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Advancing Health in America

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The Honorable Andrew N. Ferguson
Chairman
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

The Honorable Gail Slater
Assistant Attorney General
Antitrust Division, Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20503

September 8, 2025

Re: Anticompetitive activity by drug companies with respect to 340B "rebate models"

Dear Chairman Ferguson and Assistant Attorney General Slater:

On behalf of our nearly 5,000 member hospitals, health systems, and other health care organizations, our clinician partners, and in particular our more than 2,000 member hospitals and health systems participating in the 340B Drug Pricing Program, the American Hospital Association (AHA) writes to alert you of recent concerted conduct by some of the world's largest drug companies. These companies have restricted access to 340B discounts through their coordinated imposition of "rebate models." These actions may violate federal antitrust laws and therefore warrant your immediate attention.

Just last month, the United States Court of Appeals for the Second Circuit permitted a putative class action to proceed against certain drug companies for an alleged horizontal price-fixing conspiracy based on strikingly similar behavior. *See Mosaic Health, Inc. v. Sanofi-Aventis U.S., LLC,* No. 24-598, 2025 WL 2232879 (2d Cir. Aug. 6, 2025). In that case, plaintiffs alleged that defendant drug companies violated both federal and state antitrust law by conspiring to limit the 340B drug discount for certain diabetes drugs purchased through contract pharmacies. The Second Circuit concluded that plaintiffs adequately pleaded an antitrust conspiracy: "The proposed second amended complaint plausibly alleges that Defendants acted similarly enough in substance by restricting Section 340B Drug Discount pricing and raising prices in the market of certain popular diabetes medication over the course of months.… The Defendants' policies also have a similar anti-competitive effect of limiting or eliminating the availability of Section 340B Drug Discounts." *Id*. at *8.

Regrettably, the Biden Administration did not investigate those allegedly anticompetitive activities. This Administration should not make the same mistake — especially now that hospitals and health systems are faced with a second, similar set of facts.

Within the past year, a group of competitor drug companies — many of which also participated in the scheme alleged in *Mosaic Health, Inc.*— attempted to impose another mechanism to restrict access to 340B drug discounts: the "rebate model." These drug companies sought to switch from providing "upfront discounts" on 340B drugs to a model in which 340B hospitals must purchase even the costliest drugs at full price and then submit for a rebate. If successful, this concerted effort would essentially obligate America's safety-net hospitals to advance interest-free loans to the world's largest and most profitable drug companies. This new "rebate model" would inflict untold harm on hospitals, patients and communities. And for your purposes, the publicly available information suggests potential anticompetitive activity.

We therefore respectfully request that the Federal Trade Commission (FTC) and Antitrust Division of the United States Department of Justice (DOJ) investigate the drug companies' concerted efforts to impose these rebate models within the 340B Program. As in *Mosaic Health. Inc.*, these efforts bear the strong stench of parallel conduct. Here, like in that case, the drug companies' "announced policies were similar enough in substance, timing, and effect" to raise legitimate anticompetitive concerns. *Id*. at *11.

We have been heartened by this Administration's oft-stated commitment to holding drug companies accountable. We also are encouraged by its commitment to "Make America Competitive Again."[1] An investigation of this kind of potential anticompetitive behavior is consistent with these commitments. And it is long overdue.

THE 340B PROGRAM

The 340B Drug Pricing Program "was intended to enable certain hospitals and clinics 'to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.'" *Am. Hosp. Ass'n v. Hargan*, 289 F. Supp. 3d 45, 47 (D.D.C. 2017) (quoting H.R. Rep. 102-384, pt. 2, at 12 (1992)). For more than 30 years, the 340B Program has helped safety-net hospitals manage rising prescription drug costs and expand access to care. Specifically, Section 340B of the Public Health Service Act requires drug manufacturers participating in Medicaid to sell certain

[1] Donald J. Trump (@realDonaldTrump), Truth Social (Dec. 4, 2024, 12:21 PM), https://truthsocial.com/@realDonaldTrump/posts/113595703893773894 (cited in *Assistant Attorney General Gail Slater Delivers Remarks to the Ohio State University Law School*, United States Department of Justice (Aug. 29, 2025), https://www.justice.gov/opa/speech/assistant-attorney-general-gail-slater-delivers-remarks-ohio-state-university-law-school).

outpatient drugs at discounted prices to hospitals and health systems that care for high numbers of low-income and other underserved patients. 340B hospitals use these savings to provide free care for uninsured patients, free or low-cost medications, services in mental health clinics, opioid treatment, and a host of other beneficial programs. As Justice Kavanaugh wrote for a unanimous Supreme Court just a few years ago: "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 738 (2022).

Over the last several years, drug companies have begun to aggressively limit access to these drug discounts. For example, beginning in 2020, drug companies began restricting the distribution of 340B drugs through community or specialty pharmacies, also known as contract pharmacies. Despite Department of Health and Human Services (HHS) guidance permitting 340B hospitals to access drug discounts through these channels — including an HHS Office of General Counsel Advisory Opinion issued during the first Trump Administration[2] — more than 40 drug companies pushed forward in tandem to implement these restrictions. These contract pharmacy restrictions, which are the subject of the above-mentioned *Mosaic Health* antitrust lawsuit, have cost hospitals millions of dollars and forced many to curtail important patient services.

POTENTIAL ONGOING ANTITRUST CONSPIRACY

More recently, pharmaceutical manufacturers developed a second scheme to restrict access to 340B discounts: the sudden, unilateral imposition of "rebate models." Under these models, drug companies would no longer provide the required 340B discounts at the time of sale. Instead, breaking from three decades of precedent, those drug companies would force hospitals and other providers to pay the full price for 340B drugs and then pay the discounts in the form of "rebates."

The announcement of these rebate models came like a bolt from the blue, shocking hospitals and health systems across the nation. There was no prior concerted lobbying effort on the part of drug companies prior to their announcement. There was no indication whatsoever. The world's largest drug companies simply stated — within days and weeks of each other — that this was now how it would be done, take it or leave it. As HHS observed, however, the use of these rebate models would "fundamentally shift[] how the 340B Program has operated for over 30 years." Health Resources and Services Administration, *340B Program Notice: Application Process for the 340B Rebate Model Pilot Program; Correction*, 90 Fed. Reg. 38165, 38165 (Aug. 7, 2025). And as alleged in *Mosaic Health, Inc.*, if the drug companies are successful in achieving this fundamental shift in how the 340B Program operates, hospitals will lose both "the

[2] Robert Charrow, General Counsel, United States Department of Health and Human Services, *Advisory Opinion 20-06 On Contract Pharmacies Under The 340b Program* (Dec. 30, 2020).

ability to generate 340B Savings" and "the ability to provide the range of healthcare services and savings for patients that they would have been able to offer absent [the drug companies'] conduct." *Mosaic Health, Inc. v. Sanofi-Aventis U.S.*, Case No. 6:21-cv-06507, Compl. ¶ 233 (Dkt. 1) (W.D.N.Y. July 30, 2021).

Like their earlier imposition of contract pharmacy restrictions, this abrupt pivot by several drug companies occurred in concert — to an astonishing degree. In August 2024, Johnson & Johnson announced that it would be implementing a rebate model for 340B drug discounts. Within a week, Eli Lilly announced the same. And then, like clockwork, over the course of the next few months, Bristol Myers Squibb, Sanofi, and Novartis all made similar announcements. As of the date of this letter, all five drug companies are in active litigation against HHS to force the approval of their rebate models.[3] And this coordinated effort may well succeed in limiting access to 340B discounts: in response to this coordinated pressure from these drug companies, HRSA recently announced a "pilot program" to test the rebate models.

The timeline, in itself, raises suspicions of parallel conduct:

Date	Drug Company	Event
July 24, 2024	Johnson & Johnson	Meeting with HRSA regarding 340B utilization trends, audit efforts, and rebate model plans
July 31, 2024	Johnson & Johnson	Letter to HRSA regarding implementation of 340B rebate model
August 14, 2024	Johnson & Johnson	HRSA letter seeking additional information about proposed 340B rebate model and warning of potential illegality
August 16, 2024	Johnson & Johnson	Letter to HRSA regarding implementation of 340B rebate model and addressing questions
August 22, 2024	Johnson & Johnson	Email to HRSA regarding forthcoming announcement to covered entities regarding rebate program
August 23, 2024	Johnson & Johnson	Announcement of forthcoming implementation of 340B rebate model
August 30, 2024	Eli Lilly	Email communication to HRSA seeking meeting to implement new process for 340B discounts
September 4, 2024	Eli Lilly	Meeting with HRSA and Kalderos regarding rebate proposal

[3] The AHA has filed *amicus* briefs in each of these lawsuits, providing additional information about the costs of these restrictions to 340B hospitals and patients around the country. *See, e.g.,* Br. of the American Hospital Association, et al., *Novartis Pharmaceuticals Corporation, et al., v. Kennedy*, Nos. 25-5177, 25-5179, 25-5220, 25-5221, 25-5236 (D.C. Cir. Aug. 5, 2025), *at* https://www.aha.org/amicus-brief/2025-08-05-aha-others-defend-hhs-decision-reject-340b-rebate-models-drug-companies.

September 9, 2024	Eli Lilly	Letter to HRSA following up on meeting and further explaining forthcoming 340B rebate model
September 12, 2024	Johnson & Johnson	Letter to HRSA regarding implementation of 340B rebate model
September 17, 2024	Johnson & Johnson	HRSA letter warning of potential illegality and demanding J&J cease implementation of the program
September 18, 2024	Eli Lilly	HRSA letter seeking additional information about proposed 340B rebate model and warning of potential illegality
September 19, 2024	Johnson & Johnson	Letter to HRSA regarding implementation of 340B rebate model and clarifying details
September 23, 2024	Eli Lilly	Letter to HRSA to provide additional requested information and reiterate view that model is lawful
September 27, 2024	Johnson & Johnson	HRSA letter warning of Pharmaceutical Pricing Agreement (PPA) termination and referral to HHS Office of Inspector General (OIG) if it implements the rebate model
September 30, 2024	Johnson & Johnson	Letter to HRSA withdrawing new rebate model
October 21, 2024	Johnson & Johnson	Meeting with HRSA regarding steps to facilitate rebate model + email requesting HRSA's response by October 28
October 29, 2024	Johnson & Johnson	Email to HRSA following up
October 30, 2024	Johnson & Johnson	HRSA email reporting that it is still reviewing information
October 22, 2024	Bristol Myers Squibb	Meeting with HHS regarding implementation of new rebate model
October 24, 2024	Bristol Myers Squibb	Letter to HRSA following up on meeting regarding implementation of 340B rebate model
November 1, 2024	Sanofi	Letter to HRSA informing of plan to implement 340B credit model
November 4, 2024	Bristol Myers Squibb	HRSA letter seeking additional information about proposed 340B rebate model and warning of potential illegality
November 12, 2024	Bristol Myers Squibb	Letter to HRSA responding to request for additional information
November 12, 2024	Sanofi	HRSA letter seeking additional information about proposed 340B rebate model and warning of potential illegality

November 12, 2024	Johnson & Johnson	Email to HRSA regarding planned lawsuit challenging final determinations from letters dated August 14, September 17, and September 27
November 12, 2024	Johnson & Johnson	Lawsuit filed against HHS and HRSA in support of 340B rebate model
November 12, 2024	Sanofi	HRSA letter to Sanofi regarding rebate model proposal (described in December 13 HRSA letter)
November 14, 2024	Eli Lilly	Lawsuit filed against HHS and HRSA in support of 340B rebate model
November 15, 2024	Sanofi	Letter to HRSA responding to questions and sharing plan to announce new model on November 22.
November 21, 2024	Sanofi	HRSA letter reiterating its view that the credit model would be unlawful
November 21, 2024	Bristol Myers Squibb	HRSA letter reiterating its view that the rebate model would be unlawful
November 22, 2024	Sanofi	Announcement of forthcoming implementation of 340B rebate model
November 26, 2024	Bristol Myers Squibb	Lawsuit filed against HHS and HRSA in support of 340B rebate model
December 2024	Novartis	Letter to HRSA regarding implementation of 340B rebate model
December 13, 2024	Sanofi	HRSA letter warning of risk of PPA termination or other consequences if Sanofi proceeds
December 16, 2024	Sanofi	Lawsuit filed against HHS and HRSA in support of 340B rebate model
January 14, 2025	Novartis	HRSA letter seeking additional information about proposed 340B rebate model and warning of potential illegality; warning of risk of PPA termination
January 15, 2025	Novartis	Lawsuit filed against HHS and HRSA in support of 340B rebate model

This chronology speaks for itself.

The activity here is remarkably similar to what the Second Circuit found to plausibly allege an antitrust conspiracy in *Mosaic Health, Inc*. *See, e.g*., *Mosaic Health, Inc. v. Sanofi-Aventis U.S*., Case No. 6:21-cv-06507, Compl. ¶¶ 116-123 (Dkt. 1) (W.D.N.Y. July 30, 2021); *id*. at ¶ 180 ("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."). For instance, the *Mosaic* plaintiffs pointed to a series of communications from competitor drug companies to HHS informing the agency of their plan to impose restrictions on drug discounts to contract pharmacies. *See, e.g*., *id.* at ¶ 117 ("On July 24, 2020, … 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."); *id.* at ¶ 120 ("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."); *id*. at ¶ 123 ("On December 1, 2020, Novo Nordisk informed HHS of the drug company's policy.").

The U.S. District Court for the Western District of New York dismissed the complaint and denied plaintiffs' motion for leave to file a second amended complaint. But on appeal, the Second Circuit reversed. The court of appeals explained that plaintiffs reasonably demonstrated an antitrust conspiracy through "inferences that may fairly be drawn from the behavior of the alleged conspirators." *Mosaic* at *3 (citing *Michelman v. Clark-Schwebel Fiber Glass Corp.,* 534 F.2d 1036, 1043 (2d. Cir. 1976)).

The Second Circuit first determined that the *Mosaic* plaintiffs pleaded facts sufficient to meet the "parallel conduct" standard: the effort by defendants to implement similar policies, announced at a similar time, with a "similar anti-competitive effect of limiting or eliminating the availability of Section 340B Drug Discounts." *See Mosaic* at *8. Although the individual drug company policies contained some differences, the court of appeals determined that those differences do not undermine their parallel nature or the overall effect of limiting drug discount access.

Next, the Second Circuit found that plaintiffs had sufficiently pleaded facts in support of the requisite "plus factors." In addition to showing parallel conduct, a complaint requires some factual context suggesting agreement (*i.e*., "plus factors"), which may include:

> [T]raditional evidence of conspiracy: statements permitting an inference that the defendants entered into an agreement. They may also include evidence of other circumstances giving rise to a less direct inference of conspiracy, such as 'a common motive to conspire, evidence that shows that the parallel acts were against the apparent individual economic self-interest of the alleged conspirators, and evidence of a high level of interfirm communications.'

Mosaic at *4 (citing *Anderson News, L.L.C. v. American Media, Inc.*, 899 F.3d 87, 104 (2d Cir. 2018) (internal citations omitted)). The Second Circuit held that the *Mosaic* plaintiffs adequately alleged those "plus factors," including that the drug companies shared a common motive to mitigate the regulatory threats and that the alleged conduct would have been against any individual company's economic interest because acting alone would have risked loss of market share and even federal program participation. *See id*. at *9-10.

We have observed a comparable — and perhaps even more extensive — pattern with the rebate models. As the above chronology illustrates, this group of drug companies

appears to have undertaken parallel conduct close in time. The requisite "plus factors" are present, too:

- *First*, the drug companies share a motive. The actors are competitor drug companies, all of which have strong motivation to limit 340B hospital access to drug discounts for their own financial benefit.

- *Second*, it would be "against the apparent individual economic self-interest of the alleged conspirators" to undertake this activity alone. Without the strength of numerosity, each individual drug company would risk losing market share by making it more burdensome for 340B hospitals to purchase discounted drugs. And even more detrimentally, the individual companies would risk their ability to participate in federal programs, which, as the Second Circuit noted, is a far more likely outcome for a single drug company acting alone than for many acting in concert. *See Mosaic* at *10 ("Plaintiffs' allegation that by acting collectively, Defendants limited their exposure only to civil monetary penalties, is plausible because, if one had acted alone, that Defendant would have been exposed to the greater risk of exclusion from Medicare and Medicaid. Given the need for patients to have these drugs on the market, Defendants at the very least avoid being cut off from the market altogether by allegedly acting in concert."). This is particularly salient here, where J&J initially tried and then walked back its rebate model following HRSA threats of enforcement action; only after other drug companies engaged with HRSA regarding their rebate model proposals did J&J push forward to file suit.

- *Third*, the drug companies have had ample opportunity to conspire among themselves, in many of the same ways alleged in *Mosaic Health, Inc*. *Mosaic Health, Inc. v. Sanofi-Aventis U.S*., Case No. 6:21-cv-06507, Compl. ¶¶ 214-216 (Dkt. 1) (W.D.N.Y. July 30, 2021). In addition, among the five drug companies that have pursued a rebate model, *three* have hired counsel from the same law firm, Hogan Lovells. In fact, a single lawyer from that firm represents two of the potential co-conspirators. *Cf. Assistant Attorney General Gail Slater Delivers Remarks to the Ohio State University Law School*, United States Department of Justice (Aug. 29, 2025), https://www.justice.gov/opa/speech/assistant-attorney-general-gail-slater-delivers-remarks-ohio-state-university-law-school ("Unfortunately, we at the Antitrust Division have concluded that a few actors — many of them at Big Law firms — can undermine sound antitrust enforcement for everyone"). In addition, it is suspicious that several of these drug companies propose implementing their models with the same third-party product: Beacon by Second Sight Solutions.[4] We expect that further investigation will expose additional communications and contacts among these drug companies.

[4] *See* https://beaconchannelmanagement.com/.

CONCLUSION

If successful, this potential antitrust conspiracy will devastate the 340B hospitals that serve America's rural and other underserved populations. **It is therefore time for FTC and DOJ to act. We urge you to investigate this behavior and take the necessary steps to address any and all antitrust violations.**

We appreciate your careful consideration of these issues. Please contact me if you have any questions or feel free to have a member of your team contact Julie Schenker, AHA's deputy general counsel, at jschenker@aha.org.

Sincerely,

/s/

Chad Golder
General Counsel and Secretary

CC: Thomas Engels, Administrator, Health Resources and Services Administration