NOTICE OF EXEMPT SOLICITATION

NAME OF REGISTRANT: Eli Lilly & Co.
NAME OF PERSON RELYING ON EXEMPTION: Trinity Health
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To: Eli Lilly Shareholders
Subject: Shareholder Proposal to Report Oversight of Risks Related to Anticompetitive Pricing Strategies
Date: March 22, 2021
Contact: Catherine Rowan, Director, Socially Responsible Investments, Trinity Health
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Trinity Health and co-filers Adrian Dominican Sisters, Bon Secours Mercy Health, Friends Fiduciary Corporation, Mercy Investment Services and the Sisters of Charity of St. Elizabeth urge you to vote FOR Item 10: “Shareholder Proposal to Report Oversight of Risks Related to Anticompetitive Pricing Strategies” (the “Proposal”) which requests a Board report to shareholders on how it oversees risks related to anticompetitive practices, including whether the full board or a board committee has oversight responsibility, whether and how consideration of such risks is incorporated into board deliberations regarding strategy, and the board’s role in the company’s public policy activities related to such risks, at Eli Lilly’s annual general meeting on May 2, 2022. The full resolution asks:

RESOLVED that shareholders of Eli Lilly and Company (“Eli Lilly”) ask the board of directors to report to shareholders on how it oversees risks related to anticompetitive practices, including whether the full board or board committee has oversight responsibility, whether and how consideration of such risks is incorporated into board deliberations regarding strategy, and the board’s role in Eli Lilly’s public policy activities related to such risks. The report should be prepared at reasonable expense and should omit confidential or proprietary information, as well as information about existing litigation and claims of which Eli Lilly has notice.

Why should shareholders be concerned with anti-competitive practices in the industry?

Anticompetitive practices can often push the limits of law and regulation and have drawn significant scrutiny from federal regulators. The Food and Drug Administration has focused on promoting competition as a way to moderate drug prices, issuing a Drug Competition Action Plan and policy guidance and a Biosimilars Action Plan. Former FDA Commissioner Scott Gottlieb complained at a roundtable on generic drugs that branded companies “are exploiting loopholes in our rules in ways that upset the careful balance between access and innovation.” Further, the Federal Trade Commission (FTC) has focused on curbing anti-competitive conduct in the pharmaceutical sector, with then acting Chairwoman Rebecca Kelly Slaughter stating in May 2021 that “[f]or decades, the FTC has challenged a number of illegal anticompetitive practices in the pharmaceutical industry that can lead to high drug prices. The Commission should consider ways to build on this work by addressing emerging and evolving practices that have the potential to harm consumers [and] . . . when investigating potentially anticompetitive conduct, we should consider the full breadth of the FTC Act’s prohibition on unfair methods of competition.”
The proponents believe strategies to expand monopolies, through such anticompetitive practices such as pay-for-delay, product hopping, evergreening of patents, pricing collusion, etc. without any meaningful new science or invention do not help create long-term value for the company or for shareholders. More importantly, it exacts a heavy cost on health systems and communities.

Engaging in such practices presents legal, financial, regulatory and reputational risks that, unmanaged, may threaten a company’s social license to operate.

Why should shareholders be concerned with anti-competitive practices at Eli Lilly?

· A three-year investigation on drug pricing by the US House Committee on Oversight and Reform, released in December 2021, found that Eli Lilly and other pharmaceutical companies “use patent protections and market exclusivities granted by the FDA to suppress generic competition.” It also noted Eli Lilly along with Novo Nordisk and Sanofi control around 90% of the insulin market in the United States. The report described “internal documents [that] show the three largest insulin manufacturers raised their prices in lockstep in order to maintain ‘pricing parity’ and that senior executives encouraged this practice.” A chart in the report indicates how Eli Lilly and Novo Nordisk practiced ‘shadow pricing’ in raising their rapid-acting insulin products Humalog and NovoLog, from at least 2008 to 2018. From 1996-2017 “Eli Lilly raised the price of its 10mL vial of Humalog subcutaneous solution a total of 34 times for a cumulative price increase of more than 1,200%”.

· The House report states that after biosimilar competition to Humalog was introduced in 2018, Eli Lilly introduced an authorized generic version of Humalog in 2019 (at $137 vial, compared to Humalog’s $275) and has not raised Humalog’s price since. Unlike true generics, which are produced by competing drug companies, authorized generics are sold by the original manufacturer at a discounted price. The authorized generic has marketing exclusivity until the original brand drug loses its patent, which means the drug maker maintains its monopoly for that drug.

· T1 International, an organization led by people with or impacted by Type 1 diabetes that advocates for access to insulin has found this authorized generic version is still unaffordable -even with a second price reduction of the generic version, to $80.

Legislative, regulatory and legal risks facing Lilly and its pricing of insulin

· Eli Lilly states in its 2021 Form 10-K: “Additional policies, regulations, legislation, or enforcement, including as a result of the regulatory priorities of the current U.S. presidential administration and other regulatory authorities worldwide, could adversely impact our business and revenue. For example, pending legislation in the U.S. could result in government negotiation of the price of some of our medicines, including insulin.”

· President Biden, in his March 2022 State of the Union address, urged Congress to reduce the out-of-pocket insurance cost of insulin to $35 a month. The American Diabetes Association and The Endochrine Society endorsed the cap. The President called on Congress to give Medicare the power to negotiate with drug companies for lower prices.

· The 10-K reports that Eli Lilly has received subpoenas from 2 state attorneys general and civil investigative demands from 3 other state attorneys general offices about the sale and pricing of insulin products. In early 2022 The Michigan State Attorney General was granted court approval to investigate Eli Lilly’s insulin pricing practices, under Michigan’s consumer protection law. Harris County, Texas is moving forward with a lawsuit against several drug manufacturers, including Eli Lilly, and pharmacy benefit managers for conspiring to inflate the price of insulin.
We are concerned that these strategic risks are not fully addressed by Eli Lilly’s board of directors

- Lilly’s Statement in Opposition to the proposal does not mention anticompetitive practices or risks related to competition, nor does it discuss risks related to specific anticompetitive practices relevant to Lilly such as pricing collusion. Instead, Lilly points to information in the proxy statement and on the ESG page of its website about decision-making around pricing and actions it has taken to address pricing and access concerns under board oversight.

- Eli Lilly has not disclosed any information as to how the Board oversees risks related to anti-competitive practices or competition-related risk, which is the essential objective of the Proposal. Eli Lilly’s board should be able to demonstrate to shareholders that it has applied rigorous oversight, with clear criteria, expectations and regular review, to management decisions about pricing, patents, and innovation. Boilerplate or vague language about general strategic oversight is not sufficient in light of intensive regulatory scrutiny over practices both within the US and abroad.

We therefore urge shareholders to vote FOR Item 10

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i See Transcript of Public Meeting, U.S. Food and Drug Administration, “The Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access,” July 18, 2017, at p.11 (available at https://www.fda.gov/media/107217/download) (then-Commissioner Gottlieb stating at a public meeting/roundtable on speeding access to generic drugs that FDA wants to “make sure that, in places where Congress intended for there to be vigorous drug competition, such competition actually reaches the market” and that the FDA has a role to play in bringing down drug prices by “encouraging competition”)(hereinafter, “the Transcript).  


iv Transcript, at p.15.