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June 3, 2026

Via E-mail and USPS Certified Mail

The Honorable Thomas J. Engels
Administrator
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

The Honorable T. March Bell
Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, S.W.
Washington, DC 20201

RE: Eli Lilly's June 1, 2026 Letter

Dear Administrator Engels and Inspector General Bell:

We are the law firm identified in Eli Lilly's June 1, 2026, letter to Administrator Engels.[1] We write because Lilly misrepresented our interactions in an apparent attempt to mislead HHS as part of its continued efforts to wrest oversight and enforcement authority away from a federal agency and install itself as the 340B Program's *de facto* administrator.

Between May 15, 2026, and May 29, 2026, Hall Render participated in approximately twelve meetings with Lilly personnel as legal counsel to our clients. We joined each of these calls at our clients' individual requests. There was, and continues to be, no coordination among our clients regarding their actions with respect to Eli Lilly. Instead, now that it is finally listening to covered entities, Lilly is apparently frustrated by the fact that our clients independently sought, received, and acted on sound legal advice to have counsel present in meetings with a drug manufacturer seeking to compel the production of non-standard Protected Health Information. Below, we present the facts in response to Lilly's baseless allegations and affirmative misrepresentations.

[1] Letter from Eli Lilly & Co., to Honorable Thomas J. Engels, Adm'r, HRSA (June 1, 2026).

1. Covered Entities Are Not Coordinating a "Boycott" of Lilly.

Lilly's hyperbolic and conclusory rhetoric about a "boycott" is unfounded. Lilly provides no evidence (because it cannot) that covered entities engaged in any collective action, much less a "boycott." Instead, covered entities each are independently seeking, receiving and unilaterally acting on sound, objective and, unsurprisingly, consistent legal advice. Moreover, Lilly's boycott claims are implausible—the covered entities' position here could not result in anticompetitive effects and, instead, promote efficiency.

Each of these meetings between a covered entity and Lilly was scheduled for fifteen minutes, although some lasted as few as six minutes. Lilly personnel on the calls included Lilly's SVP of Government Strategy and Federal Accounts, its Senior Director of Specialty Accounts, and Lilly's in-house legal counsel. During these meetings, we informed Lilly on behalf of our clients that legality is a threshold issue. Lilly repeatedly assured our clients that it took their HIPAA concerns seriously and would provide a written analysis. It never did so. Instead, it sent you its June 1st letter.

2. Our Clients' Objections Are Not Pretextual.

Just because our clients' concerns are simply stated, Lilly assumes they are pretextual. They are not. No court has ever analyzed a demand like Lilly's. In fact, the only time a court has considered Lilly's restrictions on 340B shipments, it determined that Lilly cannot create unilateral, extra-statutory restrictions on 340B pricing.[2] And the only time a federal court of appeals addressed a manufacturer's data submission requirements, it considered only technical burden, not whether the disclosure was HIPAA-compliant. Further, the court qualified its conclusion, stating that the only evidence in the record was a declaration from a manufacturer's employee.[3]

No federal court has addressed this issue, and neither the law nor the facts are on Lilly's side. Contrary to Lilly's assertion that covered entities only submit de-identified data, the HIPAA Expert Determination regarding the 340B ESP platform ***states that it reidentifies patient information***. It goes on to state that the platform "ensure[s] that the Medical Benefits Claims Data it receives is fully de-identified when in Second Sight's control, **not when in the hands of the** covered entities or **pharmaceutical manufacturers**."[4] That means that when covered entities' data is "disclosed" to manufacturers, it still constitutes Protected Health Information under and subject to the HIPAA Privacy Rule: "*Disclosure of a code or other means of record identification designed to enable coded or otherwise de-identified information to be re-identified constitutes disclosure of protected health information*[.]"[5]

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[2] Amended Partial Final Judgment, *Eli Lilly & Co. v. HHS*, No. 21-cv-00081, at 2 (S.D. Ind. Apr. 14, 2022) ("42 U.S.C. § 256b, correctly construed, does not permit drug manufacturers . . . to impose unilateral extra-statutory restrictions on their offer to sell 340B drugs to covered entities . . . .").

[3] *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 463 (D.C. Cir. 2024).

[4] BRADLEY MALIN, EXPERT'S ASSESSMENT OF SECOND SIGHT 340B ESP™ DE-IDENTIFICATION PROCEDURES FOR MEDICAL BENEFITS CLAIMS DATA 19 (2026) (emphasis added).

[5] 45 C.F.R. § 164.502(d)(2)(i) (emphasis added).

It is incumbent on Lilly to explain what HIPAA exception applies to the disclosure it demands, which our clients' have consistently asked Lilly to do. Lilly's analysis should address the plain language of the Privacy Rule and how that impacts the characterization of the data being shared. Instead of analyzing the law, however, Lilly cites a webpage. And despite being presented with these concerns more than three weeks ago, Lilly to date has not provided any legal analysis (i) responding to the concern that the requested data constitutes Protected Health Information under HIPAA, and not de-identified information, due to its ability to be re-identified; or (ii) explaining what HIPAA exception would authorize the disclosure of such Protected Health Information to the manufacturer under HIPAA.

Legality is a threshold issue. An offer that requires covered entities to violate the law is simply not a *bona fide* offer, and any manufacturer—Lilly included—that enforces such an offer has violated its Pharmaceutical Pricing Agreement.

3. 340B Covered Entities Have Not In Fact Acquiesced to Lilly's Threats.

Lilly tried to convince you and our clients that its policy is inevitable, claiming in its letter and in our clients' meetings that "the overwhelming majority" of covered entities have acquiesced to Lilly's demands."[6] But in January, Lilly told you that 800 covered entities were already submitting data voluntarily. Now, in June, only 1,550 more are submitting data. There are 27,000 covered entities in the 340B Program; less than 9 percent have given in to Lilly's threats. Lilly also trumpets that it has received nearly 800,000 claims since January 1, 2026. That means each acquiescing entity has submitted, on average, a paltry 340 claims. Lilly's numbers don't add up and are constructed to offer a misleading narrative of broad capitulation that does not withstand scrutiny. It is simply trying to normalize nonstandard practices in an effort to abdicate its obligations under the 340B Program.

4. Lilly's Policy Is Itself Pretextual.

Lilly wants you to believe that its demands are tailor-made to address a problem. But Lilly's claims about pervasive duplicate discounts are smoke and mirrors. In January, Lilly told you it suspected that it paid 57,000 Medicaid duplicate discounts in 2022. Lilly chose not to mention that Medicaid paid for *more than 6 million prescriptions for Lilly's products* in the same year. That is an error rate of less than 1 percent.

During our meetings, Lilly told our clients it wanted patient data so it could avoid duplicate discounts in Medicaid and Medicare. We asked why Lilly then demanded data for all payors. We also asked how that demand would meet HIPAA's "minimum necessary" requirement.[7] Lilly had no answer.

The likely answer is found in the very website Lilly cited in its letter to you. There, the 340B ESP platform's terms and conditions state that submitted data may be used "in order to…

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[6] Letter from Eli Lilly & Co. to HRSA, *supra* note 1.

[7] *See* 45 C.F.R. §§ 164.502(b), 164.514(d).

evaluate compliance with Participating Pharmaceutical Manufacturers' policies."[8] Said more plainly, Lilly apparently intends to use covered entities' data to stand in the shoes of a regulatory agency to investigate and enforce compliance with its own self-serving interpretation of the law.

5. 340B Covered Entities Are Not Opposed to Transparency.

Lilly tries to paint covered entities as the problem, claiming that they are opposed to 340B transparency "in any form[.]"[9] This is laughably wrong. Since 2023, at least fifteen states have enacted laws requiring covered entities to report 340B claims data in some form or fashion. As far as we are aware, not a single covered entity or trade group has sued to oppose these laws. In contrast, about twenty-one states have passed laws requiring manufacturers to ship 340B drugs to contract pharmacies, and a drug manufacturer or PhRMA (Lilly's trade group with a budget exceeding $500 million) has sued to challenge every single one of them.

In reality, covered entities only oppose manufacturers' twisted version of transparency, where drug companies bully safety-net hospitals and clinics into turning over patient records in the search of more profits. Lilly began turning the screws on covered entities in September 2020. Since then, it has paid out more than $24.3 *billion* in shareholder dividends,[10] it has achieved a market capitalization of over $1 trillion, and its stock price has increased more than seven-fold. The issue is not transparency. It is, and always has been, about money.

6. HRSA Should Not Take Lilly's Bait.

Lilly's letter is base lawfare and lobbying. We doubt that HHS leaked Lilly's letter to the press. That was likely Lilly's doing. We assume that Lilly is trying to bait HRSA into action. It would love for HHS to step in and declare Lilly's policy unlawful, creating an opportunity for the manufacturer to sue HHS before it can complete a full investigation into Lilly's piracy. This is the same playbook Lilly and other manufacturers used in 2021.

We instead urge HHS to open an investigation through the Office of Inspector General. Lilly's June 1st letter is an admission it will soon knowingly and intentionally overcharge 340B covered entities for covered outpatient drugs in violation of the 340B statute. This conclusion flows from basic logic:

- The 340B statute requires that a manufacturer make a *bona fide* offer to a covered entity.[11]
- An offer that requires a covered entity to violate the law cannot be a *bona fide* offer.

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[8] 340B ESP™ Covered Entity Portal Terms of Use, 340B ESP, https://340besp.com/terms-of-use (October 4, 2024).

[9] Letter from Eli Lilly & Co. to HRSA, *supra* note 1.

[10] To add context to this astounding number, 24.3 billion seconds ago, it was the year 1256, and England had not yet called its first parliament.

[11] *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 462 (D.C. Cir. 2024) ("[S]ection 340B does require drug manufacturers to make an 'offer,' and even the manufacturers concede that this means at least a bona fide offer.").

- Lilly's offer requires covered entities to disclose Protected Health Information, yet Lilly has not identified which HIPAA exception would permit this disclosure.

An OIG investigation into Lilly would be justified both legally and financially. As the party pressing for changes, Lilly bears the burden of proving that its policy is lawful. At the very least, it should demonstrate that it applied critical thought to its plans before upending the 340B Program. It failed to do so when we asked on behalf of our clients, and it is now threatening to punish covered entities for exercising appropriate due diligence. Now, OIG should ask the same question on behalf of the American people.

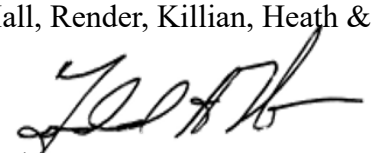
As to return on investment, Lilly admits that it is sitting on 800,000 claims' worth of coercively obtained data that its vendor's terms and conditions allow to be monetized.[12] If each of these were an overcharge, Lilly could owe more than $5.7 billion in civil monetary penalties.[13]

Finally, Lilly's superficial analysis of patient privacy rules raises substantial questions regarding its own confidentiality practices. Lilly's National Drug Rebate Agreement requires it to hold states' drug utilization data confidential and to "observe confidentiality statutes, regulations, and other properly promulgated policy concerning such data."[14] Lilly uploads the states' data to 340B ESP. If the data license Lilly grants to Second Sight is anything like the license Second Sight demands of covered entities, Lilly may be violating its NDRA on a daily basis.

As always, we would be honored to work with HHS to help stabilize the 340B Program. We can be reached at the contact information above.

Respectfully yours,

Hall, Render, Killian, Heath & Lyman, P.C.



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[12] 340B ESP, *supra* note 8 ("[Covered Entity] grant[s] Second Sight a worldwide, sublicensable, non-exclusive, royalty-free, perpetual, irrevocable license to collect, process, disclose, create derivative works of and otherwise use the Covered Entity Claims Data . . . .").

[13] Of course, HRSA's regulations use a per-order, not per-claim analysis. 42 C.F.R. § 10.11(b). Since Lilly has chosen only to disclose the number of claims it possesses, calculating a per-order penalty is impossible at this stage.

[14] Announcement of Medicaid Drug Rebate Program National Rebate Agreement, 83 Fed. Reg. 12,770, 12,786 (Mar. 23, 2018).