



September 21, 2020

Anat Hakim
Senior Vice President and General Counsel
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285

Dear Ms. Hakim:

I am responding to your September 8, 2020 letter to the Deputy Secretary and me. In that letter, you requested a pre-enforcement advisory opinion (“AO”) as to whether Lilly’s new unilateral policy involving the 340B program would subject Lilly to sanctions. Under that policy, Lilly will cease extending 340B pricing to pharmacies under contract with covered entities, unless the covered entity lacks an in-house pharmacy.¹ In such a case, Lilly will extend 340B pricing to only one designated contract pharmacy. As we understand it, Lilly has already implemented that policy for Cialis and has since extended the same policy for its other covered outpatient drugs.

As we have indicated in earlier correspondence, although the Health Resources and Services Administration (“HRSA”) has significant initial concerns with Lilly’s new policy, it continues to review that policy and has yet to make a final determination as to any potential action. Correspondingly, Lilly cannot and should not view the absence of any questions from the government as somehow endorsing Lilly’s policy especially when this Department is leading the government’s response to the COVID-19 pandemic.

In the interim, we have four concerns with your letters that do not relate to the legal propriety of your unilateral price increases.

First, Lilly sought to unilaterally impose an artificial deadline on HRSA’s decision-making when it asserted in its May 18, 2020, letter to HRSA that unless it heard from HRSA to the contrary by June 30, 2020, it would assume that HRSA had no objections to its price restructuring for Cialis and would implement the same on July 1. Lilly imposed a similar set of deadlines for the rest of its drugs, indicating in its August 19, 2020 letter to HRSA that unless Lilly heard to the contrary by August 31, 2020, it would begin charging higher prices to pharmacies under contract with covered entities serving the disadvantaged on September 1. Lilly cannot and should not seek to impose such deadlines on the government’s deliberations—especially when HRSA is playing a pivotal role in responding to an unprecedented pandemic. Nor is Lilly entitled to know the substance of those ongoing deliberations.

¹ In addition to the September 8 letter from you, Lilly has submitted four other letters with respect to its proposal to scrap 340B pricing to contract pharmacies—dated August 27, 2020, August 19, 2020, July 17, 2020, and May 18, 2020.

Second, Lilly's decision to interpret HRSA's responses as tantamount to definitive agency agreement with Lilly's position is incorrect. As noted above, HRSA is still evaluating how to proceed.

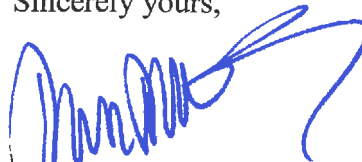
Third, Lilly's designation of its letters of September 8 and May 18 as exempt from disclosure under FOIA Exemptions 4, 6, and 7 and containing trade secrets under 18 U.S.C. § 1905 is fundamentally in error. Exemption 4 covers trade secrets and commercial confidential information. Lilly's legal position is neither. Moreover, we could find nothing in any of your letters that qualifies as either a trade secret or commercial confidential information. Exemption 6 relates to "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." We could find nothing in any of the Lilly letters that would qualify for this exemption. Exemption 7 relates to law-enforcement records. It is unclear why Lilly believes that Exemption 7 applies.

Fourth, we believe that the timing of your pricing changes is, at the very least, insensitive to the recent state of the economy. Although the economy is rebounding at a record rate, the unemployment and under-employment rates are still temporarily higher than at the beginning of the year due to COVID-19. Many Americans and many small businesses have had difficulty making ends meet. Lilly, on the other hand, seems to be enjoying an outstanding year. The price of Lilly's stock has increased by more than 11 percent since January 1, 2020, reflecting, among other things, the fact that your company's comprehensive income jumped from \$1.414 billion during the second quarter of 2019 to \$1.615 billion for the second quarter of 2020, an increase of more than 14 percent.

In contrast, during this same period, most health care providers, many of which are covered entities under section 340B, were struggling financially and requiring federal assistance from the Provider Relief Fund established by the CARES Act. Many continue to struggle and depend on emergency taxpayer assistance. It is against this backdrop that you are effectively increasing the prices of 10 mg and 20 mg Cialis by more than 500,000 percent and have done the same for other drugs in your portfolio.

In your letter, you noted that at least one covered entity has been the subject of a *qui tam* False Claims Act suit arising, in part, out of the 340B program. See Letter to the Deputy Secretary from Ms. Hakim (Lilly) at 2 n.6 (July 17, 2020); Letter to Rear Admiral Pedley from Mr. Asay (Lilly) at 11 n.36 (May 18, 2020). Please bear in mind that a similar suit against Lilly is a potential consequence in the event that Lilly knowingly violates a material condition of the program that results in over-charges to grantees and contractors.

Sincerely yours,



Robert P. Charrow
General Counsel