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June 10, 2021

VIA EMAIL

Diana Espinosa
Acting Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
Rockville, MD 20857

Re: Your Letter to Eli Lilly and Company dated May 17, 2021

Dear Acting Administrator Espinosa:

I write on behalf of Eli Lilly and Company ("Lilly") in response to your letter of May 17, 2021, following Judge Barker's Minute Order entered on May 27, 2021, in Case No. 1:21-cv-81-SEB-MJD (S.D. Ind.), concerning the 340B Program. Lilly supports the goal of ensuring that all patients have meaningful access to prescription medications. Consistent with that long-held position, Lilly participates in and supports the 340B Program as it was originally intended by Congress, and continues to offer to this day its prescription drug products at steep discounts to ***all*** covered entities (even those without an in-house pharmacy), in order to directly serve low-income and indigent patient populations.

Your letter reflects HRSA's "determin[ation]" that Lilly is not in compliance with HRSA's current interpretation of the 340B Statute, 42 U.S.C. § 256b. Contrary to views it previously expressed, HRSA now claims the 340B Statute unambiguously requires Lilly to "offer[] its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements," including where covered entities themselves do not purchase, take title to, or take possession of drugs prior to delivery to contract pharmacies.

As explained below, Lilly respectfully submits that determination is both inconsistent with the agency's prior conduct and public statements and wrong on the merits. Nor is there any lawful or reasonable basis for your threat to impose civil monetary penalties if Lilly does not accede to the agency's latest change of position. Subject to those views, and reserving all of Lilly's rights, I also address your request for an update with respect to Lilly's future plans for repayment and contract pharmacy purchases.

I. The May 17 Letter Constitutes an Unexplained and Unreasonable Departure from Prior Agency Statements and Conduct.

Your May 17 letter's "determin[ation]" that Lilly is in violation of the 340B Statute is arbitrary and capricious, in violation of the Administrative Procedure Act. Among other things, it represents an unexplained and unreasonable departure from the agency's prior positions.

To begin, your letter fails to acknowledge that HRSA has changed its views about what the 340B Statute requires from the opinion expressed in the agency's own longstanding guidance, which it has now disclaimed. ***First***, in 1996, the agency issued guidance expressly limiting permissible contract pharmacy use to no more than a single contract pharmacy per covered entity, and did not require manufacturers to honor those contract pharmacy arrangements. *See* 61 Fed. Reg. 43,549, 43,551 (Aug. 23, 1996). In 2010, the agency issued further guidance suggesting that covered entities could enter an unlimited number of contract pharmacy arrangements, but still did not claim any statutory authority to force ***manufacturers*** to ship 340B product to those contract pharmacies and indeed expressly disavowed the notion that the new guidance imposed additional burdens on manufacturers. *See* 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010) ("This guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law."). But in the HHS General Counsel's December 30, 2020 "Advisory Opinion," the agency announced its view for the first time that the 340B Statute not only requires Lilly "to deliver its covered outpatient drugs to those contract pharmacies" at "no more than the 340B ceiling price" but that it does so unambiguously, U.S. Dep't of Health & Human Servs. Office of the General Counsel, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program, at 1 (Dec. 30, 2020)—forcing the agency to disclaim its original 1996 guidance, which Lilly continues to honor.[1] ***Second***, the agency's 2010 guidance noted what the agency believed were the "essential elements" of any "contract pharmacy arrangement[]," including the requirement that "[t]he covered entity will purchase the drug, maintain title to the drug and assume responsibility for establishing its price." 75 Fed. Reg. at 10,277. Your letter, however, purports to impose a blanket requirement that Lilly "offer[] its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements," regardless of whether the covered entity ever takes title to the drugs.

But HRSA's shifting guidance was not the only reason Lilly was surprised to receive your May 17 letter. As you know, that letter comes after numerous requests by Lilly seeking either clear guidance or a meeting to obtain HRSA's or HHS's view of whether the 340B Statute imposes an obligation to extend 340B prices to or through contract pharmacies—and ***the source*** of that

[1] *See* Hearing Tr. 67:6-15, *ASTRAZENECA Pharms. LP v. Becerra*, No. 21-27-LPS (D. Del. May 27, 2021) ("THE COURT: 'So 1996 guidance, limiting it to one contract pharmacy was a wrong interpretation of the statute; correct?' MS. WESTMORELAND: 'Imposing that limitation is not consistent with the agency's understanding of the statute as expressed in the 2010 guidance and since that time.' THE COURT: 'And is that based on some amendment to the statute subsequent to 1996 guidance?' MS. WESTMORELAND: 'No, Your Honor . . . .'").

supposed obligation (*e.g.*, statute, regulation or guidance, or other provision). Rather than answering Lilly clearly, HRSA and HHS made multiple statements over the past 12 months, both in private and in public, repeatedly affirming the conclusion that there is no statutory or other binding requirement related to 340B contract pharmacy sales.

Representations and actions by HRSA and HHS, relied upon by Lilly, demonstrate that the statute is far from clear as to whether manufacturers must honor contract pharmacy arrangements or whether there is any binding authority related to the same. These include:

1. **HRSA's June 11 Response to Lilly's May 18 Letter Regarding Cialis Distribution:** On June 11, 2020, HRSA responded to Lilly's May 18 proposal to distribute Cialis directly to covered entities and certain contract pharmacies by stating that contract pharmacies are *"not independent covered entities" and that the agency's "contract pharmacy advice" was "guidance" and did not constitute "binding regulations."*

2. **HRSA's June 17 Response to Lilly's Reply to HRSA's June 11 Response:** On June 16, Lilly responded to HRSA's June 11 email confirming its understanding *"that the contract pharmacy guidance published by HRSA is advice and not a regulation, and thus does not impose binding obligations on manufacturers" and that "[a]lthough HRSA encourages Lilly to reconsider," it does "not say that we are prohibited from moving forward.*" Lilly also stated that "[i]f we have misunderstood your reply in any manner, please inform us immediately, as we will be moving forward soon." On June 17, HRSA responded only to confirm that its June 11 communication to Lilly was inadvertently addressed to an individual not affiliated with Lilly but raising no concerns about Lilly's understanding of the substance of HRSA's response.

3. **HRSA's July Response to 340B Health's Letter Regarding Cialis Distribution:** According to a July 2020 340B Health "Member Alert," HRSA corresponded with a trade association representing covered entities and stated that, in response to Lilly's Cialis distribution plan, HRSA had "reviewed Lilly's plan" and that "HRSA issued guidance in 2010 related to contract pharmacies; *however, the guidance is not legally enforceable. HRSA's current authority to enforce certain 340B policies contained in guidance is limited unless there is a clear violation of the 340B statute.*"

4. **HRSA's July 9 Statement to 340B Report:** According to a July 9 article in *340B Report*, HRSA responded to a reporter's question related to the 2010 contract pharmacy guidance by stating, "[t]he 2010 guidance is still in effect. *However, guidance is not legally enforceable. Regarding the 340B Program's guidance documents, HRSA's current authority to enforce certain 340B policies contained in guidance is limited unless there is a clear violation of the 340B statute*."

5. **HRSA's August 20 Statement to Inside Health Policy:** According to an August 20 article in *Inside Health Policy*, HRSA stated that the agency "strongly encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy

arrangements" but that "*[w]ithout comprehensive regulatory authority, HRSA is unable to develop enforceable policy to ensure clarity in program requirements across all the interdependent aspects of the 340B Program.*" HRSA noted that it was "still considering this matter."

6. **HRSA's August 26 Response to Lilly's August 19 Letter Regarding All Products:** On August 19, Lilly wrote to HRSA to inform the agency that Lilly intended to expand the Cialis distribution program described in its May 18 letter to all products. In an August 26 letter, HRSA for the first time raised the specter of civil monetary penalties but again *declined to identify any statutory violation precipitated by Lilly's contract pharmacy distribution practices*.

7. **HRSA's Failure to Respond to Lilly's Request After Lilly's August 27 Email:** On August 27, Lilly promptly responded to HRSA's August 26 letter asking HRSA to explain, preferably by August 31—before Lilly was to expand its contract pharmacy distribution program to all products—whether Lilly was in "violation of the statute" and to *"then please identify with specificity the agency's grounds for that position." HRSA never replied to that request.*

8. **HHS's September 21 Response to Lilly's July 17 Letter and Meeting Request:** Concurrently, Lilly had been seeking legal clarity from higher levels within HHS. On July 17, 2020, Lilly sent a letter to Deputy Secretary Eric Hargan and HHS General Counsel Robert Charrow explaining its understanding of the 340B Statute's requirements and requesting a meeting to discuss the Cialis distribution program. Lilly wrote to *"request a virtual meeting to discuss this matter with you at your earliest convenience and to identify options for avoiding costly and unnecessary litigation." HHS responded two months later and did not accommodate Lilly's meeting request* (though the administrative record subsequently demonstrated that the HHS General Counsel's office granted similar meetings requests from representatives of covered entities and contract pharmacies). Instead, on September 21, 2020, HHS threatened Lilly with possible civil monetary penalties and a *qui tam* action but did not clearly articulate any statutory violation related to Lilly's distribution arrangements.

9. **HHS Office of General Counsel's Failure to Respond to Lilly's September 24 Letter:** On September 24, Lilly responded to HHS's September 21 letter, stating that "[t]hese serious, converging threats are what prompted Lilly to ask HHS to confirm that it will not seek sanctions against Lilly, and consistent with HRSA's prior statements, confirm that Lilly's limited distribution program to contract pharmacies does not violate the 340B statute." Lilly also pointed out that the HHS "letter raises only the spectre of potential *qui tam* actions, not of any direct enforcement action by the government. Nonetheless, the fact that you have identified this as a 'potential consequence' is still further reason that *the government should promptly make its position clear*." *The government did not respond*.

10. **HRSA's Statement to the Government Accountability Office (GAO) in the December 14 Report:** The GAO Report documents HRSA's prior recognition that there is no clear language in the 340B Statute delineating rights or obligations pertaining to contract pharmacies. The GAO Report notes that "HRSA officials reported that there were instances among fiscal year 2019 audits in which *the agency did not issue findings for a failure to comply with guidance related to contract pharmacies in part because the 340B statute does not address contract pharmacy use* and, therefore, there may not have been a clear statutory violation."

11. **HRSA's December 14 Statement in the Preamble to the Administrative Dispute Resolution (ADR) Rule:** In the preamble to the December 14 ADR Final Rule, HRSA stated that "a panel charged with resolving [a] dispute may find it necessary to resolve related issues such as whether someone is a 'patient' *or whether a pharmacy is part of a 'covered entity.'*" 85 Fed. Reg. 80,632, 80,633 (Dec. 14, 2020). It is difficult to square HRSA's position in the May 17 letter demanding immediate and unrestricted sales to or through contract pharmacies as an unambiguous requirement under the 340B Statute with its December 14 statement that ADR panels must decide whether contract pharmacies are "part of" a covered entity.

12. **HHS December 30, 2020 Advisory Opinion:** Finally, HHS issued a final rule on this issue under the guise of a putatively "non-binding" advisory opinion. That advisory opinion "conclude[d]" *for the first time* that "a drug manufacturer in the 304B Program 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." U.S. Dep't of Health & Human Servs. Office of the General Counsel, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program, at 1 (Dec. 30, 2020). Attorneys for the government have disavowed the Advisory Opinion as just "the general counsel's advice" that has "absolutely no impact" on the totally "separate administrative process" of which the May 17 letter is a part. Hearing Tr. 40:1-11, 42:14-15, *Eli Lilly & Co. v. Becerra*, No. 1:21-cv-81-SEB-MJD (S.D. Ind. May 27, 2021).

In light of this history, Lilly is troubled by the increasingly punitive tone of the government's communications, culminating in your May 17 decision. Equally troubling was the May 17 letter's failure to acknowledge the pending litigation on this matter, much less maintain consistency with HRSA's stated position in that case. The agency's frequent changes in its understanding of the 340B Statute's relationship to contract pharmacies, and the statutory source (if any) for its preferred views, creates confusion, and is arbitrary and capricious. Federal agencies owe regulated parties, the public, and the courts a reasoned explanation when they change their mind about something. HRSA, however, has failed to provide this. In any event, as explained below, HRSA certainly cannot compound the problem by threatening to impose penalties on those who refuse to go along with the agency's latest interpretation.

II. The May 17 Letter Is Contrary to Law.

Your May 17 letter's interpretation of the 340B statute is also wrong. The 340B Statute's plain language does not require Lilly to deliver discounted drugs to contract pharmacies or to putative patients of covered entities who acquire drugs through contract pharmacies. Instead, it requires Lilly to provide 340B discounts to "each covered entity." 42 U.S.C. § 256b(a)(1). Congress identified the entities that qualify as a "covered entity" under the statute: certain children's hospitals, cancer hospitals, critical access hospitals, and family planning clinics, among others. *Id.* § 256b(a)(4). Congress's specific enumeration of these entities implies its conscious omission of contract pharmacies (and any other for-profit entities like them). *See, e.g.*, *United Dominion Indus. v. United States*, 532 U.S. 822, 836 (2001). This is especially true because Congress chose to define what the term covered entity "means"—signifying an exhaustive list—not merely what that term "includes." *See* 42 U.S.C. § 256b(a)(4); *United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1114-15 (D.C. Cir. 2009). Given the "particularization and detail" of this provision, and the 340B Statute generally, there is no plausible argument that Congress inadvertently failed to include contract pharmacies or other similar for-profit entities in defining covered entities. *Iselin v. United States*, 270 U.S. 245, 250 (1926). Nor does Congress's silence on the subject allow the agency to create new regulatory requirements the legislature did not. *See, e.g.*, *Aid Ass'n for Lutherans v. USPS*, 321 F.3d 1166, 1174 (D.C. Cir. 2003) (rejecting as "entirely untenable under well-established case law" the argument "that the disputed regulations are permissible because the statute does not expressly foreclose the construction advanced by the agency"). Neither courts nor federal agencies have any "right, in the guise of construction of an act, to either add words to or eliminate words from the language used by congress." *GE Betz, Inc. v. Zee Co., Inc.*, 718 F.3d 615, 624-25 (7th Cir. 2013) (internal quotation marks omitted).

In your May 17 letter, HRSA takes the position that Lilly is required to deliver 340B discounted drugs, not to covered entities, but to an unlimited number of contract pharmacies. That is inconsistent with the statute, and inconsistent with how the government has interpreted the statute for years. The 340B Statute applies to drugs "***purchased*** by a covered entity," and requires manufacturers to "***offer each covered entity*** covered outpatient drugs for purchase at or below the applicable ceiling price." 42 U.S.C. § 256b(a)(1). Nothing in the statute requires manufacturers to offer discounted drugs to contract pharmacies. And nothing in the statute transforms drug inventory ordered by a contract pharmacy into stock "purchased by a covered entity." *Id.* The May 17 letter, however, effectively changes Congress's commands. Instead of requiring manufacturers to offer discounted drugs to covered entities, as the statute requires, your letter purports to require manufacturers to deliver discounted drugs to contract pharmacies. That is not what the statute says—and it certainly is not ***unambiguously*** what it says, as HHS's December 30 Decision claims.

The May 17 letter's interpretive error is particularly clear in light of the way so-called "contract pharmacy arrangements" work in practice. Under the prevailing "replenishment model," contract pharmacies sell drugs out of their regular inventory to patients, and only later deduce, often through algorithms, whether a patient ***might have been*** a patient of a covered entity, which could have made a purchase subject to a 340B discount. If so, the contract pharmacy will then ask

the manufacturer to provide it with an after-the-fact credit, or possibly additional quantities of the relevant drug, at 340B discounted prices, in order to "replenish" the contract pharmacy's general inventory, all on the theory that some covered entity ***theoretically could have*** made (but, in fact, did not make) the purchase at 340B discounted prices (assuming the patient in fact was properly a patient of some covered entity). In this model, covered entities need not take title to 340B discounted drugs. Indeed, there is no sense in which ***either*** the originally dispensed drugs ***or*** the replenishment stock has been "purchased by a covered entity" from a manufacturer. *Id.* The only entity that purchases drugs in this model is a contract pharmacy, and Lilly has no statutory obligation to provide 340B discounts on such purchases.

It would strain the statutory text beyond its breaking point to accept HRSA's position that when Congress inserted the "purchased by" and "must offer" language into the 340B Statute, it meant to obligate manufacturers to acquiesce to the replenishment model and massively expand the scope of the 340B Program. Congress does not "alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions," nor does it "hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001). HRSA's reading impermissibly smuggles in a vast expansion of the 340B Program, vitiating other provisions of the 340B Statute aimed at preventing the many ills (including price arbitrage) that such an expansion would work. *See, e.g.*, 42 U.S.C. § 256b(a)(5). Indeed, given the significantly increased "opportunities for drug diversion" created by contract pharmacy schemes, it is affirmatively implausible to suggest that Congress intended to undermine its prohibitions on such diversion and upset the carefully-crafted 340B Program by endorsing such a contract pharmacy scheme—much less through such an otherwise-unassuming provision. Perhaps that is why HRSA appears to have endorsed the "replenishment model" only in 2013, as part of a policy document aimed at GPOs—and without any hint that HRSA thought manufacturers were required to participate in contract pharmacies' use of such a model. *See* HRSA, 340B Drug Pricing Program Notice Release No. 2013-1, Statutory Prohibition on Group Purchasing Organization Participation (Feb. 7, 2013). And in any case, interpreting the 340B Statute as HRSA proposes would transform it into an unconstitutional condition. It would impermissibly burden and condition manufacturers' access to Medicaid on an improper, A-to-B private wealth transfer in violation of the Takings Clause. *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 543 (2005). And it would do so without regard to the Supreme Court's requirement that such conditions be proportional to public harms. *See also Dolan v. City of Tigard*, 512 U.S. 374 (1994).

Lilly complies entirely with the requirements of the 340B Statute, properly understood. Lilly not only offers full 340B discounts to all covered entities as required, but also voluntarily allows covered entities lacking an in-house pharmacy to designate one outside contract pharmacy to receive and dispense 340B product. This policy is consistent both with the plain language of the 340B Statute and its original intent, while protecting against the abuses inherent in the prevailing contract pharmacy model, in which covered entities do not "purchase" and need not take and maintain title to drugs that are dispensed to putative patients of the covered entities, let alone before or by the time of such dispensing.

As you know, the meaning of the 340B Statute is now at issue in pending litigation before multiple federal courts. In the case currently pending before Judge Barker, Lilly has sought review under the Administrative Procedure Act of HHS's December 30, 2020 "Advisory Opinion," because (among other reasons) it is inconsistent with the 340B Statute for the reasons articulated above. In addition, at the government's urging, Lilly amended its complaint to present direct challenges to your May 17, 2021 letter and its final determination that Lilly is in violation of the 340B Statute. At the end of that litigation, it will be for the courts to determine the meaning of federal law and whose interpretation of the 340B Statute is right. Lilly will of course abide by the courts' final resolution of the merits of that question (including any appellate proceedings), and trusts that the agency will, too.

III. Lilly Should Not Be Subjected to Civil Monetary Penalties for Engaging in Good-Faith Litigation Necessary to Resolve Statutory Ambiguity.

As discussed above, the 340B Statute does not obligate drug manufacturers to provide discounted drugs to (or through) an unlimited number of contract pharmacies, let alone in which covered entities do not purchase the drugs actually dispensed to their putative patients themselves. Certainly it does not do so unambiguously, in a way that would preclude reasonable disagreement on that question. At a minimum, the agency's inconsistent positions, coupled with the length of time it took the agency to issue its (unexplained) May 17, 2021 letter, make clear that the 340B Statute is, ***at best for the agency***, ambiguous on the question of whether sales to or through contract pharmacies are required. But even if the Court ultimately concludes that HRSA and HHS are right that Lilly is obligated to provide 340B discounted drugs to an unlimited number of contract pharmacies, there would be no basis to impose civil monetary penalties for past purported "overcharges" as the May 17 letter threatens. That is so for several reasons.

First, civil monetary penalties are available only for "knowing[]" and "intentional[]" overcharges. 42 U.S.C. § 256b(d)(1)(B)(vi)(III). For all the reasons explained above and in Lilly's briefs in the pending litigation matter filed in the U.S. District Court for the Southern District of Indiana, Lilly is not knowingly or intentionally engaged in any overcharges. Rather, it is abiding by an objectively reasonable interpretation of the 340B Statute's terms and awaiting a final judicial determination about whether Lilly's interpretation is correct. Good-faith, reasonable disagreements about statutory requirements do not and cannot give rise to civil monetary penalties. *See Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 69-70 (2007) (one cannot act in reckless disregard of a statute's meaning unless one's interpretation is "objectively unreasonable"). That point has special force here, since in its 1996 Guidance, and for the majority of the 340B Program's life, ***HRSA itself*** agreed with Lilly that the 340B Statute did not require manufacturers to work through an unlimited number of contract pharmacy arrangements. *See, e.g.*, Tom Mirga, *HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020); June 11, 2020 Ltr. from HHS to Lilly in response to Lilly's Revised Distribution Plan (noting that "contract pharmacies" "are not independent covered entities" and that its "contract pharmacy advice" was "guidance" and not "binding regulations"); 61 Fed. Reg. at 43,550, 43,555. In proceedings before the U.S. District Court for the District of Delaware, the government has now disclaimed that interpretation. *See supra* n.1. To put it mildly, the agency's acknowledged

confusion about the 340B Statute's meaning renders civil monetary penalties inappropriate. Indeed, it demonstrates that manufacturers do not act knowingly and intentionally by declining to adopt the agency's evolving position: If the agency itself could not consistently and clearly identify the statutory command that Lilly is supposedly violating, then it cannot ascribe willfulness to Lilly's failure to agree with the agency's ultimate view.

Second, civil monetary penalties would not be authorized by HHS's own regulations under these circumstances. HHS's own civil monetary penalties rule explains that "it 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." 82 Fed. Reg. 1,210, 1,224 (Jan. 5, 2017); *see also* 42 C.F.R. § 10.11(b) (defining "an instance of overcharging" as "any order for a covered outpatient drug, by NDC, which results in a covered entity paying more than the ceiling price … for that covered outpatient drug."). Contrary to that clear instruction, your May 17 letter appears to treat as an overcharge Lilly's refusal to honor contract pharmacies' requests for chargebacks—*i.e.*, to be reimbursed money for drugs the contract pharmacy (not the covered entity) purchased and then dispensed to a patient. That is not an overcharge, and civil monetary penalties do not attach to it. Moreover, HHS's regulations on civil monetary penalties also make clear that there can be no overcharge if "a covered entity did not initially identify the purchase to the manufacturer as 340B-eligible ***at the time of purchase***." 82 Fed. Reg. at 1,221 (emphasis added). But as explained above, under the replenishment model, ***no one*** determines 340B eligibility "at the time of purchase." Rather, contract pharmacies purportedly do that retrospectively.

Third, your threat to impose thousands of dollars in civil monetary penalties for ***each instance*** of alleged overcharges, in addition to repayment, would be unconstitutionally disproportionate. That is true both under the Excessive Fines Clause, *see Austin v. United States*, 509 U.S. 602, 609-10 (1993), and the Due Process Clause, *see State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408, 425 (2003). This would be especially excessive on those "penny priced" 340B products at which Lilly is already effectively giving the product for free to 340B covered entities.

IV. Lilly's Future Plans Regarding Contract Pharmacy Purchases.

The May 17 letter requests that Lilly "provide an update on its plan to restart selling, without restriction, covered outpatient drugs at the 340B price to covered entities that dispense medications through contract pharmacy arrangements." At present, it is Lilly's plan to await and abide by the courts' final resolution of the merits of the question presented in the instant litigation, and trusts that the agency will, too. In the event the courts find that manufacturers must honor an unlimited number of contract pharmacy arrangements, Lilly will work to establish a mechanism that ensures those arrangements are agency relationships where the covered entity actually (1) makes the purchase in advance of the 340B product being dispensed, (2) takes and maintains title, and (3) assumes responsibility for establishing the price, not delegating that to the contract pharmacy.

* * *

For all those reasons, we urge you to rescind your May 17, 2021 letter's determination; withdraw the threat to seek civil monetary penalties to punish Lilly for disagreement with HRSA's latest interpretation of the 340B Statute; and await a decision on the merits from the Article III courts charged with saying "what the law is."

Sincerely,

/s/ John C. O'Quinn, P.C.
John C. O'Quinn, P.C.
Counsel for Eli Lilly and Company

CC: Andrew A. Kassof, P.C.
Kate Talmor, U.S. Department of Justice