UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF NEW YORK

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

Plaintiffs,

vs.

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

Defendants.

6:21-cv-6507 (EAW)

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR LEAVE TO FILE A SECOND AMENDED COMPLAINT

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PRELIMINARY STATEMENT

Plaintiffs move for leave to amend to address the Court's September 2, 2022 decision granting Defendants' motion to dismiss.

This antitrust case seeks redress on behalf of safety-net healthcare providers who provide care to the uninsured and underinsured. Such providers, including Plaintiffs Mosaic Health, Inc. and Central Virginia Health Services, Inc., have been seriously injured by collusion among Defendants Sanofi-Aventis, U.S. (Sanofi), Eli Lilly and Company and Lilly USA, LLC (Eli Lilly), Novo Nordisk Inc. (Novo Nordisk), and AstraZeneca Pharmaceuticals LP (AstraZeneca). Those four drug-makers controlled the markets for diabetes medications that are critical to the patient populations served by Plaintiffs and all safety-net providers. Defendants used their collective domination of those critical markets to decimate a longstanding discount channel for drug sales, discounts called Contract Pharmacy 340B Drug Discounts.[1] Together, Defendants choreographed the restriction of the overwhelming bulk of drug sales through that discount channel.

By acting together, Defendants achieved what would have been impossible acting alone. They were able to clamp down on discounts without significantly endangering their respective market shares because all four market players moved soon enough in time to avoid effective price competition. And Defendants were likewise able to dodge a severe regulatory sanction that could have feasibly punished any one of them for terminating those discounts, but could not feasibly have been used to punish all four of them jointly. Defendants profited at the expense of covered entities, like Plaintiffs, who collectively lost access to billions of dollars of drug discounts.

[1] This memorandum incorporates terms defined in the Amended Complaint, Dkt. 41.

Through their motion to dismiss, Defendants persuaded the Court to dismiss Plaintiffs' (First) Amended Complaint (FAC) on the grounds that the FAC did not adequately allege that Defendants' concerted action "had the same or even similar impacts on the availability" of their discounts. Opinion at 16, Dkt. 71 (Opinion). Defendants pressed these arguments by characterizing their policies on restrictions as much more permissive than they actually are and much more permissive than pled in the FAC, suggesting minimal impact on drug discount availability. For instance, Defendants argued that Sanofi's policy had no impact on most 340B providers because it required only "five minutes" of work for providers to receive discounts. Defs. Reply at 9, Dkt. 66 (Reply). And Defendants suggested that Eli Lilly allowed any covered entity without an in-house pharmacy to obtain access to discounts at "unlimited contract pharmacies." *Id*. Citing these and other arguments by Defendants, the Court held that the FAC insufficiently alleged that Defendants' "conduct ultimately achieved the same or a substantially similar end result." Opinion at 15.

Plaintiffs' proposed Second Amended Complaint (SAC) addresses this issue with abundant and detailed data and facts. The SAC cites Government-compiled data now available demonstrating exactly how similar Defendants' restrictions were, with those restrictions each doing immense damage to previously existing drug discounts. Across the board, Defendants' restrictions had the same impact of immediately and drastically eliminating most Contract Pharmacy 340B Drug Discounts in the amount of 60-90% by unit volume and 70-95% by lost savings. The reason Defendants achieved the same basic results is that they imposed the same basic restrictions, as the SAC demonstrates.

Moreover, the SAC methodically addresses the exceptions that Defendants presented to this Court as broadly permissive, and explains why each is actually far narrower or much more

impractical than Defendants claimed, and why Defendants' policies thus achieved the same outcome, despite different packaging. The SAC sets the record straight on the true scope of Defendants' exceptions. It marshals extensive information to show that Sanofi's data-sharing demands were indeed commercially unreasonable, quoting, among other authorities, the United States Department of Justice, which has labelled them "infeasible." Likewise, the SAC makes clear that Eli Lilly's exceptions were exceedingly narrow, leading to the nearly full elimination (95%) of discount savings. The SAC clarifies that Eli Lilly did not, in fact, have an exception that allowed "unlimited contract pharmacies" to safety-net providers lacking in-house pharmacies, citing repeated statements by Eli Lilly, including its submissions to other courts. The rich detail in the SAC shows exactly what the Court has demanded Plaintiffs describe for all four Defendants—that their "conduct ultimately achieved the same or a substantially similar end result." Opinion at 15.

For these reasons and those set out below, Plaintiffs respectfully request that the Court grant leave them to file the SAC.

BACKGROUND

A. This action challenges Defendants' coordinated rollback of drug discounts.

Plaintiffs are federally qualified health centers funded by the Federal government to provide healthcare services to people in medically underserved areas. *See* (First) Am. Compl., Dkt. 41 (FAC) ¶¶ 1, 5, 9-10. Just like other safety-net clinics and hospitals, Plaintiffs treat uninsured and underinsured patients who often have nowhere else to turn, and Plaintiffs are deemed "covered entities," entitled to participate in the 340B Drug Discount Program. *Id.*, ¶¶ 1, 5, 9-10, 21-22. 340B Drug Discounts generate savings and revenues (340B Savings), *see id.* ¶ 23, which are critical to supporting Plaintiffs and other safety-net providers, *see id.* ¶¶ 24-25.

A substantial portion of 340B Savings are generated at retail pharmacies (Contract Pharmacies), which dispense drugs purchased by Plaintiffs or other safety-net providers to their patients in their communities. *Id.* ¶¶ 3, 53-54.

Diabetes is a common disease state for patients of covered entities, like Plaintiffs, and diabetes medications make up a significant portion of prescriptions in the 340B program. *See id.* ¶¶ 73-74. Defendants dominate three of the most significant and lucrative diabetes drug markets: (i) rapid-acting analog insulins; (ii) long-acting analog insulins; and (iii) incretin mimetics. *See id.* ¶¶ 68, 74, 79, 84, 87. And these are blockbuster markets for each Defendant. *See id.* ¶ 92 (45% of Eli Lilly U.S. revenue); ¶ 94 (77% of Novo Nordisk U.S. revenue); ¶ 96 ("defining feature" for Sanofi; $1.7 billion in annual U.S. revenue); ¶ 97 ("largest therapy area" targeted by AstraZeneca; $419 million in annual U.S. revenue). Defendants directly compete with each other in producing these blockbuster drugs, *see id.* ¶¶ 149-163, and, as of mid-2020, faced no other competition, *see id.* ¶¶ 164-177. Defendants exclusively controlled these drug markets.

Defendants used their market control to massively restrict Contract Pharmacy 340B Drug Discounts. For more than a decade, drug companies had uniformly provided Contract Pharmacy 340B Drug Discounts. *Id.*, ¶¶ 55, 59. That had been the universal and uninterrupted practice of all one thousand-plus drug companies participating in the 340B Program. *Id.* ¶¶ 58-61, 125-127. But, in the second half of 2020, Defendants broke that decade-plus industry precedent and became the sole manufacturers—among thousands—to announce and implement restrictions on Contract Pharmacy 340B Drug Discounts. *See id.* ¶¶ 4, 129-135.

Defendants' unprecedented restrictions, alone among thousands of other companies in the 340B Program, were coordinated. In a move too coincidental to be mere chance, two of the Defendants announced restrictions (the first one, only privately) a mere business day apart, to be

effective on the exact same day, months later. *See id.* ¶¶ 118-119, 224-226. No Defendant cited any immediate cause for its abrupt restrictions, and none explained why it would suddenly impose restrictions at a time when no other companies were doing so. *See id.* ¶¶ 119, 121-123. If any one Defendant had acted alone to impose restrictions, it "would have risked losing significant market share in the lucrative markets for diabetes treatments," *id.*, ¶¶ 7, 185-194, and would have subjected itself to the federal government revoking coverage of its drugs, *see* Pls. Mem. at 12-14, Dkt. 58. By colluding together, however, they successfully avoided these risks.

Plaintiffs' class action is brought on behalf of all safety-net providers whose 340B Savings have been substantially reduced by Defendants' collusion. *See* FAC, ¶¶ 8, 243-247. The action challenges such collusion as violating federal antitrust law, *see id.*, ¶¶ 255-265, State antitrust laws, *see id.*, ¶¶ 266-272, and State unjust enrichment laws, *see id.*, ¶¶ 273-279.

B. Defendants moved to dismiss, arguing that their unprecedented Contract Pharmacy 340B Drug Discounts restrictions were not "similar."

Defendants moved jointly to dismiss the FAC,[2] arguing, among other things, that their common conduct of imposing unprecedented Contract Pharmacy 340B Discount restrictions was so distinct as to not plausibly constitute "parallel conduct." Defs. Mem. at 22-24, Dkt. 47-1 (Defs. Mem.). The FAC had set out that each Defendant, in the second half of 2020, had broken a decade-plus industrywide precedent by limiting Contract Pharmacy 340B Drug Discounts. Yet Defendants argued that their groundbreaking restrictions of identical discounts were not even "similar" to one another. *Id.* at 26; Reply at 13.

[2] Locally-based Mosaic Health, Inc. filed the original complaint as the sole plaintiff. *See* Compl., Dkt. 1. Before Defendants filed any response, *see* Fed. R. Civ. P. 15(a)(1)(B), Plaintiffs filed the FAC to add co-plaintiff Central Virginia Health Services, Inc, *see* FAC Ex. 1 (Redline), Dkt. 41-1. The FAC otherwise contained minor updates and nits. *See id.*

Defendants pressed this position by characterizing their policies as minimally disruptive and unlikely to have had any significant impact on Contract Pharmacy 340B Drug Discounts. Defendants, for instance, claimed that Sanofi "d[id] ***not*** limit the number of contract pharmacies" at all. Reply at 9 (emphasis in original); *id.* at 6, 22. In truth, the FAC alleged that Sanofi had "cut off all Contract Pharmacy 340B Drug Discounts…unless covered entities provided new consideration" by providing "sensitive prescription claims data to a Sanofi vendor through a software portal on commercially unreasonable terms." FAC, ¶ 120. Yet Defendants brushed this off as a "legal conclusion." Reply at 9. And, on the basis of attorney affidavit submissions, Defendants argued that Sanofi asked for nothing other than "five minutes" of any covered entity's time. *Id.* Defendants painted Plaintiffs as aberrational for "cho[osing] to limit their ability to use contract pharmacies rather than take five minutes every two weeks to upload minimal claims data." *Id.*

Similarly, Defendants suggested that Eli Lilly's Contract Pharmacy 340B Drug Discounts were quite limited in scope. Contradicting Plaintiffs' allegations in the FAC, Defendants claimed that "Lilly allows unlimited contract pharmacies if certain requirements are met." Reply at 10. Although Defendants left such "certain requirements" unspecified, their assertion conflicted with the FAC's allegation that Eli Lilly allowed only a single pharmacy (and only for covered entities lacking an in-house pharmacy), just as AstraZeneca had. *See* FAC, ¶¶ 118, 121. Further contradicting the FAC's description of Eli Lilly's "special exception to permit Contract Pharmacies to pass along certain insulin products at cost," Defendants challenged the FAC's allegation that the exception was "so narrow that it was virtually meaningless," *Id.*, ¶ 122. They insisted that this exception—which required covered entities to find pharmacies willing to bear

the costs of receiving, storing, and dispensing insulin for free—could not plausibly be viewed as "commercially infeasible." Def. Mem. at 24 n.11.

Likewise, Defendants suggested that both Novo Nordisk's and AstraZeneca's restrictions were limited. They argued that Novo Nordisk had a narrow approach because its policy applied only to hospitals, *see* Reply at 10, and that AstraZeneca's policy was limited because it applied to "only some AstraZeneca drugs," *see* Reply at 10; Def. Mem. at 23. By focusing on such variations over commonalities, Defendants claimed that the "implications" of their common Contract Pharmacy 340B Drug Discount restrictions "var[ied] widely." Defs. Mem. at 13.

C. The Court dismissed the FAC for insufficiently showing that Defendants' "conduct ultimately achieved the same or a substantially similar end result."

The Court accepted Defendants' arguments. It held that the FAC failed to sufficiently allege parallel conduct because it "contain[ed] no facts from which it can plausibly be concluded that Defendants' disparate policies, which were adopted over the course of several months, had the same or even similar impacts on the availability of contract pharmacy 340B drug discounts to covered entities." Opinion at 16.

The Court credited Defendants' characterizations of their own policies. As to Sanofi, the Court accepted its claim that it had "continue[d] to allow" 340B Drug Discounts at "unlimited contract pharmacies," *id.* at 12, rejecting the FAC's allegation that Sanofi's data reporting *quid pro quo* for such discounts was "commercially unreasonable," *id.* Because of Sanofi's efforts to minimize its policy, the Court found the "lack of information regarding the impact of Sanofi's policy" in the FAC "particularly problematic." *Id.* at 16. As to Eli Lilly, the Court credited Eli Lilly's cryptic assertion that its policy "'allows unlimited contract pharmacies if certain requirements are met,'" *id.* at 13 n.5, apparently believing that Eli Lilly allowed unlimited Contract Pharmacies—rather than a single Contract Pharmacy, as alleged in the FAC—to be

used by any covered entity without an in-house pharmacy. *Id.* at 13 n.5 (citing Defendants' "confirm[ation]" that Eli Lilly allowed "'unlimited contract pharmacies'" to find no "single-pharmacy limitation"); *id.* at 15 (concluding that Eli Lilly's restrictions simply did not apply to "covered entities without an in-house pharmacy"). And the Court recited Defendants' points suggesting that Novo Nordisk's and AstraZeneca's restrictions likely had limited impacts. *Id.* at 15-16.

In that context, the Court rejected as "conclusory" the FAC's allegation that each Defendant's policy had decimated Contract Pharmacy 340B Drug Discounts. *Id.* at 15. The Court recognized that the FAC alleged that "the 'net effect' of each of the policies was to 'end[] nearly all Contract Pharmacy 340B Drug Discounts for AstraZeneca, Eli Lilly, Novo Nordisk, and Sanofi drugs.'" *Id.* But, in light of Defendants' arguments suggesting their policies had little impact on Contract Pharmacy 340B Drug Discounts, the Court concluded that the FAC had not "plausibly alleged that Defendants' disparate conduct ultimately achieved the same or a substantially similar end result." *Id.* at 15.

The Court thus granted Defendants' motion to dismiss Plaintiffs' antitrust claims. *See id.* at 16-17, 19. The Court likewise dismissed the unjust enrichment claims as inadequately pled. *See id.* at 17-18. The Court conditionally granted Plaintiffs' request for leave to amend, instructing Plaintiffs to file a "viable proposed second amended complaint" along with any motion for leave to amend. *Id.* at 19.

D. The proposed SAC details Defendants' joint efforts and their common impacts.

Plaintiffs' proposed SAC clarifies and details the impact of Defendants' joint efforts in restricting Contract Pharmacy 340B Drug Discounts to address the Court's concerns. The

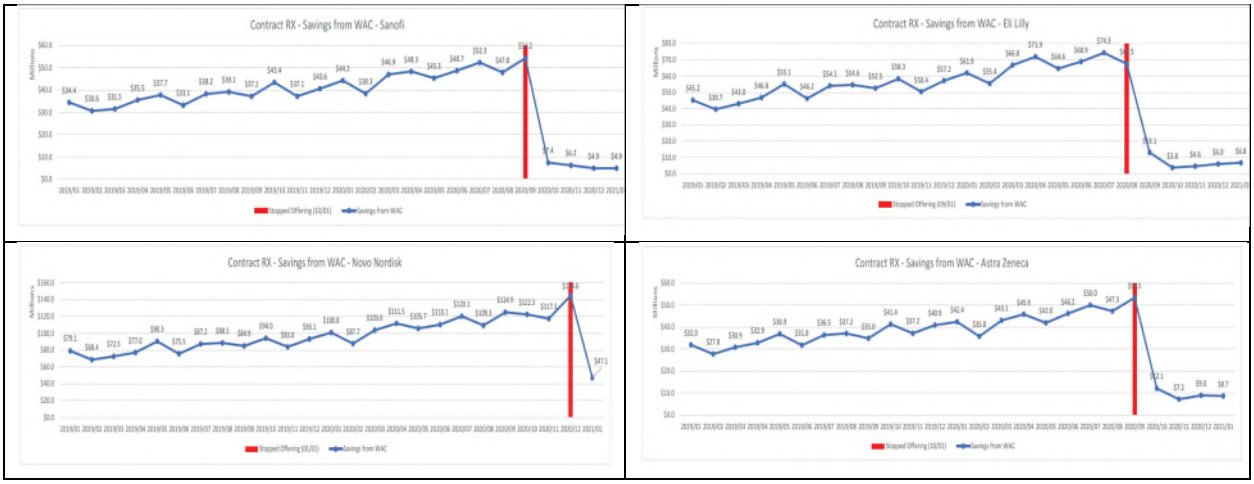
proposed Second Amended Complaint is attached as **Exhibit 1**, and a redline comparing the proposed amendments to the FAC is attached as **Exhibit 2**. *See* Local R. Civ. P. 15(a)-(b).

The SAC details the common impact of Defendants' policies. The SAC explains that, while Defendants included various exceptions "to paint their common policies as distinct," they knew "that their exceptions were marginal and that their common policies would result in the same outcome and result for each Defendant." SAC, ¶ 8. The SAC cites the ends achieved by those policies. Specifically, the result of each Defendant's policy was the same—"immediately decreasing [each Defendant's] sales through the Contract Pharmacy 340B Drug Discount channel by 60-90% (by volume) or 70-95% (by lost 340B Savings)." *Id.*

The SAC backs this assertion up with detailed data. Using Government-compiled sales data, the SAC shows, Defendant by Defendant, that "[n]otwithstanding variations in the Defendants' set of exceptions, their common shared innovation of restricting Contract Pharmacy 340B Drug Discounts ultimately achieved the same result among all Defendants—the elimination of the bulk of their Contract Pharmacy 340B Drug sales." *Id.*, ¶ 177. The SAC includes data documenting the immediate and sustained decline of Contract Pharmacy 340B Drug Discounts as soon as each Defendant imposed its restrictions. The SAC thus shows that "Defendants' coordinated restrictions had the common effect of ending the vast majority of Contract Pharmacy 340B Drug Discounts for their drugs." *Id.* at 55.

The SAC includes Government-compiled graphs, showing the common impact of Defendants' common restrictions. They graph the precipitous drop both in Contract Pharmacy 340B Drug Discount sales and in 340B Savings following each Defendant's imposition of restrictions. For instance, the graphs below illustrate the drop-off in 340B Savings (in blue)

following the imposition of restrictions (in red) for each Defendant (clockwise from top left: Sanofi; Eli Lilly; AstraZeneca; Novo Nordisk):



Id., ¶¶ 181, 198, 217, 229.

The SAC explains why Defendants' policies had these same impacts, by identifying their shared approaches and the limited scope of their exceptions. In particular, as to their common approaches, the SAC explains that each Defendant shared the primary tactic of "refusing to permit the sale of 340B Drugs to covered entities for shipment to Contract Pharmacies," a policy that, until it was adopted by the four Defendants, "was unprecedented in the history of the 340B Drug Program." *Id.*, ¶ 144; *see also id.*, ¶¶ 144-153. The SAC then walks through Defendants' exceptions to further explain why, notwithstanding any such exceptions, each Defendant succeeded in immediately flattening their Contract Pharmacy 340B Drug Discounts.

The SAC goes into detail about Sanofi's data-sharing exception, which Sanofi had presented as minimal and not impactful. The SAC cites the United States Department of Justice's conclusion that Sanofi's demands are, in fact, "infeasible for covered entities." *Id.*, ¶ 188. The SAC explains why these demands are so infeasible, setting out the legal privacy and liability risks posed, the potential conflict with existing contracts, the significant (more than "five-minute") administrative burden, and the financial risks flowing from sharing such sensitive

data. *See id.*, ¶¶ 188-193. In addition to the Justice Department, the SAC backs up its allegations with industry survey results and American Hospital Association filings. *See id.*

The SAC likewise clarifies that Eli Lilly's exceptions were narrow and impractical. While Eli Lilly presented its exceptions as significant, the SAC cites the conclusion of the Justice Department that Eli Lilly's restrictions led to the nearly full elimination (95%) of 340B Savings at Contract Pharmacies. *See id.*, ¶ 199. As to the exception for covered entities without an in-house pharmacy, the SAC demonstrates that the exception truly permits only a single Contract Pharmacy, not the "unlimited contract pharmacies" suggested by Defendants. Reply at 9. To do this, the SAC cites multiple statements by Eli Lilly itself, including Eli Lilly's own court filings. *See id.*, ¶¶ 204-207. The SAC also details how "narrow" that exception is, citing conclusions of a United States District Court Judge and the Justice Department. *See id.* As for Eli Lilly's insulin-related exception, the SAC explains how "exceedingly narrow and completely infeasible" that exception is, too. The SAC supports this allegation with the Justice Department's conclusion that this exception is "not reasonable or workable in practice," the American Hospital Association's explanation that it requires covered entities to "*lose* money," and a 340B pharmacist's sworn statement that the exception is "entirely impractical because pharmacies will not agree to dispense drugs without any compensation," as the exception requires. *Id.*, ¶¶ 208-212 (emphasis in original).

Ultimately, for all four Defendants, the SAC alleges that their common effort to restrict Contract Pharmacy 340B Drug Discounts had a common effect—an immediate, precipitous drop in Contract Pharmacy 340B Drug Discounts, with the loss of 70-95% of 340B Savings, and the 60-90% decrease in discount sales by volume. *Id.*, ¶ 8. The SAC shows that each Defendant's

restrictions "led to the readily foreseeable immediate elimination of the overwhelming majority of [their] Contract Pharmacy 340B Drug Discount sales." *Id.*, ¶¶ 194, 214, 226, 239.

Separately, the SAC limits the unjust enrichment claims to just 20 States (Arizona, Hawaii, Illinois, Iowa, Maine, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, New York, Oregon, Rhode Island, South Dakota, Utah, Vermont, Virginia, West Virginia, and Wisconsin) and elaborates on the elements of each such claim. *Id.*, ¶¶ 388-480.

ARGUMENT

THE COURT SHOULD GRANT LEAVE TO AMEND.

A. Leave to amend should be freely granted.

Federal Rule of Civil Procedure 15(a) dictates that a "court should freely give leave" to amend "when justice so requires." Fed. R. Civ. P. 15(a)(2). "The Supreme Court has emphasized that amendment should normally be permitted, and has stated that refusal to grant leave without justification is 'inconsistent with the spirit of the Federal Rules,'" *Rachman Bag Co. v. Liberty Mut. Ins. Co.*, 46 F.3d 230, 235 (2d Cir. 1995) (quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962)), and a "liberal, pro-amendment ethos dominates the intent and judicial construction of Rule 15(a)(2)," 3 James W. Moore et al., Moore's Federal Practice - Civil § 15.14[1], Lexis (database updated Sept. 2022). "This permissive standard is consistent with [courts'] 'strong preference for resolving disputes on the merits.'" *Williams v. Citigroup, Inc.*, 659 F.3d 208, 212–13 (2d Cir. 2011) (quoting *New York v. Green*, 420 F.3d 99, 104 (2d Cir. 2005)).

"It is the usual practice upon granting a motion to dismiss to allow leave to replead." *Cortec Indus., Inc. v. Sum Holding L.P.*, 949 F.2d 42, 48 (2d Cir. 1991). Indeed, if "[t]he deficiency in the complaint arguably involves a failure to plead with particularity . . . leave to amend is usually afforded." *Pross v. Katz*, 784 F.2d 455, 459 (2d Cir. 1986). Amendment is

particularly appropriate where discovery has not yet commenced. *See, e.g.*, *Pasternack v. Shrader*, 863 F.3d 162, 174 (2d Cir. 2017) (reversing order denying leave to amend, where "essentially no discovery has been undertaken in this case").

The Court may deny leave for futility. "Futility is a determination, as a matter of law, that proposed amendments would fail to cure prior deficiencies or to state a claim under Rule 12(b)(6) of the Federal Rules of Civil Procedure." *Panther Partners Inc. v. Ikanos Commc'ns., Inc.*, 681 F.3d 114, 119 (2d Cir. 2012). "While futility is a valid reason for denying a motion to amend…, this is true only where it is beyond doubt that the plaintiff can prove no set of facts in support of his amended claims." *Miccio v. ConAgra Foods, Inc.*, 224 F. Supp. 3d 200, 203 (W.D.N.Y. 2016) (internal quotation marks omitted) (quoting *Pangburn v. Culbertson*, 200 F.3d 65, 70-71 (2d Cir. 1999)). And, "[b]ecause the standard on a motion for leave to amend is the same as that on a Rule 12(b)(6) motion to dismiss, 'the Court cannot consider facts outside the pleadings in considering the futility of an amendment.'" *Rochester Drug Coop., Inc. v. Hiscox Ins. Co.*, 545 F. Supp. 3d 21, 24 (W.D.N.Y. 2021) (quoting *A. v. Hartford Bd. of Educ.*, No. 3:11-CV-1381 CSH, 2012 U.S. Dist. LEXIS 126387, at *4 (D. Conn. Sept. 6, 2012)).

B. The SAC cures what the Court previously identified as deficiencies.

The Court should grant Plaintiffs leave to file their SAC because the SAC cures what the Court previously identified as deficiencies in the FAC, both as to parallel conduct and as to unjust enrichment.

1. The SAC amply alleges the common result of Defendants' restrictions.

The SAC provides all the detail the Court previously identified as lacking with respect to parallel conduct. The Court granted the motion to dismiss on the ground that the FAC failed to sufficiently allege the Defendants' policies "had the same or even similar impacts on the availability of contract pharmacy 340B drug discounts to covered entities." Opinion at 16; *see*

id. at 15 (finding FAC had not "plausibly alleged that Defendants' disparate conduct ultimately achieved the same or a substantially similar end result").

The SAC richly details the common impact of each Defendant's policy, showing that each policy led to the immediate decrease of sales through the Contract Pharmacy 340B Drug Discount channel by 60-90% in volume and 70-95% in lost 340B Savings. *See* SAC, ¶ 8. In addition, the SAC further details how Defendants implemented common policies, *see id.*, ¶¶ 144-156, and why their various exceptions were so marginal that their policies accomplished the same results, *see id.*, ¶¶ 177-239. The SAC shows that each Defendant's restrictions "led to the readily foreseeable immediate elimination of the overwhelming majority of [their] Contract Pharmacy 340B Drug Discount sales." *Id.*, ¶¶ 194, 214, 226, 239. These details fill in each of the areas identified by the Court as lacking.

2. The SAC narrows and elaborates on the unjust enrichment claims.

In addition, consistent with this Court's recent decision in *Miami Products & Chemical Co. v. Olin Corp.*, No. 1:19-cv-00385 EAW, Dkt. 501, 2022 U.S. Dist. LEXIS 154213 (W.D.N.Y. Aug. 26, 2022), the SAC narrows and elaborates on the unjust enrichment claims. Following that decision, the SAC amply pleads claims under Arizona, Hawaii, Illinois, Iowa, Maine, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, New York, Oregon, Rhode Island, South Dakota, Utah, Vermont, Virginia, West Virginia, and Wisconsin law. *See id.*, at *10-18; *compare* Am. Consol. Compl., ¶¶ 157-264 *with* SAC ¶¶ 388-480.

The Court dismissed the unjust enrichment claims in the FAC for a lack of elaboration, rather than any legal defect in the claims. *See* Opinion at 17-18. Nevertheless, nineteen of the twenty State law unjust enrichment claims here are supported by this Court's decision in *Miami Products*. And, as to twentieth, the claim under Virginia law, the SAC comports with the

holding in *In re Generic Pharmaceuticals Pricing Antitrust Litigation*, 368 F. Supp. 3d 814, 849-852 (E.D. Pa. 2019) (permitting unjust enrichment claims in Virginia).

CONCLUSION

Plaintiffs respectfully request that the Court grant their motion for leave to amend and enter an order permitting Plaintiffs to file the proposed SAC.

Dated: October 3, 2022
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Exhibit 2

Redline Comparison First Amended Complaint Against Second Amended Complaint

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UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF NEW YORK

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

Plaintiffs,

vs.

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

Defendants.

~~FIRST~~SECOND AMENDED COMPLAINT

Class Action
Jury Trial Demanded

6:21-cv-6507 (EAW)

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

INTRODUCTION

1. This case challenges coordination by four drug companies to boost their profits at the expense of the safety-net hospitals and clinics that care for patients who have nowhere else to turn. Those four drug companies—defendants here—should directly compete with each other. Yet, instead of competing for business, they worked together to boost their profits by coordinating to retract a long-standing discount for safety-net hospitals and clinics. That coordination allowed each defendant to individually avoid competitive pressure and prevent

individual market share losses including through adverse government action limiting federal healthcare program coverage, while restricting safety-net hospitals' abilities to deliver robust and affordable healthcare options to patients. ~~That~~Their horizontal agreement was a *per se* violation of state and federal antitrust laws. This antitrust class action seeks injunctive and compensatory relief for the safety-net hospitals and clinics harmed by the drug companies' anti-competitive agreement.

2. The defendants here are four drug companies that dominate three key markets for diabetes treatments. They are: Sanofi-Aventis U.S., LLC (Sanofi); Eli Lilly and Company and Lilly USA, LLC (together, Eli Lilly); Novo Nordisk Inc. (Novo Nordisk); and AstraZeneca Pharmaceuticals LP (AstraZeneca) (collectively, Defendants). They dominate the lucrative diabetes markets for: (i) rapid-acting analog insulins; (ii) long-acting analog insulins; and (iii) incretin mimetics. These markets account for billions of dollars of annual U.S. sales for Defendants and, as such, are among the most important drug markets for the Defendants. At the time their conspiracy began, Defendants faced no significant competition, apart from one another, in these multi-billion--dollar markets.

3. The discount that Defendants conspired to limit was a special discount offered to safety-net hospitals and clinics, which purchase drugs filled by their patients at retail pharmacies. The discount is calculated by a mathematical formula codified at Section 340B of the Public Health Service Act, 42 U.S.C. § 256b and is known as the 340B Drug Discount. For at least a decade, drug companies offered the 340B Drug Discount to safety-net hospitals and clinics, not only for on-site use but also for purchase and distribution by retail pharmacies. Those pharmacies, typically called contract pharmacies (Contract Pharmacies), have contracts with safety-net providers, which allows the providers to purchase drugs on their own accounts,

discounted with the 340B Drug Discount, to be delivered to and dispensed by the Contract Pharmacies. Drug companies, including Defendants, have argued that their provision of 340B Drug Discounts at Contract Pharmacies is voluntary, not mandated by law. But, for at least a decade, nearly all pharmaceutical companies, including Defendants, had offered safety-net providers drugs at 340B Drug Discounts for dispensing at Contract Pharmacies (Contract Pharmacy 340B Drug Discounts). And, with all pharmaceutical competitors regularly offering Contract Pharmacy 340B Drug Discounts, patients benefitted, because safety-net hospitals and clinics have been able to use savings from those discounts to expand healthcare services and lower healthcare costs for patients. Contract Pharmacies have been a multi-billion-dollar discount channel for the sale of drug inventory.

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

5. The Plaintiffs and Class Members harmed by those actions are safety-net hospitals and clinics, which provide healthcare services to low-income and underserved patients,

funded in significant part through savings from 340B Drug Discounts. The Plaintiffs are Mosaic Health, Inc. (Mosaic Health) and Central Virginia Health Services, Inc. (CVHS). Mosaic Health is a federally qualified health center (FQHC) comprised of 22 safety-net clinics: Charlotte School Based Health Center; Clinton Family Health; Edison Tech Community Health Center; Freddie Thomas Health Center; Genesee Health service; John James Audubon Health Center; Martin Luther King Jr. Health Center; Mosaic Health Rushville; Mosaic Health Mount Morris; Mosaic Health Lyons; Mosaic Health Utica; Mosaic Health Utica Dental; Mosaic Health Ilion; Newark Internal Medicine; Riedman Health Center; Unity Dental at St. Mary's; Unity Dental at Ridgeway; Unity Family Medicine at Orchard Street; Unity Family Medicine at St. Mary's; Wolcott Primary Care; Women's Center at Clinton Family; and Women's Center at Rochester General Hospital. CVHS is also a FQHC comprised of 18 safety-net clinics: CVHS Brunswick; CVHS Buckingham; CVHS Caroline; CVHS Charles City; CVHS Charlotte; CVHS Charlottesville; CVHS Children's Dental; CVHS Crimson-Clinic; CVHS Downtown Petersburg; CVHS Farmville; CVHS Fredericksburg; CVHS Hopewell - Prince George; CVHS King William; CVHS Louisa; CVHS Petersburg; CVHS Peterson; CVHS Southern Albemarle; and CVHS Westmoreland. Each of these safety-net clinics is a covered entity participating in the 340B Drug Discount Program with contracts with retail pharmacies. For years, these clinics have obtained Contract Pharmacy 340B Drug Discounts from nearly all drug companies, including Defendants, and have been able to use the resulting savings to expand healthcare options and services for patients in their communities.

6. Defendants' conspiracy began in the summer of 2020. Through mid-summer, Defendants had spent millions collectively lobbying the federal government (in efforts not challenged here) to limit 340B Drug Discounts with respect to diabetes ~~medicines~~medications.

A long-running lobbying campaign by drug companies had sought (i) to limit the level of hospital participation in the 340B Program, (ii) to limit which patients could qualify for 340B Drug Discounts, (iii) to require that all discounts be passed through to patients at the point of sale, and/or (iv) to restrict the availability of Contract Pharmacy 340B Drug Discounts. But Defendants' lobbying efforts failed. That failure became evident on July 24, 2020, when President Trump issued Executive Order 13937 addressing the 340B Drug Discount in the context of insulin medication and injectable epinephrine. The executive order did little to accomplish any of Defendants' goals. ~~As soon as it became clear that~~But Defendants' collective lobbying efforts ~~had failed, Defendants turned~~offered them an opportunity to develop another plan focused on just the last of those goals—collusively eliminating or limiting Contract Pharmacy 340B Drug Discounts for their drugs, most significantly including their drugs dominating rapid-acting analog insulin, long-acting analog insulin, and incretin mimetic sales. ~~Indeed, on~~On July 24, 2020, the very same day that the executive order was issued, the first ~~defendant~~Defendant, AstraZeneca, revealed its intention to restrict Contract Pharmacy 340B Drug Discounts.

7. The other Defendants executed similar plans in short order. While Defendants' Plan A (lobbying the federal government to restrict 340B Drug Discounts) may have been perfectly legal and legitimate, their Plan B (agreeing among themselves to restrict Contract Pharmacy 340B Drug Discounts) was not. The plan worked only with buy-in from each of the other Defendants. If any Defendant had acted alone, it would have risked losing significant market share in the lucrative markets for diabetes treatments, including through severe adverse action from regulators; and, over time, safety-net providers could have purchased drugs from that Defendant's competitors to access Contract Pharmacy 340B Drug Discounts to maximize

healthcare services and to lower costs for patients. But, by acting together, Defendants safeguarded themselves against competition in the lucrative diabetes medication markets. ~~Defendants' conspiracy has succeeded in raising prices, by eliminating Contract Pharmacy 340B Drug Discounts, while protecting their market position from competition from one another.~~Moreover, by acting collectively, Defendants left regulators unable to take the harshest of actions —restricting coverage of their insulins by federal healthcare programs—because, if regulators took consistent punitive action against all four Defendants, it would leave thousands of healthcare program participants without any options for these critical drugs.

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

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

~~8.~~10. That conspiracy is doing immense damage to Plaintiffs and other safety-net hospitals and clinics, and, consequently, to the healthcare options available to the patients they serve. Congress gave safety-net hospitals and clinics "access to [340B Drug Discounts] . . . to

enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992). Defendants' conspiracy is having the opposite effect—limiting the ability of safety-net hospitals and clinics to reach more patients and provide more healthcare services by causing significant financial shortfalls for Plaintiffs and other safety-net hospitals and clinics alike. The savings that hospitals and clinics generate from Contract Pharmacy 340B Drug Discounts are used, among other things, to expand the medical services available to the communities served by safety-net facilities, especially for the uninsured or underinsured, and to provide charity care or subsidized pharmacy benefits to help meet the healthcare needs of needy patients. Defendants' conspiracy has threatened those services and benefits. Because Defendants' conspiracy violates state and federal antitrust laws, and the common law, Plaintiffs seek class-wide damages, and injunctive, and other equitable relief.

PARTIES

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

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

~~10.~~12. Plaintiff Central Virginia Health Services, Inc. is a nonprofit healthcare organization with its principal place of business in New Canton, Virginia. Central Virginia Health Services, Inc. is a federally qualified health center that receives funds from the U.S. Department of Health and Human Services, Health Resources and Services Administration to provide healthcare services to people residing in medically underserved areas, regardless of their ability to pay. CVHS includes 18 safety-net clinics participating in the 340B Program: CVHS Brunswick; CVHS Buckingham; CVHS Caroline; CVHS Charles City; CVHS Charlotte; CVHS Charlottesville; CVHS Children's Dental; CVHS Crimson-Clinic; CVHS Downtown Petersburg; CVHS Farmville; CVHS Fredericksburg; CVHS Hopewell - Prince George; CVHS King William; CVHS Louisa; CVHS Petersburg; CVHS Peterson; CVHS Southern Albemarle; and CVHS Westmoreland. CVHS has had contract pharmacy arrangements in place since at least approximately July 2011.

~~11.~~13. Defendant Sanofi-Aventis U.S., LLC is a Delaware limited liability company with its principal place of business in Bridgewater, New Jersey. Sanofi-Aventis U.S., LLC is a wholly owned subsidiary of the French company, Sanofi.

~~12.~~14. Defendant Eli Lilly and Company is an Indiana corporation with its principal place of business in Indianapolis, Indiana.

~~13.~~15. Defendant Lilly USA, LLC is an Indiana limited liability company with its principal place of business in Indianapolis, Indiana. Lilly USA, LLC is a wholly owned subsidiary of Eli Lilly and Company.

~~14.~~16. Defendant Novo Nordisk Inc. is a Delaware corporation with its principal place of business in Plainsboro, New Jersey. Novo Nordisk Inc. is the United States affiliate of the Danish company, Novo Nordisk A/S.

~~15.~~17. Defendant AstraZeneca Pharmaceuticals LP is a Delaware limited partnership with its principal place of business in Wilmington, Delaware. AstraZeneca Pharmaceuticals LP is a wholly owned subsidiary of the English company, AstraZeneca Pharmaceuticals PLC.

JURISDICTION AND VENUE

~~16.~~18. This Court has subject matter jurisdiction over the claims arising under federal antitrust laws under 15 U.S.C. §§ 4, 15, and 26, and 28 U.S.C. §§ 1331 and 1337. This Court has supplemental jurisdiction over the State Law claims arising under ~~State laws under~~ 28 U.S.C. § 1367. This Court also has diversity jurisdiction over this class action of the State law claims under 28 U.S.C. § 1332(d) because the aggregate amount in controversy exceeds $5,000,000, there are more than one hundred Class Members, and Members of the Class are citizens of states different from that of one of the Defendants. Likewise, this Court has diversity jurisdiction over the named Plaintiffs' claims under 28 U.S.C. § 1332(a) because all of the named Plaintiffs are citizens of different States than all of the Defendants and the amount in controversy exceeds $75,000.

~~17.~~19. This Court has personal jurisdiction over Defendants under Rule 4(k)(1)(A) of the Federal Rules of Civil Procedure and NY CPLR § 302 because, *inter alia*, Defendants transact and do business within the State of New York, contract to supply goods and services within the

State of New York, regularly solicit business and derive substantial revenue from drugs sold in the State of New York, and/or should reasonably expect the acts described in this complaint to have consequences in the State of New York.

~~18.~~20. Venue is appropriate in this District under 15 U.S.C. § 22 because Defendants each transact business in this district and may be found in this district. Venue is also appropriate in this District under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claim occurred in this district; and, in the alternative, venue is appropriate in this District under 28 U.S.C. § 1391 because Defendants are not all residents of the same State and are subject to this Court's personal jurisdiction.

ALLEGATIONS

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

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

~~19.~~21. Prior to Defendants' conspiracy, all drug companies participating in Medicaid and Medicare Part B had offered Contract Pharmacy 340B Drug Discounts as part of their participation in the 340B Drug Discount Program.

~~20.~~22. The 340B Drug Discount Program dictates the calculation of the 340B Drug Discount. The 340B Drug Discount is provided by the manufacturer to the covered entities participating in the 340B Drug Discount Program. That program provides the infrastructure for drug companies to offer the 340B Drug Discount through contract pharmacies. And, until the second half of 2020, all drug companies participating in Medicaid and Medicare Part B had offered the Contract Pharmacy 340B Drug Discount.

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

~~21.~~23. The 340B Drug Discount Program was created in 1992 by Section 340B of the Public Health Service Act, 42 U.S.C. § 256b (Section 340B), to require discounts on outpatient drugs purchased by healthcare providers serving underserved populations. "Under § 340B," "manufacturers participating in Medicaid must offer discounted drugs to covered entities, dominantly, local facilities that provide medical care for the poor." *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 115 (2011).

~~22.~~24. The program ensures that certain safety-net hospitals and clinics, deemed "covered entities" under the statute, have access to discounts when purchasing outpatient drugs. 42 U.S.C. § 256b(a)(4). As defined by Section 340B, covered entities include a number of health clinics, such as: federally qualified health centers; federally qualified health center look-alikes; native Hawaiian health centers; tribal or urban Indian health centers; Ryan White HIV/AIDS clinics; black lung clinics; comprehensive hemophilia diagnostic treatment centers; Title X family planning projects; sexually transmitted disease clinics; and tuberculosis clinics. *See* 42 U.S.C. § 256b(a)(4). In addition, and as likewise defined by Section 340B, covered entities include hospitals meeting certain statutory criteria, such as: children's hospitals; critical access hospitals; free standing cancer hospitals; sole community hospitals; rural referral centers; and disproportionate share hospitals. *See* 42 U.S.C. § 256b(a)(4).

~~23.~~25. The purpose of the 340B Drug Discount Program is "to enable [covered entities] to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 120-384(II), at 12 (1992). Covered entities with access to 340B Drug Discounts can do so in various ways. For one, a covered entity can save money when paying the ceiling price for a covered outpatient drug needed for an

uninsured or an underinsured patient; there, 340B Drug Discounts represent an expense savings for unreimbursed care. Moreover, for patients with insurance, a covered entity can net revenue from the spread between the drug's price—lowered by the 340B Drug Discount—and any reimbursement above that price. The net savings and revenue generated through access to 340B Drug Discounts is sometimes referred to as 340B Savings.

~~24.~~26. 340B Savings are often a critical component of covered entities' ability to provide healthcare services to patients. For some covered entities, including federally qualified health centers, 340B Savings directly subsidize the covered entities' efforts to make drugs affordable to patients at lower costs. For other covered entities, including many hospital participants, 340B Savings helps them fund and expand critical services for the most vulnerable patients, such as addiction and mental health services, and charity care, among other things.

~~25.~~27. 340B Savings are critical to the named Plaintiffs. For example, Mosaic Health's 340B Savings help fund sliding fee discounted medications for patients in need.

~~26.~~28. The clinics that are 340B covered entities predominantly serve low-income or underserved patient populations. For instance, federally qualified health centers are community-based health care providers that receive funds from HHS to provide primary care and other services in underserved areas. They must meet a stringent set of requirements, including providing care on a sliding-fee scale based on patients' ability to pay. Moreover, under federal grant requirements, federally qualified health centers must use any 340B Savings in furtherance of their healthcare safety-net mission. *See* 42 U.S.C. § 254b(e)(5)(A), (D).

~~27.~~29. The hospitals that are 340B covered entities bear disproportionate burdens in serving low-income and underserved patient populations. For instance, disproportionate share hospitals are, by definition, hospitals that serve a significantly disproportionate number of low-

income patients. Moreover, to be a covered entity for the 340B Drug Discount Program, a private hospital that meets the disproportionate share hospital definition must also be a nonprofit and must agree to provide charity care. *See* 42 U.S.C. § 256b(a)(4)(L).

~~28.~~30. Section 340B directs the Secretary of the Department of Health and Human Services (HHS) to enter into an agreement with every drug manufacturer participating in State Medicaid programs and Medicare Part B. 42 U.S.C. § 256b(a); *see also* 42 C.F.R. § 10.2. These agreements are known as pharmaceutical pricing agreements (PPAs). Every drug manufacturer participating in Medicaid or Medicare Part B enters into a PPA and offers 340B Drug Discounts. Drug companies that refuse to sign a PPA cannot participate in Medicaid and Medicare Part B. More than 1,000 drug companies have signed PPAs with HHS, including each of the Defendants and all of the other top 250 drug companies.[1]

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

~~29.~~31. Since its inception, the 340B Drug Discount has been a defined discount, specific to each drug, calculated by the 340B Drug Discount Program.

~~30.~~32. Section 340B and PPAs dictate the methodology for calculating 340B Drug Discounts. Section 340B creates the discount by imposing a ceiling price. *See* 42 U.S.C. § 256b(a)(1); *see also* 42 C.F.R. § 10.10. The ceiling price for a drug is generally equal to the "Average Manufacturer Price" minus a "Unit Rebate Amount." 42 C.F.R. § 10.10(a). The extent to which the ceiling price reduces the available price for drugs is known as the 340B Drug Discount. 340B Drug discounts often provide savings of 20% to 50%.

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

~~31.~~33. Drug companies must report their 340B ceiling prices on a quarterly basis. *See* 42 U.S.C. § 256b(a)(1). Those reports must be made to the Health Resources and Services Administration (HRSA), the HHS agency that administers the 340B Drug Discount Program. HRSA makes ceiling prices available to covered entities through its 340B Office of Pharmacy Affairs Information System (340B OPAIS), an online database that allows covered entities to access ceiling prices for covered outpatient drugs.

~~32.~~34. The 340B Drug Discount is thus a defined discount, calculated by statutory rules, and verifiable through 340B OPAIS.

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

~~33.~~35. Under Section 340B and PPAs, drug companies—not drug distributors—are responsible for offering covered entities the 340B Drug Discount.

~~34.~~36. This is clear from the statute, which states that each PPA "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase" at a price including the 340B Drug Discount. 24 U.S.C. § 256b(a)(1).

~~35.~~37. Defendants themselves have acknowledged that the obligation to provide 340B Drug Discounts to covered entities is theirs alone. As Sanofi has explained, "Section 340B . . . requires drug manufacturers participating in the 340B Program to offer certain drugs at a significant discount to a list of entities (known as 'covered entities') defined by statute." *See* Complaint ¶ 23, *Sanofi-Aventis U.S., LLC v. Azar*, 21-cv-634 (D.N.J. filed Jan. 12, 2021). Similarly, Eli Lilly has stated, "Under the 340B Statute, pharmaceutical manufacturers 'must' offer steep discounts on their products to certain 'covered entities.'" *See* Complaint, *Eli Lilly and Company v. Azar*, 21-cv-81 (S.D. Ind. filed Jan. 12, 2021). For its part, Novo Nordisk has spelled out that "Section 340B of the Public Health Service Act requires pharmaceutical

manufacturers to offer their outpatient drugs at deeply discounted prices to an enumerated list of 'covered entities' for the purpose of ensuring that vulnerable and low-income patients have better access to prescription medications." *See* Complaint ¶ 2, *Novo Nordisk Inc. v. Azar*, 3:21-cv-806 (D.N.J. filed Jan. 15, 2021). So too, AstraZeneca has acknowledged "its statutory obligations . . . to offer 340B drugs to each covered entity on non-discriminatory terms at the 340B price." *See* Complaint ¶ 3, *AstraZeneca Pharmaceuticals LP v. Azar*, 1:21-cv-27 (D. Del. filed Jan. 12, 2021). As AstraZeneca has further detailed, the 340B Program requires that each "manufacturer must 'offer each covered entity covered outpatient drugs for purchase' at a specified [340B] discount price . . . This is known as Section 340B's 'must-offer' requirement." *Id.* ¶ 20.

~~36.~~38. Consequently, as a matter of law and practice, 340B Drug Discounts are offered by, funded by, and provided by drug companies to covered entities.

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

~~37.~~39. ~~Oftentimes~~Often, drug companies rely on distributors and suppliers, such as Cardinal Health, Inc., and McKesson Corporation, to arrange for drug purchasing with covered entities.

~~38.~~40. But those arrangements do not change the nature of the 340B Drug Discount. That discount remains a discount offered and provided by drug companies to covered entities. Indeed, as noted above, drug companies are obligated to provide 340B Drug Discounts to covered entities themselves.

~~39.~~41. As the Federal rules state, "Manufacturers have an obligation to ensure that the 340B discount is provided through distribution arrangements made by the manufacturer." *See* 42 C.F.R. § 10.11(b)(2); *see also* Final Rule, 82 Fed. Reg. 1220, 1224 ("Manufacturers are

ultimately responsible for ensuring a covered entity receives a drug at or below the 340B ceiling price" and "have control over the distribution of covered outpatient drugs, including those distributed by wholesalers, distributers, and agents.").

~~40.~~42. Drug companies ensure that they are offering and providing 340B Drug Discounts to covered entities, even when a distributor serves as an intermediary, by various arrangements. Most commonly, the drug company instructs the distributor to provide the 340B Drug Discount for the sale of any covered outpatient drugs to covered entities. The distributor includes that discount, at the instruction of the drug company, and reports the discounts back to the drug company. The drug company then funds the discount, oftentimes by paying a distributor's invoice for the 340B Drug Discount amount provided (a procedure sometimes called a chargeback). Distributors have no ability to keep any of the 340B Drug Discount. Rather, all of the 340B Drug Discount is conveyed from the drug company to the covered entity.

~~41.~~43. In this way and others, drug distributors do no more than convey 340B Drug Discounts from drug companies to covered entities. Drug distributors themselves have no access to 340B Drug Discounts.

~~42.~~44. Consequently, even when drug distributors serve as intermediaries, the 340B Drug Discount is offered and provided from the drug companies to the covered entities. Drug companies alone can remove those discounts from the distribution stream by refusing to offer them to covered entities or by restricting the circumstances under which such discounts can be accessed by covered entities.

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

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

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

~~44.~~46. As HHS has noted, this gap was "not surprising" because "the Program is aimed at benefiting providers" that can be some combination of "small, remote, resource-limited, receiving federal assistance, or serving disadvantaged populations." *See* U.S. Dep't of Health & Human Servs. Office of the General Counsel, *Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program*, at 4 (Dec. 30, 2020). Some of these "are the poster children of providers that one would expect to lack an in-house pharmacy." *Id.*

~~45.~~47. Because of this gap, covered entities sought regulatory assistance in promoting access to 340B Drug Discounts through Contract Pharmacies. And "[a]s early as 1993, several covered entity groups . . . came forward to assist [HHS] in developing a workable mechanism to use outside pharmacies." *Id.*

~~46.~~48. HHS recognized the problem this gap presented. As it explained, "if these covered entities could not use their affiliated pharmacies in order to participate in the 340B program," "they would be faced with the untenable dilemma of having either to expend precious resources to develop their own in-house pharmacies (which for many would be impossible) or

forego participation in the program altogether." Final Notice, 61 Fed. Reg. 43,550 (Aug. 23, 1996).

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

~~47.~~49. In order to expand access to 340B Drug Discounts, in 1996 and 2010, HHS set out guidelines for access to 340B Drug Discounts at Contract Pharmacies.

~~48.~~50. In 1996, HHS issued a final notice with guidelines for drug companies and covered entities to use in setting up Contract Pharmacy arrangements, so that covered entities could access 340B Drug Discounts at Contract Pharmacies. Final Notice, 61 Fed. Reg. 43,549 (Aug. 23, 1996). HHS articulated its position "that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating [340B] manufacturer, the statute directs the manufacturer to sell the drug at the [340B] discounted price." *Id.* at 43,549. When "the entity directs the drug shipment to its contract pharmacy, [there is] no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance." *Id.* at 43,549-550.

~~49.~~51. The 1996 final notice provided basic guidelines for implementing Contract Pharmacies to access 340B Drug Discounts. The guidelines encouraged written agreements between the covered entity and the Contract Pharmacy. *See id*. at 43,555. Under the guidelines, the covered entity would purchase the drug, but a "'ship to, bill to' procedure may be used in which the covered entity purchases the drug [and] the manufacturer bills the entity for the drug that it purchased, but [the manufacturer] ships the drug directly to the contract pharmacy." *Id.* The notice included guidelines for limiting the purchase of 340B Drug Discounts to drugs purchased for eligible patients of the covered entity. *See id*.

~~50.~~52. In 2010, HHS issued another final notice with additional guidelines for the use of Contract Pharmacies to access Contract Pharmacy 340B Drug Discounts. *See* Final Notice, 75 Fed. Reg. 10,272 (Mar. 5, 2010).

~~51.~~53. The 2010 final notice included guidelines for the use of "multiple contract pharmacy arrangements," greenlighting the use of multiple retail pharmacies as Contract Pharmacies for a covered entity. *See id*. at 10,273.

~~52.~~54. HRSA's Office of Pharmacy Affairs has facilitated the use of Contract Pharmacies through its 340B OPAIS. In accordance with HHS instructions, covered entities register the names and locations of their Contract Pharmacies in the 340B OPAIS database. Drug companies can access that same database to verify that a particular pharmacy is serving as a Contract Pharmacy for a particular 340B covered entity before making 340B Drug Discounts available to a covered entity purchasing drugs for shipment to that pharmacy location.

~~53.~~55. The expansion of Contract Pharmacies increased opportunities for covered entities to generate 340b Savings and has provided real benefits for patients, including by expanding patient access and choice. For instance, prior to the expansion, patients of federally qualified health centers were typically able to receive subsidized drugs (on a sliding-fee scale) at a single pharmacy, which might have been far from the health center's patients' homes or otherwise inconvenient. After the expansion, however, patients of federally qualified health centers now typically have a wide range of choices and are able to use a wide variety of Contract Pharmacies. Thus, for example, whereas Mosaic Health patients previously had a single pharmacy location to obtain sliding-fee scale drugs, they can now visit over a dozen different locations.

~~54.~~56. The expansion of Contract Pharmacies has also benefitted patients by expanding the range of covered entities' healthcare services available and by allowing covered entities to fund additional charity care. For instance, 340B Savings have supported hospitals' abilities to provide substantial uncompensated and charity care, including for unreimbursed care for cancer patients, unreimbursed care for substance abuse treatment, subsidizing losses for pediatric care, and supporting community health programs. Those efforts have expanded the breadth and quality of healthcare services available to patients and have reduced the costs of those services, including drugs, to the neediest.

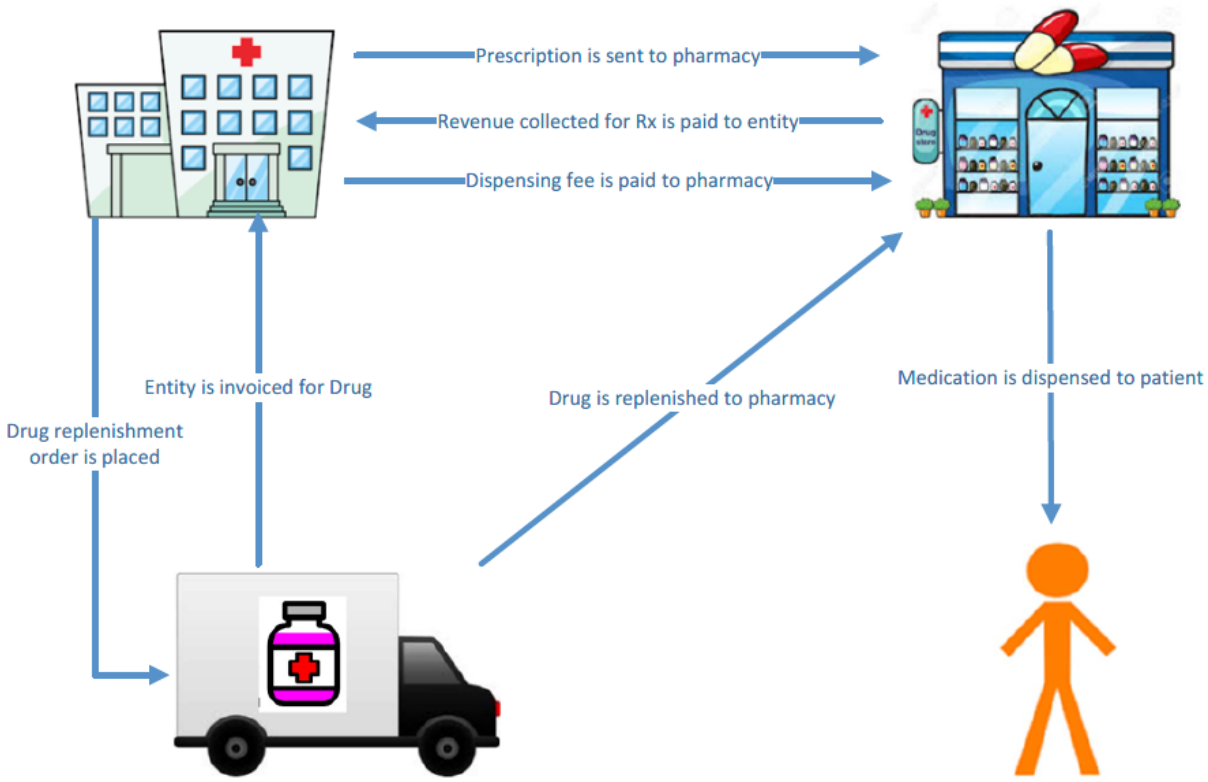
3. After that, drug companies participating in the 340B Drug Discount Program universally offered Contract Pharmacy 340B Drug Discounts.

~~55.~~57. Since at least 1996, and in greater volumes since 2010, all drug companies participating in the 340B Drug Discount Program have offered Contract Pharmacy 340B Drug Discounts to covered entities. To do so, drug companies have offered covered entities the 340B Drug Discount on covered outpatient drugs purchased on the covered entities' own accounts but shipped to their registered Contract Pharmacy sites.

~~56.~~58. Oftentimes, this is accomplished through arrangements among covered entities, Contract Pharmacies, distributors, and so-called 340B vendors. A typical arrangement is as follows: A covered entity's patient arrives at a Contract Pharmacy (*e.g.*, a RiteAid) for a covered outpatient drug; the pharmacy fills the patient's prescription. The pharmacy, sometimes itself and sometimes working with a 340B vendor (*e.g.*, CaptureRx) running matching algorithms, reviews the pharmacy prescription to identify the patient's prescription as 340B eligible and to match it to a particular covered entity. If it is so matched, the pharmacy fills the prescription with inventory from the purchasing account of that covered entity—the account ~~by~~through which the covered entity purchases covered outpatient drugs and obtains Contract Pharmacy 340B Drug

Discounts from drug companies. The pharmacy then charges the patient for any required co-pay or, if the patient is uninsured, any required fee, adjusted downward as appropriate by any sliding-fee scale arrangement between the pharmacy and the covered entity (as is often the case with federally qualified health centers). To the extent the patient has insurance coverage from third-parties, such as private insurers or Medicare Part D, the pharmacy collects those reimbursements for the covered entity's account. The pharmacy then remits any amounts collected—whether from the patient or from a third party—to the covered entity, and the covered entity pays the pharmacy a dispensing fee.

~~57.~~59. The arrangements described above can be visualized as follows:



~~58.~~60. Contract pharmacy arrangements have thus allowed covered entities to obtain Contract Pharmacy 340B Drug Discounts and, consequently, to generate 340B Savings. These arrangements have been the status quo for more than a decade.

~~59.~~61. For more than a decade, all pharmaceutical companies participating in Medicaid and Medicare Part B have offered Contract Pharmacy 340B Drug Discounts to covered entities. This has been the universal practice of all drug companies participating in the 340B Program until the recent events (by just a few companies) described in this Complaint.

~~60.~~62. ~~The most recent~~Recent data published by HHS in June 2021 reflects that more than 4,000 covered entities have Contract Pharmacy arrangements to obtain Contract Pharmacy 340B Drug Discounts. HRSA data as of September 30, 2022, shows that, in New York State alone, more than 2,900 Contract Pharmacies have registered Contract Pharmacy arrangements with covered entities.

~~61.~~63. ~~Even now, with the significant exception of Defendants~~Until the Defendants' launched their conspiracy, every one of the 1,000-plus drug companies participating in the 340B Program—and every one of the top 250 drug companies~~, apart from Defendants—continues to offer~~—offered Contract Pharmacy 340B Drug Discounts.

~~62. Defendants' recent actions are the exceptions that prove the rule.~~

C. Any drug company that, acting alone, restricted Contract Pharmacy 340B Drug Discounts ~~could~~would seriously jeopardize its market share ~~over months or years~~.

~~63.~~64. Any drug company that restricted the availability of Contract Pharmacy 340B Drug Discounts would put its market share at risk.

~~64.~~65. Hospitals and clinics can and do prefer certain drugs over others. Where drugs are clinically equivalent or therapeutically interchangeable, hospitals and clinics will consider other factors. Those factors can include the cost of the drugs to the patient or hospital/clinic, or

the ability of the drug to ~~provide~~generate net revenue to support the clinical operations of the hospital/clinic. Typically, a drug with a Contract Pharmacy 340B Drug Discount would be preferred to a clinically equivalent and therapeutically interchangeable drug without a Contract Pharmacy 340B Drug Discount because it would result in 340B Savings.

~~65.~~66. Hospitals and clinics can steer patients towards preferred drugs in various ways. For instance, a hospital or clinic can decide to stock its inventory with one of a series of clinically equivalent or therapeutically interchangeable drugs. If that drug were successfully administered during an outpatient visit, it would more likely be prescribed. As another example, a prescribing physician at a hospital or clinic could choose to start new patients on a particular medicine among a series of clinically equivalent or therapeutically interchangeable drugs. Through these and other actions, hospitals and clinics can influence which drug, out of a series of clinically equivalent or therapeutically interchangeable drugs, is prescribed for their patients.

~~66.~~67. Significantly, however, most efforts to steer patients towards a particular drug, among a series of clinically equivalent or therapeutically interchangeable drugs, require months or years to complete. The efforts are most successful with new patients, who may receive an administered drug for the first time during an outpatient visit or may receive a prescription for a particular type of drug (*e.g.*, an incretin mimetic) for the first time. New patients arrive gradually, which takes time. As for existing patients, any efforts to convert their usage from one drug to another within a series of clinically equivalent or therapeutically interchangeable drugs is typically a slower process.

~~67.~~68. Consequently, the market share of a drug company that limited Contract Pharmacy 340B Drug Discounts would eventually be threatened by competitors that continued to offer clinically equivalent and therapeutically interchangeable drugs to covered entities with

Contract Pharmacy 340B Drug Discounts. That threat, however, would require many months to materialize.

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

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

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

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

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

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

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

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

76. No rational manufacturer would risk acting alone to limit the sale of Contract Pharmacy 340B Drug Discounts because the United States has maintained that any such limitation violates Section 340B. The Government could feasibly restrict a single manufacturer from federal healthcare programs without unduly undermining the mission of those federal healthcare programs in delivering critical medications to others because the exclusion of one manufacturer would not disrupt the availability of drugs of that manufacturer's competitors.

77. A rational manufacturer would risk acting in coordination with its competitors to limit the sale of Contract Pharmacy 340B Drug Discounts. The reason is that, if a manufacturer

of critical medications, such as diabetes medications, conspired with all of the competing manufacturers of such medications, the Government could not feasibly restrict that group of manufacturers from federal healthcare programs. Any effort by the Government to exclude that group of manufacturers would undermine the mission of the federal healthcare programs by disrupting the availability of critical drugs needed by program participants. Thus, any manufacturer could protect itself against the risk of crippling sanctions by conspiring with its competitors.

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

~~68.~~78. Defendants dominate three of today's most lucrative markets for diabetes treatments: (i) rapid-acting analog insulins; (ii) long-acting analog insulins; and (iii) incretin mimetics. Defendants compete against each other, as horizontal competitors, in these markets.

~~69.~~79. Diabetes occurs when a person has too much glucose (a type of sugar) in their blood stream. Insulin is involved in the pathway that permits glucose to leave the bloodstream and enter cells. With insufficient insulin, glucose remains at high levels in the blood, leading to high blood sugar levels.

~~70.~~80. There are two types of diabetes. Type 1 diabetes, which is usually diagnosed in children and young adults, is a condition in which the body does not produce any insulin. Type 2 diabetes, which is the more common form, is a condition in which the body either produces insufficient insulin or where cells become resistant to insulin to a certain degree. All patients with Type 1 diabetes require insulin treatments; and about a quarter of patients with Type 2 diabetes require insulin treatments.

~~71.~~81. Diabetes is a widespread disease in the United States. Over 30 million people, making up nearly ten percent of the Nation's population, live with diabetes. It is a life-

threatening disease that, for many, requires daily treatments to survive. Absent treatment, diabetes can cause serious harm and organ damage. Moreover, untreated diabetes can lead to diabetic ketoacidosis, which can be fatal. Indeed, according to the Centers for Disease Control and Prevention, diabetes was the seventh leading cause of death in 2019.

~~72.~~82. Diabetes is often coincident with low-income populations and in lower-income neighborhoods that are underserved by private healthcare practices. *See, e.g.*, Gaskin, et al., "Disparities in Diabetes: The Nexus of Race, Poverty, and Place," 104 Am. J. Public Health 2147 (Nov. 2014).

~~73.~~83. Diabetes is likewise a common area of treatment for 340B covered entity hospitals and clinics. According to HRSA, one in seven federally qualified health center patients has diabetes and nearly one in three of those has uncontrolled diabetes.

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

~~74.~~85. Consequently, diabetes medications make up a significant portion of 340B covered entities' outpatient prescriptions and 340B Drug Discounts. And three of the most significant diabetes medications are rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics.

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

~~75.~~86. Analog insulins are a type of human insulin. They are an important treatment for diabetes. Indeed, clinicians often prefer analog insulins to other forms of insulin, and the American Diabetes Association recommends analog insulins for the treatment of individuals with both type 1 diabetes and type 2 diabetes.

~~76.~~87. There are both rapid-acting analog insulins and long-acting analog insulins.

~~77.~~88. Sanofi, Eli Lilly, and Novo Nordisk all produce and sell rapid-acting analog insulins. Eli Lilly developed Humalog, the first analog (meaning, man-made) insulin in the mid-1990s; it is a rapid-acting analog insulin that can be rapidly absorbed. Novo Nordisk then developed its own rapid-acting analog insulin, Novolog, around 2000. And, in 2018, Sanofi launched a follow-on insulin product, Admelog, based on Eli Lilly's Humalog.

~~78.~~89. Since 2019, Eli Lilly has sold Humalog both under the brand name Humalog and as an authorized generic called insulin lispro. Since January 2020, Novo Nordisk has sold Novolog both under the brand name Novolog and as an authorized generic called insulin aspart.

~~79.~~90. Sanofi, Eli Lilly, and Novo Nordisk currently manufacture and sell the following rapid-acting analog insulins, which are clinically equivalent and therapeutically interchangeable, with each drug capturing the approximate market share listed,[2] as of July 2020:

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

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

~~80.~~91. Eli Lilly also sells biosimilar versions of Humalog. On June 15, 2020, the FDA approved another Eli Lilly rapid-acting analog insulin, Lyumjev. Eli Lilly began selling Lyumjev in the United States on or about October 7, 2020.

~~81.~~92. In addition to rapid-acting analog insulins, there are rapid-acting recombinant human insulins. Those insulins are Humulin R, sold by Eli Lilly, and Novolin R, sold by Novo Nordisk.

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

~~82.~~93. Another class of insulin are long-acting analog insulins. The American Diabetes Association has described long-acting analog insulin as the "most convenient initial insulin regimen." Am. Diabetes Ass'n, *Approaches to Glycemic Care*, 38 Diabetes Care S52, S57 (2016).

~~83.~~94. Sanofi, Eli Lilly, and Novo Nordisk all produce and sell long-acting analog insulins. Around 2000, Sanofi introduced the first long-acting analog insulin, Lantus. Then, Novo Nordisk introduced its own long-acting analog insulin, Levemir. Those drugs were followed by Toujeo, Sanofi's higher-dose long-acting analog insulin; Tresiba, another long-acting analog insulin from Novo Nordisk; and Basaglar, Eli Lilly's long-acting analog insulin.

~~84.~~95. Sanofi, Eli Lilly, and Novo Nordisk currently manufacture and sell the following long-acting analog insulins, which are clinically equivalent and therapeutically interchangeable, with each drug capturing the approximate market share listed,[3] as of July 2020:

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

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

~~85.~~96. Another class of diabetes medications, apart from insulins, is the class of incretin mimetics called glucagon-like peptide 1 agonists (GLP-1). These drugs work by increasing the level of hormones called incretins. Incretins help the body produce more insulin and can reduce the amount of excess glucose being produced by the liver.

~~86.~~97. Sanofi, Eli Lilly, Novo Nordisk, and AstraZeneca all produce and sell incretin mimetics. Eli Lilly developed the first incretin mimetic, Byetta (now sold by AstraZeneca), from the saliva of a lizard, the gila monster, and introduced it in 2005. Since then, the FDA has approved incretin mimetics by Sanofi, Eli Lilly, Novo Nordisk, and AstraZeneca.

~~87.~~98. Sanofi, Eli Lilly, Novo Nordisk, and AstraZeneca currently manufacture and sell the following incretin mimetics, which are clinically equivalent and therapeutically interchangeable, with each drug capturing the approximate market share listed,[4] as of July 2020:

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

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

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

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

~~88.~~99. Defendants manufacture and sell other competing drugs, as well.

~~89.~~100. For instance, Eli Lilly and AstraZeneca both produce competing antipsychotic medications to treat bipolar disorder and schizophrenia. Eli Lilly produces the drug Zyprexa, and AstraZeneca produces the drug Seroquel.

~~90.~~101. But such drugs, along with Defendants' other competing drugs, make up relatively small fractions of Defendants' collective sales of covered outpatient drugs in the 340B Drug Discount Program, compared to their collective sales of rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics.

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

~~91.~~102. Within the United States, Defendants annually sell billions of dollars of rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics. For each Defendant, these diabetes medications contribute significantly to the company's financial performance, representing hundreds of millions or billions of dollars in annual sales for each company.

~~92.~~103. At Eli Lilly, for instance, rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics are the most significant drugs in the company's portfolio.

Trulicity, its incretin mimetic, generated more than twice as much revenue as any other Eli Lilly product in 2020, with U.S. revenues of $3.8 billion. *See* Eli Lilly Annual Report (2020) at 46. Eli Lilly's second highest revenue generating drugs are its rapid-acting analog insulins, Humalog and Insulin Lispro, which generated U.S. revenue of $1.5 billion. *See id.* Eli Lilly's long-acting analog insulin drug, Basaglar, was also among its highest revenue producing drugs, generating revenue of $842.3 million in the U.S. Together, Eli Lilly's rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics account for $6.2 billion, or nearly 45%, of its 2020 U.S. revenue.

~~93.~~104. These drugs are also a significant part of Eli Lilly's strategy for growth. Eli Lilly announced that its 2020 revenue growth "was driven by increased volume primarily for" a handful of drugs, including Trulicity, *id.* at 45, which had grown by 23% year-over-year, and that Eli Lilly's future "[r]evenue growth is expected to be driven by volume from Trulicity," first among a list of other drugs. *Id.* at 55. Indeed, in 2021, Eli Lilly reported that "[r]evenue of Trulicity . . . increased 28 percent in the U.S." *See* Eli Lilly Annual Report (2021) at 44.

~~94.~~105. At Novo Nordisk, too, rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics are the most significant drugs in the company's portfolio. Together, Novo Nordisk's rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics accounted for approximately $7.3 billion (converted from a reported $44.3 billion DKKs), or 77%, of its 2020 U.S. revenue. *See* Novo Nordisk Annual Report (2020) at 54.

~~95.~~106. These drugs are part of Novo Nordisk's business strategy, as well. Novo Nordisk describes its business, first and foremost, as "a world leader in Diabetes care," with "one of the broadest diabetes product portfolios in the industry, including new generation insulin, a full portfolio of modern insulin and human insulin as well as a portfolio of GLP-1 receptor

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

~~96.~~107. At Sanofi, rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics make up a significant portion of the company's business and are a defining feature of the company's history. Together, Sanofi's rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics accounted for approximately $1.7 billion (converted from a reported $1.4 billion Euros) in 2020 U.S. revenue. *See* Sanofi Form 20-F (2020) at 64.

~~97.~~108. Incretin mimetics are a substantial part of AstraZeneca's business, as well as an area targeted for growth. AstraZeneca reported U.S. sales of $382 million for Bydureon in 2020 and $37 million for Byetta. *See* AstraZeneca Annual Report (2020) at 187. Moreover, the company's 2020 annual report highlighted that diabetes is the company's largest therapy area world market, at an estimated size of $99.6 billion, or approximately a full half of the overall therapy markets targeted by the company. *See id.* at 36.

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

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

111. Likewise, Sanofi has boasted about its "strong position" in the long-acting analog insulin market. *See* Sanofi, IR Thematic Call on Diabetes, Presentation at 29 (June 16, 2014). Sanofi has tracked and highlighted its market share in the United States. *See id.* at 30. Rather than focusing merely on short-term profits, Sanofi has presented the market share issue as one of

long-term retention of patients. Sanofi has thus claimed that it is "uniquely positioned to sustain a strong foothold in diabetes with Toujeo® and other new product opportunities." *Id.* at 33.

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

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

~~98.~~113. Among the various drugs sold by Defendants, sales of their rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics are particularly significant among sales at Contract Pharmacies serving covered entities' patients.

~~99.~~114. Upon information and belief, the overwhelming majority of Contract Pharmacy 340B Drug Discounts for drugs sold by Defendants at Contract Pharmacies are attributable to their rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics. Upon information and belief, approximately 80% of covered entities' 340B Savings from Defendants are attributable to Defendants' rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics, whereas all of Defendants' other drugs account for only 20% of 340B Savings at Contract Pharmacies.

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

115. Defendants' price-fixing conspiracy began as soon as their collective lobbying efforts failed. Through mid-summer, Defendants had spent millions collectively lobbying the federal government (in efforts not challenged here) to limit 340B Drug Discounts with respect to diabetes medicines. Defendants, as part of long-running lobbying by drug companies, had

sought to limit the level of hospital participation in the 340B Program, limit which patients could qualify for 340B Drug Discounts, require that all discounts be passed through to patients, and limit the availability of Contract Pharmacy 340B Drug Discounts. But Defendants' lobbying efforts failed. That failure became evident with the issuance of Executive Order 13937, which did little to limit Contract Pharmacy 340B Drug Discounts. ~~As soon as it became clear that Defendants' collective lobbying efforts had failed, Defendants turned to another~~

~~100.~~116. While the lobbying efforts themselves were a failure, the collective effort to lobby brought Defendants together and gave them the opportunity to work together on rolling out coordinated Contract Pharmacy 340B Drug Discount restrictions. Thus, alongside their collective lobbying efforts, Defendants, upon information and belief, developed a fallback plan focused on just one of their goals—collusively eliminating or otherwise limiting Contract Pharmacy 340B Drug Discounts for their drugs, which dominate the rapid-acting analog insulin, long-acting analog insulin, and incretin mimetic markets of diabetes medications.

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

~~101.~~117. On July 24, 2020, then-President Donald Trump issued Executive Order 13937, entitled, "Access to Affordable Life-Saving Medications." *See* 85 Fed. Reg. 45,755 (July 29, 2020). The executive order addressed the use of insulin (as well as epinephrine) within the 340B Drug Discount Program. The order noted that "[i]nsulin is a critical and life-saving medication that approximately 8 million Americans rely on to manage diabetes," and that "[t]he price of insulin in the United States has risen dramatically over the past decade." *Id.* The order further noted that "many Americans still struggle to purchase these products." *Id.*

~~102.~~118. The executive order noted that the 340B Drug Discount lowers the price of insulin for covered entities. ~~As the order recited, while "[t]he list price for a single vial of insulin~~

~~today is often more than $250," "many of these products" may be purchased under the 340B Program "at a price of one penny per unit of measure." *Id.* The order then~~The order stated, with significant qualification, that "[t]hese steep discounts, however, are not *always* passed through to low-income Americans at the point of sale." *Id.* (emphasis added). The executive order was aimed at addressing that issue.

~~103.~~119. But the executive order was extremely limited in scope. In particular, it applied only to federally qualified health centers. The President ordered only that HHS should "take action to ensure future grants . . . are conditioned upon [federally qualified health centers] having established practices to make insulin . . . available at the discounted price paid by the [federally qualified health center] grantee or sub-grantee under the 340B Prescription Drug Program (plus a minimal administration fee) to individuals with low incomes, . . . who: (a) have a high cost sharing requirement for . . . insulin; (b) have a high unmet deductible; or (c) have no health care insurance." *Id.*

~~104.~~120. Executive Order 13937 promised to have relatively little impact on the volume of 340B Drug Discounts for insulin medications for several reasons.

~~105.~~121. *First*, because the order was limited to federally qualified health centers, it would have no impact on any of the other categories of covered entities. The order did not apply to any of the other nine categories of clinics that can be covered entities. Nor did it apply to any hospital covered entities.

~~106.~~122. *Second*, the order appeared to impose largely redundant legal requirements. Federally qualified health centers are funded through Section 330 of the Public Health Services Act, 42 U.S.C. § 254b. Under that authority, HHS "may make grants for the costs of the operation of public and nonprofit private health centers that provide health services

to medically underserved populations." 42 U.S.C. § 254b(e)(1)(A). For a health center to obtain such funding, it must provide "the required primary health services" set out in the statute. 42 U.S.C. § 254b(k)(3)(A). And those "required primary health services," by definition, include the provision of "pharmaceutical services." 42 U.S.C. § 254b(b)(1)(A)(i)(V). Moreover, under HRSA's Health Center Compliance Manual, health centers "must operate in a manner such that no patient shall be denied service due to an individual's inability to pay," and are already obligated to provide a "full discount to individuals and families with annual incomes at or below [the poverty line]." So, it was unclear what real effects the executive order might have in changing patient prices for insulin.

~~107.~~123. *Third*, and relatedly, the executive order did not appear to impact sales of insulin medication to federally qualified health centers in the 340B Program. As noted, federally qualified health centers must ensure their patients have access to drugs. Those centers would seek to do so at the best price. Requiring federally qualified health centers to pass all 340B Savings onto patients would not change the health centers' incentives—they would still seek to purchase the same volume of drugs, with Contract Pharmacy 340B Drug Discounts included. So, as long as federally qualified health centers purchased the same volume of drugs and, as per the executive order, continued to do so with Contract Pharmacy 340B Drug Discounts, insulin-manufacturers' profit margins would be unaffected.

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

~~108.~~124. Upon information and belief, Defendants worked together to lobby the Federal Government, including HHS and White House, to obtain legal or agency guidance changes to limit 340B Drug Discounts, particularly for diabetes medicines like analog insulin and incretin mimetics. This allegation is supported by Defendants' lobbying records.

~~109.~~125. In the reporting periods that encompassed lobbying in advance of the President's executive order (*i.e.*, April 1 through June 30, and July 1 through September 30), Defendants spent significant resources lobbying the Federal Government. According to their public disclosures, each Defendant in that period lobbied the Federal Government regarding the 340B Program: Sanofi spent upwards of $320,000 on external lobbyists and upwards of $1.9 million of its own resources on that effort; Eli Lilly spent upwards of $290,000 on external lobbyists and upwards of $3.18 million of its own resources; Novo Nordisk spent upwards of $250,000 on external lobbyists and upwards of $90,000 of its own resources; and AstraZeneca spent upwards of $240,000 on external lobbyists and upwards of $1.23 million of its own resources on that effort. In total then, Defendants report spending upwards of $1.1 million on external lobbyists and upwards of $6.4 million of their own resources lobbying 340B Drug Discounts in this short period.

~~110.~~126. Not only were Defendants lobbying the Federal Government as to 340B Drug Discounts, but they were also lobbying regarding insulin and other diabetes medication issues. The three Defendants dominating the analog insulin markets—Sanofi, Eli Lilly, and Novo Nordisk—all report lobbying insulin issues alongside 340B Drug Discount issues. And both Novo Nordisk and AstraZeneca report lobbying diabetes issues at the same time.

~~111.~~127. Defendants were coordinated in their lobbying during this time period, both in terms of issues as set out above and in terms of lobbyists. They used common lobbyists. For instance, all four Defendants report that, in this period, they used the lobbying firm, Tarplin, Downs & Young LLC to lobby the Federal Government on the 340B Drug Discount issue, and concomitantly, insulin or diabetes. Further, in the same period, both Sanofi and AstraZeneca used the lobbying firm W Strategies, LLC to lobby 340B Drug Discounts. And Sanofi, Eli Lilly,

and Novo Nordisk used the common lobbying firm Williams and Jensen, PLLC to lobby the same issue in this same period. Moreover, some of these lobbyists frankly revealed that their lobbying focused on "Executive Orders regarding drug pricing," including Executive Order 13937.

~~112.~~128. This common effort allowed Defendants to coordinate and communicate about their strategies on limiting 340B Drug Discounts, including Contract Pharmacy 340B Drug Discounts, for diabetes medications such as analog insulins and incretin mimetics. Defendants were speaking with the same lobbying firms about the same issues at the same time. At the very least, they were communicating indirectly, through these common firms.

~~113.~~129. It is much more likely that Defendants were also communicating directly about their lobbying strategies with their common lobbyists. Significantly, the common lobbying firms—including Tarplin, Downs & Young and Williams and Jensen, PLLC—reported working on these same 340B issues during this same period for the drug manufacturers' association, PhRMA. Each Defendant is a member of PhRMA. Given the common lobbying firms working for each Defendant and their common association in the same time period on the same issues, all in advance of an executive order on those issues, it is most likely that Defendants would have been on common calls to discuss strategy. Upon information and belief, in advance of the President's issuance of Executive Order 13937, Defendants communicated directly with each other about strategies for limiting 340B Drug Discounts.

~~114.~~130. Upon information and belief, Defendants' lobbying efforts focused on the four strategies that the pharmaceutical industry and its advocates had long pursued to limit 340B Drug Discounts: (1) limiting the level of hospital participation in the 340B Program, (2) limiting

which patients could qualify for 340B Drug Discounts, (3) requiring that all discounts be passed through to patients, and (4) limiting the availability of Contract Pharmacy 340B Drug Discounts.

~~115.~~131. Defendants lobbying efforts largely failed, as Defendants were unable to obtain meaningful changes to the availability of 340B Drug Discounts through lobbying. The drug companies' perception that Executive Order 13973 was largely meaningless is reflected in the tweets of AIR340B, a drug company association aimed at limiting the scope of the 340B Program, which hosts a webpage dedicated to challenging the propriety of Contract Pharmacy 340B Drug Discounts. *See* AIR340B, "Contract Pharmacies' Troubling Role in the 340B Drug Discount Program" (last visited May 14, 2021). In the wake of the executive order, AIR340B tweeted, "[T]he administration's executive order on insulin and #340B . . . misses the mark by not targeting the large hospitals;" "this narrow change does not address the myriad of remaining issues that prohibit 340B from currently functioning as it was intended;" and "we are disappointed the administration targeted FQHCs, not DSH hospitals."

~~116.~~132. ~~Given the failure of~~While these lobbying efforts~~,~~ largely failed, the collective lobbying effort provided Defendants~~, upon information and belief, then turned~~ with the opportunity to ~~their~~jointly develop a collective fallback plan ~~B, which~~ focused on just one of their strategies—~~their~~a coordinated ~~withdrawal~~restriction of Contract Pharmacy 340B Drug Discounts.

IV. ~~After their joint~~Joint lobbying efforts ~~failed,~~gave Defendants ~~coordinated a~~an opportunity to coordinate their rollback of Contract Pharmacy 340B Drug Discounts.

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

~~117.~~133. Defendants engaged in a coordinated campaign to limit Contract Pharmacy 340B Drug Discounts. That plan ~~began~~went into effect as soon as the President's

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

~~118.~~134. On Friday, July 24, 2020, the same day that President Trump issued Executive Order 13937, AstraZeneca informed HHS of the drug company's intention to limit Contract Pharmacy 340B Drug Discounts. It did so by letter from Christie Bloomquist, AstraZeneca's Corporate Affairs Vice President for North America, to Rear Admiral Krista Pedley, the Director of HRSA's Office of Pharmacy Affairs. The letter stated that, "Beginning on October 1, 2020, AstraZeneca plans to adjust [its] approach for the products listed," "such that AstraZeneca will recognize one contract pharmacy per covered entity for those covered entities that do not maintain an on-site dispensing pharmacy." The products listed included AstraZeneca's incretin mimetics, Bydureon and Byetta.

~~119.~~135. In its Friday, July 24th letter to HHS, AstraZeneca did not explain the timing of its sudden change in approach to Contract Pharmacy 340B Drug Discounts. Rather,

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

~~120.~~136. Yet, within days of AstraZeneca's privately communicated letter to HRSA, Sanofi publicly announced its sudden plans to impose similarly novel restrictions on Contract Pharmacy 340B Drug Discounts—and on the exact same timeline. ~~Specifically, on or about~~Sanofi was, at the time, a $132 billion company; and it would have been virtually impossible for Sanofi to have vetted and cleared such a dramatic and unprecedented change in its pricing practices on a few days' notice. Yet, just a single business day after AstraZeneca's Friday announcement, on Monday, July 27, 2020, Sanofi informed all 340B Program covered entities that Sanofi would be "implementing a new 340B program integrity initiative." That "initiative" would cut off all Contract Pharmacy 340B Drug Discounts, which had been in place for a decade, unless covered entities provided new consideration to Sanofi. The newly required consideration was entry into a contract to provide sensitive prescription claims data to a Sanofi vendor, Second Sight Solutions, through a software portal called 340B ESP on commercially unreasonable terms~~.~~ (as more fully explained below). Otherwise, "340B claims data [would] no longer be eligible" for Contract Pharmacy 340B Drug Discounts. Significantly, Sanofi announced that the date it would begin limiting Contract Pharmacy 340B Drug Discounts was

October 1, 2020—the same date that AstraZeneca would limit Contract Pharmacy 340B Drug Discounts, too. ~~Sanofi was, at the time, a $132 billion company; and it would have been virtually impossible for Sanofi to have vetted and cleared such a dramatic and unprecedented change in its pricing practices on a few days' notice.~~As described in further detail below, the immediate impact of Sanofi's restrictions was the same as that resulting from AstraZeneca's restrictions—nearly eliminating 340B Drug Discounts on diabetes drugs as of October 1, 2020.

~~121.~~137. ~~Three~~Only three weeks later, Eli Lilly informed HHS of the drug company's intention to limit Contract Pharmacy 340B Drug Discounts in nearly the precise manner AstraZeneca had privately outlined in its letter to HHS. By letter dated August 19, 2020, Eli Lilly's Senior Director of Government Strategies sent a letter to Rear Admiral Krista Pedley, the Director of HRSA's Office of Pharmacy Affairs, just as Christie Bloomquist at AstraZeneca had done. The letter stated the same plan as AstraZeneca, albeit commencing one month earlier: "[E]ffective September 1, [2020], we . . . [will] discontinue our practice of voluntarily honoring requests for 340B 'contract pharmacies' for orders on all Lilly products except where," primarily, "a covered entity does not have an in-house pharmacy."

~~122.~~138. Eli Lilly added a special exception to permit Contract Pharmacies to pass along certain insulin products at cost. But that exception was infeasible for covered entities and pharmacies, as it required the Contract Pharmacies to fill prescriptions without any fee whatsoever. Specifically, Eli Lilly stated that it would offer the Contract Pharmacy 340B Drug Discount only where "[n]o insurer or payer is billed for the Lilly insulin dispensed" and "[n]either the covered entity nor the contract pharmacy marks-up or otherwise charges a dispensing…fee for the Lilly insulin." This exception was so narrow that it was virtually meaningless: Lilly prevented the collection of any revenue by a covered entity to offset the

dispensing fee the covered entity would have to pay the Contract Pharmacy. This exception was commercially infeasible, as Eli Lilly understood.

~~123.~~139. Eli Lilly, like AstraZeneca and Sanofi, offered no explanation why suddenly, after a decade of offering Contract Pharmacy 340B Drug Discounts, Eli Lilly decided to stop them in late 2020. The absence of an explanation was particularly strange because, months earlier, Eli Lilly had informed HHS of a much narrower change to its Contract Pharmacy 340B Drug Discounts—ceasing to offer discounts on a single drug, Cialis. Eli Lilly informed HHS of that decision just two months earlier, by letter dated May 18, 2020. But while the May 18 letter cited global concerns with Contract Pharmacies, it announced the decidedly narrower action of simply ceasing to offer discounts on Cialis. In May 2020, Eli Lilly did not inform HHS that it would cease to offer Contract Pharmacy 340B Drug Discounts altogether. Significantly, Eli Lilly did not then announce any restrictions on Contract Pharmacy 340B Drug Discounts for its rapid-acting analog insulins (Humalog and Insulin Lispro), its long-acting analog insulin (Basaglar), or its incretin mimetic (Trulicity). Eli Lilly first announced those restrictions, instead, only in coordination with AstraZeneca and Sanofi in the summer of 2020.

~~124.~~140. Novo Nordisk waited several more months before announcing that it would stop offering Contract Pharmacy 340B Drug Discounts to hospital covered entities. On December 1, 2020, Novo Nordisk informed HHS of the drug company's policy. In particular, Novo Nordisk, along with its competitors AstraZeneca, Eli Lilly, and Sanofi, would limit the availability of Contract Pharmacy 340B Drug Discounts. The Novo Nordisk restrictions were a variation on the competitors' theme—it would stop offering Contract Pharmacy 340B Drug Discounts to all hospital covered entities. Novo Nordisk announced that this restriction would be effective on January 1, 2021.

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

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

143. Each Defendant attributed its restrictions to purported concerns about program integrity. No Defendant cited any immediate cause for its sudden and unprecedented restrictions. None claimed the failure of their lobbying efforts was the trigger. None offered any explanation why it alone would impose such restrictions at that point in time. Eli Lilly claimed it was acting in response to abuses of the 340B Program that had been increasing over the years. *See* Eli Lilly Letter dated Aug. 19, 2020, at 1. AstraZeneca referenced audits that had been

taking place since 2017. *See* AstraZeneca Letter dated July 24, 2020, at 3. Novo Nordisk offered no explanation, but has since publicly stated its restrictions were likewise based on concerns of "systemic abuses," *see* Compl., *Novo Nordisk, Inc. v. HHS*, 21-cv-806, Dkt. 1 (D.N.J. Jan. 15, 2021). And Sanofi cited general program integrity concerns. *See* Sanofi Letter of July 2020. None of those rationales explained why Defendants suddenly announced and imposed their discount restrictions in late 2020.

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

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

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

146. Sanofi has since repeatedly explained that its policy is not to permit the sale of its drugs to covered entities for shipment to Contract Pharmacies. Sanofi restated this position in a complaint against HHS filed on January 12, 2021, stating that, under its restrictions, a covered "entity simply may not order discounted drugs for shipment to contract pharmacies." Compl., ¶ 48, *Sanofi-Aventis v. HHS*, 3:21-634, Dkt. 1 (D.N.J. Jan. 12, 2021). In its amended complaint in the same action, Sanofi stressed that its policy means that "a covered entity is not

'overcharged'—indeed, it typically is not charged at all," because Sanofi sells such drugs directly to pharmacies, not to the covered entities. Second Am. Compl., ¶ 177, *Sanofi-Aventis v. HHS*, 3:21-634, Dkt. 78 (D.N.J. May 25, 2021). Then, again, by letter to HRSA dated June 1, 2021, Sanofi reiterated that its primary method for restricting covered entity access to 340B Drugs is by refusing to make its drugs available to covered entities, such that "[o]nly the pharmacy is charged, and . . . no covered entity is charged." *See* Letter to HRSA, dated June 1, 2021, at 24.

147. Likewise, Eli Lilly imposed its restrictions primarily through Defendants' shared policy of refusing to permit the sale of 340B Drugs to covered entities for shipment to Contract Pharmacies. As part of Eli Lilly's initial announcement of its restrictions to covered entities, it explained that "[e]ffective September 1, 2020, Lilly is limiting distribution of all 340B ceiling priced product directly to covered entities and their child sites only." "Covered entities," it announced, would no longer "be eligible to purchase Eli Lilly and Company products at the 340B ceiling price for shipment to a contract pharmacy."

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

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

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

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

152. AstraZeneca has since repeatedly explained that its policy is not to permit the sale of its drugs to covered entities for shipment to Contract Pharmacies. AstraZeneca told the U.S. District Court for the District of Delaware that, under its policy of refusing to ship, "[t]o the extent that a patient of the covered entity fills her prescription at a pharmacy not [permitted by] AstraZeneca's policy, the dispensed medicine," going forward, would not have been "sold to the

covered entity, but rather" would have been "purchased by the pharmacy." AstraZeneca Mem. at 23, *AstraZeneca Pharm. LP v. Becerra*, 21-cv-27, Dkt. 91 (D. Del. July 23, 2021). Under this policy, "there is no sale at all to the covered entity," who typically cannot obtain AstraZeneca's drugs for shipment to Contract Pharmacies, and thus is "never charged."

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

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

~~125.~~154. Defendants' abrupt limitation of Contract Pharmacy 340B Drug Discounts were historically unprecedented.

~~126.~~155. Prior to Defendants' actions in late 2020, each company had regularly offered Contract Pharmacy 340B Drug Discounts for a decade.

~~127.~~156. Indeed, prior to Defendants' actions in 2020, the entire pharmaceutical industry—including all of the largest 250 drug companies, as well as every drug company with drugs covered by Medicaid and Medicare Part B—had regularly offered Contract Pharmacy 340B Drug Discounts for their covered outpatient drugs for at least a decade.

~~128.~~157. Moreover, shortly before its coordination with the other Defendants, Eli Lilly had considered withdrawing Contract Pharmacy 340B Drug Discounts and decided against

doing so, outside of a very narrow set of certain Cialis formulations. Eli Lilly abruptly changed its approach in coordination with the other Defendants.

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

~~129.~~158. Not a single other major pharmaceutical company joined the Defendants in their coordinated scheme to limit or eliminate Contract Pharmacy 340B Drug Discounts~~.~~ at the time they did so.

~~130.~~159. In 2020, two top drug manufacturers—Merck and Novartis—asked covered entities to participate in the same software program mandated by Sanofi. But, unlike Sanofi, neither Merck nor Novartis cut off Contract Pharmacy 340B Drug Discounts for covered entities unwilling to participate. A much smaller drug company, United Therapeutics, announced plans to restrict Contract Pharmacy 340B Drug Discounts, but it has not implemented that policy.

~~131.~~160. It was not until late 2021 that any major drug company implemented any similar restrictions on Contract Pharmacy 340B Drug Discounts. They did so more than a year after Defendants announced their restrictions. Specifically, Boehringer Ingelheim imposed restrictions beginning on August 1, 2021, and Merck imposed restrictions beginning on September 1, 2021. Merck, however, limited its restrictions mainly to antidiabetic drugs, such as Januvia, Janumet, Segluromet, and Steglatro. Other manufacturers initiated restrictions later, in 2022.

~~132.~~161. Defendants comprise fewer than 0.4% of the more than 1,000 drug companies that have signed PPAs with HHS.

~~133.~~162. Defendants, as direct competitors with each other in three key markets for diabetes medications, have restricted Contract Pharmacy 340B Drug Discounts.

~~134.~~163. ~~The~~When Defendants imposed their restrictions, the other more than 99.6% of drug companies ~~have~~ continued to offer Contract Pharmacy 340B Drug Discounts without restrictions. Those drug companies include some of the largest drug companies, such as Roche, Johnson & Johnson, Pfizer, AbbVie, Amgen, Bristol Myers Squibb, GlaxoSmithKline, Gilead, Bayer, Biogen, Takeda, Bausch Health, Alexion, and Regeneron, as well as more than a thousand others.

~~135.~~164. Defendants' common attribute, as the very few drug companies ~~restricting~~that had announced substantial restrictions on Contract Pharmacy 340B Drug Discounts by the end of 2020, is their joint domination of the three key diabetes medication markets. As of July 2020, Defendants controlled the entire market for each of those markets: (i) rapid-acting analog insulins; (ii) long-acting analog insulins, and (iii) incretin mimetics. They had no competition.

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

~~136.~~165. Defendants' novel restrictions were unusual not only because they were imposed after a decade of offering Contract Pharmacy 340B Drug Discounts or because they were imposed by Defendants alone among major pharmaceutical companies, but also because they were imposed despite warnings by regulators that such restrictions were illegal.

~~137.~~166. On September 2, 2020, HRSA released a public statement to the *340B Report*, an online media outlet, that HHS was "considering whether manufacturer policies [restricting Contract Pharmacy 340B Drug Discounts], including Lilly's, violate the 340B statute and whether sanctions may apply."

~~138.~~167. On September 21, 2020, HRSA posted a letter to its public website warning manufacturers of potentially dire consequences for restricting Contract Pharmacy 340B

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

~~139.~~168. On October 6, 2020, the Office of the Attorney General of the State of Connecticut sent letters to Sanofi, AstraZeneca, and Eli Lilly, "urg[ing] [each] to abandon its recent actions of unilaterally restricting access to low cost drug pricing by covered entities." The letters stated that the companies' "threats to flout federal requirements and discontinue appropriate 340B drug pricing are especially appalling given that these critical safety-net healthcare institutions are on the front lines of our response to the ongoing COVID-19 pandemic." The letters deemed the companies' actions "outrageous." Moreover, the Connecticut Attorney General stated that "[d]enying outpatient access to appropriate 340B drug pricing is a clear violation of federal law," which "disrupt[s] long-settled expectations and existing contractual arrangements for dispensing 340B drugs." The Attorney General ended his letter with the threat that his "office will not stand idly by while Eli Lilly and other drug companies prioritize profits over access to affordable prescription medication and other critical medical services for vulnerable communities."

~~140.~~169. The next day, the Connecticut Attorney General issued a press release announcing his letters to Sanofi, Eli Lilly, and AstraZeneca. The press release was entitled, "AG

Tong Demands Drug Makers Abandon Unlawful Actions Imperiling Access to Affordable Prescriptions for Low-Income Patients." The press release included a hyperlink to the letters to drug manufacturers.

~~141.~~170. On December 20, 2020, HHS General Counsel Robert P. Charrow issued an eight-page single-spaced advisory opinion concluding that restrictions on Contract Pharmacy 340B Drug Discounts were illegal under the terms of Section 340B. *See* HHS General Counsel, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program (Dec. 30, 2020). The opinion noted, in a reference to the actions of Defendants, that "[r]ecently, certain drug manufacturers participating in the 340B Program are declining to distribute covered outpatient drugs through contract pharmacies at the ceiling price" (*i.e.*, with Contract Pharmacy 340B Drug Discounts). *See id.* at 1. The opinion noted that "[f]or 24-plus years, manufacturers have offered the ceiling price to covered entities using contract-pharmacy distribution." *Id.* at 5 n.5. For reasons detailed in the opinion, HHS concluded that "covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients." *Id.* at 8.

~~142.~~171. The same day, HHS issued a press release announcing its advisory opinion. The press release was entitled, "HHS Releases Advisory Opinion Clarifying that 340B Discounts Apply to Contract Pharmacies." The press release included a hyperlink to the advisory opinion.

172. ~~More recently, on~~Soon thereafter, the United States Department of Justice (DOJ) reiterated the harshest sanction for 340B noncompliance, which the 340B statute makes plain:

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

~~143.~~173. On May 17, 2021, HRSA sent letters to each Defendant demanding that each "restart selling, without restriction, covered outpatient drugs at the 340B price to covered entities that dispense medications through contract pharmacy arrangements." The letters stated HRSA's conclusion that the Defendants' restrictions "are in direct violation of the 340B statute." Moreover, the letters warned each Defendant of potentially massive civil monetary penalties of up to $5,883 per instance of overcharge.

~~144.~~174. ~~Even more recently, on~~On June 18, 2021, the Office of General Counsel for HHS announced its intention to pursue Defendants for unlawfully restricting the availability of Contract Pharmacy 340B Drug Discounts. The Notice withdrew the legal opinion of December 20, 2020, "in the interest of avoiding confusion." But the Notice made clear that "its withdrawal of the Opinion does not impact the ongoing efforts of the Health Resources and Services Administration (HRSA) to enforce the obligations that 42 U.S.C. § 256b places on drug manufacturers, including HRSA's May 17, 2021 violation letters concerning restrictions placed on contract pharmacy arrangements."

~~145.~~175. ~~Most recently, on~~On September 22, 2021, HRSA sent letters to each Defendant announcing a referral to the HHS Office of the Inspector General (OIG) for violating the law. Each letter recounted that on "May 17, 2021, HRSA instructed" each Defendant "to comply with its 340B statutory obligations and to immediately begin offering [340B Drug Discounts] to covered entities that dispense the discounted medications through their contract pharmacy arrangements," and that HRSA had informed each Defendant "that continued failure to provide the 340B price to covered entities utilizing contract pharmacies could result in civil monetary penalties." The letters then stated that, given each Defendant's "continued refusal to comply, HRSA has referred this issue to the HHS Office of the Inspector General (OIG) in accordance with the 340B Program Ceiling Price and Civil Monetary Penalties Final Rule."

176. Despite these warnings from regulators, Defendants persisted in restricting access to Contract Pharmacy 340B Drug Discounts.[5] Defendants did so, notwithstanding the potential exclusion of Medicaid and Medicare coverage of their drugs.

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

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

[5] ~~By letter dated February 2, 2021, however, Sanofi purported to limit its restrictions to five covered entity types: consolidated health center programs, disproportionate share hospitals, critical access hospitals, rural referral centers, and sole community hospitals. These restrictions continue to restrict Plaintiffs' abilities to obtain Contract Pharmacy 340B Drug Discounts.~~

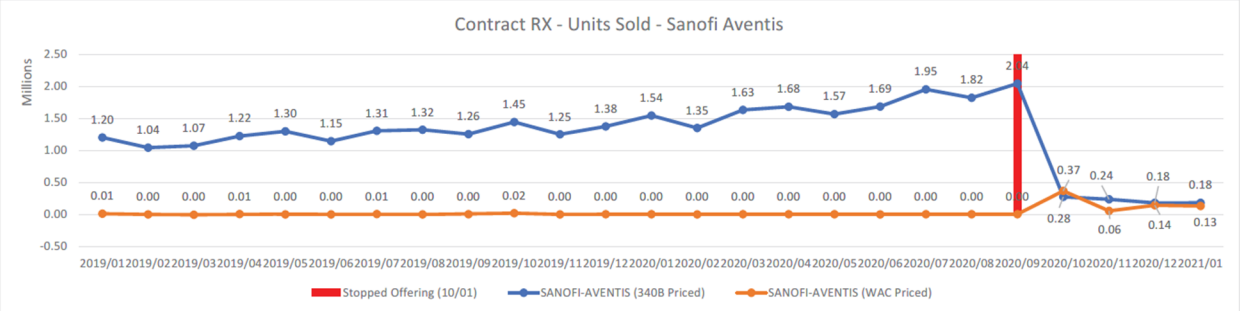
achieved the same result among all Defendants—the elimination of the bulk of their Contract Pharmacy 340B Drug sales.

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

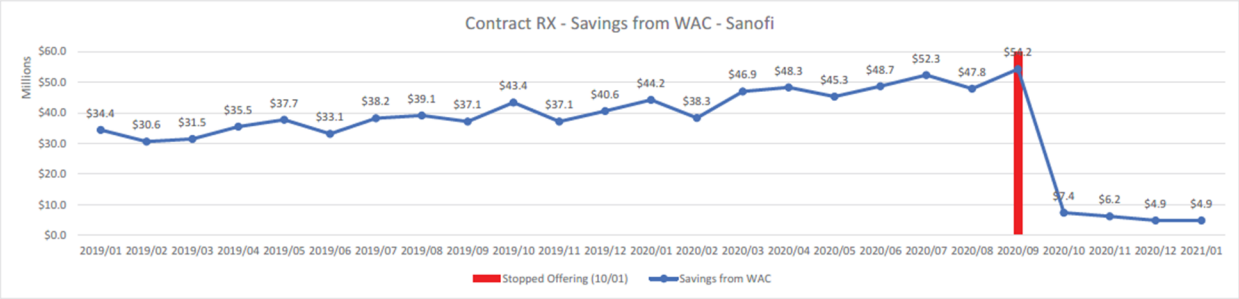
1. Sanofi's restrictions led to the elimination of the overwhelming majority of Sanofi's Contract Pharmacy 340B Drug Discount sales.

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

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



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



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

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

184. Indeed, in the immediate wake of Sanofi's restrictions, Contract Pharmacies became unable to receive the overwhelming majority of shipments of covered entities' desired drug purchases. An example is Avita Pharmacy, "a national chain that almost exclusively contracts with and dispenses for covered entities, including community health centers and AIDS

clinics." Gov't Mem. at 8, *Sanofi-Aventis v. HHS*, 3:21-cv-634, Dkt. 89 (D.N.J. June 16, 2021). According to HHS, Avita Pharmacy serves "270 covered-entity clients—98% of whom do not operate their own pharmacies." *Id.* And "all were being denied 340B pricing" of Sanofi's drugs.

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

186. This dramatic and immediate impact was predictable.

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

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

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

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

191. The administrative burdens imposed by Sanofi's demand are extensive. The Government has reported that "Sanofi demands bi-weekly submission of data, which in some instances may require the submitter to organize or reformat the data they otherwise collect to prepare such a submission." Gov't Mem. at 10, *Sanofi-Aventis v. HHS*, 3:21-cv-634, Dkt. 89 (D.N.J. June 16, 2021). The American Hospital Association has detailed, in over five pages of a brief, the "onerous burdens" Sanofi's demands would impose on 340B providers, including extensive data collection and submission. *See* Amicus Br., Am. Hosp. Assoc. at 25-29, *Sanofi-Aventis v. HHS*, 21-3167, Dkt. 35 (3d Cir. May 17, 2022). And, in a recent survey, more than 80% of covered entities that had concerns about data-sharing were reported that it was "[h]ighly

burdensome to compile and submit" the claims data demanded by Sanofi, with three-quarters also concerned that doing so could "conflict with contract pharmacy services agreements" currently in place. 340B Health Survey at 9.

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

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

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

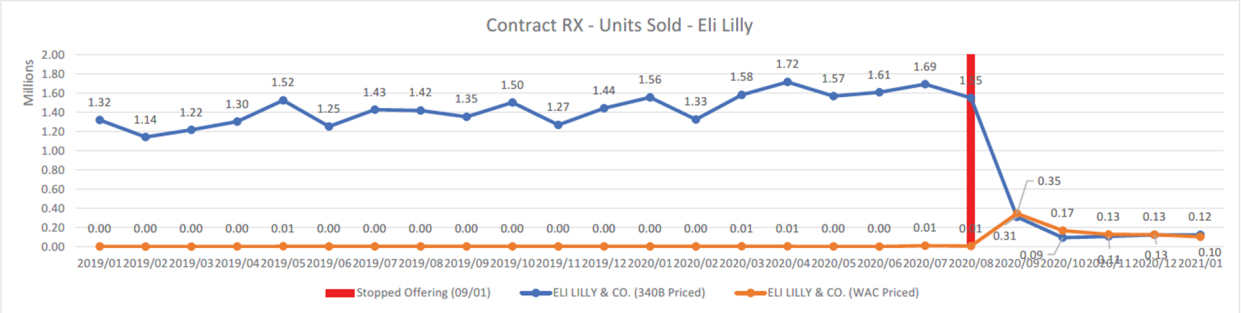
195. While Sanofi later tweaked its restrictions by limiting their application to the most significant covered entities, effective March 1, 2021, those restrictions have continued to restrict Plaintiffs' abilities to obtain Contract Pharmacy 340B Drug Discounts and continued to restrict the overwhelming volume of Contract Pharmacy 340B Drug Discount sales. Indeed, Sanofi itself recognized, in its announcement of this change, that its restrictions were aimed at the

overwhelming volume of Contract Pharmacy 340B Drug Discount sales. Sanofi stated that it was applying its restrictions to those "categories of covered entities that have historically accounted for a significant share of contract pharmacy dispensing."

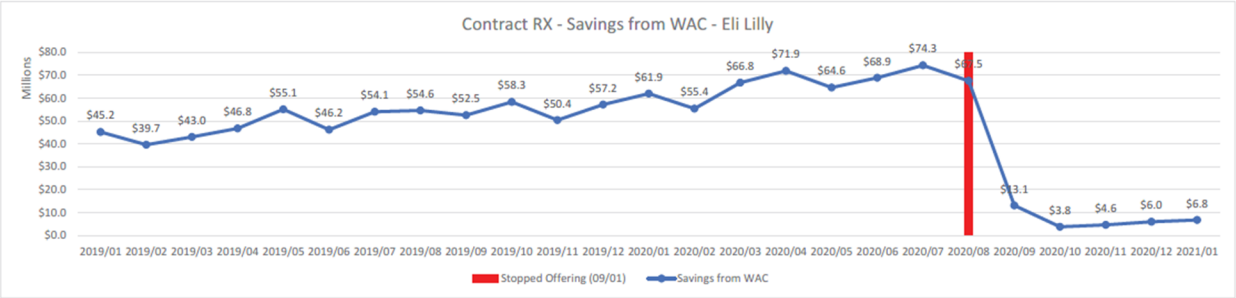
2. Eli Lilly's restrictions led to the elimination of the overwhelming majority of Eli Lilly's Contract Pharmacy 340B Drug Discount sales.

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

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



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



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

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

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

operate their own pharmacies." *Id.* And "all were being denied 340B pricing" of Eli Lilly's drugs.

202. This dramatic and immediate impact was predictable.

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

204. First, Eli Lilly offered a narrow single-pharmacy exception. It set out, in its initial announcement, an exception permitting those "[c]overed entities that do not have an in-house pharmacy" to "designate a contract pharmacy location." Eli Lilly reiterated that this exception did not permit more than a single designated Contract Pharmacy. For instance, in a letter to HRSA dated June 10, 2021, Eli Lilly explained that it would "allow[] covered entities lacking an in-house pharmacy to designate one outside contract pharmacy." And, in an announcement to covered entities in December 2021, El Lilly explained that, "[s]ince September 2020, Lilly has limited distribution of all 340B ceiling-priced product directly to covered entities and their child sites only, plus their wholly owned and affiliated contract pharmacies, with the exception of . . . covered entities that lack an in-house retail pharmacy," "who may designate a single contract pharmacy."

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

206. The single-pharmacy exception was narrow and altogether insufficient to mitigate the "precipitous decline in drug sales at 340B prices." As the United States District Court for the Southern District of Indiana found, "Lilly's refusal to deliver 340B drugs to more than one contract pharmacy often renders hollow its 'offer' to sell [drugs with 340B Drug Discounts].

Because these are prescription drugs, some of which cover controlled substances, they can be shipped only to locations that provide the proper legal infrastructure, including state licensing, DEA registration, staff pharmacists, etc., to accept delivery or, and dispense, pharmaceuticals. . . . [C]overed entities often serve vulnerable populations scattered over large geographic areas, making it impossible for all patients to fill their prescriptions each month on-site or in a single contract pharmacy location." *Eli Lilly & Co. v. HHS*, 1:21-81, 2021 U.S. Dist. LEXIS 209257, at 61 n.13 (S.D. Ind. Oct. 29, 2021).

207. As DOJ has explained, "covered entities often serve vulnerable populations over huge geographic areas with transportation and timing difficulties, making it impossible for all patients (tens of thousands per provider, in some cases) to fill their prescriptions each month on-site or in just one location." Gov't Reply Mem. at 24, *Eli Lilly*, 1:21-cv-81, Dkt. 125 (S.D. Ind. June 25, 2021). Thus, as DOJ further explained, "it strains credulity that one pharmacy could serve [a covered entity] as well" as multiple Contract Pharmacies. Trans. of July 30, 2021, at 60:11-12, *Eli Lilly & Co.*, 1:12-cv-81, Dkt. 139 (Aug. 5, 2021). Indeed, if the single-Contract Pharmacy exception were effective, "340B sales would not have taken the nosedive" that they did. Gov't Reply Mem. at 25, *Eli Lilly*, 1:21-cv-81, Dkt. 125 (S.D. Ind. June 25, 2021).

208. Second, Eli Lilly offered an exceedingly narrow and completely infeasible insulin-related exception. Eli Lilly announced that it would "grant an exception" for some, but not all, "Lilly insulin products." The exception did not extend to incretin mimetics. To qualify, covered entities need to reach out to Eli Lilly and "be prepared to submit documentation demonstrating that" four specified conditions were met. These conditions were: (1) that "all 340B eligible patients . . . acquire their Lilly insulins . . . at the 340B price," (2) that "[n]either the covered entity nor the contract pharmacy mark[] up or otherwise charge[] a dispensing fee

for the Lilly insulin," (3) that no "insurer or payer [be] billed for the Lilly insulin dispensed," and (4) that the "covered entity provides claim-level detail (CLD) demonstrating satisfaction of these terms and conditions." As DOJ has explained, Eli Lilly thus "purported to contain an exception for insulin—but conditioned it on novel, onerous restrictions . . . including that insurance not be billed for insulin, no markup or dispensing fee be charged to the patient, and that the covered entity provide Lilly detailed information demonstrating compliance with Lilly's conditions." Gov't Mem. at 9, *Eli Lilly v. Becerra*, 1:21-cv-81, Dkt. 88 (S.D. Ind. Apr. 20, 2021).

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

210. Even more fatal to this claimed exception's feasibility is the fact that Eli Lilly's stated it would require covered entities to find Contract Pharmacies willing to dispense insulin for free. That is impossible, given the expenses and risks associated with dispensing drugs. As one pharmacist explained in a sworn affidavit, "Lilly has stated that it will allow 340B covered entities to access its insulin products at contract pharmacies if certain conditions are met. One of those conditions is that the pharmacy not collect a dispensing fee as compensation for filling the prescription. This condition makes the Lilly insulin 'exception' entirely impractical because pharmacies will not agree to dispense drugs without any compensation." Affidavit of Peter

Johnson, RPh., ¶ 16, *Ryan White Clinics for 340B Access v. Azar*, 1:20-cv-2906, Dkt. 24 (D.D.C. Nov. 23, 2020).

211. As DOJ has explained, "pharmacies provide the necessary infrastructure to allow covered entities to access the benefits of the 340B Program, including paying for all of the retail space, licensing, human resources, and other requirements to store and dispense pharmaceuticals. They collect a reasonable, set fee for that service and pass on savings either to indigent patients or to the covered entity. Lilly cannot demand pharmacies perform these services *for free*." Gov't Reply Mem. at 24, *Eli Lilly*, 1:21-cv-81, Dkt. 125 (S.D. Ind. June 25, 2021).

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

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

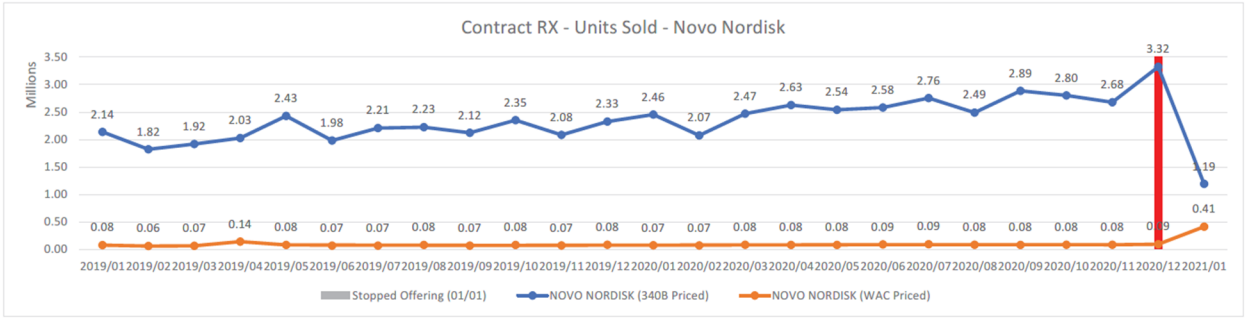
214. Eli Lilly's restrictions led to the readily foreseeable immediate elimination of the overwhelming majority of Eli Lilly's Contract Pharmacy 340B Drug Discounts sales, particularly of its rapid-acting insulins, long-acting insulins, and incretin mimetics. As Eli Lilly's CFO reported to investors,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

utilization in the 340B segment, primarily for the diabetes portfolio"); Eli Lilly, 10-Q at 49 (Q3 2021) (same).

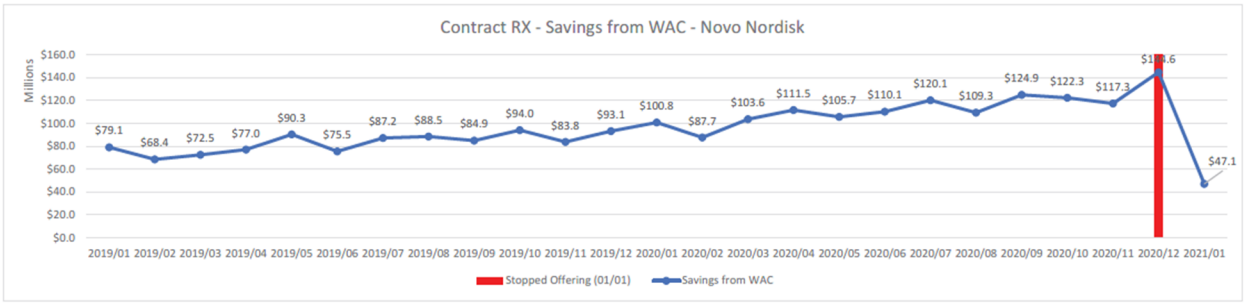
3. Novo Nordisk's restrictions led to the elimination of the overwhelming majority of Novo Nordisk's Contract Pharmacy 340B Drug Discount sales.

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

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



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



218. As DOJ has concluded, Novo Nordisk's restrictions "caused a precipitous decline in drug sales at 340B prices." Gov't Br. at 18, *Novo Nordisk v. HHS*, 21-3168, Dkt. 49 (3d Cir. July 7, 2022). "For example, in the month before announcing its new policy," Novo Nordisk "had sold 3.32 million units of drugs at the 340B prices; the month after it adopted the new policy, that number dropped by more than 2 million units—a decline of 64%." *Id.* HHS calculated that covered entities suffered "$100 million in lost savings from Novo [Nordisk] . . . in just a single month." *Id.* at 19. The data shows a decline from $144.6 million in monthly savings in December 2020 to $47 million in savings upon the immediate impact of Novo Nordisk's restrictions in January 2021, a decline of nearly 70%.

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

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

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

222. This dramatic and immediate impact was predictable.

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

224. Novo Nordisk limited its restrictions to hospital covered entities. But that limitation did not substantially mitigate the dramatic decline of Novo Nordisk's Contract Pharmacy 340B Drug Discount sales because, as PhRMA has noted, the "vast majority of 340B sales are to hospitals," approximately 90%. *See* PhRMA, "340B 101" at 16 (Nov. 2017); *accord* GAO, "340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements" at 2 (Dec. 2019).

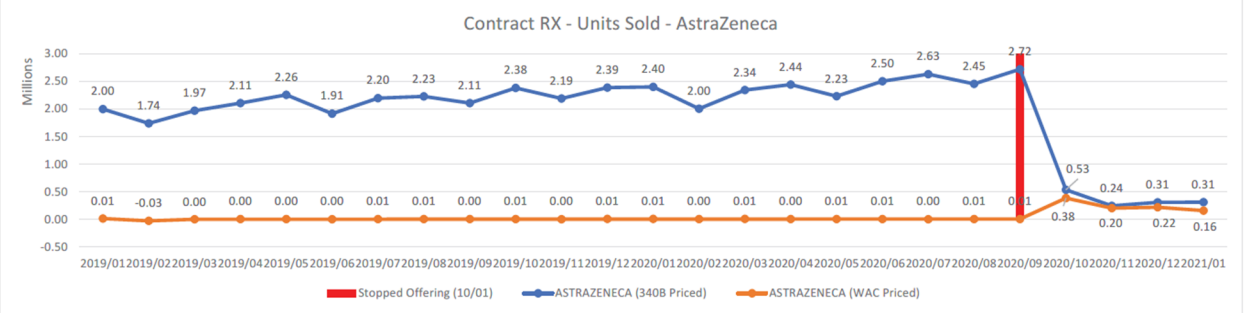
225. Novo Nordisk itself characterized its restrictions as effectively ending shipments of drugs to Contract Pharmacies. Following the conclusion of the first quarter of Novo Nordisk's implementation of its restrictions in Q1 2021, Novo Nordisk's CFO explained those restrictions as "basically, we stopped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

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

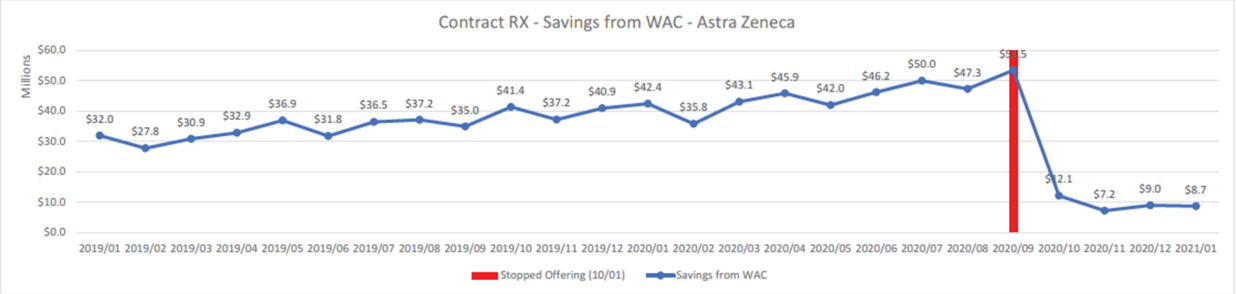
4. AstraZeneca's restrictions led to the elimination of the overwhelming majority of AstraZeneca's Contract Pharmacy 340B Drug Discount sales.

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

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



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



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

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

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

233. Indeed, in the immediate wake of AstraZeneca's restrictions, Contract Pharmacies became unable to receive the overwhelming majority of shipments of covered entities' desired

drug purchases. An example is Avita Pharmacy, "a national chain that almost exclusively contracts with and dispenses for covered entities, including community health centers and AIDS clinics." Gov't Mem. at 8, *AstraZeneca v. HHS.*, 1:21-cv-27, Dkt. 93 (D. Del. July 23, 2021). According to HHS, Avita Pharmacy serves "270 covered-entity clients—98% of whom do not operate their own pharmacies." *Id.* And "all were being denied 340B pricing" of AstraZeneca's drugs.

234. This dramatic and immediate impact was predictable.

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

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

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

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

[the] policy even when they were eligible to do so." *Id.* at 85:12-14. Further, AstraZeneca conceded that many covered entities use multiple Contract Pharmacies and "can't place purchases through those contract pharmacies." *Id.* at 85:20-22.

~~146.~~239. AstraZeneca's restrictions thus led to the readily foreseeable immediate elimination of the overwhelming majority of AstraZeneca's Contract Pharmacy 340B Drug Discounts sales, particularly of its incretin mimetics.

CONSPIRACY ALLEGATIONS

~~147.~~240. Defendants engaged in concerted action to restrict Contract Pharmacy 340B Drug Discounts.

I. Defendants are ~~Horizontal Competitors~~horizontal competitors.

~~148.~~241. Defendants directly compete with one another, including in their sales of rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics.

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

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

~~149.~~242. Defendants Sanofi, Eli Lilly, and Novo Nordisk directly compete against each other in manufacturing and/or selling rapid-acting analog insulins.

~~150.~~243. Defendants' competing rapid-acting analog insulins include Sanofi's Apidra and Admelog; Eli Lilly's Humalog and Insulin Lispro; and Novo Nordisk's Fiasp, Novolog, and Insulin Aspart.

~~151.~~244. Apidra, Admelog, Humalog, Insulin Lispro, Fiasp, Novolog, and Insulin Aspart are each clinically equivalent and therapeutically interchangeable with one another.

~~152.~~245. The FDA categorizes drugs into pharmacological classes. The FDA categorizes Apidra, Admelog, Humalog, Insulin Lispro, Fiasp, Novolog, and Insulin Aspart in

the pharmacological class of insulin analog. The only other drugs in the same pharmacological class are the long-acting analog insulins listed below.

~~153.~~246. For the last decade, including during and since July 2020, Defendants Sanofi, Eli Lilly, and Novo Nordisk have competed with each other in the manufacture and sale of rapid-acting analog insulins.

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

~~154.~~247. Defendants Sanofi, Eli Lilly, and Novo Nordisk directly compete against each other in manufacturing and/or selling long-acting analog insulins.

~~155.~~248. Defendants' competing long-acting analog insulins include Sanofi's Lantus and Toujeo; Eli Lilly's Basaglar; and Novo Nordisk's Levimir and Tresiba.

~~156.~~249. Lantus, Toujeo, Basaglar, Levimir, and Tresiba are each clinically equivalent and therapeutically interchangeable with one another.

~~157.~~250. The FDA categorizes Lantus, Toujeo, Basaglar, Levimir, and Tresiba in the same pharmacological class of insulin analog. The only other long-acting analog insulin in this pharmacological class is a new entrant, Semglee, manufactured by Mylan and Biocon Ltd, which was not being sold in the United States in July 2020. The only other drugs categorized in the insulin analog pharmacological class are the rapid-acting analog insulins listed above.

~~158.~~251. Since 2015, including during and since July 2020, Defendants Sanofi, Eli Lilly, and Novo Nordisk have competed with each other in the manufacture and sale of long-acting analog insulins.

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

~~159.~~252. Defendants Sanofi, Eli Lilly, Novo Nordisk, and AstraZeneca directly compete against each other in manufacturing and/or selling incretin mimetics.

~~160.~~253. Defendants' competing incretin mimetics include Sanofi's Adlyxin; Eli Lilly's Trulicity; Novo Nordisk's Victoza, Ozempic, and Rybelsus; and AstraZeneca's Bydureon and Byetta.

~~161.~~254. Adlyxin, Trulicity, Victoza, Ozempic, Rybelsus, Bydureon, and Byetta are each clinically equivalent and therapeutically interchangeable with one another.

~~162.~~255. The FDA categorizes Trulicity, Victoza, Ozempic, Rybelsus, Bydureon, and Byetta in the pharmacological class of GLP-1 Receptor Agonist. The only other drug in the same pharmacological class, Saxenda (another Novo Nordisk drug), is FDA-approved for weight management, not diabetes.

~~163.~~256. Since 2016, including during and since July 2020, Defendants Sanofi, Eli Lilly, Novo Nordisk and AstraZeneca have competed with each other in the manufacture and sale of incretin mimetics.

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

~~164.~~257. Defendants' products dominate each market.

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

~~165.~~258. As of July 2020, Defendants sold the only available rapid-acting analog insulins: Sanofi's Apidra and Admelog; Eli Lilly's Humalog and Insulin Lispro; and Novo Nordisk's Fiasp, Novolog, and Insulin Aspart.

~~166.~~259. That remains true today.

~~167.~~260. No other rapid-acting analog insulins are available in the United States.

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

~~168.~~261. As of July 2020, Defendants sold the only available long-acting analog insulins: Sanofi's Lantus and Toujeo; Eli Lilly's Basaglar; and Novo Nordisk's Levimir and Tresiba.

~~169.~~262. These drugs continue to dominate the market today.

~~170.~~263. The sole competitive drug, Semglee, has a long way to go before it can capture market share. Around October 2020, Mylan and Biocon introduced Semglee as another long-acting analog insulin. But competition within the diabetic medications market is slow-moving. As Biocon explained on April 29, 2021, it "witnessed [only] a modest uptake of biosimilar Insulin Glargine (*Semglee***)* following its launch in FY21." Biocon attributed the slow increase in market share to "the timing of approval impacting formulary contracting cycles for CY21." *See* Biocon Ltd., "Biocon Q4FY21 Revenue at Rs2,044 Cr, Up 26%," (Apr. 29, 2021), at https://www.biocon.com/biocon-q4fy21-results/. Biocon's Chief Operating Officer, Shreehas P. Tambe has explained that there was "a slower than usual ramp-up for these products," and "other similar products in the market in the first 12-months have had a single-digit market share," before they "get to preferred or exclusive formulary status." Biocon Limited Q3 FY21 Earning Conference Call Transcript (Jan. 22, 2021), at https://www.biocon.com/biocon-q4fy21-results/.

3. Defendants face no competition for incretin mimetics.

~~171.~~264. As of July 2020, Defendants sold the only available incretin mimetics: Sanofi's Adlyxin; Eli Lilly's Trulicity; Novo Nordisk's Victoza, Ozempic, and Rybelsus; and AstraZeneca's Bydureon and Byetta.

~~172.~~265. That remains true today.

~~173.~~266. No other incretin mimetics are available in the United States.

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

~~174.~~267. Few competitors compete in the manufacture and sale of rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics.

~~175.~~268. The rapid-acting analog insulin market is dominated by only three companies—Sanofi, Eli Lilly, and Novo Nordisk.

~~176.~~269. The long-acting analog insulin market is dominated by only three companies—Sanofi, Eli Lilly, and Novo Nordisk.

~~177.~~270. The incretin mimetic market is dominated by only four companies—Sanofi, Eli Lilly, Novo Nordisk, and AstraZeneca.

II. Defendants ~~Restricted~~restricted Contract Pharmacy 340B Drug Discounts in ~~Parallel~~parallel.

~~178.~~271. Defendants acted in parallel to restrict Contract Pharmacy 340B Drug Discounts.

~~179.~~272. Defendants announced their planned restrictions in near lockstep, between July 2020 and December 2020. On July 24, 2020, AstraZeneca privately informed HHS of its planned restrictions. Three days later, on July 27, 2020, Sanofi announced that it would impose its restrictions. Three weeks later, on August 19, 2020, Eli Lilly informed HHS of its restrictions. And within three-and-a-half months, on December 1, 2020, Novo Nordisk informed HHS of its restrictions.

~~180.~~273. Likewise, Defendants imposed their restrictions in near lockstep, between September 2020 and January 2021. Eli Lilly imposed its restrictions beginning on September 1, 2020. Both AstraZeneca and Sanofi imposed their restrictions beginning just one month later, on October 1, 2020. And Novo Nordisk imposed its restrictions just three months later, on January 1, 2021.

~~181.~~274. Each Defendant imposed similar restrictions on Contract Pharmacy 340B Drug Discounts. AstraZeneca, Eli Lilly, and Novo Nordisk, with minor and largely insignificant exceptions, limited the availability of all Contract Pharmacy 340B Drug Discounts. So too, Sanofi limited the availability of all Contract Pharmacy 340B Drug Discounts, with an exception for covered entities agreeing to provide Sanofi with sensitive prescription information through Sanofi's software vendor on commercially unreasonable terms. ~~The net effect of each restriction was the same—ending nearly all Contract Pharmacy 340B Drug Discounts for AstraZeneca, Eli Lilly, Novo Nordisk, and Sanofi drugs.~~

275. As detailed above, the net effect of each restriction was the same—ending the overwhelming majority of all Contract Pharmacy 340B Drug Discount sales for AstraZeneca, Eli Lilly, Novo Nordisk, and Sanofi drugs. Government-compiled data shows, for instance, that the immediate impact of Defendants' restrictions was a decline of 60%-90% of such sales by units or 70-95% as measured by lost 340B Savings.

~~182.~~276. These announced changes were close enough in time to effectively prevent any covered entity from steering prescriptions to competitors (*i.e.*, other Defendants). Because covered entities prescribe drugs, new prescriptions require new doctor-patient interactions. Those occur only periodically. Accordingly, it takes many months to transition a provider's patients from one preferred drug to another. Defendants announced their restrictions on Contract Pharmacy 340B Drug Discounts close enough in time to one another that covered entities could not, and did not, make significant progress in transitioning patients from one drug (for which Contract Pharmacy 340B Drug Discounts had been made unavailable) to another drug (for which Contract Pharmacy 340B Drug Discounts were still, temporarily, available).

~~III. Defendants Conspired in Imposing Their Parallel Restrictions.~~

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

III. Defendants conspired in imposing their parallel restrictions.

~~183.~~278. The nature and timing of the parallel conduct described above, set within the context of this industry, is strongly suggestive of conspiracy, rather than of independent action. Among the facts plausibly suggestive of an agreement are the following: (i) acting alone in eliminating or restricting the Contract Pharmacy 340B Drug Discounts would have been against any single Defendant's unilateral self-interest because it would risk market share; (ii) acting alone in restricting Contract Pharmacy 340B Drug Discounts would have been against any single Defendant's unilateral self-interest because it would risk severe regulatory sanctions, including loss of coverage of their diabetes medications by federal healthcare programs; (iii) Defendants shared a common motive to raise prices by avoiding the Contract Pharmacy 340B Drug Discount, if they could do so jointly~~; (iii)~~ , to avoid both the loss of market share and the risks of the most severe regulatory sanctions; (iv) Defendants' restrictions were historically unprecedented; (~~iv~~v) indeed, Defendants' restrictions ~~remain~~remained anomalous in the pharmaceutical industry~~; (v~~ for years; (vi) there are a small number of competitors in the rapid-

acting analog insulin, long-acting analog insulin, and incretin mimetics areas (*i.e.*, the four Defendants); (~~vi~~vii) there are significant barriers to entry for new competitors; (~~vii~~viii) Defendants engaged in a high volume of communications immediately in advance of their concerted action; (~~viii~~ix) Defendants' alleged antirust conspiracies in the past, including fixing prices for rapid-acting analog insulin and long-acting analog insulin, and their alleged similar price manipulation of these same drugs; and (~~ix~~x) within three days of AstraZeneca privately informing HRSA of its plan to restrict Contract Pharmacy 340B Drug Discounts, Sanofi publicly announced its corresponding restrictions, which is too close in time to be a coincidence.

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

~~184.~~279. It would have been against any single Defendant's self-~~interests~~interest to restrict Contract Pharmacy 340B Drug Discounts~~. Doing~~ for at least two reasons. First, doing so, while a Defendant's competitors continued to offer Contract Pharmacy 340B Drug Discounts, would have put the Defendant at a significant competitive disadvantage. Second, doing so, while a Defendant's competitors offered alternative diabetes medications, would have exposed the Defendant to the most severe regulatory sanction of loss of federal healthcare program coverage for the Defendant's drugs, including its diabetes medications.

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

~~185.~~280. If a single Defendant had restricted Contract Pharmacy 340B Drug Discounts, its market share and sales volumes in the financially important markets for rapid-acting analog insulins, long-acting analog insulins, or incretin mimetics would have been seriously threatened.

~~186.~~281. Access to Contract Pharmacy 340B Drug Discounts is a critically important economic issue for covered entities. Indeed, access to such discounts is oftentimes

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

~~187.~~282. Covered entities' drug preferences are generally more important for Defendants' drug sales and market share than individual consumer preferences. Consumers do not choose prescription medications directly; they must be prescribed by a physician. And physicians are often employed by or associated with covered entities, which can share preferences with physicians as to preferred drugs among a class of clinically equivalent and therapeutically interchangeable medications.

~~188.~~283. If a single Defendant restricted Contract Pharmacy 340B Drug Discounts on its drug, then covered entities, including 340B hospitals, could have taken steps to steer their prescribing physicians towards prescribing the competing drugs that offered Contract Pharmacy 340B Drug Discounts, as the drugs are all clinically equivalent and therapeutically interchangeable. And covered entities would have had strong economic incentives to do so to generate the 340B Savings that the 340B Program was designed to produce for covered entities.

~~189.~~284. Defendants knew that their drugs were considered by the medical community as clinically equivalent and therapeutically interchangeable with the other Defendants' drugs.

~~190.~~285. Defendants understood that covered entities would have strong incentives to prescribe drugs with Contract Pharmacy 340B Drug Discounts, instead of drugs for which manufacturers had restricted Contract Pharmacy 340B Drug Discounts.

~~191.~~286. Defendants understood that covered entities would have taken steps to prescribe competing drugs that offered Contract Pharmacy 340B Drug Discounts, instead of drugs for which manufacturers had restricted Contract Pharmacy 340B Drug Discounts.

~~192.~~287. Defendants understood that, if they acted alone, they were at risk of losing sales and market share, both in the short-term and the long-term.

~~193.~~288. For these reasons and others, Defendants had strong incentives not to act alone in restricting Contract Pharmacy 340B Drug Discounts.

~~194.~~289. Drug manufacturers' strong incentives not to act alone in restricting Contract Pharmacy 340B Drug Discounts ~~is~~are illustrated by the actions of other drug companies which did not engage in a conspiracy to restrict Contract Pharmacy 340B Drug Discounts. More than 1,000 other drug companies participate in the 340B Program. They sell drugs in markets distinct from the markets for rapid-acting analog insulins, long-acting analog insulins, or incretin mimetics. Those 1,000-plus other drug companies did not impose restrictions on Contract Pharmacy 340B Drug Discounts because, just as for Defendants (if they had acted alone), imposing any such restrictions would be competitively disadvantageous and against their individual economic self-interest.

~~**B. Defendants had a common motive to conspire.**~~

2. ~~Defendants had a~~ Any Defendant restricting discounts alone would risk loss of federal healthcare program coverage.

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

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

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

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

294. Eli Lilly has affirmatively pled that, by restricting 340B Drug Discounts, it fears "the potential revocation of [its] ability to participate in and receive reimbursements under the pervasive Medicare and Medicaid programs." Compl. at 4-5, *Eli Lilly & Co. v. Azar*, 21-cv-81,

Dkt. 1 (S.D. Ind. Jan. 12, 2021); *see also* Am. Compl. at 4-5, *Eli Lilly & Co. v. Azar*, 21-cv-81, Dkt. 17 (S.D. Ind. Jan. 25, 2021).

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

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

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

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

B. Defendants had common motives to conspire.

~~195.~~299. Defendants had common ~~motive~~motives to conspire to restrict Contract Pharmacy 340B Drug Discounts, collectively.

~~196.~~300. ~~If~~First, if Defendants could together raise prices by restricting Contract Pharmacy 340B Drug Discounts, without decreasing any Defendant's sales or market share, each

Defendant would earn higher profits, thus increasing ~~their~~its already substantial annual sales revenues.

~~197.~~301. Defendants understood that if they collectively restricted Contract Pharmacy 340B Drug Discounts, they would collectively make higher profits.

~~198.~~302. Defendants understood that if they collectively restricted Contract Pharmacy 340B Drug Discounts, they would not need to compete for covered entity prescribing preferences by offering Contract Pharmacy 340B Drug Discounts. Each Defendant controlled U.S. market shares worth hundreds of millions, or billions, of dollars annually, and none wanted to put those market shares at further risk by competing as to the availability of Contract Pharmacy 340B Drug Discounts. Defendants understood that if they jointly restricted Contract Pharmacy 340B Drug Discounts, those discounts would be equally unavailable for each of the competitors' drugs.

303. Defendants ultimately achieved this first objective. By implementing a common and shared policy of primarily refusing to permit the sale of 340B Drugs to covered entities for shipment to Contract Pharmacies, Defendants succeeded in eliminating the overwhelming majority of their Contract Pharmacy 340B Drug Discount sales, earning higher profits, and avoiding competition over the availability of Contract Pharmacy 340B Drug Discounts on their critical rapid-acting insulins, long-acting insulins, and incretin mimetics, among other drugs.

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

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

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

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

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

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

would have jeopardized the ability of federal healthcare programs to deliver critical diabetes medications.

C. Defendants' sudden restrictions were historically unprecedented.

~~199.~~310. Defendants' restrictions were imposed suddenly after a decade of offering Contract Pharmacy 340B Drug Discounts.

~~200.~~311. Defendants and all other drug companies participating in Medicaid or Medicare Part B had consistently offered Contract Pharmacy 340B Drug Discounts for at least decade. "For 24-plus years, manufacturers have offered the ceiling price to covered entities using contract-pharmacy distribution." *See* HHS General Counsel, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program at 5 n.5 (Dec. 30, 2020).

~~201.~~312. After a decade of consistently offering Contract Pharmacy 340B Drug Discounts, Defendants suddenly announced restrictions on Contract Pharmacy 340B Drug Discounts during the second half of 2020.

~~202.~~313. These changes were made despite warnings from regulators that such changes were viewed as illegal. These changes were made when no other drug manufacturer imposed similar restrictions.

~~203.~~314. The sudden, historically unprecedented change made by four direct competitors within the drug industry is indicative of conspiracy, rather than independent action.

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

~~204.~~315. Defendants imposed restrictions, even though nearly the entire remainder of the pharmaceutical industry—thousands of manufacturers participating in the 340B Drug Discount Program—did not.

~~205.~~316. ~~More~~Throughout 2020 and most of 2021, more than 99.6% of drug companies ~~continue~~continued to offer Contract Pharmacy 340B Drug Discounts without

restrictions. Those drug companies ~~include~~included some of the largest drug companies, such as Roche, Johnson & Johnson, Pfizer, AbbVie~~, Amgen~~, Bristol Myers Squibb, GlaxoSmithKline, Gilead, Bayer, Biogen, Takeda, Moderna, Bausch Health, Alexion, and Regeneron, as well as more than a thousand others.

~~206.~~317. The fact that Defendants—as each other's sole competitors as of July 2020 for rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics—restricted Contract Pharmacy 340B Drug Discounts, while nearly the entire remainder of the industry did not, strongly suggests that Defendants acted in coordination with each other, rather than out of their own self-interest.

~~207.~~318. Moreover, the fact that Eli Lilly considered restricting Contract Pharmacy 340B Drug Discounts earlier in 2020, but decided against doing so (except for a narrow band of Cialis formulations) until it could ensure that the other Defendants would also ~~decided to~~ do so, strongly suggests that Defendants acted in coordination with each other, rather than out of their self-interest. If it had been in Eli Lilly's self-interest to independently limit all Contract Pharmacy 340B Drug Discounts, it would have done so when it limited Cialis discounts.

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

~~208.~~319. The existence of few competitors for a product makes that product more conducive to a price-fixing conspiracy, such as the elimination, reduction, or restriction of a discount.

~~209.~~320. Defendants Sanofi, Eli Lilly, and Novo Nordisk—just three companies—are the sole competitors manufacturing and selling rapid-acting analog insulins in the United States.

~~210.~~321. Defendants Sanofi, Eli Lilly, and Novo Nordisk—again just three companies—were the sole competitors manufacturing and selling long-acting analog insulins in the United States as of July 2020. A fourth competitor, Mylan/Biocon, recently joined the competition, but has had insufficient opportunities to gain market share. Defendants Sanofi, Eli Lilly, and Novo Nordisk still compete in selling long-acting analog insulins among just four competitors, and Defendants Sanofi, Eli Lilly, and Novo Nordisk dominate the market, with more than 90% of sales of long-acting analog insulins.

~~211.~~322. Defendants Sanofi, Eli Lilly, Novo Nordisk, and AstraZeneca—just four companies—are the sole competitors manufacturing and selling incretin mimetics in the United States.

~~212.~~323. Because so few firms compete in the manufacture and sale of rapid-acting analog insulin, long-acting analog insulin, and incretin mimetics, an effective pricing conspiracy relating to those drugs requires the coordination of only a few firms. That makes the market more conducive to conspiracy.

F. There are significant barriers for any new competitors.

~~213.~~324. Defendants' conspiracy is further facilitated by significant barriers to entry, which effectively prevent would-be competitors from seeking a competitive advantage by offering Contract Pharmacy 340B Drug Discounts to compete against Defendants.

~~214.~~325. New market entrants face significant barriers to entry into the rapid-acting analog insulin, long-acting analog insulin, and incretin mimetics markets. These barriers include intellectual property, costs of manufacture, and expenses related to regulatory oversight.

~~215.~~326. As recently reported by the Center for Biosimilars, in the article, "Panel: Insulin Biosimilar Competition May Be Scant at Best," industry experts have explained that "[i]t's not easy to break into the insulin market." "Insulin is a biologic that is very difficult to

consistently produce at high purity in large volumes that would be necessary for distribution, and very few manufacturers have the resources to perfect this process and convince regulators that they can get it right, the panelists [at the Festival of Biologics USA] said." "Many companies have attempted to bring rival insulin products . . . and have failed because the pharmacokinetics of these products are extremely difficult to match precisely with originator products, [Sundar] Ramanan, [PhD, BMA, vice president and head of Global Regulatory Affairs for Biocon] said." "'That's barrier number 1. Barrier number 2 is we need to have economies of scale, and that requires a large capital investment, and not many companies have that to combine with the science. This limits the number of players that are coming in beyond the ones that are truly committed.'" *See* Tony Hagen, "Panel: Insulin Biosimilar Competition May Be Scant at Best," The Center for Biosimilars (Mar. 31, 2021), *at* https://www.centerforbiosimilars.com/view/panel-insulin-biosimilar-competition-may-be-scant-at-best.

~~216.~~327. Those barriers to entry and others allow Defendants to engage in a pricing conspiracy among themselves without being threatened by other firms.

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

~~217.~~328. Defendants had ample opportunity to conspire and were engaged in high levels of communications in advance of their imposition of restrictions.

~~218.~~329. ~~The~~ Defendants engaged in high levels of communication about the subjects of the conspiracy through lobbying. In the second and third quarters of 2020, before and at the time of the commencement of the conspiracy, Defendants were engaged in a joint lobbying campaign. That campaign related to 340B Drug Discounts and diabetes medicines. Defendants used common lobbyists and appear to have communicated directly with each other about their

lobbying campaign. ~~It is likely~~Upon information and belief, during that joint lobbying effort, Defendants planned their restrictions on Contract Pharmacy 340B Drug Discounts as a fallback position if their lobbying efforts failed. ~~When~~Then, when their lobbying efforts ~~failed~~did fail, Defendants immediately imposed coordinated restrictions on Contract Pharmacy 340B Drug Discounts.

~~219.~~330. ~~The~~ Defendants also engaged in high levels of communications through industry associations, including PhRMA. Each Defendant is a member of PhRMA and on its Board of Directors. In July 2020, PhRMA's Board of Directors included Eli Lilly's CEO, David Ricks (serving as Chairman-Elect); Sanofi's CEO, Paul Hudson; Novo Nordisk's Executive Vice President & Head of North America Operations, Douglas J. Langa; and AstraZeneca's Executive Director & CEO, Pascal Soriot. The most prominent advocacy issue on the PhRMA website, listed first among the only two issues with graphic displays, was "340B." And the 340B page to which that graphic was hyperlinked present "Contract Pharmacies" as an "Area[] for Needed 340B Reform." Defendants, as PhRMA Board members, ~~likely~~ communicated among themselves ~~about PhRMA's~~, and their most prominent advocacy issue~~,~~ was 340B Drug Discounts, including Contract Pharmacy 340B Drug Discounts.

H. Most Defendants have been alleged to have engaged in antitrust conspiracies and price manipulation for diabetes medications in the past.

~~220.~~331. Separate and apart from their coordination of restrictions on Contract Pharmacy 340B Drug Discounts, Eli Lilly, Sanofi, and Novo Nordisk have been alleged to have conspired to fix prices on rapid-acting analog insulin and long-acting analog insulin, allowing them to raise prices in lockstep. Private federal court litigation was filed based on those claims. *See generally* Amended Complaint, *In re Direct Purchaser Insulin Pricing Litig.*, 3:20-cv-03426 (D.N.J. filed Nov. 6, 2020).

332. Similarly, Eli Lilly, Sanofi, and Novo Nordisk have been charged with wrongfully colluding with pharmacy benefit managers (PBMs) to artificially raise insulin prices. Both private and Government entities are pursuing these claims. *See generally* Third Amended ~~Complaint,~~Compl., *In re Indirect Purchaser Insulin Pricing Litig.*, 3:17-00699 (D.N.J. Apr. 20, 2021) (presenting RICO and consumer fraud claims, among others); *see also* ~~Complaint,~~Compl., *Minnesota v. Sanofi-Aventis US LLC*, 3:18-cv-14999 (D.N.J.) (pursuing unjust enrichment and consumer fraud claims).

333. Moreover, other government entities have reached similar conclusions. On January 14, 2021, the Senate Finance Committee issued a report on its two-year investigation "into the skyrocketing price of insulin," concluding, as stated by Committee Chair Senator Chuck Grassley, that "[t]his industry is anything but a free market." *See* United States Senate Committee on Finance, "Grassley, Wyden Release Insulin Investigation, Uncovering Business Practices Between Drug Companies and PBMs That Keep Prices High: Bipartisan Investigation on Rising Insulin Costs Finds Skyrocketing Prices are a Result of Companies Putting Profits Over Consumers' Interest" (Jan. 14, 2021).

334. And~~, most recently~~, on June 8, 2021, the Attorney General for the State of Mississippi filed suit against the companies and PBMs for "working in tandem to manipulate and inflate insulin prices." Attorney General Lynn Fitch, Press Release, "AG Lynn Fitch Files Lawsuit Against Insulin Manufacturers and PBMs Over Insulin Pricing Scheme," (June 8, 2021~~).~~); *see also* Second Am. Compl., ¶¶ 13, 15, Mississippi v. Eli Lilly and Co., 21-cv-674, Dkt. 16-5 (S.D. Miss. Oct. 29, 2021) ("In the last decade alone, [they] have in tandem increased the prices of their insulins up to 1000%, taking the same increase down to the decimal point within a few days of each other.").

~~221.~~335. Most recently, Albany County filed suit against Sanofi, Eli Lilly, and Novo Nordisk for engaging in an "Insulin Pricing Scheme" to "sharply increase[] the reported prices of their respective diabetes drugs in lockstep, even though the cost to produce these drugs decreased over that period." Compl. ¶ 15, *County of Albany v. Eli Lilly and Company*, 22-981 (N.D.N.Y. Sept. 16, 2022).

~~222.~~336. In addition to these public charges, there are reported investigations of similar conduct by the Attorneys General of Colorado, New Mexico, New York, Vermont, and Washington.

I. ~~AstraZeneca and Sanofi, the first two conspirators to reveal restrictions,~~Defendants acted too closely in time for it to be coincidental, especially because AstraZeneca did not publicly reveal its plans.

~~223.~~337. Defendants coordinated their restrictions in a manner that cannot adequately be attributed to either coincidence or conscious parallelism. This is best illustrated by the first two Defendants to reveal their restrictions—AstraZeneca and Sanofi.

~~224.~~338. AstraZeneca was the first Defendant to reveal its plans to restrict Contract Pharmacy 340B Drug Discounts. But it did not do so publicly. Rather, AstraZeneca informed its regulator, HRSA, that it would restrict Contract Pharmacy 340B Drug Discounts beginning on October 1, 2020. AstraZeneca provided that information to HRSA on July 24, 2020. AstraZeneca did not publish its plans at that time.

~~225.~~339. Yet, Sanofi, the second Defendant to reveal its plans to restrict Contract Pharmacy 340B Drug Discounts, did so within three days of AstraZeneca's non-public announcement. Moreover, Sanofi revealed that it too would implement those restrictions beginning on October 1, 2020, the same date that AstraZeneca had communicated privately to HRSA.

~~226.~~340. The timing coordination between AstraZeneca and Sanofi cannot be attributed to Sanofi responding to AstraZeneca's letter to HRSA revealing its plans because AstraZeneca did not make any public announcement in July about its plans. Nor can the coordination be attributed to coincidence. After at least a decade of offering Contract Pharmacy 340B Drug Discounts, the odds of two direct competitors—AstraZeneca and Sanofi—revealing novel restrictions, starting on the same day (October 1, 2020), just three days apart are near zero.

~~227.~~341. The coordination between AstraZeneca and Sanofi is a result of conspiracy, not coincidence. That conspiracy extended to all of the Defendants. Indeed, the conspiracy was most effective only with the participation of each of the Defendants.

ANTITRUST INJURY

I. Defendants' conspiracy has restrained competition.

~~228.~~342. Defendants' actions have restrained competition by eliminating pricing discounts that otherwise would have been available to the Plaintiffs and Class Members.

~~229.~~343. Defendants' conspiracy has been effective at allowing them to increase their profits by restricting Contract Pharmacy 340B Drug Discounts, without threatening any Defendant's market share and by protecting each Defendant from competition on discounts.

~~230.~~344. Because each Defendant announced and/or imposed its restrictions within a relatively short number of months, covered entities were unable to effectively respond. The time needed to move patients from one drug to another is generally measured in months. The Defendants coordinated their restrictions in near-enough lockstep to prevent covered entities from moving patients.

~~231.~~345. Through their coordination, Defendants have avoided a significant form of price competition, *i.e.*, on Contract Pharmacy 340B Drug Discounts.

~~232.~~346. Defendants have profited by billions of dollars by restricting Contract Pharmacy 340B Drug Discounts. Government-compiled data shows that Defendants profited by avoiding hundreds of millions of dollars of Contract Pharmacy 340B Drug Discounts each month. That data shows Sanofi avoiding $43 million in monthly rebates, Eli Lilly avoiding $63.7 million in monthly rebates, Novo Nordisk avoiding $97.5 million in monthly rebates, and AstraZeneca avoiding $46 million in rebates. Over two years, such avoidance would have permitted each Defendant to increase profits by over one billion dollars a piece.

II. Plaintiffs have been harmed by Defendants' conspiracy.

~~233.~~347. Plaintiffs and other covered entities have been injured by Defendants' restraint on competition.

~~234.~~348. Defendant drug companies, as horizontal competitors, coordinated their pricing policies in a successful effort to limit access to Contract Pharmacy 340B Drug Discounts, while avoiding competition with one another on the availability of discounts. This has permitted Defendants to profit at the expense of the covered entities purchasing their drugs, thereby threatening to reduce the healthcare services and discounts available to Plaintiffs' and other covered entities' patients.

~~235.~~349. Horizontal competitors who coordinate their pricing policies engage in "competition-reducing" conduct. The 340B covered entities transact in the commerce directly affected by the conduct and are thus "within that area of the economy endangered by the breakdown of competitive conditions." They have been injured in their business and property as a result and have been unable to offer the level of healthcare services to patients as they would have been able to offer absent Defendants' conduct.

~~236.~~350. Covered entities have been injured by losing access to 340B Savings. Before Defendants' conspiracy, each Defendant offered drugs to covered entities for purchase

with Contract Pharmacy 340B Drug Discounts. As a result of the conspiracy, and as its aim, Defendants no longer offer such discounts to covered entities. The covered entities, including Plaintiffs, have lost the ability to generate 340B Savings as a result and, consequently, have also lost the ability to provide the range of healthcare services and savings for patients that they would have been able to offer absent Defendants' conduct.

~~237.~~351. These losses are quantifiable in at least two distinct ways.

~~238.~~352. *First*, at times, covered entities have purchased Defendants' drugs for dispensing at Contract Pharmacies without access to the Contract Pharmacy 340B Drug Discounts. Covered entities, including Plaintiffs, have been overcharged for those purchases because the purchase price did not include the 340B Drug Discount. The Complaint refers to these damages as "overcharges."

~~239.~~353. *Second*, and ~~quite~~most often, covered entities have not purchased drugs for dispensing at Contract Pharmacies because of their lost access to Contract Pharmacy 340B Drug Discounts. ~~In those cases, the drugs that would have been purchased by the covered entities have been purchased by the Contract Pharmacies on the Contract Pharmacies' own accounts because, among other reasons, the unavailability of Contract Pharmacy 340B Drug Discounts has made the covered entities' purchase of the drugs economically impracticable.~~ Covered entities can show and quantify, through pharmacy dispensing data and otherwise, 340B-eligible transactions that would have been filled with 340B Drugs if the Defendants had not restricted access to Contract Pharmacy 340B Drug Discounts, and, therefore, can quantify the 340B Savings lost as a consequence of Defendants' conspiracy. The Complaint refers to these damages as "lost 340B Savings revenues."

~~240.~~354. Together, overcharges, lost 340B Savings revenues, and the threat of ongoing and continued overcharges and lost 340B Savings revenues have injured Plaintiffs and other covered entities and have reduced and/or threaten to reduce the range of healthcare services and options for the patients and communities served by Plaintiffs and other covered entities, including the uninsured and underinsured.

355. Plaintiffs and other covered entities have suffered these harms even though a particular Defendant may have, at some point, provided Contract Pharmacy 340B Drug Discounts to them during the conspiracy. Defendants' succeeded in eliminating the overwhelming majority of Contract Pharmacy 340B Drug Discounts without risking significant market share losses or loss of federal healthcare program coverage. Defendants' success was only possible because of their conspiracy. Thus, overcharges and lost 340B Savings revenues suffered, related to any particular Defendant, arise because of, and from, the conspiracy between all the Defendants.

III. Only ~~Covered Entities~~covered entities have been ~~Directly Harmed~~directly harmed by ~~the~~ Defendants' ~~Conspiracy~~conspiracy.

~~241.~~356. Covered entities are the only actors that have been directly harmed by the conspiracy, while their patients and communities have been indirectly harmed. By contrast, wholesalers that deliver drugs have not been directly harmed because they are not entitled to retain and do not retain any portion of the Contract Pharmacy 340B Drug Discounts. Those discounts are made available by the Defendants only to the covered entities. ~~Because~~Becausse 340B Drug Discounts exist by reason of a statutory obligation that runs only to the 340B covered entities, wholesalers were never overcharged and suffer no antitrust injury on account of the Defendants' illegal agreement to restrict Contract Pharmacy 340B Drug Discounts. Accordingly, only covered entities—and not wholesalers—have suffered antitrust injuries.

~~242.~~357. Apart from covered entities, there are no other efficient enforcers. No other class of persons or entities has any self-interest to vindicate the public interest in antitrust enforcement because no other class of persons or entities has directly suffered as a result of the Defendants' conspiracy.

CLASS ALLEGATIONS

~~243.~~358. Pursuant to Federal Rule of Civil Procedure 23, Plaintiffs bring this action on behalf of the following class:

> All covered entities in the 340B Program with Contract Pharmacy arrangements in place, and which have issued prescriptions for Defendants' drug products since September 1, 2020.

~~244.~~359. There are thousands of Class Members geographically dispersed through the United States. Joinder of all Members of the Class is thus impracticable.

~~245.~~360. Class Members are readily identifiable from public records.

~~246.~~361. Plaintiffs' claims are typical of the claims of the Class embers. Plaintiffs' interests are not antagonistic to the claims of the other Class Members, and Plaintiffs have no material conflicts with any other Class Members that would make class certification inappropriate.

~~247.~~362. Plaintiffs and all class members were damaged by the same wrongful conduct of Defendants. Plaintiffs and all Class Members were unable to obtain Contract Pharmacy 340B Drug Discounts from Defendants and, accordingly, have standing.

~~248.~~363. Plaintiffs will fairly and adequately protect and represent the interests of all Class Members. Plaintiffs' interests are consistent with, and not antagonistic to, those of the class members.

~~249.~~364. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular expertise pursuing class action litigation involving alleged antitrust violations.

~~250.~~365. Questions of law and fact common to Plaintiffs and Class Members predominate over questions that may affect only individual Class Members because the Defendants have acted on grounds generally applicable to the entire class. Determining damages with respect to the class as a whole is thus appropriate.

~~251.~~366. The predominant common legal and factual questions applicable to all Class Members include, but are not limited to, the following:

a. Whether Defendants participated in a contract, combination, or conspiracy to fix prices by restricting access to Contract Pharmacy 340B Drug Discounts;

b. The duration and extent of the alleged contract, combination, or conspiracy;

c. Whether such a contract, combination, or conspiracy is a *per se* violation of the Sherman Act and/or State laws;

d. Whether, and to what extent, Defendants' antitrust violations caused injury to Plaintiffs and Class Members; and

e. The nature and scope of injunctive relief necessary to restore a competitive market and remove the effects of Defendants' conspiracy.

~~252.~~367. These common questions do not vary among the Class Members and predominate over questions affecting only individual class members. The Court may and the jury may thus resolve these issues without reference to the individual circumstances of any Member of the Class.

~~253.~~368. Class action treatment is a superior method for the fair and efficient adjudication of the claims asserted by all Class Members. Such treatment will permit many

similarly situated entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender.

~~254.~~369. The benefits of proceeding through a class mechanism, including providing all Class Members a method for obtaining redress on claims that they could not practicably pursue individually, substantially outweigh potential difficulties in the management of this litigation as a class action.

FIRST CLAIM—FEDERAL ANTITRUST VIOLATIONS
~~(~~Injunctive relief and treble damages for lost 340B Savings revenue~~)~~
On behalf of Plaintiffs and Class Members

~~255.~~370. Plaintiffs hereby repeat the allegations in the foregoing paragraphs as if fully set forth herein.

~~256.~~371. Defendants and their co-conspirators entered into, established, and maintained a continuing contract, combination, or conspiracy in unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

~~257.~~372. In formulating and effectuating their contract, combination, or conspiracy, Defendants and their co-conspirators engaged in anticompetitive activities, the purpose and effect of which were to artificially fix the prices of drugs by agreeing to coordinate and eliminate, reduce, or limit the availability of Contract Pharmacy 340B Drug Discounts in a manner that deprived covered entity purchasers in the United States of a significant mechanism of price competition.

~~258.~~373. The contract, combination, or conspiracy had the direct, substantial, and reasonably foreseeable effect upon commerce within the United States of: (a) increasing prices available to Plaintiffs and Class Members for drugs offered by Defendants, by artificially raising

or fixing such prices by eliminating Contract Pharmacy 340B Drug Discounts; (b) depriving Plaintiffs and Class Members of 340B Savings revenue; (c) depriving Plaintiffs and Class Members of free, open, and unrestricted competition in the sale of drugs offered by Defendants, by restricting Contract Pharmacy 340B Drug Discounts; and (d) unlawfully restraining, suppressing, or eliminating competition in the prices paid for Defendants' drugs, by eliminating, reducing, or limiting the availability of Contract Pharmacy 340B Drug Discounts.

~~259.~~374. Defendants' contract, combination, or conspiracy was *per se* unlawful price-fixing.

~~260.~~375. Each Defendant has committed at least one overt act to further the conspiracy alleged, including by eliminating, reducing, or limiting the availability of Contract Pharmacy 340B Drug Discounts.

~~261.~~376. The conspiracy is having its intended effect, as Defendants have been benefiting from their collusion and the elimination of competition, both of which artificially inflated the prices of Defendants' drugs for Plaintiffs and Class Members at Contract Pharmacies and deprived Plaintiffs and Class Members of 340B Savings revenue.

~~262.~~377. As a result of Defendants' unlawful conduct, Plaintiffs and other Class Members have been and are being injured in their business and property in that they have been losing 340B Savings through the eliminated, reduced, or limited availability of Contract Pharmacy 340B Drug Discounts, specifically, through lost 340B Savings revenues.

~~263.~~378. Plaintiffs and other Class Members are entitled to treble damages, along with costs and attorneys' fees, as per Section 4 of the Clayton Act, 15 U.S.C. § 15.

~~264.~~379. Defendants' conduct continues to threaten similar loss and damage in violation of the antitrust laws.

~~265.~~380. Plaintiffs and other Class Members are entitled to injunctive relief to prevent Defendants' illegal conduct and remove all of the lingering effects of such conduct, along with costs and attorneys' fees, as per Section 16 of the Clayton Act, 15 U.S.C. § 26.

SECOND CLAIM—STATE ANTITRUST CLAIMS
~~(~~Damages for overcharges and lost 340B Savings revenue~~)~~
On behalf of Plaintiffs and Class members under their respective States' laws

~~266.~~381. Plaintiffs hereby repeat the allegations in the foregoing paragraphs as if fully set forth herein.

~~267.~~382. Beginning at least as early as July 24, 2020 (the exact date being unknown to Plaintiffs and within the exclusive knowledge of Defendants), Defendants entered into, established, and maintained a continuing contract, combination, or conspiracy in unreasonable restraint of trade.

~~268.~~383. The purpose and effect of the conspiracy was to artificially fix and maintain the prices of 340B drugs by agreeing to eliminate, reduce, or limit the availability of Contract Pharmacy 340B Drug Discounts in a manner that deprived Plaintiffs and Class Members of a significant mechanism of price competition.

~~269.~~384. The contract, combination, or conspiracy had a direct, substantial, and reasonably foreseeable effect upon commerce within the United States and within each of the States by: (a) increasing prices paid by Plaintiffs and Class Members for 340B Drugs sold by Defendants; (b) depriving Plaintiffs and Class Members of 340B Savings that they would otherwise have received in the absence of the conspiracy; and (c) depriving Plaintiffs and Class Members of free, open, and unrestricted competition in the purchase of 340B Drugs sold by Defendants.

~~270.~~385. As a result of Defendants' unlawful conduct, Plaintiffs and other Class Members have been injured in their business and property by paying inflated prices for 340B Drugs and/or by being deprived of 340B Savings.

~~271.~~386. By engaging in the conduct described above, Defendants formed a contract, combination, or conspiracy in restraint of trade in violation of the following State laws:

a. Ariz. Rev. Stat. §§ 44-1401, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Arizona.

   i. In accordance with the requirements of Ariz. Rev. Stat. § 44-1415, contemporaneously with the filing of this Complaint, counsel is sending letters by certified mail, return receipt requested, to: Mark Brnovich, Attorney General of Arizona, informing him of the existence of the Class Action Complaint, identifying the relevant state antitrust provisions, and enclosing a copy of a Class Action Complaint.

b. Cal. Bus. & Prof. Code §§ 16720, and 16750(a), *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of California.

c. Conn. Gen. Stat. §§ 35-3, et seq., with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Connecticut.

d. D.C. Code §§ 28-4501, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the District of Columbia.

e. 740 Ill. Comp. Stat. §§ 10/1, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Illinois.

f. Fla. Stat. §§ 501.201, *et seq*., with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Florida. This statute has been interpreted in harmony with section 5(a)(1) of the Federal Trade Commission Act and the Sherman Act.

~~f.~~g. Iowa Code §§ 553.1, et seq., with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Iowa.

~~g.~~h. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to Class Members which are Kansas residents.

~~h.~~i. Me. Rev. Stat. Ann. 10, §§, 1101 *et seq.,* with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Maine.

~~i.~~j. Md. Comm. Laws. Ann. §§ 11-204 *et seq.,* with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Maryland.

~~j.~~k. Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Michigan.

~~k.~~l. Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. §§ 8.31 *et seq.*, with respect to Class Members which are Minnesota residents.

~~l.~~m. Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Mississippi.

~~m.~~n. Neb. Rev. Stat. §§ 59-801, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Nebraska.

~~n.~~o. Nev. Rev. Stat. Ann. §§ 598A.010, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Nevada.

i. In accordance with the requirements of Nevada Revised Statute § 598A.210(3) contemporaneously with the filing of this Complaint, counsel is sending letters by certified mail, return receipt requested, to: Aaron Ford, Attorney General of Nevada, informing him of the existence of the Class Action Complaint, identifying the relevant state antitrust provisions, and enclosing a copy of a Class Action Complaint.

~~o.~~p. N.H. Rev. Stat. Ann. §§ 356:1, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of New Hampshire.

~~p.~~q. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of New Mexico.

~~q.~~r. N.Y. Gen. Bus. L. §§ 340, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of New York.

i. In accordance with the requirements of N.Y. Gen. Bus. L. § 340(5), contemporaneously with the filing of this Complaint, counsel is sending letters by certified mail, return receipt requested, to: Letitia James, Attorney General of New York, informing her of the existence of the Class Action Complaint, identifying the relevant state antitrust provisions, and enclosing a copy of a Class Action Complaint.

~~r.~~s. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of North Carolina.

~~s.~~t. N.D. Cent. Code Ann. §§ 51-08.1-01, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of North Dakota.

~~t.~~u. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Oregon.

~~u.~~v. R.I. Gen. Laws §§ 6-36-1, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Rhode Island.

i. In accordance with the requirements of R.I. Gen. Laws § 6-36-21, contemporaneously with the filing of this Complaint, counsel is sending letters by certified mail, return receipt requested, to: Peter Neronha, Attorney General of Rhode Island, informing him of the existence of the Class Action Complaint, identifying the relevant state antitrust provisions, and enclosing a copy of a Class Action Complaint.

~~v.~~w. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of South Dakota.

~~w.~~x. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Tennessee.

~~x.~~y. Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Utah.

i. In accordance with the requirements of Utah Code Ann. § 76-10-3109 contemporaneously with the filing of this Complaint, counsel is sending letters by certified mail, return receipt requested, to: Sean Reyes, Attorney General of Utah, informing him of the existence of the Class Action Complaint, identifying the relevant state antitrust provisions, and enclosing a copy of a Class Action Complaint.

~~y.~~z. W.Va. Code §§ 47-18-1, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of West Virginia.

~~z.~~aa. Wis. Stat. §§ 133.01, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Wisconsin.

~~272.~~387. Defendants' conduct had substantial intrastate effects. Covered entities in the 340B Program with Contract Pharmacy arrangements in place reside within each of the above-listed States and were denied or limited in receiving Contract Pharmacy 340B Drug Discounts from Defendants. Defendants' conspiracy caused those entities to pay inflated prices for Defendants' 340B Drugs and/or to lose 340B Savings at multiple Contract Pharmacies within each State, thereby threatening to reduce the healthcare services and discounts available to the covered entities' patients in each State. The continuing scheme to limit or eliminate Contract Pharmacy 340B Drug Discounts directly affects and disrupts commerce within each State.

THIRD CLAIM—STATE UNJUST ENRICHMENT
~~(~~Damages for overcharges~~)~~
On behalf of Plaintiffs and Class Members under their respective States' laws

~~273.~~388. Plaintiffs hereby repeat the allegations in the foregoing paragraphs as if fully set forth herein.

~~274.~~389. Defendants have benefited from the above-described conduct at the expense of Plaintiffs and the Class ~~Members~~, and Defendants continue to retain those benefits under circumstances where it would be unjust to do so. Specifically, by engaging in the foregoing unlawful or inequitable conduct, Plaintiffs and the Class have been deprived of or restrained in their ability to purchase drugs that, but for Defendants' wrongful conduct, would have been eligible for purchase with Contract Pharmacy 340B Drug Discounts (340B eligible drugs), and therefore, Plaintiffs and the Class have been overcharged for purchases of 340B eligible drugs.

~~275. Specifically, Defendants have colluded to deprive Plaintiffs and the Class Members of access to Contract Pharmacy 340B Drug Discounts and have thereby improperly retained the value of those discounts for their own benefit and to the detriment of Plaintiffs and the Class Members. By engaging in this conduct, Defendants have met the elements of unjust enrichment in the following states specifically because:~~

~~a. Under Alabama common law, Defendants hold money that belong in equity and good conscience, to the Plaintiffs and retention of that money is unjust because Defendants engaged in collusion to receive that money;~~

~~b. Under Alaska common law, Plaintiffs conferred a benefit upon Defendants, Defendants appreciated the benefit, and it is inequitable for Defendants to retain the value of the benefit;~~

~~c. Under Arizona common law, Defendants have been enriched by a benefit, Plaintiffs have been impoverished by not receiving the benefit, there is a relationship between the enrichment and the impoverishment, Defendants do not have an adequate justification for being unjustly enriched, and there is not an adequate remedy at law;~~

~~d. Under Arkansas common law. Defendants, through its collusion, unjustly received and is enriched by money to which it was not entitled and which caused detriment to the Plaintiffs;~~

~~e. Under California common law, Defendants have been unjustly enriched by a benefit at the expense of Plaintiffs and there is an underlying legal basis for receiver, specifically the antitrust violations at issue;~~

f. Under Colorado common law, Defendants received a benefit at Plaintiffs' expense and the Defendants collusion make it unjust for the Defendants to retain the benefit without commensurate compensation;

g. Under Connecticut common law, Defendants unjustly received and are enriched by money to which they were not entitled and which caused detriment to the Plaintiffs;

h. Under D.C. common law, Defendants unjustly received and are enriched by money to which they were not entitled and which caused detriment to the Plaintiffs;

i. Under Delaware common law, Defendants have been enriched by a benefit, Plaintiffs have been impoverished by not receiving the benefit, there is a relationship between the enrichment and the impoverishment, Defendants do not have an adequate justification for being unjustly enriched, and there is not an adequate remedy at law;

j. Under Florida common law, Plaintiffs conferred a direct benefit upon Defendants, Plaintiffs appreciated the benefit, Defendants also appreciated the benefit, and the circumstances, specifically Defendants' collusion, makes retention of the benefit inequitable without paying value for the benefit;

k. Under Georgia common law, Plaintiffs conferred a benefit upon Defendants, equity requires that the Defendants compensate the Plaintiffs for the benefit; and the parties did not have a legal contract;

l. Under Hawaii common law, Plaintiffs conferred a benefit upon Defendants and Defendants have unjustly retained that benefit as the expense of the Plaintiffs;

m. Under Indiana common law, Plaintiffs conferred a benefit upon Defendants at the express or implied consent of Defendants, allowing the Defendants to retain the benefit without restitution would be unjust, and Plaintiffs expected payment;

n. Under Illinois common law, Defendants have been enriched by the receipt of a benefit at the expense of the Plaintiffs and it would be unjust to allow Defendants to retain the benefits under these circumstances;

o. Under Iowa common law, Defendants have been enriched by the receipt of a benefit at the expense of the Plaintiffs and it would be unjust to allow Defendants to retain the benefits under these circumstances;

p. Under Kansas common law, Plaintiffs conferred a benefit upon Defendants, Defendants appreciated the benefit, and it is inequitable for Defendants to retain the value of the benefit;

q. Under Kentucky common law, a benefit was conferred upon the Defendants at the Plaintiffs' expense under circumstances, specifically the collusion among

~~Defendants, that make in unjust for Defendants to retain the benefit without paying for it;~~

~~r. Under Louisiana common law, Defendants were enriched, Plaintiffs were impoverished, there was a rational connection between enrichment and the impoverishment, there is a lack of justification for the enrichment, and there is an absence of any other legal remedy;~~

~~s. Under Maine common law, Plaintiffs conferred a benefit upon Defendants, Defendants appreciated the benefit, and it is inequitable for Defendants to retain the value of the benefit;~~

~~t. Under Maryland common law, Plaintiffs conferred a benefit upon Defendants, Defendants appreciated the benefit, and it is inequitable for Defendants to retain the value of the benefit;~~

~~u. Under Massachusetts common law, Defendants hold property, the circumstances dictated that in equity and good conscience, the Defendants ought not retain the property because of their collusion;~~

~~v. Under Michigan common law, Defendants have received a benefit and retention of that benefit would result in an inequity;~~

~~w. Under Minnesota common law, Defendants have unjustly received and retained a benefit that they are not entitled to and the Plaintiffs lack an adequate legal remedy at law;~~

~~x. Under Mississippi common law, there is no legal contract between Defendants and Plaintiffs, Defendants are in possession of money that, in good conscience and justice, it should not retain, and Defendants should deliver the property to another;~~

~~y. Under Missouri common law, Plaintiffs conferred a benefit on Defendants, who recognize and accept that they have received a benefit, and the enrichment is unjust because of the Defendants' collusion;~~

~~z. Under Montana common law, a benefit was conferred upon Defendants to the detriment of Plaintiffs and Defendants are at fault or otherwise engaged in misconduct by colluding, Defendants took advantage of Plaintiffs;~~

~~aa. Under Nebraska common law, Defendants have unjustly received and retained a benefit that, in justice and fairness, they ought to return to Plaintiffs;~~

~~bb. Under Nevada common law, Defendants hold property, the circumstances dictated that in equity and good conscience, the Defendants ought not retain the property because of their collusion;~~

~~cc. Under New Hampshire common law, through their collusion or otherwise wrongful acts, unjustly received a benefit to the detriment of Plaintiffs such that it would be unconscionable for Defendants to retain the benefit;~~

~~dd. Under New Jersey common law, Plaintiffs conferred a benefit upon Defendants; retention of the benefit without payment would be unjust, and Defendants were enriched beyond their contractual rights;~~

~~ee. Under New Mexico common law, Defendants have knowingly benefited at Plaintiffs' expense and in a manner such that allowing the Defendants to retain the benefit would be unjust;~~

~~ff. Under New York common law, Defendants have been enriched at Plaintiffs' expense and permitting Defendants to retain the benefit conferred would be against equity and good conscience;~~

~~gg. Under North Carolina common law, Plaintiffs conferred a non-gratuitous benefit on the Defendants, who realized some value from the benefit, and it would be inequitable for Defendants to retain the benefit in light of Plaintiffs' impoverishment;~~

~~hh. Under North Dakota common law, Defendants were enriched, Plaintiffs were impoverished, there was a rational connection between enrichment and the impoverishment, there is a lack of justification for the enrichment, and there is an absence of any other legal remedy;~~

~~ii. Under Oklahoma common law, it would be inequitable, based on Defendants collusion, for them to retain the benefit received at the expense of Plaintiffs;~~

~~jj. Under Oregon common law, a benefit was conferred on Defendants, of which Defendants are aware, and, under the circumstances, it would be unjust to allow retention of the benefits without requiring the Defendants to pay for it;~~

~~kk. Under Pennsylvania common law, Plaintiffs conferred a benefit on Defendants, who appreciated or recognized the benefits, and the Defendants wrongfully secured, through their collusive acts, those benefits, such that it would be inequitable for Defendants to retain the benefits;~~

~~ll. Under Rhode Island common law, Plaintiffs conferred a benefit upon Defendants, Defendants appreciated the benefit, and it is inequitable for Defendants to retain the value of the benefit;~~

~~mm. Under South Carolina common law, Plaintiffs conferred a non-gratuitous benefit on the Defendants, who realized some value from the benefit, and it would be inequitable for Defendants to retain the benefit in light of Plaintiffs' impoverishment;~~

~~nn. Under South Dakota common law, a benefit was conferred on Defendants, of which Defendants are aware, and, under the circumstances, it would be unjust to allow retention of the benefits without requiring the Defendants to pay for it;~~

~~oo. Under Tennessee common law, Plaintiffs conferred a benefit upon Defendants, Defendants appreciated the benefit, it is inequitable for Defendants to retain the~~

~~value of the benefit, and Plaintiffs have exhausted their remedies against Defendants or pursuit would be futile;~~

~~pp. Under Texas common law, Defendants, through their collusion or otherwise wrongful acts, unjustly received a benefit to the detriment of Plaintiffs such that it would be unconscionable for Defendants to retain the benefit;~~

~~qq. Under Utah common law, Plaintiffs conferred a benefit upon Defendants, Defendants have knowledge of the benefit, it would be unjust for Defendants to retain the value of the benefit, and Plaintiffs lack an adequate remedy at law;~~

~~rr. Under Vermont common law, a benefit was conferred on Defendants, who accepted the benefit, and, in light of the circumstances, equity and good conscience demand that Defendants return the benefit;~~

~~ss. Under Virginia common law, Plaintiffs conferred a benefit on Defendants, the Defendants knew of and accepted the benefit, the Defendants should reasonably be expected to repay the Plaintiffs; and the Plaintiffs do not have a remedy at law;~~

~~tt. Under Washington common law, Plaintiffs conferred a benefit on Defendants, who appreciated or had of the benefit, the retention by the Defendants of the benefit under such circumstances would be inequitable for the Defendants to retain the benefit, and the Plaintiffs do not have an adequate remedy at law;~~

~~uu. Under West Virginia common law, Defendants have received money, to which they were not entitled and the payment was a mistake on the part of Plaintiffs;~~

~~vv. Under Wisconsin common law, Plaintiffs conferred a benefit upon Defendants, Defendants have knowledge of the benefit, and it would be unjust for Defendants to retain the value of the benefit.~~

~~276.~~ The financial benefits enjoyed by Defendants ~~through the~~because of their wrongful ~~collusive~~ conduct described above are directly traceable to the losses, in the form of overcharges, suffered by Plaintiffs and the Class ~~Members~~ from not having access to, or having limited access to, Contract Pharmacy 340B Drug Discounts ~~because of Defendants' collusion.~~

~~277. Specifically, Defendants have colluded to deprive Plaintiffs and the Class Members of access to Contract Pharmacy 340B Drug Discounts and have thereby retained the value of those discounts for their own benefit and to the detriment of Plaintiffs and the Class Members.~~

~~278.~~390. ~~The financial benefit enjoyed by Defendants through the wrongful collusive conduct described above are directly traceable to the losses suffered by Plaintiffs and the Class Members from not having access to, or having limited access to, Contract Pharmacy 340B Drug Discounts because of Defendants' collusion~~.

391. It would be inequitable under unjust enrichment principles for Defendants to be permitted to retain amounts derived from ~~Defendants' unfair~~ their collusive and ~~unconscionable methods, acts, and trade practices of collusion~~inequitable conduct as alleged in this Complaint, through any resulting overcharges.

392. Consequently, Defendants have been unjustly enriched by Plaintiffs and Class Members, which made purchases of Defendants' drugs at Contract Pharmacies without access to the Contract Pharmacy 340B Drug Discounts, in violation of the common law of the following states and territories in the United States, as outlined below:

Arizona

393. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Arizona at prices that were more than they would have been but for Defendants' actions.

394. Defendants have been enriched by revenue resulting from unlawful overcharges for 340B eligible drugs.

395. Plaintiffs and the class have been impoverished by the overcharges for 340B eligible drugs resulting from Defendants' unlawful conduct.

396. Defendants' enrichment and Plaintiffs' and the Class's impoverishment are connected. Defendants have paid no consideration to any other person for any benefits they received from Plaintiffs and the Class.

397. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

398. There is no justification for Defendants' receipt of the benefits causing their enrichment and Plaintiffs' impoverishment, because Plaintiffs paid prices higher than they would have been in the absence of the wrongful conduct alleged above that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges.

399. To the extent required, Plaintiffs' and the Class's unjust enrichment claim is alleged where they have no remedy at law.

Hawaii

400. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Hawaii at prices that were more than they would have been but for Defendants' actions.

401. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

402. It is unjust for Defendants to retain the benefits received without compensating Plaintiffs and the Class.

Illinois

403. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Illinois at prices that were more than they would have been but for Defendants' actions.

404. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

405. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to Plaintiffs and the Class.

406. It is against equity, justice, and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

407. To the extent required, Plaintiffs' and the Class's unjust enrichment claim is alleged where they have no remedy at law.

Iowa

408. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Iowa at prices that were more than they would have been but for Defendants' actions.

409. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

410. Defendants have been enriched by revenue resulting from unlawful overcharges for 340B eligible drugs, which revenue resulted from the wrongfully inflated prices paid by Plaintiffs and the Class, which inured to Defendants' benefit.

411. Defendants' enrichment has occurred at the expense of Plaintiffs and the Class.

412. It is unjust for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

Maine

413. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Maine at prices that were more than they would have been but for Defendants' actions.

414. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

415. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to Plaintiffs and the Class.

416. Defendants were aware of and appreciated the benefit bestowed upon them by Plaintiffs and the Class.

417. Defendants were unjustly enriched at the expense of Plaintiffs and the Class.

Michigan

418. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Michigan at prices that were more than they would have been but for Defendants' actions.

419. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

420. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to Plaintiffs and the Class.

421. Defendants were unjustly enriched at the expense of Plaintiffs and the Class.

Minnesota

422. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Minnesota at prices that were more than they would have been but for Defendants' actions.

423. Defendants appreciated and knowingly accepted the benefits bestowed upon them by Plaintiffs and the Class. Defendants have paid no consideration to any other person for any of the benefits they have received from Plaintiffs and the Class.

424. It is inequitable for Defendants to accept and retain the benefits received without compensating Plaintiffs and the Class.

425. To the extent required, Plaintiffs' and the Class's unjust enrichment claim is alleged where they have no remedy at law.

Mississippi

426. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Mississippi at prices that were more than they would have been but for Defendants' actions.

427. Defendants retain the benefit of overcharges received on the sales of340B eligible drugs, which in equity and good conscience belong to Plaintiffs and the Class on account of Defendants' anticompetitive conduct.

Nebraska

428. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Nebraska at prices that were more than they would have been but for Defendants' actions.

429. Defendants received money from Plaintiffs and the Class as a direct result of the unlawful overcharges, and have retained this money. Defendants have paid no consideration to any other person in exchange for this money.

430. In justice and fairness, Defendants should disgorge such money and remit the overcharged payments back to Plaintiffs and the Class.

Nevada

431. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Nevada at prices that were more than they would have been but for Defendants' actions.

432. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

433. Defendants appreciated the benefits bestowed upon them by Plaintiffs and the Class, for which they have paid no consideration to any other person.

434. Defendants have knowingly accepted and retained the benefits bestowed upon them by Plaintiffs and the Class.

435. The circumstances under which Defendants have accepted and retained the benefits bestowed upon them by Plaintiffs and the Class are inequitable in that they result from Defendants' unlawful overcharges for 340B eligible drugs.

436. To the extent required, Plaintiffs' and the Class's unjust enrichment claim is alleged where they have no remedy at law.

New Mexico

437. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in New Mexico at prices that were more than they would have been but for Defendants' actions.

438. Defendants have knowingly benefitted at the expense of Plaintiffs and the Class from revenue resulting from unlawful overcharges for 340B eligible drugs.

439. To allow Defendants to retain the benefits would be unjust because the benefits resulted from anticompetitive pricing that inured to Defendants' benefit and because Defendants have paid no consideration to any other person for any of the benefits they received.

New York

440. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in New York at prices that were more than they would have been but for Defendants' actions.

441. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully

inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

442. Defendants have been enriched by revenue resulting from unlawful overcharges for 340B eligible drugs, which revenue resulted from overcharges paid by Plaintiffs, which inured to Defendants' benefit. The relationship between Defendants and Plaintiffs and the Class within the state of New York is not too attenuated because Defendants are aware that the 340B eligible drugs they manufacture, sell, and distribute are purchased by Plaintiffs and the Class within the state of New York. Moreover, Defendants' obligation to provide their Drugs at 340B discount prices is an obligation that runs directly to Plaintiffs and the Class.

443. Defendants' enrichment has occurred at the expense of Plaintiffs and the Class.

444. It is against equity and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

445. To the extent required, Plaintiffs' and the Class's unjust enrichment claim is alleged where they have no remedy at law.

Oregon

446. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Oregon at prices that were more than they would have been but for Defendants' actions.

447. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

448. Defendants were aware of the benefit bestowed upon them by Plaintiffs and the Class.

449. It would be inequitable and unjust for Defendants to retain any of the overcharges for 340B eligible drugs derived from Defendants' unfair conduct without compensating Plaintiffs and the Class.

Rhode Island

450. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Rhode Island at prices that were more than they would have been but for Defendant's actions.

451. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

452. Defendants were aware of and/or recognized the benefit bestowed upon them by Plaintiffs and the Class.

453. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and the Class.

South Dakota

454. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in South Dakota at prices that were more than they would have been but for Defendants' actions.

455. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully

inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

456. Defendants were aware of the benefits bestowed upon them by Plaintiffs and the Class.

457. Under the circumstances, it would be inequitable and unjust for Defendants to retain such benefits without reimbursing Plaintiffs and the Class.

458. To the extent required, Plaintiffs' and the Class's unjust enrichment claim is alleged where they have no remedy at law.

Utah

459. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Utah at prices that were more than they would have been but for Defendants' actions.

460. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

461. Defendants were aware of or appreciated the benefit bestowed upon them by Plaintiffs and the Class.

462. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and the Class.

463. To the extent required, Plaintiffs' and the Class's unjust enrichment claim is alleged where they have no remedy at law.

Vermont

464. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Vermont at prices that were more than they would have been but for Defendants' actions.

465. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

466. Defendants accepted the benefit bestowed upon them by Plaintiffs and the Class.

467. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and the Class.

Virginia

468. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Virginia at prices that were more than they would have been but for Defendants' actions.

469. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

470. Defendants accepted the benefit bestowed upon them by Plaintiffs and the Class.

471. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and the Class.

472. To the extent required, Plaintiffs' and the Class's unjust enrichment claim is alleged where they have no remedy at law.

West Virginia

473. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in West Virginia at prices that were more than they would have been but for Defendants' actions.

474. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

475. Defendants were aware of or appreciated the benefit bestowed upon them by Plaintiffs and the Class.

476. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiffs and the Class.

Wisconsin

477. Defendants unlawfully overcharged Plaintiffs and the Class, which made purchases of 340B eligible drugs in Wisconsin at prices that were more than they would have been but for Defendants' actions.

478. Plaintiffs and the Class have conferred a direct economic benefit upon Defendants, in that the revenues received by Defendants from selling 340B eligible drugs at wrongfully inflated prices are directly related to, and flow from the overcharges paid by Plaintiffs and the Class for the purchase of 340B eligible drugs.

479. Defendants appreciated the benefits bestowed upon them by Plaintiffs and the Class and should be reasonably expected to repay Plaintiffs for the benefits conferred upon them.

~~279.~~480. This claim is asserted in the alternative to the extent that Plaintiffs lack an adequate remedy at law.

JURY DEMAND

~~280.~~481. Plaintiffs request a jury trial of all issues triable of right by a jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

1. Certifying this action as a class action, certifying Plaintiffs as Class Representatives, and appointing Plaintiffs' counsel of record as Class Counsel, all pursuant to Rule 23 of the Federal Rules of Civil Procedure;

2. Declaring Defendants' conduct violated federal and State laws;

3. Awarding money damages in an amount to be proved at trial, plus statutory damages, punitive and treble damages, and other such relief as provided by law, together with all such further relief as may be just and proper, plus pre-judgment and post-judgment interest, to Plaintiffs and Class Members;

4. Awarding the costs of bringing this action, including reasonable attorneys' fees and expenses, as further provided by the statutes cited;

5. Entry of preliminary and permanent injunctive relief prohibiting the anticompetitive conduct alleged herein and eliminating the anticompetitive effects of the same, as well as providing any appropriate restitution and/or disgorgement of all unlawful or illegal profits received by Defendants as a result of the anticompetitive conduct alleged herein; and

6. Granting all other relief to which Plaintiffs and Class Members may be entitled at law or equity.

Dated: October ~~22, 2021~~3, 2022

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