IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, *Plaintiff*, *v.* XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services; DANIEL J. BARRY, in his official capacity as Acting General Counsel of the U.S. Department of Health and Human Services; DIANA ESPINOSA, in her official capacity as Acting Administrator of the Health Resources and Services Administration; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; *and* HEALTH RESOURCES AND SERVICES ADMINISTRATION, *Defendants*.	C.A. No. 21-27 (LPS) ADMINISTRATIVE PROCEDURE ACT REVIEW OF AGENCY DECISION

PLAINTIFF'S OPENING BRIEF IN SUPPORT OF ITS
SECOND MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

The Administrative Procedure Act prohibits agencies from placing their preferred policy goals ahead of what Congress has provided. Yet that is precisely what the Health Resources and Services Administration (HRSA) has done here. HRSA's preferred policy is clear: It wants pharmaceutical manufacturers to deliver discounted 340B drugs to an unlimited number of contract pharmacies. HRSA first attempted to compel manufacturers like AstraZeneca Pharmaceuticals LP to do so through the Advisory Opinion. This Court, however, determined that a requirement to provide discounts for contract pharmacy sales was not "contained in the statute, nor (therefore) compelled by it," D.I. 78 at 22, and it set aside and vacated the Advisory Opinion, D.I. 83 ¶ 4.

HRSA has now pivoted to the May 17 letter over the Advisory Opinion, concluding yet again that AstraZeneca's policy of offering discounted 340B drugs to covered entities through a maximum of one contract pharmacy is "in direct violation of the 340B statute." AR 1.[1] Yet the May 17 letter adopts the same "legally flawed" interpretation as the Advisory Opinion; rests on the same erroneous assertion of interpretive consistency; and seeks to legislate the same outcome. This Court should accordingly reach the same result and vacate the May 17 letter.

As this Court has held, Congress did not include "contract pharmacies" in Section 340B. Inserting those words would thus be a *legislative* act—a form of substantive rulemaking that HRSA does not have authority to undertake. Nor may HRSA draw on Section 340B's silence regarding contract pharmacies to enforce its policy preference for what the statute could have said; AstraZeneca's obligations are limited to what Section 340B actually provides. Because the May 17 letter goes beyond the statute and the authority that Congress granted to HRSA—and is arbitrary and capricious for additional reasons—the May 17 letter should be set aside and vacated.

[1] Citations to the administrative record supporting the May 17 letter are in the form "AR #."

FACTUAL AND PROCEDURAL BACKGROUND

The Court is now well acquainted with the structure and history of the 340B program; with the covered entities and patient populations that the program is designed to serve; with its administration by HRSA; and with AstraZeneca's recently adopted policy concerning contract pharmacy sales. The following discussion relates only those additional facts and procedural developments directly relevant to AstraZeneca's current motion.

A. This Court Determines that the Advisory Opinion Is "Unlawful"

On December 30, 2020—after months of ignoring AstraZeneca's requests for a meeting to discuss the contract pharmacy policy it had adopted earlier that year—Robert P. Charrow, General Counsel of the Department of Health and Human Services (HHS), issued an eight-page Advisory Opinion setting out the agency's definitive position on manufacturers' obligations to honor contract pharmacy arrangements under the 340B program. AR 8048. The Opinion "conclude[d]" that a manufacturer's statutory obligations extend not just to purchases by covered entities themselves, but also to purchases made through an unlimited number of contract pharmacies. *Id.* In HHS's view, a manufacturer "is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs" whenever the pharmacy acts as a covered entity's "agent." *Id.*

AstraZeneca promptly filed suit to challenge the Advisory Opinion's numerous substantive and procedural flaws. D.I. 1, 13. Following expedited briefing and argument, this Court issued a detailed opinion on June 16, 2021, denying the government's motion to dismiss and finding the Advisory Opinion unlawful. D.I. 78. The Court announced several key conclusions about Section 340B, about HRSA's prior program guidance, and about the Advisory Opinion.

First, the Court rejected the government's "repeated contention that the [Advisory] Opinion merely restates a position that the government has held throughout the entirety of the 340B

program." *Id.* at 10. The Court found instead that the Opinion was materially different from the 1996 and 2010 Guidance, including because: the prior guidance documents predated the current version of the 340B statute and Congress's enactment of the so-called "must offer" requirement, *id.* at 10; had a different "focus" because they "were directed at covered entities" rather than at manufacturers, *id.* at 11; and used a "programmatic gap-filling" approach to the statute, in contrast to the Opinion's "fundamentally different approach" of statutory interpretation, *id.* at 12.

The Court also held that the Advisory Opinion was "the first document in which HHS explicitly concluded that ***drug manufacturers*** are required ***by statute*** to provide 340B drugs to ***multiple*** contract pharmacies." *Id.* at 12. The Court thus recognized that the government's interpretation of the statute had "evolved over time" and had "materially shifted," rejecting as "false" and "faulty" the government's assertions to the contrary. *Id.* at 12-13 & n.10. As the Court explained, "the government has dramatically expanded how covered entities may purchase 340B drugs" since the program's inception, which has "necessarily shift[ed]" the agency's view of what manufacturers "must do." *Id.* at 14-16. Given the new "obligations" on manufacturers imposed by the Opinion, the Court also concluded that AstraZeneca's suit was timely. *Id.* at 17.

Second, the Court held that the Advisory Opinion was a final agency action. It marked the "consummation" of HHS's decision-making process and created "legal consequences for AstraZeneca," by declaring that "manufacturers are 'obligated' and cannot 'refuse' to provide 340B drugs to multiple [contract] pharmacies." *Id.* at 15 (quoting AR 8048, 8055). That "mandatory" language was "fairly characterized as 'the agency's definitive position'" and an "unequivocal answer to a legal question," and it conveyed "at least the impression that HHS expects 'immediate compliance.'" *Id.* (quoting *Univ. of Med. & Dentistry v. Corrigan*, 347 F.3d 57, 69 (3d Cir. 2003)).

The Court rejected the government's argument that the availability of administrative dispute resolution (ADR) proceedings precluded AstraZeneca's challenge. ADR proceedings only

"permit a manufacturer to pursue claims against ***covered entities***," but not "to challenge ***agency*** action." *Id.* at 15. "If AstraZeneca (or another manufacturer) tries to raise the legal issue presented here in ADR proceedings," the Court further observed, "the result is preordained." *Id.* at 16. The Court also observed that the administrative record contained "no indication that the government ever grappled with" the "practical problems" that prevent a manufacturer from conducting effective audits of covered entities, a prerequisite for initiating an ADR proceeding. *Id.* at 16 n.12.

Third, on the merits, the Court concluded that Section 340B is "silent" as to "whether [a] covered entity may or must use an outside, third-party pharmacy to make purchases." *Id.* at 3. The Court noted that HRSA had acknowledged this very silence in its 1996 Guidance, which authorized covered entities to use only one contract pharmacy for dispensing 340B drugs. *Id.* at 4. Section 340B itself "is silent as to the role that contract pharmacies may play," *id.* at 18, a fact the Court found irreconcilable with the Advisory Opinion's position "that purportedly unambiguous statutory language mandates [the agency's] conclusion regarding covered entities' permissible use of an unlimited number of contract pharmacies," *id.* at 17. The Court specifically rejected the notion that manufacturers were obligated to recognize contract pharmacy sales by Section 340B's must-offer provision, which "says nothing about the permissible role (if any) of contract pharmacies." *Id.* at 18. Given the "[t]he statute's total omission of contract pharmacies," *id.* at 19, therefore, the Court held that the Opinion's analysis was "legally flawed," *id.* at 17.

The Court also observed, however, that, to the extent "the statute offers any clues on the issue, they militate against the view set out in the Opinion." *Id.* at 20. "Congress knows how to write statutes that cover agents and contractors," the Court explained, but "did not do so in the 340B statute." *Id.* at 20-21. In addition, Congress considered but did not enact language allowing contracts for *on-site* pharmacy sales, "suggest[ing] that Congress did not clearly intend to require manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies." *Id.* at 21.

Finally, because the Advisory Opinion was "based on the 'unjustified assumption' that Congress imposed" HHS's interpretation "as a statutory requirement," the Court concluded that "'[d]eference to [the] agency's interpretation'" was "'not appropriate.'" *Id.* at 23 (citations omitted). Before determining the proper form of relief in light of its legal conclusions, the Court directed the parties to provide their views on that question in a joint status report. *Id.*

B. HRSA Issues the May 17 Letter Amid This Court's Expedited Adjudication

On May 17, 2021, prior to this Court's Opinion, HRSA sent AstraZeneca a two-page letter asserting that the agency had reviewed AstraZeneca's contract pharmacy policy, and that the agency had determined that the policy has "resulted in overcharges" and is "in direct violation of the 340B statute." AR 1-2. The letter articulates a view of the statute premised on features of the Advisory Opinion that this Court has now found faulty. The letter's legal analysis reads, in full:

> Section 340B(a)(1) of the Public Health Service (PHS) Act requires that manufacturers "shall…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." This requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. Nothing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities. Section 340B(a)(1) of the PHS Act also requires manufacturers that have signed a Pharmaceutical Pricing Agreement (PPA) and PPA addendum to comply with these requirements. AstraZeneca is bound by the terms of the PPA and must ensure that the 340B ceiling price is available to all covered entities.
>
> Also consistent with section 340B(a)(1) of the PHS Act, manufacturers are expected to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs. This extends to the manner in which 340B drugs are made available to covered entities (e.g., access to 340B ceiling prices through wholesalers that make products available at non-340B ceiling prices). The 340B Program Ceiling Price and Civil Monetary Penalties Final Rule (CMP final rule) further specifies that a manufacturer's failure to provide 340B ceiling prices through the manufacturer's distribution agreements with wholesalers may violate a manufacturer's obligation under the 340B statute. HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor such purchases regardless of the dispensing mechanism.

AR 1 (footnotes omitted).

Notably, although the May 17 letter repeats some elements of the Advisory Opinion's analysis, it abandons other components of the Opinion without explanation. Among other things, the letter omits the Opinion's "assumption that contract pharmacies act as agents of covered entities." D.I. 78 at 20. In addition, the Opinion had "contend[ed] that the 'purchased by' provision of § 256b(a)(1) imposes [an] obligation on manufacturers" to provide discounts for contract pharmacy sales, *id.* at 19, but the May 17 letter does not mention the "purchased by" language at all.

The May 17 letter orders AstraZeneca immediately to resume sales to contract pharmacies; to "credit or refund all covered entities for overcharges"; and to provide "an update" of its intention to comply with HRSA's demands by June 1. AR 2; *see* D.I. 77 (noting later extension of deadline to June 10). The letter threatens that "[c]ontinued failure to provide the 340B price" for contract pharmacy sales may result in civil monetary penalties, including penalties of up to $5,883 "for each instance" of "knowingly and intentionally" overcharging covered entities. AR 2. In response, AstraZeneca filed an emergency motion with the Court seeking an administrative stay or, in the alternative, expedition of the existing proceedings. D.I. 66. The Court denied the stay but accelerated the hearing on the Advisory Opinion. D.I. 71.

C. The Court Vacates the Advisory Opinion and Orders Further Briefing

On June 18, 2021, two days after this Court's ruling that the Advisory Opinion was unlawful, the government notified the Court that HHS's General Counsel had withdrawn the Opinion "in light of ongoing confusion about [its] scope and impact." D.I. 81. The government's notice to the Court argued that the withdrawal had mooted AstraZeneca's claims, *id.*, but also asserted that the withdrawal "does not impact" HRSA's "ongoing efforts to enforce the obligations that 42 U.S.C. § 256b places on drug manufacturers, including HRSA's May 17, 2021 violation letters," D.I. 81-1. In the parties' joint status report, the government again contended that any challenge to the Opinion was moot but reiterated that "HRSA intends to continue enforcement proceedings

against AstraZeneca pursuant to the 340B statute." D.I. 82 at 4.

On June 30, the Court issued a Memorandum Order finding that withdrawal of the Advisory Opinion did not moot this litigation. D.I. 83 ¶ 1. HHS had made clear that its position on the 340B statute had not changed and that agency officials "intend to act in accordance with the withdrawn Opinion." *Id.* The Order also granted AstraZeneca's motion for summary judgment on the third count of its First Amended Complaint—that the Opinion is arbitrary and capricious—and vacated and set aside the Opinion. *Id.* ¶¶ 2, 4. The Court directed the parties to prepare a schedule for AstraZeneca to amend its complaint to add claims challenging the May 17 letter; for the government to file the administrative record; and for the parties to brief dispositive motions on the letter's legality. *Id.* at 3. The Court accepted the parties' proposed schedule, D.I. 85, and AstraZeneca filed a Second Amended Complaint, adding claims challenging the May 17 letter, D.I. 87.

D. The Administrative Record Raises Further Questions about the May 17 Letter

The administrative record discloses everything that HRSA purportedly considered when deciding that AstraZeneca's policy has "resulted in overcharges" and that AstraZeneca is "in direct violation of the 340B statute." AR 1. On its face, the record raises questions about the basis for HRSA's decision. AstraZeneca raises these questions not to supplement the record, but rather to point out that parts of the record do not align with AstraZeneca's actual contract pharmacy policy. Insofar as the Court believes the May 17 letter's legality turns on the record's accuracy or completeness, that would require the Court to vacate and remand for HRSA to address the deficiencies.

The bulk of the administrative record consists of boilerplate complaint forms submitted to HRSA by covered entities. *See* AR 110-6806. These complaints appear to have been compiled in anticipation of litigation. One covered entity admitted, for example that it had received assistance from the National Association of Community Health Centers and from Apexus, the company that serves as the 340B prime vendor: "The fine folks at Apexus and NACHC showed me how to report

when 340B drugs are unavailable at the ceiling price." AR 2272. Some covered entities said that contract pharmacy operators gave them "pre-populated" complaint forms, designed to provide HRSA with "the needed ammunition to fight back against Big Pharma." AR 4928-29 (email from Avita Pharmacy, providing covered entities with "complaint forms that we have pre-populated with the drugs that are impacted by the actions taken by the three drug companies"). Indeed, nearly all of the covered entity letters recite the following *identical* complaint, without further elaboration: "I am forced to pay WAC [wholesale acquisition cost] for [the drugs] for my contract pharmacies." *See, e.g.*, AR 287, 293, 1193, 1611, 1683, 1831, 1894, 1908, 1938, 2060, 2255, 2274, 2325, 2623, 2627, 2655, 2916, 3250, 4346, 4352, 4377, 4694, 4833, 5031, 5042, 5123, 5304, 6586.

Many of these complaints are questionable on their face. For example, approximately a quarter of the complaints submitted involve oncology or specialty medicines to which AstraZeneca's new policy does *not* apply.[2] AstraZeneca's policy in fact does not apply to these products, which are distributed through specialty networks. Many complaints also involve non-AstraZeneca products.[3] A preliminary review reveals other anomalies. For example, 26 complaints were submitted by entities that, according to AstraZeneca's records, have not purchased AstraZeneca products at any time in the past.[4] And most of the entities that submitted complaints have not designated contract pharmacies under AstraZeneca's policy, even though they may be eligible to do so. Finally, the bulk of the complaints were submitted in October 2020, immediately after AstraZeneca

[2] *Compare, e.g.*, AR 115-21, 234-40, 525-32, 713-20, 885-92, 998-1005, 1069-76, 1641-47, 2204-10, 3045-51, 4313-20, 5888-99, 6542-48, 6620-26 (complaints about products including Iressa, Tagrisso, Fasenra, Imfinzi, Lynparza, Lumoxiti, Koselugo, and Faslodex), *with* Second Am. Compl., Ex. G (D.I. 86-1 at 28-30) (list of products subject to AstraZeneca's policy).

[3] For instance, 44 complaints involve Movantik. *E.g.*, AR 174-180, 262-68, 651-57, 657-63, 945-52, 1183-90, 2363-69, 4847-4959. AstraZeneca divested its rights to that product in February 2020, well before implementing its contract pharmacy policy. *See* Press Release, *AstraZeneca divests global rights to Movantik* (Feb. 25, 2020), https://bit.ly/3eC2Fgk.

[4] *E.g.*, AR 229-33, 346-57, 672-80, 773-80, 1636-47, 2378-84, 3323-27.

implemented its new policy. Since then, AstraZeneca has worked directly with covered entities—including many of the covered entities that have submitted complaints—to clarify the new policy and to assist the covered entities in designating a contract pharmacy.

LEGAL STANDARD

In a challenge brought under the Administrative Procedure Act (APA), "the district judge sits as an appellate tribunal," and the "'entire case' on review is a question of law." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001). "Summary judgment thus serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *Soccer Ctrs., LLC v. Zuchowski*, No. 17-cv-1024, 2017 WL 4570290, at *5 (D.N.J. Oct. 13, 2017) (citation omitted). Under the APA, a reviewing court must "hold unlawful and set aside agency action, findings, and conclusions found to be," among other things: "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law"; "in excess of statutory jurisdiction, authority, or limitations"; or "without observance of procedure required by law." 5 U.S.C. § 706(2)(A), (C), (D).

ARGUMENT

I. The May 17 Letter Is Based on the Same "Legally Flawed" Reading of Section 340B as the Advisory Opinion

This Court has held that the text of Section 340B does not require manufacturers to provide discounts for unlimited contract pharmacy sales and that the Advisory Opinion's contrary conclusion was "legally flawed." D.I. 78 at 17. Those holdings dictate the outcome here. Because the May 17 letter is premised on the same "legally flawed" interpretation as the Advisory Opinion, it too must be set aside and vacated. *See ACLU v. Mukasey*, 534 F.3d 181, 187 (3d Cir. 2008) ("Under the law-of-the-case doctrine, 'when a court decides upon a rule of law, that decision should

continue to govern the same issues in subsequent stages in the same case.'") (quoting *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 816 (1988)).

A. Section 340B Does Not Require Manufacturers to Honor Unlimited Contract Pharmacy Arrangements

1. Like the Advisory Opinion, the May 17 letter concludes that the text of Section 340B alone requires manufacturers to recognize unlimited contract pharmacy sales. Just as the Advisory Opinion "assert[ed] that its conclusions are compelled by the 'plain meaning' of the 340B statute," D.I. 78 at 7, the letter maintains that "AstraZeneca's actions … are in direct violation of the 340B statute." AR 1. The conclusions announced by both documents are remarkably similar:

Advisory Opinion (AR 8048)	**May 17 Letter** (AR 1)
"[T]he core requirement of the 340B statute, as also reflected in the PPA and Addendum, is that manufacturers must 'offer' covered outpatient drugs at or below the ceiling price for 'purchase by' covered entities." AR 8049.	"Section 340B(a)(1) of the Public Health Service (PHS) Act requires that manufacturers 'shall…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.'" AR 1.
"This fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs." AR 8049.	"This requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs." AR 1.
"In this setting, neither the agency nor a private actor is authorized by section 340B to add requirements to the statute." AR 8049.	Any "restrictions on 340B pricing to covered entities that dispense medications through pharmacies under contract" are "in direct violation of the 340B statute." AR 1.
"[M]anufacturers cannot condition sale of a 340B drug at the 340B ceiling price … ." AR 8052 (citation omitted).	"Nothing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities." AR 1.
"The Department's longstanding interpretation of the statute, as expressed through guidance, is that manufacturers are required to offer ceiling prices even where contract pharmacies are used." AR 8051.	"HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor such purchases regardless of the dispensing mechanism." AR 1.

The May 17 letter thus carries forward the Advisory Opinion's legally flawed conclusions. Like the Opinion, the letter concludes "that the 340B statute requires manufacturers to honor [contract pharmacy] purchases regardless of the dispensing mechanism." AR 1. Like the Opinion, the letter insists that the agency's position has been "consistent[] since the issuance of its 1996 contract pharmacy guidance." *Id.* And like the Opinion, the letter does not purport to fill any statutory gaps, to interpret ambiguous terms, or to impose any substantive requirements besides those contained in the statute itself. Rather, the agency's view continues to be that AstraZeneca's policy violates "its obligations under section 340B(a)(1)." AR 2.

Indeed, it could hardly be otherwise. The Advisory Opinion was issued by HHS's General Counsel, the "chief legal officer of the Department." Statement of Organization, Functions, and Delegations of Authority, 86 Fed. Reg. 6349, 6349-50 (Jan. 21, 2021). The General Counsel "[s]upervises all legal activities of the Department *and its operating agencies*," including HRSA. *Id.* at 6,351 (emphasis added). HRSA issued the May 17 letter while the Opinion was still operative. Although Defendants have tried to distance themselves from the Opinion, the letter incorporates the same legal conclusions and analysis.

2. Because the May 17 letter reaches the same conclusion as the Advisory Opinion and uses the same flawed reasoning, this Court's analysis applies with equal force. The May 17 letter "wrongly determines that purportedly unambiguous statutory language mandates its conclusion regarding covered entities' permissible use of an unlimited number of contract pharmacies." D.I. 78 at 17. The must-offer provision, on which the letter relies, "says nothing about the permissible role (if any) of contract pharmacies." *Id.* at 18. Nor does any other provision of Section 340B impose requirements "with respect to covered entities' use of pharmacies." *Id.*; *see id.* at 18-19.

Indeed, insofar as "the statute offers any clues on the issue, they militate against the view set out in the" May 17 letter. *Id.* at 20. ***First***, the comprehensive list of covered entities does not

include contract pharmacies: "It is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication." *Id.* ***Second***, other statutory provisions "cut against HHS's position." *Id.* Congress addressed agency and contractor relationships elsewhere in the statute establishing the 340B program, yet included no such language in Section 340B. "Congress knows how to write statutes that cover agents and contractors, but it did not do so in the 340B statute." *Id.* at 21. ***Third***, "legislative history is of no greater assistance to the government." *Id.* Congress "specifically contemplated"—but decided against—"language referring to drugs 'purchased and dispensed by, or ***under a contract entered into for on-site pharmacy services*** with' covered entities." *Id.* (quoting S. Rep. No. 102-259, at 2 (1992)). This "suggests that Congress did not clearly intend to require manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies." *Id.*

In sum, the May 17 letter's view that the statute requires manufacturers "to deliver 340B drugs to an unlimited number of contract pharmacies" is not merely incorrect, *id.*, but also is irreconcilable with this Court's invalidation of the Advisory Opinion. The letter seeks to impose a requirement that is neither "contained in the statute" nor "compelled by it." D.I. 78 at 22. "[O]nly Congress may add requirements to the 340B statute." *Id.* at 21. Because the letter is "based on the 'unjustified assumption' that Congress imposed [the agency's] interpretation as a statutory requirement," the letter is legally flawed. *Id.* at 23 (quoting *Am. Lung Ass'n v. EPA*, 985 F.3d 914, 944 (D.C. Cir. 2021)). The letter should accordingly be "set aside and vacated," just like the Advisory Opinion. D.I. 83 ¶ 4 (emphasis omitted).[5]

[5] Congress's *silence* about contract pharmacies does not render Section 340B *ambiguous* regarding whether a manufacturer must honor contract pharmacy sales. Since the only "relevant command" to manufacturers appears in 42 U.S.C. § 256b(a)(1), D.I. 78 at 18, but nothing in that provision "require[s]" manufacturers "to deliver 340B drugs to an unlimited number of contract pharmacies," *id.* at 21, the statute unambiguously imposes *no* such requirement. *See Coffelt v. Fawkes*, 765 F.3d 197, 202 (3d Cir. 2014) ("Even where a statute is 'silent' on the question at issue," that

B. The May 17 Letter Offers No Valid Reason for Finding AstraZeneca in Violation of Its Section 340B Obligations

It is a fundamental principle of administrative law that "a court may uphold agency action only on the grounds that the agency invoked when it took the action." *Michigan v. EPA*, 576 U.S. 743, 758 (2015) (citing *SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943)). "When the reasons that an agency provide[s] at the time it t[akes] the challenged action 'are inadequate,' the agency's action may not be sustained." *B'hood of Locomotive Eng'rs & Trainmen v. Fed. R.R. Admin.*, 972 F.3d 83, 117 (D.C. Cir. 2020) (citation omitted); *see Dep't of Homeland Sec'y v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1907 (2020). The May 17 letter offers little support for its conclusion that AstraZeneca's policy "ha[s] resulted in overcharges and [is] in direct violation of the 340B statute." AR 1. And the scant reasons that HRSA *does* provide have already been rejected by this Court.

First, pointing to the statute's must-offer provision, the May 17 letter contends that "[n]othing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities." AR 1. But as this Court has already explained, the must-offer provision "says nothing about the permissible role (if any) of contract pharmacies." D.I. 78 at 18. The May 17 letter's argument is based on the unjustified premise that "pharmaceutical manufacturers are required to deliver 340B drugs to an unlimited number of contract pharmacies." *Id.* at 21. But such a requirement is neither "contained in the statute" nor "compelled by it." *Id.* at 22.

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is not the same as "an ambiguity tied up with the provisions of the statute.") (citation omitted). In this case, as AstraZeneca argued in its prior motion for summary judgment, D.I. 43 at 9-12, Section 340B as written unambiguously permits AstraZeneca's contract pharmacy policy. But to the extent the Court finds Section 340B does not affirmatively authorize AstraZeneca's policy, Section 340B at most is silent on the question, not ambiguous.

Second, the May 17 letter asserts that, under the must-offer provision, "manufacturers are expected to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs," and that this obligation "extends to the manner in which 340B drugs are made available to covered entities." AR 1. But AstraZeneca's policy complies with this requirement. AstraZeneca continues to make its medicines available to covered entities at the discounted price through its wholesalers, just as it makes its products available to other customers. While AstraZeneca's "offer" is the same to all entities, the contract pharmacy distribution model that some covered entities use is unique to the 340B context. The administrative record fails to identify any non-340B entities that purchase drugs from AstraZeneca through contract pharmacies, and AstraZeneca is aware of none. AstraZeneca's decision to recognize one contract pharmacy per covered entity thus does not discriminate against covered entities.

Third, the May 17 letter asserts that "HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to offer such purchases regardless of the dispensing mechanism." AR 1. But this Court has already rejected the "false premise that the government's position has been consistent throughout the history of the 340B Program." D.I. 78 at 16 (citation omitted). In fact, the May 17 letter, like the Advisory Opinion, "treads 'new ground'" in several respects. *Id.* at 10 (quoting *Indep. Equip. Dealers Ass'n v. EPA*, 372 F.3d 420, 428 (D.C. Cir. 2004)). The May 17 letter is based on the must-offer provision, which "Congress did not codify … until March 23, 2010, ***after*** HRSA issued the 2010 Guidance." *Id.* The "focus" of the May 17 letter, which is "directed toward drug manufacturers," is also "different from the focus of the 1996 and 2010 Guidance," both of which "were directed toward covered entities." *Id.* at 11. And the May 17 letter's "mode of analysis" is "fundamentally different" than the "programmatic gap-filling" in which the 1996 and 2010 Guidance engaged. *Id.* at 11-12. As this Court observed, AstraZeneca's policy "would not have run afoul of the 1996 Guidance—

yet it directly contradicts" the May 17 letter. *Id.* at 12. In sum, while the Advisory Opinion was "the first document in which [the agency] explicitly concluded that drug manufacturers are required by statute to provide 340B drugs to multiple contract pharmacies," *id.*, the May 17 letter is the second. And now that this Court has set the Advisory Opinion aside, the May 17 letter is the *only* such document.

II. The May 17 Letter Exceeds HRSA's Authority and Is Arbitrary and Capricious

"Not only must an agency's decreed result be within the scope of its lawful authority, but the process by which it reaches that result must be logical and rational." *Michigan*, 576 U.S. at 750 (citation omitted). The May 17 letter violates these requirements in several independent ways. ***First***, the letter imposes a substantive requirement that goes beyond the requirements imposed by the statute itself—a form of legislative rulemaking that exceeds the limited authority that Congress has delegated to the agency. ***Second***, the letter is based on the incorrect assumption that its conclusions are compelled by the statutory text, as well as the erroneous view that the agency has consistently interpreted the statute since 1996.

A. The May 17 Letter Is an Unauthorized Legislative Rule

The May 17 letter declares that "AstraZeneca must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements." AR 2. Because the letter imposes substantive requirements on AstraZeneca where the statute itself imposes none, it is a "legislative rule" that exceeds HRSA's authority.

1. "'Legislative' rules," in contrast to "'[i]nterpretive' rules," are rules "that impose new duties upon the regulated party." *Chao v. Rothermel*, 327 F.3d 223, 227 (3d Cir. 2003). "The practical question inherent in the distinction between legislative and interpretive regulations is whether the new rule effects a substantive regulatory change to the statutory or regulatory regime." *Elec.*

Privacy Info. Ctr. v. U.S. Dep't of Homeland Sec., 653 F.3d 1, 6-7 (D.C. Cir. 2011) (citation omitted); *see Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993).

The May 17 letter's conclusions "that AstraZeneca's actions have resulted in overcharges and are in direct violation of the 340B statute," AR 1, are quintessential legislative rules. Like the Advisory Opinion, the May 17 letter "announces unqualified conclusions" and uses "mandatory" language making clear that the agency "expects 'immediate compliance.'" D.I. 78 at 14-15 (quoting *Univ. of Med. & Dentistry of N.J.*, 347 F.3d at 69); *see NRDC v. EPA*, 643 F.3d 311, 321 (D.C. Cir. 2011) ("[T]he inquiries into whether the agency action was final and whether the agency action was a rule were essentially the same."). And, most critically, "in the absence of" the May 17 letter, "there would not be an adequate legislative basis for enforcement action or other agency action" against AstraZeneca for its contract pharmacy policy. *Am. Mining Cong.*, 995 F.2d at 1112. As this Court has recognized, the obligation "to deliver 340B drugs to an unlimited number of contract pharmacies" is *not* "contained in the statute." D.I. 78 at 22. In seeking to impose that obligation on AstraZeneca, the May 17 letter "impose[s] new duties." *Chao*, 327 F.3d at 227.

The conclusion that the May 17 letter is a legislative rule flows directly from this Court's invalidation of the Advisory Opinion. This Court repeatedly observed that Section 340B "is silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs." D.I. 78 at 18; *see id.* ("[T]he statute is simply silent on this point."); *id.* at 20 ("Congress was silent on the issue"). Filling statutory silence in a way that creates substantive rights or obligations is a quintessential act of *legislative*, not interpretive, rulemaking. *See Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1817 (2019) ("[W]hen the government establishes or changes an avowedly 'gap'-filling policy, it can't evade its notice-and-comment obligations … ."); *Star Enter. v. EPA*, 235 F.3d 139, 146 (3d Cir. 2000) ("If … the rule is based on an agency's power

to exercise its judgment as to how best to implement a general statutory mandate, the rule is likely a legislative one." (quoting *Navigation Co. v. Pomeroy*, 34 F.3d 1255, 1263 (3d Cir. 1994)).

2. Before an agency may engage in legislative rulemaking, two conditions must be satisfied. ***First***, Congress must have left "a gap to fill" in the relevant statute. *NRDC v. EPA*, 749 F.3d 1055, 1064 (D.C. Cir. 2014). ***Second***, the agency must have been delegated "authority to issue … regulations" filling that particular gap. *Id.* at 1063. Neither condition is satisfied here.

Whether a statute leaves a "gap to fill" is not the same question as whether the statute is silent. "Even where a statute is 'silent' on the question at issue, such silence 'does not confer gap-filling power on an agency unless the question is in fact a gap—an ambiguity tied up with the provisions of the statute.'" *Coffelt v. Fawkes*, 765 F.3d 197, 202 (3d Cir. 2014) (quoting *Lin-Zheng v. Att'y Gen.*, 557 F.3d 147, 156 (3d Cir. 2009) (en banc)). Statutory ambiguity exists only if the relevant "words may reasonably admit of different meanings." *Mellon Bank, N.A. v. Aetna Bus. Credit, Inc.*, 619 F.2d 1001, 1011 (3d Cir. 1980). Courts have thus held that a statute's "silence on [a] point is not ambiguous" if it is "contrary to all other textual and contextual evidence of congressional intent." *Coffelt*, 765 F.3d at 202, 204 (citation omitted).

APA case law illustrates the difference between genuine statutory *ambiguity* (gap to fill) and statutory *silence* (no gap). For example, in *Verizon Communications, Inc. v. FCC*, 535 U.S. 467 (2002), the Supreme Court considered a statute that directed the FCC to set a "just and reasonable rate for [certain] network elements … *based on the cost* of providing the … network element." *Id.* at 497-98 (quoting 47 U.S.C § 252(d)(1) (emphasis added; parenthetical omitted)). Because the statute required rates to be based on "cost[s]," but did not further define the term, the Court found the statute ambiguous regarding the types of costs that could be considered. *Id.* at 500-01. "[W]ithout any better indication of meaning than the unadorned term," the Court explained,

"the word 'cost'" is "a chameleon" that allows for "broad methodological leeway." *Id.* at 500 (citation omitted).

In *Lin-Zheng*, by contrast, the *en banc* Third Circuit found that a statutory silence had left *no* gap to fill. At issue there was the statutory definition of "refugee," which was defined to include "a person" who had been forced to abort a pregnancy or undergo sterilization, or a "person" who had otherwise been persecuted for "resistance to a coercive population control program." 557 F.3d at 151 (quoting 8 U.S.C. § 1101(a)(42)). The relevant agency (the Board of Immigration Appeals) argued that, because the statute was silent as to whether it applied to "spouses," Congress had left a gap for the agency to fill. *Id.* at 152-53. The Third Circuit disagreed, holding that Congress's "silence" with regard to spouses did not create any gap to be filled. *Id.* at 156 (citation omitted). The Third Circuit explained that Congress's use of the terms "person" and "undergo" indicated its intent that the statute should apply to individuals who themselves were subjected to forced medical procedures or related persecution. *Id.* While spouses were not expressly ruled out, the court observed, "[h]ad Congress wished to extend protection to that person's spouse, it could easily have defined 'refugee' to include the person persecuted as well as his or her spouse." *Id.* at 156.

The statutory silence in this case is akin to the silence in *Lin-Zheng*. Just as Congress could have defined "refugee" to include spouses (but did not), Congress could have defined "covered entity" to include contract pharmacies (but did not), or it could have included agency relationships (but did not). Section 340B's silence on these issues thus does not create any ambiguity to be interpreted. As this Court has recognized, the statute's "relevant command" contains *no* words that can reasonably be read to require pharmaceutical manufacturers to deliver 340B-discounted drugs to an unlimited number of contract pharmacies. D.I. 78 at 18. Nor is any such requirement "contained [elsewhere] in the statute." *Id.* at 22. And indeed, "all other textual and contextual evidence of congressional intent" point *away* from the existence of such a requirement. *Coffelt*, 765 F.3d at

202 (citation omitted); *see* D.I. 78 at 20 ("If the statute offers any clues on the issue, they militate *against* the view set out in the [Advisory] Opinion") (emphasis added). There is accordingly no "gap to fill" through legislative rulemaking. Nor does Congress's failure to *forbid* discounts for contract pharmacy sales leave room for an agency to *require* such discounts. *See U.S. Telecom Ass'n v. FCC*, 359 F.3d 554, 566 (D.C. Cir. 2004) ("[T]he failure of Congress to use 'Thou Shalt Not' language doesn't create a statutory ambiguity.").

3. HRSA also "was not delegated authority to make binding rules that carry the force of law related to section 340B[(a)(1)]." *PhRMA v. HHS* (*Orphan Drug II*), 138 F. Supp. 3d 31, 48 (D.D.C. 2015). As the U.S. District Court for the District of Columbia has *twice* held, Section 340B does not grant HHS "broad rulemaking authority." *PhRMA v. HHS* (*Orphan Drug I*), 43 F. Supp. 3d 28, 42 (D.D.C. 2014); *see Orphan Drug II*, 138 F. Supp. 3d 31 at 36. Instead, "Congress specifically authorized rulemaking" only in three well-defined areas: "(1) the establishment of an administrative dispute resolution process, (2) the 'regulatory issuance' of precisely defined standards of methodology for calculation of ceiling prices, and (3) the imposition of monetary civil sanctions." *Orphan Drug I*, 43 F. Supp. 3d at 41. These "specific grant[s] of rulemaking authority" indicate that "Congress has *not* given [the agency] the broad rulemaking authority" to impose other substantive requirements—such as those for contract pharmacy sales. *Id.* at 45 (emphasis added).

Indeed, until the agency issued the Advisory Opinion in December 2020, HRSA's lack of authority to require manufacturers to recognize contract pharmacies was common ground. In June 2020, HRSA told another manufacturer that the 1996 and 2010 contract pharmacy guidance was not "binding" on manufacturers. AR 7590. On July 8, 2020, HRSA's Director of Communications stated that "although the agency 'strongly encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements,' 'HRSA's current authority to enforce certain 340B policies is limited.'" *Am. Hosp. Ass'n v. HHS*, No. 4:20-cv-8806, 2021 WL

616323, at *3 (N.D. Cal. Feb. 17, 2021) (quoting HRSA email) (ellipsis omitted); *see* Michelle Stein, *HRSA Urges Pharma To Continue 340B Discounts At Contract Pharmacies*, Pa. Office of Rural Health (Aug. 2020), https://bit.ly/3wnHDZz (quoting a statement from the same correspondence that "HRSA is unable to develop enforceable policy" with respect to contract pharmacies). And the very next day, HRSA was quoted telling a reporter that "[t]he 2010 guidance … is not legally enforceable," and that HRSA could not "compel[]" manufacturers "to provide 340B discounts on drugs dispensed by contract pharmacies." Tom Mirga, *HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020). Even in November 2020—just a month before issuing the Advisory Opinion—HRSA acknowledged that it lacks "comprehensive regulatory authority" and thus "has only limited ability to issue enforceable regulations to ensure clarity in program requirements across all the interdependent aspects of the 340B Program." AR 7720-21.

These statements correctly recognize that HRSA lacks statutory authority to engage in substantive rulemaking with respect to contract pharmacy sales. As this Court has explained, "Congress may very well want pharmaceutical manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies as a condition for manufacturers' participation in the Medicare Part B and Medicaid programs. But that kind of policymaking is for Congress, not this Court." D.I. 78 at 24. Absent statutory authorization, that kind of policymaking is not for HRSA, either.

B. The May 17 Letter Rests on the Incorrect Premises That Statutory Text Compels Its Conclusions and That the Agency Has Held a Consistent Position

Like the Advisory Opinion, the May 17 letter "is based on the 'unjustified assumption' that Congress imposed [the agency's] interpretation as a statutory requirement." D.I. 78 at 23 (quoting *Am. Lung Ass'n*, 985 F.3d at 944). The letter asserts that a manufacturer's contract pharmacy obligations flow directly from Section 340B(a)(1)'s must-offer provision; that "[n]othing in the 340B

statute" limits or qualifies that obligation; and that "[t]he 340B statute does not permit" any other approach, such as that adopted by AstraZeneca. AR 1-2. Because the agency "'wrongly believes that [its] interpretation is compelled by Congress,'" at a minimum it must be "vacat[ed] … and remand[ed] for further consideration." D.I. 78 at 23 (quoting *Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006)).

In addition, the May 17 Letter rests on the same "faulty" assertion of administrative consistency as the Advisory Opinion. D.I. 78 at 15. It should accordingly suffer the same fate. An agency "must at least display awareness that it is changing position and show that there are good reasons for the new policy." *Id.* at 13 n.11 (quoting *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016)); *see FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (agency must "display awareness that it is changing position" and cannot "depart from a prior policy *sub silentio*") (emphasis omitted). Like the Opinion, the May 17 Letter fails to acknowledge, much less explain, the change.

Indeed, the May 17 letter is in some respects *even more* of an unexplained departure, because it departs even from positions taken in the Advisory Opinion itself. The Opinion "expressly relie[d] on the assumption that contract pharmacies act as agents of covered entities," and its views "applie[d] '**to the extent** contract pharmacies are acting as agents of a covered entity.'" D.I. 78 at 20 & n.15 (quoting AR 8048). But the May 17 letter omits any mention of agency relationships. And while the Opinion "relie[d] heavily" on "the 'purchased by' provision," *id.* at 3, as did the government in defending the Opinion, *id.*, the letter does not discuss it at all.

III. The May 17 Letter Is Legally Flawed in Additional Respects

The foregoing deficiencies in the May 17 letter, by themselves, require vacating the letter and setting it aside. But the letter also erroneously claims that AstraZeneca's policy has resulted

in overcharges and threatens AstraZeneca with civil monetary penalties (CMPs). The Court should reject these claims as well.

A. AstraZeneca Has Not Overcharged Any Covered Entities

The May 17 letter concludes "that AstraZeneca's actions have resulted in overcharges." AR 1. But under AstraZeneca's policy, covered entities continue to have access to 340B drugs at discounted prices. Under AstraZeneca's program, a covered entity may purchase 340B drugs at the 340B discounted price and have them delivered either to an onsite dispensing pharmacy or to a designated contract pharmacy. These sales to covered entities at the 340B price do not result in overcharges. The letter offers no evidence or explanation of how AstraZeneca's policy has led it to overcharge any covered entity. Nor is any overcharge possible in these circumstances.

Under Section 340B, a manufacturer may face administrative "claims by covered entities that they have been overcharged," 42 U.S.C. § 256b(d)(3)(A); and HHS can impose CMPs if a manufacturer knowingly and intentionally "charges a covered entity a price for purchase of a drug that exceeds the [statutory] maximum," *id.* § 256b(d)(1)(B)(vi)(III). Those mechanisms make sense as a way to hold a manufacturer accountable for overcharging the covered entity itself for drugs sold at non-340B prices *to that entity*. The CMP regulations thus define an "instance of overcharging" as "any order for a covered outpatient drug, … which results in a covered entity paying more than the ceiling price … for that covered outpatient drug." 42 C.F.R. § 10.11(b). As the agency explained when promulgating this rule, there cannot be an overcharge without a sale: "[I]t is the actual sale of the covered outpatient drug above the 340B ceiling price by the manufacturers to the covered entity that is the subject of the overcharge per the statute." 340B Drug Pricing Program Ceiling Price and Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1224 (Jan. 5, 2017).

The "actual sale" requirement reinforces why the May 17 letter is wrong. Under the prevailing contract pharmacy model, AstraZeneca sells its medicines mostly through wholesalers, who then sell those medicines to end customers, including to retail pharmacies. To the extent that a patient of the covered entity fills her prescription at a pharmacy not designated by the covered entity under AstraZeneca's policy, the dispensed medicine was *not* sold to the covered entity, but rather was purchased by the pharmacy. The covered entities do not take possession of, or title to, the medicines. *See* May 27, 2021 Hr'g Tr. 13:13-14:6, 19:11-22, 32:5-33:15, 37:10-25 (D.I. 76). Accordingly, there is no sale at all to the covered entity, which is never charged—much less "overcharged"—for an AstraZeneca medicine in these circumstances.[6]

Insofar as the May 17 letter's (unstated) theory is that the failure to consummate a sale to a covered entity through a contract pharmacy is equivalent to an "overcharge," that theory fails on multiple levels. ***First***, it contravenes the plain meaning of "overcharge," which requires a "charge." *See Overcharge*, Merriam-Webster, merriam-webster.com/dictionary ("to make an excessive charge"). ***Second***, it contradicts the CMP regulations, under which a covered entity is overcharged only when it "pay[s] more than the ceiling price." 42 C.F.R. § 10.11(b). ***Third***, it conflicts with the agency's own guidance, which depends on an "actual sale of the covered outpatient drug above the 340B ceiling price by the manufacturers to the covered entity." 82 Fed. Reg. at 1224; *see id.* (rejecting commenter suggestion to define "overcharge" to include "incorrect treatment by a manufacturer of a registered covered entity as an organization ineligible for the 340B ceiling price").

This Court's prior decision reinforces the conclusion that no overcharge has occurred in

[6] The administrative record contains *no* evidence regarding the replenishment model used for the vast majority of contract pharmacy sales. If the Court believes that factual questions regarding the replenishment model—such as whether covered entities take title to medicines—bear on the legality of HRSA's overcharge allegations, then the lack of supporting evidence in the record is a "fail[ure] to consider an important aspect of the problem," *NVE, Inc. v. HHS*, 436 F.3d 182, 190 (3d Cir. 2006) (citation omitted), which would require vacatur of the May 17 letter.

these circumstances. The decision rejected the view that Congress "intended to include contract pharmacies as" a type of covered entity, D.I. 78 at 20, as well as "the assumption that contract pharmacies act as agents of covered entities" or that "Congress intended to include agents within the definition of 'covered entity,'" *id.* If a contract pharmacy is neither a covered entity nor an agent of a covered entity, then there can be no "overcharge" under HRSA's definition of the term (or any other definition) when drugs are purchased by a contract pharmacy at normal market prices rather than 340B prices.

B. HRSA's Threat of Civil Monetary Penalties Is Unlawful

The May 17 letter threatens AstraZeneca with CMPs of up to $5,883 "for each instance of overcharging." AR 2. As noted, the agency may impose CMPs only where a manufacturer "knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the [statutory] maximum." 42 U.S.C. § 256b(d)(1)(B)(vi)(III). The May 17 letter declares that CMPs are "warranted" unless AstraZeneca demonstrates its "willingness to comply with its obligations under section 340B(a)(1)" as *the agency* understands those obligations. AR 2. This threat of CMPs—which itself places AstraZeneca at heightened risk of sanction, *see Sackett v. EPA*, 566 U.S. 120, 126 (2012)—is legally flawed on multiple grounds.

First, CMPs are unavailable unless a manufacturer "charges a covered entity a price" that exceeds the statutory maximum. 42 U.S.C. § 256b(d)(1)(B)(vi)(III). As noted above, covered entities are not charged any price under AstraZeneca's policy, much less a price that exceeds the statutory maximum, when contract pharmacy sales are made outside the policy.

Second, this Court has held that a requirement for manufacturers "to deliver 340B drugs to an unlimited number of contract pharmacies" is neither "contained in the statute" nor "compelled by it." D.I. 78 at 21-22. The absence of such a requirement, by itself, means that AstraZeneca could not "knowingly and intentionally" violate the requirement. *See Comm'r v. Acker*, 361 U.S. 87, 91

(1959) ("The law is settled that penal statutes are to be construed strictly and that one is not to be subjected to a penalty unless the words of the statute plainly impose it.") (citations omitted).

Third, even if Section 340B were ambiguous (which, as explained in footnote 5 above, it is not), AstraZeneca's adoption of a "reasonabl[e]" interpretation of the ambiguity, D.I. 78 at 22, also forecloses any finding that the company has engaged in a knowing and intentional violation. Indeed, "[i]f the statute offers any clues on the issue, they militate *against* the view set out in the [Advisory] Opinion"—and hence the May 17 letter—and *in favor* of AstraZeneca's. *Id.* at 20 (emphasis added). Even a company that acts on an interpretation that is "erroneous" (which AstraZeneca's is not) but "not objectively unreasonable" cannot be held liable for acting "reckless[ly]"—much less for acting knowingly *and* intentionally. *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 69-70 (2007) (rejecting liability where company's "reading ha[d] a foundation in the statutory text" and had "a sufficiently convincing justification to have persuaded the District Court"); *see Long v. Tommy Hilfiger U.S.A., Inc.*, 671 F.3d 371, 376 (3d Cir. 2012) ("[A] violation does not cross the willfulness threshold just because a defendant's interpretation is erroneous; it must instead be 'objectively unreasonable.'") (quoting *Safeco*, 551 U.S. at 70); *Van Straaten v. Shell Oil Prods. Co. LLC*, 678 F.3d 486, 489 (7th Cir. 2012) (holding that "absence of a statutory or regulatory definition of the [relevant statutory] phrase" precluded finding of a "willful" violation).

Fourth, AstraZeneca implemented its contract pharmacy policy and brought this litigation based on its good-faith interpretation of Section 340B. AstraZeneca's good faith conduct also means that any violation could not be "knowing[] and intentional[]." *See Magadia v. Wal-Mart Assocs., Inc.*, 384 F. Supp. 3d 1058, 1088-89 (N.D. Cal. 2019) (good-faith litigation precluded finding of "knowing and intentional" violation until after adverse ruling put defendant on notice), *rev'd in part and vacated in part on other grounds*, 999 F.3d 668 (9th Cir. 2021).

Finally, the consistency of AstraZeneca's policy with the agency's own past guidance reinforces that there can be no knowing and intentional statutory violation. As this Court noted, the policy "would not have run afoul of the 1996 Guidance." D.I. 78 at 12. To the contrary, HRSA's own shifting view of Section 340B's requirements, *see id.* at 11-14, 22-23; Hr'g Tr. 42:8-43:6, 65:25-73:25, shows that penalizing AstraZeneca for noncompliance would be improper.

CONCLUSION

The Court should grant AstraZeneca's motion for summary judgment on all counts of the Second Amended Complaint, D.I. 86.

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Respectfully submitted,

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