

United States Senate

WASHINGTON, DC 20510

October 21, 2024

David Ricks
Chair and CEO
Eli Lilly & Company
893 S. Delaware Street
Indianapolis, IN 46285

Dear Mr. Ricks:

Eli Lilly recently launched a new telehealth platform, LillyDirect, that links patients interested in receiving specific medications with a health care provider who can virtually prescribe that medication. This manufacturer-sponsored arrangement 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 its chosen telehealth prescribers, 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 health claims. 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 added value.” This creates concern for taxpayers, as a review by the Government Accountability Office (GAO) 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) website warns, “as a physician, you are an attractive target for kickback schemes because you can be a source of referrals for ... health care ... suppliers.” 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, you stated in a Yahoo Finance interview that, "Lilly can be a trusted source to get that telehealth provided ... 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 from Eli Lilly's chosen prescribing contractor, Form Health. Form Health has a public post on its Instagram account labeled, "When do you start losing weight on Zepbound?" This appears to promote Eli Lilly's medications and erodes the appearance of independence between the telehealth company and Eli Lilly. Form Health's CEO has also stated in reporting by *STAT News* that, "Of course, when patients voice a desire, patient perspective does enter in the patient-physician conversation...." The co-CEO of another Eli Lilly telehealth vendor, 9amHealth, also added in *STAT News*' reporting, "I understand that from the outside perspective it might look like 9amHealth is moving a bit closer to Lilly," before seeking to dispel that notion.

To better understand the nature of Eli Lilly's relationship with contracted telehealth prescribers, we request written responses to the following questions by November 25, 2024:

1. Do Eli Lilly's DTC advertisements for certain medications, including commercials on television or promotions on social media, direct consumers to LillyDirect?
 - a. How much has Eli Lilly spent on such advertisements in the most recent six-month period for which data is available?
 - b. How much has Eli Lilly spent on disease awareness, continuing medical education activities, medical publications, patient advocacy/engagement, or other health promotion directed at prescribers or consumers for diseases

related to medications listed on LillyDirect in the most recent six-month period for which data is available?

2. Are any forms of insurance excluded from eligibility or participation with LillyDirect? Please list which types of insurance are not eligible to participate.
3. Does Eli Lilly direct, encourage, or educate Form Health, 9amHealth, or Cove-affiliated health care providers to prescribe Eli Lilly's medications?
4. Did Eli Lilly share, consult, or communicate with Form Health, 9amHealth, or Cove in creating the "discussion guide" for patients to speak with their Eli Lilly-linked telehealth provider?
5. What is the average duration of the virtual health care visit between a Form Health, 9amHealth, or Cove-affiliated health care provider and a patient who is connected to them via Eli Lilly's website?
 - a. After initially filling out information, are such visits always conducted via a video platform, or are there other options available?
6. Do Form Health, 9amHealth, or 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 accessed.
7. How does Eli Lilly set the compensation paid to its telehealth partners? Please provide a copy of the terms of agreement between Eli Lilly and Form Health, between Eli Lilly and 9amHealth, and between Eli Lilly and Cove.
 - a. Is Eli Lilly paying fair market value for the services of Form Health, 9amHealth, or Cove?
 - b. Does Eli Lilly make a bonus payment to Form Health, 9amHealth, or Cove based on the number of prescriptions written, including refills?
 - c. Does Eli Lilly contract with Form Health, 9amHealth, or Cove to furnish a certain number of prescriptions for certain medications?
 - d. Would the Form Health, 9amHealth, or Cove-affiliated health care provider have actual or constructive knowledge that a patient was referred to them via Eli Lilly's telehealth platform?
 - e. What metrics does Eli Lilly use to evaluate the performance of its contracts with Form Health, 9amHealth, or Cove and affiliated health care providers?
8. What data is being provided by Form Health, 9amHealth, or 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.

9. What role, if any, does Eli Lilly play in collecting, defraying, or otherwise interacting with the co-pay that is associated with the provider consultation on Eli Lilly's telehealth platforms?
10. Based upon prescribing or claims data that Eli Lilly has access to, how many prescriptions for a Eli Lilly medication have Form Health, 9amHealth, or Cove-affiliated health care providers written in the most recent 30-day period for which Eli Lilly has available information?
11. What percentage of consumers who meet virtually with a Form Health, 9amHealth, or Cove-affiliated health care provider receive a prescription for an Eli Lilly medication?
 - a. What percentage of such consumers receive a prescription for a medication manufactured by another brand-name company?
 - b. What percentage of such consumers receive a prescription for a generic medication?
 - c. What percentage of such consumers receive no prescription?
12. How much revenue has Eli Lilly generated from these telehealth platforms in the most recent 30-day period for which Eli Lilly has available information?
13. Four of the six physicians located closest to the U.S. Capitol listed on LillyDirect as providers that Eli Lilly appears to be recommending for obesity care have received payments from Eli Lilly, as reported on the Open Payments database. Outside of the contract terms with Form Health, 9amHealth, or Cove, please provide a list of all payments by Eli Lilly to each health care provider that is linked to via LillyDirect over the past 12-month period, including for "speaking," "consulting," or other goods, fees, or services.

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

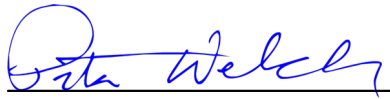
Sincerely,



Richard J. Durbin
United States Senator



Bernard Sanders
United States Senator



Peter Welch
United States Senator



Elizabeth Warren
United States Senator