



**NAME OF REGISTRANT: ABBVIE INC.**

**NAME OF PERSON RELYING ON EXEMPTION: FRIENDS FIDUCIARY CORPORATION**

**ADDRESS OF PERSON RELYING ON EXEMPTION: 1700 MARKET STREET, SUITE 1535, PHILADELPHIA, PA 19103**

April 11, 2022

Friends Fiduciary Corporation and co-filers Trinity Health, Missionary Oblates of Mary Immaculate, Mercy Investment Services, Inc., Sisters of Charity of St. Elizabeth, Northwest Women Religious Investment Trust, Bon Secours Mercy Health, Inc., Sisters of Charity Blessed Virgin Mary, and CommonSpirit Health urge you to vote FOR the: **“Stockholder Proposal on Report on Board Oversight of Competition Practices” (the “Proposal”)**

The Proposal 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 AbbVie’s annual general meeting on **May 6, 2022**. The full resolution asks:

*RESOLVED that shareholders of AbbVie Inc. ("AbbVie") 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 AbbVie'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 AbbVie has notice.*

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### Why should shareholders be concerned with anticompetitive 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 (“FDA”) has focused on promoting competition as a way to moderate drug prices,<sup>1</sup> issuing a Drug Competition Action Plan and policy guidance<sup>2</sup> and a Biosimilars Action Plan.<sup>3</sup> 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.”<sup>4</sup> Further, the Federal Trade Commission (“FTC”) has focused on curbing anticompetitive 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 as pay-for-delay, product hopping, evergreening of patents, and pricing collusion, 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 if unmanaged may threaten a company’s social license to operate.

### Why should shareholders be concerned with anticompetitive practices at AbbVie?

A three-year investigation on drug pricing by the U.S. House Committee on Oversight and Reform (the “Committee”), released in December 2021, found that AbbVie and other pharmaceutical companies “use patent protections and market exclusivities granted by the FDA to suppress generic competition and keep prices high.” AbbVie has been shown to use “patent thickets,” a strategy in which a company continually applies for patents to maintain control over the pricing of its drugs by blocking generic sales. AbbVie has applied for over 250 patents for Humira, the largest number applied for by a pharmaceutical company.<sup>5</sup> AbbVie was approved for 130 patents for Humira and 88 for Imbruvica, resulting in 29-39 years of blocking competition from generic drug manufacturers.<sup>6</sup> Ninety percent of the patent applications for Humira were filed after the drug was approved and brought to market in 2003 and over 50% were filed after 2013, allowing the drug to be protected from biosimilar competition a decade after it was first brought to market. Likewise, 55% of patent applications for Imbruvica were filed after the drug was approved by the FDA and brought to market in 2013.<sup>7</sup>

<sup>1</sup> 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”).

<sup>2</sup> Press Release, U.S. Food and Drug Administration, “FDA Tackles Drug Competition to Improve Patient Access,” June 27, 2017 (<https://www.fda.gov/news-events/press-announcements/fda-tackles-drug-competition-improve-patient-access>).

<sup>3</sup> See U.S. Food and Drug Administration, “Biosimilars Action Plan: Balancing Innovation and Competition,” July 2018 (<https://www.fda.gov/media/114574/download>).

<sup>4</sup> Transcript, at p.15.

<sup>5</sup> <https://www.i-mak.org/wp-content/uploads/2019/01/i-mak.overpatented.overpriced.report.0801.pdf>

<sup>6</sup> <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf>

<sup>7</sup> <https://www.i-mak.org/wp-content/uploads/2020/08/I-MAK-Imbruvica-Patent-Wall-2020-07-42F.pdf>



AbbVie has been shown to use the strategy of “drip feed patents” as well, where “the knowledge broadly disclosed in early patent applications is defined ever more narrowly and specifically in subsequent patent application allowing for further protection from biosimilar sales.”<sup>8</sup> The company has used this strategy for Imbruvica, securing 30 years of patent protection for various uses of the drug including, “to treat chronic lymphocytic leukemia and Waldenstrom macroglobulinemia, a type of non-Hodgkin lymphoma.”<sup>9</sup> These examples of AbbVie’s establishment of “patent thickets” around its drugs to prevent generic competition result in massive price hikes for everyday consumers.<sup>10</sup> Humira’s list price has been increased 25 times resulting in a 471% price increase since its launch, with Imbruvica’s price also increasing 82%.<sup>11</sup>

The Committee’s investigation also described AbbVie’s participation in patent settlement agreements that delay competition from would-be generic competitors, known as “pay for delay” agreements. AbbVie entered into settlement agreements with nine competitors, six of which have FDA approval for Humira biosimilars, effectively delaying the production of the biosimilar version and allowing AbbVie to “maintain monopoly pricing for Humira until January 2023.” According to AbbVie’s own internal estimations, if lower-priced biosimilars had entered the market in the first quarter of 2017, AbbVie’s U.S. net revenue would have dropped by \$1.5 billion in 2017. Based on this analysis, the introduction of biosimilar competition would have allowed for a reduction in price of Humira that could have saved the U.S. healthcare system at least \$19 billion from 2016 to 2023, and reduced prices for average drug purchasers.

The Committee report also identified AbbVie as part of a group of pharmaceutical companies participating in “product hopping” or “evergreening,” a strategy in which companies shift patients to “new products or formulations of a drug just before facing generic competition for the old formula.” AbbVie also participated in “shadow pricing,” a practice that allows companies to keep prices high by would-be competitors following each other’s price increases. Specifically, AbbVie and Amgen have engaged in shadow pricing for their products Humira and Enbrel.<sup>12</sup>

#### **Legislative, regulatory and legal risks facing AbbVie related to anticompetitive practices**

AbbVie’s reliance on patent thickets and other anticompetitive practices illustrates the company’s overdependence upon just a few drugs. This strategy does not reassure investors of the company’s long-term value. As noted in AbbVie’s 2021 Form 10-K, Humira accounted for approximately 37% of AbbVie’s total net revenues in 2021. This makes the company particularly susceptible to regulatory risk where “any significant event that adversely affects Humira’s revenues could have a material adverse impact on AbbVie’s results of operations and cash flows. These events could include loss of patent protection for Humira...[and] the commercialization of biosimilars of Humira.”<sup>13</sup> Combined, Humira and Imbruvica make up 46% of AbbVie’s total 2021 net revenue. We are concerned that AbbVie focuses on maintaining the patent protection of current drugs in order to increase revenue by increasing drug prices, opening the company up to regulatory and legal risk.

<sup>8</sup> <https://www.i-mak.org/wp-content/uploads/2020/08/I-MAK-Imbruvica-Patent-Wall-2020-07-42F.pdf>

<sup>9</sup> <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf>

<sup>10</sup> <https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf>

<sup>11</sup> <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf>

<sup>12</sup> <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf>

<sup>13</sup> [https://www.sec.gov/ix?doc=/Archives/edgar/data/1551152/000155115222000007/abbv-20211231.htm#i1293eb1bca8b4a9faecfc0731a3b171e\\_229](https://www.sec.gov/ix?doc=/Archives/edgar/data/1551152/000155115222000007/abbv-20211231.htm#i1293eb1bca8b4a9faecfc0731a3b171e_229)



Pharmaceutical companies have recently faced increased public and legislative scrutiny when it comes to soaring drug prices, presenting significant reputational risk. AbbVie notes in its 2021 Form 10-K that the company is “subject to increasing public and legislative pressure with respect to pharmaceutical pricing. In the United States, practices of managed care groups, and institutional and governmental purchasers, and United States federal laws and regulations related to Medicare and Medicaid, including the Medicare Prescription Drug Improvement and Modernization Act of 2003 and the Patient Protection and Affordable Care Act, contribute to pricing pressures.”

The recently released Committee report alone demonstrates increased scrutiny from the U.S. government, specifically the House of Representatives. The report also resulted in the Committee requesting that the FTC open a formal inquiry into “whether AbbVie’s settlement agreements and other business practices for Humira violated U.S. law.” AbbVie also faces legislative and regulatory pressures abroad. The company was one of several companies fined \$360 million by the U.K. Competition and Markets Authority for “overcharging the National Health Service in the supply of hydrocortisone tablets.”<sup>14</sup> AbbVie faces mounting legislative, regulatory, and legal risk, that combined with reputational risk, could affect the company’s bottom line and social license to operate.

**We are concerned that these strategic risks are not fully addressed by AbbVie’s board of directors**

AbbVie’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 AbbVie such as patent thickets. Instead, AbbVie points to information in the proxy statement, the company Code of Conduct, and public governance documents in which AbbVie’s risk management program focuses on reputation, decision-making around pricing and actions it has taken to address pricing and access concerns under board oversight.

With respect to pricing, the Statement in Opposition also notes that AbbVie utilizes “a number of strategies to ensure access, including pricing and reimbursement models, patient assistance programs, intellectual property licensing, and product donation.” However, these efforts do not get to the root of investor concerns around reputational and regulatory risks of price hikes due to company practices. Although these programs defray some patients’ out-of-pocket costs, “the overall cost to the health care system increases due to price increases. This cost is in turn passed on to all patients in the form of higher insurance premiums.”<sup>15</sup>

<sup>14</sup> <https://seekingalpha.com/news/3715445-abbvie-among-firms-fined-for-price-gauging-in-uk>

<sup>15</sup> <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf>



AbbVie has not disclosed any information about how the Board oversees risks related to anticompetitive practices or competition-related risk, which is the essential objective of the Proposal. AbbVie'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 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 U.S. and abroad.

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**We therefore urge shareholders to vote FOR the Proposal**

**This is not a solicitation of authority to vote your proxy. Please DO NOT send us your proxy card; Friends Fiduciary Corporation is not able to vote your proxies, nor does this communication contemplate such an event. Friends Fiduciary Corporation urges stockholders to vote for the Proposal following the instructions provided on the Company's proxy mailing.**

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