



DIVISION OF  
CORPORATION FINANCE

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

March 8, 2022

Margaret M. Madden  
Pfizer Inc.

Re: Pfizer Inc. (the "Company")  
Incoming letter dated December 22, 2021

Dear Ms. Madden:

This letter is in response to your correspondence concerning the shareholder proposal (the "Proposal") submitted to the Company by the Sisters of St. Francis Charitable Trust 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: Marie Cigrand  
Sisters of St. Francis Charitable Trust



**Margaret M. Madden**  
Senior Vice President and Corporate Secretary  
Chief Governance Counsel

Pfizer Inc. – Legal Division  
235 East 42nd Street, New York, NY 10017  
Tel 212 733 3451 Fax 646 563 9681  
margaret.m.madden@pfizer.com

**BY EMAIL** (shareholderproposals@sec.gov)

December 22, 2021

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

RE: Pfizer Inc. – 2022 Annual Meeting  
Omission of Shareholder Proposal of  
Sisters of St. Francis Charitable Trust

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, Pfizer Inc., a Delaware corporation (“Pfizer”), may exclude the shareholder proposal and supporting statement (the “Proposal”) submitted by the Sisters of St. Francis Charitable Trust (the “Proponent”) from the proxy materials to be distributed by Pfizer in connection with its 2022 annual meeting of shareholders (the “2022 proxy materials”).

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 Proponent as notice of Pfizer’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 Proponent that if the Proponent submits 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 Pfizer Inc. (“Pfizer”) 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 Pfizer’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 Pfizer has notice.

## **II. Bases for Exclusion**

We hereby respectfully request that the Staff concur with Pfizer’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 Pfizer’s ordinary business operations; and
- Rule 14a-8(i)(10) because Pfizer has substantially implemented the Proposal.

## **III. Background**

Pfizer received the Proposal via email on November 10, 2021, accompanied by a cover letter from the Proponent dated November 10, 2021. On November 11, 2021, Pfizer received an email from Wells Fargo Bank, NA verifying the Proponent’s continuous ownership of at least the requisite amount of Pfizer common stock for at least the requisite period preceding and including the date of submission of the Proposal. Copies of the Proposal, cover letter and related correspondence are attached hereto as Exhibit A.

## **IV. The Proposal May be Excluded Pursuant to Rule 14a-8(i)(7) Because the Proposal Deals with Matters Relating to Pfizer’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 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 business operations (i.e., the design, development and licensing of [the company's] software products)."

In this instance, the Proposal focuses primarily on Pfizer's legal compliance program and how it relates to Pfizer's decisions regarding its intellectual property, which are both ordinary business matters. Specifically, the Proposal's resolved clause asks for a report on how Pfizer'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 Pfizer "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 Pfizer 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. Moreover, Pfizer's management of its legal compliance program with respect to the particular issue of competition law touches upon a host of other issues that implicate Pfizer's ordinary business. For example, this includes, among other things, oversight of Pfizer's entire patent program, contracting practices, communication and relationships with Pfizer's vendors, and the supply of medicines to Pfizer's customers, all of which are global in nature and highly varied based on location. Accordingly, decisions with respect to the oversight of Pfizer's legal compliance and how it maintains its intellectual property are highly complex and at the heart of Pfizer's business as a global 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 Pfizer'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 Pfizer 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 Pfizer'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 Pfizer 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 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, Pfizer has substantially implemented the Proposal, the essential objective of which is to obtain disclosure of how Pfizer's Board identifies, oversees and analyzes risks related to Pfizer's compliance with laws and regulations. Specifically, the Proposal's resolved clause requests that Pfizer 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 Pfizer is facing "mounting pressure . . . against [its] anticompetitive practices," which "can increase pressure for new regulation, increase risk for investors, and have substantial impacts on the public." The supporting statement continues that "robust

---

\* Citations marked with an asterisk indicate Staff decisions issued without a letter.

board oversight would improve Pfizer's management of risks related to anticompetitive practices.”

Pfizer already provides extensive disclosure regarding the Board's oversight of risks related to legal compliance. In this regard, Pfizer's definitive proxy statement for the 2021 annual meeting of shareholders describes the general structure of the Board's oversight of risk:

The Board considers significant enterprise risk topics, including, among others, risks associated with our strategic plan, our capital structure, our research and development (R&D) activities, drug pricing, access and reimbursement, the COVID-19 pandemic, our [Environmental, Social and Governance] practices and human capital management. In addition, the Board receives regular reports from members of our [Executive Leadership Team] that include discussions of the risks involved in their respective areas of responsibility. The Board is routinely informed of developments that could affect our risk profile or other aspects of our business.

The Board is kept informed of its Committees' risk oversight and other activities through reports by the Committee Chairs to the full Board. These reports are presented at every regular Board meeting.<sup>1</sup>

In addition, the Regulatory and Compliance Committee of the Board has specific oversight responsibility of Pfizer's compliance program with respect to legal and regulatory requirements.<sup>2</sup> In particular, the Regulatory and Compliance Committee's Charter, which is available on Pfizer's website, provides that the Committee shall, among other things, represent and assist the Board in the following areas:

- Compliance with U.S. and ex-U.S. requirements governing product marketing, promotion, and sale, including with respect to product claims and restrictions on “off-label” promotion, interactions with healthcare professionals, compliance with U.S. federal healthcare program requirements (including product pricing and price-reporting obligations), and compliance with the U.S. Anti-Kickback statute, the U.S. False Claims Act, the U.S. Foreign Corrupt Practices Act, the physician payment reporting provisions of the U.S. Patient Protection and Affordable Care Act, and equivalent ex.-U.S. requirements as they relate to the Healthcare-Related Areas.

---

<sup>1</sup> See Pfizer's definitive proxy statement for the 2021 annual meeting of shareholders, available at <https://www.sec.gov/Archives/edgar/data/78003/000007800321000047/proxystatement.htm>.

<sup>2</sup> The Audit Committee of the Board is tasked with oversight of legal and regulatory compliance as it relates to financial matters and Pfizer's enterprise risk management. See Pfizer's Audit Committee Charter, available at [https://s28.q4cdn.com/781576035/files/governance\\_docs/committee-charters/Audit-Committee-Charter-\(Last-Reviewed-December-2020\).pdf](https://s28.q4cdn.com/781576035/files/governance_docs/committee-charters/Audit-Committee-Charter-(Last-Reviewed-December-2020).pdf) and attached hereto as Exhibit B.



- Compliance with U.S. and ex-U.S. requirements governing manufacturing quality control, including Current Good Manufacturing Practices (cGMP).
- Compliance with U.S. and ex-U.S. requirements governing the conduct of clinical trials, including Good Clinical Practices (GCP) and Good Laboratory Practices (GLP).
- Compliance with U.S. and ex-U.S. requirements governing the monitoring and reporting of product safety information.<sup>3</sup>

Moreover, as described in Pfizer's Code of Business Conduct (the "Code"), which is available on Pfizer's website, Pfizer and all its employees are required to comply with applicable industry laws and regulations.<sup>4</sup> In particular, the Code specifically covers Pfizer's compliance with antitrust laws. In a section titled "Antitrust, Fair Competition Laws & Competitive Intelligence," the Code provides that "[a]ntitrust and competition laws protect free enterprise and prohibit interactions between Pfizer and our competitors that affect prices, terms or conditions of sale, or fair competition" and that Pfizer ensures "fair competition in all our business dealings, including, among other things, distribution agreements, rebates and discounts to customers, patent, copyright, and trademark licenses, territorial restrictions on resellers, and pricing policy generally." In addition, the Code explains that Pfizer is "committed to competing fairly and following the antitrust and competition laws of all countries in which we operate," noting that "[l]aws vary and are sometimes complex, so we consult with the Legal Division before interacting with competitors or engaging in business dealings which could unfairly restrict trade." The Code also states that Pfizer only collects and uses "business information about other companies in a manner that is ethical, lawful, and meets confidential obligations." Moreover, the Code provides that Pfizer does "not permit direct or indirect discussions or contact with competitors about pricing, costs, terms or conditions of sale, or other competitively sensitive information" or any such discussions or contact with "suppliers and customers that unfairly restrict trade or exclude competitors from the marketplace."

Given the extensive disclosure in Pfizer's definitive proxy statement for the 2021 annual meeting of shareholders, the Regulatory and Compliance Committee Charter and the Code, Pfizer already has publicly disclosed how it identifies, oversees and analyzes risks related to Pfizer's compliance with laws and regulations. Therefore, Pfizer has satisfied the

---

<sup>3</sup> See Pfizer's Regulatory and Compliance Committee Charter, available at [https://s28.q4cdn.com/781576035/files/governance\\_docs/committee-charters/Regulatory-and-Compliance-Committee-Charter-\(Last-Reviewed-December-2020\).pdf](https://s28.q4cdn.com/781576035/files/governance_docs/committee-charters/Regulatory-and-Compliance-Committee-Charter-(Last-Reviewed-December-2020).pdf) and attached hereto as Exhibit C.

<sup>4</sup> See Pfizer's Code of Business Conduct, available at [https://cdn.pfizer.com/pfizercom/investors/corporate/Pfizer\\_2020BlueBook\\_English\\_08.2021.pdf](https://cdn.pfizer.com/pfizercom/investors/corporate/Pfizer_2020BlueBook_English_08.2021.pdf), relevant excerpts of which are attached hereto as Exhibit D.

Proposal's essential objective and thus its public disclosures compare favorably with those requested by the Proposal.

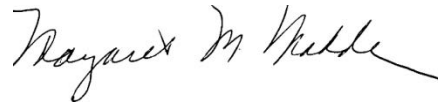
Accordingly, Pfizer believes that the Proposal may be excluded from its 2022 proxy materials pursuant to Rule 14a-8(i)(10) as substantially implemented.

## **VI. Conclusion**

Based upon the foregoing analysis, we respectfully request that the Staff concur that it will take no action if Pfizer 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 Pfizer'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 me at (212) 733-3451 or Marc S. Gerber of Skadden, Arps, Slate, Meagher & Flom LLP at (202) 371-7233.

Very truly yours,



Margaret M. Madden

Enclosures

cc: Sr. Marie Cigrand, O.S.F.  
Sisters of St. Francis Charitable Trust

Christopher Cox  
Seventh Generation Interfaith Coalition for Responsible Investment

EXHIBIT A

(see attached)



## Sisters of St. Francis Charitable Trust

[REDACTED]  
[REDACTED]  
[REDACTED]

*By E-Mail and Overnight Delivery*

November 10, 2021

Margaret M. Madden  
Vice President and Corporate Secretary, Chief Governance Counsel  
Pfizer, Inc.  
235 East 42<sup>nd</sup> Street  
New York, NY 10017  
[REDACTED]

Dear Ms. Madden,

Sisters of St. Francis Charitable Trust 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 Pfizer, Inc. (the "Company") for its 2022 annual meeting of shareholders. Sisters of St. Francis Charitable Trust is the lead filer for the Proposal and will be joined by other shareholders as co-filers.

Sisters of St. Francis Charitable Trust 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. *A letter verifying ownership is being sent separately by our custodian, Wells Fargo Bank, NA.* Sisters of St. Francis Charitable Trust intends to continue to hold such shares through the date of the Company's 2022 annual meeting of shareholders.

Sisters of St. Francis Charitable Trust is available to meet with the Company via teleconference on: Nov. 22, between 11:30 AM – 5 PM EST; Nov. 23; between 12:00 – 5:00 PM EST, Nov. 30; between 11:30 AM – 5 PM EST; or Dec. 2, between 2:00 PM – 5:00 PM EST. 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).

### **Representation – Important Notice**

**Please be advised that we will hereafter be using a representative regarding the management of this proposal. Please send any correspondence regarding this proposal including deficiency notices, no action requests or engagement scheduling to Christopher Cox, [REDACTED] and Seventh Generation Interfaith Coalition for Responsible Investment, [REDACTED]. I authorize the representative to speak on my behalf, negotiate withdrawal of the proposal and engage with the company and its representatives.**

As long-term investors in Pfizer, we our proposal relates to our concern over the growing risks associated with the company's reliance on practices that could be characterized as anticompetitive, and we hope that the issues it raises can lead to productive dialogue.

Sincerely,

Sr. Marie Cigrand, O.S.F.  
Authorized Agent: Sisters of St. Francis Charitable Trust  
Enc.

RESOLVED that shareholders of Pfizer Inc. (“Pfizer”) 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 Pfizer’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 Pfizer has notice.

### **SUPPORTING STATEMENT**

The anticompetitive practices of companies within the pharmaceutical supply chain, including drug developers such as Pfizer, are receiving increasing scrutiny from the public, regulators, and enforcers. The criticism of Pfizer 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.<sup>i</sup>

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.”<sup>ii</sup> Furthermore, upon confirmation, newly appointed FTC Chair Lina Kahn quickly moved to direct FTC staff to ramp up investigations based on seven enforcement priorities, including healthcare and pharmaceutical companies.<sup>iii</sup>

Separately, the company recently agreed to pay a \$345 million antitrust litigation settlement surrounding its EpiPen production. There, the plaintiffs, who included insurers, pension funds, and other consumers, claimed that Pfizer had engaged in anticompetitive marketing practices that led to unlawful price hikes.<sup>iv</sup> In addition, Pfizer is currently involved in litigation with Teva Pharmaceutical, which claims that Pfizer engaged in patent litigation solely to delay the introduction of Teva’s generic epinephrine injectable.<sup>v</sup>

The mounting pressure on Pfizer from regulators, enforcers, and market participants against the company’s anticompetitive practices can increase pressure for new regulation, increase risk for investors, and have substantial impacts on the public. Given the widespread concern and rapidly changing environment, we believe that robust board oversight would improve Pfizer’s management of risks related to anticompetitive practices and that shareholders would benefit from more information about the board’s role.

---

<sup>i</sup> *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>).

<sup>ii</sup> *Statement Of Acting Chairwoman Rebecca Kelly Slaughter in the Matter Regarding the Federal Trade Commission’s Report to Congress on Rebate Walls*, Fed. Trade Comm’n (May 28, 2021) (<https://www.ftc.gov/public-statements/2021/05/statement-acting-chairwoman-rebecca-kelly-slaughter-regarding-federal>).

---

<sup>iii</sup> Brennan, Zachary, *Pharma in the crosshairs: How the FTC is expanding its antitrust powers under its new chair*, Endpoints News, July 2, 2021 (<https://endpts.com/pharma-in-the-crosshairs-how-the-ftc-is-expanding-its-antitrust-powers-under-its-new-chair/>).

<sup>iv</sup> Kansteiner, Fraiser, *Pfizer antes up \$345M to settle long-running EpiPen antitrust claims as Viartis case moves ahead*, Fierce Pharma, 16 July 2021 (<https://www.fiercepharma.com/pharma/pfizer-antes-up-345m-to-settle-long-running-epipen-antitrust-claims>).

<sup>v</sup> *Id.*

EXHIBIT B

(see attached)

## **Charter Audit Committee**

### **Status**

The Audit Committee (the Committee) is a committee of the Board of Directors (the Board) of Pfizer Inc. (the Company).

### **Membership**

The Committee shall consist of three or more Directors, all of whom, in the judgment of the Board, shall be independent in accordance with New York Stock Exchange (NYSE) listing standards and all applicable laws and regulations. Each member shall, in the judgment of the Board, have the ability to read and understand the Company's basic financial statements. At least one member of the Committee shall, in the judgment of the Board, be an "audit committee financial expert" in accordance with the rules and regulations of the Securities and Exchange Commission (SEC), and at least one member (who may also serve as the audit committee financial expert) shall, in the judgment of the Board, have accounting or related financial management expertise in accordance with NYSE listing standards.

No member of the Committee may serve simultaneously on the audit committees of more than three public companies, including the Company, unless the Board determines that such simultaneous service would not impair the ability of such member to effectively serve on the Committee and such determination is disclosed in accordance with the rules of the NYSE.

The Chair of the Committee shall be designated by the Board, provided that if the Board does not designate a Chair, the members of the Committee, by a majority vote, may designate a Chair.

The members of the Committee shall be elected by the Board, based on the recommendation of the Governance & Sustainability Committee of the Board. Each member of the Committee shall serve for such term or terms as the Board may determine or until his or her earlier resignation, removal or death. Any vacancy on the Committee shall be filled by the Board. No member of the Committee shall be removed as a member, except by the Board.

### **Purpose**

The Committee shall represent and assist the Board with the oversight of: (a) the integrity of the Company's financial statements and internal controls, (b) the Company's compliance with legal and regulatory requirements (in coordination with the Regulatory and Compliance Committee of the Board), (c) the Company's independent registered public accounting firm's qualifications and independence and (d) the performance of the Company's internal audit function and independent registered public accounting firm. In addition, the Committee shall prepare a report each year for inclusion in the Company's proxy statement relating to the election of Directors. Except as otherwise required by applicable laws, regulations or listing standards, all major decisions are considered by the Board as a whole.

### **Responsibilities**

The following responsibilities are within the authority of the Committee and shall include, consistent with and subject to applicable law and rules and regulations promulgated by the SEC, the NYSE or any other applicable regulatory authority:



1. Select, retain, evaluate and, when appropriate, terminate the independent registered public accounting firm, set the independent registered public accounting firm's compensation, oversee the performance of the independent registered public accounting firm and pre-approve all audit services to be provided by the independent registered public accounting firm.
2. Pre-approve all permissible non-audit services to be provided by the independent registered public accounting firm and establish policies and procedures for the engagement of the independent registered public accounting firm to provide audit and permissible non-audit services.
3. At least annually, receive and review: (a) a report by the independent registered public accounting firm describing the independent registered public accounting firm's internal quality control procedures and any material issues raised by the most recent internal quality-control review, peer review or Public Company Accounting Oversight Board review or inspection of the independent registered public accounting firm, or by any inquiry or investigation by governmental or professional authorities, within the preceding five years, regarding one or more independent audits carried out by the firm, and any steps taken to deal with any such issues; and (b) other required reports from the independent registered public accounting firm.
4. At least annually: (a) consider and evaluate the qualifications, performance and independence of the independent registered public accounting firm, including whether the provision by the independent registered public accounting firm of permissible non-audit services is compatible with independence; and (b) obtain and review a report from the independent registered public accounting firm describing all relationships between the firm or its affiliates and the Company or individuals in a financial reporting oversight role at the Company, that may reasonably be thought to bear on the firm's independence, and discuss with the firm the potential effects of any disclosed relationships on the firm's independence.
5. Review and discuss with the independent registered public accounting firm: (a) the firm's responsibilities under generally accepted auditing standards and the responsibilities of management in the audit process; (b) the scope, timing and results of the audit; (c) any problems or difficulties that the firm encountered in the course of the audit work, and management's response; and (d) any questions, comments or suggestions the firm may have relating to the internal controls, and accounting practices and procedures, of the Company or its subsidiaries.
6. Review and approve, based on discussion with the Chief Financial Officer, the appointment, replacement or dismissal of the chief internal auditor, who shall report directly to the Committee and administratively to the Chief Financial Officer. Review annually with the Chief Financial Officer the performance of the chief internal auditor.
7. Review and discuss, at least annually, the scope and results of the internal audit program, including the current and future programs of the Company's Internal Audit Department, procedures for implementing accepted recommendations made by the independent registered public accounting firm, and any significant matters contained in reports from the Internal Audit Department.
8. Review and discuss with the independent registered public accounting firm, the Company's Internal Audit Department, and management: (a) the adequacy and effectiveness of the Company's systems of internal controls (including any significant deficiencies, material weaknesses and significant changes in internal controls reported to the Committee by the independent registered public accounting firm or management), accounting practices, and disclosure controls and procedures (and management reports thereon), of the Company and its subsidiaries; and (b) current accounting trends and developments, and take such action with respect thereto as may be deemed appropriate.
9. Review and discuss with management and the independent registered public accounting firm the annual and quarterly financial statements (including the related notes) of the Company,

including: (a) any material changes in accounting principles or practices used in preparing the financial statements prior to the filing of a report on Forms 10-K or 10-Q with the SEC; (b) any critical audit matters arising from the current period audit; (c) disclosures relating to internal controls over financial reporting; (d) the items required by applicable generally accepted auditing standards relating to the conduct of the audit of annual financial statements or review of interim financial statements; and (e) the Company's specific disclosures under "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in the Company's Forms 10-K or 10-Q filed with the SEC.

10. Recommend to the Board, based on the review described in paragraphs 4, 5 and 9 above, whether the financial statements should be included in the annual report on Form 10-K.
11. Review and discuss earnings press releases, as well as Company policies with respect to earnings press releases, financial information and earnings guidance provided to analysts and rating agencies (this function may be performed by the Chair or the full Committee).
12. Review and discuss the Company's policies with respect to risk assessment and risk management, and review contingent liabilities and risks that may be material to the Company and relevant major legislative and regulatory developments that could materially impact the Company's contingent liabilities and risks. To the extent that a review and evaluation of healthcare-related regulatory and compliance issues are relevant to the Committee's responsibilities under this paragraph 12, the Committee may rely on reports, analyses and recommendations of the Regulatory and Compliance Committee.
13. Review and discuss, at least annually, the Company's information security and technology risks (including cybersecurity), including the Company's information security and risk management programs.
14. Review: (a) the status of compliance with laws, regulations, and internal procedures; and (b) the scope and status of systems designed to promote Company compliance with laws, regulations and internal procedures, through review of reports from management, legal counsel and third parties as determined by the Committee. To the extent that a review and evaluation of healthcare-related regulatory and compliance issues are relevant to the Committee's responsibilities under this paragraph 14, the Committee may rely on reports, analyses and recommendations of the Regulatory and Compliance Committee.
15. Establish and oversee procedures for the confidential and anonymous receipt, retention and treatment of complaints regarding the Company's accounting, internal controls and auditing matters, as well as for the confidential, anonymous submissions by Company employees of concerns regarding questionable accounting or auditing matters.
16. Establish policies for the hiring of employees and former employees of the independent registered public accounting firm.
17. Obtain the advice and assistance, as appropriate, of independent counsel and other advisors as necessary to fulfill the responsibilities of the Committee, including to conduct or authorize investigations into, or studies of, matters within the Committee's scope of responsibilities, and receive appropriate funding from the Company, as determined by the Committee, for the payment of compensation to, and reimbursement of expenses incurred by, any such advisors.
18. Conduct an annual performance evaluation of the Committee and annually evaluate the adequacy of its charter.

19. At least annually, review and consider the entry by the Company into over-the-counter derivatives transactions that are exempt from clearing under Section 2(h)(1) and from trading on a swap execution facility under 2(h)(8) of the Commodity Exchange Act in accordance with Rule 50.50 of the Commodity Futures Trading Commission, and otherwise review and consider the reliance by the Company on any applicable exemptions from requirements that would otherwise apply to the Company's derivatives trading under the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law.
20. Become reasonably informed of all related party transactions (as defined under Item 404 of Regulation S-K and under the standards of the Public Company Accounting Oversight Board), including those considered by the Governance & Sustainability Committee, and any significant unusual transactions, in each case considered for disclosure in the Company's financial statements, to understand the terms, structure and business purpose of, and approval process applied to, each such transaction.

### **Meetings**

The Committee shall meet at least six times each year and at such other times as it deems necessary to fulfill its responsibilities. The Committee shall periodically meet separately, in executive session, with management, the internal auditor and chief compliance, quality and risk officer, and the independent registered public accounting firm. At least annually, the Committee shall coordinate with the Regulatory and Compliance Committee to discuss matters of mutual interest within the context of each Committee's responsibilities. The Committee shall report regularly to the Board with respect to its activities and make recommendations to the Board as appropriate. The Committee shall maintain minutes of its meetings and records relating to those meetings.

EXHIBIT C

(see attached)

## Charter

### **Regulatory and Compliance Committee**

#### **Status**

The Regulatory and Compliance Committee is a committee of the Board of Directors (the Board) of Pfizer Inc. (Pfizer or the Company).

#### **Membership**

The Regulatory and Compliance Committee (the Committee) shall consist of three or more directors, the majority of whom, in the judgment of the Board, shall be independent in accordance with New York Stock Exchange (NYSE) listing standards and applicable laws and regulations. At least one member of the Committee shall, in the judgment of the Board, have a background in healthcare. The Committee's membership shall, unless the Board determines otherwise, include at least one member of the Audit Committee, but the majority of the Committee shall not be members of the Audit Committee. The Chair of the Committee shall be an independent member of the Board who has relevant experience in law, corporate compliance, regulatory or governmental affairs, academia, or service on the board of a healthcare institution or other highly regulated company.

The Chair of the Committee shall be designated by the Board, provided that if the Board does not designate a Chair, the members of the Committee, by a majority vote, may designate a Chair.

The members of the Committee shall be elected by the Board, based on the recommendation of the Governance & Sustainability Committee of the Board. Each member of the Committee shall serve for such term or terms as the Board may determine or until his or her earlier resignation, removal or death. Any vacancy on the Committee shall be filled by the Board. No member of the Committee shall be removed as a member, except by the Board.

#### **Purpose**

The Committee shall represent and assist the Board with the oversight of significant regulatory and compliance matters in the following healthcare-related areas (Healthcare-Related Areas):

- (a) Compliance with U.S. and ex-U.S. requirements governing product marketing, promotion, and sale, including with respect to product claims and restrictions on "off-label" promotion, interactions with healthcare professionals, compliance with U.S. federal healthcare program requirements (including product pricing and price-reporting obligations), and compliance with the U.S. Anti-Kickback statute, the U.S. False Claims Act, the U.S. Foreign Corrupt Practices Act, the physician payment reporting provisions of the U.S. Patient Protection and Affordable Care Act, and equivalent ex.-U.S. requirements as they relate to the Healthcare-Related Areas.
- (b) Compliance with U.S. and ex-U.S. requirements governing manufacturing quality control, including Current Good Manufacturing Practices (cGMP);
- (c) Compliance with U.S. and ex-U.S. requirements governing the conduct of clinical trials, including Good Clinical Practices (GCP) and Good Laboratory Practices (GLP); and

- (d) Compliance with U.S. and ex-U.S. requirements governing the monitoring and reporting of product safety information.

## **Responsibilities**

1. Review and oversee Pfizer's Compliance Program, including Pfizer's compliance with the obligations of the U.S. Corporate Integrity Agreement (CIA), including but not limited to evaluating the effectiveness of the Compliance Program, including the Company's quality and compliance governance framework, and receiving periodic updates (at least four times per year) from the Chief Compliance, Quality and Risk Officer (CCQRO) about the Compliance Program and related activities.
2. Review: (i) the status of Pfizer's compliance with applicable laws, regulations, internal procedures in the Healthcare-Related Areas, and the CIA; and (ii) the scope and status of systems designed to ensure the Company's compliance with applicable laws, regulations, and internal procedures in the Healthcare-Related Areas and to monitor for non-compliance, through review of reports and information from Management, legal counsel, and third parties, including on topics such as the following examples, as they relate to the Healthcare-Related Areas:
  - (a) significant compliance and government investigations;
  - (b) FDA Warning Letters;
  - (c) reports from the Executive Compliance Committee;
  - (d) internal audits;
  - (e) Pfizer's anti-retaliation policies;
  - (f) incentive compensation for sales and marketing personnel;
  - (g) the Company's culture of integrity and the tone set by leaders throughout the organization;
  - (h) the Company's quality and compliance governance framework, including annual reports from the Quality & Compliance Committees for Commercial, Pfizer Global Supply, and Research & Development/Medical, which work to ensure effective quality and compliance risk management; and
  - (i) an annual report from the CCQRO on the state of the Compliance Program.
3. Review and oversee the performance of the CCQRO and the U.S. Compliance Committee.
4. At least annually, receive information about current and emerging risks and regulatory and enforcement trends in the Healthcare-Related Areas that may affect the Company's business operations, performance, or strategy.
5. Review the status of the implementation of the Company's Compliance Program relating to Healthcare-Related Areas with respect to companies acquired by Pfizer and in which Pfizer exercises a controlling interest.
6. Review and oversee the activities of the Office of the Ombuds, including but not limited to evaluating its effectiveness and receiving periodic updates from the Head of the Office of the Ombuds about the activities of the Office and related activities.

7. If there is a government or regulatory action that, in the judgment of the Committee, has caused significant financial or reputational damage to the Company or otherwise indicates a significant compliance or regulatory issue within the Company, then the Committee shall make a written recommendation to the Compensation Committee concerning the extent, if any, to which the incentive-based compensation of any executive, senior manager, Compliance personnel and/or attorney involved in the conduct at issue or with direct supervision over an employee that engaged in the conduct at issue should be reduced, extinguished, or recouped.
  - (a) The incentive-based compensation of any executive, senior manager, Compliance personnel and/or attorney will not be impacted if they were not involved in the misconduct or not engaged in the direct or indirect supervision of the employee involved in the misconduct.
  - (b) If, prior to any regulatory or government investigation of the conduct that is the subject of the government or regulatory action described above, any person engaged in the supervision of the employee involved in the misconduct discovers and reports the misconduct through the appropriate Company procedures (including, if required, one or more committees of the Board of Directors), in furtherance of having the matter properly investigated and remedied, then the Committee may in its discretion recommend to the Compensation Committee that no reduction of compensation is required for anyone not involved in the misconduct consistent with the intent of U.S.S.G. 8C2.5(g)(1).
  - (c) Nothing in this section is designed to limit or restrict Management or the Board from taking any disciplinary action they deem appropriate.
8. The Committee shall report at least annually to the Board of Directors on its oversight of compliance in the Healthcare-Related Areas, including: (i) the state of the Company's Compliance Program (ii) significant regulatory or compliance issues involving the Company of which the Committee has been made aware, (iii) any potential patterns of significant non-compliance identified within the Company, (iv) any significant disciplinary actions against Compliance or Corporate Audit personnel, and (v) any other issues that may reflect a systemic or widespread compliance or regulatory issue that exposes the Company to significant compliance, legal, or reputational risk.
9. The Committee shall prepare a report each year for inclusion in the Company's proxy statement.
10. The Committee shall conduct an annual performance evaluation of the Committee and annually evaluate the adequacy of its Charter.
11. Nothing in this Charter shall expand the duties or liabilities of any Company directors or officers beyond any duties and liabilities otherwise imposed by law.
12. The Committee is authorized, in its discretion, to retain outside counsel, experts and consultants in the discharge of its responsibilities.
13. The Committee is authorized, in its discretion, to require Management to conduct audits or other reviews relating to compliance, regulatory or legal concerns in the Healthcare-Related Areas. The Committee may also, in its discretion, direct whether or not the Committee should be the direct recipient of the results of such an audit or review.

## **Meetings**

The Committee shall meet at least four times each year and at such other times as it deems necessary to fulfill its responsibilities. The Committee will receive periodic reports from the CCQRO on the status of the Compliance Program and related activities. The Committee may meet separately, in executive session, with Management, the CCQRO, the General Counsel, the Chief Internal Auditor, the Head of the Office of the Ombuds, other selected Pfizer employees, and/or outside counsel and other experts or consultants selected by the Committee. The independent directors on the Committee may meet in executive session. At least annually, the Committee shall coordinate with the Audit Committee to discuss matters of mutual interest within the context of each committee's respective responsibilities. The Committee shall report regularly to the Board of Directors with respect to its activities and make recommendations to the Board of Directors as appropriate. The Committee shall maintain minutes of its meetings and records relating to those meetings.

12/2020



EXHIBIT D

(see attached)

A large, abstract graphic of a DNA double helix. The left side is a solid blue vertical bar. The right side is a white, wireframe-style double helix that appears to be glowing and moving through a light gray gradient background.

**BREAKTHROUGHS** that change patients' lives

**BLUE BOOK:** Pfizer's Code of Conduct

## In Following the Letter and Spirit of Laws

### Antitrust, Fair Competition Laws & Competitive Intelligence

Antitrust and competition laws protect free enterprise and prohibit interactions between Pfizer and our competitors that affect prices, terms or conditions of sale, or fair competition. We ensure fair competition in all our business dealings, including, among other things, distribution agreements, rebates and discounts to customers, patent, copyright, and trademark licenses, territorial restrictions on resellers, and pricing policy generally.

We are committed to competing fairly and following the antitrust and competition laws of all countries in which we operate. Laws vary and are sometimes complex, so we consult with the Legal Division before interacting with competitors or engaging in business dealings which could unfairly restrict trade.

We also only collect and use business information about other companies in a manner that is ethical, lawful, and meets confidentiality obligations.

### Our Commitment to EXCELLENCE

- We do not permit direct or indirect discussions or contact with competitors about pricing, costs, terms or conditions of sale, or other competitively sensitive information.
- We do not permit direct or indirect discussions or contact with suppliers and customers that unfairly restrict trade or exclude competitors from the marketplace
- We do not allocate markets or customers with competitors.
- We do not engage in the boycott of customers or suppliers.
- We never use, or ask any third party to use, unlawful or unethical means, such as misrepresentation, deception, theft, spying or bribery to gather information about our competitors.



**Trade association meetings** and other **industry gatherings** can pose certain risks, as they bring together competitors who might discuss matters of mutual concern. Even joking about inappropriate topics—such as marketing or pricing strategies—could be misinterpreted. If any kind of anti-competitive discussion arises, you should refuse to discuss the matter, leave the conversation immediately, and report the incident.



**A friend and former Pfizer colleague now works for a Pfizer competitor. Is it okay to discuss how her company deals with managed care companies?**

No. Competitively sensitive information may not be discussed with friends or former colleagues employed by competitor companies, whether in a business or a social setting.



**I want to know what patient recruitment exclusion criteria a competitor is using in a clinical trial. That information is not public. Can I pose as a potential patient recruit, call the research site, and ask questions?**

No. Misrepresentation—not disclosing that you are a Pfizer colleague or posing as someone you are not—is an unethical way to gain access to a competitor's confidential information. Before you engage in any competitive intelligence primary field research, consult with the Legal Division or Competitive Intelligence to confirm that your strategy is legal and ethical.



#### Learn More

- [Corporate Policy 603 \(Compliance with Antitrust Laws\)](#)
- [Corporate Policy 121 \(Competitive Intelligence Policy and Procedure\)](#)



**Sisters of St. Francis**  
**Charitable Trust**  
3390 Windsor Avenue  
Dubuque, IA 52001-1311  
563-583-9786

---

January 21, 2022

Via e-mail at [shareholderproposals@sec.gov](mailto: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 Pfizer Inc. to omit proposal submitted by Sisters of St. Francis  
Charitable Trust

Ladies and Gentlemen,

Pursuant to Rule 14a-8 under the Securities Exchange Act of 1934, Sisters of St. Francis Charitable Trust (the “Proponent”) submitted a shareholder proposal (the “Proposal”) to Pfizer Inc. (“Pfizer” or the “Company”). The Proposal asks Pfizer’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 Pfizer’s public policy activities related to such risks.

In a letter to the Division dated December 22, 2021 (the “No-Action Request”), Pfizer 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. Pfizer 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 Pfizer’s ordinary business operations; and 14a-8(i) (10), as substantially implemented. As discussed more fully below, Pfizer has not met its burden of proving its entitlement to exclude the Proposal on either of those bases, and the Proponent respectfully requests that Pfizer’s request for relief be denied.

### **The Proposal**

The Proposal states:

RESOLVED that shareholders of Pfizer Inc. (“Pfizer”) 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 Pfizer'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 Pfizer has notice.

### Ordinary Business

Rule 14a-8(i)(7) allows exclusion of proposals related to a company's ordinary business operations. Pfizer 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 Pfizer, 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*

Pfizer omits mention of the determinations issued last season in Alphabet<sup>1</sup> and Amazon,<sup>2</sup> where arguments much like those Pfizer 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.

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 Pfizer's business in response to perceptions or findings about Pfizer's anticompetitive conduct or the conduct of the industry more broadly. The Proposal's resolved clause does not ask for information about how Pfizer or its board manages or oversees compliance or the management of Pfizer's intellectual property. Instead, it focuses solely on board oversight of the risks described above.

In that regard, the Proposal differs from those in the numerous determinations Pfizer cites on pages 3-4 of the No-Action Request, many of which were cited by Alphabet and Amazon last season. Those determinations involved proposals that squarely requested reports on or policies concerning legal compliance and are therefore inapposite. The resolved clauses of these 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

---

<sup>1</sup> Alphabet, Inc. (Apr. 16, 2021).

<sup>2</sup> Amazon.com, Inc. (Apr. 9, 2021).

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).

Pfizer’s reliance on the IBM<sup>3</sup> 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 Pfizer’s intellectual property arrangements, would do no such thing.

*Pharmaceutical Companies’ Anticompetitive Practices Are a Significant Policy Issue, Both for the Industry and for Pfizer*

Companies may not rely on the ordinary business exclusion to omit proposals that “focus[] on sufficiently significant social policy issues.”<sup>4</sup> 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.”<sup>5</sup>

Over the past several years anticompetitive practices among pharmaceutical firms have generated substantial debate among the public and policy makers, qualifying the subject as a significant policy issue. 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 has also played a role: From 1995 to 2015, “60 pharmaceutical companies merged into just 10,” according to a report by the Open Markets Institute.<sup>6</sup>

The debate over anticompetitive practices has focused on:

- Overpatenting 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 or a method of administration that must be navigated by a potential generic manufacturer
- “Product hopping” in which a branded drug maker shifts the market to a new version of a product shortly before its 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

---

<sup>3</sup> International Business Machines Corporation (Jan. 22, 2009).

<sup>4</sup> Exchange Act Release No. 40018 (May 21, 1998).

<sup>5</sup> See, e.g., Duke Energy Corp. (Mar. 1, 2002); AT&T Inc. (Feb. 2, 2011).

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

- Obstructing potential makers of generic or biosimilar medicines from obtaining samples of the branded product needed for 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
- 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 took action to address anticompetitive practices by pharmaceutical companies.

In 2017, the Food and Drug Administration (“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.”<sup>7</sup> 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.”<sup>8</sup> 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.<sup>9</sup>

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],” which can justify summary denial.<sup>10</sup> 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.<sup>11</sup>

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 boosted the price of off-patent anti-fungal Daraprim by more than 4,000%.<sup>12</sup> 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.<sup>13</sup>

---

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

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

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

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

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

<sup>12</sup> <https://ag.ny.gov/press-release/2022/pharma-bro-no-more-attorney-general-james-scores-court-victory-against-convicted>

<sup>13</sup> <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 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.”<sup>14</sup> 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.”<sup>15</sup> 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.”<sup>16</sup>

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,<sup>17</sup> she successfully pushed for a change to a 2015 agency policy requiring full Commission approval of investigations and identified pharmaceutical firms as among the FTC’s top priorities.<sup>18</sup>

In July 2021, President Biden issued Executive Order 14036, the “Executive Order on Promoting Competition in the American Economy”<sup>19</sup> (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,<sup>20</sup> 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.”

Stricter scrutiny of pharmaceutical company mergers could have significant effects on company strategies, and Pfizer’s strategy specifically. Just last month, Pfizer announced it had agreed to acquire Arena Pharmaceuticals for \$6.7 billion,<sup>21</sup> capping off a year in which Pfizer also bought Trillium Therapeutics<sup>22</sup> and Amplyx

---

<sup>14</sup> <https://www.ftc.gov/news-events/press-releases/2021/03/ftc-announces-multilateral-working-group-build-new-approach>

<sup>15</sup> <https://www.ftc.gov/news-events/press-releases/2021/03/ftc-announces-multilateral-working-group-build-new-approach>

<sup>16</sup>

[https://www.ftc.gov/system/files/documents/public\\_statements/1589927/statement\\_of\\_commissioner\\_rohit\\_chopra\\_regarding\\_the\\_review\\_of\\_the\\_ftcs\\_pharmaceutical\\_merger.pdf](https://www.ftc.gov/system/files/documents/public_statements/1589927/statement_of_commissioner_rohit_chopra_regarding_the_review_of_the_ftcs_pharmaceutical_merger.pdf)

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

<sup>18</sup> <https://endpts.com/pharma-in-the-crosshairs-how-the-ftc-is-expanding-its-antitrust-powers-under-its-new-chair/>

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

<sup>20</sup> 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.

<sup>21</sup> <https://www.biospace.com/article/pfizer-to-acquire-arena-pharmaceuticals-and-lead-asset-etrasimod-in-6-7-billion-deal/>

<sup>22</sup> <https://tracxn.com/d/acquisitions/acquisitionsbyPfizer>



Pharmaceuticals.<sup>23</sup> Pfizer’s EVP and chief business innovation officer recently stated that the Company has “significant firepower” for acquisitions in 2022 and plans “to be very active in dealmaking.”<sup>24</sup> Consultant PwC predicts that the sector will have “an exceptional level” of deal activity in 2022, including several deals worth at least \$50 billion.<sup>25</sup> In recent years, Pfizer has made sizeable acquisitions, including Array BioPharma (2019),<sup>26</sup> Medivation (2016),<sup>27</sup> and Hospira (2015).<sup>28</sup> An FTC official stated in 2021 that Pfizer’s divestiture of Upjohn, which merged with Mylan to form [generic drug powerhouse] Viatris, was among the deals that should have been more intensely scrutinized.<sup>29</sup>

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.<sup>30</sup> 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.”<sup>31</sup>

Congress has taken a strong (and in many cases, bipartisan) interest in the market power of pharmaceutical firms and how it harms U.S. consumers. A multitude of bills were introduced in the past five years to address anticompetitive practices by drug companies:

- 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.<sup>32</sup> (H.R.2051 (115<sup>th</sup> and 116<sup>th</sup> Congresses)<sup>33</sup> also would have prohibited brand manufacturers’ refusal to provide samples.)
- H.R.2375 (116<sup>th</sup>)<sup>34</sup>: would create a presumption of anticompetitive effects if a generic drug or biosimilar applicant receives anything of

---

<sup>23</sup> <https://tracxn.com/d/acquisitions/acquisitionsbyPfizer>

<sup>24</sup> <https://www.fiercebiotech.com/biotech/tidy-up-your-labs-biotech-pfizer-coming-significant-firepower-and-cash-to-burn>

<sup>25</sup> <https://www.pwc.com/us/en/industries/health-industries/library/pharma-life-sciences-deals-insights.html>

<sup>26</sup> <https://tracxn.com/d/acquisitions/acquisitionsbyPfizer>

<sup>27</sup> <https://www.financierworldwide.com/pfizer-and-medivation-agree-14bn-merger#.YeYVtVjMKEs>

<sup>28</sup> <https://tracxn.com/d/acquisitions/acquisitionsbyPfizer>

<sup>29</sup> <https://www.fiercepharma.com/pharma/wake-biopharma-megabuyouts-ftc-kicks-off-review-industry-s-dealmaking>

<sup>30</sup> <https://endpts.com/fda-seeks-ftc-action-after-rejecting-petition-to-block-first-generics-for-decades-old-vasopressin/>

<sup>31</sup> <https://endpts.com/fda-seeks-ftc-action-after-rejecting-petition-to-block-first-generics-for-decades-old-vasopressin/>

<sup>32</sup> <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/access-product-samples-creates-act;>

[https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/BILL\\_S-116hr965ih.pdf](https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/BILL_S-116hr965ih.pdf)

<sup>33</sup> <https://www.congress.gov/bill/115th-congress/house-bill/2051?r=23;>

<https://www.govtrack.us/congress/bills/116/hr985>

<sup>34</sup> <https://www.govtrack.us/congress/bills/116/hr2375>

value, including an exclusive license, from a branded drug maker for agreeing not to research, develop or market a drug

- H.R.5133 (116<sup>th</sup>)<sup>35</sup>: would prohibit product hopping
- H.R.4398 (116<sup>th</sup>)<sup>36</sup>: would prohibit product hopping and provides that product hopping is presumed when a manufacturer engages in one of two types of switches
- S.1416 (116<sup>th</sup>)<sup>37</sup>: same as H.R.4398
- H.R.3991 (116<sup>th</sup>)<sup>38</sup>: 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 (116<sup>th</sup>)<sup>39</sup>: would limit which orphan drugs may be granted exclusivity by the FDA
- S.1428 (117<sup>th</sup>)<sup>40</sup>: 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<sup>th</sup>)<sup>41</sup>: same as S.3271
- H.R.1629 (117<sup>th</sup>)<sup>42</sup>: same as S.3271
- H.R.2891 (117<sup>th</sup>)<sup>43</sup>: same as S.1428
- S.1435 (117<sup>th</sup>)<sup>44</sup>: same as H.R.4398
- S.1425 (117<sup>th</sup>)<sup>45</sup>: 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 (117<sup>th</sup>)<sup>46</sup>: same as S.1425
- S.1416 (117<sup>th</sup>)<sup>47</sup>: 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 held a hearing in 2017 on “Examining the Impact of Voluntary Restricted Pharmaceutical Distribution Systems”<sup>48</sup>
- In 2017, the House Judiciary Committee’s Subcommittee on Regulatory Reform, Commercial and Antitrust Law held a hearing on “Antitrust

---

<sup>35</sup> <https://www.congress.gov/bill/116th-congress/house-bill/5133>

<sup>36</sup> <https://www.congress.gov/bill/116th-congress/house-bill/4398>

<sup>37</sup> <https://www.congress.gov/bill/116th-congress/senate-bill/1416>

<sup>38</sup> <https://www.congress.gov/bill/116th-congress/house-bill/3991>

<sup>39</sup> <https://www.congress.gov/bill/116th-congress/senate-bill/3271>

<sup>40</sup> <https://www.congress.gov/bill/117th-congress/senate-bill/1428>

<sup>41</sup> <https://www.congress.gov/bill/117th-congress/senate-bill/250>

<sup>42</sup> <https://www.congress.gov/bill/117th-congress/house-bill/1629?r=20&s=1>

<sup>43</sup> <https://www.congress.gov/bill/117th-congress/house-bill/2891>

<sup>44</sup> <https://www.congress.gov/bill/117th-congress/senate-bill/1435/text?r=82&s=1>

<sup>45</sup> <https://www.congress.gov/bill/117th-congress/senate-bill/1425/all-info>

<sup>46</sup> <https://www.congress.gov/bill/117th-congress/house-bill/2883/all-info>

<sup>47</sup> <https://www.congress.gov/bill/116th-congress/senate-bill/1416>

<sup>48</sup> <https://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=105860>; transcript available on LEXIS/NEXIS

- Concerns and the FDA Approval Process” addressing various anticompetitive practices engaged in by pharmaceutical firms.<sup>49</sup>
- The Senate Finance Committee held a hearing on “Drug Pricing in America: A Prescription for Change, Part I”<sup>50</sup> in January 2019, at which the Committee heard testimony on drug makers’ anticompetitive practices.<sup>51</sup>
  - 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 2019<sup>52</sup>; 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.”<sup>53</sup> The Subcommittee heard from experts on drug firms’ anticompetitive practices.<sup>54</sup>
  - 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,”<sup>55</sup> which focused on abuses of the patent system, including by AbbVie.<sup>56</sup>
  - 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”<sup>57</sup>

Last month, the House Committee on Oversight released a report of its investigation into pharmaceutical pricing and business practices, which took nearly three years.<sup>58</sup> According to the majority staff report, the evidence produced during the investigation showed that the companies investigated, which included Pfizer, 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.<sup>59</sup>

---

<sup>49</sup> See <https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Transcript-20170727.pdf>

<sup>50</sup> <https://www.finance.senate.gov/hearings/drug-pricing-in-america-a-prescription-for-change-part-i>

<sup>51</sup> <https://www.finance.senate.gov/imo/media/doc/29JAN2019MILLERSTMNT.pdf>

<sup>52</sup> <https://energycommerce.house.gov/committee-activity/hearings/hearing-on-lowering-the-cost-of-prescription-drugs-reducing-barriers-to>

<sup>53</sup> <https://oversight.house.gov/news/press-releases/house-judiciary-antitrust-subcommittee-to-hold-hearing-on-anticompetitive>

<sup>54</sup> <https://judiciary.house.gov/calendar/eventsingle.aspx?EventID=4528>

<sup>55</sup> <https://docs.house.gov/meetings/GO/GO00/20210518/112631/HHRG-117-GO00-20210518-SD002.pdf>

<sup>56</sup> 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>

<sup>57</sup> <https://www.judiciary.senate.gov/meetings/a-prescription-for-change-cracking-down-on-anticompetitive-conduct-in-prescription-drug-markets>

<sup>58</sup>

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

<sup>59</sup>

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

The report criticized Pfizer's conduct regarding pain medication Lyrica, finding that:

Pfizer used patent protections, market exclusivities, and other tactics to delay generic competition and keep prices high. Pfizer filed for dozens of patents on Lyrica and obtained an FDA pediatric marketing exclusivity period that the company estimated would generate an additional \$1.6 billion in revenue. Pfizer also sought to shift patients to a new controlled-release formulation of the drug before the old formulation faced generic competition, and aggressively marketed to patients and physicians to extend the Lyrica franchise and drive sales.<sup>60</sup>

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.<sup>61</sup>
- 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.<sup>62</sup>
- Oregon's Senate Bill 764 would establish a presumption similar to that contained in California's law.<sup>63</sup>
- New York's A7254 would establish a presumption similar to that contained in California's law.<sup>64</sup>
- 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."<sup>65</sup>
- Connecticut's SB262 would require drug makers that are present in the state to provide samples to generic manufacturers at a "fair market price."<sup>66</sup>
- Connecticut's SB269 would establish a presumption similar to that contained in California's law.<sup>67</sup>
- 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.<sup>68</sup>

---

<sup>60</sup>

<https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf>, at v; see also *id.* at 116-117 (describing Pfizer's efforts to shift patients to Lyrica's controlled-release formulation).

<sup>61</sup> <https://www.gibsondunn.com/ca-legislation-increases-antitrust-scrutiny-of-patent-settlements-between-branded-and-generic-pharma-manufacturers/>

<sup>62</sup>

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

<sup>63</sup> <https://olis.oregonlegislature.gov/liz/2021R1/Measures/Overview/SB764>

<sup>64</sup> <https://www.nysenate.gov/legislation/bills/2021/a7245>

<sup>65</sup> <https://www.nysenate.gov/legislation/bills/2019/s5169>

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

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

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

- 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.<sup>69</sup>

Anticompetitive practices by pharmaceutical companies and responses to those practices 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,” The Washington Post, Apr. 6, 2021<sup>70</sup>
- Amy Goldstein, “House Democrats find in three-year investigation that drug prices are ‘unsustainable, unjustifiable and unfair,’” The Washington Post, Dec. 10, 2021<sup>71</sup>
- Jim Tankersley and Cecilia Kang, “Biden’s Antitrust Team Signals a Big Swing at Corporate Titans,” The New York Times, July 24, 2021
- Editorial Board, “How Big Pharma plays games with drug patents and how to combat it,” USA Today, Jan. 18, 2019<sup>72</sup>
- Nate Raymond, “California law combating ‘pay for delay’ deals blocked by federal judge,” Reuters, Dec. 9, 2021<sup>73</sup>
- Robin Feldman, “Our patent system is broken. And it could be stifling innovation,” The Washington Post, Aug. 8, 2021<sup>74</sup>
- Sarah Karlin-Smith and Brent D. Griffiths, “FDA to examine anticompetitive practices by drug industry,” Politico, July 17, 2017<sup>75</sup>
- Sarah Zhang, “How Pharma Companies Use ‘Citizen Petitions’ to Keep Drug Prices High,” The Atlantic, Mar. 8, 2017<sup>76</sup>
- Ryan Chatelain, “House committee report blasts drug pricing strategies as ‘troubling,’” NY1, Dec. 10, 2021<sup>77</sup>
- 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,” Los Angeles Times, July 29, 2019<sup>78</sup>
- Carolyn Y. Johnson, “FDA shames drug companies suspected of using ‘gaming tactics’ to delay competition,” The Washington Post, May 17, 2018<sup>79</sup>
- David Chanen, “Price caps on drugs part of AG’s plan,” Star Tribune (Minneapolis, MN), Feb. 20, 2020 (discussing Minnesota AG’s report that highlighted abuse of patent system)

---

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

<sup>70</sup> <https://www.washingtonpost.com/outlook/2021/04/06/drug-companies-keep-merging-why-thats-bad-consumers-innovation/>

<sup>71</sup> <https://www.washingtonpost.com/health/2021/12/10/house-democrats-find-three-year-investigation-that-drug-prices-are-unsustainable-unjustifiable-unfair/>

<sup>72</sup> <https://www.usatoday.com/story/opinion/2019/07/18/big-pharma-plays-games-drug-patents-you-pay-editorials-debates/1769746001/>

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

<sup>74</sup> <https://www.washingtonpost.com/outlook/2021/08/08/our-patent-system-is-broken-it-could-be-stifling-innovation/>

<sup>75</sup> <https://www.politico.com/tipsheets/prescription-pulse/2017/07/17/fda-to-examine-anticompetitive-practices-by-drug-industry-221368>

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

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

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

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

- David Lazarus, “Outlaw secret deals on generic drugs,” Los Angeles Times, June 28, 2019
- Joe Nocera, “Here’s how drug companies game the patent system,” Chicago Tribune, Oct. 23, 2017<sup>80</sup>
- Matthew Lane, “To rein in Big Pharma over high drug prices, start with patent reform,” Roll Call, Jan. 17, 2020<sup>81</sup>
- Michael Carrier, “How Big Pharma Sandbags Generic Competition,” The 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, 2019<sup>82</sup>
- “Biden Drug Price Pressure on Patent Office Draws Skeptics,” Bloomberg, Sept. 21, 2021<sup>83</sup>
- Luke McDonagh, “How a Native American tribe came to own one of the world’s most valuable patents,” The Conversation, Nov. 20, 2017<sup>84</sup>
- David McCabe and Jim Tankersley, “Biden Steps Up Mission to Rein Big Business In,” The New York Times, July 10, 2021
- Sarah Jane Tribble, “Drugs for Rare Diseases Have Become Uncommonly Rich Monopolies,” NPR, Jan. 17, 2017<sup>85</sup>
- Eleanor Tyler and Grace Maral Burnett, “ANALYSIS: FTC Rethinks Pharma M&A After a Decade of Mega-Deals,” Bloomberg, Apr. 15, 2021<sup>86</sup>
- Ron Leuty, “‘Pay-for-delay’ plan blocked cheap generic challengers to Peninsula company’s narcolepsy drug for years, lawsuits claim,” San Francisco Business Times, Aug. 12, 2020
- David Blumenthal, “The U.S. Can Lower Drug Prices Without Sacrificing Innovation,” Harvard Business Review, Oct. 1, 2021<sup>87</sup>
- Jonathan Gardner, “The lights are no longer green’: Antitrust regulators reassess pharma deals,” BioPharma Dive, June 10, 2021<sup>88</sup>
- Jordan Williams, “FTC eyes new approach to pharmaceutical mergers,” The Hill, Mar. 16, 2021<sup>89</sup>
- Tahir Amin, “The problem with high drug prices isn’t ‘foreign freeloading,’ it’s the patent system,” CNBC, June 25, 2018<sup>90</sup>
- Josh Nathan-Kazis, “The FTC is Taking a More Aggressive Approach Toward Pharmaceutical M&A. What it Means for the Industry,” Barron’s, Mar. 17, 2021<sup>91</sup>
- Brett Kendall & Jared Hopkins, “FTC Prepares to Take a Tougher Stance on Pharmaceutical Mergers,” The Wall Street Journal, Mar. 16, 2021<sup>92</sup>

---

<sup>80</sup> <https://www.chicagotribune.com/opinion/commentary/ct-perspec-drugs-health-care-pharm-1024-20171023-story.html>

<sup>81</sup> <https://www.rollcall.com/2020/01/17/to-rein-in-big-pharma-over-high-drug-prices-start-with-patent-reform/>

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

<sup>83</sup> <https://news.bloomberglaw.com/health-law-and-business/biden-drug-price-pressure-on-patent-office-draws-skeptics>

<sup>84</sup> <https://theconversation.com/how-a-native-american-tribe-came-to-own-one-of-the-worlds-most-valuable-patents-84007>

<sup>85</sup> <https://www.npr.org/sections/health-shots/2017/01/17/509506836/drugs-for-rare-diseases-have-become-uncommonly-rich-monopolies>

<sup>86</sup> <https://news.bloomberglaw.com/bloomberg-law-analysis/analysis-ftc-rethinks-pharma-m-a-after-a-decade-of-mega-deals>

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

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

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

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

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

<sup>92</sup> <https://www.wsj.com/articles/federal-trade-commission-to-consider-tougher-line-on-pharmaceutical-mergers-11615905000>

- “Oregon lawmakers butt heads with drug companies over 'pay-for-delay' patent suits,” The Examiner (Washington, DC), Apr. 9, 2021
- 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,” The Examiner (Washington, DC), May 20, 2021
- Robert Pearl, “Why Patent Protection in the Drug Industry is Out of Control,” Forbes, Jan. 19, 2017<sup>93</sup>
- Bob Egelko, “California law designed to keep generic drugs on market allowed to stand,” San Francisco Chronicle, July 28, 2020

*The Proposal as a Whole Deals With a Significant Policy Issue; It Does Not “Touch Upon” a Significant Policy Issue While Primarily Addressing Ordinary Business Matters*

Pfizer urges that “even if the Proposal could be viewed as touching upon a significant policy issue, its focus is on ordinary business matters” of legal compliance and intellectual property management.<sup>94</sup> But legal compliance and Pfizer’s protection of its intellectual property are integral elements of the significant policy issue on which the Proposal focuses. Put another way, the *sole* focus of the Proposal, not just part of it, is a significant policy issue.

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

- In PetSmart,<sup>95</sup> the proposal asked the company to require its suppliers to attest that they had not violated certain laws related to animal cruelty. 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 Pfizer 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 CIGNA<sup>96</sup> 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 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 One<sup>97</sup> 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.”

---

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

<sup>94</sup> No-Action Request, at 5.

<sup>95</sup> PetSmart, Inc. (Mar. 24, 2011).

<sup>96</sup> CIGNA Corporation (Feb. 23, 2015).

<sup>97</sup> Capital One Financial Corp. (Feb. 3, 2005).

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. Pfizer 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**

Pfizer 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 Pfizer identifies concern oversight of risks related to anticompetitive practices, Pfizer's argument is unpersuasive.

Pfizer's substantial implementation argument rests entirely on an inaccurate framing of the Proposal's essential objective as "obtain[ing] disclosure of how Pfizer's Board identifies, oversees and analyzes risks related to Pfizer's compliance with laws and regulations."<sup>98</sup> As discussed in the previous section, the Proposal is not concerned with Pfizer'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" Pfizer 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 specific anticompetitive practices such as product hopping or pay for delay agreements. The charters for the Audit and Regulatory Compliance Committees assign responsibility for overseeing numerous specific kinds of risk, but are silent regarding competition-related risks. Likewise, platitudes regarding competition contained in Pfizer's Code of Business Conduct, such as that Pfizer is "committed to competing fairly and following the antitrust and competition laws of all countries in which we operate,"<sup>99</sup> shed no light on how the board oversees risks related to anticompetitive practices. Accordingly, Pfizer 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. Pfizer has not substantially implemented the Proposal because none of the disclosure to which it points concerns competition-related risks. Pfizer 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 Proponent respectfully requests that Pfizer's request for relief be denied.

---

<sup>98</sup> No-Action Request, at 6.

<sup>99</sup> See No-Action Request, at 8.



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 563-552-8442 or by email at [cigrandm@osfdbq.org](mailto:cigrandm@osfdbq.org)

Sincerely,

*Marie Cigrand OSF*

Marie Cigrand, OSF

Authorized Agent: Sisters of St. Francis Charitable Trust

cc: Margaret M. Madden, Esq.  
[Margaret.m.madden@pfizer.com](mailto:Margaret.m.madden@pfizer.com)