

UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

March 11, 2022

Marc S. Gerber Skadden, Arps, Slate, Meagher & Flom LLP

Re: AbbVie Inc. (the "Company")

Incoming letter dated December 22, 2021

Dear Mr. Gerber:

This letter is in response to your correspondence concerning the shareholder proposal (the "Proposal") submitted to the Company by Friends Fiduciary Corporation et al. for inclusion in the Company's proxy materials for its upcoming annual meeting of security holders.

The Proposal asks the board 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 the Company's public policy activities related to such risks.

We are unable to concur in your view that the Company may exclude the Proposal under Rule 14a-8(i)(7). In our view, the Proposal raises issues that transcend ordinary business matters.

We are unable to concur in your view that the Company may exclude the Proposal under Rule 14a-8(i)(10). Based on the information you have presented, it appears that the Company's public disclosures do not substantially implement the Proposal.

Copies of all of the correspondence on which this response is based will be made available on our website at https://www.sec.gov/corpfin/2021-2022-shareholder-proposals-no-action.

Sincerely,

Rule 14a-8 Review Team

cc: Amy Carr

Friends Fiduciary Corporation

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP

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BY EMAIL (shareholderproposals@sec.gov)

December 22, 2021

FIRM/AFFILIATE OFFICES BOSTON CHICAGO HOUSTON LOS ANGELES NEW YORK PALO ALTO WILMINGTON BEIJING BRUSSELS FRANKFURT HONG KONG LONDON MOSCOW MUNICH PARIS SÃO PAULO SEOUL SHANGHAI SINGAPORE TOKYO TORONTO

U.S. Securities and Exchange Commission Division of Corporation Finance Office of Chief Counsel 100 F Street, N.E. Washington, D.C. 20549

RE: AbbVie Inc. – 2022 Annual Meeting Omission of Shareholder Proposal of

Friends Fiduciary Corporation and co-filers¹

Ladies and Gentlemen:

We are writing pursuant to Rule 14a-8(j) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), to request that the Staff of the Division of Corporation Finance (the "Staff") of the Securities and Exchange Commission (the "Commission") concur with our view that, for the reasons stated below, AbbVie Inc., a Delaware corporation (the "Company"), may exclude the shareholder proposal and supporting statement (the "Proposal") submitted by Friends Fiduciary Corporation ("Friends Fiduciary") and co-filers from the proxy materials to be distributed by the Company in connection with its 2022 annual meeting of

The following shareholders have co-filed the Proposal: Bon Secours Mercy Health, Inc; CommonSpirit Health; Mercy Investment Services, Inc.; Missionary Oblates of Mary Immaculate-United States Province; the Sisters of Charity of Saint Elizabeth; the Sisters of Charity of the Blessed Virgin Mary, Dubuque, Iowa; and Trinity Health.

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shareholders (the "2022 proxy materials"). Friends Fiduciary and the co-filers are sometimes collectively referred to the "Proponents."

In accordance with Section C of Staff Legal Bulletin No. 14D (Nov. 7, 2008) ("SLB 14D"), we are emailing this letter and its attachments to the Staff at shareholderproposals@sec.gov. In accordance with Rule 14a-8(j), we are simultaneously sending a copy of this letter and its attachments to the Proponents as notice of the Company's intent to omit the Proposal from the 2022 proxy materials.

Rule 14a-8(k) and Section E of SLB 14D provide that shareholder proponents are required to send companies a copy of any correspondence that the shareholder proponents elect to submit to the Commission or the Staff. Accordingly, we are taking this opportunity to remind the Proponents that if the Proponents submit correspondence to the Commission or the Staff with respect to the Proposal, a copy of that correspondence should concurrently be furnished to the undersigned.

I. The Proposal

The text of the resolution contained in the Proposal is set forth below:

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.

II. Bases for Exclusion

We hereby respectfully request that the Staff concur with the Company's view that the Proposal may be excluded from the 2022 proxy materials pursuant to:

- Rule 14a-8(i)(7) because the Proposal deals with matters relating to the Company's ordinary business operations; and
- Rule 14a-8(i)(10) because the Company has substantially implemented the Proposal.

III. Background

The Company received the Proposal via FedEx on November 16, 2021, accompanied by a cover letter dated November 15, 2021 and a letter from US Bank NA, dated November 15, 2021, verifying Friends Fiduciary's continuous ownership of at least the requisite amount of Company stock for at least the requisite period preceding and including the date of submission of the Proposal. Copies of the Proposal and cover letter are attached hereto as Exhibit A. In addition, the co-filers' submissions are attached hereto as Exhibit B.

IV. The Proposal May be Excluded Pursuant to Rule 14a-8(i)(7) Because the Proposal Deals with Matters Relating to the Company's Ordinary Business Operations.

Under Rule 14a-8(i)(7), a shareholder proposal may be excluded from a company's proxy materials if the proposal "deals with matters relating to the company's ordinary business operations." In Exchange Act Release No. 34-40018 (May 21, 1998) (the "1998 Release"), the Commission stated that the policy underlying the ordinary business exclusion rests on two central considerations. The first recognizes that certain tasks are so fundamental to management's ability to run a company on a day-to-day basis that they could not, as a practical matter, be subject to direct shareholder oversight. The second consideration relates to the degree to which the proposal seeks to "micro-manage" the company by probing too deeply into matters of a complex nature upon which shareholders, as a group, would not be in a position to make an informed judgment.

The Commission has stated that a proposal requesting the dissemination of a report is excludable under Rule 14a-8(i)(7) if the substance of the proposal involves a matter of ordinary business of the company. See Exchange Act Release No. 34-20091 (Aug. 16, 1983) ("[T]he staff will consider whether the subject matter of the special report or the committee involves a matter of ordinary business; where it does, the proposal will be excludable under Rule 14a-8(c)(7)."); see also Netflix, Inc. (Mar. 14, 2016) (permitting exclusion under Rule 14a-8(i)(7) of a proposal that requested a report describing how company management identifies, analyzes and oversees reputational risks related to offensive and inaccurate portrayals of Native Americans, American Indians and other indigenous peoples, how it mitigates these risks and how the company incorporates these risk assessment results into company policies and decision-making, noting that the proposal related to the ordinary business matter of the "nature, presentation and content of programming and film production").

In accordance with the policy considerations underlying the ordinary business exclusion, the Staff consistently has permitted exclusion of shareholder proposals under Rule 14a-8(i)(7) relating to a company's general legal compliance program. *See, e.g., Navient Corp.* (Mar. 26, 2015, *recon. denied* Apr. 8, 2015) (permitting

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exclusion under Rule 14a-8(i)(7) of a proposal requesting "a report on the company's internal controls over student loan servicing operations, including a discussion of the actions taken to ensure compliance with applicable federal and state laws," as "concern[ing] a company's legal compliance program"); Raytheon Co. (Mar. 25, 2013) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting a report on "the board's oversight of the [c]ompany's efforts to implement the provisions of the Americans with Disabilities Act, the Fair Labor Standards Act, and the Age Discrimination in Employment Act," noting that "[p]roposals that concern a company's legal compliance program are generally excludable under Rule 14a-8(i)(7)"); Sprint Nextel Corp. (Mar. 16, 2010, recon. denied Apr. 20, 2010) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting that the board explain why the company has not adopted an ethics code designed to, among other things, promote securities law compliance, noting that proposals relating to "the conduct of legal compliance programs are generally excludable under rule 14a-8(i)(7)"); FedEx Corp. (July 14, 2009) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting a report on compliance by the company and its contractors with federal and state laws governing the proper classification of employees and contractors, noting that the proposal relates to the ordinary business matter of a company's "general legal compliance program"); The Coca-Cola Co. (Jan. 9, 2008) (permitting exclusion under Rule 14a-8(i)(7) of a proposal seeking an annual report comparing laboratory tests of the company's products against national laws and the company's global quality standards, noting that the proposal relates to the ordinary business matter of the "general conduct of a legal compliance program"); Verizon Communications Inc. (Jan. 7, 2008) (permitting exclusion under Rule 14a-8(i)(7) of a proposal seeking the adoption of policies to ensure that the company does not illegally trespass on private property and a report on company policies for preventing and handling such incidents, noting that the proposal relates to the ordinary business matter of a company's "general legal compliance program"); The AES Corp. (Jan. 9, 2007) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting that the board create an ethics committee to monitor the company's compliance with, among other things, federal and state laws, noting that the proposal relates to the ordinary business matter of the "general conduct of a legal compliance program").

In addition, the Staff has recognized that decisions regarding intellectual property are fundamental to a company's day-to-day operations and cannot, as a practical matter, be subject to direct shareholder oversight. In *International Business Machines Corporation* (Jan. 22, 2009), for example, the proposal requested that the company take steps to further the advancement of open source software, which the company noted allows recipients to "freely copy, modify and distribute the program source code without paying a royalty fee." In permitting exclusion under Rule 14a-8(i)(7), the Staff noted that the proposal related to the company's "ordinary

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business operations (i.e., the design, development and licensing of [the company's] software products)."

In this instance, the Proposal focuses primarily on the Company's legal compliance program and how it relates to the Company's decisions regarding its intellectual property, which are both ordinary business matters. Specifically, the Proposal's resolved clause asks for a report on how the Company's board of directors (the "Board") oversees "risks related to anticompetitive practices," including the level of the Board's oversight responsibility, how consideration of such risks are incorporated into Board deliberations regarding strategy and the Board's role in public policy activities related to such risk. The Proposal's supporting statement goes on to assert that criticism of the Company "has focused" on the use of patents to "prevent generic competition" and notes that "[r]egulators and enforcers" have scrutinized such activity. Read together, the Proposal's resolved clause and supporting statement clearly articulate a concern with the ordinary business matters of how the Company manages particular aspects of its legal compliance program with respect to competition laws and regulations and how its decisions with regard to its intellectual property, including the number of patents to apply for and the timing for such applications, relate to the legal compliance program. Decisions with respect to the oversight of the Company's legal compliance and how it maintains its intellectual property are at the heart of the Company's business as a global, researchbased biopharmaceutical company and are so fundamental to its day-to-day operations that they cannot, as a practical matter, be subject to direct shareholder oversight. Therefore, the Proposal may be excluded under Rule 14a-8(i)(7) as relating to the Company's ordinary business operations.

We note that a proposal may not be excluded under Rule 14a-8(i)(7) if it is determined to focus on a significant policy issue. The fact that a proposal may touch upon a significant policy issue, however, does not preclude exclusion under Rule 14a-8(i)(7). Instead, the question is whether the proposal focuses primarily on a matter of broad public policy versus matters related to the company's ordinary business operations. See 1998 Release; Staff Legal Bulletin No. 14E (Oct. 27, 2009). The Staff has consistently permitted exclusion of shareholder proposals where the proposal focused on ordinary business matters, even though it also related to a potential significant policy issue. For example, in *PetSmart*, *Inc.* (Mar. 24, 2011), the proposal requested that the company's board require suppliers to certify that they had not violated certain laws regulating the treatment of animals. Those laws affected a wide array of matters dealing with the company's ordinary business operations beyond the humane treatment of animals, which the Staff has recognized as a significant policy issue. In permitting exclusion under Rule 14a-8(i)(7), the Staff noted the company's view that "the scope of the laws covered by the proposal is 'fairly broad in nature from serious violations such as animal abuse to violations of administrative matters such as record keeping." See also, e.g., CIGNA Corp. (Feb.

23, 2011) (permitting exclusion under Rule 14a-8(i)(7) when, although the proposal addressed the potential significant policy issue of access to affordable health care, it also asked CIGNA to report on expense management, an ordinary business matter); *Capital One Financial Corp.* (Feb. 3, 2005) (permitting exclusion under Rule 14a-8(i)(7) when, although the proposal addressed the significant policy issue of outsourcing, it also asked the company to disclose information about how it manages its workforce, an ordinary business matter).

In this instance, even if the Proposal were to touch on a potential significant policy issue, the Proposal's overwhelming concern with how the Company manages particular aspects of its legal compliance program with respect to competition laws and regulations and how its decisions with regard to its intellectual property relate to the legal compliance program demonstrates that the Proposal's focus is on ordinary business matters. Therefore, even if the Proposal could be viewed as touching upon a significant policy issue, its focus is on ordinary business matters.

Accordingly, the Proposal should be excluded from the Company's 2022 proxy materials pursuant to Rule 14a-8(i)(7) as relating to its ordinary business operations.

V. The Proposal May be Excluded Pursuant to Rule 14a-8(i)(10) Because the Company Has Substantially Implemented the Proposal.

Rule 14a-8(i)(10) permits a company to exclude a shareholder proposal if the company has already substantially implemented the proposal. The Commission adopted the "substantially implemented" standard in 1983 after determining that the "previous formalistic application" of the rule defeated its purpose, which is to "avoid the possibility of shareholders having to consider matters which already have been favorably acted upon by the management." *See* 1983 Release; Exchange Act Release No. 34-12598 (July 7, 1976). Accordingly, the actions requested by a proposal need not be "fully effected" provided that they have been "substantially implemented" by the company. *See* 1983 Release.

Applying this standard, the Staff has consistently permitted the exclusion of a proposal when it has determined that the company's policies, practices and procedures or public disclosures compare favorably with the guidelines of the proposal. See, e.g., Eli Lilly and Co. (Feb. 26, 2021)*; Devon Energy Corp. (Apr. 1, 2020)*; Johnson & Johnson (Jan. 31, 2020)*; Pfizer Inc. (Jan. 31, 2020)*; The Allstate Corp. (Mar. 15, 2019); Johnson & Johnson (Feb. 6, 2019); United Cont'l Holdings, Inc. (Apr. 13, 2018); eBay Inc. (Mar. 29, 2018); Kewaunee Scientific

^{*} Citations marked with an asterisk indicate Staff decisions issued without a letter.

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Corp. (May 31, 2017); Wal-Mart Stores, Inc. (Mar. 16, 2017); Dominion Resources, Inc. (Feb. 9, 2016); Ryder System, Inc. (Feb. 11, 2015).

In addition, the Staff has permitted exclusion under Rule 14a-8(i)(10) where a company already addressed the underlying concerns and satisfied the essential objective of the proposal, even if the proposal had not been implemented exactly as proposed by the proponent. For example, in *The Boeing Company* (Feb. 17, 2011), the Staff permitted exclusion under Rule 14a-8(i)(10) of a proposal requesting that the company "review its policies related to human rights" and report its findings, where the company had already adopted human rights policies and provided an annual report on corporate citizenship. See also, e.g., The Wendy's Co. (Apr. 10, 2019) (permitting exclusion under Rule 14a-8(i)(10) of a proposal requesting a report assessing human rights risks of the company's operations, including the principles and methodology used to make the assessment, the frequency of assessment and how the company would use the assessment's results, where the company had a code of ethics and a code of conduct for suppliers and disclosed on its website the frequency and methodology of its human rights risk assessments); Verizon Communications *Inc.* (Feb. 19, 2019) (permitting exclusion under Rule 14a-8(i)(10) of a proposal requesting that the company's board establish a committee to oversee the company's policies and practices relating to public policy issues, including human rights, where the company's existing committees charters provided committee level oversight of public policy issues and "significant business risk exposures"); MGM Resorts Int'l (Feb. 28, 2012) (permitting exclusion under Rule 14a-8(i)(10) of a proposal requesting a report on the company's sustainability policies and performance, including multiple objective statistical indicators, where the company published an annual sustainability report).

In this instance, the Company has substantially implemented the Proposal, the essential objective of which is to obtain disclosure of how the Company's Board identifies, oversees and analyzes risks related to the Company's compliance with laws and regulations. Specifically, the Proposal's resolved clause requests that the Company disclose how the Board "oversees risks related to anticompetitive practices," including the level of the Board's oversight responsibility, how consideration of such risks are incorporated into the Board's deliberations regarding and the Board's role in public policy activities related to such risk. The Proposal's supporting statement asserts that the Company is "facing mounting pressure related to the [C]ompany's anticompetitive practices," which "can increase the likelihood [of] new regulation and increases risks for investors." The supporting statement continues that "robust board oversight would improve [the Company's] management of risks related to anticompetitive practices."

The Company already provides extensive disclosure regarding the Board's oversight of risks related to legal compliance. In this regard, the Company's

definitive proxy statement for the 2021 annual meeting of shareholders describes the general structure of the Board's oversight of risk:

The [B]oard has risk oversight responsibility for [the Company] and administers this responsibility both directly and with assistance from its committees. The [B]oard reviews enterprise risks and discusses them with our senior management on a regular basis. [The Company's] risk management program focuses on issues relevant to [the Company's] business, reputation, and strategy, including but not limited to pipeline advancement, healthcare industry dynamics such as pricing and patient access, manufacturing, regulatory and compliance matters, and others. The [B]oard and its committees regularly review environmental, social, and governance (ESG) topics that are material to [the Company].²

In addition, the Public Policy Committee of the Board has specific oversight responsibility of the Company's compliance program with respect to legal and regulatory requirements. In particular, the Public Policy Committee's Charter, which is available on the Company's website, provides that the Committee shall, among other things:

- Review the Company's compliance program with respect to legal and regulatory requirements (including, but not limited to, policies related to healthcare compliance, product quality, environmental regulations, employee health & safety and compliance with the U.S. Foreign Corrupt Practices Act of 1977, as amended) except with respect to matters of financial compliance which are the responsibility of the Audit Committee.³
- Devise a process for the dissemination of information to the Committee from management with respect to regulatory and healthcare compliance matters, including, as appropriate, presentations to the Committee from management concerning the state of regulatory compliance and all issues with respect thereto.

See the Company's definitive proxy statement for the 2021 annual meeting of shareholders, available at https://www.sec.gov/Archives/edgar/data/1551152/000155837021003318/tmb-20210507xdef14a.htm.

The Audit Committee of the Board is tasked with oversight of legal and regulatory compliance as it relates to financial matters and the Company's enterprise risk management. *See* the Company's Audit Committee Charter, available at https://investors.abbvie.com/static-files/73999c91-7d95-45b4-86df-21d1e7e574e1 and attached hereto as Exhibit C.

• Receive reports from the Chief Ethics and Compliance Officer on a regular basis.⁴

Moreover, as described in the Company's Code of Business Conduct (the "Code"), which is available on the Company's website, the Company and all its employees are required to comply with applicable industry laws and regulations.⁵ In particular, the Code specifically covers the Company's compliance with antitrust laws. In a section titled "We follow antitrust laws," the Code provides that "[t]he fair pricing of our products is essential to our commitment to improving health worldwide," which is "why we never engage in activities that restrain free trade – such as price fixing, bid rigging or other arrangements that violate antitrust laws." In addition, the Code provides that the Company will "never discuss pricing, customers or sales agreements with competitors, and [is] careful to avoid any activity that gives the appearance of restricting trade." More generally, the Code also notes that "[p]atients, health care providers, customers and suppliers know they can rely on us because we comply with the laws, regulations and codes that govern the pharmaceutical industry and our [C]ompany," including research and development, manufacturing, promoting and selling products, marketing products and distributing products. The Code further provides that the Company complies "with all applicable laws that regulate our business" and conducts business "in a transparent and ethical manner." As explained in the Code, "[m]any of these laws concern the way we promote and sell our medical products" and "[i]t is never acceptable to try to influence purchasing decisions in any way that is unethical, inappropriate or illegal or creates a potential conflict of interest."

Given the extensive disclosure in the Company's definitive proxy statement for the 2021 annual meeting of shareholders, the Public Policy Committee Charter and the Code, the Company already has publicly disclosed how it identifies, oversees and analyzes risks related to the Company's compliance with laws and regulations. Therefore, the Company has satisfied the Proposal's essential objective and thus its public disclosures compare favorably with those requested by the Proposal.

Accordingly, the Company believes that the Proposal may be excluded from its 2022 proxy materials pursuant to Rule 14a-8(i)(10) as substantially implemented.

See the Company's Public Policy Committee Charter, available at https://investors.abbvie.com/static-files/323c9ed5-ab11-444c-9ff7-cac2ec54e627 and attached hereto as Exhibit D.

See the Company's Code of Business Conduct, available at https://www.abbvie.com/content/dam/abbvie-dotcom/uploads/PDFs/COBC/cobc_English.pdf, relevant excerpts of which are attached hereto as Exhibit E.

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VI. Conclusion

Based upon the foregoing analysis, we respectfully request that the Staff concur that it will take no action if the Company excludes the Proposal from its 2022 proxy materials.

Should the Staff disagree with the conclusions set forth in this letter, or should any additional information be desired in support of the Company's position, we would appreciate the opportunity to confer with the Staff concerning these matters prior to the issuance of the Staff's response. Please do not hesitate to contact the undersigned at (202) 371-7233.

Very truly yours,

Marc S. Gerber

Enclosures

cc: Laura J. Schumacher

Vice Chairman, External Affairs and Chief Legal Officer AbbVie Inc.

Amy Carr Friends Fiduciary Corporation

Jeffrey Perkins Friends Fiduciary Corporation

Lydia Kuykendal, on behalf of Bon Secours Mercy Health Inc., CommonSpirit Health and Mercy Investment Services, Inc. Director of Shareholder Advocacy Mercy Investment Services, Inc.

Rev. Séamus P. Finn, OMI Missionary Oblates of Mary Immaculate / OIP Investment Trust (U.S. Province)

Sister Barbara Aires, SC Coordinator of Corporate Responsibility The Sisters of Charity of Saint Elizabeth Office of Chief Counsel December 22, 2021 Page 11

> Gwen Farry, BVM The Sisters of Charity of the Blessed Virgin Mary, Dubuque, Iowa

Catherine Rowan Trinity Health

EXHIBIT A

(see attached)



ADDING VALUES TO STRONG PERFORMANCE.

November 15, 2021

DELIVERY VIA PRIORITY MAIL

Corporate Secretary AbbVie Inc. 1 N. Waukegan Road North Chicago, IL 60064

Dear Corporate Secretary,

Friends Fiduciary Corporation ("Friends Fiduciary") is submitting the attached proposal (the "Proposal") pursuant to the Securities and Exchange Commission's Rule 14a-8 to be included in the proxy statement of AbbVie Inc. (the "Company") for its 2022 annual meeting of shareholders. Friends Fiduciary is the lead filer for the Proposal and will be joined by other shareholders as co-filers.

Friends Fiduciary Corporation serves more than 430 Quaker meetings, churches, and organizations through its socially responsible investment services. We have over \$675 million in assets under management. Our investment philosophy is grounded in the beliefs of the Religious Society of Friends (Quakers), among them the testimonies of peace, simplicity, integrity and justice. We are long term investors and take our responsibility as shareholders seriously. When we engage companies we own through shareholder resolutions we seek to witness to the values and beliefs of Quakers as well as to protect and enhance the long-term value of our investments.

Friends Fiduciary is available to meet with the Company on: December 9, at 11AM Eastern or December 10, at 10AM Eastern. Any co-filers will either (a) be available on those dates and times or (b) in their submission letters, authorize us to engage with the Company on their behalf, within the meaning of Rule 14a-8(b)(iii)(B).

A representative of the filers will attend the shareholder meeting to move the resolution. We look forward to meaningful dialogue with your company on the issues raised in this proposal. Please note that the contact person for this proposal is Amy Carr at Friends Fiduciary

As the lead filer, Friends Fiduciary is authorized to withdraw this resolution on our co-filers' behalf.

Friends Fiduciary has continuously beneficially owned, for at least three years as of the date hereof, at least \$2,0000 worth of the Company's common stock. Verification of this ownership is attached. Friends Fiduciary intends to continue to hold such shares through the date of the Company's 2022 annual meeting of shareholders.

Sincerely, Jeffey W. Perkins/50

Jeffery W. Perkins Executive Director

SUPPORTING STATEMENT

The anticompetitive practices of companies within the pharmaceutical supply chain, including drug developers such as AbbVie, are receiving increasing scrutiny from the public, regulators, and enforcers. The criticism of AbbVie has focused on the company's establishment of "patent thickets" around its drugs to prevent generic competition, some of which have resulted in massive price hikes for everyday consumers.

Regulators and enforcers are increasingly focused on curbing this type of behavior. In May, then-acting Chairwoman of the Federal Trade Commission (FTC) Rebecca Kelly Slaughter stated 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." Furthermore, upon confirmation, newly appointed FTC Chair Lina Kahn directed FTC staff to ramp up investigations based on seven enforcement priorities, including healthcare and pharmaceutical companies."

We are concerned over the growing risk associated with AbbVie's reliance on creating "patent thickets" and entering "pay-for-delay" settlements. AbbVie has been scrutinized for its practices surrounding Humira and Imbruvica, which were the subject of a 2021 drug pricing investigation and report published by the U.S. House Committee on Oversight and Reform.^{IV} The report details that AbbVie has applied for over 250 patents on Humira, with 90% of these applications filed after Humira was already approved, "suggesting that they were intended to block competition." The report also questions whether AbbVie transferred items of value to competitors in exchange for them staying off the market, a violation of U.S. antitrust law. These drugs represent nearly 55% of AbbVie's 2020 net revenue.

AbbVie is facing mounting pressure related to the company's anticompetitive practices. This pressure can increase the likelihood new regulation and increases risk for investors. Given this widespread concern and the rapidly changing environment, we believe that robust board oversight would improve AbbVie's management of risks related to anticompetitive practices and that shareholders would benefit from more information about the board's role.

Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices, I-MAK, 2019 (https://www.i-mak.org/wp-content/uploads/2019/01/i-mak.overpatented.overpriced.report.0801.pdf).

https://www.ftc.gov/public-statements/2021/05/statement-acting-chairwoman-rebecca-kelly-slaughter-regarding-federal

iii https://endpts.com/pharma-in-the-crosshairs-how-the-ftc-is-expanding-its-antitrust-powers-under-its-new-chair/

^{iv} *Drug Pricing Investigation AbbVie—Humira and Imbruvica*, U.S. House of Representatives Staff Report, May 2021, https://oversight.house.gov/news/press-releases/chairwoman-maloney-releases-staff-report-and-new-documents-showing-abusive-drug.

V Id. at i.

vi <u>Id</u>. at v.

vii AbbVie 2020 Form 10-K, at 46-47 (https://investors.abbvie.com/static-files/47512e94-a9a4-4035-8dbc-6eb59116bb05).

EXHIBIT B

(see attached)

BON SECOURS MERCY HEALTH

November 18, 2021

AbbVie Inc. Attn: Corporate Secretary 1 North Waukegan Road North Chicago, IL 60064

Dear Corporate Secretary:

Bon Secours Mercy Health, Inc. has long been concerned not only with the financial returns of its investments, but also with the social and ethical implications of its investments. We believe that a demonstrated corporate responsibility in matters of the environment, social and governance concerns fosters long term business success. Bon Secours Mercy Health, a long-term investor, is currently the beneficial owner of shares of AbbVie Inc.

Bon Secours Mercy Health is asking 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.

Bon Secours Mercy Health is co-filing the enclosed shareholder proposal with lead filer, Friends Fiduciary, for inclusion in the 2022 proxy statement, in accordance with Rule 14a-8 of the General Rules and Regulations of the Securities Exchange Act of 1934. Bon Secours Mercy Health has been a shareholder continuously since and including January 4, 2020, holding at least \$2,000 in market value and will continue to invest in at least the requisite number of shares for proxy resolutions through the annual shareholders' meeting. The verification of ownership by our custodian, a DTC participant, is included in this packet. A representative of the filers will attend the Annual Meeting to present the resolution as required by SEC rules.

We will plan to participate in any meetings on this proposal to the extent we are available at the time selected by the lead filer and our company. Please direct **all future correspondence** regarding this proposal to Lydia Kuykendal of Mercy Investment Services, who is authorized to speak and negotiate on Bon Secours Mercy Health's behalf. Lydia's contact information is:

We authorize Friends Fiduciary to withdraw on our behalf if an agreement

is reached.

Best regards,

Jerry Judd Senior Vice President and Treasurer

Bon Secours Mercy Health

SUPPORTING STATEMENT

The anticompetitive practices of companies within the pharmaceutical supply chain, including drug developers such as AbbVie, are receiving increasing scrutiny from the public, regulators, and enforcers. The criticism of AbbVie has focused on the company's establishment of "patent thickets" around its drugs to prevent generic competition, some of which have resulted in massive price hikes for everyday consumers.

Regulators and enforcers are increasingly focused on curbing this type of behavior. In May, then-acting Chairwoman of the Federal Trade Commission (FTC) Rebecca Kelly Slaughter stated 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." Furthermore, upon confirmation, newly appointed FTC Chair Lina Kahn directed FTC staff to ramp up investigations based on seven enforcement priorities, including healthcare and pharmaceutical companies. "

We are concerned over the growing risk associated with AbbVie's reliance on creating "patent thickets" and entering "pay-for-delay" settlements. AbbVie has been scrutinized for its practices surrounding Humira and Imbruvica, which were the subject of a 2021 drug pricing investigation and report published by the U.S. House Committee on Oversight and Reform. The report details that AbbVie has applied for over 250 patents on Humira, with 90% of these applications filed after Humira was already approved, "suggesting that they were intended to block competition." The report also questions whether AbbVie transferred items of value to competitors in exchange for them staying off the market, a violation of U.S. antitrust law. These drugs represent nearly 55% of AbbVie's 2020 net revenue.

AbbVie is facing mounting pressure related to the company's anticompetitive practices. This pressure can increase the likelihood new regulation and increases risk for investors. Given this widespread concern and the rapidly changing environment, we believe that robust board oversight would improve AbbVie's management of risks related to anticompetitive practices and that shareholders would benefit from more information about the board's role.

ⁱ Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices, I-MAK, 2019 (https://www.i-mak.org/wp-content/uploads/2019/01/i-mak.overpatented.overpriced.report.0801.pdf).

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iii https://endpts.com/pharma-in-the-crosshairs-how-the-ftc-is-expanding-its-antitrust-powers-under-its-new-chair/

^{iv} Drug Pricing Investigation AbbVie—Humira and Imbruvica, U.S. House of Representatives Staff Report, May 2021, https://oversight.house.gov/news/press-releases/chairwoman-maloney-releases-staff-report-and-new-documents-showing-abusive-drug.

VId. at i.

vi Id. at v.

vii AbbVie 2020 Form 10-K, at 46-47 (https://investors.abbvie.com/static-files/47512e94-a9a4-4035-8dbc-6eb59116bb05).



November 18, 2021

AbbVie Inc. Attn: Corporate Secretary 1 North Waukegan Road North Chicago, IL 60064

Dear Corporate Secretary:

CommonSpirit Health is concerned not only with the financial returns of its investments, but also with the social and ethical implications of its investments. We believe that a demonstrated corporate responsibility in matters of the environment, social and governance concerns fosters long-term business success. CommonSpirit Health is currently the beneficial owner of shares of AbbVie Inc..

The enclosed proposal is asking 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.

CommonSpirit Health is co-filing the enclosed shareholder proposal for inclusion in the 2022 proxy statement with lead filer, Friends Fiduciary, in accordance with Rule 14a-8 of the General Rules and Regulations of the Securities Exchange Act of 1934. CommonSpirit Health has been a shareholder continuously since and including January 4, 2020, holding at least \$2,000 in market value and will continue to invest in at least the requisite number of shares for proxy resolutions through the annual shareholders' meeting. The verification of ownership by our custodian, a DTC participant, is included in this packet. A representative of the filers will attend the Annual Meeting to present the resolution as required by SEC rules.

We will plan to participate in any meetings on this proposal to the extent we are available at the time selected by the lead filer and our company. Please direct **all future correspondence** regarding this proposal to Lydia Kuykendal of Mercy Investment Services, who is authorized to speak and negotiate on CommonSpirit Health's behalf. Lydia's contact information is:

We authorize Friends Fiduciary to withdraw on our behalf if an

agreement is reached.

Best regards,

Laura Krausa, MNM

System Director Advocacy Programs

CommonSpirit Health

SUPPORTING STATEMENT

The anticompetitive practices of companies within the pharmaceutical supply chain, including drug developers such as AbbVie, are receiving increasing scrutiny from the public, regulators, and enforcers. The criticism of AbbVie has focused on the company's establishment of "patent thickets" around its drugs to prevent generic competition, some of which have resulted in massive price hikes for everyday consumers.

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November 18, 2021

AbbVie Inc. Attn: Corporate Secretary 1 North Waukegan Road North Chicago, IL 60064

Dear Corporate Secretary:

Mercy Investment Services, Inc. ("Mercy"), as the investment program of the Sisters of Mercy of the Americas, has long been concerned not only with the financial returns of its investments, but also with their social and ethical implications. We believe that a demonstrated corporate responsibility in matters of the environment, and social and governance concerns fosters long-term business success. Mercy, a long-term investor, is currently the beneficial owner of shares of AbbVieInc.

The enclosed proposal is asking 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.

Mercy is co-filing the shareholder proposal with lead filer, Friends Fiduciary, for inclusion in the 2022 proxy statement, in accordance with Rule 14a-8 of the General Rules and Regulations of the Securities Exchange Act of 1934. Mercy has been a shareholder continuously since and including January 4, 2020, holding at least \$2,000 in market value and will continue to invest in at least the requisite number of shares for proxy resolutions through the annual shareholders' meeting. The verification of ownership by our custodian, a DTC participant, is included in this packet. One of the filers will attend the Annual Meeting to present the proposal as required by SEC rules. We authorize Friends Fiduciary to withdraw the proposal on our behalf if an agreement is reached.

We will plan to participate in any meetings on this proposal to the extent we are available at the time selected by the lead filer and our company. Please direct all future correspondence regarding this proposal to me via the information below.

Best regards,

Lydia Kuykendal

Director of Shareholder Advocacy

Tryde Tinterell

SUPPORTING STATEMENT

The anticompetitive practices of companies within the pharmaceutical supply chain, including drug developers such as AbbVie, are receiving increasing scrutiny from the public, regulators, and enforcers. The criticism of AbbVie has focused on the company's establishment of "patent thickets" around its drugs to prevent generic competition, some of which have resulted in massive price hikes for everyday consumers.

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^{tw} *Drug Pricing Investigation AbbVie—Humira and Imbruvica*, U.S. House of Representatives Staff Report, May 2021, https://oversight.house.gov/news/press-releases/chairwoman-maloney-releases-staff-report-and-new-documents-showing-abusive-drug.

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vii AbbVie 2020 Form 10-K, at 46-47 (https://investors.abbvie.com/static-files/47512e94-a9a4-4035-8dbc-6eb59116bb05).



November 19, 2021

Laura J. Schumacher Corporate Secretary AbbVie 1 North Waukegan Road, AP34 North Chicago, Illinois 60064

Email:

Dear Ms. Schumacher:

I am writing you on behalf of **the Missionary Oblates of Mary Immaculate-United States Province** to co-file the stockholder resolution on Anticompetitive Practices. In brief, the proposal states: **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.

I am hereby authorized to notify you of our intention to co-file this shareholder proposal with Friends Fiduciary Corporation. I submit it for inclusion in the 2022 proxy statement for consideration and action by the shareholders at the 2022 annual meeting in accordance with Rule 14-a-8 of the General Rules and Regulations of the Securities and Exchange Act of 1934. We are the beneficial owner, as defined in Rule 13d-3 of the Securities Exchange Act of 1934, of \$2,000 worth of the shares for at least three years as of the date hereof. We have continuously held shares of AbbVie common stock with a value of at least \$2,000 for at least one year in market value and will continue to hold at least \$2,000 of AbbVie stock through the next annual meeting. Verification of our ownership position will be sent by our custodian. A representative of the filers will attend the stockholders' meeting to move the resolution as required by SEC rules.

We truly hope that the company will be willing to dialogue with the filers about this proposal. We consider Friends Fiduciary Corporation the lead filer of this resolution. As such, Friends Fiduciary Corporation, serving as the primary filer, is authorized to act on our behalf in all aspects of the resolution, including negotiation and deputize them to withdraw the resolution on our behalf if an agreement is reached. Please note that the contact person for this resolution/proposal will be Jeffery Perkins, of Friends Fiduciary Corporation who may be reached by phone

As a co-filer, however, we respectfully request direct communication from the company and to be listed in the proxy. Sincerely,

Rev. Séamus P. Finn, OMI

Ru San O. Framon,

Missionary Oblates of Mary Immaculate / OIP Investment Trust (U.S Province)

SUPPORTING STATEMENT

The anticompetitive practices of companies within the pharmaceutical supply chain, including drug developers such as AbbVie, are receiving increasing scrutiny from the public, regulators, and enforcers. The criticism of AbbVie has focused on the company's establishment of "patent thickets" around its drugs to prevent generic competition, some of which have resulted in massive price hikes for everyday consumers.¹

Regulators and enforcers are increasingly focused on curbing this type of behavior. In May, then-acting Chairwoman of the Federal Trade Commission (FTC) Rebecca Kelly Slaughter stated 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." Furthermore, upon confirmation, newly appointed FTC Chair Lina Kahn directed FTC staff to ramp up investigations based on seven enforcement priorities, including healthcare and pharmaceutical companies. "

We are concerned over the growing risk associated with AbbVie's reliance on creating "patent thickets" and entering "pay-for-delay" settlements. AbbVie has been scrutinized for its practices surrounding Humira and Imbruvica, which were the subject of a 2021 drug pricing investigation and report published by the U.S. House Committee on Oversight and Reform. The report details that AbbVie has applied for over 250 patents on Humira, with 90% of these applications filed after Humira was already approved, "suggesting that they were intended to block competition." The report also questions whether AbbVie transferred items of value to competitors in exchange for them staying off the market, a violation of U.S. antitrust law. These drugs represent nearly 55% of AbbVie's 2020 net revenue.

AbbVie is facing mounting pressure related to the company's anticompetitive practices. This pressure can increase the likelihood new regulation and increases risk for investors. Given this widespread concern and the rapidly changing environment, we believe that robust board oversight would improve AbbVie's management of risks related to anticompetitive practices and that shareholders would benefit from more information about the board's role.

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November 18, 2021

BY EMAIL AND DELIVERY

RECEIVED

Ms. Laura J. Schumacher Corporate Secretary Dept. V364, AP34 Abb Vie, Inc. 1 North Waukegan Road North Chicago, IL 60064 NOV 23 2021

LAURA J SCHUMACHER

Re: Shareholder proposal for 2022 Annual Shareholder Meeting

Dear Ms. Schumacher,

The Sisters of Charity of Saint Elizabeth hereby co-files a shareholder proposal submitted by lead filer Friends Fiduciary in accordance with SEC Rule 14a-8, to be included in the proxy statement of Abb Vie, Inc. for its 2022 annual meeting of shareholders.

The Sisters of Charity of Saint Elizabeth has continuously held, for at least one year as of the date hereof, at least 250 shares of the Company's common stock to meet the requirements of Rule 14a-8 of the general rules and regulations of the Securities and Exchange Act of 1934, as amended. The Sisters of Charity of Saint Elizabeth intends to continue to hold such shares through the date of the Company's 2022 annual meeting of shareholders.

Friends Fiduciary is the lead filer for this proposal and is authorized to negotiate on behalf of The Sisters of Charity of Saint Elizabeth any potential withdrawal of this proposal.

We welcome the opportunity to discuss this proposal with representatives of the Company. Please feel free to contact me with any questions.

Sincerely,

Sister Barbara Aires, SC

Sester Berbara Aures

Coordinator of Corporate Responsibility

SBA/lp (Enclosure)



SUPPORTING STATEMENT

The anticompetitive practices of companies within the pharmaceutical supply chain, including drug developers such as AbbVie, are receiving increasing scrutiny from the public, regulators, and enforcers. The criticism of AbbVie has focused on the company's establishment of "patent thickets" around its drugs to prevent generic competition, some of which have resulted in massive price hikes for everyday consumers.

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Corporate Secretary
AbbVie Inc.
1 N Waukegan Road
North Chicago, IL 60064

Dear Corporate Secretary,

The Sisters of Charity of the Blessed Virgin Mary, Dubuque, Iowa, is submitting the attached proposal (the "Proposal") pursuant to the Securities and Exchange Commission's Rule 14a-8 to be included in the proxy statement of AbbVie, Inc. (the "Company") for its 2022 annual meeting of shareholders. The Sisters of Charity of the Blessed Virgin Mary, Dubuque, Iowa, is co-filing the Proposal with lead filer, Friends Fiduciary. In its submission letter, Friends Fiduciary will provide dates and times of availability to meet. We designate the lead filer to meet initially with the Company, but may join the meeting subject to our availability.

The Sisters of Charity of the Blessed Virgin Mary, Dubuque, Iowa, has continuously beneficially owned, for at least as of the date hereof, at least \$2,000 worth of the Company's common stock for more than three years. Verification of this ownership will be sent under separate cover. The Sisters of Charity of the Blessed Virgin Mary, Dubuque, Iowa intends to continue to hold such shares through the date of the Company's 2022 annual meeting of shareholders.

Sincerely,

Gwen Farry, BVM

Sisters of Charity, BVM

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SUPPORTING STATEMENT

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November 18, 2021

Jennifer Lagunas VP, Corporate Legal, Governance, Operations and Assistant Corporate Secretary
Office of the Corporate Secretary
AbbVie Inc.
1 N. Waukegan Road
North Chicago, IL 60064

Via express mail and electronic mail:

Dear Ms. Lagunas,

Trinity Health is submitting the attached proposal (the "Proposal") pursuant to the Securities and Exchange Commission's Rule 14a-8 to be included in the proxy statement of AbbVie, Inc. (the "Company") for its 2022 annual meeting of shareholders. Trinity Health is co-filing the Proposal with lead filer Friends Fiduciary Corporation ("Friends Fiduciary"). We authorize Friends Fiduciary to engage with the company on our behalf.

In its submission letter, Friends Fiduciary will provide dates and times to meet during the postfiling period as required by Rule 14a-8(b)(iii). We designate the lead filer to meet initially with the Company but may join the meeting subject to our availability.

Trinity Health has continuously beneficially owned, for at least three years as of the date hereof, at least \$2,000 worth of the Company's common stock. Verification of this ownership is enclosed. Trinity Health intends to continue to hold such shares through the date of the Company's 2022 annual meeting of shareholders.

If you have any questions or need additional information, I can be contacted at or by email at

Sincerely,

Catherine Rowan

enc.

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.

SUPPORTING STATEMENT

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We therefore urge shareholders to vote FOR this proposal.

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VId. at i.

vi Id. at v.

vii AbbVie 2020 Form 10-K, at 46-47 (https://investors.abbvie.com/static-files/47512e94-a9a4-4035-8dbc-6eb59116bb05).

EXHIBIT C

(see attached)

AbbVie Inc. Audit Committee Charter

- 1. *Purpose*. The Audit Committee of the Board of Directors shall assist the Board of Directors (the "Board") of AbbVie Inc. ("AbbVie") in fulfilling its oversight responsibility with respect to:
 - AbbVie's accounting and financial reporting practices and the audit process;
 - the quality and integrity of AbbVie's financial statements;
 - the independent auditors' qualifications, independence, and performance;
 - the performance of AbbVie's internal audit function and internal auditors;
 - legal and regulatory compliance as it relates to financial matters, including accounting, auditing, financial reporting, and securities law issues (recognizing that other board committees assist the Board in reviewing other areas of legal and regulatory compliance); and
 - AbbVie's enterprise risk management, including major financial risk exposures (recognizing that other board committees assist the Board in reviewing certain aspects of risk management);

and shall prepare the report required by the rules of the Securities and Exchange Commission to be included in AbbVie's annual proxy statement.

- 2. *Qualifications*; Organization. The Audit Committee shall be composed of at least three (3) directors. Each member must satisfy the independence and financial literacy requirements of the New York Stock Exchange, Section 10A of the Securities Exchange Act of 1934 (including the rules and regulations promulgated thereunder, the "Exchange Act"; any reference in this charter to Section 10A of the Exchange Act shall be deemed to include the rules and regulations promulgated thereunder), and this charter, as such requirements are interpreted by the Board in its business judgment. At least one member of the Audit Committee shall have accounting or related financial management expertise, as such qualification is interpreted by the Board in its business judgment. Director's fees and committee fees are the only compensation an Audit Committee member may receive from AbbVie. No member of the Audit Committee may serve simultaneously on the audit committee of more than three public companies. AbbVie's Board shall appoint, and may remove, members of the Audit Committee and the Audit Committee's Chairman, after receiving the recommendation of AbbVie's Nominations and Governance Committee.
- 3. Authority and Responsibilities. The Audit Committee is directly responsible for the appointment, termination, compensation, and oversight of the work of AbbVie's independent auditors (including the resolution of disagreements between management and the independent auditors regarding financial reporting) for the purpose of preparing or issuing an audit report or related work. It shall report regularly to the Board.

AbbVie's independent auditors shall report directly to the Audit Committee. AbbVie's internal auditors shall be ultimately accountable to the Audit Committee and the Board. The Audit Committee shall pre-approve all audit and permissible non-audit services to be rendered by the independent auditors. Alternatively, AbbVie may enter into engagements to render such services pursuant to pre-approval policies and procedures established by the Audit Committee; provided, that such policies and procedures are detailed as to the particular service, the Audit Committee is informed of each service, and such policies and procedures do not include the delegation of Audit Committee responsibilities under the Exchange Act to management. Moreover, the pre-approval requirement for permissible non-audit services shall be waived under certain circumstances described in Section 10A of the Exchange Act.

The Audit Committee may, to the extent it deems necessary or appropriate, conduct or authorize investigations into any matter within the scope of its authority and may retain legal counsel, accountants and others to assist it in the conduct of its responsibilities, including investigations. The Audit Committee shall receive appropriate funding, as determined by the Audit Committee, from AbbVie for payment of (a) compensation to the independent auditor employed by AbbVie for the purpose of rendering or issuing an audit report or performing other audit, review or attest services for AbbVie, (b) compensation to any special legal, accounting or other consultants employed by the Audit Committee and (c) ordinary administrative expenses of the Audit Committee that are necessary or appropriate in carrying out its duties. The Audit Committee may consult with management and may delegate any of its responsibilities and duties to one or more members of the Audit Committee, except to the extent such delegation would be inconsistent with the requirements of the Exchange Act or the listing rules of the New York Stock Exchange.

The Audit Committee shall:

- Prepare the report required by the rules of the Securities and Exchange Commission to be included in AbbVie's annual proxy statement.
- Meet separately, periodically, with AbbVie's independent auditors, with AbbVie's management and with AbbVie's internal auditors.
- At least annually, evaluate the qualifications, performance, and independence of AbbVie's independent auditors and appoint a firm of independent public accountants to act as AbbVie's independent auditors. This evaluation shall include the review and evaluation of the lead partner of AbbVie's independent auditors and shall take into account the opinions of AbbVie's management and internal auditors. In connection with this evaluation and appointment, the Audit Committee shall obtain and review a report by AbbVie's then current independent auditors describing:
 - the independent auditors' internal quality-control procedures;
 - any material issues raised by the most recent internal quality-control review, or peer review, of the independent auditors, or by any inquiry or investigation by

governmental or professional authorities, within the preceding five years, respecting one or more independent audits carried out by the independent auditors, and any steps taken to deal with any such issues; and

all relationships between the independent auditors and AbbVie.

The Audit Committee shall discuss with the independent auditors any relationships disclosed in that report and shall, if necessary, take appropriate action to ensure the auditors' independence:

- Oversee compliance of AbbVie's rotation policy for the partners and employees of its independent auditors with the requirements of Section 10A of the Exchange Act. The Audit Committee shall consider the regular rotation of AbbVie's independent auditors and report its conclusions to the Board.
- Meet to review and discuss with management and the independent auditors:
 - the annual audited financial statements and quarterly financial statements, including AbbVie's specific disclosures under Management's Discussion and Analysis of Financial Condition and Results of Operations (that is, under the section captioned "Financial Review") and the matters required to be discussed pursuant to Auditing Standards Section AU 380, as adopted by the Public Company Accounting Oversight Board, before their incorporation into AbbVie's filings with the Securities and Exchange Commission;
 - the independent auditors' report on the effectiveness of AbbVie's internal control over financial reporting;
 - the scope, procedures and fees for the proposed audit for the current year and, at its conclusion, review that audit including any comments or recommendations by the independent auditors;
 - earnings releases (paying particular attention to any use of "pro-forma" or
 "adjusted" non-GAAP information), as well as financial information and earnings
 guidance provided to analysts and rating agencies (this may be done generally and
 need not occur in advance of each earnings release or each instance in which
 AbbVie may provide earnings guidance);
 - the responsibilities, budget and staffing of AbbVie's internal audit function;
 - major issues regarding accounting principles and financial statement presentations, including significant changes in AbbVie's selection or application of accounting principles and major issues as to the adequacy of AbbVie's internal controls and any special audit steps adopted in light of material control deficiencies;
 - analyses prepared by management or AbbVie's independent auditors setting forth significant financial reporting issues and judgments made in connection with the

- preparation of financial statements, including analyses of the effects of alternative GAAP methods on the financial statements; and
- the effect of regulatory and accounting initiatives, as well as off-balance sheet structures (if any), on AbbVie's financial statements.
- Review and discuss with AbbVie's independent auditors:
 - any problems or difficulties encountered in the course of the audit work, including any restrictions on the scope of the independent auditors' activities or on access to requested information and management's response, any significant disagreements with management, any accounting adjustments that were noted or proposed by the auditor but were "passed" (as immaterial or otherwise), any communications between the audit team and the audit firm's national office respecting auditing or accounting issues presented by the engagement, and any "management" or "internal control" letter issued, or proposed to be issued, by the audit firm to AbbVie;
 - any report by the independent auditors required by Section 10A of the Exchange Act including any report relating to critical accounting policies and practices to be used in connection with the audit of AbbVie, all alternative treatments of financial information within generally accepted accounting principles that have been discussed with management, the ramifications of the use of those alternative disclosures and treatments, and the treatment preferred by the independent auditors, and other material written communications between the independent auditors and management; and
 - any information obtained from the independent auditors with respect to illegal acts in accordance with Section 10A.
- Review and discuss with AbbVie's internal auditors the internal audit function, the department's authority and responsibilities, budget, staffing, independence, and reporting obligations, the proposed audit plan for the coming year, the coordination of that proposed audit plan with AbbVie's independent auditors, the results of the internal audit and a specific review of any significant issues.
- Review and discuss (with management, the internal auditors and the independent auditors, as appropriate) AbbVie's enterprise risk management, including major financial risk exposures, and the steps management has taken to monitor and control those exposures, including AbbVie's risk assessment and risk management policies. Coordinate the oversight of risk management with other Board committees (recognizing that other committees also assist the Board in reviewing certain aspects of risk management).
- Review and approve, at least annually, AbbVie's decision to enter into swaps and other derivative instruments that may be subject to the end-user exception from mandatory clearing and exchange trading requirements of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010.

- Adopt policies governing the hiring of employees or former employees of the independent auditors who were engaged on AbbVie's account in compliance with Section 10A of the Exchange Act.
- Establish procedures for:
 - the receipt, retention and treatment of complaints received by AbbVie regarding accounting, internal accounting controls or auditing matters, and
 - the confidential, anonymous submission by employees of concerns regarding questionable accounting or auditing matters.
- Review any disclosures made to the Audit Committee by AbbVie's chief executive officer or chief financial officer relating to their certification obligations under Rule 13a-14 under the Exchange Act.
- Review with the independent auditors, internal auditors and financial management the adequacy, effectiveness and quality of AbbVie's accounting and financial reporting principles, policies, procedures and controls, and elicit from them any recommendations for improvements.
- 4. *Annual Performance Evaluation*. The Audit Committee shall review and assess the adequacy of its charter annually and recommend any proposed changes to the Board for approval. It also shall conduct an annual evaluation of the Audit Committee's performance.
- 5. Limitation of Audit Committee's Role. While the Audit Committee has the responsibilities and powers set forth in this charter, it is not the duty of the Audit Committee to plan or conduct audits or to determine that AbbVie's financial statements and disclosures are complete and accurate and are in accordance with generally accepted accounting principles and applicable rules and regulations. These are the responsibilities of management and the independent auditor.

EXHIBIT D

(see attached)

AbbVie Inc. Public Policy Committee Charter

- 1. *Purpose*. The Public Policy Committee of the Board of Directors shall assist the Board in fulfilling its oversight responsibility with respect to: public policy, regulatory (including regulation by the U.S. Food and Drug Administration, as well as other domestic, foreign and international regulatory bodies) and government affairs and healthcare compliance issues that affect AbbVie (recognizing that other board committees assist the Board of Directors in reviewing certain areas of legal and regulatory compliance), by discharging the responsibilities set forth below.
- 2. *Qualifications; Organization*. All members of the Public Policy Committee must satisfy the independence requirements of the New York Stock Exchange, as such requirements are interpreted by the Board in its business judgment. AbbVie's Board shall appoint, and may remove, members of the Public Policy Committee and the Committee's Chairman, after receiving the recommendation of AbbVie's Nominations and Governance Committee.
- 3. Authority and Responsibilities. To assist it in the conduct of its responsibilities, the Public Policy Committee shall consult with management and, to the extent it deems it necessary or appropriate, may seek advice and assistance from AbbVie employees or others, and may retain legal counsel and other advisors.

The Public Policy Committee shall report to the Board on a regular basis.

The Public Policy Committee may delegate any of its responsibilities and duties to one or more members of the Public Policy Committee.

The Committee will meet formally at least four times each year.

The Public Policy Committee shall:

- Review the Company's compliance program with respect to legal and regulatory requirements (including, but not limited to, policies related to healthcare compliance, product quality, environmental regulations, employee health & safety and compliance with the U.S. Foreign Corrupt Practices Act of 1977, as amended) except with respect to matters of financial compliance which are the responsibility of the Audit Committee.
- Devise a process for the dissemination of information to the Committee from management with respect to regulatory and healthcare compliance matters, including, as appropriate, presentations to the Committee from management concerning the state of regulatory compliance and all issues

with respect thereto.

- Receive reports from the Chief Ethics and Compliance Officer on a regular basis.
- Review compliance with any ongoing Corporate Integrity Agreement or similar undertakings by the Company with the U.S. Department of Health and Human Services, U.S. Department of Justice, U.S. Securities and Exchange Commission, U.S. Food and Drug Administration, or any other government agency.
- Review and evaluate AbbVie's policies and practices with respect to social responsibility, and review them with the Board as appropriate.
- Review social, political, economic and environmental trends and public policy issues that affect or could affect AbbVie's business activities, performance, and public image, and review them with the Board as appropriate.
- Review the Company's government affairs strategies and priorities, including policies for political expenditures and lobbying activities.
- Review and make recommendations to the Board regarding shareholder proposals submitted for inclusion in AbbVie's proxy materials.
- 4. *Annual Performance Evaluation*. The Public Policy Committee shall review and assess the adequacy of its Charter annually and recommend any proposed changes to the Board for approval. It shall also conduct an annual evaluation of its own performance.

EXHIBIT E

(see attached)

Inspired by Integrity

The AbbVie Code of Business Conduct



We follow industry laws and regulations

We value the long-standing trust we have earned worldwide.

Patients, health care providers, customers and suppliers know they can rely on us because we comply with the laws, regulations and codes that govern the pharmaceutical industry and our company (e.g., European Federation of Pharmaceutical Industries and Associations [EFPIA] and International Federation of Pharmaceutical Manufacturers and Associations [IFPMA]).

This is our way

Respect for each other, our business performance and our culture includes knowing and honoring the rules and regulations that govern our industry. These include laws and regulations regarding:







Promoting and selling our products







Distributing our products

Because we are a public company based in the United States, we comply with certain U.S. laws wherever we operate unless a requirement outside the United States is more restrictive and does not conflict with U.S. law.

If you are in a situation outside the United States where regulations, rules or laws seem to conflict with our Code or applicable U.S. regulations, consult your manager or seek guidance from our Legal Department.

We make product quality and safety a priority

The importance we place on product quality and safety is embedded in our culture.

This is why patients and consumers trust our products. It is also why industry authorities and medical experts respect our company.

Our manufacturing facilities adhere to Current Good Manufacturing Practices (CGMP) standards and follow stringent quality control procedures. AbbVie suppliers are subject to these standards, too, and must maintain a Quality Management System.

Report any unfavorable, unexpected or undesirable result associated with AbbVie product use, whether or not attributable to an AbbVie product, within one business day after learning of the adverse event. Call 800.633.9110 or follow local procedures for your group or affiliate so that all appropriate individuals and government regulators are informed. Your local affiliate or department may have specific procedures for reporting safety concerns.

Making a difference

A representative of a potential AbbVie supplier approaches me to request a commitment to a contract. The supplier is widely respected, and I feel the association would help improve AbbVie's performance. The representative says that our review/due diligence process isn't necessary because of his company's established reputation. I tell the representative that he cannot sidestep our policies and procedures and insist that these be followed so we can maintain our high standards.



Learn More

See our **Good Scientific Practices** policy for additional information.

Visit the Corporate Policy Portal on My AbbVie to access additional company policies and procedures on the topics covered within our Code, or ask your manager of the Office of Ethics and Compliance for additional guidance.





We maintain trustworthy business practices

We comply with all applicable laws that regulate our business.

We conduct our business in a transparent and ethical manner and comply with all applicable laws. Many of these laws concern the way we promote and sell our medical products. It is never acceptable to try to influence purchasing decisions in any way that is unethical, inappropriate or illegal or creates a potential conflict of interest. We strictly prohibit the receipt or offer of bribes and participation in corruption. We are honest, open and up-front when we interact with those who may be interested in buying or prescribing our products.



This is our way

Compliance with the law inspires trust in our culture of integrity. We abide by all laws, regulations, policies and procedures that apply to our jobs including ...

- **U.S. Anti-Kickback Statute.** We don't give anything of value to induce a health care professional to use or recommend pharmaceutical products that are paid for or reimbursed by the government.
- U.S. False Claims Act and similar laws in other countries. We don't submit
 or cause the submission of false claims for health care reimbursement to the
 government.
- Food, Drug and Cosmetic Act and similar laws in other countries. We
 don't promote a regulated product or an indication that has not received FDA
 or other appropriate regulatory approval.
- Transparency Laws. We report certain payments to physicians and other customers, as required by transparency laws and regulations in every location where we operate.
- U.S. Foreign Corrupt Practices Act, the United Kingdom Bribery Act and similar laws in other countries. We prohibit the receipt or offering of bribes and participation in corruption and adhere to all local laws and regulations that cover bribery and corruption.

If you are in a situation outside the United States where local regulations, rules or laws seem to conflict with our Code or applicable U.S. regulations, consult your manager or get guidance from our Legal Department.



Learn More

See the PhRMA Code on Interactions with Health Care Professionals and AdvaMed Code of Ethics on Interactions with Health Care Professionals.





We follow antitrust laws

We support free and honest competition.

The fair pricing of our products is essential to our commitment to improving health worldwide. This is why we never engage in activities that restrain free trade – such as price fixing, bid rigging or other arrangements that violate antitrust laws. We never discuss pricing, customers or sales agreements with competitors, and are careful to avoid any activity that gives the appearance of restricting trade.



Learn More

See our **Compliance with Antitrust Laws** policy or contact Legal for additional information.

Making a difference

During a break at an industry conference, I join a couple of AbbVie competitors and some vendors to chat over coffee. When someone begins discussing pricing and territories, I am aware that participating in this conversation could put AbbVie at risk, so I immediately excuse myself from the group and leave the room. I tell our Legal Department what happened as soon as the conference is over.

We comply with insider trading laws

In the course of our jobs, we may hear or know about a company's business activities or plans that are not yet publicized.

Information that has not been made public, but if known, may persuade a reasonable investor to buy, sell or hold a company's securities is called "inside" or "nonpublic" information. Never use this information - whether it is about AbbVie or any other company -- to conduct a trade. Never "tip" someone else on what you know so that they may trade. Insider trading and tipping are illegal.

There are many kinds of material, nonpublic information.

It could be anything you know about current, new or pending...



Even after inside information is made public, you are not allowed to use the information to trade in securities until a certain amount of time has elapsed. Contact our Legal Department if you have any questions about a transaction you are considering.



Learn More

See our **Insider Training in Securities** policy or contact Legal for additional information.

Making a difference

My neighbor works for one of AbbVie's collaboration partners and tells me that important clinical trial data for a compound being developed jointly by her employer and AbbVie will be released next week. The data suggests that the compound will be highly successful commercially. I think about purchasing the collaboration partner's stock and telling my brother, but realize that what I have heard about both companies could be considered material, nonpublic information. I keep the information confidential and do not trade in either company's stock so as not to violate our Code or the law.







January 20, 2022

Via e-mail at shareholderproposals@sec.gov

Securities and Exchange Commission Office of the Chief Counsel Division of Corporation Finance 100 F Street, NE Washington, DC 20549

Re: Request by AbbVie Inc. to omit proposal submitted by Friends Fiduciary Corp. and co-filers

Ladies and Gentlemen,

Pursuant to Rule 14a-8 under the Securities Exchange Act of 1934, Friends Fiduciary Corporation, together with seven co-filers (together, the "Proponents") submitted a shareholder proposal (the "Proposal") to AbbVie Inc. ("AbbVie" or the "Company"). The Proposal asks AbbVie's board 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.

In a letter to the Division dated December 22, 2021 (the "No-Action Request"), AbbVie stated that it intends to omit the Proposal from its proxy materials to be distributed to shareholders in connection with the Company's 2022 annual meeting of shareholders. AbbVie argues that it is entitled to exclude the Proposal in reliance on Rule 14a-8(i)(7), on the ground that the Proposal deals with AbbVie's ordinary business operations; and 14a-8(i)(10), as substantially implemented. As discussed more fully below, AbbVie has not met its burden of proving its entitlement to exclude the Proposal on either of those bases, and the Proponents respectfully request that AbbVie's request for relief be denied.

The Proposal

The Proposal states:

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.

Ordinary Business

Rule 14a-8(i)(7) allows exclusion of proposals related to a company's ordinary business operations. AbbVie argues that the Proposal relates to the Company's ordinary business operations because it addresses the Company's legal compliance program and/or management of intellectual property. Because the Proposal addresses the strategic, reputational, and public policy risks created by anticompetitive practices, not legal compliance or intellectual property issues, and because those practices are a significant policy issue generally and for AbbVie, it should not be permitted to exclude the Proposal on ordinary business grounds.

The Proposal's Subject is the Risks Associated With Anticompetitive Practices, Not Legal Compliance or Management of Intellectual Property

AbbVie omits mention of the determinations issued last season in Alphabet¹ and Amazon,² where arguments much like those AbbVie makes here did not convince the Staff that exclusion of proposals focused on anticompetitive practices was warranted. The Amazon and Alphabet resolved clauses were substantially similar to the Proposal's resolved clause; the supporting statements differed as they addressed the risks to large tech companies, rather than pharmaceutical firms, from a renewed focus on anticompetitive practices in that sector. Both Alphabet and Amazon tried to frame the proposals narrowly without reference to the larger context of the debate over monopoly power, arguing that the proposals focused on legal compliance and/or the conduct of litigation. The proponent of both proposals exhaustively documented the consistent and widespread public debate regarding anticompetitive practices by tech firms. The Staff denied relief to both companies.

¹ Alphabet, Inc. (Apr. 16, 2021).

² Amazon.com, Inc. (Apr. 9, 2021).

The Proposal focuses on board oversight of various kinds of risk created by anticompetitive practices, including the risk that governments will adopt new laws and/or regulations affecting AbbVie's business in response to perceptions or findings about AbbVie's anticompetitive conduct or the conduct of the industry more broadly. The Proposal's resolved clause does not ask for information about how AbbVie or its board manages or oversees compliance or the management of AbbVie's intellectual property. Instead, it focuses solely on board oversight of the risks described above.

Further undermining AbbVie's argument is the last sentence of the Proposal's resolved, which was not found in the Amazon and Alphabet proposals. It specifically carves out existing litigation and claims of which AbbVie has notice from disclosure in the requested report. If the Proposal truly aimed to elicit disclosure related to compliance, this carveout would work at cross purposes with it.

The Proposal differs from those in the numerous determinations AbbVie cites on pages 3-4 of the No-Action Request, many of which were cited in Alphabet and Amazon's unsuccessful requests last season. Those determinations involved proposals that squarely addressed legal compliance and are therefore inapposite. The resolved clauses of those proposals asked the companies to (i) produce reports on "the actions taken to ensure **compliance** with applicable federal and state laws" (Navient); "efforts to implement" several different fair employment statutes (Raytheon); why the company's ethics code did not promote "[c]ompliance with securities laws, and SEC rules and regulations" (Sprint Nextel); "the compliance of the company and its contractors with federal and state laws governing proper classification of employees and independent contractors" (FedEx); a comparison of laboratory tests of the company's products against national laws and the company's global quality standards" (The Coca-Cola Co.); or to (ii) take actions designed to avoid trespassing on private property by the company and/or its contractors (Verizon); "monitor [] the company's business practices to insure compliance with applicable laws, rules and regulations of the, federal, state, local governments, and the AES Code of Business Conduct, including retaliation protection for employees making a good faith report or concern of possible misconduct." (AES) (emphases added).

AbbVie's reliance on the IBM³ determination is also misplaced. The proposal at issue there was a somewhat muddled request for IBM to embrace "open source" licensing, which the proponent argued was the "NEW WORLD ORDER." As IBM made clear in its request, the open source licensing sought by the proposal would require IBM to distribute its operating system software in contravention of existing intellectual property restrictions. The Proposal, which does not suggest any changes in AbbVie's intellectual property arrangements, would do no such thing.

³ International Business Machines Corporation (Jan. 22, 2009).

<u>Anticompetitive Practices Are a Significant Policy Issue, Both for the Pharmaceutical</u> Industry and for AbbVie

Companies may not rely on the ordinary business exclusion to omit proposals that "focus[] on sufficiently significant social policy issues." To determine whether a topic qualifies as a significant social policy issue, the Division analyzes whether it is a "consistent topic of widespread public debate." Anticompetitive pharmaceutical company practices easily satisfy that standard, and AbbVie has been singled out for criticism on this issue.

Over the past several years anticompetitive practices among pharmaceutical firms have generated substantial debate among the public and policy makers. That debate has been spurred by the fact that U.S. patients pay higher prices for prescription drugs than patients anywhere else in the world. Industry consolidation also makes anticompetitive practices more salient: From 1995 to 2015, mergers reduced 60 pharmaceutical companies to 10, according to a report by the Open Markets Institute.⁶

The debate over anticompetitive practices has focused on several practices, some of which AbbVie is alleged to have engaged in:

- Over-patenting or "patent thickets" that include patents not only on a drug's
 active ingredients but also secondary patents on peripheral features like a
 pill's coating whose validity must be litigated by a potential generic
 manufacturer
- "Product hopping," in which a branded drug maker shifts the market to a new version of a product, and withdraws the original product, shortly before the original exclusivity period ends in order to thwart generic entry
- "Pay for delay" arrangements in which a potential generic manufacturer settles a patent claim by agreeing to refrain from entering the market and receives value from the branded manufacturer for doing so
- Obstructing potential makers of generic or biosimilar medicines from obtaining samples of the branded product needed for Food and Drug Administration ("FDA")-required testing, at times by refusing to allow the generic/biosimilar manufacturer to participate in the branded firm's Risk Evaluation and Mitigation System for distributing medicines that present heightened risks

⁴ Exchange Act Release No. 40018 (May 21, 1998).

 $^{^5}$ See, e.g., Duke Energy Corp. (Mar. 1, 2002); AT&T Inc. (Feb. 2, 2011).

⁶ https://www.openmarketsinstitute.org/learn/drug-prices-monopoly

- Competition- and/or innovation-decreasing merger and acquisition ("M&A") activity by pharmaceutical companies
- Abuse of the Orphan Drug Act's provision for obtaining extended exclusivity
- Using "citizen petitions" to the FDA to delay generic entry

Both the Trump and Biden Administrations have taken action to address anticompetitive practices by pharmaceutical companies.

In 2017, the FDA sought comment on the "appropriate balance between encouraging innovation in drug development and accelerating the availability to the public of lower cost alternatives to innovator drugs." The Federal Register notice of the related meeting explained that, "In some cases . . . the legal framework surrounding [patents and first-generic exclusivities] may have been applied to delay generic competition to an extent that may not have been intended by the Hatch-Waxman Amendments, and in ways that may not serve the public health. Relatedly, certain elements of the approval process for both innovator and generic drugs have been used in ways that may (depending on the circumstances) inappropriately hinder generic competition." The FDA specifically sought stakeholder input on patents, the citizen petition process, and obstacles faced by potential generic competitors in obtaining branded drug samples for testing. 9

Two years later, the FDA issued guidance setting forth "some of the considerations FDA will take into account in determining whether a [citizen] petition is submitted with the primary purpose of delaying the approval of an application [including one for approval of a generic medicine]," justifying summary denial. The FDA also publicized a list of over 30 firms that it said had unreasonably refused to provide samples of branded drugs to companies planning to manufacture generic versions.

In January 2020, the Federal Trade Commission ("FTC") and the Attorneys General ("AGs") of several states sued former Turing Pharmaceuticals CEO Martin Shkreli and two others for anticompetitive practices that allowed Turing to boost the price of off-patent anti-fungal Daraprim by more than 4,000%. ¹² A federal court recently sided with the FTC and AGs, finding that the defendants used restrictive distribution arrangements to block other potential generic manufacturers' access to Daraprim samples and delay generic competition. ¹³

⁷ https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-12641.pdf

⁸ https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-12641.pdf

⁹ https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-12641.pdf

¹⁰ https://www.fda.gov/media/130878/download, at 15-16.

¹¹ https://www.washingtonpost.com/news/wonk/wp/2018/05/17/fda-shames-drug-companies-suspected-of-using-gaming-tactics-to-delay-competition/

 $^{^{12}\} https://ag.ny.gov/press-release/2022/pharma-bro-no-more-attorney-general-james-scores-court-victory-against-convicted$

¹³ https://ag.ny.gov/sites/default/files/shkreli.pdf

The Biden Administration has prioritized and intensified efforts to address competition in the pharmaceutical industry. The FTC has indicated that it will be scrutinizing M&A transactions in the pharmaceutical industry more closely. Citing "skyrocketing" drug prices, then-acting Chair Rebecca Kelly Slaughter announced a working group consisting of the FTC and parallel agencies in other countries to "update their approach to analyzing the effects of pharmaceutical mergers." Slaughter stated that the group would address how "current theories of harm" could be updated, how "pharmaceutical conduct such as price fixing, reverse payments, and other regulatory abuses" should be treated in merger review, and the "full range of a pharmaceutical merger's effects on innovation." Commissioner Rohit Chopra opined in May 2021 that the FTC's previous "pro-merger" approach to pharmaceutical company M&A activity was "not sensible, given the FTC's mandate and the crisis we face when it comes to drug prices."

President Biden appointed Lina Khan, a prominent advocate of reinvigorating antitrust enforcement and revisiting the dominant theoretical approach to antitrust law, to chair the FTC. Though Khan may be best known for her work on digital platform monopolies, 17 she successfully pushed for a change to a 2015 agency policy that had required full Commission approval of investigations and identified pharmaceutical firms as among the FTC's top priorities. 18

In July 2021, President Biden issued Executive Order 14036, the "Executive Order on Promoting Competition in the American Economy" (the "EO"), which stated that "it is the policy of my Administration to enforce the antitrust laws to combat the excessive concentration of industry, the abuses of market power, and the harmful effects of monopoly and monopsony." The EO asserted that "patent and other laws have been misused to inhibit or delay — for years and even decades — competition from generic drugs and biosimilars, 20 denying Americans access to lower-cost drugs" and identified the healthcare industry, including pharmaceuticals, as a special area of focus. The EO also directed the Secretary of Health and Human Services to take various steps to "promote generic drug and biosimilar competition."

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 $^{^{14}\,}$ https://www.ftc.gov/news-events/press-releases/2021/03/ftc-announces-multilateral-working-group-build-new-approach

 $^{^{15}\ \, {\}rm https://www.ftc.gov/news-events/press-releases/2021/03/ftc-announces-multilateral-working-group-build-new-approach}$

 $https://www.ftc.gov/system/files/documents/public_statements/1589927/statement_of_commissioner_rohit_chopra_regarding_the_review_of_the_ftcs_pharmaceutical_merger.pdf$

¹⁷ https://nymag.com/intelligencer/article/lina-khan-ftc-profile.html

 $^{^{18}\} https://endpts.com/pharma-in-the-crosshairs-how-the-ftc-is-expanding-its-antitrust-powers-under-its-new-chair/$

¹⁹ https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy

²⁰ While non-branded versions of a small molecule drug are referred to as generics, the term biosimilar is used to refer to the equivalent version of a biologic medication.

Stricter scrutiny of pharmaceutical company M&A activity could have significant effects on company strategies. Consultant PwC predicts that the sector will have "an exceptional level" of deal activity in 2022, including several deals worth at least \$50 billion. AbbVie has relied on acquisitions, most recently of Allergan, to bolster its product offerings. In August, the FTC made a second request for documents regarding Allergan's acquisition of Soliton, though the deal ultimately was approved.

Last month, the FDA stated it would refer to the FTC Endo's unsuccessful citizen petition asking the FDA not to approve generic versions of its drug VasoStrict. In its denial of the petition, the FDA opined that the petition "does not on its face raise valid scientific or regulatory issues" and "appears to have been submitted with the primary purpose of delaying approval" of a generic version. ²⁵ The FDA said it "intends to refer this matter to the Federal Trade Commission (FTC), which has the administrative tools and the expertise to investigate and address anticompetitive business practices." ²⁶

Congress has taken a strong (and in many cases, bipartisan) interest in the anticompetitive practices of pharmaceutical firms and how they harm U.S. consumers. A multitude of bills were introduced in the past five years to address these practices:

• CREATES Act: first introduced in 2016 and passed and signed into law in 2019; it allows the putative developer of a generic/biosimilar medicine to sue the branded drug maker for refusing to sell samples of the branded product needed to test the generic/biosimilar product for equivalence.²⁷ (H.R.2051 (introduced in the 115th and 116th

 $^{^{21}\,}$ https://www.pwc.com/us/en/industries/health-industries/library/pharma-life-sciences-deals-insights.html

²² <u>See</u> https://news.abbvie.com/news/press-releases/abbvie-completes-transformative-acquisition-allergan.htm

²³ https://www.fiercebiotech.com/medtech/abbvie-s-allergan-aesthetics-faces-extended-ftc-probe-550m-soliton-acquisition

 $^{^{24}\,}$ https://www.fiercebiotech.com/medtech/allergan-aesthetics-completes-550m-soliton-buy-following-ftc-probe

²⁵ https://endpts.com/fda-seeks-ftc-action-after-rejecting-petition-to-block-first-generics-for-decades-old-vasopressin/

 $^{^{26}\,}$ https://endpts.com/fda-seeks-ftc-action-after-rejecting-petition-to-block-first-generics-for-decades-old-vasopressin/

²⁷ https://www.fda.gov/drugs/guidance-compliance-regulatory-information/access-product-samples-creates-act;

 $https://energy commerce.house.gov/sites/democrats.energy commerce.house.gov/files/documents/BILL\ S-116hr965ih.pdf$

- Congresses)²⁸ also would have prohibited brand manufacturers' refusal to provide samples.)
- H.R.2375 (116th)²⁹: would create a presumption of anticompetitive effects if a generic drug or biosimilar applicant receives anything of value, including an exclusive license, from a branded drug maker for agreeing not to research, develop or market a drug
- H.R.5133 (116th)³⁰: would prohibit product hopping
- H.R.4398 (116th)³¹: would prohibit product hopping and provides that product hopping is presumed when a manufacturer engages in one of two types of switches
- S.1416 (116th)³²: same as H.R.4398
- H.R.3991 (116th)³³: would limit the number of patents that the manufacturer of a biologic medicine can assert in a lawsuit against a company seeking to sell a biosimilar version
- S.3271 (116th)³⁴: would limit which orphan drugs may be granted exclusivity by the FDA
- S.1428 (117th)³⁵: would provide that settlement of a patent claim in connection with the sale of a drug or biologic product is presumptively anticompetitive if the filer of the generic drug or biosimilar application receives anything of value and agrees not to research, develop or sell the generic or biosimilar
- S.250 $(117^{th})^{36}$: same as S.3271
- H.R.1629 (117th)³⁷: same as S.3271
- H.R.2891 (117th)³⁸: same as S.1428
- S.1435 (117th)³⁹: same as H.R.4398
- S.1425 (117th)⁴⁰: would define the submission of "sham" citizen petitions to the FDA, those submitted to interfere with the business of a competitor, as an unfair method of competition subject to FTC civil enforcement
- H.R.2883 (117th)41: same as S.1425

²⁸ https://www.congress.gov/bill/115th-congress/house-bill/2051?r=23; https://www.govtrack.us/congress/bills/116/hr985

²⁹ https://www.govtrack.us/congress/bills/116/hr2375

³⁰ https://www.congress.gov/bill/116th-congress/house-bill/5133

³¹ https://www.congress.gov/bill/116th-congress/house-bill/4398

³² https://www.congress.gov/bill/116th-congress/senate-bill/1416

³³ https://www.congress.gov/bill/116th-congress/house-bill/3991

³⁴ https://www.congress.gov/bill/116th-congress/senate-bill/3271

³⁵ https://www.congress.gov/bill/117th-congress/senate-bill/1428

³⁶ https://www.congress.gov/bill/117th-congress/senate-bill/250

³⁷ https://www.congress.gov/bill/117th-congress/house-bill/1629?r=20&s=1

³⁸ https://www.congress.gov/bill/117th-congress/house-bill/2891

³⁹ https://www.congress.gov/bill/117th-congress/senate-bill/1435/text?r=82&s=1

⁴⁰ https://www.congress.gov/bill/117th-congress/senate-bill/1425/all-info

⁴¹ https://www.congress.gov/bill/117th-congress/house-bill/2883/all-info

• S.1416 (117th)⁴²: same as H.R.4398

Congressional hearings have dealt with a variety of drug company anticompetitive practices:

- The Subcommittee on Health Care, Benefits and Administrative Rules of the House Oversight and Government Reform Committee held a hearing in 2017 on "Examining the Impact of Voluntary Restricted Pharmaceutical Distribution Systems" 43
- In 2017, the House Judiciary Committee's Subcommittee on Regulatory Reform, Commercial and Antitrust Law held a hearing on "Antitrust Concerns and the FDA Approval Process" addressing various anticompetitive practices engaged in by pharmaceutical firms.⁴⁴
- The Senate Finance Committee held a hearing on "Drug Pricing in America: A Prescription for Change, Part I"⁴⁵ in January 2019, at which the Committee heard testimony on drug makers' anticompetitive practices.⁴⁶
- The House Committee on Energy and Commerce's Subcommittee on Health held a hearing on "Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition" in March 2019⁴⁷; witnesses testified regarding the impact of anticompetitive practices including patent thickets, pay for delay, and blocking access to samples.
- In April 2021, the House Judiciary Antitrust Subcommittee held a hearing on "Treating the Problem: Addressing Anticompetitive Conduct and Consolidation in Health Care Markets." ⁴⁸ The Subcommittee heard from experts on drug firms' anticompetitive practices. ⁴⁹
- The Senate Judiciary Committee's Subcommittee on Competition Policy, Antitrust, and Consumer Rights held a hearing in July 2021 entitled "A Prescription for Change: Cracking Down on Anticompetitive Conduct in Prescription Drug Markets" 50

⁴² https://www.congress.gov/bill/116th-congress/senate-bill/1416

 $^{^{43}\,}$ https://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=105860; transcript available on LEXIS/NEXIS

 $[\]underline{^{44}~See}$ https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Transcript-20170727.pdf

⁴⁵ https://www.finance.senate.gov/hearings/drug-pricing-in-america-a-prescription-for-change-part-i

⁴⁶ https://www.finance.senate.gov/imo/media/doc/29JAN2019MILLERSTMNT.pdf

⁴⁷ https://energycommerce.house.gov/committee-activity/hearings/hearing-on-lowering-the-cost-of-prescription-drugs-reducing-barriers-to

 $^{^{48}}$ https://oversight.house.gov/news/press-releases/house-judiciary-antitrust-subcommittee-to-hold-hearing-on-anticompetitive

⁴⁹ https://judiciary.house.gov/calendar/eventsingle.aspx?EventID=4528

 $^{^{50}\}$ https://www.judiciary.senate.gov/meetings/a-prescription-for-change-cracking-down-on-anticompetitive-conduct-in-prescription-drug-markets

AbbVie's anticompetitive practices alone formed the basis for a recent Congressional hearing. The House Committee on Oversight and Reform held a hearing in May 2021 entitled "Unsustainable Drug Prices (Part III): Testimony from AbbVie CEO Richard Gonzalez,"⁵¹ which focused on abuses of the patent system, including by AbbVie.⁵² According to one witness:

The first patents on Humira [AbbVie's largest revenue generator] were filed in 1994. As of 2020, there are at least 257 patent applications that have been filed for Humira. 90% of these patent applications were filed after Humira was approved and brought to market in 2002. AbbVie has amassed 130 granted patents for Humira—a record—giving it a staggering 39 years of patent protection.⁵³

Last month, the House Committee on Oversight released a report of its investigation into pharmaceutical pricing and business practices, which took nearly three years and included the AbbVie hearing discussed above. According to the majority staff report, the evidence produced during the investigation showed that the companies investigated engaged in a wide variety of anticompetitive practices, including using "patent protections and market exclusivities granted by FDA to suppress generic competition and keep prices high," entering into pay for delay agreements that cost consumers and payors billions, and abusing the Orphan Drug Act. The report described companies' extensive lobbying against drug pricing reforms, including through trade associations PhRMA and BIO, on whose boards AbbVie has representatives. 56

The report criticized AbbVie's conduct in several respects. It described the nine pay-for-delay agreements AbbVie has entered into to delay the entrance of

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

https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf, at ix-x.

https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf, at 71-73.

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 $^{^{51}\} https://docs.house.gov/meetings/GO/GO00/20210518/112631/HHRG-117-GO00-20210518-SD002.pdf$

 $[\]frac{52}{2}$ See https://docs.house.gov/meetings/GO/GO00/20210518/112631/HHRG-117-GO00-Wstate-AminT-20210518.pdf; https://docs.house.gov/meetings/GO/GO00/20210518/112631/HHRG-117-GO00-Wstate-KesselheimA-20210518.pdf;

https://docs.house.gov/meetings/GO/GO00/20210518/112631/HHRG-117-GO00-Transcript-20210518.pdf

 $^{^{53}}$ https://docs.house.gov/meetings/GO/GO00/20210518/112631/HHRG-117-GO00-Wstate-AminT-20210518.pdf, at 4.

biosimilar versions of Humira⁵⁷ and concluded that AbbVie abused the Orphan Drug Act by obtaining eight orphan drug designations for Humira despite it being "top-selling drug in the world."⁵⁸ AbbVie was accused of having erected a "patent thicket" around Humira, involving 257 patents, that will end up costing the U.S. health care system \$19 billion between 2016 and 2023.⁵⁹ The majority staff also characterized AbbVie as using a "drip feed' strategy to file successively more specific patents to extract a total of almost 30 years of patent protection and monopoly pricing on its cancer drug Imbruvica."⁶⁰

States have also taken up the issue of drug companies' anticompetitive practices:

- California Assembly Bill 824 was signed into law in 2019; it
 establishes a presumption that a patent claim settlement in which a
 generic manufacturer receives "anything of value" and agrees to delay
 entry into the market has anticompetitive effects, shifting the burden
 to the settling parties to show that the agreement is procompetitive.⁶¹
- Maine's LD1280, enacted in 2018, requires branded pharmaceutical firms to make samples available to "eligible product developers" at a price no higher than the wholesale acquisition cost.⁶²
- Oregon's Senate Bill 764 would establish a presumption similar to that contained in California's law.⁶³
- New York's A7254 would establish a presumption similar to that contained in California's law.⁶⁴
- New York's S5169 would require "prescription drug manufacturers to notify the attorney general of arrangements between pharmaceutical manufacturers resulting in the delay of the introduction of generic medications."

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https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf, at ix.

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oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf, at 78. 50

oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf, at 80, 83.

https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf, at 78.

 $^{61}\,$ https://www.gibsondunn.com/ca-legislation-increases-antitrust-scrutiny-of-patent-settlements-between-branded-and-generic-pharma-manufacturers/

https://www.pierceatwood.com/sites/default/files/2018%20Summary%20of%20New%20Maine%20Laws%20Supplement%2011.30.18%20Final%20Report.pdf, at 15-16.

- 63 https://olis.oregonlegislature.gov/liz/2021R1/Measures/Overview/SB764
- 64 https://www.nysenate.gov/legislation/bills/2021/a7245
- 65 https://www.nysenate.gov/legislation/bills/2019/s5169

- Connecticut's SB262 would require drug makers that are present in the state to provide samples to generic manufacturers at a "fair market price."
- Connecticut's SB269 would establish a presumption similar to that contained in California's law.⁶⁷
- In 2020, Minnesota State Attorney General Keith Ellison released recommendations for addressing prescription drug costs, including the creation of a commission that could investigate industry practices and cap the prices of some drugs. His report cited the abuse of the patent system as a factor contributing to high drug prices.⁶⁸
- A bill to establish a Prescription Drug Affordability Board has been introduced in Minnesota; the board may consider "market competition and context" under certain circumstances.⁶⁹

Anticompetitive practices by pharmaceutical companies have been the subject of an enormous amount of media coverage. A non-exhaustive list appears below (items without a footnote were obtained through LEXIS/NEXIS):

- Robin Feldman, "Drug Companies Keep Merging: Why That's Bad for Consumers and Innovation," <u>The Washington Post</u>, Apr. 6, 2021⁷⁰
- Amy Goldstein, "House Democrats find in three-year investigation that drug prices are 'unsustainable, unjustifiable and unfair," <u>The Washington Post</u>, Dec. 10, 2021⁷¹
- Jim Tankersley and Cecilia Kang, "Biden's Antitrust Team Signals a Big Swing at Corporate Titans," <u>The New York Times</u>, July 24, 2021
- Editorial Board, "How Big Pharma plays games with drug patents and how to combat it," USA Today, Jan. 18, 2019⁷²
- Nate Raymond, "California law combating 'pay for delay' deals blocked by federal judge," Reuters, Dec. 9, 2021⁷³
- Robin Feldman, "Our patent system is broken. And it could be stifling innovation," <u>The Washington Post</u>, Aug. 8, 2021⁷⁴

⁶⁶ http://www.senatedems.ct.gov/looney-news/3498-looney-210128#sthash.tPgBr0lq.dpbs

⁶⁷ https://trackbill.com/bill/connecticut-senate-bill-269-an-act-concerning-the-availability-of-generic-pharmaceuticals/1993536/

⁶⁸ https://www.ag.state.mn.us/Office/Initiatives/PharmaceuticalDrugPrices/Taskforce.asp

⁶⁹ https://www.revisor.mn.gov/bills/bill.php?f=HF801&b=house&y=2021&ssn=0

 $^{^{70}\} https://www.washingtonpost.com/outlook/2021/04/06/drug-companies-keep-merging-why-thats-bad-consumers-innovation/$

 $^{^{71}\} https://www.washingtonpost.com/health/2021/12/10/house-democrats-find-three-year-investigation-that-drug-prices-are-unsustainable-unjustifiable-unfair/$

 $^{^{72}\} https://www.usatoday.com/story/opinion/2019/07/18/big-pharma-plays-games-drug-patents-you-pay-editorials-debates/1769746001/$

⁷³ https://www.reuters.com/legal/litigation/california-law-combating-pay-for-delay-deals-blocked-by-federal-judge-2021-12-09/

 $^{^{74}\} https://www.washingtonpost.com/outlook/2021/08/08/our-patent-system-is-broken-it-could-be-stifling-innovation/$

- Sarah Karlin-Smith and Brent D. Griffiths, "FDA to examine anticompetitive practices by drug industry," Politico, July 17, 2017⁷⁵
- Sarah Zhang, "How Pharma Companies Use 'Citizen Petitions' to Keep Drug Prices High," <u>The Atlantic</u>, Mar. 8, 2017⁷⁶
- Ryan Chatelain, "House committee report blasts drug pricing strategies as 'troubling," NY1, Dec. 10, 2021⁷⁷
- Robert H. Bork, Jr., "Joe Biden's Antitrust Paradox: Where's the Consumer Welfare?" The Wall Street Journal, July 13, 2021
- Samantha Masunaga, "Three drugmakers settle with California over deals to keep generic medications off the market," <u>Los Angeles Times</u>, July 29, 2019⁷⁸
- Carolyn Y. Johnson, "FDA shames drug companies suspected of using 'gaming tactics' to delay competition," <u>The Washington Post</u>, May 17, 2018⁷⁹
- David Chanen, "Price caps on drugs part of AG's plan," <u>Star Tribune</u> (<u>Minneapolis, MN</u>), Feb. 20, 2020 (discussing Minnesota AG's report that highlighted abuse of patent system)
- David Lazarus, "Outlaw secret deals on generic drugs," <u>Los Angeles Times</u>, June 28, 2019
- Joe Nocera, "Here's how drug companies game the patent system," <u>Chicago</u> Tribune, Oct. 23, 2017⁸⁰
- Matthew Lane, "To rein in Big Pharma over high drug prices, start with patent reform," Roll Call, Jan. 17, 2020⁸¹
- Michael Carrier, "How Big Pharma Sandbags Generic Competition," <u>The</u> Wall Street Journal, Nov. 15, 2017
- Garrett Johnson and Wayne T. Brough, "Big pharma is abusing patents, and it's hurting America," CNN, Sept. 13, 2019⁸²
- "Biden Drug Price Pressure on Patent Office Draws Skeptics," Bloomberg, Sept. 21, 2021⁸³

 $^{^{75}\} https://www.politico.com/tipsheets/prescription-pulse/2017/07/17/fda-to-examine-anticompetitive-practices-by-drug-industry-221368$

⁷⁶ https://www.theatlantic.com/health/archive/2017/03/pharma-citizen-petitions-drug-prices/518544/

⁷⁷ https://www.ny1.com/nyc/all-boroughs/politics/2021/12/10/house-committee-report-blasts-drug-pricing-strategies-as--troubling-

⁷⁸ https://www.latimes.com/business/story/2019-07-29/drugmakers-settle-california-pay-for-delay-lawsuits

⁷⁹ https://www.washingtonpost.com/news/wonk/wp/2018/05/17/fda-shames-drug-companies-suspected-of-using-gaming-tactics-to-delay-competition/

 $^{^{80}\,}$ https://www.chicagotribune.com/opinion/commentary/ct-perspec-drugs-health-care-pharm-1024-20171023-story.html

 $^{^{81}\} https://www.rollcall.com/2020/01/17/to-rein-in-big-pharma-over-high-drug-prices-start-with-patent-reform/$

⁸² https://www.cnn.com/2019/09/12/perspectives/drug-patents-abuse/index.html

 $^{^{83}\} https://news.bloomberglaw.com/health-law-and-business/biden-drug-price-pressure-on-patent-office-draws-skeptics$

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- David McCabe and Jim Tankersley, "Biden Steps Up Mission to Rein Big Business In," <u>The New York Times</u>, July 10, 2021
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- Eleanor Tyler and Grace Maral Burnett, "ANALYSIS: FTC Rethinks Pharma M&A After a Decade of Mega-Deals," Bloomberg, Apr. 15, 2021⁸⁶
- Ron Leuty, "Pay-for-delay' plan blocked cheap generic challengers to Peninsula company's narcolepsy drug for years, lawsuits claim," <u>San Francisco Business Times</u>, Aug. 12, 2020
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- Jordan Williams, "FTC eyes new approach to pharmaceutical mergers," The Hill, Mar. 16, 2021⁸⁹
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- Josh Nathan-Kazis, "The FTC is Taking a More Aggressive Approach Toward Pharmaceutical M&A. What it Means for the Industry," <u>Barron's</u>, Mar. 17, 2021⁹¹
- Brett Kendall & Jared Hopkins, "FTC Prepares to Take a Tougher Stance on Pharmaceutical Mergers," The Wall Street Journal, Mar. 16, 2021⁹²
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- Editorial Board, "Drug companies conspire to keep prices high. Will Newsom disrupt 'pay for delay'?" Sacramento Bee, Oct. 4, 2019
- "Congress takes aim again at pharmaceutical giant over patent-stacking for brand-name drugs," <u>The Examiner (Washington, DC)</u>, May 20, 2021

 $^{^{84}\}$ https://theconversation.com/how-a-native-american-tribe-came-to-own-one-of-the-worlds-most-valuable-patents-84007

 $^{^{85}\} https://www.npr.org/sections/health-shots/2017/01/17/509506836/drugs-for-rare-diseases-have-become-uncommonly-rich-monopolies$

 $[\]frac{86}{https://news.bloomberglaw.com/bloomberg-law-analysis/analysis-ftc-rethinks-pharma-m-a-after-a-decade-of-mega-deals}$

⁸⁷ https://hbr.org/2021/10/the-u-s-can-lower-drug-prices-without-sacrificing-innovation

⁸⁸ https://www.biopharmadive.com/news/ftc-pharma-biotech-deal-scrutiny-slaughter/601577/

⁸⁹ https://thehill.com/policy/healthcare/543447-ftc-eyes-new-approach-to-pharmaceutical-mergers

⁹⁰ https://www.cnbc.com/2018/06/25/high-drug-prices-caused-by-us-patent-system.html

⁹¹ https://www.barrons.com/articles/ftc-aggressive-approach-pharmaceutical-merger-stocks-51615983633

 $^{^{92}}$ https://www.wsj.com/articles/federal-trade-commission-to-consider-tougher-line-on-pharmaceutical-mergers-11615905000

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The Proposal as a Whole Deals With a Significant Policy Issue; It Does Not "Touch On" a Significant Policy Issue While Primarily Addressing Ordinary Business

Matters

AbbVie urges that "even if the Proposal were to touch on a potential significant policy issue, the Proposal's overwhelming concern with how the Company manages particular aspects of its legal compliance program with respect to competition laws and regulations and how its decisions with regard to its intellectual property relate to the legal compliance program demonstrates that the Proposal's focus is on ordinary business matters. ⁹⁴ But legal compliance and AbbVie's protection of its intellectual property are integral elements of the significant policy issue itself. Put another way, the *sole* focus of the Proposal, not just part of it, is a significant policy issue.

In contrast, in the determinations AbbVie cites, the proposals raised a significant policy issue, but grafted on elements that implicated day-to-day management:

- In PetSmart, 95 the proposal asked the company to require its suppliers to attest that they had not violated certain laws. PetSmart pointed out that the laws in question governed not only animal cruelty, a significant policy issue, but also mundane matters such as record keeping. The Staff concurred and granted relief, citing the breadth of the laws referenced in the proposal. Importantly, the Staff did not concur with PetSmart's more sweeping argument, which is similar to the one AbbVie makes here: that even if animal cruelty is a significant social policy issue, the selection of suppliers is an ordinary business matter, essentially negating significant social policy issue status.
- The proposal in CIGNA⁹⁶ asked the company to report on how it was "responding to regulatory, legislative and public pressures to ensure affordable health care coverage" as well as "the measures our company is taking to contain the price increases of health insurance premiums." CIGNA argued that the second part of the resolved clause focused on the ordinary business matter of expense management, rather than health care reform, as

 $^{^{93}}$ https://www.forbes.com/sites/robertpearl/2017/01/19/why-patent-protection-in-the-drug-industry-is-out-of-control/?sh=73fa684178ca

⁹⁴ No-Action Request, at 6.

⁹⁵ PetSmart, Inc. (Mar. 24, 2011).

⁹⁶ CIGNA Corporation (Feb. 23, 2015).

- shown by the supporting statement's discussion of the relationship between administrative costs and premiums. The Staff concurred with CIGNA's view that the proposal was excludable because it addressed "the manner in which the company manages its expenses."
- Capital One⁹⁷ successfully argued that a proposal went beyond addressing the arguably significant policy issue of outsourcing to include several ordinary business matters such as "estimated or anticipated cost savings associated with job elimination actions taken by the company over the past five years."

In sum, the subject of the Proposal is anticompetitive practices by pharmaceutical companies, not legal compliance or management of intellectual property. Such practices are a significant policy issue, as shown by the widespread public debate, including numerous legislative and regulatory initiatives and substantial media coverage, over the past several years. AbbVie has thus not satisfied its burden of showing that it is entitled to omit the Proposal in reliance on Rule 14a-8(i)(7).

Substantial Implementation

AbbVie also claims that it has substantially implemented the Proposal and is entitled to omit it pursuant to Rule 14a-8(i)(10). A company need not implement a proposal exactly as it is drafted, but the company's actions must satisfy the proposal's "essential objective" in order to support exclusion. Because none of the disclosures AbbVie identifies concern oversight of risks related to anticompetitive practices, AbbVie's argument is unpersuasive.

AbbVie's substantial implementation argument rests entirely on inaccurately framing the Proposal's essential objective as "obtain[ing] disclosure of how the Company's Board identifies, oversees and analyzes risks related to the Company's compliance with laws and regulations." As discussed in the previous section, the Proposal is not concerned with AbbVie's general legal compliance program or the board's oversight of compliance risks. Instead, it seeks information about the board's role in overseeing those risks associated with anticompetitive practices.

For that reason, the "extensive disclosure" AbbVie highlights on pages 7-9 of the No-Action Request regarding oversight of legal compliance is unresponsive to the Proposal. None of that disclosure mentions anticompetitive practices or antitrust risk generally, nor does it discuss risks related to specific anticompetitive practices such as patent thickets or pay for delay agreements. The charter for the Public Policy Committee assigns responsibility for overseeing compliance with legal and regulatory requirements, but is silent regarding competition-related risks.

⁹⁷ Capital One Financial Corp. (Feb. 3, 2005).

⁹⁸ No-Action Request, at 7.

Likewise, platitudes regarding competition contained in AbbVie's Code of Business Conduct, such as that "[t]he fair pricing of our products is essential to our commitment to improving health worldwide," 99 shed no light on how the board oversees risks related to anticompetitive practices. Finally, AbbVie does not even claim to have implemented two of the three elements of the Proposal—disclosure regarding how the board takes into account risks related to anticompetitive practices when setting strategy and how the board oversees those aspects of public policy advocacy related to competition. Accordingly, AbbVie cannot be said to have satisfied the Proposal's essential objective or substantially implemented the Proposal.

* * *

The subject of the Proposal is risks related to pharmaceutical companies' anticompetitive practices, not legal compliance or intellectual property. Such practices are a significant policy issue, as shown by the widespread public debate, including numerous legislative and regulatory initiatives and substantial media coverage, over the past several years. AbbVie has not substantially implemented the Proposal because none of the disclosure to which it points concerns competition-related risks. AbbVie thus has not satisfied its burden of showing that it is entitled to omit the Proposal in reliance on Rule 14a-8(i)(7) or Rule 14a-8(i)(10), and the Proponents respectfully request that AbbVie's request for relief be denied.

We appreciate the opportunity to be of assistance to the Staff in this matter. If you have any questions or need additional information, please contact me at (215) 241-7272.

Sincerely,

Jeffery W. Perkins Executive Director

myrun

cc: Marc S. Gerber, Esq. Marc.Gerber@skadden.com

Co-filers
Lydia Kuykendal, Mercy Investments
Seamus Finn, Missionary Oblates of Mary Immaculate
Barbara Aires, Sisters of Charity of St. Elizabeth, NJ
Gwen Farry, Sisters of Charity of the Blessed Virgin Mary
Cathy Rowan, Trinity Health

⁹⁹ See No-Action Request, at 8.

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January 26, 2022

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FIRM/AFFILIATE OFFICES

U.S. Securities and Exchange Commission Division of Corporation Finance Office of Chief Counsel 100 F Street, N.E. Washington, D.C. 20549

RE: AbbVie Inc. – 2022 Annual Meeting

Supplement to Letter dated December 22, 2021

Relating to Shareholder Proposal of

Friends Fiduciary Corporation and co-filers¹

Ladies and Gentlemen:

We refer to our letter dated December 22, 2021 (the "No-Action Request"), submitted on behalf of our client, AbbVie Inc., a Delaware corporation (the "Company"), pursuant to which we requested that the Staff of the Division of Corporation Finance (the "Staff") of the U.S. Securities and Exchange Commission (the "Commission") concur with the Company's view that the shareholder proposal and supporting statement (the "Proposal") submitted by Friends Fiduciary Corporation ("Friends Fiduciary") and co-filers may be excluded from the proxy materials to be distributed by the Company in connection with its 2022 annual

The following shareholders have co-filed the Proposal: Bon Secours Mercy Health, Inc; CommonSpirit Health; Mercy Investment Services, Inc.; Missionary Oblates of Mary Immaculate-United States Province; the Sisters of Charity of Saint Elizabeth; the Sisters of Charity of the Blessed Virgin Mary, Dubuque, Iowa; and Trinity Health.

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meeting of shareholders (the "2022 proxy materials"). Friends Fiduciary and the co-filers are sometimes collectively referred to the "Proponents."

This letter is in response to the letter to the Staff, dated January 20, 2022, submitted by Friends Fiduciary (the "Proponents' Letter"), and supplements the No-Action Request. In accordance with Rule 14a-8(j), a copy of this letter also is being sent to the Proponents.

With regard to the ordinary business exclusion, the Proponents' Letter attempts to frame the Proposal as focused on a significant policy issue of "anticompetitive practices." Perhaps because, to our knowledge, the Staff has never recognized a significant policy issue of anticompetitive practices, the Proponents' Letter describes at length various laws, regulations, bills and legislative hearings that relate to antitrust and competitive practices. In doing so, however, the Proponents' Letter demonstrates precisely the point made by the Company in the No-Action Request – that the Proposal focuses on the ordinary business matter of legal compliance. The fact that there is an expansive body of laws and regulations dealing with anticompetitive practices does not demonstrate that these issues are a significant policy matter, rather, it demonstrates that this is a complex area of law with a robust legal framework. As described in the No-Action Request, the Company's compliance with this body of laws is fundamentally ordinary business. In this sense, antitrust laws and regulations define the boundaries of permissible competition and impermissible competition and exist as one component of a company's legal compliance regime. Moreover, the Proponents' Letter's reference to "board oversight of various kinds of risk created by anticompetitive practices" does little to transform this from an ordinary business matter. Accordingly, the Proposal focuses on the ordinary business matter of the Company's legal compliance.

The Proponents' Letter also draws upon examples where the Staff did not permit companies to exclude shareholder proposals under Rule 14a-8(i)(7) that also related to anticompetitive practices. Those examples, however, involved large technology companies that have been subject to high-profile and sweeping government antitrust investigations and lawsuits. These letters are distinguishable because the Company is not similarly situated. Therefore, the letters referenced in the Proponents' Letter are factually dissimilar and irrelevant to the conclusion that the Proposal relates to the Company's ordinary business matters.

In addition, the Proponents' Letter argues that the Company has not substantially implemented the Proposal because the disclosures cited in the No-Action Request do not specifically address anticompetitive practices. As described above, however, the Company's compliance with antitrust laws and regulations is

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just one aspect of the Company's overall legal compliance program and the Company already provides extensive disclosure regarding its Board of Directors' oversight and risk management relating to legal compliance. Therefore, as described further in the No-Action Request, the Company believes that it has satisfied the Proposal's essential objective and that its policies compare favorably with the Proposal.

Should the Staff disagree with the conclusions set forth in this letter, or should any additional information be desired in support of the Company's position, we would appreciate the opportunity to confer with the Staff concerning these matters prior to the issuance of the Staff's response. Please do not hesitate to contact the undersigned at (202) 371-7233.

Very truly yours,

Marc S. Gerber

cc: Laura J. Schumacher

Vice Chairman, External Affairs and Chief Legal Officer AbbVie Inc.

Amy Carr Friends Fiduciary Corporation

Jeffrey Perkins Friends Fiduciary Corporation

Lydia Kuykendal, on behalf of Bon Secours Mercy Health Inc., CommonSpirit Health and Mercy Investment Services, Inc. Director of Shareholder Advocacy Mercy Investment Services, Inc.

Rev. Séamus P. Finn, OMI Missionary Oblates of Mary Immaculate / OIP Investment Trust (U.S. Province)

Sister Barbara Aires, SC Coordinator of Corporate Responsibility The Sisters of Charity of Saint Elizabeth Office of Chief Counsel January 26, 2022 Page 4

> Gwen Farry, BVM The Sisters of Charity of the Blessed Virgin Mary, Dubuque, Iowa

Catherine Rowan Trinity Health