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 COMBINED REPLY BRIEF IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases Page(s)

Statutes, Regulations & Rules

Legislative Materials

HRSA's May 17 letter to AstraZeneca rests on the same "legally flawed" premise as the Advisory Opinion: that AstraZeneca's contract pharmacy policy is "in direct violation of the 340B statute," which "obligat[es]" manufacturers "to offer 340B pricing" for unlimited contract pharmacy sales. AR 1; D.I. 78 at 17. Nothing the government argues in defense of the letter negates that central flaw. Thus, the May 17 letter must fall for the same reasons as the Advisory Opinion.

The government's brief focuses on different statutory language than the May 17 letter does ("purchased by" versus "must offer"), violating the principle that courts must "confin[e] [their] review to a judgment upon the validity of the grounds upon which the [agency] itself based its action." *SEC v. Chenery Corp.*, 318 U.S. 80, 88 (1943). But the government's textual argument fails on its own terms. The government simply does not grapple with this Court's analysis, nor justify its continued insistence that the agency has always held the same view (apparently since 1994, not 1996). And "evidence" from the administrative record, on which the government relies, merely repackages the Advisory Opinion's flawed legal reasoning—this time articulated by covered entities, rather than by the agency itself. In the end, the government is left to argue that the 340B program would do more good if it required manufacturers to provide discounts for contract pharmacy sales. "But that kind of policymaking is for Congress, not this Court." D.I. 78 at 24.

ARGUMENT

I. The May 17 Letter's Interpretation of Section 340B Is "Legally Flawed"

The May 17 letter definitively concludes that AstraZeneca's policy is "in direct violation of the 340B statute." AR 1. For that conclusion, the letter relies upon a single statutory obligation: the must-offer provision. But this Court already concluded (correctly) that the provision "says nothing about the permissible role (if any) of contract pharmacies." D.I. 78 at 18. The government's brief, D.I. 93 (Gov. Br.), provides no meaningful defense of the May 17 letter's statutory analysis, nor any persuasive reason to read the text as imposing such an obligation.

A. The 340B Statute Does Not Require Manufacturers to Facilitate Unlimited Contract Pharmacy Sales

1. The government refers to the May 17 letter as "the Violation Letter" for a reason: It announces "a manufacturer's *obligation* under the 340B statute" to deliver discounted drugs to unlimited contract pharmacies, and it concludes that AstraZeneca's policy is "in direct violation of" that obligation. AR 1 (emphasis added). The only "obligation" identified is the must-offer provision of 42 U.S.C. § 256b(a)(1). But as this Court explained, that provision does not include a mandate to provide discounts for contract pharmacy sales. *See* D.I. 78 at 18 (must-offer provision "says nothing" about such sales); *id.* at 22 (no such "requirement is contained in the statute").

The government's brief (at 11) accuses AstraZeneca of "improperly focus[ing] on a single word—to the exclusion of necessary language found in the same subsection." But AstraZeneca focused on the must-offer provision because that is where the May 17 letter located the "statutory obligation" that AstraZeneca is supposedly violating. AR 1. After quoting the provision, the letter states: "*This requirement* is not qualified, restricted, or dependent … ." *Id.* (emphasis added). Focusing "only on the grounds cited by the pertinent agency" is not merely proper; it is mandatory. *Ricketts v. Att'y Gen. of the U.S.*, 955 F.3d 348, 351 (3d Cir. 2020) (citing *Chenery*). In any event, reading the statute "as a whole" and in context, Gov. Br. 11 (quoting *U.S. v. Atl. Rsch. Grp.*, 551 U.S. 128, 135 (2007)), does not help the government: If other provisions "offer[] any clues on the issue, they militate against the view set out in" the May 17 letter. D.I. 78 at 20.

Unlike the May 17 letter, the government's brief returns to the "'purchased by' provision" on which its prior briefing and the Advisory Opinion "relie[d] heavily." D.I. 78 at 3; *see* Gov. Br. 11-13. That provision is not among "the reasons [the agency] gave when it acted." *DHS v. Regents of Univ. of Cal.*, 140 S. Ct. 1891, 1909 (2020) (citing *Chenery*). But even if it were, this Court has explained that the purchased-by language "simply cannot bear the weight" of the government's

reliance on it. D.I. 78 at 19. The provision is "directed to the Secretary," not to manufacturers, and it "says nothing of the permissible role (if any) of contract pharmacies." *Id.* at 18. The government argues (at 13) that AstraZeneca has failed to "fulfill its duty to honor 'purchases by' covered entities" because its policy "*denies* those very purchases." That argument simply assumes its own conclusion. In reality, as this Court held, the purchased-by provision imposes no such "requirement" on AstraZeneca to provide 340B discounts for contract pharmacy sales. D.I. 78 at 22.

2. The government relies (at 14-15) on *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), but that decision undermines rather than supports the government's argument. At issue there was whether Title VII's prohibition against "an employer" who "discriminate[s] against any individual … because of such individual's … sex," 42 U.S.C. § 2000e-2(a)(1), bans discrimination against gay or transgender employees. To answer that question, the Court interpreted the "key" phrase "'because of' sex" to "incorporate the simple and traditional standard of but-for causation." 140 S. Ct. at 1739 (quotation marks omitted). Under that standard, the Court explained, "it is impossible to discriminate against a person for being homosexual or transgender without discriminating against that individual based on sex." *Id.* at 1741. The Court thus gave "Title VII's broad language" its full reach, declining to recognize a "tacit exception" to the "general statutory rule." *Id.* at 1747.

Bostock reaffirms several principles relevant here: Courts should stick to "the law as written," rather than "disregard its plain terms based on some extratextual consideration," *id.* at 1749; "if Congress had wanted to address [subject] matters in [a statute], it would have referenced them specifically," *id.* at 1746; and courts should not "abandon the statutory text" in favor of an "appeal to assumptions and policy," *id.* at 1749. Those same principles are reflected in this Court's decision invalidating the Advisory Opinion. *See* D.I. 78 at 1 ("The Court's role … is to set aside any personal views it may hold on these matters" and to focus on "the text of the 340B statute"); *id.* at 20 ("If Congress intended to include agents within the definition of 'covered entity,' it evidently knew

how to do so."); *id.* at 24 ("that kind of policymaking is for Congress, not this Court").

The government invokes *Bostock* for the proposition that "when Congress chooses not to include any exceptions to a broad rule, *courts apply the broad rule*." Br. 14 (quoting 140 S. Ct. at 1747). But that presupposes the statute's text articulates a "broad rule." That was true in *Bostock*, where Title VII contained an express provision forbidding an employer from discriminating "'because of' sex." 140 S. Ct. at 1740. The only question was "the breadth of [that] legislative command." *Id.* at 1749 (cleaned up). Here, by contrast, no "requirement" to deliver 340B-priced drugs to contract pharmacies "is contained in the statute." D.I. 78 at 22. AstraZeneca does not ask for "exceptions to a broad rule" that covers contract pharmacy sales; the 340B statute does not articulate—nor does the government identify—any such textual "broad rule."

3. The government invokes (at 13) the must-offer provision's "*additional* requirement that manufacturers cannot discriminate by treating commercial purchases more favorably than 340B purchases," yet it also admits that this requirement "in no way changed the substance of Astra's preexisting obligation." In any event, the May 17 letter does not identify any respect in which AstraZeneca treats commercial purchases more favorably. The administrative record similarly contains *no instance* in which AstraZeneca has treated commercial sales more favorably than sales to covered entities. The government's unsupported assertion (at 17) that "commercial purchasers … plainly *are* permitted to serve patients through outside dispensers" is unclear. But if it means that AstraZeneca allows any distribution model for commercial purchasers but not for covered entities, it is simply incorrect.

The equal-treatment principle also shows why the government is wrong to argue (at 16-17) that the 340B program would fall apart unless this Court reads into it an implicit obligation to deliver 340B drugs to unlimited contract pharmacies. If AstraZeneca "require[d] each covered

entity across the nation to physically pick up their purchased drugs from AstraZeneca's warehouse," or "require[d] covered entities to pay only in pennies," Gov. Br. 16, that would treat covered entities differently than commercial purchasers. But AstraZeneca's actual policy treats them the same. Indeed, the equal-treatment provision *refutes* the government's view that manufacturers must deliver 340B drugs anywhere covered entities want—"be it the lunar surface, low-earth orbit, or a neighborhood pharmacy," AR 6834—even if they would *not* do so for commercial customers.

B. The Government's Policy and Purpose-Based Arguments Are Misguided

Rather than identify relevant statutory text, the government's brief relies heavily (at 16-23) on arguments rooted in policy concerns and supposed congressional purpose. In addition to being "ground[s] not actually relied on by the agency," *Borovsky v. Holder*, 612 F.3d 917, 920 (7th Cir. 2010) (citing *Chenery*), these arguments are unpersuasive.

First, the government invokes a "presumption against ineffectiveness," under which a construction should be disfavored if it "would frustrate Congress' manifest purpose." Gov. Br. 16 (citations omitted). Even if the government were right about what Congress had in mind for the 340B program, the Supreme Court has explained that "it is ultimately the provisions of th[e] legislative commands rather than the principal concerns of our legislators by which we are governed." *Bostock*, 140 S. Ct. at 1749 (quotation marks omitted). But the government is *not* right about Congress's purpose: The "best evidence of Congress's intent is the statutory text." *NFIB v. Sebelius*, 567 U.S. 519, 544 (2012), which contains no language indicating that the 340B program was intended to facilitate arbitrage profits for covered entities *at all*—much less through contract pharmacy sales. Indeed, all relevant textual "clues … militate against th[at] view." D.I. 78 at 20.

The government's argument starts (at 16) with the incorrect assumption that "Congress' manifest purpose" in enacting Section 340B was to maximize covered entity profits. *But see* D.I. 78 at 21 ("The legislative history is of no greater assistance to the government."). To the contrary,

Congress was concerned about rising "[p]rices paid for outpatient drugs by the [Department of Veterans Affairs], and some Federally-funded clinics and public hospitals"—that is, their rising out-of-pocket expenses. AR 32. Congress accordingly enacted the 340B program to "giv[e] these 'covered entities' access to price reductions." AR 33. That purpose is served by requiring manufactures to sell discounted drugs to covered entities themselves, a requirement with which AstraZeneca's policy complies fully. The government stresses (at 16) that "in 1992 when the statute was enacted, only 5% of covered entities had an in-house pharmacy." But those were precisely the covered entities to whom Congress wanted to "giv[e] … access to price reductions." AR 33.

Nor does AstraZeneca's policy render the 340B statute "toothless in practice." Gov. Br. 17. *Every covered entity* can participate in the 340B program under AstraZeneca's policy, either by purchasing drugs directly or through a designated contract pharmacy. But perhaps the clearest refutation of the government's ineffectiveness argument comes from HRSA itself: Its "1996 Guidance limited covered entities to using no more than a single contract pharmacy," and "AstraZeneca's new policy … would not have run afoul of the 1996 Guidance." D.I. 78 at 12. The government's accusation (at 18) that AstraZeneca's policy would render the statute "meaningless in practice" thus is equally an accusation against HRSA's own approach for half of the 340B program's lifespan (1996 through 2010). And indeed, it was the *first* half—when HRSA was far closer to "the backdrop of real world facts" against which "Congress legislate[d]." Gov. Br. 16.

Ultimately, when the government points (at 18) to modern-day "practical realities," it is expressing a policy view that the 340B program would function better if AstraZeneca rescinded its approach—that the program would make a larger impact, that covered entities would earn more profits, that more patients would benefit. AstraZeneca shares the government's concerns about access and is committed to working with covered entities to ensure that every patient can obtain needed medicines at prices they can afford. But the question in this case is not about policy, but

what the statute requires. "Achieving a better policy outcome … is a task for Congress, not the courts." *Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A.*, 530 U.S. 1, 13-14 (2000).

Second, the government (at 19) "respectfully urges this Court to reconsider its assessment of the legislative history." The government does not address—much less attempt to satisfy—the legal standard for reconsideration. *See* Fed. R. Civ. P. 54(e), 59(e), 60(b); D. Del. L.R. 7.1.5(a). In any event, the Court read the legislative history correctly the first time. Congress "specifically contemplated including language referring to drugs 'purchased by and dispensed by, or ***under a contract entered into for on-site pharmacy services with***' covered entities," but ultimately "chose not to include pharmacy services" in Section 340B as enacted. D.I. 78 at 21 (quoting S. Rep. No. 102-259 at 2 (1992)). The government (at 19) ignores the emphasized language and focuses on the "purchased and dispensed by" language that was also omitted. But once Congress had dropped the (far longer and more specific) contract pharmacy language—thereby limiting 340B discounts to sales made to covered entities themselves—there was no need to specify that the covered entity who "purchased" the drug also "dispensed" it.

Finally, the government seeks (at 20) to "bolster [its] interpretation" by relying on "HRSA's guidances." *See* Br. 20-23. As explained below, the May 17 letter is based on a faulty premise that the agency has read the statute "consistently since the issuance of its 1996 contract pharmacy guidance," AR 1, and HRSA's failure to justify its multiple changes of position independently requires vacatur. *See* pp. 10-11, *infra*. But the government's attempt to bolster its interpretation fails on its own terms. Events *after* a statute's enactment—known as "[p]ost-enactment legislative history—perhaps better referred to as 'legislative future'—[are] of absolutely no significance" in interpreting the statute's meaning. *U.S. v. SCS Bus. & Tech. Inst., Inc.*, 173 F.3d 870, 878 (D.C. Cir. 1999). Even if HRSA had adopted its current reading before the Advisory Opinion (it did not), that post-enactment view cannot alter "the meaning of a prior statute." *Id.* at 878-79.

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

The May 17 letter purports to rely solely on statutory text: It concludes that "AstraZeneca's actions … are in direct violation of the 340B statute," AR 1; quotes the must-offer provision as the operative statutory "requirement," *id.*; and asserts that "the 340B statute requires manufacturers to honor [contract pharmacy] purchases regardless of the dispensing mechanism," *id.* The letter does not purport to fill any statutory gaps, to interpret ambiguous terms, or to impose requirements besides those contained in the statute itself. *See* Gov. Br. 28 ("The Violation Letter merely enforces a *pre-existing* obligation sounding in the 340B statute itself"). Therefore, when reviewing the agency's own rationale—as *Chenery* requires—the May 17 letter is invalid because it carries forward the same "legally flawed" interpretation found in the Advisory Opinion. D.I. 78 at 17.

But insofar as the May 17 letter purports to do *more* than "simply explain what the statute already requires," Gov. Br. 30 (quoting *Metro. Sch. Dist. of Wayne Twp. v. Davila*, 969 F.2d 485, 493 (7th Cir. 1992)), then the letter is an unauthorized "legislative rule" that seeks to fill statutory silence by "creat[ing] new law, rights, or duties," *Davila*, 969 F.2d at 489 (citation omitted). Congress did not leave HRSA "a gap to fill," nor did it delegate any "authority to issue … regulations" filling gaps. *NRDC v. EPA*, 749 F.3d 1055, 1063-64 (D.C. Cir. 2014); *see* D.I. 91 at 15-20.

A. The May 17 Letter Cannot Be Upheld Based on Administrative Deference

The government does not claim that Congress has given HRSA authority to impose, through legislative rulemaking, new rights and obligations with regard to contract pharmacy sales. It nevertheless claims (at 23) that its finding of a statutory violation "is based on … its decades of expertise administering the statute and thus is entitled to deference." The government also argues (*id.*) that if the Court were to "find ambiguity in the 340B statute, it should afford deference [to HRSA's position] under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944)."

1. As an initial matter, the request for deference to "expertise" in "administering" the 340B

program is inconsistent with the government's own contention (at 23) that HRSA's letter "merely enforces a *pre-existing* obligation sounding in the 340B statute itself." An agency's "exercise [of] its judgment" is a "legislative" function, not an interpretive one. *Star Enter. v. EPA*, 235 F.3d 139, 146 (3d Cir. 2000). Courts thus do not defer to an agency's "expert judgment" when the agency bases its conclusions on textual analysis. *Nat'l Treasury Emps. Union v. Horner*, 854 F.2d 490, 499 (D.C. Cir. 1988). If the May 17 letter merely articulated what the statute itself "plainly requires," Gov. Br. 12, then HRSA cannot rely on supposed "expertise administering the statute."

Even putting aside that contradiction, the 340B statute contains no "ambiguity tied up with the provisions of the statute," *Coffelt v. Fawkes*, 765 F.3d 197, 202 (3d Cir. 2014) (citation omitted), to which HRSA's supposed "expertise" might apply. The "relevant command," § 256b(a)(1), is entirely "silent as to the role that contract pharmacies may play." D.I. 78 at 18. Neither the May 17 letter nor the government's brief identifies any "words [that] may reasonably admit of different meanings." *Mellon Bank, N.A. v. Aetna Bus. Credit, Inc.*, 619 F.2d 1001, 1011 (3d Cir. 1980).

2. *Skidmore* would not apply here even if the statute were ambiguous. "*Skidmore* deference requires a court to assign a 'weight' to an administrative judgment based on 'the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.'" *Hagans v. Comm'r of Soc. Sec.*, 694 F.3d 287, 304 (3d Cir. 2012) (citation omitted). The "consisten[cy]" of the agency's position, in particular, is among the most "important factors." *Id.* As a result, "the *Skidmore* factors counsel[] against affording the agency's interpretation deference" when the agency takes "internally conflicting positions." *Id.* (citation omitted).

The May 17 letter contains only two paragraphs of analysis, almost all of which is conclusory—far less "thoroughness" than normally required. *See OfficeMax, Inc. v. U.S.*, 428 F.3d 583, 594-95 (6th Cir. 2005) ("one-page analysis" not due any deference). But "the inconsistency with

respect to the Agency's 'earlier and later' pronouncements," in particular, "defeats any claim to *Skidmore* deference." *Hornbeck Offshore Transp., LLC v. U.S. Coast Guard*, 424 F. Supp. 2d 37, 50 (D.D.C. 2006). As this Court explained, "the government's interpretation of [Section 340B] has not been consistent" through the life of the program, and its prior claims to the contrary were "predicated" on a "false premise." D.I. 78 at 12 n.10, 16; *see id.* at 13 ("[T]he government's position on drug manufacturers' obligations with respect to participation in the 340B Program has *not* remained consistent but has, instead, materially shifted."). Beyond that, the agency's continuing failure even to "*acknowledge* (much less explain) [the] change in approach" does more than merely foreclose deference; it requires vacatur. *Id.* at 13 n.11 (emphasis added); *see* D.I. 91 at 14-15.

3. In arguing for deference, the government's brief now invokes—for the first time in the six months since this case has been pending—a guidance document from 1994. *See* 59 Fed. Reg. 25,110 (May 13, 1994) (1994 Guidance). According to the government, HRSA's position has been consistent because, beginning with the 1994 Guidance, the agency "always has understood the statute to prohibit drug makers from placing restrictive conditions on covered entities' access to 340B discounts." Gov. Br. 20 (parenthetical omitted). This argument is flawed in several respects.

First, the May 17 letter is based on HRSA's claim of "consisten[cy] *since the issuance of its 1996* contract pharmacy guidance." AR 1 (emphasis added). That period obviously excludes the 1994 Guidance if the letter is judged "on the same basis articulated … by the agency itself." *Burlington Truck Lines, Inc. v. U.S.*, 371 U.S. 156, 169 (1962) (citing *Chenery*). While the agency has included the 1994 Guidance in the administrative record, AR 81-85, there is no indication in the May 17 letter (or elsewhere) that the agency actually relied on it. *Chenery* requires a court to consider an agency's "contemporaneous explanations," not "justifications belatedly advanced by advocates." *Regents of Univ. of Cal.*, 140 S. Ct. at 1909. Here, the government did not mention the 1994 Guidance before now—including briefing and argument *after* the May 17 letter. *See* D.I. 74;

May 27 Hr'g Tr. 65:25-66:2 (1996 Guidance is "the first relevant guidance"); *id.* 88:19-22 (agreeing that "the only guidance documents that [the Court has] to look at … are the '96 and the 2010").

Second, the 1994 Guidance reflects a fundamentally different "mode of analysis" than the May 17 letter. D.I. 78 at 11. Several of this Court's conclusions about the 1996 and 2010 Guidance hold true for the 1994 Guidance as well: The 1994 Guidance neither "cite[d] § 256b nor discusse[d] its particular provisions," but instead engaged in "programmatic gap-filling." D.I. 78 at 12. It also was "directed toward covered entities," *id.* at 11, not manufacturers; and it created "program guidelines" for covered entities to follow, 59 Fed. Reg. at 25,110; *see id.* at 25,112 ("Revised Entity Guidelines"). Indeed, when a commenter asked HRSA to "[r]equire manufacturers" to timely respond to discount requests, HRSA declined: "Because this issue deals with manufacturer guidelines, it is beyond the scope of this notice." *Id.* at 25,110. The lone reference to contract pharmacies, *id.* at 25,111, is thus much like the isolated sentences in the 1996 and 2010 Guidelines, on which the government defended the Advisory Opinion (incorrectly) as merely repeating HRSA's "consistent position over the past 24-plus years." D.I. 56 at 18 (quoting Advisory Opinion).

Third, even if the 1994 Guidance had imposed an obligation on manufacturers to deliver 340B drugs to unlimited contract pharmacies (it did not), that would only make HRSA's regulatory history *less consistent*: "[T]he 1996 Guidance limited covered entities to using no more than a single contract pharmacy," and AstraZeneca's current policy "would not have run afoul of the 1996 Guidance." D.I. 78 at 12. Of course, that single-pharmacy limitation renders implausible the government's insistence (at 21) that the 1994 Guidance had "made plain"—two years earlier—"that manufacturers *may not* place limitations on [contract pharmacy] sales to covered entities." But even if the government were right about the 1994 Guidance, that would add yet another row to the table showing how HRSA's views have "materially shifted." D.I. 78 at 13 (table); *see id.* at 14 (HRSA's "interpretation" has "shift[ed] every time that HHS changes its guidance").

B. The Record Exemplifies HRSA's Arbitrary and Capricious Process

The government (at 3) claims that "voluminous evidence" in the administrative record, largely consisting of complaints the agency collected from covered entities, supports its conclusion that AstraZeneca's policy has resulted in overcharges and violates the 340B statute. But the record in fact demonstrates that the May 17 letter was not the result of reasoned decision-making.

1. This round of litigation is the first time the government has shown these complaints to AstraZeneca. HRSA's refusal even to provide AstraZeneca an opportunity to respond to these allegations belies the government's claim (at 2) that it engaged in a "transparent[]" process. By relying on complaints from covered entities—and others, like a national pharmacy chain, who are not even mentioned in the statute, Gov. Br. 8—while refusing to meet with AstraZeneca or afford it an opportunity to respond, *see* AR 7608, 7698, HRSA "completely failed to consider an important aspect of the problem" before it. *NVE, Inc. v. HHS*, 436 F.3d 182, 190 (3d Cir. 2006); *cf.* D.I. 78 at 16 n.12 ("The administrative record contains no indication that the government ever grappled with" AstraZeneca's "serious concerns about its inability to conduct effective audits").

2. The substance of the complaints underscores the arbitrariness of HRSA's decision-making process. While the government emphasizes (at 3) "over six thousand pages of complaints from covered entities," less than a quarter of those pages are complaints *against AstraZeneca*. As noted in AstraZeneca's opening brief, many are incorrect on their face: Some involve products not subject to AstraZeneca's contract pharmacy policy at all; others were submitted by entities that have never purchased AstraZeneca products; and still others are from entities that have not designated a contract pharmacy, even though they are eligible to do so. *See* D.I. 91 at 7-9 & nn.2-4.

To be sure, the May 17 letter asserts that HRSA reached its conclusion "[a]fter … an analysis of the complaints HRSA has received from covered entities." AR 1. But HRSA's mere statement "that a factor was considered … is not a substitute for considering it." *Getty v. Fed. Sav. &*

Loan Ins. Corp., 805 F.2d 1050, 1055 (D.C. Cir. 1986). Instead, the Court "must make a 'searching and careful' inquiry to determine if [the agency] actually *did* consider it." *Id.* (citation omitted); *see Gerber v. Norton*, 294 F.3d 173, 185 (D.C. Cir. 2002) ("Merely '[r]eferencing a requirement is not the same as complying with that requirement.' ") (citation omitted). The record here reflects at most that HRSA accepted at face value covered entities' boilerplate assertions that they were "forced to pay" more than 340B prices, without requesting clarification or corroboration or seeking AstraZeneca's response. That is not "*reasoned* consideration." *Getty*, 805 F.2d at 1057.

3. Even taking the complaints at face value, they do not support the May 17 letter's conclusion "that AstraZeneca's actions have resulted in overcharges." AR 1. Instead, the complaints rest on the disputed *legal* premise that this Court previously rejected—namely, that "manufacturers are required to deliver 340B drugs to an unlimited number of contract pharmacies." D.I. 78 at 20.

The government contends (at 5) that "[n]umerous providers … explained that they were forced to pay the wholesale acquisition cost for Astra's drugs." But the identified complaints actually show that the covered entities were *not* claiming that AstraZeneca sold drugs at wholesale prices *to covered entities themselves*, but rather that AstraZeneca was "withholding 340B pricing" for certain *external* "pharmacy" sales. AR 1470 (Beverly Hosp.); *see* AR 287 (Alcona Health: "Manufacturers are blocking 340B prices for drugs shipped to my contract pharmacies"), 1894 (same for CCHS Augusta), 2325 (Fam. Med. Ctr. of Mich.), 2655 (HS Ohio), 4694 (N. Country HealthCare), 6586 (Maricopa Cnty. Special Health Care Dist.). These complaints show that the covered entities simply equate unavailability of 340B prices for unlimited contract pharmacy sales with being overcharged themselves: "Our inability to access 340B pricing [through contract pharmacies] for the products listed in the attachment constitute overcharges." AR 2593; *see* AR 4445-53 (similar), 5622 (similar). In fact, 340B pricing remains available to each of these covered entities, either directly or through a designated contract pharmacy. AR 7608, 7652.

The government (at 3-5) points to complaints submitted by covered entities that "included spreadsheets showing specific transactions where the 340B ceiling price was denied and the hospital was subject to WAC prices on Astra's medications." But these are similarly premised on the disputed notion that manufacturers are required to provide 340B prices for "purchases … on all ship-to accounts established to replenish drugs to pharmacies contracted with 340B covered entities." AR 6258; *see* AR 6305, 6346, 6382, 6478; *see also* AR 1458 (providing "documentation of several Manufacturers' refusal to provide 340B pricing at the contract pharmacy level"). Nothing in the spreadsheets indicates that the covered entities *themselves* have paid more than 340B prices.

4. The government points (at 5-9) to various policy concerns expressed by covered entities in declarations submitted in the ADR process, including regarding patient access to affordable medications and financial burdens that covered entities will face absent the "'additional revenue'" they previously generated "through the spread between the 340B-discount price paid by or on behalf of some patients." Gov. Br. 6. Some of these concerns pertain to the policies and products of *other* manufacturers. For example, the government refers (*id.*) to concerns about patient access to "medications such as insulin and epinephrine," which AstraZeneca does not manufacture.

AstraZeneca takes covered entities' policy concerns seriously. AstraZeneca is committed to patient access, and to ensuring that every covered entity can obtain its products at the 340B price by direct sale or by designating a contract pharmacy. Insofar as AstraZeneca's policy has financial repercussions for covered entities and contract pharmacies that have come to rely on revenue generated through unlimited contract pharmacies, AstraZeneca will continue to work with those entities to mitigate those impacts. But these policy concerns are "for Congress, not this Court," D.I. 78 at 24, and do not bear on whether AstraZeneca's policy violates the 340B statute.

III. HRSA Cannot Assess Overcharges or Civil Monetary Penalties against AstraZeneca

A. Overcharges. The government offers no argument for how AstraZeneca could "overcharge" a covered entity—within the plain meaning of that term, or under HRSA's regulatory definition, 42 C.F.R. § 10.11(b)—apart from its reliance on covered entity complaints asserting that "Astra refus[ed] 340B pricing to covered entities." Gov. Br. 25 (emphasis omitted). Yet as just explained, those assertions are based on the incorrect *legal* premise that denying 340B pricing to unlimited contract pharmacy sales is equivalent to overcharging a covered entity. Insofar as this Court believes that the overcharge accusation depends on questions about "the now-prevalent 'replenishment model'" used for contract pharmacy sales, D.I. 78 at 22 n.19, such as whether covered entities take title, the absence of administrative record evidence or findings demonstrate that HRSA "failed to consider an important aspect of the problem" before it. *NVE*, 436 F.3d at 190.

B. CMPs. The government does not deny that the May 17 letter is final agency action, but nevertheless says (at 24-25) that AstraZeneca's challenge to the letter's CMP threat is "unripe." Yet the government provides no reason to question "the fitness of the issues for judicial decision." *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 581 (1985) (citation omitted). The CMP dispute "is purely legal, and will not be clarified by further factual development." *Id.*

Indeed, the question can be resolved based solely on what this Court has *already* decided—including that: "there is more than one permissible interpretation of the 340B statute," D.I. 78 at 17; AstraZeneca's interpretation is "reasonabl[e]," *id.* at 22; all statutory clues "militate against" HRSA's position, *id.* at 20; and AstraZeneca's policy "would not have run afoul" of HRSA's past guidance, *id.* at 12. Those conclusions, in themselves, foreclose any possibility that an overcharge by AstraZeneca (even if one existed) could be "knowing and intentional." *See* D.I. 91 at 24-26.

CONCLUSION

The Court should deny Defendants' summary judgment motion and grant AstraZeneca's.

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Respectfully submitted,

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