allege a conspiracy because Defendants' disparate 340B policies were fundamentally "different in their particulars, their timing, and their outcomes." Dkt. 71 ("Order") at 13. The proposed Second Amended Complaint ("SAC") does not remedy these dispositive defects. In fact, the SAC alleges ***more differences*** between Defendants' 340B policies, and that they were implemented and modified on an ***even longer*** timeline than originally pled. It describes a set of unique policies that apply to different drugs, affect different sets of covered entities, and permit different exceptions—a far cry from the "same or a substantially similar end result" that could plausibly allege parallel conduct. *Id.* at 15.

Plaintiffs contend that they have adequately pled parallel conduct by alleging a "common result," citing data that purportedly shows a downward trend in each Defendant's sales of 340B-priced drugs. Dkt. 72-3 (Motion to Amend ("MTA")) at 13–14. But that generalized data—which relates to all 340B drug sales, not just 340B sales for diabetes treatments—is not enough to meet Plaintiffs' burden, particularly because the SAC establishes obvious alternative explanations that predict the ***exact same result***. And the SAC still fails to allege any plus factors, which are required to plausibly allege a conspiracy.

The SAC also fails for the additional reasons outlined in Defendants' previous Motion to Dismiss. Dkt. 47-1 ("MTD Mem."). First, Plaintiffs still allege an indirect-purchaser relationship under *Illinois Brick*. Second, this lawsuit remains an impermissible attempt to bypass the 340B regulatory processes and ongoing litigation (where courts have recognized that Defendants' policies are not contrary to the 340B statute). Third, while Plaintiffs' state-law allegations now include more words, they remain impermissible boilerplate recitations of the elements.

Because the SAC remains legally inadequate, the Court should deny Plaintiffs' motion to amend as "futile." *Lucente v. Int'l Bus. Machines Corp.*, 310 F.3d 243, 258 (2d Cir. 2002).

BACKGROUND

A. The 340B Program

Defendants each manufacture a broad array of drugs, including various diabetes treatments, and participate in the federal government's "340B Program." Dkt. 72-1 ("SAC") ¶¶ 2, 23.[1] Under this Program, Defendants must offer their drugs at "steep[ly] discount[ed]" prices to 15 types of "Covered Entities." *Id.* ¶ 118; 42 U.S.C. § 256b(a)(4). The "ceiling price" dictated by the 340B Program is set by a statutory formula and is far below what other purchasers pay. 42 U.S.C. § 256b(a)(1). Indeed, under the 340B Program "many of [Defendants'] products" are, by statute, offered "at a price of one penny per unit of measure." 85 Fed. Reg. 45,755 (July 24, 2020) ("Executive Order") (quoted at SAC ¶¶ 117–19).

Plaintiffs are two covered entities. SAC ¶¶ 11–12. They purchase and then sell 340B drugs to insured and uninsured patients, and "can net revenue from the spread between the drug's price—lowered by the 340B Drug Discount—and any reimbursement." *Id.* ¶ 25. Covered entities do not always dispense the 340B drugs themselves. *Id.* ¶ 3. Instead, "Contract Pharmacies" sometimes dispense covered outpatient drugs to covered entities' patients. *Id.* Contract pharmacies do "not always pass[]" all of the 340B discount on to patients. *Id.* ¶¶ 58, 118 (emphasis omitted). In 2010, for the first time, the government issued non-binding guidance indicating that it would permit covered entities to contract with an unlimited number of commercial pharmacies (like CVS or Walgreens). 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010) (quoted at SAC ¶ 53). In response, the number of contract pharmacies increased exponentially, from 1,300 in 2010 to more than 20,000 in 2017—an increase of more than 1,438%. Gov't Br. at 13, *Novo Nordisk v. HHS*, 21-3168, Dkt.

[1] Because the Court is already familiar with much of the relevant background, Defendants provide only a brief summary of key facts and incorporate their earlier pleadings for additional context and detail. *See* MTD Mem. at 3–15. For purposes of this Motion, Defendants draw on the allegations in the SAC and documents quoted therein. *See Matusovsky v. Merrill Lynch*, 186 F. Supp. 2d 397, 400 (S.D.N.Y. 2002) (relying on document "explicitly referenced" in the complaint).

56 (3d Cir. July 7, 2022) (quoted at SAC ¶ 218) (citing GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 2 (2018)); *see also* MTD Mem. at 7. This guidance, however, did not create any delivery or distribution obligation on the part of the manufacturers.

B. Defendants' 340B Policies

In May 2020, in light of "global concerns with Contract Pharmacies" (*e.g.*, duplicate discounts and diversions), Lilly announced it would no longer permit the transfer of its erectile dysfunction drug, Cialis, at the 340B price to an unlimited number of contract pharmacies. SAC ¶ 139. Defendants also allegedly participated in joint lobbying efforts regarding the 340B Program. *Id.* ¶ 115. On July 24, 2020, the President issued an Executive Order addressing certain sales of diabetes treatments under the 340B Program; however, the order "was extremely limited in scope." *Id.* ¶ 119; Executive Order at 45,755.

As in the FAC, the SAC alleges that each Defendant—and a slew of "[o]ther manufacturers"—reformed their 340B policies after the Executive Order failed to adequately address contract pharmacy abuses. SAC ¶¶ 158–60. Like the FAC, the SAC does not allege any specific lobbying or trade association meetings where an "agreement" was reached to make policy changes; rather, Plaintiffs make a vague "information and belief" allegation that Defendants "planned their restrictions" "during [their] joint lobbying effort." *Id.* ¶ 329.

The SAC in fact makes clear that Defendants independently adopted divergent 340B policy reforms in reaction to the "failure" of the Executive Order to address their 340B Program concerns, and not pursuant to any agreement. *Id.* ¶ 6. On July 24, 2020, the same day as the Executive Order was issued, AstraZeneca told the government that it would allow its drugs to be transferred to a maximum of "one Contract Pharmacy" for covered entities without an on-site pharmacy, and the next business day, Sanofi announced that it was "implementing a new 340B program integrity

initiative" that permitted 340B drugs to be shipped to contract pharmacies without limitation but only if covered entities provided "prescription claims data." *Id.* ¶¶ 135–36. In August 2020, Lilly informed the government that it would expand its Cialis policy and limit contract-pharmacy transfers of "all Lilly products" at 340B prices to instances where (1) "a covered entity does not have an in-house pharmacy," or (2) the contract pharmacy agreed "to pass along certain insulin products at cost" without a dispensing fee. *Id.* ¶¶ 137–38. And in December 2020—***seven months*** after Lilly's Cialis announcement—Novo announced that it would stop permitting shipments of 340B-priced drugs to an unlimited number of contract pharmacies, but ***only*** for "hospital covered entities." *Id.* ¶ 140. Unlike the FAC, the SAC goes on to describe ***additional*** policy reforms that each Defendant made ***over the next year***, including Sanofi's February 2021 decision to apply its 340B policies to just five types of covered entities, and Novo's January 2022 modification to permit two contract pharmacies (instead of one) for hospital covered entities. *Id.* ¶¶ 141–42.

The SAC does not deny that these policies target different groups of covered entities (*e.g.*, Novo's policy applies just to hospitals, while Lilly's applies to all covered entities). Nor does the SAC deny that Defendants' policies apply to their broader suite of (non-overlapping) products across a variety of therapeutic areas, not just the diabetes treatments where Defendants supposedly compete.[2] Instead of addressing these fundamental differences in scope and result, the SAC instead elaborates on its prior claim that certain exceptions to Defendants' policies are "narrow" and "infeasible." *Id.* ¶¶ 188, 208. Plaintiffs also point to data purporting to show that Defendants' 340B sales (not limited to diabetes treatments) trended down following their policy reforms. *Id.*

[2] The SAC avoids discussing the full scope of Defendants' policies, but the allegations and sources quoted make clear these policies went far beyond diabetes treatments. *See, e.g.*, SAC ¶¶ 137–39 (alleging that Lilly changed its policy to apply to "***all Lilly products***" (emphasis added)); Dkt. 47-5, 7/24/20 AstraZeneca Ltr. at 5–9 (quoted at SAC ¶ 135) (listing 27 different drugs that AstraZeneca's policy applied to); Gov't Br. at 16, *Novo Nordisk v. HHS*, 21-3168, Dkt. 49 (3d Cir. July 7, 2022) (quoted at SAC ¶ 218) (noting that Sanofi's data policy included non-diabetes-related drugs).

¶¶ 180–81, 197–98, 216–17, 228–29. As discussed below, this data is neither meaningful nor surprising nor suggestive of unlawful activity—and it cannot save Plaintiffs' complaint.

LEGAL STANDARD

As Plaintiffs acknowledge, "the standard on a motion for leave to amend is the same as that on a Rule 12(b)(6) motion to dismiss." MTA at 13 (quoting *Rochester Drug Coop., Inc. v. Hiscox Ins. Co.*, 545 F. Supp. 3d 21, 24 (W.D.N.Y. 2021)). "An amendment to a pleading is futile" and leave to amend should be denied if the amended complaint "could not withstand a motion to dismiss pursuant to [Rule] 12(b)(6)." *Lucente*, 310 F.3d at 258. To survive a Rule 12(b)(6) motion under *Twombly*, "a complaint must contain 'enough factual matter (taken as true) to suggest that an agreement was made.'" *In re Elevator Antitrust Litig.*, 502 F.3d 47, 50 (2d Cir. 2007) (alteration omitted) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007)).

ARGUMENT

I. AMENDMENT IS FUTILE BECAUSE PLAINTIFFS STILL FAIL TO ALLEGE A CONSPIRACY.

A. Plaintiffs have not remedied the defects the Court identified in their parallel conduct allegations.

The FAC failed to allege parallel conduct because Defendants' 340B policies were strikingly "different in their particulars, their timing, and their outcomes." Order at 13. The SAC does nothing to remedy these defects. ***First***, Plaintiffs have made no meaningful effort to contest the distinctions between Defendants' policies; if anything, their new allegations only highlight more unique attributes. *E.g.*, SAC ¶¶ 141–42. ***Second***, Plaintiffs have not shortened or explained away the timeline. In fact, Plaintiffs' new allegations ***add*** another year during which different Defendants made unique modifications to their individual policies. *Id*. ***Third***, Plaintiffs' new allegations—which purport to show that each Defendant experienced a general downward trend in 340B sales—fall far short of the types of "common result" allegations that could plausibly

suggest parallel conduct. ***Fourth***, any alleged downward trend in 340B sales cannot constitute parallel conduct because there are obvious alternative explanations that predict this ***same result***.

1. *The SAC alleges an even wider range of particulars.*

Like the FAC, the SAC alleges that Defendants implemented a "divergent" set of methods for curtailing 340B abuse that make it "dubious [] whether the conduct … can accurately be characterized as 'parallel.'" *LaFlamme v. Societe Air France*, 702 F. Supp. 2d 136, 151 (E.D.N.Y. 2010) (citation omitted). Sanofi relied on a claims-data program, while Lilly applied its policies to all covered entities for all of its drugs, subject to certain exceptions. SAC ¶¶ 136, 138. Meanwhile, AstraZeneca limited its policy to certain products, and Novo applied its policy only to hospital entities. *Id.* ¶¶ 134, 140. The SAC does not seriously dispute that these different policies were "at least somewhat distinct from one another." *Pro Music Rights, LLC v. Apple, Inc.*, 2020 WL 7406062, at *4 (D. Conn. Dec. 16, 2020). If anything, the new allegations differentiate Defendants' policies in even richer detail. *E.g.*, SAC ¶ 208 (describing Lilly's unique exception permitting unlimited contract pharmacies for insulin products if "neither the covered entity nor the contract pharmacy mark up" the drugs, and other conditions are met).[3]

Moreover, the SAC introduces ***additional differences*** between Defendants' policies, such as Sanofi's shift to applying its 340B claims-data requirements to just "five covered entity types." SAC ¶¶ 136, 141. Not only does the scope of this alleged policy differ from all other Defendants', but the change ***expanded*** the availability of Sanofi's 340B discounts. As this Court noted, when "alleged conspirators engaged in different conduct at different times," that conduct "fall[s] far

[3] Plaintiffs imply that Defendants incorrectly described Lilly's "at-cost" exception when they stated that "Lilly allows unlimited contract pharmacies if certain requirements are met." MTA at 6 (quoting Dkt. 66 ("MTD Reply") at 10). Plaintiffs are wrong. As the SAC alleges, Lilly's 340B policies do not apply to its insulins if a covered entity and contract pharmacy meet four conditions. SAC ¶ 208. This is completely consistent with Defendants' description—Lilly (and only Lilly) permits the shipment of the 340B-priced insulins to unlimited contract pharmacies if those four conditions are met. *Id.*; *see also* MTD Mem. at 13.

short of demonstrating parallel behavior." Order at 11 (quoting *Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 228 (3d Cir. 2011)).

2. *The SAC extends the already implausible timing of the alleged conspiracy.*

The SAC alleges the same expansive timeframe between Defendants' policy changes as the FAC. The seven-month gap between when Lilly first changed its Cialis policy and when Novo adopted its hospital-only policy continues to fall "short of [the type of] unusual, lockstep … behavior" that could plausibly suggest agreement. *In re Graphics Processing Units Antitrust Litig.* ("*In re GPU*"), 527 F. Supp. 2d 1011, 1022 (N.D. Cal. 2007). In fact, the SAC's new allegations ***expand*** the timeline of the supposed conspiracy. Plaintiffs now allege that a series of additional policy changes stretching another ***year*** (through January 2022) were part of Defendants' "common approach." SAC ¶¶ 141–42. The notion that Defendants engaged in a conspiracy by announcing, implementing, and modifying distinct policies at different times over the course of ***19 months*** fails on its face. *Park Irmat Drug Corp. v. Express Scripts Holding Co.*, 911 F.3d 505, 517 (8th Cir. 2018) (six-month interval "did not constitute parallel conduct"); *In re GPU*, 527 F. Supp. 2d at 1022 (three-month interval did not "implicate price-fixing").

3. *The SAC fails to allege a common outcome amounting to parallel conduct.*

Because they cannot escape the striking differences in particulars and timing, Plaintiffs instead try to allege that Defendants' policies achieved a "common result" of decreased 340B sales, MTA at 13–14, but that argument also fails. The SAC's allegations establish that the results of Defendants' policies were not the same—they varied in the drugs included, the entities impacted, and the permitted practices. *See* SAC ¶¶ 135–40.

- **Different Drugs**: Defendants' policies were ***not limited to diabetes care***, and instead applied to ***different sets of drugs*** depending on each company's portfolio and policy. *See supra* at 4 n.2. Plaintiffs do not address this inconvenient fact or explain how it is consistent with their notion of a "diabetes medication markets" conspiracy. SAC ¶ 133; *see also id.* ¶ 4. Nor do Plaintiffs provide any plausible reason that Defendants would enter an illegal conspiracy

regarding the pricing of diabetes drugs given the vastly different significance of such drugs to each company's sales. For instance, AstraZeneca's diabetes-related treatments allegedly make up only a small fraction of its suite of pharmaceuticals and revenue, while Plaintiffs allege that diabetes treatments make up 77% of Novo's 2020 U.S. revenue. *See* SAC ¶ 88–98 (AstraZeneca's sales of incretin mimetics account for only 5% of incretin mimetics sales); *id.* ¶ 105 (alleging Novo's revenue); AstraZeneca Annual Report (2020) at 187 (cited at SAC ¶ 108), available at https://bit.ly/3Stp6FO (listing AstraZeneca's U.S. revenue by drug, with diabetes treatments Bydureon and Byetta making up less than 5%).

- **Different Covered Entities**: The SAC alleges that Defendants' policies apply to distinct sets of covered entities. For example, Plaintiffs allege Novo imposed no restrictions on non-hospitals, which make up more than 10% of the market, while Sanofi narrowed its 340B data policy to apply to just "five covered entity types" in February 2021. SAC ¶¶ 141, 224.

- **Different Permitted Practices**: The SAC alleges that Defendants' policies differ on what kind of contract pharmacy relationships would be permitted. For example, according to Plaintiffs' allegations, Sanofi's supposedly "infeasible" data policy allegedly permitted ***no*** contract pharmacy sales for "the vast majority of covered entities." *Id.* ¶¶ 185, 188. By contrast, Plaintiffs allege that Novo permitted any hospital to retain "***two*** contract pharmacy locations," while Lilly's policy permitted "a ***single*** pharmacy to be designated." *Id.* ¶¶ 142, 205.

As the government explained in the very briefs Plaintiffs rely on: "These policies ***impose different substantive limitations and requirements on covered entities***" to access 340B discounts. Gov't Br. at 71, *Eli Lilly v. HHS*, 21-3405, Dkt. 37 (7th Cir. June 2022) (quoted at SAC ¶ 199) (emphasis added) (contrasting Lilly's policy with Novo's, Sanofi's, and Novartis's (another drug manufacturer not part of the alleged "conspiracy" here)).

These differences make clear that Plaintiffs do not and cannot allege any "common result." Take the named Plaintiffs as an example: Plaintiffs make no effort to allege that Novo's policy—which does not apply to them (because they are not hospitals)—has the same result as AstraZeneca's or Lilly's or Sanofi's policies. A similar inquiry would be required to analyze the resulting impact of ***each*** Defendant's distinct policies, applications, and exceptions, as applied to each and every other covered entity. Such a nuanced, individualized inquiry cannot show that Defendants' policies are so "substantially similar" that they qualify as parallel conduct. *North Am. Soccer League v. United States Soccer Fed.*, 296 F. Supp. 3d 442, 460 n.26 (E.D.N.Y. 2017).

Plaintiffs argue that they have alleged a common result by pointing to supposedly "detailed data" showing that each Defendant's 340B sales trended lower. MTA at 9 (quoting SAC ¶ 8). But the "data" Plaintiffs cite covers ***all*** types of 340B drugs, not just diabetes treatments, which is inconsistent with the diabetes-care "markets" on which they have based their lawsuit.[4] *See* SAC ¶¶ 2, 4, 133. If anything, this multi-drug data undermines Plaintiffs' premise that Defendants were only willing to act in the diabetes-treatment markets where they supposedly moved together. Moreover, the specific decrease that Plaintiffs have alleged for each Defendant varies widely, which further undercuts its probative value. For example, taking Plaintiffs' data as true, Novo's policy left almost 40% of its 340B drug sales in place, while AstraZeneca retained less than 10% of its previous volume. *Id.* ¶¶ 218, 230.

The law does not support such a low bar for parallel conduct. It is well-established that some similarities in outcome do not "constitute parallel conduct" when the circumstances as a whole fall "short of unusual, lockstep behavior." *Park Irmat*, 911 F.3d at 516–17 (allegations of parallel conduct insufficient even though the plaintiff pharmacy had alleged the common outcome of both defendants terminating it from their benefits networks because their conduct was "executed under dissimilar circumstances and separated by six months"). Here, the "dissimilar circumstances" of the particulars, timing, and scope of each Defendant's policy far outweigh any probative value of allegations that sales of Defendants' entire 340B portfolios trended in the same direction.[5] *Id*. Thus, Plaintiffs' so-called "common outcome" allegations do not allege parallel

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[4] *See* Gov't Mem. at 9–10, *Sanofi-Aventis v. HHS*, 3:21-cv-634, Dkt. 89 (D.N.J. June 16, 2021) (quoted at SAC ¶ 182) (explaining numbers cited in the SAC and stating that they measure "units sold by Sanofi," not just diabetes treatments); Gov't Brief at 5, *AstraZeneca v. HHS*, 22-1676, Dkt. 20 (3d Cir. June 21, 2022) (quoted at SAC ¶ 230) (similarly specifying that numbers described "units of 340B medications," with no mention of incretin memetic).

[5] Plaintiffs also allege that Defendants' executives described 340B changes to investors, but like the "data," these one-off statements do not show substantial similarity in light of the many other differences discussed above. *See, e.g.*, SAC ¶ 225 (quoting Novo executive as saying shipments to contract pharmacies "stopped," even though data showed Novo retained nearly 40% of 340B sales). And, contrary to Plaintiffs' view, some Defendants specifically

conduct. *See North Am. Soccer League*, 296 F. Supp. 3d at 460 n.26.

The cases this Court cited as examples of "common outcomes" remain instructive (and are easily distinguished). In *SD3*, the defendants were accused of having the black-and-white objective of boycotting the plaintiff, so the "uniform actions alleged [were] obvious" because "none of the defendants ultimately" agreed to any kind of deal with the plaintiff. *SD3, LLC v. Black & Decker (U.S.) Inc.*, 801 F.3d 412, 427 (4th Cir. 2015); *see also In re Int. Rate Swaps Antitrust Litig.*, 261 F. Supp. 3d 430, 472–74 (S.D.N.Y. 2017) (allegations of parallel conduct sufficient where defendants "refused to do business with the" plaintiff and had more than a dozen other similarities in tactics). There is nothing similar here. Plaintiffs have not alleged a boycott, as discussed below, *see infra* at 18, and Defendants' policies differed in scope and magnitude (and therefore were not obviously "uniform"). *SD3*, 801 F.3d at 427. The remaining cases this Court cited found sufficient allegations of parallel conduct based on particulars and timing not present here. *In re Broiler Chicken Antitrust Litig.*, 290 F. Supp. 3d 772, 792 (N.D. Ill. 2017) (noting allegations "that all of the defendants engaged in production cuts at the same time"); *In re Domestic Airline Travel Antitrust Litig.*, 221 F. Supp. 3d 46, 68–69 (D.D.C. 2016) (parallel conduct sufficiently pled where executives "made statements close in time" and there were "a host of other factual allegations that tend to exclude the possibility of independent action").

4. *Any purported "common result" is easily explained by the obvious alternative explanations pled in the SAC.*

Plaintiffs have also failed to allege parallel conduct because the SAC's factual allegations are consistent with at least two "obvious alternative explanation[s]" that better account for any

disclaimed Plaintiffs' argument. *See* Ex. 2 to June 1, 2021 Sanofi Ltr. to HRSA at 3, attached hereto as D'Antonio Decl., Exhibit A (quoted at SAC ¶¶ 146, 195) ("Thus, although AHA mischaracterizes our initiative as intended to limit distribution of 340B-priced drugs, instead our program solely seeks the information needed to protect our company from duplicate discounts.").

alleged decrease in 340B sales: (1) the unprofitable nature of the 340B Program, and (2) the changing regulatory landscape. *Twombly*, 550 U.S. at 567. Thus, the data Plaintiffs cite purporting to show that some 340B sales trended lower is not "probative evidence bearing on the issue of whether there is an antitrust conspiracy." *Apex Oil Co. v. DiMauro*, 822 F.2d 246, 253 (2d Cir. 1987).

First, the 340B Program required Defendants to sell their drugs at "steep" discounts. SAC ¶ 118. Plaintiffs have now deleted their admission that "many of [Defendants'] products may be purchased under the 340B Program at a price of one penny per unit of measure." *Compare* FAC ¶ 102 *with* SAC ¶ 118. But the Executive Order, which Plaintiffs quote throughout the SAC (*e.g.*, ¶¶ 117–19), discusses the prevalence of penny pricing. The Executive Order is judicially noticeable because it is "explicitly referenced" in the SAC. *Matusovsky*, 186 F. Supp. 2d at 400.

Plaintiffs acknowledge the money-losing nature of the 340B Program by alleging that Defendants, in reports to their investors, attributed their "higher net profit[s]" to the drop in 340B sales. *E.g.*, SAC ¶ 225 (citation omitted). And they recognize that if a program requires a company to "***lose*** money," it is not "reasonable or workable" for the company to do anything more than is required by law. *Id.* ¶¶ 209, 212 (citations omitted).[6] It is thus unsurprising that each Defendant—along with several "[o]ther manufacturers" not alleged to be conspirators—changed their respective 340B policies (and Lilly did so first for Cialis, a drug with no relation to diabetes). *See id.* ¶¶ 159–60. In light of the deep discounts required by 340B, each Defendant's policies were a "rational and competitive business strategy." *In re Int. Rate Swaps*, 261 F. Supp. 3d at 464 (citation omitted); *In re Google Digital Advert. Antitrust Litig.*, 2022 WL 4226932, at *13 (S.D.N.Y. Sept.

[6] Plaintiffs' admission comes in the context of their argument that Lilly's no-fee exception was "impossible" to satisfy because it required contract pharmacies to "dispense insulin for free." *See* SAC ¶ 210. This allegation is both implausible and ironic because the 340B Program imposes a similar requirement on drug manufacturers, who participate to this day.

13, 2022) (citation omitted) (no inference of conspiracy where defendants' actions made "perfect business sense").

Plaintiffs assert that 340B sales influence "prescribing and administration patterns" outside the 340B context. SAC ¶¶ 70–71. But the SAC does not allege a single fact supporting the conjecture that a doctor prescribing insulin or incretin mimetics to a non-340B patient would consider each Defendant's 340B policies instead of the health or interests of that particular patient. Plaintiffs cannot "point to some [alleged] facts that make" this theory "more than pure speculation," and therefore they cannot erase the obvious alternative explanation that each Defendant had an independent financial incentive to act. *Warren v. ResMed Corp.*, 2022 WL 2334055, at *4 (S.D.N.Y. June 28, 2022) (declining to credit plaintiff's allegation that doctor "received and relied on the documents" because this assertion was not "accompanied by a statement of the facts upon which the belief is based" (cleaned up)).

Second, the changing regulatory landscape offers an equally "obvious alternative explanation" for the timing and form of Defendants' 340B policy changes. The SAC alleges that Defendants undertook a "long-running lobbying campaign," the "failure" of which "became evident with the issuance of [the] Executive Order" on July 24, 2020. SAC ¶¶ 6, 115, 117. ***That same day***, AstraZeneca informed the government of its new policy when it learned that the Executive Order "did little." *Id.* ¶¶ 115, 134. That Order undermines Plaintiffs' conspiracy theory because it is an "obvious … reason aside from collusion that plausibly could have instigated independent decisions by" Defendants. *LaFlamme*, 70 F. Supp. 2d at 152 (cleaned up). Plaintiffs try to downplay the Executive Order's importance by wordsmithing their allegations. *Compare* FAC ¶ 116 (Defendants "turned to their plan B" because of the Executive Order) *with* SAC ¶ 132 (the Executive Order "provided Defendants with the opportunity to jointly develop a collective

fallback plan"). But they cannot escape the timeline and reality they have alleged: Defendants lobbied the government (a protected activity) to address 340B abuse; Lilly independently implemented its Cialis change; Defendants' lobbying efforts failed; and after the President issued his Executive Order, Defendants independently instituted various policies because the Order did so little to address 340B abuses. SAC ¶¶ 115, 134, 136, 137, 139, 140, 143.

Given these obvious alternative explanations, Plaintiffs' common-result allegations do not support a plausible inference of any agreement or conspiracy. Courts frequently reject attempts to establish conspiracies based on "shards of parallel conduct [that] do not give rise to an inference of agreement" because of an "obvious alternative explanation for defendants' common behavior." *In re Int. Rate Swaps*, 261 F. Supp. 3d at 464 (citation omitted) (no parallel conduct where each defendant had independent incentive "to maintain the status quo"); *LaFlamme*, 702 F. Supp. 2d at 152 (no parallel conduct where "rapidly rising jet fuel prices" explained common surcharges); *see also Twombly*, 550 U.S. at 568 (no alleged conspiracy when "complaint itself gave reasons to believe" defendants' actions were in "their best interest"). Plaintiffs' allegations that each Defendant's gross 340B sales trended lower is not "probative evidence" of "an antitrust conspiracy" because the SAC alleges "equally plausible" alternative explanations for this same result. *Apex Oil Co.*, 822 F.2d at 253–54.

B. The SAC does not remedy the complete lack of alleged plus factors.

Independently, amendment would also be futile because Plaintiffs have failed to allege "plus factors" required to support an inference of conspiracy. *Mayor and City Council of Baltimore, Md. v. Citigroup, Inc.,* 709 F.3d 129, 136 (2d Cir. 2013).

1. *The SAC fails to allege a common motive or actions against self-interest.*

Plaintiffs' theory of a common motive makes little commercial sense. Defendants had no incentive to monopolize the 340B market when drugs are sold at pennies per unit, and Plaintiffs

have no allegations that substantiate their theory that 340B sales somehow drove sales in more profitable markets. *See supra* at 12; MTD Mem. at 31–33. If Defendants were motivated by "market share," it is implausible that they would leave significant gaps between the covered entities that each policy covered, such as leaving the entire non-hospital segment for Novo to claim. *See* SAC ¶¶ 280–89. And Plaintiffs confirm that each Defendant had a unilateral interest when they allege that ***other drug manufacturers***—not part of the alleged conspiracy—adopted their own 340B reforms. *Id.* ¶¶ 159–60. Moreover, Lilly's initial policy change with respect to Cialis underscores that drug makers had an incentive to make unilateral policy changes. SAC ¶ 318; *see In re Amazon.com, Inc. eBook Antitrust Litig.*, 2022 WL 4581903, at *19 (S.D.N.Y. Aug. 3, 2022) (granting motion to dismiss because the complaint "provide[d] ample legitimate business reasons for the [defendants] to have decided to go it alone").

The SAC includes the newly pled, but previously argued, allegation that Defendants had a motive to act together because, if they acted alone, they "faced the potential loss of federal healthcare program coverage." SAC ¶ 290; *see also* Dkt. 58 (Opp. to Mot. to Dismiss ("MTD Opp.")) at 29–30 (raising this unpled argument). But this is pure speculation, contradicted by Plaintiffs' own cited sources. First, the pleadings Plaintiffs rely on for their motive theory demonstrate that Defendants sought safety not in numbers, but by filing ***their own*** lawsuits against the government asking federal courts to declare that their policies were permissible under the 340B statute. *See* SAC ¶¶ 293–96 (citing filings from these lawsuits). Second, the statements by Defendants that Plaintiffs quote contradict their safety-in-numbers theory because they suggest, at most, that each Defendant ***remained*** concerned about "the potential revocation of their ability to participate in Medicare and Medicaid" ***after*** each had already made its policy changes. *See, e.g.*, Compl. ¶ 8, *AstraZeneca Pharm. v. Azar*, 21-cv-27, Dkt. 1 (D. Del. Jan. 12, 2021) (quoted at SAC

¶ 296). By then, under Plaintiffs' theory, Defendants' so-called "safety in numbers" should have eliminated their concerns of losing federal coverage. Thus, all Plaintiffs have possibly alleged is that Defendants continued to be concerned about the potential loss of their ability to participate in federal programs after their policy changes, which cannot support Plaintiffs' speculation that Defendants had any motive to conspire to eliminate that concern.

2. *The SAC adds no allegations of interfirm communications.*

Plaintiffs' proposed amendment does nothing to add interfirm communications to their allegations. *See, e.g.*, SAC ¶¶ 328–30. The SAC still lacks the "when," "who," and "what" to turn Defendants' protected lobbying activity into any plausible indication of conspiratorial conduct. *PharmacyChecker.com, LLC v. Nat'l Ass'n of Boards of Pharmacy*, 530 F. Supp. 3d 301, 336–37 (S.D.N.Y. 2021) (general allegations of "shar[ing] a lobbyist" are "not a sufficient 'plus factor' to plausibly allege a conspiracy"). At most, Plaintiffs have alleged a "mere opportunity to conspire," which does not "support the inference that [] an illegal combination actually occurred." *Gamm v. Sanderson Farms, Inc.*, 944 F.3d 455, 466 (2d Cir. 2019) (citation omitted); *see also* MTD Reply at 23–25. Likewise, Plaintiffs' allegations that Defendants each participated in the trade group PhRMA and, as part of that group, "communicated among themselves" does not establish any inference of an agreement regarding the 340B Program. SAC ¶ 330; *see Yellow Page Solutions, Inc. v. Bell Atlantic Yellow Pages Co.*, 2001 WL 1468168, at *13 (S.D.N.Y. Nov. 19, 2001) ("[A] conspiracy will not be inferred from participation in a trade association"). Although Plaintiffs assert "[u]pon information and belief" that Defendants formed an agreement "during" their lobbying efforts, SAC ¶ 329, they cannot "merely plop 'upon information and belief' in front of a conclusory allegation and thereby render it non-conclusory." *Citizens United v. Schneiderman*, 882 F.3d 374, 384 (2d Cir. 2018).

3. *Nothing else in the SAC qualifies as a plus factor.*

As Defendants' previous briefing explained, Plaintiffs do not allege any other plus factors that provide a plausible inference of conspiracy, MTD Reply at 26–27, and nothing in the SAC changes that conclusion. Plaintiffs previously invoked Defendants' "market share" as a plus factor, and now add allegations that Defendants are "interested in protecting [their] market share." SAC ¶ 109. But market share alone is not a meaningful plus factor that can support an inference of conspiracy. *See In re Elevator Antitrust Litig.*, 2006 WL 1470994, at *10 (S.D.N.Y. May 30, 2006) ("allegations of oligopoly are insufficient to state a claim under the antitrust laws"). The SAC also purports to describe government investigations in Mississippi and Albany County but alleges no "linkage" between these investigations and the conduct at issue in this litigation or the 340B Program. SAC ¶¶ 334–35; *In re Elevator Antitrust Litig.*, 502 F.3d at 52; *see also* MTD Mem. at 35 n.15.

* * * * *

For all of these reasons, amendment would be futile. Plaintiffs' SAC still does not (and cannot) allege a conspiracy, and their third bite at the apple should be denied with prejudice.

II. AMENDMENT IS FUTILE AS TO PLAINTIFFS' FEDERAL ANTITRUST DAMAGES.

Illinois Brick's bright-line rule bars Plaintiffs' federal damages claims because Plaintiffs are indirect purchasers of Defendants' drugs. *See* MTD Mem. at 15–20; MTD Reply at 2–7; *see also Lakeland Reg'l Med. Ctr., Inc. v. Astellas US, LLC*, 763 F.3d 1280, 1285 (11th Cir. 2014) (barring provider from suing manufacturer on antitrust claims since provider purchased drugs through middleman); *Warren Gen. Hosp. v. Amgen Inc.* ("*Warren I*"), 2010 WL 2326254, at *7 (D.N.J. June 7, 2010), *aff'd*, 643 F.3d 77 ("*Warren II*") (3d Cir. 2011) (same); *In re Insulin Pricing Litig.*, 2019 WL 643709, at *13 (D.N.J. Feb. 15, 2019) (barring insulin purchasers from suing

insulin manufacturers). Plaintiffs have never disputed their indirect status. *See* MTD Opp. at 40–47 (no argument Plaintiffs are direct purchasers). Nor does the SAC solve this incurable problem. Like the prior two versions, the SAC:

- Does not allege that Plaintiffs are direct purchasers;
- Does not allege that drug manufacturers sell directly to them or that they buy directly from or pay drug manufacturers; and
- Continues to allege that drug "distributor[s] serve[] as intermediaries." SAC ¶ 42; *see also id*. ¶ 39.

These concessions compel dismissal of Plaintiffs' federal damages claims. MTD Reply at 2; *Warren II*, 643 F.3d at 88, 90 (hospital lacked standing to sue manufacturer since hospital purchased from "intermediary"). Plaintiffs' new allegations cannot overcome *Illinois Brick*.

First, Plaintiffs now seek to add allegations that Defendants have argued that covered entities have not been "overcharged." SAC ¶¶ 146, 148. Plaintiffs presumably add these allegations to try to circumvent *Illinois Brick*'s bar on overcharge damages, contending that they seek only to recover "lost profits." *See* MTD Opp. at 40–45. But attempts to refashion damages as lost revenue rather than overcharges to avoid *Illinois Brick* do not work. MTD Mem. at 19 & n.9; MTD Reply at 2–4; *Kansas v. UtiliCorp United, Inc.*, 497 U.S. 199, 216 (1990) (*Illinois Brick* is a bright-line rule; courts should not "carve out exceptions"). *Illinois Brick* precludes ***all*** indirect purchaser damages claims under the federal antitrust laws, not just overcharges. *See Howard Hess Dental Lab'ys Inc. v. Dentsply Int'l, Inc.*, 424 F.3d 363, 376 (3d Cir. 2005) (affirming dismissal and noting that indirect purchasers could eviscerate *Illinois Brick* "if only they [] frame[] their claim as one for lost profits rather than for overcharge damages"); *Drug Mart Pharm. Corp. v. Am. Home Prods. Corp.*, 2002 WL 31528625, at *10 (E.D.N.Y. Aug. 21, 2002) (precluding indirect purchaser from seeking "lost profits").

Nor can Defendants' no-overcharge statements help Plaintiffs. Defendants' filings in the

pending government cases—which are quoted in the SAC (*e.g.*, ¶ 148)—provide Defendants' views on the application of the ***regulatory*** term of art for "overcharge" and not the ***antitrust*** term. MTD Reply at 6 n.3 (explaining distinction). In any event, Plaintiffs' own allegations contradict any suggestion that their alleged lost profit damages are distinct from alleged overcharge damages. *E.g.*, SAC ¶ 153 ("covered entities pay significantly more for their purchase of 340B eligible drugs"); *id.* ¶¶ 25, 353 ("a covered entity can net revenue from the spread between the drug's price—lowered by the 340B Drug Discount—and any reimbursement above that price"); *see also* MTD Reply at 7 & n.4 (explaining that Plaintiffs' lost revenue and overcharge theories are not distinct). In short, Plaintiffs' new allegations make no difference under *Illinois Brick* and cannot save Plaintiffs' claim. *See Howard Hess*, 424 F.3d at 375 (indirect purchasers "may not recover [overcharge or] lost profits damages").

Second, Plaintiffs pepper phrases throughout the SAC alleging that Defendants "refus[e] to sell" and "refus[e] to permit the sale" of 340B drugs for shipment to contract pharmacies. SAC ¶¶ 144–53. But *Illinois Brick* applies even if there is an alleged concerted refusal to deal or sell. MTD Reply at 5–6; *UtiliCorp*, 497 U.S. at 201 ("ample justifications exist for the Court's stated decision not to carve out exceptions to the indirect purchaser rule for particular types of markets"). And Plaintiffs' new allegations fail to allege an actual boycott. For one thing, Plaintiffs do not dispute that all Defendants continue to permit the sale of drugs directly to them at 340B prices in unlimited amounts. And, despite the conclusory statement that Defendants "refus[e] to sell [340B] drugs to covered entities" for shipment to contract pharmacies, the very same allegation concedes that "at times, drugs from each Defendant have been shipped to Contract Pharmacies and charged to covered entities." SAC ¶ 153 (further contending that "none of the Defendants has been able to implement this policy comprehensively"); *see also* ¶¶ 134–42, 355 ("a particular

Defendant may have, at some point, provided Contract Pharmacy 340B Drug Discounts to them during the conspiracy").

Plaintiffs thus concede there is no actual "refusal" to sell to covered entities, which is the hallmark of a boycott case. SAC ¶¶ 153, 352 (covered entities "have purchased Defendants' drugs"). Instead, Plaintiffs' theory is that Defendants refuse to permit shipments of statutorily discounted drugs to contract pharmacies on Plaintiffs' preferred terms. That is neither a boycott nor any other sort of antitrust violation.[7] *E.g.*, *Drug Mart*, 2002 WL 31528625, at *7 & n.12 (unwillingness to engage in a relationship on plaintiffs' preferred terms is not a "'boycott' in the true sense of the word"); *FTC v. Super. Ct. Trial Laws. Ass'n*, 493 U.S. 411, 422–23 (1990) (boycott is a complete refusal to serve a customer). Accordingly, Plaintiffs' "refusal to sell" allegations cannot avoid *Illinois Brick*, making amendment pointless.

Third, the SAC alleges that drug companies "alone can remove [] discounts from the distribution stream." SAC ¶ 44. That is merely a riff on the already pled allegation that distributors and wholesalers allegedly act "at the instruction of the drug compan[ies]." *Id.* ¶ 42. Plaintiffs again appear to be advocating for an "own or control" exception to *Illinois Brick*—an exception that the Second Circuit has never recognized or addressed, and that would be inconsistent with the Supreme Court's recent affirmation that *Illinois Brick* is a "bright-line rule." *Apple Inc. v. Pepper*, 139 S. Ct. 1514, 1520 (2019). Moreover, no such exception could apply here. *See* MTD Mem. at 20. Plaintiffs' amendment does not allege—nor could it—that Defendants control distributors through "interlocking directorates, minority stock ownership, loan agreements that subject

[7] Additionally, Plaintiffs could not recover for a hypothetical boycott of ***contract pharmacies*** because they are ***covered entities***, and to the extent that Plaintiffs claim to have suffered a peripheral "loss of windfall profits" from such a boycott, that is not "injury of the type the antitrust laws were intended to prevent." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977).

[distributors] to the manufacturers' operating control, trust agreements, or other modes of control." *E.g.*, *Drug Mart*, 2002 WL 31528625, at *3; *In re Indus. Diamonds Antitrust Litig.*, 119 F. Supp. 2d 418, 422 (S.D.N.Y. 2000) (no ownership or control exception where no parent-subsidiary relationship). Unsurprisingly, courts regularly find that healthcare providers, like Plaintiffs here, are indirect purchasers vis-à-vis drug manufacturers, even where the manufacturer instructs or directs the distributor. *E.g.*, *Warren II*, 643 F.3d at 82, 87–88 (hospital was indirect purchaser even where drug "costs and rebate amounts were set by [drug maker]," not "middleman wholesaler"); *see supra* at 16 (collecting cases).

The remainder of the SAC's (unchanged) allegations do not help Plaintiffs avoid *Illinois Brick* for the reasons already explained. *See* MTD Mem. at 15–20 (addressing no direct-harm, pass-through, or legal-entitlement exceptions). Because there is "no way of getting around the conclusion that [Plaintiffs are] the second purchaser in the chain of distribution," *Warren II*, 643 F.3d at 88, Plaintiffs' request for leave to amend would be futile as to its federal damages claims.

III. PLAINTIFFS' CLAIMS ARE STILL AN IMPROPER ATTEMPT TO END-RUN *ASTRA*.

Plaintiffs' claims, even as amended, cannot proceed for the independent reason that "Congress authorized no private right of action under § 340B for covered entities." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113, 117 (2011) (explaining Congress vested HHS with exclusive authority to oversee 340B Program); *see* MTD Mem. at 35–36. Because Plaintiffs' so-called "antitrust" claims cannot be resolved without adjudicating what the 340B statute requires, their claims are barred as a matter of law. *See Broder v. Cablevision Sys. Corp.*, 418 F.3d 187, 198 (2d Cir. 2005) (plaintiff cannot attempt to show a "violation of a federal law under which no private right of action exists" by pleading alternative causes of action). Although the Court's dismissal ruling did not address this issue, nothing in the SAC cures the fundamental defect that

Plaintiffs' supposed "antitrust" case really just seeks to improperly impose their favored interpretation of what the 340B statute requires. *See* MTD Reply at 28. Amendment is thus futile.

Plaintiffs continue to dress their claims in antitrust garb, but as previously explained, they do not fit the antitrust mold. MTD Mem. at 36–38; MTD Reply at 28–32. Plaintiffs have not alleged any traditional price-fixing conspiracy or plausible boycott claim. *Id.*; *see also supra* at 18–19. They still fail to allege that any Defendant has ever charged more than the "fair market" or "competitive" prices for their drugs, much less conspired to manipulate those prices, as is characteristic of price-fixing suits. MTD Mem. at 36–37. And their new allegations that Defendants "refuse to sell" on Plaintiffs' preferred terms do not plead a boycott. The confused nature of the amendment highlights that Plaintiffs are seeking to enforce the 340B statute in the disguise of an antitrust suit. MTD Reply at 30–31.

Plaintiffs' theory is that the 340B statute requires Defendants to transfer their drugs at non-market, statutorily-set prices to an unlimited number of commercial contract pharmacies, and that by adopting policies that limit when they will facilitate those transfers, Defendants have conspired to make it more difficult for covered entities to "access" drugs at discounted prices. *See* SAC ¶¶ 4, 348. But, as with the FAC, the "antitrust" theories set forth in the SAC are "hopelessly intertwined" with the 340B statute, *Wegoland Ltd. v. NYNEX Corp.*, 27 F.3d 17, 21 (2d Cir. 1994), because only that statute grants Plaintiffs "access" to manufacturers' drugs at deeply discounted prices. That directly implicates *Astra* and its private enforcement ban. *See* 563 U.S. at 116–17.

The proposed amendment does not change or even clarify Plaintiffs' affirmative injunction request. SAC Prayer ¶ 5; MTD Mem. at 37; MTD Reply at 30–31. Plaintiffs have never refuted that they are seeking to force Defendants to permit shipments of their non-market, statutorily priced drugs to an unlimited number of contract pharmacies. But for the Court to order the

affirmative relief Plaintiffs seek, it would have to conclude that covered entities have a right to 340B prices ***and*** a related right under the statute to force Defendants to permit shipments of their 340B-discounted drugs to any number of contract pharmacies. MTD Reply at 30–32. Plaintiffs' desired injunction thus runs headfirst into *Astra*, and adjudicating Plaintiffs' "antitrust" claims would "displace and distort" the regulatory process. *Rothstein v. Balboa Ins. Co.*, 794 F.3d 256, 262–63 (2d Cir. 2015) (applying filed-rate doctrine to bar fraud claims that would interfere with regulatory rate-setting process).

Pending government litigation will resolve the circumstances under which covered entities are entitled to access non-market 340B prices. As the SAC recognizes, each Defendant (and several other manufacturers) have filed individual suits against the government regarding these very issues—whether the 340B statute requires manufacturers to permit shipments of their statutorily-priced drugs to an unlimited number of contract pharmacies. *See, e.g.*, SAC ¶¶ 146, 148, 152; *see also* MTD Mem. at 13–15. Courts around the country have continued to set aside and vacate the government's actions against drug manufacturers, noting recently that "Congress did not clearly intend for drug manufacturers to be required to facilitate sales of covered drugs for dispensing by an unlimited number of contract pharmacies." *AstraZeneca Pharms. LP v. Becerra*, 2022 WL 484587, at *6 (D. Del. Feb. 16, 2022); *see also Novartis Pharms. Corp. v. Espinosa*, 2021 WL 5161783, at *9 (D.D.C. Nov. 5, 2021) ("The plain language, purpose, and structure of the statute do not prohibit the manufacturers from imposing any conditions on their offers of 340B-priced drugs to covered entities."). These matters are ongoing, and many are on appeal.[8]

[8] Six cases challenging whether Section 340B requires manufacturers to transfer drugs to an unlimited number of contract pharmacies without any other limitations are currently on appeal. *Novartis Pharms. Corp. v. Johnson*, No. 21-5299 (D.C. Cir.); *United Therapeutics Corp. v. Espinosa*, No. 21-5304 (D.C. Cir.); *Eli Lilly & Co. v. U.S. Dept. of Health & Human Servs.*, No. 21-3128 (7th Cir.); *Sanofi-Aventis U.S., LLC v. U.S. Dept. of Health & Human Servs.*, Nos. 21-3167, 21-3379 (3d Cir.); *Novo Nordisk Inc. et al. v. U.S. Dept. of Health & Human Servs.*, No. 21-3168 (3d Cir.); *AstraZeneca Pharms, LP v. Becerra*, No. 22-1676 (3d Cir.).

In sum, Plaintiffs' claims are still "in substance one and the same" as a "suit[] to enforce § 340B," and are therefore barred as a matter of law. *Astra*, 563 U.S. at 114; *see also* MTD Mem. at 38–40 (explaining the antitrust laws in particular cannot be used to circumvent *Astra*). Amendment would therefore be futile, and Plaintiffs' motion for leave to amend should be denied with prejudice. *See Conboy v. AT&T Corp.*, 241 F.3d 242, 257–58 (2d Cir. 2001) (affirming dismissal of attempt to enforce New York's deceptive business practices statute because no private right of action); *Broder v. Cablevision Sys. Corp.*, 329 F. Supp. 2d 551, 560 (S.D.N.Y. 2004) (noting that "[a]ttempts to circumvent the bar against private actions through artful pleading will not be countenanced by the courts, and such theories of recovery will be dismissed").

IV. THE PROPOSED STATE-LAW AMENDMENTS ARE ALSO FUTILE.

In response to the Court's Order, Plaintiffs have dropped several of their legally baseless state-law claims. But their remaining claims still suffer from fundamental pleading defects. As a preliminary matter, as with the FAC, the SAC's state antitrust claims "fail for the same reason as their Sherman Act § 1 claim—they have not plausibly alleged the existence of a conspiracy." Order at 17. Amendment is thus futile. Furthermore, although the SAC has made cosmetic changes to lengthen Plaintiffs' unjust enrichment allegations, Plaintiffs have added no substance, and each claim still depends on their flawed antitrust claims. They remain impermissible "generic pleading[s]," and Plaintiffs' amendment is therefore futile as to these claims as well. *Id.* (quoting *Miami Prod. & Chem. Co. v. Olin Corp.*, 546 F. Supp. 3d 223, 247 (W.D.N.Y. 2021)).

First, because Plaintiffs' antitrust claims fail, so too do their unjust enrichment claims. Each unjust enrichment claim rests on the allegation that Defendants "unlawfully overcharged Plaintiffs" for 340B drugs. *See* SAC ¶¶ 393–480. Plaintiffs' only theory of how Defendants "unlawfully overcharged" them is through the purported antitrust conspiracy. *See id.* ¶¶ 352, 393 (defining "overcharges"). The unjust enrichment claims thus "fall" with the antitrust ones. *In re*

Novartis & Par Antitrust Litig., 2019 WL 3841711, at *7 (S.D.N.Y. Aug. 15, 2019) (dismissing unjust enrichment claims because they were "duplicative of" and would "rise and fall with" antitrust claims); *see also Cleary v. Philip Morris Inc.*, 656 F.3d 511, 517 (7th Cir. 2011) ("[I]f an unjust enrichment claim rests on the same improper conduct alleged in another claim, then the unjust enrichment claim will be tied to this related claim—and, of course, unjust enrichment will stand or fall with the related claim.").[9]

Second, Plaintiffs still engage in the sort of "generic pleading" that sank their unjust enrichment claims initially. Order at 17. Plaintiffs have now stretched their previous complaint's boilerplate allegations across 92 paragraphs—but the claims continue to rest on conclusory, formulaic assertions, with no meaningful new specificity. *See, e.g.*, SAC ¶¶ 393, 400, 403, 408, 413, 418, 422, 426, 428, 431, 437, 440, 446, 450, 454, 459, 464, 468, 473, 477 (repetitively alleging that "Defendants unlawfully overcharged" in each state).

Plaintiffs have copied language from the unjust enrichment claims that this Court accepted in *Miami Products & Chemical Co. v. Olin Corp.* ("*Miami Products II*"), but in that case, the plaintiffs had ***adequately alleged*** a national price-fixing conspiracy under which ***every domestic sale*** of caustic soda was an overcharge. 2022 WL 3701159, at *1 (W.D.N.Y. Aug. 26, 2022) (emphases added). The SAC is readily distinguishable on two grounds. To begin, Plaintiffs have failed to allege a conspiracy. *See supra* at Section I. Additionally, Plaintiffs allege a conspiracy to "***limit or eliminate***" certain 340B sales, not charge more for them, let alone charge more in every given state for which a claim is asserted. *See* SAC ¶¶ 144, 158; *GEICO Corp. v. Autoliv, Inc.*, 345 F. Supp. 3d 799, 818 (E.D. Mich. 2018) (requiring "direct assertion that [plaintiffs]

[9] Under New York law, such duplicative claims are categorically barred regardless of the merits of the antitrust allegations. *In re Namenda Indirect Purchaser Antitrust Litig.*, 2021 WL 2403727, at *38 (S.D.N.Y. Jun. 11, 2021) ("duplicative unjust-enrichment claims cannot exist under New York law" if they "will be proven using the same evidence as the[] antitrust" claims).

actually purchased," in each relevant state, the product subject to alleged price-fixing conspiracy).

Third, Plaintiffs' unjust enrichment claims are futile for other, state-specific reasons.

- **Michigan:** Plaintiffs' Michigan unjust enrichment claim fails for the independent reason that they must "clearly show that the defendant and the plaintiff were ***in contact with one another*** during the course of" the alleged improper conduct; such facts are not present here given the parties' indirect-purchaser relationship. *A & M Supply Co. v. Microsoft Corp.*, 2008 WL 540883, at *2 (Mich. Ct. App. Feb. 28, 2008) (emphasis added).
- **Mississippi:** Plaintiffs' Mississippi unjust enrichment claims fail because "[u]nder Mississippi law, unjust enrichment is not itself a cause of action," and instead, "an equitable remedy closely associated with implied contracts and trusts," which Plaintiffs have not pled. *In re Hard Disk Dive Suspension Assemblies Antitrust Litig.*, 2021 WL 4306018, at *24 (N.D. Cal. Sept. 22, 2021); *see also Hughes v. Shipp*, 324 So. 3d 286, 290, 293 (Miss. 2021) (unjust enrichment claim allowed because breach of contract claim was unavailable).
- **Virginia and Illinois**: The laws of Virginia and Illinois do not permit unjust enrichment claims by indirect purchasers such as Plaintiffs because those states follow *Illinois Brick*. *E.g.*, *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1089–90 (N.D. Cal. 2014) (dismissing indirect purchaser unjust enrichment claim brought under Illinois and Virginia laws); MTD Reply at n.19 (collecting cases regarding Illinois law).

Fourth, Plaintiffs previously conceded that the two named Plaintiffs cannot bring individual suits under the laws of states other than their home states, New York and Virginia. *See* MTD Opp. at 51; *see also Richards v. Direct Energy Servs., LLC*, 915 F.3d 88, 106 (2d Cir. 2019) (affirming dismissal because named plaintiff "could not sue on his own behalf" under the relevant state law even if he could represent a class under such law). Their amended claims, which continue to press individual out-of-state claims on their own behalf, fail. *E.g.*, SAC ¶ 393 (alleging "Defendants unlawfully overcharged Plaintiffs and the Class . . . in Arizona").

CONCLUSION

For all these reasons, as well as those in the prior dismissal briefing, Plaintiffs' request for leave to amend should be denied with prejudice.

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing was filed electronically with the United States District Court for the Western District of New York through the Court's ECF System on October 27, 2022.

/s/ *Daniel E. Laytin*