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' JOINT MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS

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INTRODUCTION

Plaintiffs claim that four drug manufacturers—AstraZeneca Pharmaceuticals, Eli Lilly and Company and Lilly USA, LLC (together, "Lilly"), Novo Nordisk, and Sanofi-Aventis U.S. LLC—engaged in a "price-fixing conspiracy." But Plaintiffs' allegations have very little to do with either ***price*** or a ***conspiracy***. Plaintiffs fail to satisfy the basic requirements for stating an antitrust claim. Instead, their suit is an improper attempt to expand their statutory rights under a federal healthcare program.

Plaintiffs' claims concern Section 340B of the Public Health Service Act, which requires manufacturers to "offer" their drugs at deeply discounted, non-market prices—as low as ***one cent*** per unit—to certain "covered entities." Plaintiffs admit that each Defendant continues to offer its drugs, including its diabetes drugs, to covered entities. Nonetheless, Plaintiffs complain that each Defendant has limited the circumstances under which it will transfer and deliver its discounted drugs to commercial, for-profit pharmacies (called "contract pharmacies") at the request of covered entities. The legality of Defendants' different policies and the proper interpretation of the 340B statute are being litigated in other courts and should not be at issue in this case. Instead, this case purports to raise solely questions of antitrust law. According to Plaintiffs, Defendants must have "conspired" to implement their policies and, as a result, somehow agreed to "fix prices" for diabetes treatments. But Plaintiffs allege ***no*** facts that plausibly suggest coordination among Defendants, whose policies differ from each other, were announced and implemented at different times over the course of many months, and are not limited to diabetes treatments.

For several independent reasons, Plaintiffs fail to state a claim. ***First***, Plaintiffs lack standing to sue for damages because they admit that they are not direct purchasers of Defendants' drugs. Rather, they concede that "drug companies rely on distributors and suppliers . . . to arrange for drug purchasing with covered entities" and that distributors thus "serve as intermediaries."

First Am. Compl. ("FAC"), Dkt. 41, ¶¶ 37, 42. That break in the chain dooms Plaintiffs' federal antitrust damages claim under *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977), and its progeny.

Second, Plaintiffs' conspiracy claims fail because they do not allege an agreement among Defendants. Plaintiffs do not even try to plead an agreement through direct evidence—*i.e.*, the proverbial "smoking gun." Nor do Plaintiffs allege circumstantial evidence of collusion: The complaint does not place Defendants in the same room, on the same phone line, or on the same email thread even once relating to anything other than constitutionally protected lobbying efforts that Plaintiffs concede they are not challenging here.

Indeed, Plaintiffs' own allegations establish that Defendants did not even engage in any parallel conduct, a necessary element of any circumstantial case. According to Plaintiffs, each Defendant announced materially different 340B policy changes at entirely different times. For instance, in July 2020, Sanofi announced a policy requiring covered entities to submit minimal claims data in order to have 340B-priced drugs shipped to contract pharmacies. Plaintiffs do not allege that ***any*** other Defendant made similar changes. Novo's policy, announced in December 2020 (well after the other Defendants' policy changes were public), applies only to ***hospital*** entities in certain circumstances—which does not include any of Plaintiffs' 40 clinics.

The complaint also confirms that each Defendant's policy changes made unilateral business sense absent any "conspiracy." When providing drugs for as low as a "penny per unit" on a 340B transaction, manufacturers ***lose*** money. It is therefore entirely rational for any manufacturer to take steps to limit those transactions to only what is statutorily required—regardless of what other manufacturers are doing. Plaintiffs suggest that Defendants were motivated to conspire because they all sell diabetes treatments. But that theory makes no sense and is not supported by plausible factual allegations. Defendants' policies apply to more than their

diabetes treatments. Moreover, as Plaintiffs concede, other manufacturers ***not*** named in the complaint have also adopted new 340B contract pharmacy policies. The timing of the policy changes is also explained by Plaintiffs' own allegations: After long-pursued (legitimate) lobbying efforts resulted in a "limited" Executive Order, many manufacturers—including at least four others not named as co-conspirators—began implementing 340B policy changes.

Third, Plaintiffs' claim is not actionable under the antitrust laws. Their true claim stems from their dissatisfaction with the terms on which contract pharmacies may access each Defendant's 340B drugs. The 340B statute, not the antitrust laws, defines the circumstances under which manufacturers must "offer" discounted prices to covered entities. Moreover, the Supreme Court has made clear that the 340B statute creates no private right of action for suits against manufacturers. *See Astra USA, Inc. v. Santa Clara Cnty*, 563 U.S. 110, 113 (2011). Knowing this, Plaintiffs try to transform their complaint into an antitrust case, but no amount of artful pleading, or sprinkling of antitrust buzzwords like "conspiracy" and "price-fixing," can make it one.

Finally, each of the state-law claims also fails. Plaintiffs' state-law antitrust claims are deficient for the same reasons as their federal claim. Their unjust enrichment claims cannot survive either. Among other things, Plaintiffs' rote listing of claims under the laws of 48 jurisdictions does not actually ***plead*** those claims, and that is doubly true for states that do not recognize unjust enrichment as a standalone basis for relief or have other requirements that Plaintiffs fail to plead.

BACKGROUND

A. Defendants Develop And Manufacture A Wide Array Of Life-Saving Drugs, Including Diabetes Treatments.

Defendants are among the world's leading manufacturers of a broad spectrum of life-saving pharmaceuticals, including diabetes-related treatments. *See*, *e.g.*, FAC ¶¶ 2, 88–90.

Diabetes is a chronic condition that affects more than 30 million people in the United States, "making up nearly ten percent of the Nation's population." *Id.* ¶ 71. If untreated, it can lead to serious harm, organ damage, and death. *Id.* Diabetes medications developed and produced by Defendants have become critical treatments for the millions of Americans afflicted by diabetes. *See id.* ¶¶ 71, 74–87, 101.

While Plaintiffs focus on diabetes, Defendants manufacture a wide array of drugs aimed at treating all different types of conditions. *See, e.g.*, *id.* ¶¶ 88–89. For example, Plaintiffs recognize that diabetes-related treatments make up only a small fraction of AstraZeneca's suite of pharmaceuticals. *Id.* ¶¶ 76–87 (recognizing AstraZeneca does not manufacture insulins and alleging that its sales account for only 5% of incretin mimetics sales).

Although each Defendant develops and manufactures a broad array of drugs, Defendants are generally not in the business of distribution. *Id.* ¶ 37. As Plaintiffs explain, "drug distributors serve as intermediaries" in the sale and distribution process. *Id.* ¶ 42; *see also id.* ¶ 40. Defendants "rely on distributors and suppliers, such as Cardinal Health, Inc., and McKesson Corporation" to distribute their products. *Id.* ¶ 37. As a result, downstream purchasers like hospitals, clinics, pharmacies, and others typically buy Defendants' drugs from these intermediary distributors, known as wholesalers, rather than directly from Defendants. *Id.* ¶ 238 (alleging entities "have purchased Defendants' drugs" from intermediary distributors); *id.* ¶ 241 (recognizing that "wholesalers [] deliver drugs").

B. Defendants Participate In The 340B Program.

In 1992, Congress established the 340B Program to "require discounts on outpatient drugs purchased by healthcare providers serving underserved populations." FAC ¶ 21; *see also* Section 340B of the Public Health Service Act, 42 U.S.C. § 256b. The 340B Program is administered by the Health Resources and Services Administration ("HRSA"), an agency within the Department

of Health and Human Services ("HHS"). FAC ¶¶ 28, 31; *Astra*, 563 U.S. at 120 ("Congress made HHS administrator of . . . the 340B Program."). Each Defendant participates in the 340B Program.

Under the 340B Program, manufacturers must offer certain drugs to "covered entities"—a statutorily defined term that includes fifteen specifically enumerated types of healthcare providers serving vulnerable or underserved populations—for purchase "at or below the applicable [statutorily defined] ceiling price."[1] 42 U.S.C. §§ 256b(a)(1), (4). For-profit, commercial pharmacies (*e.g.*, Walgreens and CVS) are not "covered entities" and therefore are not entitled to buy medications from manufacturers at the discounted 340B prices. *See id*.

The 340B "ceiling price" is set according to a prescribed statutory formula. *Id*. § 256b(a)(1)–(2), (b)(1); *see also* FAC ¶ 30. It is calculated by taking the difference between the manufacturer's Average Manufacturer Price and its Medicaid rebate amount. 42 U.S.C. § 256b(a)(1)–(2), (b)(1); *see also* FAC ¶¶ 29–32. These ceiling prices are significantly lower than what other purchasers pay for the same product, and can be as low as one penny per unit of measure. FAC ¶¶ 21, 29–30, 102. Covered entities that pay these steeply discounted prices are able to bill patients and insurers for higher amounts and pocket the difference. *See id*. ¶ 23.

Plaintiffs Mosaic Health, Inc. and Central Virginia Health Services, Inc. ("CVHS") allege that they are federally qualified health centers made up of 40 safety-net clinics, collectively. *Id*. ¶ 5. According to Plaintiffs, each of their clinics is a covered entity participating in the 340B Program. *Id*. Plaintiffs allege that covered entities are "funded in significant part through savings from 340B Drug Discounts." *Id*. That is, after purchasing manufacturers' drugs at the deeply discounted 340B price, covered entities can then sell them to insured patients at a higher price.

[1] Manufacturers must participate in the 340B Program to receive coverage or reimbursement for their products under Medicaid and Medicare Part B. 42 U.S.C. § 1396r-8(a)(1), (5).

Indeed, as Plaintiffs acknowledge, covered entities generate considerable "revenue from the spread between the drug's price—lowered by the 340B Drug Discount—and any reimbursement [by a patient's insurer] above that price." *Id*. ¶ 23.

C. The 340B Program Has Evolved Over Time, Leading To Serious Program Integrity Concerns.

Under 340B, drug manufacturers must offer their drugs to "each covered entity" for purchase at discounted prices. 42 U.S.C. § 256b(a)(1); FAC ¶¶ 21, 34. Nothing in the statute requires manufacturers to transfer their drugs at 340B prices to third-party commercial pharmacies.

In 1996, however, HRSA issued non-binding guidance purporting to allow covered entities to contract with a single "contract pharmacy" to dispense covered outpatient drugs on their behalf in connection with the 340B Program. 61 Fed. Reg. 43,549 (Aug. 23, 1996). This allowance was narrow. It applied only to covered entities ***without*** an in-house pharmacy—and even then, such covered entities could each contract with just ***one*** contract pharmacy. *Id*. at 43,551, 43,555.

In 2010, HRSA issued new non-binding guidance purporting to relax the statutory limits on covered entities' ability to contract with pharmacies. *See* 75 Fed. Reg. 10,272 (Mar. 5, 2010); *see also* FAC ¶¶ 50–51. The 2010 guidance indicated that ***all*** covered entities, not just those without an in-house pharmacy, would be permitted to contract with commercial pharmacies to dispense 340B-discounted drugs. 75 Fed. Reg. at 10,275, 10,277–78. It further stated that covered entities would be allowed to enter into an ***unlimited*** number of arrangements with an ***unlimited*** number of contract pharmacies—whether the pharmacy is across the street or across the country. *Id*. at 10,275–78 As with the 1996 guidance, the 2010 guidance was styled as a non-binding interpretive rule, did not go through the notice-and-comment procedures, and made clear that it "neither imposes additional burdens" "nor creates any new rights [] under the law." *Id*. at 10,273.

In the first seven years following the 2010 guidance, the GAO reported a ***1,438% increase*** in the number of contract pharmacies, from 1,300 in 2010 to nearly 20,000 in 2017. *AstraZeneca Pharm. LP v. Becerra*, 2021 WL 2458063, at *3 (D. Del. June 16, 2021) (citing U.S. Gov't Accountability Office, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 2 (June 2018), https://www.gao.gov/assets/700/692697.pdf ("2018 GAO Report") (last visited Nov. 11, 2021)). And according to HRSA's own figures, there are now more than ***225,000*** arrangements between contract pharmacies and covered entities. *See* HRSA, 340B Contract Pharmacy Database, https://bit.ly/3nLdX3X (last visited Nov. 11, 2021).[2]

These contract pharmacies obtain the significantly discounted 340B drugs through contracts with covered entities. The government has reported that 75 percent of these pharmacies are nationwide, for-profit chains like CVS and Walgreens. 2018 GAO Report, at 20. As Plaintiffs acknowledge, these contract pharmacies charge "the patient for any required co-pay or . . . fee" and to "the extent the patient has insurance coverage from third-parties . . . the pharmacy collects those reimbursements." FAC ¶ 56. After remitting amounts collected to the covered entity, "the covered entity pays the pharmacy a dispensing fee." *Id*.

What this means is that contract pharmacies use covered entities to secure massively discounted drugs while charging patients and insurers higher prices. The contract pharmacies then remit the difference to the covered entity and recoup a hefty fee from the covered entity. At the

[2] For background, Defendants cite to judicially-noticeable government websites and reports. *See*, *e.g.*, *Mathews v. ADM Milling Co.*, 2019 WL 2428732, at *4 (W.D.N.Y. June 11, 2019) ("Courts routinely take judicial notice of governmental records retrieved from official government websites."); *Paskar v. City of New York*, 3 F. Supp. 3d 129, 134 (S.D.N.Y. 2014) ("Official government reports and other types of government records are appropriate for judicial notice.").

end, pharmacies like Walgreens and CVS retain as profit a portion of the discount intended to benefit vulnerable patients. *See id*. ¶¶ 57–58.

The HHS Office of Inspector General ("HHS OIG") has expressed concerns about the 340B Program. HHS OIG testified before Congress that it had "identified a number of challenges and inconsistencies arising from the widespread use of contract pharmacy arrangements." HHS OIG Testimony, Examining Oversight Reports on the 340B Drug Pricing Program, Testimony of Ann Maxwell, Assistant Inspector Gen. for Evaluation and Inspections, OIG Before the U.S. S. Comm. on Health, Educ., Labor, and Pensions, at 5 (May 15, 2018), https://bit.ly/3lCv4Uj (last visited Nov. 11, 2021). For instance, HHS OIG explained that the use of contract pharmacies can result in "inconsistencies in whether uninsured patients benefit directly from the 340B program." *Id*. In addition, contract pharmacy operations are often "complex" and result in "variation in eligibility determinations;" as HHS OIG notes, dispensing a 340B drug to an ineligible patient (referred to as "diversion") is prohibited by law. *Id*. at 5–6; *see also* 42 U.S.C. § 256b(a)(5)(B), (d)(2)(A). Similarly, "duplicate discounts"—*i.e.*, where the manufacturer ends up providing both a 340B discount and a Medicaid rebate on the same prescription—are also prohibited by the 340B statute. 42 U.S.C. § 256b(a)(5)(A).

On July 24, 2020, the President issued an Executive Order echoing some of these key concerns—namely, that 340B discounts "are not always passed through to low-income Americans at the point of sale." Exec. Order No. 13,937, 85 Fed. Reg. 45,755 (July 24, 2020). The President ordered HHS to take steps to ensure that future grants available to federally qualified health centers, like Plaintiffs here, be conditioned on making insulin and injectable epinephrine available to patients at the 340B-discounted price. *Id*.

D. Against This Backdrop, Defendants Independently Announced Changes To Their 340B Policies And Practices.

In the context of this evolving 340B landscape and concerns regarding program integrity, manufacturers began announcing changes to their 340B policies. FAC ¶¶ 117–24, 130–31. The complaint recognizes that eight manufacturers—Lilly, AstraZeneca, Sanofi, Novo, Merck, Novartis, United Therapeutics, and Boehringer Ingelheim—announced policy changes within the last two years. *Id*. Plaintiffs, however, focus on only half of the manufacturers who made policy changes—the four Defendants. But as Plaintiffs' allegations make clear, each Defendant's policy changes were entirely distinct and rolled out at various points over the course of many months.

1. *Lilly*

Plaintiffs allege that, on May 18, 2020, Lilly informed HHS that due to "global concerns with Contract Pharmacies," it planned to make changes to its 340B policies with regard to its drug, Cialis—a pharmaceutical drug that treats enlarged prostate and erectile dysfunction (not diabetes). FAC ¶ 123 (citing May 18, 2020 Lilly letter to HRSA); *see also* D'Antonio Aff. at Ex. A, May 18, 2020 Lilly Letter to HRSA.[3] Plaintiffs do not allege that Lilly's policy change violated 340B or was part of any conspiracy. Indeed, "HRSA concluded that its Contract Pharmacy Guidances were non-binding and that [Lilly's] plan did not give rise to any enforceable violation of the 340B statute." D'Antonio Aff. at Ex. B, August 19, 2020 Lilly Letter to HRSA, at 1.

HRSA publicly posted Lilly's "Limited Distribution Plan Notice For Cialis" on its website in July 2020. *See* HRSA, Limited Distribution Plan Notice for Cialis® (tadalafil) Erectile Dysfunction NDCs, https://bit.ly/3n3DaWS (last visited Nov. 11, 2021). The notice explained that

[3] Plaintiffs' complaint selectively references and quotes this and other letters from Defendants. *See* FAC ¶¶ 118–24. The Court may therefore take judicial notice of their entire contents on a motion to dismiss. *See*, *e.g.*, *Matusovsky v. Merrill Lynch*, 186 F. Supp. 2d 397, 400 (S.D.N.Y. 2002) (relying on document "explicitly referenced" in the complaint and dismissing complaint).

"[e]ffective July 1, 2020, Lilly is limiting distribution of 340B ceiling price product of [certain] Cialis formulations directly to covered entities . . . . Contract pharmacies will not be eligible to receive these formulations of Cialis at the 340B ceiling price." *Id*. It further stated that "[c]overed entities that do not have an in-house pharmacy may contact 340B@lilly.com regarding the exception process to designate a contract pharmacy location." *Id*.

Lilly thereafter informed HRSA that it planned to expand its 340B policy changes beyond Cialis. Plaintiffs allege that on August 19, 2020, Lilly informed HHS that it planned to "discontinue [its] practice of voluntarily honoring requests for 340B 'contract pharmacies' for orders on all Lilly products" in certain circumstances. FAC ¶ 121. As Plaintiffs concede, this policy change was not absolute. Lilly informed the government that there were circumstances in which it would continue to honor requests to use contract pharmacies. For instance, Lilly would continue to honor contract pharmacy requests for covered entities that do not have an in-house pharmacy. *Id*.; *see also* Ex. B, at 1. In addition, Lilly announced it would allow distributors to ship 340B-discounted drugs to contract pharmacies where "[n]either the covered entity nor the contract pharmacy marks-up or otherwise charges a dispensing . . . fee for the Lilly insulin." FAC ¶ 122. Such a requirement ensures that patients "directly benefit from the significant 340B discounts on Lilly insulins." Ex. B, at 3. Importantly, Lilly also continues to offer all covered drugs to all covered entities at or below the ceiling price, as required by statute.

Lilly explained it was making these changes "in response to documented and widespread abuses of the 340B Program that had been increasing over the years," particularly related to the proliferation of the use of contract pharmacies. *Eli Lilly and Co. v. Cochran*, 526 F. Supp. 3d 393, 401 (S.D. Ind. 2021). Lilly also explained that its policy was (1) consistent with the government's conclusion that its (near-identical) Cialis policy change "did not give rise to any enforceable

violation of the 340B statute" and (2) supportive of the Executive Order's goal to "pass on the 340B ceiling price to vulnerable patients." Ex. B, at 1–2.

2. *AstraZeneca*

On July 24, 2020, the same day as the 2020 Executive Order, AstraZeneca sent a letter notifying HHS that it planned "to adjust [its] approach" regarding contract pharmacies for 27 of its products. FAC ¶ 118; *see also* D'Antonio Aff. at Ex. C, July 24, 2020 AstraZeneca Letter to HRSA. AstraZeneca informed HHS that, with regard to specifically enumerated products, it would "recognize one contract pharmacy per covered entity for those covered entities that do not maintain an on-site dispensing pharmacy." FAC ¶ 118; Ex. C, at 1.

AstraZeneca explained that this change was based on a multitude of factors, including the "text of the 1992 [340B] statute, as well as the text of the 1996 notice," and "audits that had been taking place since 2017." FAC ¶ 119. AstraZeneca noted that its "new approach" would "help to mitigate the significant compliance issues that exist—and that AstraZeneca has experienced—with covered entity contract pharmacy arrangements." Ex. C, at 1. AstraZeneca confirmed it remained "committed to ensuring that [its] products remain available to patients of covered entities" and that it would continue to "make its products available to ***all covered entities*** at or below the applicable ceiling price." *Id*. at 3 (emphasis added).

3. *Sanofi*

Plaintiffs allege that on or about July 27, 2021, within days of the 2020 Executive Order, Sanofi announced it would be "implementing a new 340B program integrity initiative." FAC ¶ 120. Sanofi explained that it was implementing this initiative because it was "concerned about the rate of duplicate discounting on Medicaid prescriptions filled with 340B-purchased drugs." D'Antonio Aff. at Ex. D, July 2020 Sanofi Letter to Covered Entities, at 1. Its approach to mitigating these concerns was unique: To "address duplicate discounts," which the 340B statute

expressly prohibits, Sanofi announced it would begin requiring covered entities to submit minimal, de-identified claims data for 340B prescriptions of Sanofi products filled through contract pharmacies. FAC ¶ 120; Ex. D, at 1. Sanofi explained it would then "use this data to match against rebate claims it receives to ensure it isn't paying ineligible discounts." Ex. D, at 1.

Sanofi noted that its new policy "should not place significant burden on 340B covered entity operations." Ex. D, at 2. As long as covered entities submit the minimal claims data requested for applicable drugs and in the applicable circumstances, there would be no other changes to Sanofi's 340B policies—*i.e.*, a covered entity could continue using ***multiple*** contract pharmacies with no limitation.

If a covered entity elected not to provide claims data, it would "no longer be eligible" to place orders for Sanofi products dispensed through a contract pharmacy. FAC ¶ 120; Ex. D, at 2. Critically, however, Sanofi made clear that "[a]ll 340B covered entities will continue to be able to purchase Sanofi products at the 340B price when shipped to an address registered on the 340B covered entity database." Ex. D, at 2. In no event would covered entities lose access to 340B discounts from Sanofi when drugs were shipped to that covered entity, even if they chose not to comply with Sanofi's claims data policy for contract pharmacies. Sanofi later explained, on February 2, 2021, that its policy 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." FAC ¶ 146 n.5.

4. *Novo*

Novo did not take any action with regard to its 340B policies for "several more months." FAC ¶ 124. It was not until December 1, 2020 that Novo "informed HHS of the drug company's policy"—months after other drug manufacturers' public announcements. *Id*. ¶ 124; *see also id*. ¶ 119 (AstraZeneca "ma[d]e its plan public [in] mid-August 2020"); *id*. ¶ 120 ("Sanofi publicly

announced" its plans "on or about July 27, 2020"); *id*. ¶ 138 ("On September 21, 2020, HRSA posted a letter to its public website . . . addressed to Eli Lilly" stating that it had "concern" with Lilly's new policy and describing policy). Novo's policy change was also unique: it relates only to "***hospital*** covered entities," and not to any of the other types of statutorily defined covered entities, such as clinics. FAC ¶ 124 (emphasis added). Specifically, Novo explained that it would no longer deliver (or facilitate the delivery of) 340B discounted drugs to third-party contract pharmacies at the request of "any of the six 'hospital' covered entity types" unless the covered entity lacked its own in-house pharmacy. D'Antonio Aff. at Ex. E, December 1, 2020 Novo Letter to HRSA, at 1. It is unclear how Novo's policy has any impact on Plaintiffs—which are health centers comprised of 40 safety-net clinics. FAC ¶ 5.

* * *

In sum, Plaintiffs allege that each Defendant's policy is entirely distinct and the policies' effects and implications vary widely:

	AstraZeneca	**Sanofi**	**Lilly**	**Novo**
Allows one contract pharmacy for each covered entity that does not have an in-house pharmacy (FAC ¶¶ 118, 121)	✓		✓	
No limit on contract pharmacies passing along diabetes products at cost if dispensed without fee (FAC ¶ 122)			✓	
Requires claims data (FAC ¶ 120)		✓		
Applies only to specific products (FAC ¶ 118)	✓			
Applies only to specific facilities (FAC ¶¶ 124, 146 n.5)		✓		✓
Applies to *all* products and facilities (FAC ¶ 121)			✓	

Over the last year, the government has contested the legality of Defendants' and other manufacturers' policy changes through various opinions and letters. FAC ¶¶ 141–45. In turn, each Defendant and other manufacturers have independently brought suit challenging the

government's actions with respect to their individual policies.[4] Each manufacturer's policy is thus already being independently reviewed by federal courts across the country. Many of these courts have recently issued judgments in these matters, resulting in a variety of outcomes—and notably, thus far, ***every*** court considering these issues has vacated or set aside the government's actions at least in part, despite disagreeing on the scope of manufacturers' rights and authority under the statute.[5]

Separately, covered entities—including even ***Plaintiffs***—have filed administrative dispute resolution ("ADR") petitions against drug manufacturers (including Defendants) to challenge their policies. *See*, *e.g.*, D'Antonio Aff. at Ex. F, *Nat'l Assoc. of Comm. Health Ctrs. v. Sanofi-Aventis U.S. LLC and AstraZeneca PLC*, Petition No: 210112-2 (H.H.S. Aug. 31, 2021) (petition filed by association of federally qualified health centers, including Mosaic and CVHS, against AstraZeneca and Sanofi, alleging overcharges resulting from each manufacturer's 340B policy changes). Covered entities have made those filings because, as the Supreme Court has explained, "Congress authorized no private right of action under § 340B for covered entities who claim they have been charged prices exceeding the statutory ceiling." *Astra*, 563 U.S. at 113. Instead, "Congress directed HRSA to create a formal dispute resolution procedure" for covered entities to challenge

[4] *Astrazeneca Pharms. LP v. Becerra*, 1:21-cv-00027 (D. Del. filed Jan 12, 2021); *Eli Lilly and Co. v. Becerra*, 1:21-cv-00081 (S.D. Ind. filed Jan. 12, 2021); *Sanofi-Aventis U.S., LLC v. U.S. Dept. of Health and Human Servs.*, 3:21-cv-00634 (D.N.J. filed Jan. 12, 2021); *Novo Nordisk Inc. v. U.S. Dept. of Health and Human Servs.*, 3:21-cv-00806 (D.N.J. filed Jan. 15, 2021); *Novartis Pharmaceuticals Corp. v. Espinosa*, No. 1:21-cv-01479 (D.D.C. filed May 31, 2021); *United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-01686 (D.D.C. filed June 23, 2021); *Boehringer Ingelheim Pharmaceuticals, Inc. v. Becerra*, No. 1:21-cv-02826 (D.D.C. filed Oct. 25, 2021); *see also* FAC ¶ 35.

[5] *See Lilly*, 1:21-cv-00081, Dkt. 144, 145 (Oct. 29, 2021); *Sanofi*, 3:21-cv-00634, Dkt. 110, 111 (Nov. 5, 2021); *Novo*, 3:21-cv-00806, Dkt. 69, 70 (Nov. 5, 2021); *Novartis*, No. 1:21-cv-01479, Dkt. 31, 32 (Nov. 5, 2021); *United Therapeutics*, No. 1:21-cv-01686, Dkt. 31, 32 (Nov. 5, 2021).

manufacturers' compliance with 340B. *Id*. at 121. For this reason, lawsuits brought by covered entities in an attempt to end-run *Astra* have been dismissed or stayed in favor of administrative enforcement. *See*, *e.g.*, *Am. Hosp. Ass'n v. Dep't of Health & Hum. Servs.*, 2021 WL 616323, at *4–5 (N.D. Cal. Feb. 17, 2021) (dismissing suit alleging HHS "unlawfully [] refused to take specific enforcement actions to block the manufacturers' changes" because "there is no private right of action for enforcement under the 340B Program"). In short, each Defendant's (and other manufacturer's) policy is already being assessed in a variety of proceedings across the country.

LEGAL STANDARD

To survive a motion to dismiss, a plaintiff must plead "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). That requires "more than labels and conclusions [or] a formulaic recitation of the elements of a cause of action." *Twombly*, 550 U.S. at 555. Under *Twombly*, "it is not enough 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) (quoting *Twombly*, 550 U.S. at 556); *accord Rochester Drug Co-op., Inc. v. Biogen Idec U.S.*, 130 F. Supp. 3d 764, 768–69 (W.D.N.Y. 2015) (Wolford, J.) ("The plausibility standard 'asks for more than a sheer possibility' that a defendant has acted unlawfully." (quoting *Iqbal*, 556 U.S. at 678)).

ARGUMENT

I. PLAINTIFFS DO NOT HAVE STANDING TO ASSERT FEDERAL ANTITRUST DAMAGES CLAIMS BECAUSE THEY ARE INDIRECT PURCHASERS.

Only direct purchasers have standing to bring a claim for damages under the federal antitrust laws. *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977); *accord Simon v. KeySpan Corp.*,

694 F.3d 196, 201 (2d Cir. 2012) (concluding that indirect purchaser claims were barred). Courts are clear that *Illinois Brick* establishes a "bright-line rule." *Apple Inc. v. Pepper*, 139 S. Ct. 1514, 1520 (2019); *accord Spinner Consulting LLC v. Stone Point Cap. LLC*, 623 B.R. 671, 676 (D. Conn. 2020), *aff'd*, 843 F. App'x 411 (2d Cir. 2021) (same). As the Supreme Court recently explained, this longstanding bright-line rule "is grounded on the 'belief that simplified administration improves antitrust enforcement.'" *Apple*, 139 S. Ct. at 1522 (citing 2A P. Areeda, H. Hovenkamp, R. Blair, & C. Durrance, Antitrust Law ¶ 346e, p. 194 (4th ed. 2014)).

An indirect purchaser is barred from seeking damages regardless of the label it affixes to its allegations or the explanations it provides. *See Kansas v. UtiliCorp United, Inc.*, 497 U.S. 199, 199 (1990) (refusing to create exception to *Illinois Brick* indirect purchaser rule); *Drug Mart Pharm. Corp. v. Am. Home Prods. Corp.*, 2002 WL 31528625, at *10 (E.D.N.Y. Aug. 21, 2002) (refusing to "endorse an *Illinois Brick* exception"); *Spinner Consulting*, 623 B.R. at 676 (noting *Illinois Brick* does not create "any 'carve out exceptions'"); *Warren Gen. Hosp. v. Amgen Inc.* ("*Warren II*"), 643 F.3d 77, 87 (3d Cir. 2011) (rejecting argument that the district court "improperly exalted form over substance in failing to look beyond the existence of a wholesaler" in analyzing hospital's "purchaser status").

Plaintiffs ***do not allege*** that they directly purchased diabetes drugs from ***any*** Defendant. Rather, they concede that "[o]ftentimes, drug companies rely on distributors and suppliers . . . to arrange for drug purchasing with covered entities," and "drug distributors ***serve as intermediaries***." FAC ¶¶ 37, 42 (emphasis added). In other words, Plaintiffs do not allege that drug manufacturers sell directly to them, or that they buy directly from manufacturers. Instead, Plaintiffs implicitly acknowledge that they purchase 340B drugs from intermediary distributors

and thus are ***indirect*** purchasers with respect to each Defendant.[6] *Id.* ¶ 40; *see Spinner Consulting*, 623 B.R. at 676 ("Where a plaintiff must operate through another actor in a distribution chain before the product reaches it, the plaintiff is not a direct purchaser.").

Courts routinely dismiss antitrust suits brought by providers against drug manufacturers for lack of standing where, as here, the provider purchased the drugs ***indirectly*** through a wholesaler or distributor. *See Lakeland Reg'l Med. Ctr., Inc. v. Astellas US, LLC*, 763 F.3d 1280, 1285 (11th Cir. 2014) (barring healthcare provider from suing drug manufacturer on antitrust claims); *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 (3d Cir. 2011) (same); *In re Hypodermic Prod. Antitrust Litig.*, 484 F. App'x 669, 675 (3d Cir. 2012) (same); *In re Generic Pharms. Pricing Antitrust Litig.*, 386 F. Supp. 3d 477, 487 (E.D. Pa. 2019) (same); *see also Delaware Valley Surgical Supply, Inc. v. Johnson & Johnson*, 523 F.3d 1116, 1122–25 (9th Cir. 2008) (precluding healthcare provider from suing medical product manufacturer). In fact, courts have expressly barred insulin purchasers from suing drug manufacturers in light of their indirect purchaser relationship. *In re Insulin Pricing Litig.*, 2019 WL 643709, at *13 (D.N.J. Feb. 15, 2019) (barring RICO claims under *Illinois Brick* because plaintiffs "failed to allege that they directly purchased the analog insulin from Defendants").

The Third Circuit's decision in *Warren*, affirming dismissal of a hospital's antitrust claim against a drug manufacturer for lack of standing because the hospital was an indirect purchaser, is

[6] Plaintiffs further acknowledge this dispositive point through their gerrymandered damages claims—*i.e.*, choosing ***not*** to seek "overcharge" damages for their Sherman Act claim. Plaintiffs allege they "pa[id] inflated prices for Defendants' 340B drugs" and seek to recover overpayments. FAC ¶ 272. Tellingly, however, Plaintiffs seek such damages only for their state-law claims. *Compare id.* First Claim (not seeking overcharge damages related to federal claim) *with* Second and Third Claims (seeking overcharge damages on state law claims). This is presumably because Plaintiffs ***know*** that they did not directly pay Defendants (and instead paid distributors) and ***know*** that they cannot seek indirect damages under federal law. *See Simon*, 694 F.3d at 201.

particularly instructive. *Warren II*, 643 F.3d at 80. There, the hospital, on behalf of itself and a putative class, alleged that the manufacturer illegally tied together discounts and rebates on its products. *Id*. The court saw past the plaintiff's references to itself as a "direct purchaser" and as in a "direct relationship" with the manufacturer. *Id*. at 79, 82–83, 87–91; *see also Warren I*, 2010 WL 2326254, at *2–3. Nor was the court convinced by the hospital's arguments that it should be deemed the direct purchaser since the challenged rebates were paid "directly" from the manufacturer to the hospital and it was "the first 'overcharged' purchaser" in the chain. *Warren II*, 643 F.3d at 79, 88. Notwithstanding these allegations, the court held there was "no way of getting around the conclusion that [the hospital] is the second purchaser in the chain of distribution" and thus its claims were barred under *Illinois Brick*'s "bright line rule." *Id*. at 88, 96.

So too here: Plaintiffs cannot disguise that they are indirect purchasers through imprecise allegations that they "have purchased Defendants' drugs." FAC ¶ 238. Indeed, while Plaintiffs allege that they "pa[id] inflated prices for Defendants' 340B drugs," *id*. ¶ 272, they conspicuously do not allege which entity they purportedly overpaid or what specific products they even bought. *See, e.g.*, *id*. ¶ 238 (using passive voice to state that "[c]overed entities, including Plaintiffs, have been overcharged").

To be sure, Plaintiffs' complaint contains allegations presumably designed to try to avoid dismissal under *Illinois Brick*. But Plaintiffs target exceptions that simply do not exist:

- **"Pass-Through":** Plaintiffs allege that "wholesalers . . . do not retain any portion" of the 340B discounts. FAC ¶ 241. But "even if one hundred percent of the [discounts] were passed-on," Plaintiffs, as indirect payors, "would still lack antitrust standing." *Paycom Billing Servs., Inc. v. Mastercard Int'l, Inc.*, 467 F.3d 283, 291-92 (2d Cir. 2006); *see also Simon*, 694 F.3d at 204 ("the allegation [] that 100% of the costs were passed on is not sufficient to establish standing"); *Drug Mart*, 2002 WL 31528625, at *8 (only direct purchasers can bring suit "even if every cent of the overcharge was promptly and fully passed").

- **"Legal Entitlement":** Plaintiffs allege that Defendants have a statutory "obligation to provide 340B Drug Discounts to covered entities." FAC ¶¶ 34–35. Yet the indirect purchaser bar applies even if Plaintiffs could show that, under 340B, they are "legally entitled" to access the alleged discounts through contract pharmacies. *See UtiliCorp*, 497 U.S. at 217–18 (no standing even though "regulations and tariffs" required indirect purchaser to pay direct purchaser's costs); *Simon*, 694 F.3d at 202–03 (no standing even though indirect purchaser was "contractually required" to pay intermediary's costs); *Warren I*, 2010 WL 2326254 (D.N.J. June 7, 2010) (similar).

- **"Direct-Harm":** Plaintiffs' allegations that they have been "directly harmed" by Defendants' policies do not absolve them of their indirect purchaser problem either. FAC ¶ 241.[7] There are "no 'direct-harm' or 'first victim' exceptions to the indirect purchaser rule." *In re Zantac (Ranitidine) Prod. Liab. Litig.*, 2021 WL 2685640, at *9 (S.D. Fla. June 30, 2021).[8]

- **"Lost Revenue":** Plaintiffs also try to avoid *Illinois Brick* by framing their price-fixing overcharge damages claim as one for "lost 340B Savings revenue." *See* FAC ¶ 239. But indirect purchasers cannot seek to recover damages under federal antitrust law, regardless of how they label them. *See Salveson v. JP Morgan Chase & Co.*, 2014 WL 12770235, at *2 (E.D.N.Y. Nov. 26, 2014), *aff'd*, 663 F. App'x 71 (2d Cir. 2016) ("[A] bright line rule emerged from *Illinois Brick*: only direct purchasers have standing . . . to seek damages for antitrust violations.") (citation omitted); *see also Howard Hess Dental Lab'ys Inc. v. Dentsply Int'l, Inc.*, 424 F.3d 363, 375–76 (3d Cir. 2005) ("Plaintiffs may not recover lost profits damages because they are indirect purchasers.").[9]

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[7] Nor is it clear how Plaintiffs have been "harmed" at all (directly or indirectly). First, there are no alleged quantity restrictions on sales to covered entities under ***any*** Defendant's policy. Moreover, Plaintiffs do not (and cannot) allege that they have been completely precluded from having Defendants' 340B-discounted drugs shipped to contract pharmacies. *See* FAC ¶¶ 122, 120, 124. In fact, there are no limits on the number of pharmacies Plaintiffs may contract with (so long as certain requirements are met) for at least some Defendants.

[8] Nor does it make any difference that Plaintiffs allege that the "wholesalers that deliver drugs have not been directly harmed." FAC ¶ 241. That another entity has not been harmed does not transform Plaintiffs into a "direct purchaser," which is the only relevant inquiry here. *See Spinner Consulting*, 623 B.R. at 676; *Warren II*, 643 F.3d at 88 (only the technical "mechanics of the transactions" matter to determine direct purchaser status).

[9] In any event, Plaintiffs' purported lost "savings" revenue is really the same as the purported overcharges. Plaintiffs claim they have "been losing 340B Savings through the eliminated, reduced, or limited availability of Contract Pharmacy 340B Drug Discounts, specifically, through lost 340B Savings revenues." FAC ¶ 262. Stated differently, Plaintiffs allege that because Defendants limit the instances in which distributors are permitted to send drugs to contract pharmacies, Plaintiffs have (1) chosen to purchase fewer drugs at the discounted rate (alleged "overcharges"), and (2) also lost the fees that contract pharmacies otherwise provide to Plaintiffs

- **"Instruction to Provide":** Plaintiffs allege that "the drug company instructs the distributor to provide the 340B Drug Discount for the sale of any covered outpatient drugs to covered entities." FAC ¶ 40. But that falls far short of pleading the narrow "own or control" exception to *Illinois Brick*. *See*, *e.g.*, *Drug Mart*, 2002 WL 31528625, at *3 ("control exception" did not apply where defendants did not control wholesalers through "interlocking directorates, minority stock ownership, loan agreements that subject the wholesalers to the manufacturers' operating control, trust agreements, or other modes of control separate from ownership of a majority of the wholesalers' common stock." (internal citation omitted)).

At bottom, no amount of artful pleading can obscure Plaintiffs' concession that they are indirect purchasers of the diabetes drugs at issue here. Accordingly, black-letter law compels dismissing their federal antitrust damages claim as a matter of law under *Illinois Brick*'s bright-line rule.

II. PLAINTIFFS HAVE NOT ALLEGED A "CONSPIRACY."

Plaintiffs' conspiracy claims fail as a matter of law because they do not allege an agreement among Defendants to restrict access to 340B discounted drugs. The "crucial question" for Plaintiffs' claims is "whether the challenged [] conduct stem[s] from independent decision or from an agreement, tacit or express.'" *Twombly*, 550 U.S. at 553 (internal quotations and citation omitted). Without an "agreement," there can be no conspiracy.

A plaintiff may allege an "agreement" in one of two ways. First, a plaintiff may "assert direct evidence that the defendants entered into an agreement"—*i.e.* a "smoking gun." *Mayor & City Council of Baltimore, Md. v. Citigroup, Inc.*, 709 F.3d 129, 136 (2d Cir. 2013).

(alleged "lost revenues"). Plaintiffs' request for lost revenue—as opposed to overcharges—cannot save their claim as a matter of law. *See Drug Mart*, 2002 WL 31528625, at *8 (barring indirect purchasers from bringing "lost profits" damages claim because they in fact sought overcharges). To hold otherwise would imply that *Illinois Brick* "really meant that indirect purchasers do have standing to sue, but for lost profits rather than overcharge damages"; such a proposition is "untenable." *Howard Hess Dental Lab'ys Inc.*, 424 F.3d at 375–76 (barring indirect purchaser from bringing "lost profits" damages claims).

Second, a plaintiff may allege an agreement with circumstantial evidence. That approach requires a plaintiff to allege "parallel conduct" among defendants. Allegations of parallel conduct alone are not enough, however, to state an antitrust conspiracy claim. *Twombly*, 550 U.S. at 553 ("parallel business behavior . . . falls short of conclusively establish[ing] agreement or . . . itself constituting a Sherman Act offense." (internal quotations and citation omitted)). A plaintiff must also allege "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." *Citigroup*, 709 F.3d at 136 (citation omitted). However, if "[s]uch factors in a particular case could lead to an equally plausible inference of mere interdependent behavior," then the plaintiff has not satisfied its pleading burden, and the claim must be dismissed. *Id*. at 137.

Here, Plaintiffs fail to allege an agreement under either method. They do not even attempt to allege any direct evidence of a conspiracy. Nor do they sufficiently allege a circumstantial claim. Far from alleging parallel conduct, Plaintiffs' complaint concedes that each Defendant enacted a different 340B policy at a different time. Moreover, Plaintiffs' complaint concedes that each Defendant had unilateral reasons for enacting such policies, which precludes Plaintiffs from establishing plus factors as a matter of law.

A. Plaintiffs Do Not Allege *Any* Direct Evidence Of A Conspiracy.

Nothing in Plaintiffs' complaint comes close to alleging direct evidence of an agreement between Defendants. There are no factual allegations establishing an agreement between Defendants to change their 340B policies to place limits or conditions on the distribution of 340B discounted drugs. Indeed, the complaint's allegations do not specifically place Defendants (or even ***any subset*** of them) in the same room or on the same phone line ***even once***. *Cf. Citigroup*, 709 F.3d at 136 ("recorded phone call in which two competitors agreed" to the challenged conduct is direct evidence of a conspiracy); *Cosmetic Gallery, Inc. v. Schoeneman Corp.*, 495 F.3d 46, 52

(3d Cir. 2007) ("memorandum . . . detailing the discussions from a meeting of a group of alleged conspirators" can serve as direct evidence).

The only alleged discussions among Defendants relate to lobbying—which numerous other manufacturers, not named as defendants, participated in as well. FAC ¶¶ 6–7, 108–13, 218 (alleging Defendants were members of industry associations and "used common lobbyists" to "engage[] in a joint lobbying campaign"). But those lobbying efforts are "not challenged here." *Id*. ¶¶ 6–7, 100. For good reason; they are protected from antitrust scrutiny under the *Noerr-Pennington* doctrine. *See Eastern R.R. Presidents' Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *United Mine Workers of America v. Pennington*, 381 U.S. 657 (1965).

B. Plaintiffs Do Not Allege Any Circumstantial Evidence Of A Conspiracy.

Plaintiffs also do not plead sufficient circumstantial evidence of a conspiracy. First, they fail to plausibly allege parallel conduct. Instead, the complaint makes clear that Defendants enacted entirely distinct policies at different times. Nor do Plaintiffs plead any plausible plus factors. Plaintiffs' own allegations establish that each Defendant had legitimate reasons for making changes to its 340B policies, regardless of what other manufacturers were doing. Such allegations doom Plaintiffs' conspiracy claims.

1. *Plaintiffs' Allegations Of "Parallel Conduct" Fall Far Short.*

a. Each Defendant made completely different—not parallel—changes to its 340B policies.

Where alleged conduct is distinct, it cannot constitute "parallel conduct." *See Pro Music Rights, LLC v. Apple, Inc.*, 2020 WL 7406062, at *4 (D. Conn. Dec. 16, 2020) (granting motion to dismiss where defendants' conduct was "at least somewhat distinct from one another"); *LaFlamme v. Societe Air France*, 702 F. Supp. 2d 136, 151 (E.D.N.Y. 2010) (granting motion to dismiss where court was "dubious [] whether the conduct alleged . . . can accurately be characterized as

'parallel'" because defendants' actions were "divergent (in some instances varying by a factor of three)"); *Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 228–29 (3d Cir. 2011) (affirming dismissal because the "allegations fall far short of demonstrating parallel behavior" where defendants took different actions—*i.e.*, "choosing to decline, decrease, and even increase credit to [retailer] at different time periods").

Here, Plaintiffs have pled themselves out of court. As described above, Plaintiffs' own allegations establish that each Defendant took a different approach to reforming its 340B policy. Plaintiffs allege that each Defendant's policy has elements that are ***unique*** to its program. The complaint likewise shows on its face that Defendants did ***not*** uniformly decline to ship their 340B covered drugs to contract pharmacies.

More specifically, for certain "listed" products, AstraZeneca's policy directs distributors to limit transferring 340B discounted drugs to "one contract pharmacy per covered entity for those covered entities that do not maintain an on-site dispensing pharmacy." FAC ¶ 118. Sanofi's policy, meanwhile, requires certain covered entities to provide "prescription claims data to a Sanofi vendor through a software portal" before they can have Sanofi's products shipped to contract pharmacies. *Id.* ¶ 120.[10] Even though a limit on the use of contract pharmacies is the core of Plaintiffs' conspiracy theory, Sanofi's program *does not limit* the number of contract pharmacies that a covered entity can use, so long as the covered entity provides the requested minimal data.

[10] Plaintiffs' assertion that this initiative was "commercially unreasonable" is not only conclusory but also contradicted by the very document they purport to summarize for support: the requested data takes less than five minutes to upload and "should not place significant burden on 340B covered entity operations." Ex. D, at 2; *see Pickett v. Migos Touring, Inc.*, 420 F. Supp. 3d 197, 205 (S.D.N.Y. 2019) ("[W]hen a document relied on in the complaint contradicts allegations in the complaint, the document, not the allegations, controls.").

Regarding Lilly, Plaintiffs allege that it stopped "voluntarily honoring requests for 340B 'contract pharmacies' for orders on all Lilly products except where . . . a covered entity does not have an in-house pharmacy." *Id.* ¶ 121. In addition, Plaintiffs concede that Lilly announced a distinct "exception to permit Contract Pharmacies to pass along certain insulin products at cost" if the insulin is dispensed without a dispensing fee. *Id.* ¶ 122.[11]

Lastly, Plaintiffs allege Novo introduced its own distinct program, under which it directs distributors in certain circumstances to stop transferring its drugs at 340B discounted prices to an unlimited number of contract pharmacies at the request of "hospital covered entities." FAC ¶ 124. This policy is particularly noteworthy, as it ***does not apply*** to any of Plaintiffs' 40 safety-net clinics—none of which are "hospital covered entities." In short, as Plaintiffs allege, no two Defendants—much less all Defendants—took "uniform" action regarding their policy changes.

b. Each Defendant announced its distinct policy changes at various points over the course of seven months—not in "near lockstep."

Plaintiffs admit that "Defendants did not announce their plans at identical times," FAC ¶ 117, but at varying intervals ***over the course of seven months***. Each announcement was widely publicized and part of a broader discussion about the government's failure to address increased waste and abuse in the 340B Program. *See id.* ¶ 115 (describing tweets by a pharmaceutical association, sent in the "wake of the executive order" and describing it as "miss[ing] the mark" and failing to "address the myriad of remaining issues" regarding 340B).

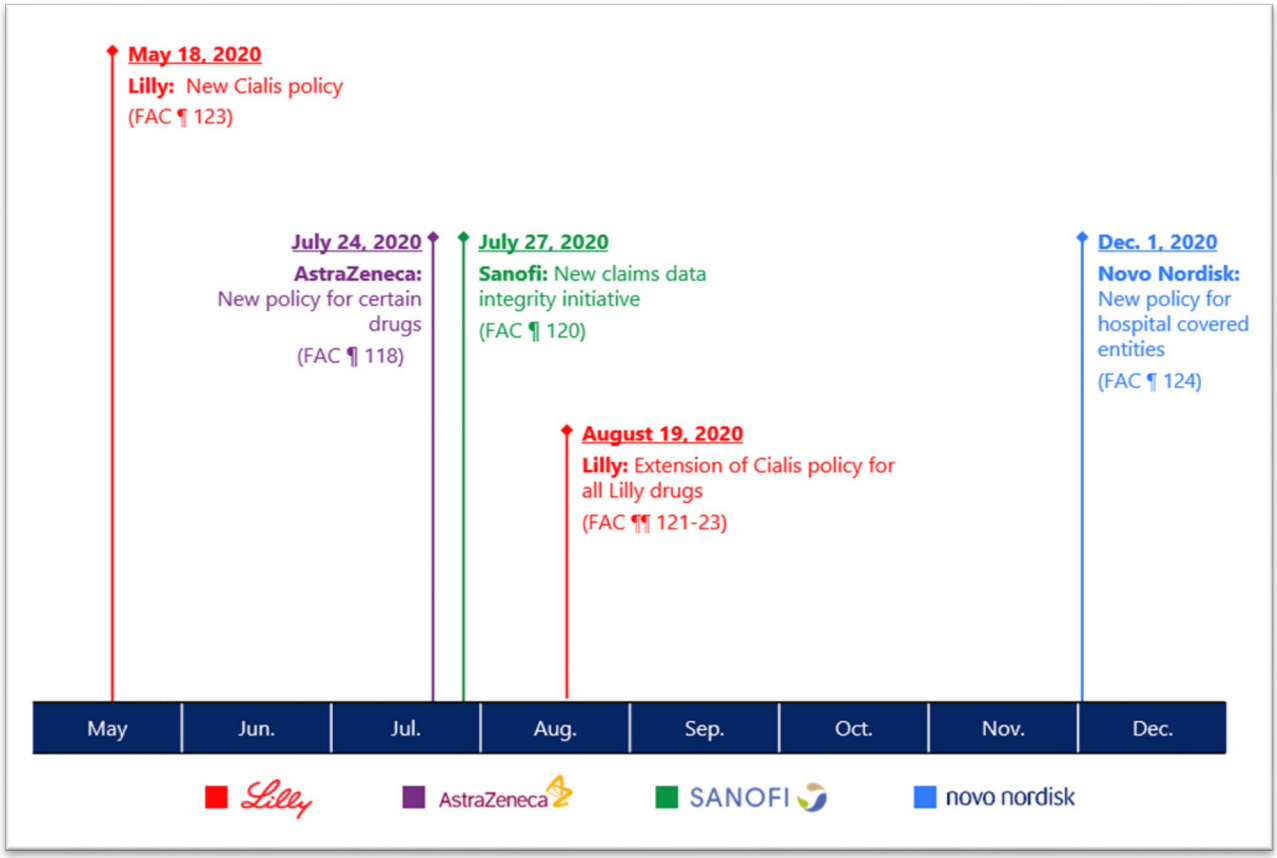
[11] Although Plaintiffs assert this exception was "commercially infeasible," their roundabout reasoning is again belied by their own allegations. Plaintiffs allege the exception was infeasible because "Lilly prevented the collection of any revenue by a covered entity to offset the dispensing fee the covered entity would have to pay the Contract Pharmacy." FAC ¶ 122. But in the same breath, Plaintiffs admit that the special exception "required the Contract Pharmacies to fill prescriptions ***without any fee whatsoever***." *Id.* (emphasis added). Lilly's exception therefore was aimed at ensuring there would be no added costs for covered entities to bear.

Once again, Plaintiffs' own allegations belie their conclusory conspiracy allegations. *See* FAC ¶¶ 118–24.

Plaintiffs allege that on May 18, 2020, Lilly "informed HHS of a [] narrow[] change" to its 340B policy, related only to "a single drug, Cialis." *Id.* ¶ 123. Plaintiffs do not allege that ***any*** other drug manufacturer (Defendant or otherwise) made similar policy changes at or around that time. Nor do Plaintiffs allege that any other drug manufacturer (again, Defendant or otherwise) made similar policy changes relating to drugs similar to Cialis.

Plaintiffs allege that two months later, on July 24, 2020, AstraZeneca informed HHS that for a subset of its products, it would "recognize one contract pharmacy per covered entity." *Id.* ¶ 118. Next, Plaintiffs allege that "within days," Sanofi announced its (entirely distinct) policy change. *Id.* ¶ 120. Three weeks later (and ***after*** AstraZeneca's and Sanofi's unique policy changes were made public), Plaintiffs allege that Lilly informed HHS of another change to its policy. Specifically, Plaintiffs plead that, on August 19, 2020, Lilly stated that it would discontinue honoring requests for 340B contract pharmacies for ***all*** Lilly products, not just Cialis, with exceptions described above. *Id.* ¶¶ 121–22.

Three months later, on December 1, 2020—over six months after Lilly's initial announcement, and after ***all*** of the above-described conduct was public—Novo disclosed that it would no longer transfer 340B discounted drugs to contract pharmacies at the request of hospital covered entities and, instead, would only deliver the drugs to the covered hospital entity itself (if it has an in-house pharmacy) or to one selected contract pharmacy (if it lacks an in-house pharmacy). FAC ¶ 124; *see also* D'Antonio Aff. at Ex. E.



As shown above, these allegations are insufficient to show parallel conduct that would support a plausible conspiracy claim. Where, as here, the allegations reveal that Defendants took decidedly different approaches at different times, they "fall far short of demonstrating parallel behavior." *Burtch*, 662 F.3d at 228 (no conspiracy claim where defendants took different actions at different times); *see also LaFlamme*, 702 F. Supp. 2d at 151 (no conspiracy claim where conduct was unique and imposed just weeks apart); *In re Late Fee & Over-Limit Fee Litig.*, 528 F. Supp. 2d 953, 962 (N.D. Cal. 2007), *aff'd*, 741 F.3d 1022 (9th Cir. 2014) (no conspiracy claim where defendants imposed different late-fee price levels at different times).

Put simply: Plaintiffs do not—and cannot—allege that all Defendants acted in the same (or similar) way or at the same (or similar) time. Plaintiffs' own complaint "undermines [their]

assertion that [D]efendants' 'parallel' conduct supports an inference of a conspiracy" to limit the 340B Program. *Anderson News, LLC v. Am. Media, Inc.*, 899 F.3d 87, 105 (2d Cir. 2018).

c. There are "obvious alternative explanations" for Defendants' purportedly "parallel" conduct.

It is well established that a conspiracy claim based on parallel conduct should be dismissed if there is an "obvious alternative explanation" for defendants' behavior. *Twombly*, 550 U.S. at 567–69. For instance, a conspiracy claim should be dismissed if it "made perfect business sense" for each defendant to engage in the challenged conduct independently, *Citigroup*, 709 F.3d at 138, or if "common economic experience, or . . . independent self-interest is an obvious alternative explanation for defendants' common behavior." *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 326 (3rd Cir. 2010); *see also In re Int. Rate Swaps Antitrust Litig.*, 261 F. Supp. 3d 430, 464 (S.D.N.Y. 2017) (concluding allegations of parallel conduct did not give rise to inference of agreement where "the pleadings [] supply good reason, as a matter of rational and competitive business strategy, for any individual [defendant to act] independently").

In *Citigroup*, for example, the plaintiff alleged that defendant financial institutions conspired to simultaneously exit a collapsing auction rate securities market. *Citigroup*, 709 F.3d at 138. The Second Circuit found that the failing market made it "unsurprising" and "expected" that defendants would independently choose to exit the market at the same time. *Id.* Indeed, the defendants' conduct in that case "made perfect business sense." *Id.* The plaintiff's conspiracy allegations were therefore insufficient to avoid dismissal under *Twombly*. *Id.* at 138–39. Similarly, in *In re Insurance Brokerage Antitrust Litigation*, the Third Circuit affirmed dismissal where an "obvious alternative explanation" for the defendants' purportedly "parallel" conduct was that each defendant believed that its profits would suffer without the challenged practice. 618 F.3d at 350.

Here, Plaintiffs' complaint provides obvious alternative explanations for Defendants' purportedly "parallel" conduct. ***First***, Plaintiffs allege that "[t]he list price for a single vial of insulin today is often more than $250." FAC ¶ 102. Under 340B, however, many products—including insulin—may be purchased "at a price of one penny per unit of measure." *Id*. Plaintiffs admit that this 99.99% discount is "steep." *Id*. Moreover, Plaintiffs allege that manufacturers must "ship[] the drug," thereby adding additional costs for the manufacturer to bear on top of the discount. *Id.* ¶ 49; *see also* Ex. B, at 3 ("Lilly does not seek to recoup the cost to manufacture or distribute penny priced insulins when they are sold to 340B covered entities"). And duplicate discounts (*i.e.*, 340B discounts plus rebates paid to Medicaid) can drive manufacturers' costs even higher.

Defendants' actions (as alleged) therefore "made perfect business sense": By revising their policies, each Defendant independently took action that would reduce the potential for abuse of the 340B Program. FAC ¶¶ 100, 118–24. Each Defendant's independent desire to address abuses by commercial pharmacies is an "obvious alternative explanation" for the purportedly "parallel" conduct. *Citigroup*, 709 F.3d at 138; *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d at 350. Indeed, because it made good business sense, Lilly instituted its policy changes for Cialis ***months earlier***. FAC ¶ 123. Plaintiffs do not and cannot allege that Lilly's Cialis-related policy change was anything but unilateral conduct.

Plaintiffs further concede that ***other*** drug manufacturers—not alleged to be co-conspirators—took similar (and likewise perfectly sensible) action. *See id.* ¶¶ 130–31 (United Therapeutics and Boehringer Ingelheim announced plans to "restrict Contract Pharmacy 340B Drug Discounts," and Merck and Novartis "asked covered entities to participate in the same [claims data] software program mandated by Sanofi"). These manufacturers do not compete in

the alleged diabetes medication markets and are not part of the purported conspiracy.[12] Thus, these independent actions confirm there are legitimate business justifications for the challenged conduct (and plainly contradict Plaintiffs' unsupported claim that Defendants' conduct is "anomalous in the pharmaceutical industry"). FAC Section III.D, ¶¶ 183, 204.

Second, Plaintiffs' allegations confirm that there are additional "obvious alternative explanations" for each Defendant's conduct. As explained above, over the last decade, the number of contract pharmacies dispensing 340B drugs has increased dramatically. There were only 1,300 contract pharmacies in 2010; by 2017, there were ***20,000***, which has resulted in over ***225,000*** arrangements between contract pharmacies and covered entities today. *See supra* at 7. This expansion has led to well-documented abuses of the program, including duplicate discounts and diversion. *See supra* at 8.

Plaintiffs allege Defendants thus lobbied the federal government "to require that all discounts be passed through to patients at the point of sale, and/or [] to restrict the availability of Contract Pharmacy 340B Drug Discounts." FAC ¶ 6. Plaintiffs concede these efforts were not new. They were aimed at the same initiatives "that the pharmaceutical industry and its advocates had long pursued." *Id.* ¶ 114; *see also* ¶ 100 (describing "long-running lobbying" campaign). Plaintiffs further admit that at least one Defendant had been monitoring audits of 340B discounts that had been taking place since 2017. *Id*. ¶ 119.

[12] Nor are Plaintiffs' allegations of injury (*i.e.*, that it has been injured through "eliminated, reduced, or limited availability of ***Contract Pharmacy 340B Drug Discounts***, specifically, through lost ***340B Savings revenues***") tied to any cognizable antitrust market in which Defendants compete with each other. *See* FAC ¶ 262 (emphasis added). "Contract Pharmacy 340B Drug Discounts" and "340B Savings revenues" are not properly defined antitrust markets in which the Defendants compete, and the Complaint is devoid of specific claims that there has been any effect on competition for the sale of the diabetes treatments sold by the Defendants.

Defendants' 340B obligations in this changing landscape were not settled. As one court recently noted, "there is more than one permissible interpretation of the 340B statute," and "[t]he statute is silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs." *AstraZeneca*, 2021 WL 2458063, at *8–9 (permitting administrative law challenge to 340B interpretation to move forward).

Ultimately, on July 24, 2020, the President issued Executive Order 13937. Although the Order confirmed that insulin discounts should be "passed through to low-income Americans," Plaintiffs allege it was "limited in scope," as it did not set forth any explicit requirements regarding how to achieve that. 85 Fed. Reg. 45,755; FAC ¶¶ 101–03. Accordingly, Plaintiffs allege "Defendants turned to another plan" to "eliminat[e] or otherwise limit[] Contract Pharmacy 340B Drug Discounts for their drugs." FAC ¶ 100; *see also* ¶ 117 ("Th[e] plan began ***as soon as*** the President's executive order was released." (emphasis added)). Stated differently, Plaintiffs allege that because the Executive Order did not concretely achieve Defendants' "long pursued" goals, it served as a stimulus or impetus for change. FAC ¶ 114.

Thus, according to Plaintiffs' own allegations, the Executive Order and the shifting and uncertain 340B landscape are additional "obvious alternative reasons" for each Defendant's independent policy changes.[13] *See LaFlamme*, 702 F. Supp. 2d at 152 (dismissing complaint where "rapidly rising jet fuel prices" were an "obvious potential 'stimuli' and 'discernible reason' aside from collusion that plausibly could have instigated independent decisions by defendants to impose surcharges"). Plaintiffs' conspiracy claims are inadequate. *Twombly*, 550 U.S. at 567–69.

[13] This context clearly contradicts Plaintiffs' unsupported claim that Defendants' policy changes were "abrupt" or "historically unprecedented." FAC ¶¶ 4, 125, 183, 199–203. Rather, they were the result of "long pursued" efforts (and an ongoing dispute over the scope of the government's regulatory authority and the statutory requirements). *Id.* ¶ 114.

2. *Plaintiffs Fail To Allege Any Plausible Plus Factors.*

Even if Plaintiffs had adequately alleged parallel conduct without obvious alternative explanations, the complaint would still fail to state a claim, as it is devoid of any plausible "plus factors." *See Twombly*, 550 U.S. at 553. The Second Circuit has set forth examples of plus factors, including: "[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." *Citigroup*, 709 F.3d at 136. Beyond conclusory assertions and boilerplate recitations, Plaintiffs fail to plead ***any*** plus factors.

a. Plaintiffs Fail To Identify A Plausible Common Motive Or Show That The Acts Were Against Defendants' Individual Self-Interest.

Plaintiffs allege that Defendants' desire to "raise prices by restricting Contract Pharmacy 340B Drug Discounts" is evidence of a "common motive to conspire." FAC ¶¶ 195–98. Plaintiffs further plead that "[i]t would have been against any single Defendant's self-interests to restrict Contract Pharmacy 340B Drug Discounts." *Id.* ¶ 184. That is because, according to Plaintiffs' allegations, any Defendant acting alone would "put its market share at risk," as covered entities would have "steer[ed] their prescribing physicians towards prescribing the competing drugs that offered Contract Pharmacy 340B Drug Discounts." *Id.* ¶¶ 63, 188. Plaintiffs' claims are unsupported and undercut by their other allegations.

To begin, Plaintiffs' theory makes no commercial sense. Plaintiffs recognize that Defendants' products—some of which ordinarily list for over $250 per vial—are often sold under 340B for about "one penny per unit." FAC ¶ 102; *accord Eli Lilly & Co. v. Cochran*, 2021 WL 981350, at *1 (S.D. Ind. Mar. 16, 2021) (recognizing the "penny per pill" reality of 340B sales). These admittedly "steep" discounts mandated by statute leave little room for Defendants to recoup their costs from manufacturing and shipping the drugs, let alone profit from 340B sales.

FAC ¶¶ 35, 49. Accordingly, Defendants faced little downside in acting unilaterally, even if that meant losing 340B sales and "market share." It makes no sense that any Defendant would want to preserve market share of one-penny sales. It is thus "implausible" that Defendants were motivated to act together when it was in each Defendant's self-interest to act alone to limit the availability of these steep discounts where not required by law. *Kramer v. Pollock-Krasner Found.*, 890 F. Supp. 250, 256 (S.D.N.Y. 1995) (discounting motive allegation when it was based on "implausible" economic story).

That Defendants' policies apply to more than just their diabetes-related products confirms this conclusion: Other manufacturers compete in those markets, yet they are not alleged to have made similar policy changes. If it were truly an "all-or-nothing" situation as Plaintiffs posit—with the manufacturers in the relevant "market" all needing to act together—then Defendants would not have implemented their policies for non-diabetes drugs without all competing manufacturers in those other "markets" also doing the same. Particularly for AstraZeneca, whose alleged share of "the incretin mimetics market" is just five percent, FAC ¶ 87, it would make no sense to jeopardize sales on the rest of its drug portfolio—yet that is Plaintiffs' illogical theory. On the flip side, the fact that Plaintiffs admit at least ***four other*** manufacturers announced their own 340B restrictions (not pursuant to the alleged conspiracy) further confirms that Defendants' acts were ***not*** against their individual economic self-interest. *Id.* ¶ 130–31.

Plaintiffs' theory also falls apart upon a closer review of the distinct policy changes at issue. Plaintiffs allege that "[i]f a single Defendant restricted Contract Pharmacy 340B Drug Discounts on its drug," then covered entities "could have taken steps to steer their prescribing physicians towards prescribing the competing drugs" that offered the discounts. *Id.* ¶ 188. By contrast, Plaintiffs claim, if all Defendants acted together "by restricting Contract Pharmacy 340B

Drug Discounts," then they could "earn higher profits" "without decreasing any Defendant's sales or market share." *Id*. ¶ 196. As a preliminary matter, merely alleging that Defendants sought to "earn higher profits" is not enough to sustain a conspiracy claim. *See In re Late Fee & Over-Limit Fee Litig.*, 528 F. Supp. 2d at 964 ("[I]f 'a motive to achieve higher prices' were sufficient, every company in every industry could be accused of conspiracy because they all 'would have such a motive.'" (citation omitted)). But in any event, Novo's policy ***does not restrict*** many covered entities, including clinics like Plaintiffs, in any way. Plaintiffs cannot explain why they and other non-hospital covered entities still cannot "steer" prescriptions to Novo's drugs for the discount price, contrary to their claim that Defendants' "conspiracy" prevented doing just that. *Id*. ¶ 188. Nor, for that matter, do Plaintiffs explain why covered entities could not similarly steer their patients to Sanofi's drugs, simply by agreeing to provide minimal claims data, as Sanofi otherwise does not limit the use of contract pharmacies.

b. Plaintiffs Have Not Pled A "High Level" of Interfirm Communications.

Plaintiffs assert that "Defendants had ample opportunity to conspire and were engaged in high levels of communications in advance of their imposition of restrictions." FAC ¶ 217. Under settled Second Circuit law, however, allegations based on a "mere opportunity to conspire" do not "support the inference that [] an illegal combination actually occurred." *Gamm v. Sanderson Farms, Inc.*, 944 F.3d 455, 466 (2d Cir. 2019); *see also Pro Music*, 2020 WL 7406062, at *7 (dismissing complaint where it "d[id] not allege particulars" and only alleged "substantial opportunities to communicate and collude[,] and [that] certain forums provide[d] [defendants] with ample opportunity to [conspire]"); *In re Inclusive Access Course Materials Antitrust Litigation*, 2021 WL 2418333, at *10 (S.D.N.Y. June 14, 2021) (rejecting allegation that "trade association [] served as a convenient forum for [] conspiratorial planning" because a "description of

opportunities to conspire . . . does not raise the inference that [defendants] actually engaged in any unlawful activity").

Plaintiffs allege just two (unsurprising) facts in support of their "opportunity to conspire" theory: (1) each Defendant is a member of the Board of the trade association PhRMA (along with many other non-Defendants); and (2) Defendants "used common lobbyists." FAC ¶¶ 111, 113, 218–19. Beyond this, Plaintiffs cite no specific dates or times of any purported meetings where communications supposedly occurred. In fact, Plaintiffs do not even summarily allege that any specific discussion ever actually occurred; rather, they merely plead that such conversations were "likely." *See*, *e.g.*, *id.* ¶ 219 ("Defendants, as PhRMA Board members, ***likely*** communicated among themselves about … 340B Drug Discounts." (emphasis added)); *id*. ¶ 113 ("It is much more ***likely*** that Defendants were also communicating directly about their lobbying strategies with their common lobbyists." (emphasis added)).

In other words, Plaintiffs ask this Court to infer extensive communications in order to draw a further inference of an agreement. Such a leap—based solely on speculation that Defendants' legitimate lobbying efforts and participation in trade associations gave them an "opportunity to conspire"—is not enough.[14] *Id.* ¶ 217. The Second Circuit has confirmed that much more is required; in *Citigroup*, the complaint made "two vague references to isolated discussions"—*i.e.*, even ***more*** than Plaintiffs allege here—but the Court held those "are not enough plausibly to allege a 'high level' of interfirm communications." 709 F.3d at 139–40. Similarly, this Court has indicated that it is not enough merely to "allege that Defendants' membership in trade associations *could* have been a means for them to make an agreement." *Miami Products & Chemical Co. v.*

[14] Moreover, as noted, such communications are plainly protected and immune from antitrust liability under *Noerr-Pennington*. *See supra* at 22.

Olin Corporation, et al., 449 F. Supp. 3d 136, 164-65 (W.D.N.Y. 2020) (Wolford, J.) (emphasis in original) (denying motion to dismiss where plaintiffs tied specific meetings among defendants to announcements of price increases on multiple dates over the course of years). Plaintiffs' allegations pale in comparison to those cases: In sharp contrast with the plaintiffs in *Miami Products*, Plaintiffs point to no specific meetings or communications between Defendants, but rather merely allege that their trade association and lobbying efforts generally *could* have led to an agreement. Such speculative and vague allegations "are a far cry from cases in which courts have found high levels of interfirm communications to be a plus factor that made an alleged agreement plausible." *Pro Music*, 2020 WL 7406062, at *7.

In sum, Plaintiffs' allegations, even taken together, fail to establish plus factors sufficient to support a conspiracy inference.[15] Plaintiffs' conspiracy claims should be dismissed.

III. PLAINTIFFS' CLAIMS ARE AN IMPROPER ATTEMPT TO END-RUN *ASTRA* AND ADJUDICATE AN ALLEGED VIOLATION OF THE 340B STATUTE.

Plaintiffs' claims also cannot proceed for the independent reason that they are an improper attempt to circumvent the fact that "Congress authorized no private right of action under § 340B for covered entities." *Astra*, 563 U.S. at 113. Plaintiffs allege that Defendants' contract pharmacy policies have made it more difficult for them to "access" drugs at the 340B price. But as the Supreme Court recognized, Congress exclusively vested HHS with authority to oversee the 340B Program "and assigned no auxiliary enforcement role to covered entities." *Id.* at 117. Because this suit is an impermissible attempt to enforce 340B (by dressing it up in antitrust and unjust

[15] Plaintiffs' stray references to other litigation and investigations—which they concede are entirely "[s]eparate and apart from" the 340B allegations here—also do not state a plausible plus factor. FAC ¶¶ 220–22. "[A]bsent any evidence of linkage" between the outside proceedings and the conduct alleged here, such allegations "provide an insufficient factual basis" to support a conspiracy claim. *In re Elevator Antitrust Litig.*, 502 F.3d at 52.

enrichment clothing), Plaintiffs' complaint should be dismissed with prejudice. *See Broder v. Cablevision Sys. Corp.*, 418 F.3d 187, 198 (2d Cir. 2005) (holding that plaintiff could not attempt to show a "violation of a federal law under which no private right of action exists" by pleading alternative causes of action).[16]

A. Plaintiffs' "Price Fixing" Theory Is Barred Under *Astra* Because It Is Really Just A 340B Violation Claim In Disguise.

Plaintiffs allege in cursory fashion that Defendants have "increas[ed] prices," FAC ¶ 258, and "artificially fix[ed] the prices of drugs," *id.* ¶ 257. But Plaintiffs do not actually allege that ***any*** Defendant ever charged more than their standard retail or wholesale (*i.e.*, competitive) prices. Nor do they allege that Defendants conspired to manipulate the non-market 340B prices. As Plaintiffs admit, the statutory ceiling prices are set through a "mathematical formula" specified in the statute, *see id*. ¶¶ 3, 32, not through competitive market forces. Stated differently, Plaintiffs do not actually allege Defendants agreed to fix (or limit competition regarding) any price at all—which is the very "essence of price fixing." *Major League Baseball Props., Inc. v. Salvino, Inc.*, 542 F.3d 290, 335 (2d Cir. 2008) (Sotomayor, J., concurring).

Fairly deciphered, Plaintiffs' claims allege (and thus depend on proving and awarding relief that recognizes) that Defendants have violated the 340B statute. Plaintiffs' theory is that Defendants conspired to adopt policies that limit the circumstances under which they will transfer their drugs at the statutorily-set, non-market prices to commercial pharmacies. *See id*. ¶¶ 3–4, 118, 120–21, 124. But Plaintiffs do not deny that each Defendant continues to offer drugs for purchase by covered entities at the 340B prices in any quantity. Nor do Plaintiffs seek to access the "fair

[16] As noted above, other suits brought by covered entities in an attempt to end-run *Astra* have been dismissed or stayed in favor of administrative enforcement. *See*, *e.g.*, *Am. Hosp. Ass'n*, 2021 WL 616323, at *4–5.

market" or "competitive" prices of Defendants' drugs, as is typical in a price-fixing case. Indeed, the irony here is that Plaintiffs purport to bring a "price fixing" claim, yet the relief they seek is ***not*** for Defendants to set their own competitive, market-based prices, but instead for Defendants' prices to be fixed in more circumstances. That is, Plaintiffs seek to impose an obligation on manufacturers to deliver drugs to an unlimited number of contract pharmacies at the 340B-discounted price. *Id*. ¶¶ 47–51.

Most telling is Plaintiffs' requested relief. Although the requested injunction is not clearly defined, Plaintiffs apparently seek an order requiring Defendants to ***withdraw*** their recent contract pharmacy policies, and to ***resume*** shipping 340B-discounted drugs to an unlimited number of contract pharmacies, without limitation. In other words, Plaintiffs ask this Court to find that Defendants' policies violate the statute and order Defendants to transfer their 340B-discounted drugs to contract pharmacies. But Plaintiffs have no right to access manufacturers' drugs at non-market statutory ceiling prices ***except under the specific terms provided in the 340B statute***. Plaintiffs' claims and requested relief are thus predicated on a question of statutory enforcement: In requiring manufacturers to "offer" their drugs at discounted prices to covered entities, *see* 42 U.S.C. § 256b(a)(1), does the 340B statute impose an additional obligation on manufacturers to deliver those drugs to an unlimited number of commercial pharmacy locations around the country?[17] Under *Astra*, private entities like Plaintiffs cannot raise this 340B enforcement question here. 563 U.S. at 113.

Indeed, "[t]hough labeled differently," Plaintiffs' purported antitrust claims are "in substance one and the same" as a "suit[] to enforce § 340B." *Id*. at 114. "Their treatment,

[17] As noted, this statutory question is at the heart of numerous cases already being litigated against the government in courts across the country.

therefore, must be the same, '[n]o matter the clothing in which [covered] entities dress their claims.'" *Id*. (citation omitted).

B. The Antitrust Laws *In Particular* Cannot Be Used To Side-Step *Astra*.

Courts have long recognized that parties cannot employ novel legal theories to enforce statutes that do not provide a private right of action. *See Conboy v. AT&T Corp.*, 241 F.3d 242, 257–58 (2d Cir. 2001) (affirming dismissal of claim under New York's deceptive business practices statute attempting to enforce a provision of the statute with no private right of action); *Broder*, 418 F.3d at 198–99 (similar). These principles apply with particular force to conspiracy statutes, including the antitrust laws and RICO. *See Norman v. Niagara Mohawk Power Corp.*, 873 F.2d 634, 637 (2d Cir. 1989) ("Artful invocation of controversial civil RICO [conspiracy claim], particularly when inadequately pleaded, cannot conceal the reality that the gravamen of the complaint herein is section 210 harassment."); *Siegel Transfer, Inc. v. Carrier Express, Inc.*, 856 F. Supp. 990, 1009 (E.D. Pa. 1994) (holding that a plaintiff cannot circumvent a federal statute's "enforcement provisions by labelling their claim as one for civil conspiracy").

For good reason. It is well settled that "[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue," which includes "an awareness of the significance of regulation." *Verizon Commcn's Inc. v. Law Offices of Curtis V. Trinko LLP*, 540 U.S. 398, 411 (2004). Because economic regulations and antitrust laws often serve "similar goals," "antitrust analysis must sensitively 'recognize and reflect the distinctive economic and legal setting' of the regulated industry to which it applies." *Town of Concord, Mass. v. Boston Edison Co.*, 915 F.2d 17, 22 (1st Cir. 1990) (citation omitted).

The need to take account of an underlying regulatory regime is especially important where, as here, the governing statute regulates prices and provides administrative remedies for alleged overcharges. *See* 42 U.S.C. § 256b(a)(1), (d)(3)(B); *Astra*, 563 U.S. at 121 ("Congress directed

HRSA to create a formal dispute resolution procedure, institute refund and civil penalty systems, and perform audits of manufacturers."). Courts have thus held, for example, that when a federal agency authorizes a specified rate, private party antitrust suits related to that rate are barred. *Cf. Rothstein v. Balboa Ins. Co.*, 794 F.3d 256, 262–63 (2d Cir. 2015) (filed-rate doctrine precludes judicial decisions that indirectly require determining the reasonableness of rates; rejecting antitrust claims that "invite judicial meddling in issues of insurance policy" as "forbidden under the principle of nonjusticiability").

Here, similarly, Plaintiffs' antitrust theory cannot stand because it is "hopelessly intertwined" with the 340B statutory requirements. *Wegoland Ltd. v. NYNEX Corp.*, 27 F.3d 17, 21 (2d Cir. 1994). Plaintiffs have no right to access drugs at non-market prices, except under the terms set forth in the 340B statute, and federal regulators have the exclusive authority to enforce purported violations in court. *See Astra*, 563 U.S. at 115–16. Moreover, in establishing a 340B rate, Congress has "forsworn the paradigm of competition." *In re Stock Exchange Options Trading Antirust Lit.*, 317 F.3d 134, 147 (2d Cir. 2003) (recognizing that antitrust laws do not apply "when the regulatory scheme is so pervasive that Congress must be assumed to have forsworn the paradigm of competition"). Thus, adjudicating Plaintiffs' purported "antitrust" claims would "displace and distort the regulatory process." *Rothstein*, 794 F.3d at 263; *see also Verizon Commcn's*, 540 U.S. at 415 (holding "[i]t would be a serious mistake to conflate the [] goals" of a regulatory scheme and the antitrust laws, and to permit the antitrust claim to proceed). Adjudicating Plaintiffs' claims would also interfere with pending government litigation over what 340B requires.

Plaintiffs' attempt to side-step *Astra* should accordingly be dismissed with prejudice. *See, e.g.*, *Conboy*, 241 F.3d at 257–58 (affirming dismissal where plaintiff attempted to couch a claim

based on a statutory provision without a private right of action as a deceptive business act claim under a different provision); *Broder v Cablevision Sys. Corp.*, 329 F. Supp. 2d 551, 560 (S.D.N.Y. 2004) (dismissing claims with prejudice and 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" (internal citations omitted)).

IV. EACH OF PLAINTIFFS' STATE-LAW CLAIMS FAIL.

Under Counts II and III, Plaintiffs allege a kitchen-sink of claims under state antitrust statutes and unjust enrichment laws, all listed without elaboration in a few cursory paragraphs. *See* FAC ¶¶ 271, 275. These undeveloped claims should be dismissed on multiple grounds.

A. Like Plaintiffs' Federal Antitrust Claim, Their State Antitrust Claims Fail Because Plaintiffs Have Not Plausibly Alleged A Conspiracy.

Relying on the same alleged conduct as their federal antitrust claim, Plaintiffs allege violations of 26 states' antitrust statutes. *Id.* at ¶¶ 266–72. Fatally for these claims, however, each of the relevant state statutes requires plausible allegations of a conspiracy to restrain trade, as Plaintiffs acknowledge. *See id.* ¶ 271 (alleging that Defendants violated "the following State laws" through "a contract, combination, or conspiracy in restraint of trade"). Indeed, it is well-settled that these state statutes are to be interpreted in accordance with corresponding federal law. *See*, *e.g.*, *In re Magnesium Oxide Antitrust Litig.*, 2011 WL 5008090, at *7 n.9 (D.N.J. Oct. 20, 2011) (dismissing state antitrust claims and explaining that the following state antitrust statutes "are construed in accordance with federal antitrust principles": Arizona, California, District of Columbia, Illinois, Iowa, Kansas, Maine, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin); *Vacco v. Microsoft Corp.*, 260 Conn. 59, 65 (Conn. 2002) (same as to Connecticut); Md. Code, Com. Law § 11-202(a)(2) (same as to

Maryland); R.I. Gen. Laws § 6-36-2(b) (same as to Rhode Island). Accordingly, for the reasons stated above in Section II, this Court should dismiss all of Plaintiffs' state antitrust claims.[18]

B. Plaintiffs' Common-Law Unjust Enrichment Claims Also Fail.

Plaintiffs' complaint also includes unjust enrichment claims under the common law of 47 states and the District of Columbia. *See* FAC ¶¶ 273–79. These claims should be dismissed for at least five independent reasons.

First, Plaintiffs' "copy-and-paste" approach to their unjust enrichment claims fails to meet basic pleading requirements. In *Miami Products & Chemical Company v. Olin Corporation*, this Court recently dismissed similar unjust enrichment claims under the laws of 48 states and the District of Columbia where the plaintiff relied on "generic pleading" and made no attempt to allege the specific unjust enrichment elements required by each state. 2021 WL 2588090, at *13 (Wolford, J.) (noting that state unjust enrichment requirements "vary widely"). As this Court explained, plaintiffs "cannot simply enumerate a long list of state-law claims for states where they might otherwise have no available antitrust recovery and rely on the defendants and the court to sort out whether or how those laws can act as surrogates for antitrust law." *Id*. (quoting *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 255–56 (D. Conn. 2015) (similarly dismissing a hodge-podge of unjust enrichment claims that were "listed" but not "truly pleaded")).

[18] Plaintiffs' antitrust claims under New Hampshire law should be dismissed for the additional reason that New Hampshire bars antitrust suits by indirect purchasers like Plaintiffs. *See supra* Section I; *In re Keurig Green Mountain Single-Serve Coffee Antitrust Litig.*, 383 F. Supp. 3d 187, 263 (S.D.N.Y. 2019) (New Hampshire has "expressly adopted the *Illinois Brick* rule against indirect purchaser suits"). And Plaintiffs' antitrust claims under Illinois law should be dismissed because "the Illinois Antitrust Act bars indirect purchaser class actions." *In re Loestrin 24 FE Antitrust Litig.*, 410 F. Supp. 3d 352, 371–72 (D.R.I. 2019) (dismissing indirect purchaser class action claims under Illinois Antitrust Act); 740 Ill. Comp. Stat. 10/7(2) ("[N]o person shall be authorized to maintain a class action in any court of this State for indirect purchasers.").

The same result is warranted here. Like the plaintiffs in *Miami Products*, Plaintiffs here plead that the same "factual foundation" underlying their antitrust claims is "also actionable" as unjust enrichment. 2021 WL 2588090, at *13; FAC ¶¶ 273–74. Rather than "truly pleading" those unjust enrichment claims, Plaintiffs rely on a "long list" of boilerplate, conclusory assertions that Defendants have violated 48 different jurisdictions' unjust enrichment laws. *Miami Prods.*, 2021 WL 2588090, at *13; FAC ¶ 275. These "bald assertion[s] that the alleged antitrust conduct violates dozens of non-antitrust laws" are "not entitled to deference," nor are they "sufficient to satisfy Rule 8 under *Twombly* and *Iqbal*." *In re Aggrenox*, 94 F. Supp. 3d at 255–56; *see also Miami Prods.*, 2021 WL 2588090, at *14 ("This is the type of formulaic, conclusory pleading that *Twombly* and *Iqbal* are meant to eliminate.").[19]

Second, the unjust enrichment claims fail because they are duplicative of Plaintiffs' antitrust claims. In *In re Novartis & Par Antitrust Litigation*, the court held that the unjust enrichment claims failed because they were "unnecessary and duplicative of" the state antitrust claims and would "rise and fall with [the] statutory claims." 2019 WL 3841711, at *7 (S.D.N.Y. Aug. 15, 2019); *accord Rochester Drug Co-op.*, 130 F. Supp. 3d at 781 (dismissing "remaining claims . . . premised on [] assertion that [d]efendant's conduct violated the [state antitrust] Act" with prejudice because plaintiff did "not adequately ple[a]d a claim for relief under the [state antitrust] Act").

[19] Complicating these defects is that Plaintiffs purport to represent a ***nationwide*** class for their unjust enrichment claims. FAC ¶¶ 243–44. There is no "plausible source of federal substantive law from which an unjust enrichment claim would arise." *In re Dollar Gen. Corp. Motor Oil Mktg. & Sales Practices Litig.*, 2017 WL 3863866, at *5 (W.D. Mo. Aug. 3, 2017). Nor have Plaintiffs attempted to allege why, for example, New York's unjust enrichment law applies to putative class members who reside in 49 other states and jurisdictions.

Here too, Plaintiffs' unjust enrichment claims are duplicative. Plaintiffs incorporate all allegations supporting their antitrust claims into the unjust enrichment count, and then contend in boilerplate fashion that Defendants have "benefited from the above-described conduct at the expense of Plaintiffs and the Class" and have "deprive[d]" them of 340B discounts. FAC ¶¶ 273–75. Plaintiffs then simply recite the purported elements of 48 jurisdictions' unjust enrichment laws while failing to allege any facts or circumstances that independently support such claims. Accordingly, the unjust enrichment claims "are unnecessary and duplicative of [Plaintiffs'] statutory claims" and should be dismissed. *In re Novartis & Par Antitrust Litig.*, 2019 WL 3841711, at *7; *see also In re Ford Tailgate Litig.*, 2014 WL 1007066, at *5 (N.D. Cal. Mar. 12, 2014) (dismissing unjust enrichment claims as duplicative because they "relie[d] upon the same factual predicate" as statutory claims); *In re Milo's Dog Treats Consol. Cases*, 9 F. Supp. 3d 523, 544 (W.D. Pa. 2014) (dismissing unjust enrichment claims as duplicative because they "rest[ed] on the same facts" and sought the same relief as statutory claims); *Licul v. Volkswagen Grp. of Am., Inc.*, 2013 WL 6328734, at *7 (S.D. Fla. Dec. 5, 2013) (dismissing unjust enrichment claim as duplicative because it constituted "a vague catch-all that does no more than incorporate by reference the alleged wrongdoing already addressed by their other legal causes of action"); *In re Apple & AT&T iPad Unlimited Data Plan Litig.*, 802 F. Supp. 2d 1070, 1077 (N.D. Cal. 2011) (dismissing unjust enrichment claims as duplicative of statutory claims).

Third, Plaintiffs' unjust enrichment claims are deficient because they do not adequately plead that Plaintiffs conferred a benefit on Defendants. Although unjust enrichment laws vary, "almost all states at minimum require plaintiffs to allege that they conferred a benefit or enrichment upon defendant." *In re Digital Music Antitrust Litig.*, 812 F. Supp. 2d 390, 411 (S.D.N.Y. 2011) (quotation marks omitted).

Here, Plaintiffs do not even ***attempt*** to plead this basic and necessary element for many states. *Compare, e.g.*, FAC ¶ 275(a), (d), (g), (h), (u) (no allegations that Plaintiffs conferred a benefit on Defendants with respect to claims under the laws of Alabama, Arkansas, Connecticut, District of Columbia, Massachusetts, and Michigan) *with Matador Holdings, Inc. v. HoPo Realty Invs.*, 77 So. 3d 139, 145 (Ala. 2011) (must plead plaintiff conferred a benefit under Alabama law); *Trickett v. Spann*, 613 S.W.3d 773, 777 (Ark. Ct. App. 2020) (same under Arkansas law); *Sanchez-Ballesteros v. Anderson*, 2010 WL 3328331, at *8 (Conn. Super. Ct. Aug. 3, 2010) (same under Connecticut law); *Falconi-Sachs v. LPF Senate Square, LLC*, 142 A.3d 550, 556 (D.C. 2016) (same under D.C. law); *Stewart Title Guar. Co. v. Kelly*, 146 N.E.3d 1142, 1151 (Mass. App. Ct. 2020) (same under Massachusetts law); *Bellevue Ventures, Inc. v. Morang-Kelly Inv., Inc.*, 836 N.W.2d 898, 901 (Mich. Ct. App. 2013) (same under Michigan law). And even where Plaintiffs halfheartedly attempt to satisfy this pleading requirement, the allegations merely "parrot[]" the element and thus are plainly insufficient. *Rinehart v. Lehman Bros. Holdings Inc.*, 817 F.3d 56, 67 (2d Cir. 2016); *see* FAC ¶ 275(b) (Alaska: "Plaintiffs conferred a benefit upon Defendants"); *see also* FAC ¶ 275(j), (k), (l), (m), (p), (s), (t), (y), (dd), (gg), (kk), (ll), (mm), (oo), (qq), (ss), (tt), (vv) (same as to Florida, Georgia, Hawaii, Indiana, Kansas, Maine, Maryland, Missouri, New Jersey, North Carolina, Pennsylvania, Rhode Island, South Carolina, Tennessee, Utah, Virginia, Washington, and Wisconsin).

Fourth, Plaintiffs assert unjust enrichment claims under the laws of California, Illinois, Mississippi, and New Hampshire, but those states do not recognize an independent cause of action for unjust enrichment. *See In re Apple and AT&T iPad Unlimited Data Plan Litig.*, 802 F. Supp. 2d at 1077 ("[C]ourts have repeatedly held that 'there is no cause of action in California for unjust enrichment'"); *Toulon v. Cont'l Cas. Co.*, 877 F.3d 725, 741 (7th Cir. 2017) ("Unjust enrichment

does not constitute an independent cause of action" under Illinois law) (citation omitted); *Cole v. Chevron USA, Inc.*, 554 F. Supp. 2d 655, 671 (S.D. Miss. 2007) (dismissing unjust enrichment claims because "[u]nder Mississippi law, unjust enrichment is not an independent theory of recovery") (citation omitted); *General Insulation Co. v. Eckman Const.*, 992 A.2d 613, 621 (N.H. 2010) ("[U]njust enrichment generally does not form an independent basis for a cause of action.") (citation omitted). As a result, Plaintiffs' unjust enrichment claims under those states' common laws must be dismissed.

Fifth, Plaintiffs do not have standing as indirect purchasers to bring their unjust enrichment claims under the laws of Alaska, Arkansas, Colorado, Delaware, Florida, Georgia, Idaho, Indiana, Kentucky, Louisiana, Massachusetts, Missouri, Montana, New Hampshire, New Jersey, Oklahoma, Pennsylvania, South Carolina, Virginia, and Washington. *See supra* Section I. "The majority of courts in this circuit have followed the rule that indirect purchasers may not allege autonomous unjust enrichment claims if that state follows *Illinois Brick*." *Sergeants Benevolent Assoc. Health & Welfare Fund v. Actavis, plc*, 2018 WL 7197233, at *57 (S.D.N.Y Dec. 26, 2018). Accordingly, Plaintiffs' unjust enrichment claims must be dismissed under the laws of all states that follow *Illinois Brick*. *See United Food & Commercial Workers Local 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1089–90 (N.D. Cal. 2014) (dismissing unjust enrichment claims under twenty-four state laws because plaintiff "cannot circumvent the *Illinois Brick* prohibition absent authority from the courts of those states"); *see also Miami Prods.*, 2021 WL 2588090 at *5 ("[A]ny state that has not expressly passed *Illinois Brick* repealer legislation or interpreted its law in such a way as to override the rule of *Illinois Brick* is presumed to have decided to follow federal law, including the *Illinois Brick* limitation on indirect purchaser claims.") (citation omitted).

Plaintiffs' common-law unjust enrichment claims must similarly be dismissed in states that ban common-law recovery by indirect purchasers. These states are Alabama, Alaska, Arkansas, Colorado, Connecticut, Delaware, Florida, Georgia, Idaho, Illinois, Indiana, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Missouri, Montana, New Hampshire, New Jersey, North Dakota, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Texas, Virginia, and Washington.[20]

[20] *See In re Novartis and Par Antitrust Litig.*, 2019 WL 3841711, at *6 (dismissing indirect purchaser unjust enrichment claims based on laws of Alabama, Florida, Georgia, Idaho, Kentucky, Maine, Michigan, New Jersey, North Dakota, Pennsylvania, and Rhode Island); Alaska Stat. Ann. § 45.50.577(i); Ark. Code Ann. § 4-75-315(B); Colo. Rev. Stat. Ann. § 6-4-111(2); *In re Niaspin Antitrust Litig.*, 42 F. Supp. 3d 735, 764 (E.D. Pa. 2014) (indirect purchasers cannot bring suit under Connecticut Antitrust Act or Unfair Trade Practices Act); *In re K-Dur Antitrust Litig.*, 2008 WL 2660780, at *5 (D.N.J. Feb. 28, 2008) (indirect purchasers cannot bring damages claims under Delaware antitrust laws and cannot circumvent bar by recasting as unjust enrichment claim); *Berghausen v. Microsoft Corp.*, 765 N.E.2d 592, 594 (Ind. Ct. App. 2002) (indirect purchaser lacks standing under Indiana antitrust law); *In re Flonase Antitrust Litig.*, 692 F. Supp. 2d 524, 544–45 (E.D. Pa. 2010) (indirect purchasers cannot recover under Illinois Antitrust Statute or unjust enrichment claim); *Sheet Metal Workers Loc. 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, 737 F. Supp. 2d 380, 436, 442, 446–47 (E.D. Pa. 2010) (indirect purchasers precluded under *Illinois Brick* from bringing unjust enrichment claims under Kentucky, Oklahoma, and Texas law); Md. Code Ann., Com. Law § 11-209(b); *Free v. Abbott Lab'ys, Inc.*, 176 F.3d 298, 301 (5th Cir. 1999) (indirect purchasers lack standing to bring Louisiana antitrust claim); *Winters v. Ocean Spray Cranberries, Inc.*, 296 F. Supp. 3d 311, 324–25 (D. Mass 2017) (Massachusetts antitrust law precludes indirect purchaser suits) (citing *Ciardi v. F. Hoffmann-La Roche, Ltd.*, 436 Mass. 53 (2002)); *In re Lithium Ion Batteries Antitrust Litig.*, 2014 WL 4955377, at *19 (N.D. Cal. Oct. 2, 2014) (indirect purchasers may not bring antitrust claims under Missouri antitrust statute); *In re Cathode Ray Tube (Crt) Antitrust Litig.*, 2010 WL 11488485, at *2 (N.D. Cal. Sept. 30, 2010) (noting Montana has not repealed *Illinois Brick* and "the private standing provision" of state antitrust statute is substantially identical to federal law); *LaChance v. U.S. Smokeless Tobacco Co.*, 931 A.2d 571, 576–77 (N.H. 2007) (indirect purchasers do not have standing under New Hampshire antitrust law); *In re Wiring Device Antitrust Litig.*, 498 F. Supp. 79, 86–88 (E.D.N.Y. 1980) (South Carolina follows *Illinois Brick* and limits recovery under state antitrust statute to direct purchasers); *In re TFT-LCD (Flat Panel) Antitrust Litig.*, 599 F. Supp. 2d 1179, 1191–92 (N.D. Cal. 2009) (dismissing Virginia and Montana unjust enrichment claims because plaintiffs cannot circumvent limitations of state antitrust laws); *Blewett v. Abbott Laboratories*, 86 Wash. App. 782, 788–89 (1997) (private indirect purchasers may not bring claim under Washington law).

C. As Individual Plaintiffs, Mosaic and CVHS Cannot Bring Claims Under The Laws Of States Other Than New York And Virginia.

Plaintiffs assert a nationwide class. FAC ¶¶ 243–44. But Mosaic and CVHS are wholly New York and Virginia entities, respectively, without activities in other states. Thus, neither Mosaic nor CVHS can maintain state claims on their own behalf under laws of any states other than New York or Virginia. The complaint states that Mosaic is a New York organization based in Rochester, New York and includes 22 New York clinics. *See id*. ¶ 9. And CVHS concedes its principal place of business is in New Canton, Virginia and includes 18 Virginia clinics. *Id*. ¶ 10. Plaintiffs do not allege they have any presence or activity in any other state. Nor do they provide any basis to conclude that a non-resident plaintiff with no connection to any state other than New York or Virginia may sue under another state's laws to challenge out-of-state conduct by non-resident defendants. Thus, Plaintiffs fail to state claims on their own behalf under the laws of states other than New York or Virginia, warranting dismissal of their individual non-New York and non-Virginia state-law claims, respectively. *See*, *e.g.*, *Richards v. Direct Energy Servs., LLC*, 915 F.3d 88, 106 (2d Cir. 2019) (affirming dismissal of named plaintiff's own claims under Rule 12(b)(6) because he "could not sue ***on his own behalf***" under the relevant state law even if he could represent a class under such law (emphasis added)); *Mayor of Baltimore v. Actelion Pharms. Ltd.*, 995 F.3d 123, 133–34 (4th Cir. 2021) (individual named "plaintiffs may not seek relief for ***their own injuries***" under other states' statutes without showing they have statutory standing (emphasis added)).

CONCLUSION

For the reasons discussed above, Defendants respectfully request that the Court grant their joint motion dismiss Plaintiffs' complaint in its entirety with prejudice.

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