## United States Senate

WASHINGTON, DC 20510

March 11, 2025

Demetri Karagas Chief Executive Officer Thirty Madison, Inc 3701 Broadway, Apt 3A Astoria, NY 11103

Dear Mr. Karagas:

Through a partnership with Cove, a subsidiary of Thirty Madison, Eli Lilly has launched a new telehealth platform that links patients interested in receiving its migraine medication, with a health care provider from Cove who can virtually prescribe the pharmaceutical. This manufacturer-sponsored arrangement, LillyDirect, appears intended to steer patients toward particular medications and creates the potential for inappropriate prescribing that can increase spending for federal health care programs. We write to learn more about the financial relationship between Eli Lilly and Cove given the potential implications for the federal Anti-Kickback Statute (AKS).

Direct-to-consumer (DTC) advertising of prescription drugs has been shown to increase both patient demand for specific medications and the likelihood of a patient receiving a prescription for that drug. Pharmaceutical manufacturers like Eli Lilly spend an estimated \$6 billion annually in DTC advertising to boost patient awareness and demand for advertised medications. The U.S. is one of only two developed countries in the world that permits such advertisements. The American Medical Association has stated, "direct-to-consumer advertising inflates demand for new and expensive drugs, even when these drugs may not be appropriate."

A recent study found that more than two-thirds of drugs advertised on television were considered "low therapeutic value." This creates concern for taxpayers, as a review by the Government Accountability Office found that the small number of prescription drugs advertised on television accounted for 58 percent of Medicare's overall spending on prescription drugs between 2016-2018. For example, these DTC advertisements helped to balloon Medicare spending on Eli Lilly's Trulicity to more than \$6.2 billion in 2022.

Telehealth can help to address barriers to care, including by expanding access for patients facing transportation barriers, helping to overcome stigma, and identifying providers when there may be workforce shortages. But those important aspects of care can be undermined without comprehensive services that ensure a thorough patient evaluation and follow-up, especially if there is any appearance of a conflict of interest for the treatment provider.

The launch of Eli Lilly's telehealth platform raises questions about the nature of Eli Lilly's relationship with its contracted telehealth prescribers and the potential for inducement of prescriptions payable by federal health programs. The Department of Health and Human Services' Office of the Inspector General (HHS OIG) warns, "as a physician, you are an attractive target for kickback schemes because you can be a source of referrals for ... health care

... suppliers." The HHS OIG adds, "many ... companies want your patients' business and would pay you to send that business their way."

After describing Eli Lilly's medications and the benefit they can have for patients, Eli Lilly's telehealth platform provides a link for patients to instantly connect with a doctor and fill prescriptions via an online pharmacy. This creates the impression that any patient interested in a particular medication can indeed receive it with just a few clicks, and the appearance of Eli Lilly's approval that these chosen providers can ensure a patient receives the given medication.

In 2022, the HHS OIG issued a Special Fraud Alert to notify health care practitioners of the specific risks of schemes involving telehealth platforms that "intentionally paid physicians ... kickbacks to generate ... prescriptions for medically unnecessary ... medications, resulting in submission of fraudulent claims to Medicare [and] Medicaid." According to the HHS OIG, fraudulent aspects of these arrangements for prescribers may include: limited interaction with the purported patient, limited opportunity to review the patient's medical records, and/or a directive to prescribe a preselected item, regardless of clinical appropriateness.

The nature of the LillyDirect platform appears to reflect many aspects of the HHS OIG warning for potential fraud. Unsurprisingly, a patient coming straight from Eli Lilly's website to a telehealth appointment with a prescriber chosen by Eli Lilly is overwhelmingly more likely to ask for Eli Lilly's medication. Indeed, Eli Lilly's CEO stated, "patients report kind of doctor shopping to find someone who will write them what they know is a solution." Further, that prescriber may have an incentive to prescribe such medication, whether or not it is medically necessary or clinically appropriate. Payments by Eli Lilly hold the potential to induce specific actions of the prescribing pen.

These concerns are underscored by statements in the "How does Cove work?" section of Cove's website about its business model, in which a patient first purchases a treatment plan prior to beginning the consultation process with a medical provider, which Coves states typically takes only "10 minutes." Cove further states that "As soon as your Cove provider determines the best medications for your migraine, you'll receive an email asking you to approve your treatment plan." Not only does this create the impression that the patient will almost certainly leave with a medication, rather than letting the medical evaluation dictate the treatment course, but it suggests that a consultation with a health care provider about a medical condition is the same as an online shopping experience.

To better understand the nature of Eli Lilly's relationship with Cove, we request written responses to the following questions by April 15, 2025:

- 1. Are any forms of insurance excluded from eligibility or participation with the LillyDirect/Cove page? Please list which types of insurance are not eligible to participate.
- 2. Does Eli Lilly direct, encourage, or educate Cove-affiliated health care providers to prescribe Eli Lilly's medications?

- 3. Did Eli Lilly share, consult, or communicate with Cove in creating the "discussion guide" for patients to speak with their Eli Lilly-linked telehealth provider?
- 4. What is the average duration of the virtual health care visit between a Coveaffiliated health care provider and a patient who is connected to them via LillyDirect?
  - a. Your website suggests that, "in most cases, you'll only interact with your Cove provider via Cove's secure messaging portal." After initially filling out information, are such visits always conducted via a video platform, or are there other options available?
- 5. Do Cove-affiliated health care providers always review the medical history and records of a patient who is connected to them via Eli Lilly's website? If so, please describe in detail how those records are always accessed.
- 6. Are Cove-affiliated health care providers restricted in any way on which medications they can prescribe?
  - a. Are Cove-affiliated health care providers encouraged or rewarded in any way to prescribe certain medications? If so, please describe.
- 7. Does the patient/customer select or identify medication they are interested in obtaining prior to, or during, the consultation?
  - a. If so, what limitations are there on the medications a patient/customer can select?
- 8. How many pharmaceutical companies does Cove have a contractual relationship with for telehealth services, aside from Eli Lilly?
- 9. How did Eli Lilly set the compensation paid to Cove? Please provide a copy of the terms of agreement between Eli Lilly and Cove.
  - a. What is the duration of the contract term between Eli Lilly and Cove?
  - b. What is the amount of the financial payment by Eli Lilly and Cove under the contract?
  - c. Is Eli Lilly paying fair market value for the services of Cove? Is Eli Lilly paying more for such services than other pharmaceutical companies are paying Cove for such services?
  - d. Does Eli Lilly make a bonus payment to Cove based on the number of prescriptions written, including refills?
  - e. Does Eli Lilly contract with Cove to furnish a certain number of prescriptions for certain medications?
  - f. Would the Cove-affiliated health care provider have actual or constructive knowledge that a patient was referred to them via Eli Lilly's telehealth platform?
  - g. What performance metrics are included in the contract for Eli Lilly's evaluation of its contract with Cove and affiliated health care providers?

- 10. What data is being provided by Cove to Eli Lilly as part of these agreements? Please list all fields or categories of data being provided to Eli Lilly, including patient information, consumer behavior information, and marketing outcomes information.
- 11. What role, if any, does Eli Lilly play in collecting, defraying, or otherwise interacting with the co-pay that is associated with the Cove provider consultation through LillyDirect?
  - a. If no prescription is issued, is the consultation fee waived, refunded, or reduced?
- 12. Across all clients and services, what percentage of consumers who meet virtually with a Cove-affiliated health care provider receive a prescription?
  - a. How many total (broken out by new and refill) prescriptions did Coveaffiliated health care providers write over the most recent six-month period?
  - b. Of that total, how many were for an Eli Lilly medication?
  - c. What percentage of all consumers who meet virtually with a Coveaffiliated health care provider receive a prescription for an Eli Lilly medication?
  - d. What percentage of all such consumers receive a prescription for a medication manufactured by another brand-name company?
  - e. What percentage of all such consumers receive a prescription for a generic medication?
  - f. What percentage of all such consumers receive no prescription?
- 13. How many individual prescribers affiliated with Cove offer telehealth services under the Eli Lilly contract via LillyDirect?
  - a. How many of those individuals are independent contractors with Cove?
  - b. Does Eli Lilly have knowledge of who the individual prescribers are that are connected to patients via Cove?

Thank you for your attention to this matter. We look forward to your response.

Sincerely,

Richard J. Durbin

United States Senator

Elizabeth Warren

United States Senator

Peter Welch

United States Senator

Bernard Sanders

United States Senator