UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

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

Plaintiffs,

-against-

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

Defendants.

Civil Action No. 21-cv-6507

DEFENDANT NOVO NORDISK INC.'S BRIEF IN SUPPORT OF MOTION TO DISMISS COMPLAINT

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INTRODUCTION AND SUMMARY OF ARGUMENT

Novo Nordisk Inc. ("Novo") submits this individual brief because the paucity of allegations against Novo require dismissing Novo from this action and demonstrate the Amended Complaint's fatal deficiencies as to all Defendants. The Amended Complaint relies on allegations of parallel conduct coupled with an alleged improper motive, but the alleged conduct is far from parallel and the alleged motive is nonsensical, especially when considering the conclusory Novo-specific allegations. The Amended Complaint alleges that Novo announced its contract pharmacy policy on December 1, 2020 (to take effect one month later)—several months *after* the *public* announcements made by the other Defendants, but the Amended Complaint includes no allegations that plausibly establish any agreement involving Novo or any of the other Defendants or that plausibly distinguish Novo from other non-Defendant manufacturers who also changed their policies. The Amended Complaint acknowledges that Novo's policy is very different from the other Defendants' policies, which are also very different from each other. Moreover, while the Amended Complaint alleges that Defendants were motivated to conspire because they would purportedly lose market share if they did not conspire to change their contract pharmacy policies, that motive is not supported by substantial or plausible allegations. Furthermore, a deficiency fatal to the Amended Complaint is that Novo's policy does not even apply to Plaintiffs, which are non-hospital clinics. As a result, Plaintiffs have not been impacted (much less harmed) by Novo's policy, which renders implausible the motive alleged as to all Defendants.

BACKGROUND

This case relates to a very public and heavily litigated dispute over the requirements of the 340B statute. The statute requires manufacturers to offer their drugs at deeply discounted prices to hospitals and certain other entities that serve indigent patients (collectively, "covered entities"). *See* 42 U.S.C. § 256b(a)(1). Plaintiffs, which are federally qualified health centers, participate in

the 340B program and have contracts with retail pharmacies ("contract pharmacies"). FAC ¶ 3. As the Amended Complaint recognizes, Novo and other manufacturers have taken the position that, as long as they offer their drugs to covered entities for purchase at the discounted 340B price, they are not required to transfer their discounted drugs to contract pharmacies for the convenience of covered entities. Defendants have filed separate actions to clarify the law and to uphold their interpretations of the statutory requirements. *See* FAC ¶¶ 3, 6, 7, 35. The outcome of those cases, however, is irrelevant to the antitrust issues presented before this Court in the Amended Complaint.

ARGUMENT

To state a claim under Section 1 of the Sherman Act, *see* 15 U.S.C. § 1, a plaintiff must allege facts sufficient to establish a plausible basis for concluding that challenged conduct stems not from an "independent decision" but from a conspiracy. *Starr v. Sony BMG Music Ent.*, 592 F.3d 314, 321 (2d Cir. 2010) (quoting *Theatre Enters., Inc. v. Paramount Film Distrib. Corp.*, 346 U.S. 537, 540 (1954)). In addition, when a complaint "names multiple defendants, plaintiffs must make allegations that plausibly suggest that each defendant participated in the alleged conspiracy." *In re SSA Bonds Antitrust Litig.*, No. 16 CIV. 3711, 2020 WL 1445783, at *5 (S.D.N.Y. Mar. 25, 2020) (quoting *Hinds Cnty. Miss. v. Wachovia Bank N.A.*, 620 F. Supp. 2d 499, 513 (S.D.N.Y. 2009)). "Allegations about the defendants as a general collective block, or generalized claims of parallel conduct, must . . . be set aside . . . as impermissible group pleading." *In re Mexican Gov't Bonds Antitrust Litig.*, 412 F. Supp. 3d 380, 388 (S.D.N.Y. 2019). These requirements are especially important in the context of the 340B statute, which includes no private right of action. *See Astra USA, Inc. v. Santa Clara Cnty.,* 563 U.S. 110, 117 (2011).

The allegations against Novo (and the other Defendants) do not satisfy these requirements. The only allegations that even attempt to suggest that Novo participated in a conspiracy appear in a few short paragraphs. Those allegations assert in conclusory fashion that (1) Novo first informed

HHS about, and then implemented, its contract pharmacy policy nearly 7 months after the first Defendant publicly announced its policy, *see* FAC ¶¶ 179–184, (2) Novo's policy, while different, has similarities to other Defendants' policies, *see id.* ¶ 181, and (3) a member of Novo's leadership serves on the Board of Directors of an industry association, *see id.* ¶ 219.[1] That is the sum total of Plaintiffs' allegations that Novo participated in a conspiracy to fix prices, which is insufficient to satisfy minimum pleading requirements. *See Rochester Drug Co-op, Inc. v. Bioden Idec U.S. Corp.*, 130 F. Supp. 3d 764, 772–781 (W.D.N.Y 2015) (dismissing claims under New York's antitrust statute for failing to allege sufficient facts).

First, Plaintiffs' allegations lack necessary factual support to plausibly state a claim that Novo participated in a conspiracy. They do not include any "specification of any particular activities" by Novo. *Id.* at 773 (quoting *In re Elevator Antitrust Litig.*, 502 F.3d 47, 51 (2d Cir. 2007)). Nor do they identify *when* Novo allegedly entered a conspiratorial agreement. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007) ("conclusory allegation[s] of agreement at some unidentified point do] not supply facts adequate to show illegality"). Nor do the allegations constitute "plausible grounds to infer an agreement" because, while the alleged conduct is arguably "consistent with conspiracy, [it is] just as much in line with a wide swath of rational and competitive business strategy unilaterally prompted by common perceptions of the market." *In re Elevator*, 502 F.3d at 51 (quoting *Twombly*, 550 U.S. at 554, 556).

[1] The Amended Complaint's other allegations involving Novo include general allegations regarding Novo's principal place of business, *see* FAC ¶ 14, positions that it has taken in 340B-related litigation, *id.* ¶ 35, the names and alleged market share of products that Novo sells, *see id.* ¶¶ 78–79, 83–84, 86–87, alleged revenues resulting from the sale of its products, *see id.* ¶ 94, statements that Novo has made about its products, *see id.* ¶ 95, general allegations about Novo's lobbying activities, *see id.* ¶¶ 109–111, allegations that Novo competes with the other Defendants, *see id.* ¶¶ 149–177, and allegations that Novo is involved in other litigation, *see id.* ¶¶ 220–221. None of these background allegations supply the necessary elements of a claim against Novo or cure the pleading defects of the Amended Complaint.

Plaintiffs also offer no reason why Novo would file litigation against the government highlighting its policy if it were part of an illicit conspiracy to raise prices. Indeed, if anything, Plaintiffs' allegations are more consistent with the conclusion that Novo's policy resulted from its own independent judgment. As the Amended Complaint and the judicially noticeable materials discussed in the joint brief show, Novo's decision to stop transferring drugs to contract pharmacies is part of a larger, ongoing dispute over the statutory requirements and the government's failure to address 340B program abuses, which have caused the program to expand with billions of dollars being taken for the benefit of contract pharmacies. *See N.Y. Jets LLC v. Cablevision Sys. Corp.*, No. 05 Civ. 2875, 2005 WL 2649330, at *6 (S.D.N.Y. Oct. 17, 2005) (conduct "aimed at securing government action" is "immune from antitrust liability") (citing cases).

Second, the few bare factual allegations that are included in the Amended Complaint undermine any viable theory that Novo (or any other Defendant) participated in a conspiracy. For example, the allegation that Novo implemented its policy on December 1, 2020—nearly 7 months after the first Defendant announced a new contract pharmacy policy and more than 3½ months after all of the other Defendants had announced their distinct contract pharmacy policies, *see* FAC ¶124—undercuts any inference of "conscious parallelism." *Todd v. Exxon Corp.*, 275 F.3d 191, 198 (2d Cir. 2001); *see also LaFlamme v. Societe Air France*, 702 F. Supp. 2d 136, 151 (E.D.N.Y. 2010) (no conspiracy claim where conduct was unique and imposed weeks apart). So does the omission from the Amended Complaint of any allegations that Novo met with or had any conversations with other Defendants to discuss prices. The only coordinated conduct that Plaintiffs allege relates to lobbying activities, which Plaintiffs expressly disclaim as the basis for their lawsuit. *See* FAC ¶ 6.

Far from being "parallel," Novo's alleged policy changes are distinct from those attributed to any other Defendant—indeed, each of the Defendants' policies are different. For instance, unlike Sanofi's policy, *see* FAC ¶ 120, Novo's policy requires no data from covered entities, *see* FAC ¶ 124.[2] Moreover, unlike the other Defendants' policies, non-hospital covered entities, such as Plaintiffs, are explicitly excluded from Novo's policy. *Id.* That is antithetical to the glue that purportedly ties Defendants together—that Defendants conspired because they all needed to limit the use of contract pharmacies in order not to lose market share. FAC ¶¶ 181–195.

Third, the Amended Complaint includes no allegations that Novo's conduct resulted in an actual antitrust injury. There are no allegations that Plaintiffs purchase drugs directly from Novo, as opposed to wholesale distributors. *See* FAC ¶¶ 37, 40–42; *see also Ill. Brick Co. v. Illinois*, 431 U.S. 720 (1977). Nor are there any allegations that Novo reached an agreement with other manufacturers to change its policy or that Novo has ever prevented Plaintiffs from purchasing drugs at the discounted price. To the contrary, as noted above, Novo's policy does not even apply to Plaintiffs. Even if it did, the Amended Complaint fails to state a viable theory of antitrust liability. Plaintiffs are not complaining about anti-competitive conduct that has influenced competitive market prices. They are asserting an unwritten statutory right to force Novo and other manufacturers to deliver drugs purchased at discounted, non-market prices to commercial pharmacies. Whether that theory is viable turns on a proper interpretation of the 340B statute, but importantly cannot be litigated in a private action brought by covered entities, such as Plaintiffs. *See Santa Clara*, 563 U.S. at 117. If there is a violation of the statute, it must be enforced through

[2] Novo's December 1, 2020 announcement is cited in the Amended Complaint, including its limitation to "hospital covered entities." FAC ¶ 124. The Amended Complaint notes that Plaintiffs are federally qualified health centers (*i.e.*, "grantees") and not hospital covered entities. *See* FAC ¶ 5; *see also* 42 U.S.C. § 256b(a)(4).

the regulatory processes that Congress designed. The antitrust laws should not be wielded to create a private remedy under the 340B statute that Congress did not authorize. *See id*.

CONCLUSION

For these reasons, and the reasons set forth in Defendants' joint motion, the Court should dismiss the Amended Complaint with prejudice as to Novo, as well as the other Defendants. Plaintiffs should not be permitted yet another opportunity to amend.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing was filed electronically with the United States District Court for the Western District of New York through the Court's ECF System on November 12, 2021.

/s/ Carolyn Nussbaum
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