UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ELI LILLY AND COMPANY, Plaintiff, v. ROBERT F. KENNEDY, JR., Secretary of Health and Human Services et al., *et al.*, Defendants.	Civil Action No. 24-3220 (DLF)
BRISTOL MYERS SQUIBB COMPANY, Plaintiff, v. ROBERT F. KENNEDY, JR, Secretary of Health and Human Services et al., Defendants.	Civil Action No. 24-3337 (DLF)
NOVARTIS PHARMACUTICALS CORP, Plaintiff, v. ROBERT F. KENNEDY, JR, Secretary of Health and Human Services et al., Defendants.	Civil Action No. 25-0117 (DLF)

DEFENDANTS' MEMORANDUM OF POINT AND AUTHORITIES IN SUPPORT OF ITS CROSS MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO PLAINTIFFS' MOTIONS FOR SUMMARY JUDGMENT

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Defendants the Secretary of Health and Human Services, and the Administrator of the Health Resources and Services Administration ("the Agency") respectfully submit this memorandum of points and authorities in support of their cross motion for summary judgment and in opposition to Plaintiffs' motions for summary judgment in these cases, which have been joined for purposes of dispositive motions briefing.

INTRODUCTION

The Court should grant summary judgment in Defendants' favor because the Agency's decision to prevent Plaintiffs from implementing a rebate model to effectuate 340B price reductions was within its statutory authority. Moreover, Plaintiffs' proposed cash rebate models would have upended the way the 340B Program has operated for more than thirty years and thus the Agency's decision to prevent Plaintiffs from implementing those models "at this time" was not arbitrary and capricious. Finally, Plaintiffs claims that the Agency's decision violates their procedural and substantive due process rights lack merit and should be dismissed.

BACKGROUND

I. Statutory and Regulatory Background.

In 1992, Congress created a program, administered by the Secretary of Health and Human Services, through which certain safety-net healthcare providers, including hospitals, community health centers, and other federally funded entities (collectively known as "covered entities") serving low-income patients could receive drug price reductions See Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967–71 (1992), codified at § 340B, Public Health Service Act, 42 U.S.C. § 256b (1992). The program has dual benefits: Drug discounts "enable these entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services," and may directly benefit uninsured and

underinsured patients when covered entities opt to pass along the discounts by helping patients afford costly medications. H.R. Rep. No. 102-384, pt. 2, at 12 (1992).

To achieve these benefits, Congress directed the Secretary to enter into an agreement, known as a Pharmaceutical Pricing Agreement ("pricing agreement") "with each manufacturer of covered outpatient drugs under which the amount required to be paid … to the manufacturer for [such] drugs . . . purchased by a covered entity . . . does not exceed [the ceiling price]." 42 U.S.C. § 256b(a)(1). The ceiling price is derived from components of each drug's "average" and "best" price as calculated under the Medicaid Drug Rebate Program. *Id.* Each pricing agreement "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.*; see also, 58 Fed. Reg. 27,289, 27,291 (May 7, 1993). In essence, the statute requires participating drug manufacturers to offer their pharmaceutical products to covered entities at reduced cost. 58 Fed. Reg. at 27,289. Examples of qualifying covered entities include federally qualified health centers that serve populations such as the homeless, uninsured, and rural populations, family planning clinics, entities providing outpatient early intervention services for HIV diseases, state-operated AIDS drug assistance programs, black lung clinics, hemophilia diagnostic treatment centers, Native Hawaiian health centers, and disproportionate share hospitals, i.e. hospitals that serve a disproportionate share of Medicare, Medicaid, and other low income uninsured patients. *Id.;* see also 42 U.S.C. § 256b(a)(4).

To incentivize pharmaceutical companies to participate in the program, known as the "340B Program," Congress conditioned drug makers' access to a federal benefit—coverage of their products under Medicaid and Medicare Part B—on manufacturers' participation in the program. *Id.* § 1396r-8(a)(1); *id.* § 256b(a). Pharmaceutical companies thus may opt out of

providing discounted drugs to safety-net providers and their low-income patients, but then lose access to drug coverage under federal health-insurance programs. 42 U.S.C. § 256b(a)(4) (defining "covered entity")

Although the statute "has no explicit language as to whether the required reduction in price should be obtained by an initial reduction in the purchase price (i.e., a discount mechanism) or received as a required reduction in cost rebated after purchase, dispensing, and payment are completed (i.e., a rebate option)," the statute "provides that the amount to be paid to the manufacturers for covered drugs takes "'into account any rebate or discount, as provided by the Secretary.'" 62 Fed. Reg. 45,823, 45,824 (Aug. 29, 1997) (quoting 42 U.S.C. § 256b(a)(1)). Guidance published when the 340B Program first began recognized the use of discounts and allowed rebates only in the context of covered entities recouping the 340B price for purchases made prior to the initial implementation of the 340B Program. 58 Fed. Reg. at 27291-92. Historically, the price reductions have been effectuated through upfront discounts on the purchase price, but the Agency has made exceptions for instance in the case of drugs sold to a certain category of covered entities called AIDS Drug Assistance Programs. 62 Fed. Reg. at 45,824.

Importantly, "the pricing agreements that the manufacturers sign to opt into the 340B Program are not transactional, bargained-for contracts. They are uniform agreements that recite the responsibilities § 340B imposes, respectively, on drug manufacturers and the Secretary." *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 113 (2011). Thus, when a manufacturer signs a pricing agreement, the manufacturer is agreeing to the "terms and conditions" of the program as stated in the statute. Manufacturers that do not comply with the terms of the pricing agreement, which evidences manufacturers' assent to opt-in to the requirements of the statute, can be subject

to termination from the 340B Program and civil monetary sanctions. 42 U.S.C. § 256b(d)(1)(B)(vi).

II. Factual Background

Plaintiffs Eli Lilly and Company ("Lilly"), Bristol Myers Squibb Company ("Bristol Myers"), and Novartis Pharmaceuticals Corporation ("Novartis") (collectively "Plaintiffs") are pharmaceutical manufacturers and have separate Pharmaceutical Pricing Agreements with the Agency to participate in the 340B Program. Each Plaintiff has sought to unilaterally effectuate 340B price reductions through rebates rather than upfront discounts. The Agency has advised Plaintiffs not to implement rebates because the Secretary has not "provided" for rebates as a mechanism to effectuate price reductions for the covered entities to which Plaintiffs sell their products.

A. Eli Lilly and Co.

Lilly contacted the Agency on August 30, 2024, requesting a meeting to discuss implementing a "cash replenishment" system for 340B sales. AR 257. Lilly proposed that the transactions would be facilitated through a data exchange platform owned and operated by Kalderos. AR 257-58. The following week, on September 4, 2024, representatives from Lilly and Kalderos met with the Agency to discuss the proposal. AR 260. Five days later, Lilly followed up with a letter explaining why Lilly intended to implement a cash rebate model. *Id.* Lilly included an addendum to the letter that responds to the questions HRSA had during the meeting and provided a copy of the slides Lilly presented during the meeting. *Id.*

Under Lilly's proposal, all covered entities would purchase Lilly's products at the market price. AR 272. The covered entities would then submit a claim through Kalderos's platform, known as Truzo, for a cash rebate. *Id*. The rebate would equal the difference between the market price and the 340B ceiling price. *Id*. Lilly would make weekly payments for all approved rebate

claims. *Id*. Lilly informed the Agency that it intended to implement this proposal beginning November 1, 2024. AR 272.

On September 18, 2024, the Agency informed Lilly that "[t]o date, the Secretary has not provided for such rebate model as proposed by Lilly." AR 292. The Agency cautioned Lilly that "implementing such a proposal at this time would be inconsistent with the statutory requirements for the 340B Program, which require the approval of a rebate model such as Lilly has proposed." *Id.* The Agency also posed a series of questions to Lilly to better understand the planned rebate model. *Id.* Five days later, Lilly responded that they were "disappointed" that the Agency "reject[ed] Lilly's cash replenishment model" and by the Agency's determination that implementing a rebate model without affirmative approval would violate the 340B statute. AR 295. Lilly also provided answers to the Agency's questions and asked the Agency to let them know by October 7, 2024, whether the information provided in the letter would cause the Agency to change its decision. AR 301. On November 14, 2024, less than two months after the Agency had informed Lilly that it could not approve the rebate model "to date," AR 292, Lilly filed suit. See generally, Lilly Compl.

B. Bristol Myers Squibb Company

On October 8, 2024, a representative from Bristol Myers contacted the Agency claiming that Bristol Myers had "developed some fresh ideas that we believe could significantly enhance transparency in the 340B program[,]" and requested a meeting to discuss those ideas. AR 307. The Agency met with Bristol Myers representatives on October 22, 2024, and two days later, Bristol Myers followed up with a "white paper" explaining its proposed rebate model and attached the slide deck that they presented to the Agency at the meeting. AR 316. Bristol Myers requested that the Agency "acknowledge in writing by November 4, 2024, [Bristol Myers's] right to implement [their] intended 340B rebate model." AR 317.

Under the Bristol Myers proposal, all covered entities would purchase covered drugs at market prices. AR 330. After dispensing a drug to a 340B eligible patient, the covered entity would then submit data to a platform operated by the Berkeley Research Group, known as the Beacon Platform, demonstrating that the dispensed unit was eligible for the 340B price. *Id.* Within ten days, Bristol Myers would send the covered entity a rebate for the difference between the market price of the drug and the 340B discount price. *Id.* Initially, Bristol Myers would use the rebate system exclusively for all covered entity purchases of Eliquis. *Id.* Bristol Myers chose Eliquis because it is the only Bristol Myers product that the Secretary of Health and Human Services has designated for maximum fair price negotiation under Medicare Drug Price Negotiation Program. *Id.* Bristol Myers claimed that the cash rebate model would guard against covered entities obtaining both the Maximum Fair Price and a 340B discount on the same unit of Eliquis. *Id.* Bristol Myers proposed implementing the rebate model in early 2025. AR 329

On November 4, 2024, the Agency informed Bristol Myers that "[t]o date, the Secretary has provided for such a rebate model" like the one that Bristol Myers had proposed. AR 342. The Agency cautioned Bristol Myers that "implementing such a proposal at this time would be inconsistent with the statutory requirements for the 340B Program, which require the approval of a rebate model such as [Bristol Myers] has proposed." *Id.* The Agency also posed a series of questions to Bristol Myers about how the planned rebate model would operate. *Id.* The following week, Bristol Myers responded with "information requested by the [Agency]" and a letter explaining that Bristol Myers did not believe Secretarial approval was required for Bristol Myers to implement a rebate model. AR 345. On November 21, 2024, the Agency advised Bristol Myers by email that the Agency had "recently received inquiries from manufacturers related to different proposed rebate models for the 340B Program," and that the Agency was "in the process of

reviewing these varied inquiries, which would significantly and unilaterally alter the administration of the Program." *Id.* The Agency reiterated that implementing the rebate proposal without Secretarial approval "would violate Section 340B(a)(1) of the Public Health Service Act." *Id.* The Agency followed up with a formal letter on December 13, 2024, which conveyed that, "to date, the Secretary has neither approved or disapproved [Bristol Myers's] rebate model." AR 347. But by the time the Agency sent Bristol Myers this letter, Bristol Myers had already filed suit. *See generally*, Bristol Myers Compl.

C. Novartis Pharmaceuticals Corporation

Novartis contacted the Agency on December 17, 2024, advising the Agency that Novartis intended to implement a rebate model beginning June 1, 2025. AR 427. Novartis requested that the Agency "acknowledge in writing by January 7, 2025, Novartis's right to implement the contemplated 340B rebate model," and that absent acknowledgment, Novartis would assume that the Agency had disapproved the model. *Id.* Novartis proposed implementing the model for all products that are eligible for 340B pricing but limiting it, at least initially, to disproportionate share hospitals. AR 435. Like Bristol Myers, Novartis proposed using the Beacon Platform to collect data from the covered entities. *Id.* Disproportionate share hospitals would purchase Novartis products at the market price and subsequently submit data through the Beacon platform, to validate whether a given purchase was eligible for 340B pricing. *Id.* Novartis would issue the covered entity a rebate for the difference between the market price of the package and the 340B price after the covered entity dispenses enough eligible units of a given drug to equal a "package size" of the drug. *Id.*

In a letter dated January 14, 2025, the Agency informed Novartis that the Secretary had not "provided" for a rebate model and had "neither approved nor disapproved" the rebate model that Novartis proposed. AR 439. The Agency cautioned Novartis that implementing the proposed

rebate model "at this time would be inconsistent with the statutory requirements for the 340B Program, which requires the approval of Novartis's proposed rebate model." *Id.* Just one day later, Novartis filed suit. *See generally*, Novartis Compl.

III. Procedural Background.

On February 6, 2025, the Court issued a Minute Order observing that each of the three above-captioned cases "involve common questions of law and fact," and that 340B Health, UMass Memorial Medical Center, and Genesis Healthcare System have moved to intervene in each case. See Min. Order Feb. 6, 2025. The Court ordered the parties in each case to "notify the Court of their respective positions on consolidating these actions under Rule 42[.]" *Id.* Although the parties proposed different ways in which these cases could be consolidated, the Court ultimately accepted the parties' proposal on "joint briefing and hearing schedule" on dispositive motions and motions to intervene. Min. Order, Feb. 24, 2025.

LEGAL STANDARDS

The Administrative Procedure Act ("APA") provides that final agency action can be set aside only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "unsupported by substantial evidence in a case . . . reviewed on the record of an agency hearing provided by statute." *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 413–15 (1971); see also 5 U.S.C. § 706(2)(A), (E). Courts review de novo issues of statutory interpretation and "must exercise their independent judgment in deciding whether an agency has acted within its statutory authority, as the APA requires." *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2273 (2024)*; see also U.S. Sugar Corp. v. EPA*, 113 F.4th 984, 997 (D.C. Cir. 2024). "Courts must 'interpret statutes, no matter the context, based on the traditional tools of statutory construction.'" *Pac. Gas & Elec. Co. v. Fed. Energy Regul. Comm'n*, 113 F.4th 943, 947 (D.C. Cir. 2024) (quoting Loper Bright, 144 S. Ct. at 2268). "Therefore, when 'addressing a question of statutory

interpretation, we begin with the text.'" *Id.* at 948 (*quoting City of Clarksville v. Fed. Energy Regul. Comm'n*, 888 F.3d 477, 482 (D.C. Cir. 2018)).

Agency action is arbitrary and capricious if based on an unlawful interpretation of statute or regulations, or if it is "not rational and based on consideration of the relevant factors." *FCC v. Nat'l Citizens Comm. for Broad.*, 436 U.S. 775, 803 (1978). The Secretary's factual findings can be set aside only if they are "unsupported by substantial evidence" in the administrative record. 5 U.S.C. § 706(2)(A); see also Overton Park, 401 U.S. at 413–15. The substantial evidence standard is satisfied if the final agency decision is supported by "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Consolo v. Fed. Mar. Comm'n*, 383 U.S. 607, 619–20 (1966) (internal quotation marks and citation omitted); *see also City of South Bend v. Surface Transp. Bd.*, 566 F.3d 1166, 1170 (D.C. Cir. 2009). Substantial evidence is "something less than the weight of the evidence, and the possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence." *Consolo*, 383 U.S. at 620 (citations omitted); *SEC v. Fed. Lab. Rels. Auth.*, 568 F.3d 990, 995 (D.C. Cir. 2009).

ARGUMENT

I. The Agency's Decision to Require Agency Approval Before Instituting a Rebate Model is Consistent With the 340B Statute.

When interpreting a statute, the court starts with the text of the statute. *Van Buren v. United States*, 593 U.S. 374, 381 (2021) ("We start where we always do: with the text of the statute.") The text supports the Agency's position that Secretarial approval is required before a manufacturer initiates any rebate regime. In relevant part, the statute states,

> The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs . . . purchased by a covered entity on or after the first day

> of the first month that begins after the date of the enactment of this section, does not exceed [the ceiling price].

42 U.S.C. § 256b(a)(1). The statute instructs the Secretary to "enter into an agreement with each manufacturer of covered outpatient drugs . . ." *Id.* The "agreement" is the Pharmaceutical Pricing Agreement. AR 036-47. That agreement is "a uniform agreement[] that recite[s] the responsibilities § 340B imposes, respectively, on drug manufacturers and the Secretary." *Astra USA*, 563 U.S. at 113. Under the pricing agreement, "the amount required to be paid' "to the manufacturer for covered outpatient drugs" "purchased by a covered entity" "does not exceed" the ceiling price. 42 U.S.C. § 256b(a)(1). Put simply, the manufacturer enters into an agreement with the Secretary where the manufacturer agrees not to charge covered entities more than the ceiling price for covered outpatient drugs. *Id.*

Crucially, the amount that the manufacturer may charge a covered entity must take "into account any rebate or discount, as provided by the Secretary." *Id.* "Provided" is the past tense of "provide," a common definition of which is "to have as a condition" or to "stipulate." Provide, Merriam-Webster.com, https://www.merriam-webster.com/dictionary/provide. Thus, the Secretary may "have as a condition" or "stipulate" that the price to be paid will include a rebate or discount. 42 U.S.C. § 256b(a)(1); Provide, Merriam-Webster.com. In other words, in instances where the Secretary is providing "any rebate or discount," the Secretary has discretion to determine whether the manufacturer can sell the drugs to the covered entity at the ceiling price by way of an upfront discount or a rebate.

To be sure, Congress did not mandate that the manufacturers effectuate the price reductions though upfront discounts, but Congress also did not contemplate a regime where a manufacturer would choose whether to offer discounts or rebates without approval of the Secretary. Such an interpretation would render the phrase "as provided by the Secretary" inoperative and superfluous

Under Plaintiff's reading, "as provided by the Secretary" would become "as provided by the manufacturer," or would be deleted altogether. Under the "canon against surplusage," a Court should strive to give effect "'to all [statutory] provisions, so that no part will be inoperative or superfluous, void or insignificant.'" *Cares Cmty. Health v. Health and Human Serv*., 944 F.3d 950, 960-61 (D.C. Cir. 2019) *(quoting, Rubin v. Islamic Republic of Iran*, 583 U.S. 202, 213 (2018)). Because Defendants have offered "[an] interpretation that gives effect to every clause and word of the statute," *Marx v. Gen. Revenue Corp*., 568 U.S. 371, 385 (2013), the Court should find that it is the correct reading of the statute.

Plaintiffs argue that any restriction on the selection of a rebate or discount must be contained within the Pharmaceutical Pricing Agreement. Lilly Mot. at 36-37; Bristol Myers Mot. at 34; Novartis Mot at 32. Plaintiffs are incorrect. The pricing agreement is not a regulatory vehicle or bargained for contract, rather the pricing agreement is a uniform agreement that "recite[s] the responsibilities § 340B imposes, respectively, on drug manufacturers and the Secretary." *Astra USA Inc*., 563 U.S. at 113. As manufacturers, Plaintiffs are required to sign the pricing agreement to participate in the 340B Program. 58 Fed. Reg. 27,289, 27,291 (May 7, 1993); *see also, Astra USA Inc*., 563 U.S. at 113 (pricing agreements "are not transactional, bargained-for contracts"). Because the Agency's authority to determine whether price reductions are offered through upfront discounts or rebates is found within the text of the statute, and the pricing agreement merely recites the respective responsibilities of the Secretary and the manufacturer specified in the statute, an amendment to the pricing agreement is not required for the Agency to deny (or approve) Plaintiffs' requests to implement unapproved rebate models. AR 292. For similar reasons, the heading "requirements for agreement with Secretary" does not undermine the Agency's interpretation of the statute. 42 U.S.C. § 256b(a). Because the pricing agreement "recite[s] the responsibilities §

340B imposes, respectively, on drug manufacturers and the Secretary," *Astra USA Inc.*, 563 U.S. at 113, the heading merely confirms what the pricing agreement is.

Additionally, not only does the natural reading of the statute support the Agency's position that Secretarial approval is required before a manufacturer implements a rebate model, but also,"[w]hat legislative history there is reinforces the text." *Fed. Educ. Ass'n Stateside Region v. FLRA*, 104 F.4th 275, 284 (D.C. Cir. 2024). Specifically, the report from the House Energy and Commerce Committee explains that "Federal Medicaid matching funds would not be available for State spending on any of a manufacturer's covered outpatient prescription drugs unless the "manufacturer enters into, and complies with, an agreement with the Secretary" under which covered entities "would pay the same amount for a covered outpatient drug that Medicaid pays." H.R. Rep. No. 102-384, pt. 2, at 8 (1992). The price reductions "would be at least as great as those which Medicaid receives under the rebate program," and "would be implemented, at the discretion of the Secretary, either by a poin-of-purchase discount, a rebate, or other mechanism." *Id.* at 12. Notably, the report specifies that "the Secretary would have the discretion to determine the mechanism (rebate, point-of-purchase discount, or otherwise) for assuring this price reduction." *Id*. Although the legislation "does not specify whether 'covered entities' would receive these favorable prices through a point-of-purchase discount, through a manufacturer rebate, or through some other mechanism," Congress expected that the Secretary "will use the mechanism that is the most effective and most efficient from the standpoint of each type of 'covered entity.'" *Id.* at 16. Nowhere does the report suggest that the manufacturer can unilaterally decide whether to offer covered entities discounts or rebates. *Id.*

Accordingly, the Court should find that the Agency's decision to block Plaintiffs from implementing a rebate model without Secretarial approval is consistent with the text of the statute.

II. The Agency Decision to Prohibit Plaintiff from Instituting an Unapproved Rebate Model was Not Arbitrary and Capricious.

The Agency's decision to deny Plaintiffs' requests to implement an unapproved rebate model was not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *Tourus Records, Inc. v. Drug Enforcement Admin.*, 259 F.3d 731, 736 (D.C. Cir. 2001). Under the APA, an agency action may be arbitrary and capricious if the agency explained its decision in a way that runs counter to the evidence before the agency or is so implausible that it could not be ascribed to a difference in view or agency expertise. *Escobedo v. Green*, 602 F. Supp. 2d 244, 248 (D.D.C 2009) (citing *Motor Veh. Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). "As the Supreme Court has explained, 'the scope of review under the arbitrary and capricious standard is narrow and a court is not to substitute its judgment for that of the agency.'" *Id.* Although the court's review under the "arbitrary and capricious" standard is "searching and careful," it is also "narrow." *Marsh v. Or. Natural Res. Council*, 490 U.S. 360, 377-78 (1989); *see also Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). The ultimate question under this narrow standard of review is whether the agency's action was reasonable. *Fed. Commc'n Comm'n v. Fox Television Stations*, 556 U.S. 502, 514-15 (2009).

Here, the Agency acted reasonably when it declined to allow manufacturers to unilaterally implement cash rebate models. First the Agency's decision was consistent with longstanding exercise of its authority to "provide" for rebates or discounts. Second, the Agency considered Plaintiffs' policy arguments for why cash rebates were an optimal method to effectuate 340B price reductions; however, because Plaintiffs' proposed rebate models would disrupt how the 340B Program has operated for more than thirty years, the Agency appropriately declined to disturb the *status quo* for now.

A. The Agency's Decision is Consistent with Its Statutory Authority and Past Practices

To date, the Secretary has not "provided" for the rebates that Plaintiffs proposed. AR 292 (quoting 42 U.S.C. § 256b(a)(1)). Because the Secretary had not "provided' that rebates should be 'tak[en] into account" when calculating "the amount required to be paid," if Plaintiffs began requiring covered entities to purchase 340B eligible drugs at the market rate and then seek rebates from Plaintiffs after the covered entity dispenses the drug to an eligible patient, then Plaintiffs would be violating 42 U.S.C. § 256b(a)(1). AR 292, 342. 439. Moreover, although the Agency has never said that rebates would not be approved under any circumstances, the Agency has long envisioned upfront discounts as the preferred price reduction mechanism, because "[c]overed entities generally preferred a discount system, because they could negotiate lower prices and needed less initial outlay of drug purchasing money." 62 Fed. Reg. at 45,824.

The statute does not prohibit rebate models in the abstract, but it does prohibit instituting rebate models unilaterally. 42 U.S.C. § 256b(a)(1). In communications with the Agency, Plaintiffs maintained that they could implement the rebate model without permission from the Agency. AR 295, 321, 428. In response, the Agency advised Plaintiffs that that the Secretary had not "provided for" the rebates that Plaintiffs proposed "to date." AR 292, 342, 439. The Agency never said never.

Plaintiffs argue that the Agency's treatment of their proposed rebate models is arbitrary and capricious because the Agency permits manufacturers to effectuate price reductions through rebates for AIDS Drug Assistance Programs but not for other types of covered entities. Lilly Mot. at 42; Bristol Myers Mot. at 37; Novartis Mot. at 37. These arguments lack merit. In recognizing rebates for AIDS Drug Assistance Programs, the Agency reiterated the Secretary has the authority to determine the mechanism that is "most effective and most efficient." 62 Fed. Reg. 45,823,

45,824 (Aug. 29, 1997) (citing H.R. Rep. No. 102-384, pt. 2, at 16). The appropriate mechanism will vary depending on the needs of the covered entity. *Id.* "A mechanism that is appropriate to one type of 'covered entity,' such as community health centers, may not be appropriate to another type, such as State AIDS drug assistance programs." 62 Fed. Reg. at 45,824. The Agency determined that rebates were an appropriate mechanism to effectuate price reductions for AIDS Drug Assistance Programs because many AIDS Drug Assistance Programs used purchasing systems that made it difficult for them to access reduced cost drugs through direct discounts. *Id.*; *see also* 63 Fed. Reg. 35,239, 35,240 (Jun. 29, 1998). Plaintiffs here have not asserted that the covered entities that they sell their products to have similar issues with their purchasing systems. *See, generally*, Lilly Mot.; Novartis Mot. This makes the cash rebate models that Plaintiffs seek to impose materially different from the rebate models that the Agency permitted for AIDS Drug Assistance Programs.

Plaintiffs argue that in allowing rebates for AIDS Drug Assistance Programs, the Agency "recognized" a system that was already in use rather than approve a new system. Bristol Myers Mot at 38-39. Even if this is accurate, the AIDS Drug Assistance Program rebates are in existence because the Agency "recognized" them after a notice and comment process, a process that has not occurred here. 63 Fed. Reg. at 35,241-42. The Agency sought "comments on the proposal of a rebate option for State AIDS Drug Assistance Programs." 62 Fed. Reg. at 45,824. Both the manufacturers and the AIDS Drug Assistance Programs submitted comments to the Agency supporting the rebate option, *id*. at 35,239, and the Agency never disclaimed its authority to block the rebate system if it did not conclude that rebates were an appropriate mechanism to effectuate discounts for AIDS Drug Assistance Programs. 62 Fed. Reg. at 45,824.

Notably, one commenter wrote that their "(favorable) response to the recognition of a rebate program for the [AIDS Drug Assistance Programs] would be different if [the Agency] proposed a rebate program for all covered entities." 63 Fed. Reg. 35,241-42. The commenter "urge[ed] that the rebate mechanism be an option only for meeting the unique needs of the [AIDS Drug Assistance Programs] and that [the Agency] not consider any further expansion to other categories of entities. *Id.* at 35,241. The Agency responded, "[a]t this time, we agree. This notice only recognizes a rebate option for [AIDS Drug Assistance Programs] that receive assistance under Title XXVI of the Public Health Service Act." *Id.* at 35,242. Since then, the Agency has not recognized a rebate option for any other type of covered entity, or even solicited public comments on a proposal to expand the rebate model to other covered entities.

The Agency considered the manufacturers' contention that the rebate models should be treated like the product replenishment models that the Agency has permitted but identified meaningful distinctions between the two models. AR 203. Plaintiffs' characterization of the product replenishment model as a rebate system is, at best, misleading. *See e.g.*, Novartis Mot at 39. Under the product replenishment model, a covered entity makes an initial bulk purchase of drugs at the wholesale cost. AR 203. The covered entity then dispenses those drugs to both 340B-eligible and non-eligible patients. AR 060. A third-party administrator or other entity evaluates the claims data to determine how many units of a drug were dispensed to a 340B eligible patient. *Id*. Once the covered entity has dispensed enough 340B eligible units of a particular drug to equal that drug's "package size," the covered entity purchases a package of those drugs from the manufacturer at the 340B discount price. *Id.* In other words, the covered entity "replenishes" its stock of a particular drug at the 340B discount price. *Id*.

The Agency identified key distinctions between the two models. AR 203. Most glaringly, under the product replenishment model, the covered entity only pays the wholesale price for its initial purchase and then makes its subsequent, i.e. "replenishment purchases" at the 340B price. *Id*. Thus, under the replenishment model, the manufacturer provides an upfront discount for every purchase except for the initial purchase. *Id*. But under Plaintiffs' proposed rebate models, covered entities would need to make every purchase at the wholesale price and then wait for the manufacturer to issue a rebate. *Id.* In other words, under the product replenishment model, the covered entities receive upfront discounts for all purchases except for the initial purchase, but under the cash rebate models, upfront discounts would be nonexistent. *Id.*

Additionally, the covered entities voluntarily chose to receive discounts through the product replenishment process. AR 203. In contrast, Plaintiffs seek to impose their rebate models on the covered entities regardless of whether the covered entities believe that cash rebates are the optimal mechanism to receive 340B discounts. See AR 272, 320, 428. Plaintiffs dismiss this argument as evidence that the Agency is "playing favorites" between the manufacturers and the covered entities. See e.g., Novartis Mot. at 42. But Plaintiffs ignore key differences between the Agency's relationships with manufacturers and covered entities embodied within the statute. The statute regulates the price that covered entities pay for drugs dispensed to eligible patients. 42 U.S.C. § 256b(a)(1). The statute does not allow manufacturers to unilaterally charge covered entities wholesale acquisition costs of drugs even if the manufacturer reimburses the covered entity at a later date. *Id.* Moreover, the covered entities and the manufacturers are not similarly situated because, unlike the covered entities, the manufacturers enter into pricing agreements with the Agency. AR 036-47. As explained above, the pricing agreements "recite the responsibilities § 340B imposes, respectively, on drug manufacturers and the Secretary of HHS." *Astra USA Inc.*,

563 U.S. at 113. Thus, the Agency can ensure that the manufacturer conducts itself in accordance with the pricing agreement. No similar agreement exists between the Agency and any covered entity. Congress empowered the Agency to ensure covered entities comply with their obligations under the program through different means, specifically, audits. 42 U.S.C. § 256b(a)(5)(A).

Tellingly, if Plaintiffs were correct that the two models are "functionally indistinguishable," Bristol Myers Mot. at 43, Plaintiffs would not be seeking the Court's intervention to allow them to replace the product replenishment model with a new mechanism to effectuate 340B pricing.

B. The Agency's Decision Preserves the 340B Program As It Has Operated for Over Thirty Years.

Plaintiffs advance a multitude of policy arguments extoling the benefits of their rebate models and argue that the Agency has not considered "all aspects of the problem." Lilly Mot. at 45. (quoting, *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43). But crucially, the Agency has "neither approved nor disapproved" Plaintiffs' proposed rebate models and Plaintiffs were aware of the Agency's position before filing suit. *See e.g.*, AR 347. Plaintiffs and other pharmaceutical manufacturers have presented policy arguments advocating for cash rebate models, but other stakeholders have advanced their own policy arguments urging the Agency to reject the rebate models. Trade associations representing covered entities including 340B Health, AR 568, America's Essential Hospitals, AR 572, and the American Hospital Association, AR 575-79, are concerned that covered entities, operating with limited cash on hand would have difficulty finding sufficient funds to pay market prices for drugs at every purchase. Similarly, a bi-partisan group of 189 members of the House of Representatives urged the Secretary to reject Plaintiffs' proposed rebate models. AR 538-50. These Representatives argued that "under the rebate model, impacted safety-net hospitals would be required to purchase drugs at the high sticker price, instead of the

substantially lower 340B discount, and wait for an undetermined period to receive the 340B discount as a rebate. This model would reduce resources available for providing comprehensive services to patients and communities, undermining the core purpose of 340B." AR 538.

Plaintiffs identify what they perceive to be flaws in the product replenishment model and argue that these flaws make it easier for covered entities to take duplicative discounts. See e.g. Novartis Mot. at 35. Covered entities are barred from obtaining a price reduction under both Medicaid and the 340B Program. 42 U.S.C. § 256b(a)(5)(A). If a manufacturer has "reasonable cause" to believe that a particular covered entity is taking duplicative discounts, then the manufacturer may audit "the records of the entity that directly pertain to the entity's compliance with" the prohibitions on diversion and duplicate discounts "with respect to drugs of the manufacturer," so long as the manufacturer "act[s] in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits." *Id.* To initiate an audit, the manufacturer must submit an audit workplan to the Agency and, if the Agency determines that reasonable cause for the audit exists, "the Department will not intervene" in the manufacturer's audit of the covered entity. 61 Fed. Reg. 65,406, 65,410 (Dec. 12, 1996).

After the audit is complete, the auditors prepare an audit report, which is provided to the Agency and the covered entity. *Id.* The covered entity has thirty days to provide its response to the report's findings and recommendations, including any planned actions to address the findings. *Id*. After an audit and review of the findings (if any), the Agency may take enforcement action against the covered entity, which can include ordering the covered entity to repay the manufacturer for the amount of price reduction that the covered entity received in connection with the diversion or duplicate discount, 42 U.S.C. § 256b(a)(5)(D), (d)(2)(B)(v)(I), or, in some circumstances, a covered entity's removal from the 340B Program. *Id.* § 256b(d)(2)(B)(v)(II).

Plaintiffs argue that the product replenishment model makes it impossible to establish reasonable cause. *See e.g.*, Novartis Mot. at 35, 54. This argument lacks merit. A manufacturer can establish reasonable cause that a covered entity is taking duplicative discounts by showing "significant changes in quantities of specific drugs ordered by a covered entity and complaints from patients/other manufacturers about activities of a covered entity." 61 Fed. Reg. 65,406. Even under the product replenishment model, a manufacturer can track which covered entities are purchasing their drugs and the quantities of those purchases. If Plaintiffs have reasonable cause to believe that a covered entity is taking duplicative discounts, then Plaintiffs can present an audit workplan to the Agency and audit that covered entity's use of the program. 42 U.S.C. § 256b(a)(5)(A). Prior to 2024, there were thirty instances where the Agency received an audit workplan from a manufacturer and allowed the manufacturer to conduct the audit. Britton Decl. ¶ 15 (citing *U. of Wash. Med. Ctr. v. Becerra*, Civ. A. No. 24-2998 (RC) (ECF No. 22-1)). Because Plaintiffs can audit covered entities to ensure compliance with the terms of the program, Plaintiffs do not need to unilaterally impose cash rebates on the manufacturers to ensure the program's integrity.

Except for AIDS Drug Assistance programs, 340B price reductions have been effectuated through upfront discounts for the thirty-three years that the program has operated. 63 Fed. Reg. 35,241-42. For this reason, widespread adoption of rebate models would cause unprecedented disruption to the program. See e.g., 565-69. Given the potential disruption, the Agency is justified in conducting a searching inquiry and taking a measured approach to these rebate requests. Lilly, Bristol Myers, and Novartis first contacted the Agency on August 30, 2024, October 8, 2024, and December 17, 2024, respectively. AR 207, 307, 457. Lilly and Bristol Myers filed suit roughly two months after raising the issue with the Agency, and Novartis waited just twenty-seven days.

As an added wrinkle, Plaintiffs' communications with the Agency and subsequent lawsuits coincided with a transition of Administration. The Agency's obligation to consider "all aspects of the problem," includes considering not just the manufacturers' preferences and bottom line, but also how the changes would affect the operations of covered entities and the wellbeing of patients who rely on 340B drugs. *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43. Plaintiffs have not allowed the Agency to evaluate these issues to reach a final decision as to whether the proposed rebate models are consistent with the 340B statute.

In theory, as was done in 1998 when the Agency finalized guidance to permit rebates for AIDS Drug Assistance Programs, Plaintiffs and the other manufacturers could have collaborated with the Agency to develop a price reduction mechanism that addressed all stakeholders' concerns. Instead, Plaintiffs rushed to Court to seek an order allowing them to unilaterally impose rebate models on covered entities. As discussed, such an order would not only negatively impact covered entities, but it would also upend the 340B Program as it has operated for thirty-three years.

C. Plaintiffs' Concerns About the Relationship Between the 340B Program and the Medicare Negotiation Program are Premature.

Relatedly, Plaintiffs' claim that the Agency's decision not to allow them to immediately implement a cash rebate model makes it difficult for them to comply with the Inflation Reduction Act. Bristol Myers Mot. at 47; Novartis Mot. at 43-44. As previously stated, the Agency has neither approved nor disapproved the proposed rebate models. Therefore, it would be premature to examine the Agency's review of the rebate model in relation to the Inflation Reduction Act.

For context, the Inflation Reduction Act requires the Secretary of Health and Human Services, through the Centers for Medicare and Medicaid Services ("CMS"), to establish the Medicare Drug Price Negotiation Program ("Negotiation Program"), through which he will negotiate the prices Medicare pays for certain covered drugs of manufacturers that agree to

participate in the Negotiation Program: those with the highest Medicare Parts B and D expenditures and no generic or biosimilar competitors and that have been marketable for at least seven years (for drugs) and 11 years (for biologics) (i.e., products that have long enjoyed little market competition). See 42 U.S.C. §§ 1320f *et seq.* To carry out the Negotiation Program, the statute requires CMS to first identify a set of negotiation-eligible drugs; the agency is then to select up to ten such drugs for negotiation for initial price applicability year 2026, up to fifteen for initial price applicability years 2027 and 2028, and up to twenty for initial price applicability year 2029 and subsequent years. *Id*. § 1320f-1(a)–(b). After selecting the drugs, CMS is directed to negotiate with the manufacturer of each selected drug to reach agreement on a "maximum fair price" for that drug. *Id.* § 1320f-3. If the manufacturer agrees to negotiate and the negotiations are successful, the manufacturer signs an addendum to its negotiation agreement establishing the maximum price at which the drug will be made available to Medicare beneficiaries. *Id.* § 1320f-3. For drugs with a negotiated price in effect that are dispensed, furnished, or administered to a maximum fair price eligible individual, manufacturers must offer covered entities the lesser of the maximum fair price or the 340B ceiling price. 42 U.S.C. § 1320f-2(d). For the purposes of the Negotiation Program, each of the Plaintiffs is connected in some fashion to one of the ten drugs that CMS selected for negotiation for initial price applicability year 2026 (i.e., Eliquis with respect to Bristol Meyers, Jardiance with respect to Lilly, and Entresto with respect to Novartis). Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026 (Aug. 2023), available at: https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf (last visited, Mar. 4, 2025).

Even if the Court were inclined to examine the relationship between the Negotiation Program and the 340B Program, which would be premature given that the Agency has not rejected

the rebate models, Plaintiffs overstate the need to establish a 340B rebate model to meet their obligations under the Negotiation Program, as applicable.[1] The Negotiation Program and the 340B Program are separate programs, created by separate statutes and administered by separate agencies. CMS, not HRSA, is responsible for administering the Negotiation Program. 88 Fed. Reg. 1,387 (Jan. 10, 2023). Plaintiffs argue that cash rebates are "the only feasible means" to prevent duplication of Negotiation Program discounts and 340B discounts. Bristol Meyers Mot at 47. Specifically, Plaintiffs argue that under a 340B product replenishment model, it is impossible to avoid duplicate discounts because manufacturers only have 14 days to pay refunds to effectuate the maximum fair price under the Negotiation Program, if applicable, and a covered entity will often not have identified drugs as 340B eligible until much later. *Id.* But CMS already fully addressed and rejected this position in final agency guidance implementing the Negotiation Program. In the relevant guidance, CMS explained that a credit/debit leger system will be available to accrue credits and debits for Negotiation Program claims that are later identified as 340B eligible so that nonduplication can occur after the fourteen-day prompt payment period. CMS, Medicare Drug Price Negotiation Program: Final Guidance, at 56 (Oct. 2, 2024), https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf (last visited Mar. 11, 2025).

[1] Likewise, Lilly's claim that a rebate model is necessary for it to comply with the IRA's Part D inflation-rebate program does not alter this conclusion. Indeed, Lilly's feasibility arguments in this context are even weaker than for the Negotiation Program. Since there is a lag time between the sale of a 340B drug and the issuance of a rebate report for an applicable period, and 340B drugs will not be excluded from the rebate calculation until beginning January 1, 2026, the earliest possible impact on Lilly would be roughly June 2027. See 42 C.F.R. §§ 428.203(b)(2); 428.401(c). In light of this, and the fact that the Agency has not rejected the rebate models, Lilly's concern that it will be unable to comply with the IRA's Part D requirements unless it is allowed to proceed with a rebate model now is premature.

Plaintiffs also argue that they do not have access to the information necessary to establish that a claim is 340B eligible. Novartis Mot. At 34. CMS has likewise addressed that issue by encouraging drug manufacturers to work with 340B covered entities and their third-party claims administrators to obtain the necessary information. Negotiation Program Guidance at 232. Moreover, pursuant to recent D.C. Circuit precedent, Plaintiffs maintain that they already have the right to attach reasonable conditions to 340B transactions "including data-reporting conditions." Novartis Mot at 6. Manufacturers' alleged lack of data regarding 340B transactions to make deduplication efforts work outside of a rebate model is entirely inconsistent with their asserted right to impose data-reporting conditions on 340B covered entities. Simply because manufacturers might prefer a 340B rebate model, does not give them the authority to supplant the Secretary's authority to approve a rebate model for 340B purposes or rush the Secretary's decision on the matter. Indeed, the CMS guidance reiterated the manufacturer's "continued responsibility to comply with statutory obligations pursuant to section 340B(a)(1) of the PHS Act, including the obligation to offer the 340B ceiling price to eligible entities," CMS Medicare Drug Price Negotiation, at 56 *supra,* and requires that the manufacturers' nonduplication plans remain "consistent with 340B statutory requirements." *Id.* at 58,

Finally, it is worth noting that Novartis proposed implementing a cash rebate system for all 340B eligible sales to disproportionate share hospitals. AR 439. Novartis has not limited its cash rebates to Entresto, the only Novartis drug that has been selected for the Negociation Program. *Id., see also,* Medicare Drug Price Negotiation Program: Selected Drugs for 2026, supra. Thus, Novartis's representation that it has chosen to implement cash rebates to guard against duplication of 340B and Negation Program discounts, Novartis Mot. at 45, should be viewed with skepticism.

Under APA review, the question for this Court is whether the agency adequately explained its decision or if the decision "may be reasonably discerned." *Bowman Transp., Inc. v. Ak.-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974); *see also Xcel Energy Servs. Inc. v. FERC*, 41 F.4th 548, 557 (D.C. Cir. 2022) ("We will uphold a decision of less-than-ideal clarity if the agency's path may reasonably be discerned."); *see also CSL Plasma Inc. v. Customs & Border Prot.*, 628 F. Supp. 3d 243, 261 (D.D.C. 2022) ("[A] brief explanation is not arbitrary and capricious just because of its brevity."). Here, the Agency considered Plaintiffs' reasons for why Plaintiffs should be permitted to implement the rebate model, found those reasons wanting, "explained why Plaintiffs need Secretarial approval before implementing their proposed rebate models.. AR 202-04. In other words, the Agency "considered all aspects of the problem" and "cataloged its concerns," and thus the Agency's decision was neither arbitrary nor capricious. *Am. Farm Bureau Fed'n v. EPA,* 559 F.3d 512, 527 (D.C. Cir. 2009).

III. Plaintiffs' Due Process Claims Lack Merit.

Finally, separate from their APA claims, Bristol Myers, Compl. ¶¶ 105-107 and Novartis, Compl. ¶¶ 133-136, brought claims for violation of substantive due process, and Novartis brought claims for violation of procedural due process, both under the Fifth Amendment. Novartis Compl. ¶¶ 137-45. Courts have rejected such artful pleading efforts where the constitutional analysis is identical to the APA analysis. *See Fares v. Smith*, 249 F. Supp. 3d 115, 120 (D.D.C. 2017), *aff'd*, 901 F.3d 315 (D.C. Cir. 2018) *see also Hegab v. Long*, 716 F.3d 790, 797 (4th Cir. 2013) ("Hegab's constitutional claims are in substance merely creative recharacterizations of his allegation that the [agency] made the wrong decision and that its decision was irrational and unsupported by the evidence."). Courts have also frowned upon attempts by plaintiffs to use constitutional claims to avoid the strictures Congress imposed on APA litigation. *See, e.g., Viet. Veterans of Am. v. Shinseki* 599 F.3d 654 (D.C. Cir. 2010) (refusing to allow plaintiffs to pursue

due process claims in district court when, under the APA, the plaintiffs' identical unreasonable delay claims under Section 706(2) of the APA was barred due to an adequate alternative remedy); *Chiayu Chang v. U.S. Citizenship & Immigr. Servs.*, 254 F. Supp. 3d 160 (D.D.C. 2017) (refusing to allow plaintiffs to conduct discovery in support of a constitutional claim where discovery was not permitted under nearly identical APA claims).

Bristol Myers and Novartis's due process claims are based on the Agency's refusal to allow them to unilaterally implement a cash rebate model to effectuate 340B price reductions, which makes their arguments in support of their due process claims substantially similar to their arguments under the APA. Bristol Myers Mot. at 51-53. Thus, the Court should dismiss Plaintiffs' constitutional claims and confine its analysis to the APA. But even if the Court were inclined to examine Plaintiffs' substantive and procedural due process claims, as explained below, the claims fail on the merits.

A. Bristol Myers and Novartis's Substantive Due Process Claims Fail.

To state a substantive due process claim against a federal actor, a plaintiff must identify a right "guaranteed by the first eight Amendments," "deeply rooted in our history and tradition," or "essential to our Nation's scheme of ordered liberty," based on "a careful analysis of the history of the right at issue." *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 237-38 (2022). Plaintiffs argue that they have a constitutionally protected property interest in the covered outpatient drugs subject to the 340B Program and the Inflation Reduction Act, and that the Inflation Reduction Act guarantees them the right to nonduplication of the maximum fair price and the 340B price concessions. Bristol Myers Mot at 52; Novartis Mot. at 45-46. But the Agency's decision not to allow Plaintiffs to implement cash rebate models "at this time" does not force Plaintiffs to acquiesce to duplicative discounts. AR 439.

Although substantive due process "normally imposes only very slight burdens on the government to justify its actions, it imposes none at all in the absence of a liberty or property interest." *George Wash. Univ. v. District of Columbia*, 318 F.3d 203, 206 (D.C. Cir. 2003). Property interests do not arise under the Constitution, but "are created and their dimensions are defined by existing rules or understandings that stem from an independent source such as state law." *Town of Castle Rock v. Gonzales*, 545 U.S. 748, 756 (2005) (internal quotation marks omitted). "To have a property interest in a benefit, a person clearly must have more than an abstract need or desire for it," or "a unilateral expectation of it." *Bd. of Regents of State Colleges v. Roth*, 408 U.S. 564, 577 (1972). "He must, instead, have a legitimate claim of entitlement to it." *Id.*

Plaintiffs do not have a liberty or property interest in being able to effectuate 340B price reductions through cash rebates. As explained in Part I above, the 340B statute vests the Agency with discretion as to whether it is going to "provide" for cash rebates as a method to effectuate 340B discounts. 42 U.S.C. § 256b(a)(1). For more than thirty years, the 340B Program primarily operated through direct discounts. 62 Fed. Reg. at 45,824. Additionally, nothing in the applicable portion of the Inflation Reduction Act gives Plaintiffs the right to unilaterally impose cash rebate models on covered entities. The statute states that the manufacturer,

> (1) shall not be required to provide access to the maximum fair price . . . , with respect to such selected drug and maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at a covered entity described in section 340B(a)(4) of the Public Health Service Act, to such covered entity if such selected drug is subject to an agreement described in section 340B(a)(1) of such Act and the ceiling price . . . is lower than the maximum fair price for such selected drug; and
>
> (2) shall be required to provide access to the maximum fair price to such covered entity with respect to maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at such entity at such ceiling price in a nonduplicated amount to the ceiling price if such maximum fair price is below the ceiling price for such selected drug.

42 U.S.C. § 1320f–2(d).

The statute requires the manufacturer to provide the drug to the covered entity at the lesser of the ceiling price or the maximum fair price and guarantees that the manufacturer does not need to provide both the ceiling price and the maximum fair price on the same unit of drug. *Id*. But the statute does not give manufacturers the right to ensure that they are not providing duplicative discounts by implementing a cash rebate model. *Id*. Although Plaintiffs may prefer to use cash rebates as a means to ensure compliance with this provision, Plaintiffs have alternative means, including manufacturer audits, 42 U.S.C. § 256b(a)(5)(A)

Even if Plaintiffs identified a property interest in the drugs that they sell as part of the 340B Program and the Negotiation Program, Plaintiffs have failed plausibly allege a substantive due process violation. "Once a property interest is found, . . . substantive due process constrains only egregious government misconduct." *George Wash. Univ.*, 318 F.3d at 209. A plaintiff must plausibly allege that the challenged action works a "grave unfairness," which requires a (1) "substantial infringement of [the] law prompted by personal or group animus" or (2) "deliberate flouting of the law that trammels significant personal or property rights." *Id.* (internal quotation marks omitted). For the same reasons that the Agency's decision not to allow Plaintiffs to unilaterally implement unapproved rebate models at this time is not arbitrary and capricious, it also does not cause "grave unfairness." *Id.* Plaintiffs are not claiming that the Agency is forcing them to provide duplicative discounts under both the 340B Program and the Negotiation Program, rather, they simply claim that the Agency is not allowing them to implement a cash rebate model that Plaintiffs believe is the best method for them to prevent covered entities from obtaining duplicative discounts. *See e.g.*, Bristol Myers Mot. at 53. Whether Plaintiffs proposed cash rebate models were the optimal method to ensure that covered entities do not take duplicative discounts

is immaterial to whether the Agency's choice was rational, which is all that the Constitution requires. *See Nguyen v. INS*, 533 U.S. 53, 78 (2001) ("The fact that other means are better suited to the achievement of governmental ends therefore is of no moment under rational basis review.").

Importantly, Plaintiffs are not required to participate in the 340B Program. Although Plaintiffs' decision to cease participation in the 340B Program would result in Plaintiffs no longer receiving reimbursements for their products under Medicare and Medicaid, 42 U.S.C. § 1396r-8(a)(1); 42 U.S.C. § 256b(a), if Plaintiffs decide that complying with the conditions of the program are too onerous, then they can cease to sell their products to 340B and Medicare patients and instead sell only to patients with private insurance. *See e.g., Livingston Care Center, Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991) ("Providers of health care who choose to participate in the federally sponsored program for the aged and disabled do so with no guarantee of solvency...those who opt to participate in Medicare are not assured of revenues"). Plaintiffs argue that losing the ability to participate in Medicare would be financially devastating. See e.g. Novartis Mot. at 38-39. But because "there is no constitutional right (or requirement) to engage in business with the government, the consequences of that participation cannot be considered a constitutional violation." *Dayton Area Chamber of Commerce v. Becerra*, 696 F. Supp. 3d 440, 467 (S.D. Ohio 2024) (*citing, Livingston Care Center,* 934 F.2d at 720)).

Accordingly, the Court should dismiss Bristol Myers and Novartis's substantive due process claims.

B. Novartis's Procedural Due Process Argument Lacks Merit.

Novartis separately argues that the Agency's decision to prevent them from unilaterally implementing a cash rebate system amounts to a violation of their procedural due process rights. Novartis Mot. at 51. This argument also lacks merit. To determine whether a plaintiff has stated a valid procedural due process claim, courts first ask "whether there exists a liberty or property

interest of which a person has been deprived," and if so, "whether the procedures followed were constitutionally sufficient." *Del. Riverkeeper Network v. Fed. Energy Regul. Comm'n*, 895 F.3d 102, 107 (D.C. Cir. 2018) (*quoting Swarthout v. Cooke*, 562 U.S. 216, 219 (2011)).

Novartis argues that it has a property interest in its patented drug products and the revenue it derives from them and it is deprived of that property interest when it is forced to sell its products for prices below the rates it could obtain in voluntary, arms-length transactions. Novartis Mot. at 51-51. But this argument is based on the false premise that Novartis is being "forced" to do anything. As just explained in Part A, above participation in Medicare and the 340B Program is voluntary and when an entity "voluntarily participates in a price-regulated program or activity, there is no legal compulsion to provide service and thus there can be no" deprivation of property. *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d. Cir. 1993) (collecting cases); *see also, Franklin Mem'l Hosp. v. Harvey*, 575 F.3d 121, 129 (1st Cir. 2009) ("Of course, where a property owner voluntarily participates in a regulated program, there can be no unconstitutional taking."). Hospitals, nursing homes, and other providers have, for decades, raised similar arguments against other limits on Medicare reimbursements—and courts have, for decades, rejected such claims. *See, e.g., Baker Cnty. Med. Servs., Inc. v. U.S. Att'y Gen*., 763 F.3d 1274, 1276, 1279– 80 (11th Cir. 2014) (collecting cases); *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993).

Second, Novartis argues that it is being deprived of a property interest because it is being forced to offer prices lower than those required by the 340B statute or the [Inflation Reduction Act]." Novartis Mot. at 52. But Novartis is not being forced to offer prices lower than those required under either statute. The Agency has simply declined, at this time, to allow Novartis to implement the cash rebate model, AR 435, that is Novartis's preferred method to monitor whether

covered entities are receiving discounts from the 340B Program and the Negotiation Program. AR 439.

Novartis is receiving all the process it is due. "The fundamental requirement of due process is the opportunity to be heard at a meaningful time and in a meaningful manner." *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976); see also, *Doe by Fein v. District of Columbia*, 93 F.3d 861, 868 (D.C. Cir. 1996) (a procedural due process claim "necessarily presents the question of what, if any, additional process is due."). Novartis contacted the Agency on December 17, 2024, requesting that the Agency "acknowledge in writing by January 7, 2025 Novartis's right to implement the contemplated 340B rebate model," and absent that acknowledgment, Novartis would assume that the Agency has disapproved the model. AR 427 The Agency advised Novartis, in a letter date January 14, 2025:

> To date, the Secretary has not provided for such a rebate model. The Secretary has neither approved or disapproved Novartis' rebate model. Therefore, implementing such a model at this time would be inconsistent with the statutory requirements for the 340B Program, which require the approval of Novartis's proposed rebate model.

AR 439. The correspondence included additional questions about Novartis's proposal. *Id.* Rather than answer the Agency's questions, Novartis filed suit the following day. *See generally*, Novartis Compl.

The Agency's January 14, 2025, letter demonstrates that the Agency was attempting to give Novartis a meaningful opportunity to be heard, but Novartis declined that opportunity. *Id.* Novartis's failure to avail itself of the available process is fatal to its procedural due process claim. *See Chavis v. Garrett*, 419 F. Supp. 3d 24, 38 (D.D.C. 2019)*; Badgett v. District of Columbia*, 925 F. Supp. 2d 23, 32 (D.D.C. 2013) ("However, where, as here, procedural safeguards exist to obviate prejudice from delay and a plaintiff fails to take advantage of those measures, no such

constitutional violation occurs."); *see also New York State National Organization for Women v. Pataki*, 261 F.3d 156, 168-69 (2d Cir. 2001);

Accordingly, because Novartis has not demonstrated a constitutionally protected property interest, or that it was "deprived of a meaningful opportunity to be heard," *Kelley v. District of Columbia*, 893 F. Supp. 2d 115, 124 (D.D.C. 2012), the Court should grant Defendant's summary judgment on Novartis's procedural due process claim.

CONCLUSION

For these reasons the Court should grant Defendant's cross motion for summary judgment and deny Plaintiffs' motions.

Dated: March 17, 2025

Respectfully submitted,

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