Notice of Exempt Solicitation

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

Dear Fellow AbbVie Inc. Shareholder,

Friends Fiduciary with co-filers Mercy Investment Service, Inc., Bon Secours Mercy Health, Inc., Sisters of Charity, The Sisters of the Order of St. Dominic (Grand Rapids), The Sisters of Charity of the Blessed Virgin Mary, Trinity Health, Common Spirit Health, NEI Investments, Northwest Women Religious Trust (Sisters of Saint Joseph of Peace), Providence St. Joseph Health, and The Sisters of St. Francis of Philadelphia, write to urge you to vote **FOR Item 8,** "Stockholder Proposal – to issue a Report on Patent Process" (the "Proposal"), at AbbVie Inc.'s ("AbbVie's" or the "Company's") annual general meeting on May 3, 2024.

RESOLVED, that shareholders of AbbVie Inc. ask the Board of Directors to establish and report on a process by which the impact of extended patent exclusivities on product access would be considered in deciding whether to apply for secondary and tertiary patents. Secondary and tertiary patents are patents applied for after the main active ingredient/molecule patent(s) and which relate to the product. The report on the process should be prepared at reasonable cost, omitting confidential and proprietary information, and published on AbbVie's website.

We believe that establishing a process would be beneficial to AbbVie and its shareholders because extended exclusivity periods gained from secondary patents, and the resulting delay in generic entry, limit patient access, create regulatory and reputational risk, and saddle the health care system and the economy with unsustainable costs. While AbbVie states that the Company does "take into account…the potential impact on patient access", there is no disclosure around the Company's process by which patient access is considered.

We are not asking for authority to vote your proxy and no proxy cards will be accepted. Please vote your proxy according to the instructions in AbbVie's proxy statement.

Notice of Exempt Solicitation

Friends Fiduciary
ADDING VALUES TO STRONG PERFORMANCE.

Prescription drugs have assumed an increasingly important role in American health care, and that trend is likely to continue: One study estimates that "[p]rescription drug spending on retail and non-retail drugs is poised to grow 63% from 2020 to 2030, reaching $917 billion dollars."[1] Prescription drugs—and branded specialty medicines in particular—are costly in the U.S. The rise in spending on prescription drugs outpaces increases in health care spending more generally,[2] and three in 10 Americans on a prescription drug report not taking their medicine as prescribed due to cost.[3] A poll asking respondents to identify their top priority issue appearing in the Build Back Better bill found that allowing the federal government to negotiate drug prices topped the list.[4]

Federal law tries to strike a balance between incentivizing innovation and promoting affordability. Obtaining a patent for a new drug gives the manufacturer a period of exclusive marketing rights, generally for 20 years.[5] Once the patent expires, manufacturers are free to make generic versions of the drug—or in the case of a biologic, a biosimilar version—which drives down prices.[6] An academic commentator described the balance struck by this regulatory regime:

> On the one hand, originators play an important role in developing new and improved medicines for the benefit of society. On the other hand, generic companies benefit society by supplying cheaper equivalents of the originators' medicines, which leads to the reduction of drug prices and facilitates access to affordable medicines. When the interests of these two players are kept in balance, benefits are maximised for society, which receives innovative and improved medicines, as well as timely access to generic drugs.[7]

We believe that balance is now out of whack. Given the high prices their drugs command absent competition, branded drug makers have strong incentives to delay generic competition as long as possible. One strategy they use is creating so-called "patent thickets," numerous overlapping patents on a drug filed after the primary patent has been granted and the drug approved by the Food and Drug Administration ("FDA") that would be expensive and time-consuming for a potential generic manufacturer to challenge.[8] This strategy can allow branded drug makers to hold off generic (or biosimilar, in the case of a biologic medicine) competition for several years or more.

---

[1] https://www.i-mak.org/wp-content/uploads/2022/09/Overpatented-Overpriced-2022-FINAL.pdf, at 2 (citing Charles Roehrig and Ani Turner, Projections of the Non-Retail Prescription Drug Share of National Health Expenditures Report, Altarum, July 2022).

[2] https://sgp.fas.org/crs/misc/R46221.pdf, at 2.

[3] https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/

[4] https://www.politico.com/news/2021/10/01/drug-price-negotiation-poll-harvard-514831

[5] https://sgp.fas.org/crs/misc/R46221.pdf, at 1.

[6] https://www.fda.gov/files/drugs/published/Exclusivity-and-Generic-Drugs--What-Does-It-Mean-.pdf; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6534750/ ("Prices can drop as much as 20% when the first generic enters the market; with multiple generics, the prices may eventually drop by 80–85%.")

[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7592140/

[8] See ncbi.nlm.nih.gov/pmc/articles/PMC7592140/(" The denser the web of secondary patents, the more difficult it is for generics to develop their generic equivalents, even if they know that only a few patents of a large portfolio would, in fact, be valid and infringed by their products."); https://sgp.fas.org/crs/misc/R46221.pdf, at 1-2.

We are not asking for authority to vote your proxy and no proxy cards will be accepted. Please vote your proxy according to the instructions in AbbVie's proxy statement.

Notice of Exempt Solicitation

These later-filed patents, which are referred to as secondary and tertiary[9] patents, relate to properties of the drug other than the active ingredient, such as methods of administration, manufacturing processes, dosing regimens, and additional indications.[10] Critics of the practice argue that secondary patents tend to be low quality, as they are invalidated in litigation at a higher rate than primary patents, and that they allow drug makers to benefit from extended exclusivity periods without engaging in additional innovation.[11] AbbVie has used secondary and tertiary patents, filing a total of 247 patent applications on Humira in the U.S., 89% of which were filed after the drug was first approved and on the market[12] and has similarly filed 165 patent applications for Imbruvica, 55% of which were filed after the drug first received FDA approval.[13]

Secondary patents have a significant impact on health care spending and the economy, exacerbating inequalities in access to medicines and straining both public and private sector budgets. One study analyzed the 12 best-selling drugs, which had been on the market for an average of 15 years, and found large numbers of secondary patents providing an average exclusivity period of 38 years.[14] That study called patent abuse the "root cause" of unsustainably high drug prices. Biosimilar versions of Humira entered the U.S. market in 2023 after AbbVie reached a settlement with Amgen in 2016. Amgen argued that most of AbbVie's patents on Humira were invalid after AbbVie sued the company for its biosimilar version of Humira that had the potential to win regulatory approval. Amgen, followed by nine other manufacturers, entered into agreements with AbbVie to delay the market entry of their biosimilars until 2023.[15] However, while AbbVie is losing its market exclusivity on the drug, some of Humira's manufacturing patents still extend to 2034, making it necessary for other biosimilar manufacturers to "pursue individual patent dance procedures with AbbVie in order to launch their own candidates."[16] Patents granted on Imbruvica protect commercial exclusivity for 29 years.[17]

---

[9] A secondary patent relates to "peripheral features" of a drug, while a tertiary patent applies to a drug-device combination, such as the EpiPen. https://blog.petrieflom.law.harvard.edu/2018/04/30/tertiary-patents-an-emerging-phenomenon/

[10] https://sgp.fas.org/crs/misc/R46221.pdf, at 9.

[11] E.g., Editorial Board, "Save America's Patent System," The New York Times, Apr. 17, 2022[1] ("Twelve of the drugs that Medicare spends the most on are protected by more than 600 patents in total, according to the committee. Many of those patents contain little that's truly new. But the thickets they create have the potential to extend product monopolies for decades. In so doing, they promise to add billions to the nation's soaring health care costs -- and to pharmaceutical coffers."); https://www.cnbc.com/2018/06/25/high-drug-prices-caused-by-us-patent-system.html; https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf; Robin Feldman, "Our patent system is broken. And it could be stifling innovation," The Washington Post, Aug. 8, 2021[1]

[12] https://www.i-mak.org/wp-content/uploads/2020/10/i-mak.humira.report.3.final-REVISED-2020-10-06.pdf

[13] https://www.i-mak.org/wp-content/uploads/2020/08/I-MAK-Imbruvica-Patent-Wall-2020-07-42F.pdf

[14] https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf

[15] https://www.nytimes.com/2023/01/28/business/humira-abbvie-monopoly.html#:~:text=Amgen%20argued%20that%20most%20of,their%20own%20versions%20of%20Humira.

[16] https://www.pharmaceutical-technology.com/comment/abbvies-successful-hard-ball-with-humira/?cf-view

[17] https://www.i-mak.org/wp-content/uploads/2020/10/i-mak.humira.report.3.final-REVISED-2020-10-06.pdf; https://www.i-mak.org/wp-content/uploads/2020/08/I-MAK-Imbruvica-Patent-Wall-2020-07-42F.pdf

Notice of Exempt Solicitation

Another study by the same organization found "questionable – and likely unmerited" secondary patents on three blockbuster drugs and estimated that the U.S. healthcare system would bear approximately $55 billion in excess costs for those three drugs during the extended exclusivity periods facilitated by the drugs' secondary patents.[18] (Studies show that the introduction of generic versions of a drug lead to significantly lower prices.[19]) Prior to biosimilar entry, the extended monopoly on Humira alone was estimated to cost American payers and taxpayers an excess of $14.4 billion.[20] One analysis found that Medicare, "spent $2.2 billion more on the drug from 2016 to 2019 than it would have if competitors had been allowed to start selling their drugs promptly."[21] In the five year period from 2012 to 2016, "taxpayers spent, through Medicare and Medicaid purchases, a total of 9.2 billion on Humira."[22]

Secondary and tertiary patents not only impact health care spending but the economy as a whole, threatening the financial returns of diversified shareholders who rely on a healthy economy to support their portfolios. In diversified portfolios, the most important factor determining return is not how individual companies in that portfolio perform ("alpha"), but rather how the market performs as a whole ("beta"). Research has shown "alpha is about one-tenth as important as beta [which] drives some 91 percent of the average portfolio's return."[23] Over the long run, diversified portfolios rise and fall with GDP or other indicators of the intrinsic value of the economy. The creation of patent thickets threatens economic productivity: when medicine is made artificially more expensive, patients use less medicine than they would otherwise, reducing public health, an important element of a strong economy. Lack of access to medicine can result in early and excess mortality, which will lead to a potential economic output loss of up to 2.6 percent of GDP by 2030 in low-income countries and 0.9 percent in upper-middle income countries.[24] Increasing the cost of healthcare exacerbates inequality, which negatively impacts economic growth[25] as well as the potential reduction in innovation created by companies putting resources into extending patents rather than developing new drugs.

---

[18] https://www.i-mak.org/americas-overspend/

[19] https://www.fda.gov/media/133509/download, at 2; https://www.fda.gov/media/161540/download, at 6; https://pubmed.ncbi.nlm.nih.gov/34904207/; https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf; https://www.cbo.gov/publication/57772

[20] https://www.i-mak.org/wp-content/uploads/2020/10/i-mak.humira.report.3.final-REVISED-2020-10-06.pdf

[21] https://www.nytimes.com/2023/01/28/business/humira-abbvie-monopoly.html

[22] https://www.i-mak.org/wp-content/uploads/2020/10/i-mak.humira.report.3.final-REVISED-2020-10-06.pdf

[23] Stephen Davis, Jon Lukomnik, and David Pitt-Watson, What They Do with Your Money, Yale University Press (2016).

[24] Blake C. Alkire et al., "The Economic Consequences Of Mortality Amenable To High-Quality Health Care In Low- And Middle-Income Countries," Health Affairs 37, no. 6 (June 2018): 988–96, https://doi.org/10.1377/hlthaff.2017.1233

[25] Causa, de Serres, and Ruiz, *Growth and Inequality* (a one percent increase in inequality leads to a decrease in GDP of 0.6-1.0 percent).

We are not asking for authority to vote your proxy and no proxy cards will be accepted. Please vote your proxy according to the instructions in AbbVie's proxy statement.

Notice of Exempt Solicitation

The role of secondary and tertiary patents in keeping prescription drug prices high has received increasing amounts of media and regulatory scrutiny. For example, the editorial boards of *The New York Times*[26] and *USA Today* published editorials decrying the proliferation of such patents and their impact on the health care system. Patent thickets are often depicted as "gaming" or "abusing" the U.S. patent system.[27] AbbVie was the subject of a New York Times article calling the company "the poster child for many of the biggest concerns in the pharmaceutical industry," with the article noting that patients in need of Humira often said they either had to forgo treatment or were planning to "delay their retirement in the face of enormous out-of-pocket costs." The price of Humira has increased about 30 times over the past 20 years,[28] with the drugs list price increasing 60% between 2016 and 2021.[29] The Financial Times has also called AbbVie out for "aggressively" protecting its exclusive right to sell Humira in the US, allowing the company to "ratchet up prices" resulting in the US paying roughly five times what patients pay in the EU for Humira due to extended exclusivity in the US market.[30] Recently, the Institute for Clinical and Economic Review's yearly report found Humira's 2% price increase between 2021-2022 was not supported by clinical data and caused healthcare spending to increase by $386 million.[31] According to Reuters, following the introduction of Humira biosimilars into the US market in 2023, eight Humira biosimilars were launched in the US with unbranded versions of Humira biosimilars resulting in a list price 81% cheaper than Humira.[32]

Rising pressures to contain specialty drug costs, combined with a perception that branded drug firms are engaged in anti-competitive behavior, could lead to increased regulation. Indeed, President Biden issued an Executive Order (the "E.O.") in 2021 directing the Secretary of Health and Human Services to "promote generic drug and biosimilar competition."[33] Pursuant to the E.O., the FDA and Patent and Trademark Office ("PTO") are collaborating to implement strategies to lower drug prices.[34] AbbVie itself was the subject of an investigation by the House Oversight Committee for what the investigation found was "abusive drug pricing" for Humira and Imbruvica.[35]

---

[26] https://www.nytimes.com/2022/04/16/opinion/patents-reform-drug-prices.html

[27] See, e.g., https://www.reuters.com/business/healthcare-pharmaceuticals/consumer-group-says-drugmakers-abuse-us-patent-system-keep-prices-high-2022-09-16/; https://www.cnn.com/2019/09/12/perspectives/drug-patents-abuse/index.html; https://www.chicagotribune.com/opinion/commentary/ct-perspec-drugs-health-care-pharm-1024-20171023-story.html; https://www.nbcnews.com/health/health-news/gaming-us-patent-system-keeping-drug-prices-sky-high-report-says-rcna47507

[28] https://www.nytimes.com/2023/01/28/business/humira-abbvie-monopoly.html

[29] https://www.i-mak.org/2021-top-selling/

[30] https://www.ft.com/content/2a576979-5ec9-4511-8634-08e5731d9f10

[31] https://icer.org/wp-content/uploads/2023/04/UPI_2023_Report_121123.pdf

[32] https://www.reuters.com/business/healthcare-pharmaceuticals/boehringer-launches-unbranded-humira-biosimilar-81-discount-2023-10-02/

[33] https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/, at section 5(p)(vi).

[34] https://www.uspto.gov/sites/default/files/documents/PTO-FDA-nextsteps-7-6-2022.pdf

[35] https://oversightdemocrats.house.gov/news/press-releases/chairwoman-maloney-releases-staff-report-and-new-documents-showing-abusive-drug

We are not asking for authority to vote your proxy and no proxy cards will be accepted. Please vote your proxy according to the instructions in AbbVie's proxy statement.

Notice of Exempt Solicitation

The relationship between extended exclusivity periods and high drug prices is addressed in several bills that have been introduced, as well as in congressional hearings.[36] In June 2022, a bipartisan group of Senators wrote to the director of the PTO about patent thickets. The letter stated: "In the drug industry, with the most minor, even cosmetic, tweaks to delivery mechanisms, dosages, and formulations, companies are able to obtain dozens or hundreds of patents for a single drug. This practice impedes generic drugs' production, hurts competition, and can even extend exclusivity beyond the congressionally mandated patent term." It closed by asking the PTO to "consider changes to your regulations and practices to address [overpatenting] problems where they start, during examination."[37] The Biden Administration is also proposing a framework, using the authority of the Bayh-Dole Act, "to guide government agencies on how to use march-in authorities if a drug's price is considered too high."[38]

Pharmaceutical companies argue that secondary and tertiary patents are necessary to incentivize continued innovation related to a drug. AbbVie's Statement in Opposition states that the company's "ethical decision-making extends to protecting our intellectual property, which covers meaningful innovation and investment in our life-changing medicines."[39] But the Proposal does not seek to prohibit companies from applying for secondary and tertiary patents on its medicines, only for the impact on patient access to be part of the mix of considerations and for the company to report on the process by which the impact on patient access is considered when deciding to apply for such patents. AbbVie states that it considers many factors when assessing whether to apply for a patent to cover a certain innovation, including taking into account "the size of the underlying investment and the potential impact on patient access." However, the existing disclosures provided in the document *Intellectual Property and Patient Access* linked on AbbVie's website gives no further information as to the process by which AbbVie considers and weighs the potential impacts on patient access.[40]

There is evidence that companies delay marketing and innovation on an existing drug by filing for secondary patents strategically, close to the primary patent's expiration, in order to provide the longest exclusivity extension.[41] For example, AbbVie's initial patent on Humira was set to expire in 2016, with nearly 50% of the applications in the U.S. filed by the company from 2014 onwards.[42] This timing suggests that patient benefit is not always the sole motivation for such innovations on approved medicines. AbbVie is also one of ten pharmaceutical companies to which the FTC sent letters regarding improper Orange Book-listed patents out of concern that "wrongfully listed patents can significantly drive up the prices Americans must pay for medicines…while undermining fair and honest competition."[43] The FTC has noted that the focus of this effort was on listed patents related to a delivery device rather than an active ingredient patent.[44]

---

[36] See https://www.durbin.senate.gov/newsroom/press-releases/durbin-cassidy-introduce-remedy-act-to-lower-drug-prices-by-curbing-patent-manipulation-promoting-generic-competition#:~:text=The%20REMEDY%20Act%20amends%20FDA,that%20delay%20generic%20market%20entry; https://www.congress.gov/bill/117th-congress/house-bill/2873; https://www.judiciary.senate.gov/imo/media/doc/Testimony%20-%20July%2013%202021_Rachel_Moodie.pdf; https://oversight.house.gov/news/press-releases/house-judiciary-antitrust-subcommittee-to-hold-hearing-on-anticompetitive; https://energycommerce.house.gov/committee-activity/hearings/hearing-on-lowering-the-cost-of-prescription-drugs-reducing-barriers-to; https://www.finance.senate.gov/hearings/drug-pricing-in-america-a-prescription-for-change-part-i

[37] www.leahy.senate.gov/imo/media/doc/20220608%20Letter%20to%20PTO%20on%20repetitive%20patents.pdf

[38] https://www.npr.org/sections/health-shots/2023/12/07/1217882958/white-house-proposes-to-march-in-on-patents-for-costly-drugs

[39] https://www.sec.gov/ix?doc=/Archives/edgar/data/1551152/000155837024003496/abbv-20240503xdef14a.htm

[40] https://www.abbvie.com/who-we-are/policies-disclosures.html

[41] See ncbi.nlm.nih.gov/pmc/articles/PMC7592140/

[42] https://www.i-mak.org/wp-content/uploads/2020/10/i-mak.humira.report.3.final-REVISED-2020-10-06.pdf

[43] https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-challenges-more-100-patents-improperly-listed-fdas-orange-book

[44] https://www.npr.org/2023/11/08/1211459920/the-ftc-is-threating-legal-action-against-drug-makers-over-patent-abuses

We are not asking for authority to vote your proxy and no proxy cards will be accepted. Please vote your proxy according to the instructions in AbbVie's proxy statement.

Some companies argue that their existing patient access programs, such as co-pay assistance and medicine donations, obviate the need for establishing a process like that requested in the Proposal. AbbVie notes in its Statement in Opposition that the company "has numerous mechanisms to ensure access to our innovative medicines, including those that remain exclusive." The Company states it donates to "independent charitable foundations that provide co-pay assistance to patients in need."[45] The company also points to myAbbVie Assist which provides patient assistance programs "intended for people that live in the United States, have limited or no health insurance coverage and demonstrate qualifying financial need," providing assistance to nearly 200,000 people in 2022.[46] Such programs, while facilitating access for a select group of patients, do not promote affordability more generally, as the introduction of a generic drug would. Helping a relatively small number of patients does not address systemic issues, such as the strain placed on the health care system by extended exclusivity periods and the societal impact of undertreatment of disease, which can include lower labor force participation and productivity, increased social services costs, poorer patient quality of life, and higher health care costs later on in a patient's life when the impact of undertreatment may be more difficult to remedy.[47]

More generally, reliance on patent thickets may actually diminish branded drug manufacturers' incentives to continue developing innovative medicines. If a manufacturer can obtain a longer period of exclusivity for a top-selling drug, it has a reduced motivation to develop new drugs.[48] As one academic study put it: "Rather than creating new medicines—sallying forth into new frontiers for the benefit of society—drug companies are focusing their time and effort extending the patent life of old products. This, of course, is not the innovation one would hope for. The greatest creativity at pharmaceutical companies should be in the lab, not in the legal department."[49]

Finally, the existence of disclosure on a company's pricing and/or access programs is sometimes held up as a reason the Proposal is unnecessary. Disclosures, standing alone, are insufficient because they do not effect a change in process like the one sought by the Proposal. Adopting a process is the Proposal's core element, and the reporting component is designed to ensure that shareholders are apprised of AbbVie's adoption of the process.

We recognize the value created by pharmaceutical innovation, and the Proposal would not limit in any way the Company's ability to obtain so-called primary patents covering drugs' active ingredients or require a particular outcome when the Company analyzes whether to pursue secondary and tertiary patents. The Proposal simply asks the Company to take the impact on patient access into account when making decisions about applying for such patents. It would not impose a specific weighting for access considerations, nor would it dictate how access should be measured. The Company would have total discretion over those and other details.

---

[45] https://www.sec.gov/ix?doc=/Archives/edgar/data/1551152/000155837024003496/abbv-20240503xdef14a.htm

[46] https://www.abbvie.com/patients/patient-support/patient-assistance.html

[47] See, e.g., https://www.oecd.org/els/health-systems/Focus-on-Health-Making-Mental-Health-Count.pdf; https://www.lse.ac.uk/business/consulting/assets/documents/the-value-of-early-diagnosis-and-treatment-in-parkinsons-disease.pdf; https://www2.deloitte.com/us/en/insights/industry/health-care/economic-cost-of-health-disparities.html; https://www.mathematica.org/news/new-study-uncovers-the-heavy-financial-toll-of-untreated-maternal-mental-health-conditions.

[48] ncbi.nlm.nih.gov/pmc/articles/PMC7592140/

[49] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6534750/

Notice of Exempt Solicitation

We therefore urge shareholders to vote FOR Item 8.

For more information, please contact me, as noted below.

Sincerely,

Jeffery W. Perkins
Executive Director
Friends Fiduciary Corporation
jperkins@friendsfiduciary.org

We are not asking for authority to vote your proxy and no proxy cards will be accepted. Please vote your proxy according to the instructions in AbbVie's proxy statement.
